UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE

Primary Care and Population Science

Development of an educational intervention to support implementation of nasal balloon autoinflation for glue ear: a mixed methods approach

by

Jane Louise Vennik

Thesis for the degree of Doctor of Philosophy

September 2017

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF MEDICINE

Primary care health research

Thesis for the degree of Doctor of Philosophy

DEVELOPMENT OF AN EDUCATIONAL INTERVENTION TO SUPPORT IMPLEMENTATION OF NASAL BALLOON AUTOINFLATION FOR GLUE EAR: A MIXED METHODS APPROACH

Jane Louise Vennik

Nasal balloon autoinflation has been found in clinical trials to be an effective, non-surgical treatment for otitis media with effusion (OME) that is applicable to primary care where most affected children initially present. Research findings suggest that it is a feasible and safe treatment which has the potential to improve ear-related quality of life for children and families, whilst enhancing primary care management and adherence to the NICE recommended 3 month active monitoring period. However, implementing new research findings into routine clinical practice can be challenging. Whilst nasal balloon autoinflation may be effective in the context of a clinical trial, it is not clear how generaliseable it is to the normal primary care setting.

The main aim of this PhD is to facilitate wider implementation of the nasal balloon using the Normalization Process Theory to help understand how the treatment can become routinised and embedded in every day primary care practice.

A qualitative study of GPs views and experiences of primary care management of children with OME provided important information about the context for implementation. A secondary analysis of qualitative data from multiple stakeholders (GPs, nurses and parents) then identified that a high quality demonstration video would promote engagement and uptake of the nasal balloon, and thus minimize the potential burden on the GP consultation. A theory-based educational intervention (LittleEARS) was then developed, guided by the medical literature, qualitative enquiry, multi-expert knowledge, and end-user feedback. Additionally, to help facilitate better active monitoring for OME, the Two Alternative Auditory Disability and Speech Reception Test (TADAST) was further developed, evaluated and embedded within the educational intervention. A feasibility study was then conducted to assess acceptability, demand, practicality and implementation of the educational intervention in families of children with OME.

The qualitative work has provided a valuable insight into the potential barriers and facilitators for implementation of the nasal balloon for OME in child in primary care. The LittleEARS educational intervention appears to be both appropriate and potentially useful to families of children with OME during the recommended 3 month active monitoring period. However, further work is required to confirm acceptability and feasibility to the wider primary care population.

The use of Normalization Process Theory (NPT) helped towards a better understanding of the processes for implementation, and provided an appropriate theoretical framework for my research.

Table of Contents

ABSTRACT ..... **v**

List of tables ..... **ix**

List of figures ..... **xi**

Declaration of Authorship ..... **xiii**

Glossary ..... **xv**

Acknowledgements ..... **xvii**

Chapter 1: Introduction. **1**

1.1 Rationale for the research 1

1.2 Personal motivation and background 2

1.3 Research aims and objectives 3

1.4 Thesis timeline 4

1.5 Chapter summary 5

Chapter 2: Otitis media with effusion (OME) **7**

2.1 Introduction 7

2.2 Background 7

2.3 Literature review of autoinflation for otitis media with effusion 19

2.4 Summary 34

Chapter 3: Implementation theory and nasal balloon autoinflation **35**

3.1 Introduction 35

3.2 Theoretical approaches to implementation 36

3.3 Using Normalization Process Theory to underpin implementation research 48

3.4 Using NPT in this research project 50

3.5 Summary 53

Chapter 4: Philosophy and methodology **55**

4.1 Introduction 55

4.2 Philosophical stance 55

4.3 Methodology 57

4.4 Methods of enquiry 58

4.5 Summary 59

Chapter 5: Qualitative research: exploring GP views and experiences of OME and nasal balloon autoinflation in primary care **61**

5.1 Introduction 61

5.2 Aims and objectives 61

5.3 Methods 62

5.4 Findings 73
5.5 Discussion 96
5.6 Conclusion 102
Chapter 6: Qualitative research: secondary analysis of existing qualitative data 105
6.1 Introduction 105
6.2 Aims and objectives 105
6.3 Methods 106
6.4 Results and findings 111
6.5 Discussion 127
6.6 Conclusion 133
Chapter 7: Further development and evaluation of a hearing disability test (TADAST) 135
7.1 Introduction 135
7.2 Background 136
7.3 Aims and objectives 143
7.4 Further development of the TADAST 144
7.5 Final format of the wTADAST-24 146
7.6 Methods 149
7.7 Results 154
7.8 Discussion 164
7.9 Conclusion 170
Chapter 8: Development of an educational intervention for glue ear (LittleEARS) 171
8.1 Introduction 171
8.2 Aims and objectives 172
8.3 Methods 172
8.4 Findings 194
8.5 Discussion 204
8.6 Conclusion 210
Chapter 9: Feasibility study of the LittleEARS educational intervention to support nasal balloon autoinflation in primary care and audiology. 211
9.1 Introduction 211
9.2 Aims and objectives 212
9.3 Methods 212
9.4 Results 224

9.5 Discussion 240
9.6 Conclusion 252
Chapter 10: Discussion 253
10.1 Introduction 253
10.2 Overview of this thesis 253
10.3 Comparison with existing literature 256
10.4 Use of NPT in this research 263
10.5 Strengths and limitations 266
10.6 Future research 268
10.7 Personal reflections 270
10.8 Dissemination activities 277
10.9 Conclusion 280
Appendix A Background and literature review 281
A.1 Autoinflation Randomised Trial: AIRS 281
A.2 Literature search criteria for update to autoinflation systematic review. 290
Appendix B GP qualitative study (chapter 5): 291
B.1 Invitation pack to participants. 291
B.2 Ethics committee approval. 296
B.3 Interview topic guide. 297
Appendix C Secondary analysis (chapter 6): 303
Appendix D Development of the wTADAST-24 311
D.1 Floor and ceiling effects identified in previous versions of the TADAST – TADAST-50 (Riley, 1996)[188] 311
D.2 wTADAST-24 word/picture pairs 313
D.3 wTADAST-24 Screenshots 321
D.4 Participant information pack 324
D.5 Identification of pictures from the wTADAST-24 330
Appendix E Developing the LittleEARS educational intervention (chapter 8): . 331
E.1 List of patient information leaflets 331
E.2 Invitation pack 332
E.3 Expert panel questions 336
E.4 Final layout of the LittleEARS educational intervention 337
E.5 Instructions for using the nasal balloon 338
E.6 Symptom Diary 339
E.7 Sticker reward chart 340

E.8 Printout for teachers 341
Appendix F Feasibility study (chapter 9) 343
F.1 Ethics committee approval 343
F.2 GP invitation pack 348
F.3 Participant login pack 353
F.4 Outcome measures - follow up questionnaire 354
F.5 Outcome measures – OMQ-14 358
List of References 363

List of tables

Table 1: Studies included in the 2013 Cochrane Review of autoinflation 20
Table 2: Tympanometric classification (based on modified Jerger Classification[84]) 24
Table 3: NPT evaluation of nasal balloon autoinflation intervention 51
Table 4: Agreement of codes 70
Table 5: Coding framework 71
Table 6: Example of charting 72
Table 7: Themes identified in the analysis 73
Table 8: Identifying interview participants 73
Table 9: Participant and practice characteristics 74
Table 10: Primary Data Set 1 108
Table 11: Primary Data Set 2 109
Table 12: Sample characteristics 111
Table 13: Quotations illustrating *Coherence* 115
Table 14: Quotations illustrating *Cognitive Participation* 119
Table 15: Quotations illustrating *Collective Action* 123
Table 16: Quotations illustrating *Reflexive Monitoring* 126
Table 17: Developmental stages of the TADAST hearing disability test 139
Table 18: wTADAST-24 final word/picture pairs 144
Table 19: Sample characteristics 155
Table 20: Missing data 156
Table 21: wTADAST-24 and repeat wTADAST-24 Total Scores 157
Table 22: Sub-domains of the TADAST 158
Table 23: Structure and summary of LittleEARS educational intervention 186
Table 24: Thematic analysis of think aloud studies 191
Table 25: Sample characteristics for think aloud interviews 194
Table 26: Sample characteristics for the expert panel 195
Table 27: Summary of major changes after think aloud interviews. 196
Table 28: Quotations illustrating themes from the think aloud interviews 200
Table 29: Final contents of the educational intervention 203
Table 30: TIDieR Checklist for the LIttleEARS Education Intervention 208

Table 31: GP practice demographics 224
Table 32: Recruitment in Primary Care 225
Table 33: Paediatric audiology demographics 225
Table 34: Recruitment in paediatric audiology 225
Table 35: Characteristics of screened children using the wTADAST-24 (First screening cohort on the CONSORT n=56). 227
Table 36: Baseline hearing test scores (n=56) 228
Table 37: Baseline characteristics (n=14) 231
Table 38: Devices used to access the educational intervention 233
Table 39: Unique page views for the LittleEARS educational intervention 234
Table 40: Summary statistics for standardised OMQ-14 scores 239
Table 41: Ongoing parental concerns at 3 months 240
Table 42: Publication plans 279

List of figures

Figure 1: Child demonstrating nasal balloon autoinflation 17
Figure 2: PICO 23
Figure 3: PRISMA flow chart..... 25
Figure 4: 'Risk of bias' summary for included studies..... 26
Figure 5: Meta-analysis of 1 month outcomes (ear-based analysis) 30
Figure 6: Prescribing data for Otovent nasal balloon (number of packs prescribed per month)..... 33
Figure 7: PARIHS Framework 41
Figure 8: Consolidated Framework for Implementation Research 43
Figure 9: Normalization Process Theory 45
Figure 10: Mapping of 4 key themes from the framework analysis..... 75
Figure 11: Mapping promoting and inhibiting factors..... 110
Figure 12: Main findings associated with the theoretical constructs of NPT..... 112
Figure 13: Example of redrawing of 'boot' for the wTADAST-24..... 145
Figure 14: wTADAST-24 – computer screen shot 147
Figure 15: Results page of wTADAST-24 148
Figure 16: wTADAST-24 Testing Schedule 151
Figure 17: Test set-up for wTADAST-24 and wTADAST-36 evaluation 152
Figure 18: Bland-Altman plot (test-retest reliability of the wTADAST-24) 160
Figure 19: Bland-Altman plot of score difference against mean of wTADAST-24 and wTADAST-36 scores (20 items) 161
Figure 20: Box plot wTADAST-24 scores/teacher identified group 162
Figure 21: Box plot wTADAST-24 scores/parent-identified group 163
Figure 22: Flow chart of planning, developing and refining the LittleEARS educational intervention..... 180
Figure 23: Diagrammatic instructions for inflating the nasal balloon 183
Figure 24: Screen shot of LittleEARS educational intervention..... 188
Figure 25: Comments made during Think Aloud studies (n=9) 201
Figure 26: Inclusion/exclusion criteria for feasibility study..... 216
Figure 27: Flow chart for feasibility study..... 217

Figure 28: CONSORT diagram 226
Figure 29: Box plot wTADAST-24 scores/number of parent reported concerns..... 229
Figure 30: Distribution of test scores (maximum score 24)..... 230
Figure 31: Parent views of acceptability, usefulness and usability of the educational intervention (5 point Liker scale) n=9 236
Figure 32: Parent views of the Otovent nasal balloon (5 point Likert Scale) n=9 237

Declaration of Authorship

I, Jane Louise Vennik, declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

Title of Thesis: Development of an educational intervention to support implementation of nasal balloon autoinflation for glue ear: a mixed methods approach

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. None of this work has been published before submission.

Signed: ……

Date:……10th September 2017 …….

Glossary

AIRS	Autoinflation randomised trial
AM	Active monitoring
ATT	Automated McCormick Toy discrimination Test
AOM	Acute otitis media
BCT	Behaviour change technique
CAQDAS	Computer-assisted qualitative data analysis software
CCG	Clinical commissioning group
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
CLAHRC	Collaborations for Leadership in Applied Health Research & Care
dB	Decibel
ENT	Ear, Nose and Throat
GCP	Good clinical practice
GP	General Practitioner
HTA	Health Technology Assessment
MRC	Medical Research Council
NHS	National Health Service
NNTB	Number needed to treat to benefit
NNTH	Number needed to treat to harm
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NoMAD	Measurement instrument for the Normalization Process Theory
NPM	Normalization Process Model
NPT	Normalization Process Theory
NRes	National research ethics committee
OM	Otitis media
OM8-30	30 point questionnaire measuring impact of OME
OME	Otitis media with effusion (or glue ear)
OMQ-14	14 point questionnaire measuring impact of OME
OR	Odds ratio
PARIHS	Promoting Action on Research Implementation in Health Services
PCT	Primary Care Trust
PICO	Defining a clinical question in terms of Patient/Intervention/Comparator/Outcome
PIS	Participant information sheet
PROM	Patient reported outcome measure
PTA	Pure tone audiometry
RCT	Randomised controlled trial
SD	Standard deviation
SPCR	School for Primary Care Research
TADAST	Two alternative Auditory Disability and Speech reception Test
URTI	Upper Respiratory Tract Infection
wTADAST-24	Web hearing test – 24 items (latest version)
wTADAST-34	Web hearing test – 36 items

Acknowledgements

There are a great many people who have made my PhD journey possible, and to whom I am really thankful.

Firstly I am extremely grateful to Dr Ian Williamson for the opportunity to further my academic study whilst working as a trial manager for the AIRS study. Ian has been consistently supportive and encouraging throughout my time in Primary Medical Care and has provided expert guidance and unwavering support throughout.

I was privileged to have an incredibly supportive and experienced supervisory team for my PhD. I would like to thank Professor Michael Moore who encouraged me to think and work independently, giving me the skills and confidence that I need for my future research career. Dr Hazel Everitt was always available for advice, helping me to see clearly when things became overwhelming. Dr Caroline Eyles provided much-needed expertise and guidance with my qualitative work.

I would also like to thank Primary Care and Population Sciences (PCPS) and the School for Primary Care Research (SPCR) for giving me this fantastic opportunity. Early discussions with Professor George Lewith gave me the encouragement and confidence I needed to pursue this pathway, and George was always extremely generous with his time, providing advice and support along the way.

At times when I wondered if I would ever finish, my friends, family and colleagues were always there to spur me on. I am especially thankful to my wonderful husband, Peter, who has been a tremendous support, from listening to the daily trials and tribulations of undertaking a PhD, to patiently reading through my final thesis. I am also extremely proud of my children, Ella and Max, who were studying hard for their own futures during my PhD journey.

Finally, my thanks extend to the participants who took part in my research studies, including the GPs, nurses, audiologists, parents, teachers, and the delightful children at Halterworth County Primary School in Romsey, without whom this PhD would not have been possible.

Chapter 1: Introduction.

This thesis presents a body of applied health research designed to promote the wider implementation of nasal balloon autoinflation in the early management of otitis media with effusion (OME) in primary care. This common childhood condition causes temporary conductive hearing loss which potentially disadvantages children at an important stage in their speech, language and educational development. The effectiveness of nasal balloon autoinflation as a treatment for OME has been established but is yet to be widely used in primary care. This research explores the translation of research evidence for nasal balloon autoinflation into general clinical practice, using an implementation theory to underpin the process.

1.1 Rationale for the research

Otitis media with effusion (OME), or glue ear, is a common, but under recognised condition of early childhood. It is caused by a collection of mucoid or secretory fluid in the middle ear, and when persistent, can lead to intermittent conductive hearing loss. Current management strategies typically involve a period of 3 months active monitoring period or 'watchful waiting' followed by referral for grommet surgery for those most severely affected.[1] Evidence has found that nasal balloon autoinflation is effective in helping to clear middle ear effusions in young school children with unilateral or bilateral glue ear and could improve natural resolution during the watchful waiting period.[2 3] However, promoting the uptake of a novel treatment such as nasal balloon autoinflation from research findings into everyday practice is challenging. Whilst the nasal balloon (Otovent™) has been available on prescription and over-the-counter for more than 10 years, it is not yet well-known or widely used in clinical practice.

The Cooksey report in 2006 identified a translational gap in the critical path from developing a research question to changing healthcare practice.[4] In the case of glue ear, there is a current gap between the research evidence for nasal balloon autoinflation and its wider use in primary care. Changing practice is complex and

multifaceted and the publication of trial results are rarely enough to bring about a change in clinical practice. Successful implementation of new evidence requires careful consideration of the social, political and financial context in which implementation is planned, together with consideration of the requirements of different stakeholders, such as patients, healthcare providers, commissioners and policy makers. Wider implementation of the nasal balloon in primary care practice requires a better understanding of: how GPs currently manage children with OME; the organisational processes involved; the current local and national guidelines for managing these children; referral pathways; and local experience and expertise. Additionally, to implement a new treatment such as the nasal balloon, there should be a good structure in place to better monitor and manage children during this period.

The work presented in this PhD involved exploring the potential barriers and facilitators to wider implementation of the nasal balloon by reviewing the available evidence and conducting empirical qualitative work to better understand the context for implementation. Outcomes of this work led to the development of an educational intervention and an updated hearing disability test to promote better structured monitoring of glue ear in primary care and wider implementation of the nasal balloon.

The use of a theoretical model for implementation, the Normalization Process Theory[5], enhanced the understanding of promoting and inhibiting factors to wider implementation of the nasal balloon, and provided a coherent, rigorous, theoretically sound basis for the research undertaken in this PhD project.

1.2 Personal motivation and background

My interest in this topic came about through my work with Dr Ian Williamson and the AIRS (autoinflation randomised study[2 3]). Details of the AIRS study are presented in Appendix A. I was employed as the research manager for this multicentre, randomised controlled trial between 2011 and 2014. During this time I was responsible for the day to day management of the trial which included identifying and training practice staff in the trial methods; supporting recruitment and patient follow-up; coordinating data management; supporting analysis and interpretation of trial findings; and contributing

to trial reports and publications. During this period I also undertook an MRes in public health (primary care) at University of Manchester in my own time to further my research skills and knowledge. Alongside the research training modules there was a requirement to conduct some empirical research. I identified a gap in the AIRS trial programme and proposed a nested qualitative study exploring nurse and parent views and experiences of the nasal balloon method. The aim was to provide contextual information and identify barriers and facilitators to future implementation of the nasal balloon for use alongside clinical effectiveness and economic findings of the trial. This qualitative study formed the basis of my MRes research dissertation and was also written up as part of the overall trial report[3].

The results of the AIRS study became available in September 2013 which found the nasal balloon method to be effective in clearing middle ear effusions in school-aged children with glue ear in primary care. My interest in implementation research had been kindled through my qualitative work and I was really keen to further disseminate and implement the research findings with the potential to bring about a change in practice and ultimately benefit families and children. I was extremely fortunate in securing funding through the School of Primary Care Research (SPCR) which facilitated further implementation research in this field.

1.3 Research aims and objectives

The aim of this PhD was to facilitate wider implementation of nasal balloon autoinflation in the early management of otitis media with effusion (OME) in primary care.

The key objectives were as follows:

i) To explore how GPs currently manage children with OME in primary care, including diagnostic methods, monitoring, treatments and referral strategies through a review of the literature and qualitative research methods.

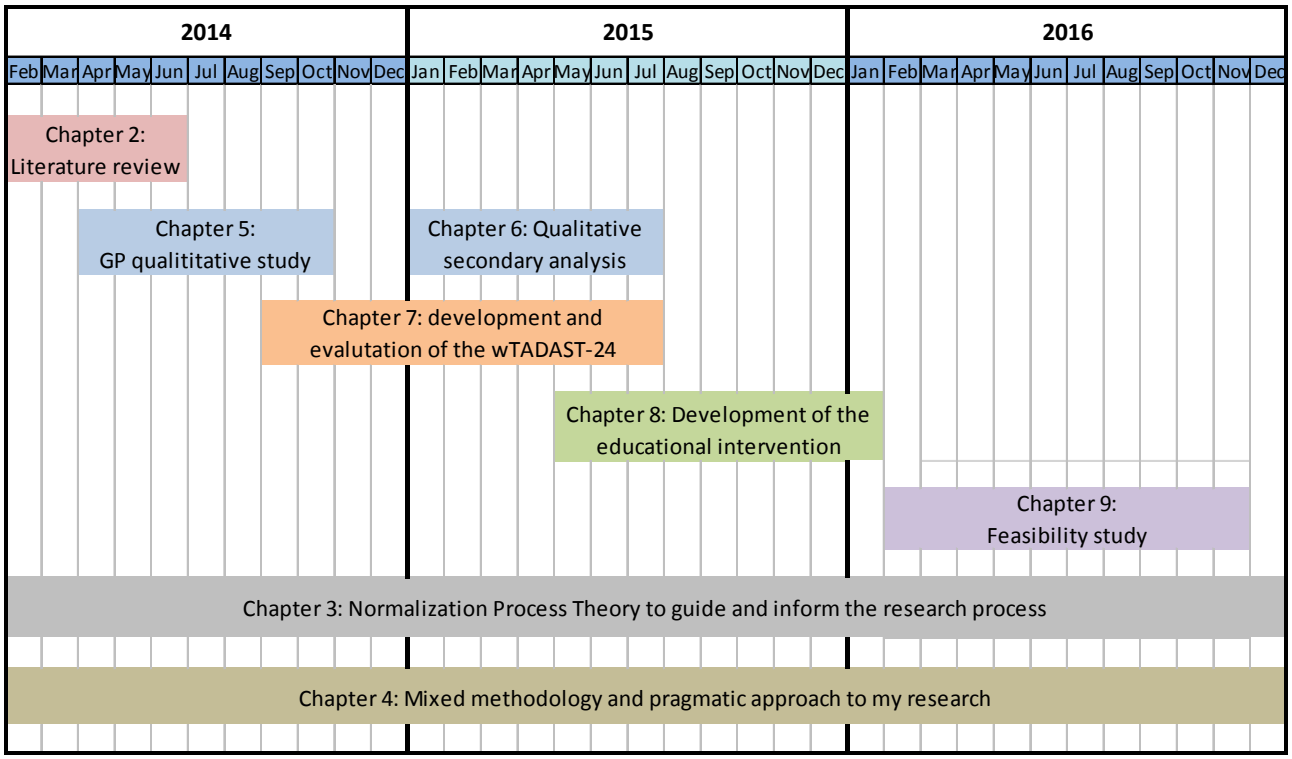
ii) To identify barriers and facilitators to wider implementation of use of nasal balloon autoinflation from the perspective of the different stakeholders, including GPs, practice nurses, parents and children through a secondary analysis of qualitative data.

iii) To further develop and evaluate an accessible online hearing disability test (wTADAST-24) to facilitate better monitoring and management of OME in primary care.

iv) To develop and pilot an educational intervention (LittleEARS) with families of children with OME, to support more structured primary care monitoring and use of nasal balloon autoinflation in children with OME.

1.4 Thesis timeline

My research was carried out between February 2014 and December 2016. The following Gantt chart presents the chapters of work undertaken during this time period.



1.5 Chapter summary

Chapter 1: Introduction to my PhD

Chapter 2: Otitis media with effusion: Background and literature Review

In chapter 2 I present a background to otitis media with effusion, beginning with a review of the epidemiology, diagnosis, treatment and management options. I discuss the potential impact of persistent OME on children and their families, and describe how it can affect quality of life and the educational development of young children. Finally I present a systematic search of the current evidence for autoinflation as a treatment for OME and introduce the potential inhibiting factors to wider implementation of the nasal balloon method. This chapter provides the basis for my PhD.

Chapter 3: Implementation theory and nasal balloon autoinflation

In Chapter 3 I present a theoretical framework for my research. The Normalization Process Theory of implementation is reviewed, compared and contrasted to other potential theories and justified as appropriate to underpin my research project.

Chapter 4: Philosophy and methodology

Chapter 4 presents my philosophical stance as a critical realist and I then discuss and justify the selection of a pragmatic approach and the use of mixed methods to guide this body of applied health research.

Chapter 5: Qualitative research: exploring GP views and experiences of OME and nasal balloon autoinflation

Chapter 5 presents my first empirical chapter, a qualitative study exploring GPs views and experiences of diagnosing and managing children with OME in primary care. The outcome of this study provides information about the organisational and political environment for implementation of the nasal balloon.

Chapter 6: Qualitative research: secondary analysis of existing qualitative data

Chapter 6 reports a secondary analysis of existing qualitative interview data from GPs, practice nurses and parents of children with glue ear. This analysis, focuses on the work required for implementation of the nasal balloon treatment itself, using the

Normalization Process Theory to explore the generative mechanisms of implementation. This work informs and guides the development of the LittleEARS educational intervention to support wider implementation of the nasal balloon treatment.

Chapter 7: Further development and evaluation of a hearing disability test (TADAST)

Chapter 7 presents a significant development and evaluation of an existing hearing disability test (wTADAST-24) in a new web format that is more reliable, relevant and acceptable to families and children, and applicable to primary care and community setting. The wTADAST-24 forms part of the LittleEARS educational intervention and facilitates self-monitoring by parents of their child's hearing disability in the community setting.

Chapter 8: Development of an educational intervention for glue ear (LittleEARS)

Chapter 8 describes the design and development of the novel LittleEARS educational intervention to support parents of children with OME. It provides practical and evidence-based information about glue ear and training in the correct use of the nasal balloon. The educational intervention was based on evidence from the literature, qualitative enquiry, expert knowledge, and user feedback from the previous chapters in this thesis.

Chapter 9: Feasibility study of the LittleEARS educational intervention to support nasal balloon autoinflation in primary care and audiology.

Chapter 9 presents a study evaluating acceptability and feasibility of the LittleEARS educational intervention to support active monitoring and the nasal balloon in children from both primary care and audiology.

Chapter 10: Discussion

The final chapter (Chapter 10) presents an overview of the research conducted as part of my PhD and I discuss the key findings in relation to current literature and clinical practice. I present a review of the strengths and limitations of my research, and reflect on the theory and methodology used in this research. Finally I propose future directions for my research and potential applications in the wider NHS setting.

Chapter 2: Otitis media with effusion (OME)

2.1 Introduction

In this chapter I present the background to my thesis, beginning with a review of the current literature about otitis media with effusion (OME) including epidemiology and risk factors for OME and the challenges of diagnosis and management in primary care. I discuss the potential impact of persistent OME on children and their families, and describe how it can affect quality of life and the educational development of young children. Finally I present a systematic review of the current evidence for autoinflation as a treatment for OME, including different methods and devices, and introduce the potential inhibiting factors to wider implementation of the nasal balloon method. This review and summary of the empirical evidence provides the basis for supporting wider implementation of nasal balloon autoinflation in primary care.

2.2 Background

2.2.1 Otitis media with effusion

Otitis media with effusion or glue ear is a result of a build-up of fluid or mucoid secretions in the middle ear space[6]. This can dampen vibration of the tympanic membrane and reduce movement of the auditory ossicles, resulting in a decrease in transmission of sound to the inner ear. Middle ear effusions can affect one or both ears and often develop after an acute ear infection. However, the fluid is non-infectious and as such not normally associated with pain or discharge[7].

Background prevalence of OME peaks around the age of 2 years old possibly due to the high incidence of acute otitis media (AOM) in this age group[8]. A second peak occurs at the age of 5 years coinciding with the start of primary education for many children when the spread of upper respiratory infections is often high[9]. OME is an episodic condition with natural resolution occurring in ~50% of children by 3 months[10 11], with less than 10% persisting beyond 1 year[12]. A study of British school children reported that the background prevalence fell to below 6% by the age of 8

years[12] indicating that the condition is self-limiting i.e. that for most children it will not persist beyond early childhood. Seasonal variation has been reported, with higher rates of middle ear effusions in autumn and winter when upper respiratory infections are most frequent. This is particularly true for temperate climates like the UK. [12 13]

The incidence of OME is particularly high in children with congenital conditions such as cleft palate and Down syndrome. 90% of children with cleft palate have a history of OME[14], whilst 55-95% of children with Down syndrome have conductive hearing loss associated with middle ear effusions.[15]

A meta-analysis of risk factors for recurrent or chronic OM in 2014 found that the greatest risks for chronic OM were previous episodes of AOM/recurrent otitis media (OR 11.41) and upper respiratory tract infections (URTIs) (OR 6.59).[16] Other important associated risk factors that have been identified are allergy/atopy, second-hand smoke, maternal education, and low social status. There is no evidence to suggest that there is any gender difference between boys and girls, only that boys are slightly more likely to get acute respiratory infections[17] which in turn is a risk factor for OME. The link between tobacco smoke exposure and childhood infections such as URTIs and middle ear disease has been well established[18]. However the mechanisms for this relationship are not entirely clear but may be through suppression of the immune system or local effects on the respiratory tract. Parental smoking has been shown to increase acute middle ear infections[17] and chronic or recurrent OM in children[16] compared to the general population. As a modifiable risk factor, effective methods should be taken to reduce children's exposure to second-hand smoke.

Risk factors such as maternal education and socioeconomic status are closely linked and there has long been a debate as to whether lower social status increases the risk factors for OME. A cohort study of Sicilian school children found that the prevalence of OME was most strongly associated with lower maternal education[19], whilst a meta-analysis found that patients with chronic or recurrent OM were more likely to be from lower socio-economic groups than the controls[16]. There is also a link between socioeconomic status and acute otitis media, which in turn is a risk factor for OME[17]. The relationship between social status and middle ear disease is likely to be due to a

complexity of factors rather than a single factor alone, and these may include reduced access to healthcare, poor housing and environmental conditions[20].

2.2.2 Impact of OME on speech, language and development

Hearing impairment can have a broad impact on children's health and development[21]. Reduced hearing can lead to functional problems in noisy nursery and school environments and potentially impact on wider social interactions, behaviour, language and educational development[21]. A cohort study in New Zealand reported that children with bilateral OME were more likely to have delays in speech, motor development and have some aspects of behavioural difficulties at the age of 5 years than children with normal hearing.[22] When followed up at 7, 9 and 11 years, children still had significantly lower scores for speech, reading and teacher-reported behaviour[23]. Another study showed that developmental problems including reading ability, hyperactivity and behavioural difficulties persisted into the late teenage years[21]. Nevertheless, some weaker evidence from a Turkish school showed no significant difference in academic performance of primary school children between those with OME compared to those with normal ears[24]. It is known that speech, language and educational development is associated with many variables including the age of the child, cognitive development, ethnicity and socio-demographic status[25]. However, it is likely that prolonged or severe middle ear effusions may increase the impact on the child's quality of life and educational development.

2.2.3 Recognising and diagnosing OME

Early identification of hearing problems in children has the potential to prevent longer term consequences such as speech and language problems and developmental delay. Associated hearing loss can often go unrecognised in young children, especially where symptoms are seen to overlap with perceived normal childhood behaviours such as ignoring instructions, saying 'what' and 'pardon' etc.[3] Often hearing symptoms come to light in the classroom, where children need to function in a usually noisier environment than the home and some may be unable to use lip-reading skills to facilitate understanding of the teacher. Where parents are concerned about their

child's hearing, the first point of contact for advice is often the child's GP, the health visitor or the school nurse. In the UK there are approximately 200,000 GP consultations each year for suspected OME[26].

GPs generally rely on history taking and otoscopy for diagnosis of OME with only a limited number having access to the more objective measure of tympanometry in the primary care setting[27]. Otoscopy has good sensitivity for OME but lacks specificity, meaning that in most cases, GPs have little more than chance of diagnosing the condition with otoscopy alone. Pneumatic otoscopy is recommended in the updated American Clinical Practice Guidelines for OME[28] to improve diagnostic accuracy, but it is not widely performed in the UK by GPs or specialists. By contrast, tympanometry is more widely available in secondary care and is found to be comparable in diagnostic accuracy to pneumatic otoscopy[29].

Audiological services in the UK are a specialism which encompasses hearing, tinnitus and balance, with a combined function for diagnostics and non-medical treatment[30]. Paediatric audiology services are responsible for the UK hearing screening programmes, paediatric diagnostic services, and hearing aid provision. A universal programme of screening was introduced in 2006 (the Newborn Hearing Screening Programme[31]) which resulted in much earlier diagnosis of sensorineural hearing loss, reducing the median age of diagnosis from ~18 months to 2 months of age. School Entry Screening is another childhood screening programme designed to identify children with sensorineural and conductive hearing losses (such as those associated with OME), however, coverage of this service is variable[32].

When children are referred for audiological assessment by their GP or school nurse there are a range of tests available depending on the age of the child. Pure tone audiometry (PTA) is used to measure hearing sensitivity and relies on children being old enough to respond to instructions and concentrate with a repetitive test. The pure tone threshold is the quietest sound audible to children at least 50% of the time at each test frequency. However, the level of background noise may significantly affect results, especially at the lower frequencies, and therefore PTA is not useful for testing in community settings like the GP surgery or in the classroom. In controlled situations

it provides a relatively objective measure of conductive, sensorineural or mixed hearing loss, but does not provide a measure of the potential disability associated with hearing loss. Visual reinforcement audiometry (VRA) is a method of PTA suitable for children aged 6 months to 2 years, where children are trained to look toward a sound source and are rewarded through a visual reinforcement (e.g. a flashing light or toy). In this way, PTA can be conducted in children too young to reliably follow instructions. Play audiometry can be used with slightly older children where the response to sound is to perform a play activity, like putting a peg in a hole.

Speech perception tests are more naturalistic and can start when a child is 18 months old and able to understand simple verbal instructions. The McCormick Toy Discrimination Test[33] was developed for children aged 18-30 months and comprised pairs of toys e.g. duck/cup and children are asked 'Where is the duck?' and the response is noted by which toy the child looks at. Children about the age of 30 months have a wider and more expressive vocabulary and are more engaged in the testing process. The Kendall Toy Test[34] was developed in 1954, and comprises of 3 lists of 15 words (10 test words and 5 distractors). Children are asked to point to the correct toy when its name is spoken at a sound level of 40dB. Speech perception tests can be performed in quiet or noisy environments and are therefore a good measure of how children manage in everyday settings.

In summary, there are a range of tests available to help with the objective diagnosis of middle ear effusions, however, most need to be conducted in a specialist setting where there is no background noise to invalidate the test results. Additionally the available tests measure objective hearing loss rather than the consequential impact of hearing loss on the child's speech, language and educational development.

2.2.4 Treatment and management options for OME

NICE (2008) gives guidance to healthcare professionals on how children aged 12 years and under with suspected OME should be assessed, who should be referred and who should be offered surgical intervention[35]. The main recommendations include: a formal assessment involving clinical history taking; clinical examination; audiological

assessment; and tympanometry. Children with documented persistent bilateral OME cases over 3 months, with associated hearing impairment, are considered suitable for surgical intervention.

2.2.4.1 Active monitoring/watchful waiting for OME

Active monitoring is a way of closely monitoring a patient to check for improvement (or lack of improvement) or worsening of a condition, whilst watchful waiting involves a waiting period before any intervention is used. However, the terms 'active monitoring' and 'watchful waiting' are commonly used interchangeably for glue ear.

The NICE guidelines[35] recommend a 3-month period of active monitoring to allow for natural resolution of glue ear and potentially reduce the need for surgical intervention. This period is defined as children having documented persistent bilateral OME and hearing loss over the 3 month period, as assessed by tympanometry and audiometry, and is most commonly associated with secondary care management of OME. However, children commonly first present in primary care with symptoms of OME and a period of active monitoring may also be appropriate in this setting whilst waiting for natural resolution or referral. Nonetheless, there have been questions about whether GPs have the techniques for active monitoring/watchful waiting in light of having limited access to audiological equipment[27].

2.2.4.2 Medical management

Antibiotics are commonly used to treat OME in practice[36], contrary to the NICE guidelines which state that antibiotics are not recommended for the management of OME[35]. However, a recent updated Cochrane review of antibiotics for OME included 3663 children in 23 trials[37] and found that children treated with antibiotics in secondary care were more likely to have complete resolution of middle ear effusions at 2-3 months than the controls (RR 2.00, CI 1.58, 2.53. NNTB of 5). However treated children were also more likely to experience diarrhoea, vomiting or skin rash. No effect on the overall rate of grommet surgery was found, and no studies reported more child-centred effects on speech, language development or quality of life. The review concluded that the benefits of using antibiotics in children with OME needs to be

balanced against the likelihood of harms, especially in the context of emerging global antimicrobial resistance. GP prescribing of antibiotics has been historically driven by patient/carer demand[38 39], but little is specifically known about the driving factors for the use of antibiotics in more chronic middle ear disease. A study eliciting parent's beliefs and knowledge about the management of acute otitis media (AOM), as opposed to otitis media with effusion (OME), in Australian pre-school children found that parents did not have a good understanding of the factors causing AOM, and often just assumed that antibiotics were the best treatment option[40]. Another study of Icelandic parent perspectives of antibiotics for AOM[41] found that parents were concerned that antibiotic treatment could harm their child by either causing resistance or impairing their immune systems. A UK study of parental concerns and expectations of treatment for children with AOM, found that parents were generally satisfied that antibiotics were not prescribed if reassurance was given that their child was not suffering from something more serious[42]. These studies have presented emerging views and experiences of antibiotics for acute middle ear disease and further work is still required to understand what parents think and understand about antibiotics for the treatment of the chronic condition of OME/glue ear and the implications for GPs when considering prescribing.

Oral and nasal steroids have a potential role to clear middle ear effusions by suppressing inflammatory mediators.[43 44] However, a Cochrane review in 2010 concluded there was no benefit of topical nasal steroids in resolving OME at any time point.[45] A course of oral steroids may however speed resolution in the short term, but further research is needed concerning both short and long term benefit and any potential harms before this treatment could be considered for treating OME[45]. A large trial funded by the Health Technology Assessment (HTA) programme is currently under way to answer these questions[46].

Antihistamines and decongestants have been assessed for effectiveness in clearing middle ear effusions in a Cochrane systematic review[47]. Pooled data from the meta-analysis have shown no benefit in clearing effusions and concluded that antihistamines

and decongestants have a high incidence of side-effects such as gastrointestinal upset, irritability, drowsiness and dizziness, and are therefore likely to cause harms.

In summary, the medical options available for OME are limited. There is inadequate evidence for the routine use of antibiotics for OME, and antihistamines and decongestants are ineffective with associated harms. The important issues concerning appropriateness and safety of oral steroids for OME are yet to be answered.

2.2.4.3 GP management of OME

A key clinical challenge for GPs is selecting which children with suspected OME may be managed conservatively in primary care, and which cases warrant onward early referral to audiology or ENT services. Approximately 50% of children who are referred to ENT do not have middle ear effusions at the time of hospital consultation[48] suggesting that there is uncertainty and imprecision around community diagnosis. Surprisingly little is known about how GPs manage OME in primary care. Early management and decisions to refer are, nonetheless, likely to be *ad hoc* and driven by clinical history and parental concerns[49].

With half of children resolving naturally within 3 months[9 10], there is a strong case for a period of active monitoring/watchful waiting in primary care before onward referral is considered necessary.

2.2.4.4 Surgical management

The NICE guidelines[35] recommend grommet surgery for children with persistent middle ear fluid with hearing loss and associated disability (i.e. speech/language delays or educational/behavioural problems). Grommet surgery is a day procedure which involves myringotomy, drainage of the middle ear fluid and insertion of ventilation tubes (grommets) in the tympanic membrane. There were a total of 27,387 surgical procedures for grommet insertion in the UK from 2015-16[50] with the highest grommet rates seen in children aged 5-9 years old. At an estimated cost of £1358.00 per surgical case[51], this represents a significant cost to the NHS.

A Cochrane review examined the evidence for effectiveness of surgical intervention[52] and showed that grommets were moderately effective in the 12 months post-surgery period with improvement in mean hearing levels between 5 and 12 dB HL[1]. By 18 months, however, no difference in hearing levels was found in those who had surgery compared to those who didn't, due to the natural resolution or 'cure' rate in the non-surgical controls. A prospective study of the impact on quality of life in paediatric otolaryngology practices in the United States reported a large, immediate improvement (14 days post-surgery) for most children using the OM-6 survey and Satisfaction with Decision Scale[53]. However it was difficult to control for placebo effects after surgery. The main complications of grommet surgery include ear discharge (2 - 49% of children within 6 months), tympanosclerosis (27 - 38% at 24 months), persistent tympanic membrane perforation (>1%) and *pars tensa* atrophy or retraction. Atrophy occurring after surgery can lead to permanent hearing loss of 3-4 dB HL [7].

Despite modest improvement in hearing levels and the potential for adverse effects parents generally appear satisfied with grommet surgery. A postal survey of parents of children >15 years old from 3 centres in the UK found that the majority thought surgery had been the correct treatment for their child which resulted in an improvement in hearing and a reduction in ear infections[54]. However, the response rate from parents was described as unsatisfactory at only 65%, and the questionnaires used had not been validated, implying a potential response and ascertainment bias[54]. A more recent observational survey of 426 Danish parents also found that 95% of parents were satisfied with the surgical treatment for OME and reported an improvement in the child and family's quality of life[55]. It is difficult, however, to disentangle self-selection effects when parents are not blinded to an intervention.

The extent to which the NICE guidelines are being implemented across the UK is presently uncertain. An audit of three London hospitals found that only 59% of

[1] These hearing losses are generally considered to be clinically relevant. Sound levels of 30dB is like a whisper, whilst normal conversation is at 60dB. Hearing levels are on a logarithmic scale, so every 10dB increase results in a doubling of the sound level. Ear wax typically produces 10dB hearing loss.

patients were on the care pathway specified by the NICE guidelines[56]. A retrospective case notes review of 5 secondary care centres found that only 32% cases complied with the core criteria of two audiograms 3 months apart with hearing levels of <25dB as set out in the guidelines.[1] Reasons for non-compliance with guidelines were given as clinicians attempting to personalise care to individual children and parental preferences for surgery.

In summary, grommet surgery is a recommended and effective intervention for a selected minority of children with persistent bilateral OME and associated hearing disability. However, effects of surgery are short term, often necessitating further surgery, and there are potentially associated adverse effects which may be unacceptable for families.

2.2.4.5 Other non-medical management options

2.2.4.5.1 Hearing aids

Hearing aids are an option for children and families whose preference is to avoid surgery or repeat surgery. A few studies have assessed the effectiveness of hearing aids and their acceptability to families. In a study of 39 parents of children with bilateral hearing aids for treating OME, the majority reported them easy to use and 66% were completely satisfied with OME being managed with hearing aids[57]. A mean improvement of 17dB hearing level was achieved (higher than that achieved with surgery) and stigma of using hearing aids was reported as minimal by the small sample of parents. In a more recent study of parents of children with cleft palate (where OME is highly prevalent) parents expressed concerns about the potential for social stigma although parents of children who did use a hearing aid thought they were well accepted, especially in younger children[58]. An economic evaluation of hearing aids vs grommet surgery found that hearing aids alone is associated with a cost per QALY gained of £11,593, compared to £8227 for grommet surgery (incremental cost-effectiveness ratio (ICER) for surgery compared with the HAs strategy was £ 5,086 per QALY gained)[59]. So whilst cost effectiveness favours surgery, hearing aids have the

potential to improve hearing levels for children during the active monitoring/watchful waiting period, for those families who express a preference to avoid surgery.

2.2.4.5.2 Nasal balloon autoinflation

Nasal balloon autoinflation is a promising treatment for OME applicable to larger primary care populations[60]. The treatment involves nasally inflating a purpose manufactured balloon daily for 1-3 months or until the fluid clears. A Cochrane meta-analysis in 2013[60] found that autoinflation was an effective treatment at >1 month compared to standard care, although studies were small (full details are presented in section 2.3: Literature review of autoinflation for otitis media with effusion). The NICE guidelines[60] in 2008 recommend that the nasal balloon could be used during the active monitoring period in those children who '*are likely to cooperate with the procedure'*. Additionally, the more recent MedTech Innovations Briefing for Otovent™[61], in their review of the nasal balloon, suggest that the nasal balloon could be used in children with glue ear during or after an active observation period following diagnosis, to help avoid the need for surgery.

Figure 1: Child demonstrating nasal balloon autoinflation

Reproduced with permission from Kestrel Medical Ltd

2.2.4.6 **Self-management**

Self-management is an important part of healthcare, particularly with the increase in number of people living with a chronic condition and an ongoing squeeze on healthcare resources in the UK[62]. (NHS Five Year forward View). Self-management can be facilitated by improving patients understanding of their health condition, which in turn can increase satisfaction with management and adherence to treatment regimens[63 64].

For families of children with glue ear, supporting self-management involves educating families about the health condition, self-monitoring for changes, and knowing when to seek professional help and advice. Research has found that providing good quality information about OME increases parental satisfaction with the consultation and treatment options[192]. Another study found that parents of children with glue ear valued printed information and also used the internet to supplement the information given at the consultation[65]. However, there is a wide variation in the quality of information about glue ear available on the internet, with variable readability and coherency[66]. In addition, there is limited information and tools to help parents to monitor their child's symptoms, or any practical advice about how to use the nasal balloon during the active monitoring period.

In summary, non-medical treatments such as hearing aids are an option for families who prefer to avoid surgery, and the nasal balloon autoinflation is a promising treatment applicable to primary care and may help improve natural resolution rates and improve quality of life for those children who are waiting for resolution or referral. Self-management, by providing education, information and support for OME, has the potential to enhance the recommended 3-month active monitoring period.

2.3 Literature review of autoinflation for otitis media with effusion

2.3.1 Background

The role of Eustachian tube dysfunction in glue ear has been well documented[67]. Improving the function of the Eustachian tubes and equalising middle ear pressures can be achieved using the Valsalva or Politzer manoeuvres. The Valsalva manoeuvre[68] involves the forced expiration against a closed airway achieved by closing the mouth and blowing out, whilst closing off the nostrils. The Politzer manoeuvre[69-71] is a method of inflating the middle ear by blowing air up the nose whilst swallowing. Both manoeuvres aim to ventilate the middle ear by equalizing the internal pressure with atmospheric pressure. This leads to both improved oxygenation of the middle ear and drainage of the effusion, resulting in better sound conduction through the tympanic membrane to the inner ear.

A number of devices and techniques have been used to achieve middle ear inflation. 'Politzerization' for OME was first achieved by squeezing a rubber bulb held to one nostril, closing the other nostril whilst swallowing water[72]. Modification of this technique used different external pressure sources to deliver the ventilation including a syringe[73] and an electrical pressure device[74]. However, Politzerization was found to be limited due to the equipment that was needed, and not particularly well accepted by patients. Arick[75] and Silman[76] (2000) developed a portable, hand-held device as a constant and reliable air-source for the modified Politzer method (EarPopper™) suitable for use outside of the hospital setting. The current retail cost of the device in the UK is £99 and is therefore not accessible or feasible for all affected families.

Balloon autoinflation was first described by Hunt-Williams who used a carnival blower with balloon attached for children to inflate via the nostrils [77] and two further trials were conducted using the same technique[78] [71]. The purpose manufactured nasal balloon (Otovent™) was first described by Stangerup in 1992 and consists of a latex balloon attached to a connecting nozzle[79]. The nozzle is held up against one nostril whilst closing off the other nostril. The balloon is slowly inflated with forced exhalation (Figure 1). The tension in the balloon delivers a pressure equivalent to 300-400mm of

water, similar to submerging in a swimming pool to a depth of less than half a metre. Treatment involves inflating the balloon via each nostril 3 times per day for 1-3 months. The balloon needs to be changed each week and the connecting nozzle can be washed in warm, soapy water.

The most recent systematic review is a 2013 Cochrane review of autoinflation for hearing loss associated with otitis media with effusion[60] and is reviewed in the following section.

2.3.1 Cochrane systematic review of autoinflation

The Cochrane review[60] in 2013 identified 8 randomised controlled trials of autoinflation for inclusion in a meta-analysis. The studies included in the review used a range of autoinflation techniques including the carnival blower/balloon[71 78], Politzerization[75 80 81], and the Otovent™ nasal balloon[79 82 83]. The study participants were generally children under the age of 16 years, with the exception of the Lesinskas study which included adults between 16 and 75 years[80]. All included studies were small, with short-term follow up. A total of 702 participants were included in the review. Details of the 8 studies are presented in Table 1

Table 1: Studies included in the 2013 Cochrane Review of autoinflation

	Participants	***Interventions***	***Outcomes***
Arick 2005[75]	94 children, 4-11 years with middle ear effusion (MEE)	Intervention: Modified Politzer for 7 weeks. Control: equal care without intervention.	Air conduction thresholds for each ear
Blanshard 1993[82]	85 children, 3-10 years, with bilateral OME on tympanometry	Intervention: Otovent 3 times daily for 3 months Control: equal care without intervention.	Tympanometry and pure tone audiometry (PTA)
Brooker 1992[78]	40 children, 3-10 years, with uni or bilateral OME	Intervention: Carnival balloon 3 time daily for 3 weeks. Control: equal care without intervention.	PTA and tympanometry

De Nobili 2008[81]	40 children, 4-10 years, with OME and tubaric dysfunction.	Intervention and control: inhalation, Politzer and aerosol with water therapy for 12 days. Intervention group: home therapy of Otovent 3 times daily for 1 week for 2 consecutive months.	Tympanometry
Ercan 2005[83]	60 children, mean 6.2yrs, with uni or bilateral OME.	Intervention: Otovent 3 times daily for 6 weeks plus nasal irrigation 3 times daily for 6 weeks. Control: saline irrigation for 6 weeks.	Pneumatic otoscopy and tympanometry
Fraser 1977[71]	85 children, 3-12 years, with bilateral OME.	Intervention: Carnival blower twice daily for 6 weeks. Other arms: equal care without intervention.	PTA and tympanometry
Lesinskas 2003[80]	198 adults, 16-75 years, with uni or bilateral OME	Intervention: Politzer inflation twice daily for 10 days +/- antibiotics. Control: equal care without intervention.	Pooled scores of pneumatic otoscopy, tympanometry, patient complaint and audiometry.
Stangerup 1992[79]	100 children, 3-10 years, with uni or bilateral OME.	Intervention: Otovent 3 times daily for up to 4 weeks. Control: equal care without intervention.	Tympanometry

The studies included in the review used a range of outcome measures including tympanometry, audiometry, and composite outcome measures. The reviewers reported problems combining outcome data due to a lack of consistency of outcome measures used in the studies. A composite measure of any outcome which signified improvement was used at time points of <1 month and $\geq$ 1 month. Pooled estimates favoured autoinflation when compared to control at $\geq$1 month using these composite outcomes (relative risk of cure 1.74, 95% CI 1.22 to 2.50).

A sub-group analysis was conducted based on the type of intervention. 5 of the 8 studies used autoinflation via Otovent™ nasal balloon or carnival blower/balloon (both Valsalva methods). Analysis showed a non-significant effect of the treatment compared to the controls, both in the under 1 month (RR 1.47, CI 0.69 to 3.13) and

over 1 month time periods (RR1.22, CI 1.00 to 1.49). There were considerable heterogeneity between the studies, and it is also questionable whether the carnival blower is an equivalent treatment to the Otovent™ nasal balloon, although the Cochrane reviewers classified it as such (the carnival blower, or party blower, is a toy which unfurls with a whistling sound when blown hard, which may provide less resistance than the nasal balloon).

Adverse events were reported as similar in both intervention and control groups, although there were some reports of discomfort associated with autoinflation. Compliance was reported in 6 of the 8 included studies, with 5 studies reported it as good or satisfactory. However, one study involved the physician delivering the treatment[80].

The authors of the review concluded that because of the low cost and absence of adverse events, autoinflation should be considered whilst waiting for natural resolution.

2.3.2 Aims and objectives

The aim of this literature review is as follows:

i) To assess the effectiveness of autoinflation compared with no treatment in children and adults with otitis media with effusion, by updating the 2013 Cochrane Systematic Review.

ii) To present a narrative review of the literature with respect to contextual issues around acceptability and compliance with the nasal balloon in children and their families.

Figure 2 presents the PICO model for this systematic review of the literature.

Figure 2: PICO

Participants	Adults or children with unilateral or bilateral middle ear effusions using tympanometry (type B or C2) +/- pneumatic otoscopy or audiometry.
Intervention	Any form of autoinflation that increases the intranasal pressure (e.g. Otovent™ nasal balloon, Politzer device).
Comparison	No autoinflation but otherwise treated equally to the intervention group
Outcomes	• Improvement in tympanometry to type A or C1 • Difference in hearing level on pure-tone audiometry • Improvement measured as a composite of change in tympanogram and/or audiometry.
Study designs	Randomised controlled trials.

2.3.3 Search strategy and methods

This literature review was carried out as an update to the 2013 Cochrane review and followed guidance from the Cochrane Handbook of Systematic Reviews and the NHS Centre for Reviews and Dissemination, University of York. The search strategy was replicated from the 2013 Cochrane review and is presented in Appendix A.

Types of studies: I included randomised controlled trials. I also made note of the non-randomised studies of the Otovent™ nasal balloon which might add context or practical information about usage of the nasal balloon method.

Types of participants: I included studies of adults and children with a diagnosis of unilateral or bilateral middle ear effusions using tympanometry (type B or C2) +/- pneumatic otoscopy or audiometry.

Types of intervention: I included studies of any form of middle ear insufflation, including the nasal balloon method and Politzerization, in both primary and secondary care settings.

Comparison: I included studies comparing the intervention with no autoflation but treated equally to those in the intervention arm.

Types of outcomes: primary outcomes included:

i) Improvement in tympanometry from Type B/C2 (negative pressure) to type A/C1 (normal middle ear pressures) according to the modified Jerger Classification (see Table 2).

Table 2: Tympanometric classification (based on modified Jerger Classification[84])

	Middle Ear Pressure	***Tympanogram***	***Positive predictive value for OME***
Type A	+200 to -99	Peak	Normal
Type C1	-100 to -199	Peak	Normal
Type C2	-200 to -399	Peak	54%
Type B	$\geq$ 400	Flat trace	88%

ii) Differences in hearing level on pure-tone audiogram (average 10dB improvement over the frequencies 250Hz to 2000Hz)

iii) Improvement measure as a composite of change in tympanogram and/or audiometry.

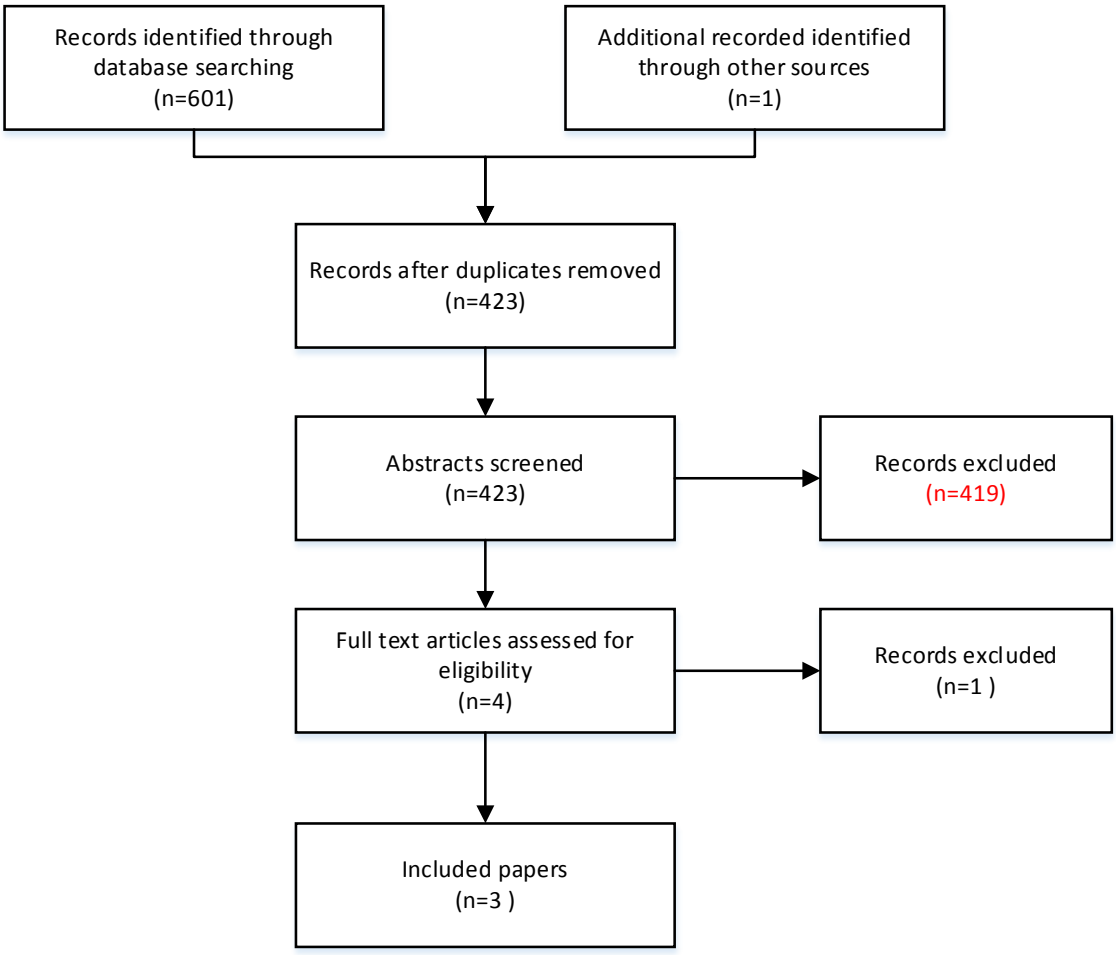
iv) Improvement in the impact of OME is an important outcome for parents and children. The OM8-30 (further refined to the OMQ-14) is an ear-related quality of life measure, developed within two large studies of OME in the UK[85 86] and validated using data sets from a large European study.[87] It is a functional health status measure completed by the parent (proxy measure) and measures 3 domains of hearing including i) reported hearing difficulties and speech concerns, ii) behaviour and developmental impact; and iii) ear-related physical ill health. Improvement in QOL can be assessed by change in total OMQ-14 score, whereby a change in ~0.5 SD is considered to be a moderate effect size[88]. Further details of the OM8-30/OMQ-14 are presented in section 7.2.1.

Search Methods: An electronic search was conducted with the following databases: Ovid MEDLINE, EMBASE, ISRCTN registry, Clinicaltrials.gov, UKCRN Portfolio database, using the search criteria presented in Appendix A. The search criteria were amended from the Cochrane Review to include EarPopper™ which identified an additional relevant study using Politzerization.

The search was conducted on 7th February 2017 and was restricted to literature published between April 2013 (date of last Cochrane update) and 7th February 2017.

2.3.4 Updated literature review

Figure 3: PRISMA flow chart



The updated literature review undertaken as part of this PhD identified 4 studies that have the potential to add to the evidence for autoinflation[2 89-91]. On review of the full articles, I identified that one study[90] was not a randomised controlled trial and

therefore would be excluded from any future update to the Cochrane Systematic Review for autoinflation (figure 3). In addition a further 2 studies registered on ClinicalTrials.gov are currently in progress and are therefore not included as part of this review.

I assessed the identified papers using the Cochrane 'Risk of Bias' assessment tool[92] and the results are presented in Figure 4. The Williamson study 2015 (AIRS)[2 3] was assessed for bias in the NICE Medtech Innovations Briefing[61] for Otovent™ using the same risk of bias tool. I have presented this assessment of bias for objectivity as I am a co-author of this study.

Figure 4: 'Risk of bias' summary for included studies

	Random sequence generation (selection bias)	***Allocation concealment (selection bias)***	***Comparability of groups at pre-test (detection bias)***	***Blinding of outcomes (detection bias)***	***Incomplete outcome data (attrition bias)***	***Selective reporting (reporting bias)***
Williamson (2015*)	Low	Low	Unclear	Unclear	Low	Low
Banigo (2016)	Low	Unclear	Unclear	Unclear	Low	Low
Bidarian-moniri (2014)	Low	Unclear	Unclear	Unclear	Low	Low

**Assessment of risk according to the Medtech Innovations Briefing 2016*

The following presents a critique of the identified RCTs and a summary of how it adds to the current evidence for autoinflation for OME.

Williamson[2] (2015) conducted a randomised controlled trial of nasal balloon autoinflation (Otovent™) compared to routine care in 4-11 year old school children with unilateral or bilateral OME (Autoinflation Randomised Study – AIRS). 320 children

were recruited through 43 primary care centres in the UK, and were randomised to receive Otovent™ 3 times per day for 1-3 months plus standard care, versus standard care alone. Outcome was measured by improvement in tympanometry (Type B to A/C1) at 1 and 3 months, assessed by experts masked to the treatment group allocation. This study was reviewed as part of the MedTech Innovations Briefing 2016[61] using the Cochrane Risk of Bias tool[92] and was considered to be of higher quality and lower risk of bias compared to the studies included in the 2013 Cochrane Review[60]. The nasal balloon was found to be effective in clearing middle ear effusions (47.3% of children in the treatment group versus 35.6% in the control group with normal tympanograms at 1 month, RR1.36, CI 0.99-1.88) and improving ear-related child and parent quality of life (adjusted between group difference in change from baseline OMQ-14 score -0.42, 95% CI -0.63 to -0.22 representing an adjusted Effect Size of 0·48 (of an SD) p=<0·0001 favouring intervention). Compliance with the Otovent™ treatment (reported usage of the nasal balloon '*most'* or '*all of the time'*) was 89% at 1 month and 80% at 3 months. Adverse events were reported as mild, infrequent and similar in the two treatment arms. In summary, the study found that use of nasal balloon autoinflation in young children with OME was effective both in clearing middle ear effusions and improving ear-related quality of life.

Banigo*[89]* reviewed the effectiveness of the EarPopper™ device in improving hearing outcomes and reducing ventilation tube insertion rate in children with persistent OME. 29 children aged between 4-11 years with persistent OME over 3 months on the waiting list for ventilation tube surgery were recruited via secondary care in the study. Children were randomised to receive the EarPopper™ device, twice per day in each nostril, for 7 weeks or the control group (no treatment). The primary outcome was the change in air conduction thresholds between baseline and 7 weeks. Secondary outcomes were compliance with the treatment, adverse events and rate of ventilation tube surgery. This study was a single blind study where, similar to other methods of autoinflation, blinding of treatment allocation is not possible. The audiologist was blinded to the allocation of treatment, although it is possible that this information could have been conferred by the parent/child during the final assessment, representing an unclear level of detection bias. The study used a computer –

generated sequence for treatment allocation, although there was no information presented about allocation concealment. Follow-up rates were good and outcome measures were reported in full. The study found that air conduction improved across all frequencies in the treatment group by 10.9dB, (P<0.001) compared to 3.6dB (P=0.201) in the control group. However, no confidence intervals were presented for this data, and the analysis did not control for differences in baseline severity. Compliance with the device was reported as over 90%, and ventilation tube rate was 53% in the treatment group compared to 78.5% in the controls. Adverse events included discomfort in the ears following use of the EarPopper™ device. In summary, this study found significant improvement in hearing levels following treatment with the EarPopper™ device and has the potential to reduce ventilation tube surgery. The study however, did not use tympanometry as an objective measure of middle ear effusions, and study numbers were small meaning that further research would be required to confirm these findings. The device, however, has potential for use in the younger age group, who are less likely to be able to self-inflate a nasal balloon.

The Moniri-Otovent[90] device is a novel method of autoinflation which consists of an inflatable facemask, attached via a T-junction to an Otovent™ balloon and a handheld pump hidden inside a teddy bear. The facemask covers the child's nose and mouth and the air is pumped into the system by hand. The attached balloon regulates the pressure applied and give visual feedback. Bidarian-Moniri[91] evaluated the effectiveness and compliance with this novel autoinflation device in 45 children aged 2-8 years with persistent bilateral OME and a history of hearing loss, on the waiting list for Grommet surgery. The study was a crossover design, where children were randomised to receive autoinflation or control. After 4 weeks, the two groups were crossed over so each group received both active and control, and were assessed again after 8 weeks. The primary outcomes were the improvement in middle-ear pressure and hearing thresholds at 8 weeks. Children were randomly allocated to one of the two treatment groups using a computer generated randomisation sequence. However, it is not detailed whether allocation was concealed from the recruiting doctors, suggesting an unclear risk of bias. This study was a single-blind study as the method is unsuitable for blinding to participants. Audiometric assessments were

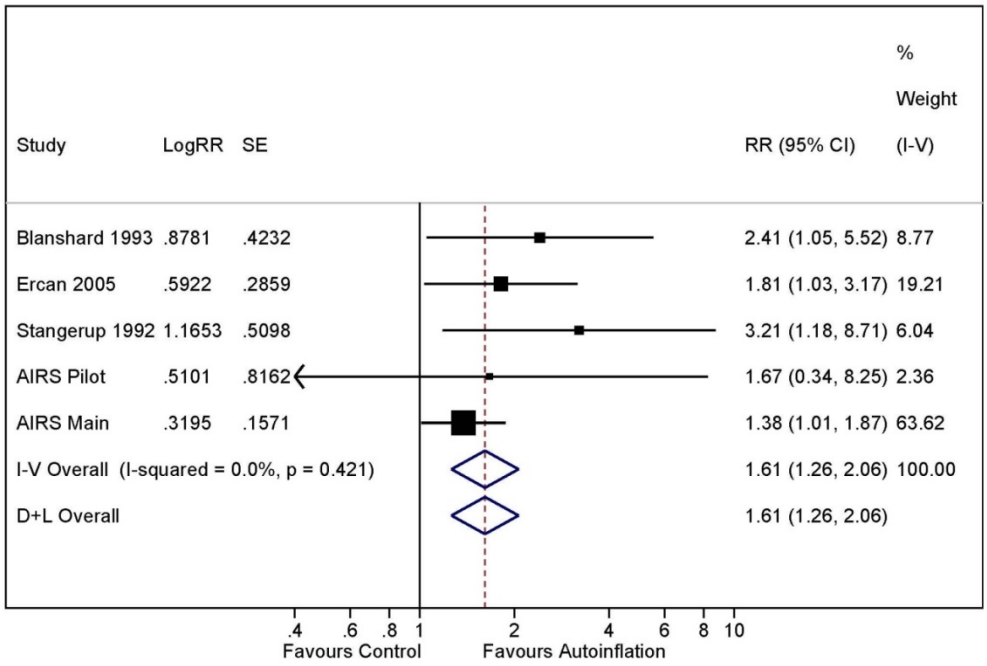
performed by an audiologist who was blinded to the treatment allocation, although no details were given about attempts to minimise the possibility of parents/children informing the audiologist of the treatment group. In addition, there is no information about blinding of the tympanometric outcomes, suggesting an unclear risk of detection bias.

At 4 weeks, an improvement in mean middle ear pressure of 166daPa ($p<0.0001$) and best ear hearing threshold of 6dB ($p<0.0001$) was found in the treatment group compared to 19daPa and 1dB respectively in the control group. Additionally at 4 weeks, improvement in tympanometry from type B to A/C1 was 19/44 ears (43%) in the treated group compared to 3/46 (7%) in the control group. The study was not analysed using a crossover analysis due to expected carry-over effects between the two treatment periods. The 8 week crossover data, whilst potentially reducing confounding factors because each child acted as their own control, meant that there was no control group at 8 weeks with which to compare outcomes. The treatment method, however, has the potential for use in the younger age group, but may be limited by the cost of the device and may be most applicable to the secondary care setting.

2.3.5 Summary of systematic literature review

This updated systematic literature search identified an additional 3 studies of autoinflation with the potential to be included in a future update to the Cochrane Systematic Review. The Williamson study[2 3] was the first large study in primary care of nasal balloon autoinflation. Adding the data from this study to the Cochrane meta-analysis significantly increases the sample size of studies using similar outcomes. A preliminary meta-analysis was conducted as part of the AIRS study and the resultant estimated aggregate effect size of autoinflation was found to be RR1·61, CI 1·26 to 2·06, I-squared heterogeneity 0·0%[3] using tympanometric outcomes (Figure 5).

Figure 5: Meta-analysis of 1 month outcomes (ear-based analysis)



I-V, inverse variance method. D+L DerSimonian and Laird method.

Adverse events were infrequent and mild, and therefore add to the previous conclusions that this low-harm treatment could be considered for children whilst waiting for natural resolution.

2.3.6 Narrative review of nasal balloon autoinflation

This section provides contextual information about the use of the nasal balloon method. A number of research studies of Otovent™ nasal balloon were excluded from the Cochrane Review due to being of either lower quality or not for treatment of otitis media with effusion[93-95]. However, these research studies provide some contextual information and are included here as part of this review about acceptability, compliance and cost effectiveness of the nasal balloon method.

2.3.6.1 Acceptability and ease of use

There have been anecdotal concerns from some ENT specialists that children are unable to perform nasal balloon autoinflation, or that treatment with the balloon may be an unnecessary burden for the family. Only a handful of published studies have

reported information about acceptability and ease of use of the nasal balloon. One study reported the nasal balloon to be *'acceptable'*[78] to children whilst others described it as *'fun'* or '*amusing'*[79 83]. A nested qualitative study in the AIRS randomised controlled trial[3] reported parents describing the nasal balloon as a '*natural, holistic treatment',* which was '*acceptable* 'as a treatment for glue ear and a '*novelty for the children'*.

Studies have shown that successful autoinflation with the nasal balloon can be dependent on a child's age[94 95]. A study of barotitis (occlusion of the middle ear due to changes in atmospheric pressure) after flying reported (n=45 children, 49 adults) that only 53% of 2-6 year olds could inflate the balloon compared to 72% of 7-9 year olds and >94% of older children/adults[94]. However, the author of this study suggested that younger children could be better taught the technique by their parents prior to the flight. The AIRS study found that most children were able to master the technique with good instruction and some practice[3]. In this study, nurses demonstrated the technique to the families and children. They emphasised the need for pre-stretching the balloon (by hand or mouth) to help with the initial inflation. Additionally, plenty of encouragement and support by the parents and healthcare providers helps the children to engage with and master the technique. A telephone follow-up by nurses provided additional support for families and allowed early identification if the child was having problems. In the AIRS study only 4/160 (<3%) children aged 4-11 years did not manage to master the technique which is lower than was previously reported, but this study included school aged children who were considered most likely to be able to comply with the technique[2 3].

2.3.6.2 **Compliance with the nasal balloon**

Good compliance with autoinflation treatment has been linked to effectiveness[82], however the factors that influence compliance remain uncertain. There has been variation in compliance reported in the studies of nasal balloon autoinflation. Compliance was, nevertheless, good in the AIRS study, with 89% of parents reporting that the nasal balloon was used '*most'* or '*all of the time'* during the first month of treatment[3]. Previous studies have been more vague about levels of compliance

describing them simply as "*satisfactory*" [83] and "*good*"[78]. However, there were no further details about how it was measured and what might have influenced compliance. Parents reported that making the treatment as part of the child's daily routine, like when cleaning teeth or taking medicines/inhalers, was key to remembering to use the nasal balloon[3]. Children naturally adopt daily routines around their school and home life and it has been theorised that compliance with certain medical treatments is improved by adopting good daily routines[96]. Similarly, family routines have also been found to significantly affect the management of childhood asthma, thus reducing the burden of treatment for the family.[97] However, compliance over a longer treatment period may also be a problem for some families. Some parents reported more difficulties if treatment went on for more than 4 weeks, although this was not reflected in the levels of compliance in the AIRS randomised controlled trial[2].

Overall the research suggests that good compliance is achievable. However, there is limited information about what might influence this, especially over the longer treatment period.

2.3.6.3 **Cost effectiveness of the nasal balloon.**

The Otovent™ nasal balloon is currently available on prescription (Drug Tariff price £4.90 excluding VAT) or can be purchased online or at some leading pharmacists at a cost of £7.84 for a pack of 5 balloons (1 months treatment).

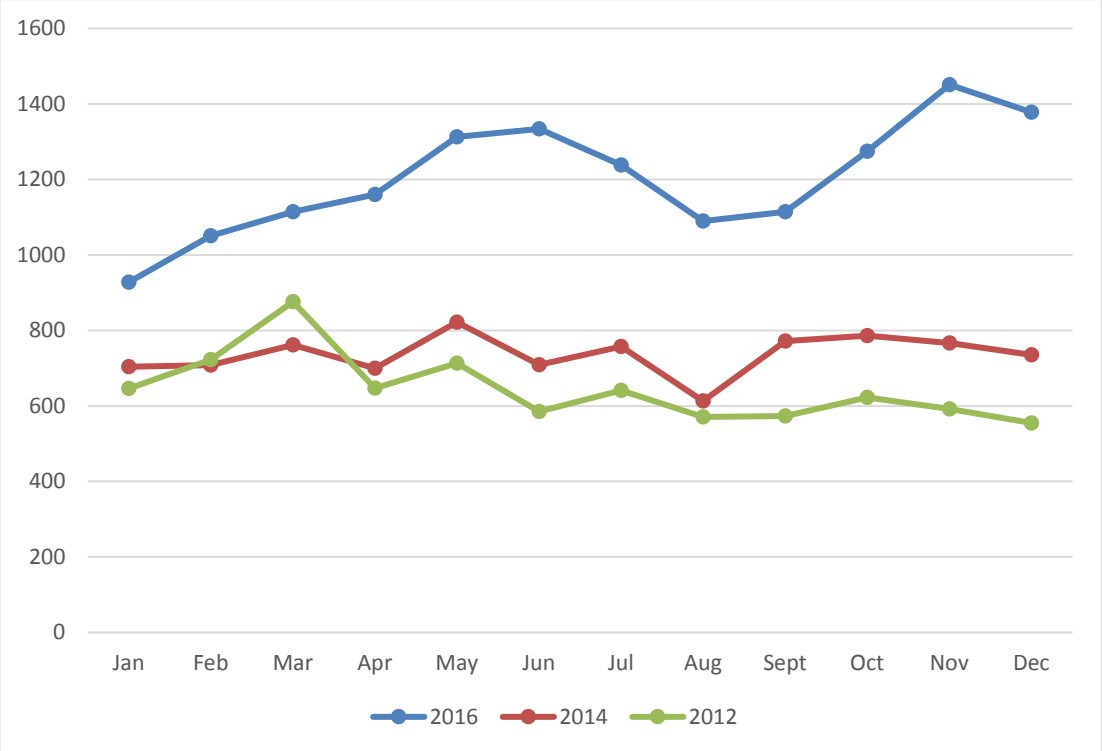
An economic analysis was conducted as part of the AIRS study[3] and found that the Otovent™ device was likely to be cost-effective at conventional cost per QALY thresholds. The cost per case resolved was found to be £132. This suggests that the use of the Otovent™ nasal balloon could provide good value for money for the NHS. However, the economic analysis was only based on 3 month outcomes. Service use was followed up for 12 months and there were no differences in hospitalisations for grommet surgery between the treatment and standard care arms, although all children in the standard care arm were offered Otovent™ at the end the 3 month trial which may have confounded the results. At an estimated cost of £1358.00[51] per surgical case

for grommet insertion, the Otovent™ has a potential to provide significant cost savings for the NHS, although further research is required to assess longer term benefits of its use.

2.3.6.4 Extent of use in the UK

The nasal balloon (Otovent™) has been available on prescription and over-the-counter for more than 10 years. Monthly prescribing data published by the NHS Business Services Authority suggest that approximately 15,000 Otovent packs are currently being prescribed per annum, although this doesn't take into account those that may be been purchased over-the-counter or from the internet.

Figure 6: Prescribing data for Otovent nasal balloon (number of packs prescribed per month)



The AIRS study was the first primary care study of nasal balloon autoinflation, and suggested that it offers an effective, non-surgical treatment for families and children affected by OME in the community setting. The study was published in 2015 and since then there has been a modest increase in prescribing of the nasal balloon (figure 6). There is a potential for wider use in this setting, however it is unclear about the extent

to which GPs are aware of the nasal balloon as a potential treatment for OME, and what they might need to support its use.

2.4 Summary

OME is an important childhood condition, which can impact on children's quality of life with potential educational, behavioural and social consequences. Primary care is often the first point of contact for parents who have concerns about their child's hearing and general practitioners are faced with the challenge of how to manage a child with OME and deciding when to refer for surgical intervention. There are limited medical treatment options for OME, with antibiotics, nasal steroids, antihistamine and decongestants often prescribed but all are either ineffective or have significant associated harms. Grommet surgery is an effective intervention for a selected minority of children with persistent bilateral OME and associated hearing disability. However, effects of surgery are short term and there are potentially associated adverse effects which may be unacceptable for families. Nasal balloon autoinflation is a promising treatment for OME which is applicable to primary care and may help improve natural resolution rates and improve quality of life for those children who are waiting for resolution or referral. However, the treatment is not yet widely known or used in primary care. Barriers and facilitators to implementation of use of the nasal balloon are not well understood at present, and trial evidence alone is unlikely to be sufficient to promote a wide uptake in primary care. This chapter has provided a background of OME and identified gaps in knowledge about diagnosis and management in the primary care setting and provides some context for wider implementation of the nasal balloon.

Chapter 3: Implementation theory and nasal balloon autoinflation

The literature review presented in chapter 2 identified that the nasal balloon method, whilst shown to be effective in treating young children with OME, is not widely known about or used in primary care. Publication of trial results and dissemination activities are rarely enough to bring about a change in clinical practice, and ultimately a potential benefit for patients. Successful implementation of new evidence into practice requires careful consideration of a range of factors including the social, political and financial context in which implementation is planned, together with the requirements of the different stakeholders such as patients, healthcare providers, commissioners and policy makers. Taking a theoretical approach to implementation research provides a framework within which to better consider potential facilitators and barriers to successful implementation, may help to plan implementation of new treatments, and help to understand why implementation succeeds or fails. In this chapter I discuss the use of implementation theory, give a brief review of theoretical models and frameworks, and justify why I selected the Normalization Process Theory (NPT)[5] to underpin this research project.

3.1 Introduction

Evidence-based practice (EBP) concerns the integration of best available high-quality evidence and individual clinical expertise in decision-making about the care of individual patients[98]. The adoption of EBP in healthcare systems is aimed at improving quality of healthcare provision and outcomes for patients. However, despite the vast resources spent on research, patient outcomes have not improved at the same rate as the advances in clinical and health service knowledge[99]. Many patients do not receive best care according to the evidence, receive unnecessary or harmful care, or are not on the appropriate care pathway[100].

For patient outcomes to change, the findings of research studies need to be adopted more efficiently into clinical practice. However, this translation of evidence to practice

can be unpredictable and complex[100]. Traditional approaches have relied on dissemination of evidence to clinicians using clinical guidelines, medical education, conferences and medical journals. Clinical guidelines are an important tool to help physicians evaluate research and make good clinical decisions, but are rarely enough to implement research findings into clinical practice[101]. The work by Cabana and colleagues[102] suggested that *'simply knowing about a guideline is not enough to change practice'*. Whilst a simple strategy of dissemination might be appropriate for modest changes, more complex interventions often require more effort and consideration.

Implementation research has developed over the last 10 years identifying strategies to address this '*second translational gap'* [4] between evidence and practice. In response to the Cooksey Report[4] in 2006 the Clinical Effectiveness Research Agenda Group[103] was established to define the research agenda for the NHS. One of their key recommendations was to use theory to underpin the implementation process. Their professional view was that using theory offers a framework that can be applied across different settings and can enhance the better understanding of facilitators and barriers to implementation. The absence of a theoretical underpinning can make it difficult to understand why implementation of an intervention succeeds or fails, and reduces the opportunities to develop strategies to promote implementation.

Implementing wider use of the nasal balloon for OME is complex and publication of the AIRS randomised controlled trial[2] alone is unlikely to result in a wide uptake of this treatment in primary care. Using implementation theory in this project will help to identify barriers and facilitators to wider implementation and help plan and pilot an educational intervention to support both the active monitoring period and the nasal balloon treatment in primary care and the community.

3.2 Theoretical approaches to implementation

Implementation research has continued to expand and develop over the last 10 years and there are now a large array of theories, frameworks, models and toolkits available to help researchers with implementation projects[104]. However, understanding

terminology and navigating through the vast number of theories and guidance in order to choose the most appropriate one is challenging. The following sections review implementation theories, models and frameworks, and describes how NPT was selected to underpin this research project.

3.2.1 Theories, models and frameworks

'Theories' are a system of ideas, principles or statements to facilitate the understanding of facts, events or behaviours. They are generally abstract, broadly applicable and not specific to the content or topic of a research project or intervention. *Impact theories* describe hypotheses and assumptions about how an intervention facilitates change, whilst *process theories* describe how things should be organised to facilitate change. An implementation theory is thought to facilitate both understanding and explanation of causal factors and mechanisms of implementation. An example is the theory of Organizational Readiness for Change[105] which refers to organisation members' commitment to change and a shared belief in their capability to change. Effective implementation is more likely when members initiate change themselves, exert greater effort and work collaboratively, with a shared understanding of change. This theory is potentially useful in this research project which requires a commitment of healthcare professionals to implement the wider use of the nasal balloon and a commitment by the parents to adhere to the treatment regimen.

'Models' are closely related to theory but have a narrower scope and tend to be more descriptive rather than explanatory. For example, an implementation model is used to *describe* the process of implementing a new practice, rather than *analyse* what factors or processes influence the outcome. An example of an implementation model is the Normalization Process Model[106] which was developed to help explain the processes concerned with operationalising complex interventions and embedding them in everyday practice. This model has been used by researchers to understand the challenges of implementing a new tuberculosis treatment programme in South Africa[107] and help identify logistical issues, hierarchical relationships and training needs that may hinder the process of implementation. This model would potentially be useful for understanding the processes of implementing the nasal balloon, including

challenges within the GP practice and barriers and facilitators to use of the balloon in the family environment.

'Frameworks' provide a structured and systematic way of developing, managing and evaluating interventions. They normally consist of descriptive categories, such as constructs or concepts, to describe factors that influence implementation. Similar to implementation models, they provide relevant description but not explanation of the mechanisms of change. An example is the Theoretical Domains Framework(TDF)[108], developed by consensus of experts, which includes 12 theoretical domains, grounded in psychological theory, to study implementation of evidence-based practice, and to assist in identifying and understanding associated problems. This model was used in a study to develop a parental-supervised teeth-brushing intervention to prevent dental decay in young children[109]. Using the TDF allowed researchers to capture the complexity of the intervention and develop a universal and targeted intervention applicable across individual, social and structural levels. This framework is potentially relevant to this research project of developing an intervention to support the use of the nasal balloon in primary care, which also has a level of complexity, involves the development of an educational intervention and needs to be applicable at the individual and wider sociodemographic levels.

3.2.2 Selecting appropriate theory

Theories, models and frameworks were described in the previous section in distinct categories, however, in the literature the terms are often used interchangeably. For example, Damschroder[110] used the term 'theory' to collectively refer to models, theories and frameworks, whilst Tabak[104] used the term 'models' to collectively refer to theories and frameworks.

An ever-increasing number of theories, frameworks and models makes it difficult for the researcher to decide which one is most appropriate for their research project. To address this problem, a number of systematic reviews have attempted to steer researchers through the field of implementation research by reviewing and evaluating available theories.

Tabak[104] conducted a narrative review of 61 models (theories and frameworks) of dissemination and implementation, providing an inventory of models used in implementation science with guidance on how to select a model to inform study design and implementation. The models were categorised according to three domains: i) construct flexibility, ii) dissemination/implementation and iii) sociological framework.

i) **Construct flexibility** is the flexibility of the model constructs. 'Broad models' give researchers the flexibility to apply the model to a range of implementation activities, whilst 'operational models' detail the step by step processes for implementation.

ii) **Dissemination and/or implementation category** classifies the models based on whether the model is focused on dissemination or implementation or focuses equally on both.

iii) **Sociological framework** is the level at which the model operates including individual, organisational, community, system or policy level. These categories are helpful to researchers when selecting an appropriate model.

My research project is focused on the implementation of nasal balloon autoflation rather than purely dissemination of research findings, therefore an implementation-focused theory was most appropriate for this research project. In addition, my research is set in primary care and the community, therefore requiring a model designed for the individual, organisational and community level, with a moderate degree of flexibility so I could use it in a more generaliseable and adaptable way. Whilst it was not possible to review all of the models that fit this selection criteria, there were three models that I considered to be potentially useful for this research project: i) Promoting Action on Research Implementation in Health Services (PARIHS framework)[111], ii) Consolidated Framework for Implementation Research (CFIR)[110] and iii) Normalization Process Theory (NPT)[5]. Each of these theories are focused towards the implementation end of the dissemination-implementation continuum and have been developed and evaluated in healthcare-related fields, which is most appropriate

for my research project. A brief review of each of the three theories is presented as follows:

3.2.3 Promoting Action on Research Implementation in Health Services (PARIHS Framework)

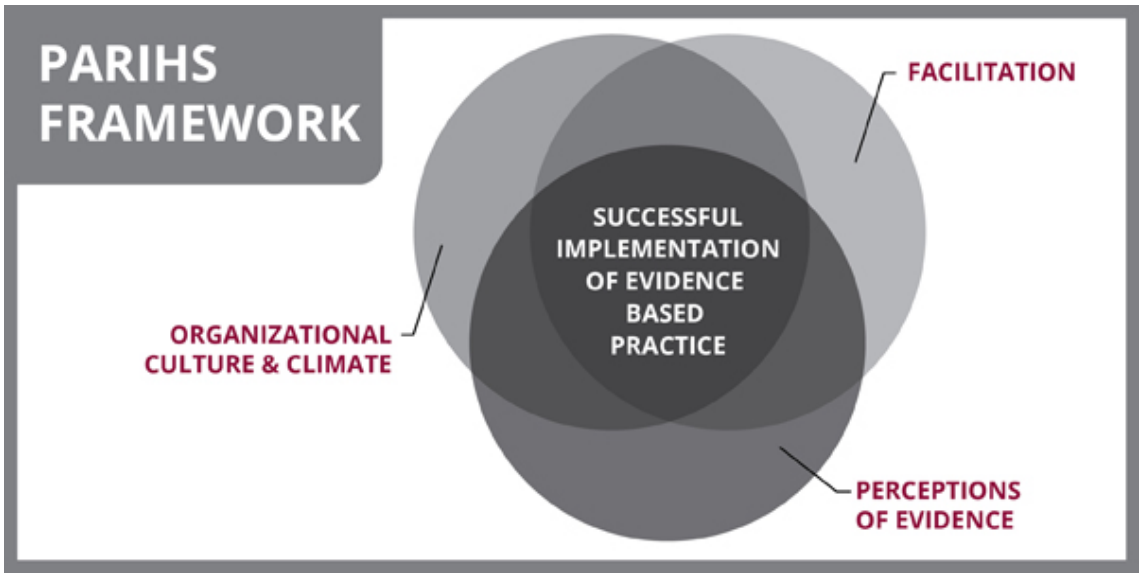
The PARIHS Framework[111] is a conceptual framework that outlines three main interacting determinants for successful implementation in healthcare: type and quality of evidence; context in which an intervention was implemented; and the way in which the evidence or intervention is introduced. The theory proposes that successful implementation is likely to occur when i) evidence is aligned with professional and behavioural belief, ii) healthcare context, including culture, leadership and systems, are receptive to implementation and iii) mechanisms are in place so that implementation can be facilitated. The framework was developed inductively based on the PARIHS authors' experiences of practice improvement and guideline implementation, and since its original publication in 1998 there have been a number of developments and refinements[112]. The current refinement is structured as follows:

i) **Evidence**: The PARIHS framework suggests that evidence from multiple sources are important for successful implementation. Whilst research evidence is often thought of as the strongest and most relevant form of evidence, it is important for implementation to also consider practitioner expertise, patient preferences and local context including community level data and improvement initiatives.

ii) **Context**: the environment or context in which the intervention is to be implemented needs to be considered for successful implementation. This includes an understanding of the culture, leadership structure, relevance and fit of the intervention to the local environment or organisation and availability of resources for implementation.

iii) **Facilitation**: the type of support or facilitation that is needed to bring about change is important to achieve the desired outcome. This includes careful consideration of the type of facilitation required, a clear definition of the purpose of facilitation and skills and attributes of the facilitator.

Figure 7: PARIHS Framework



Reproduced from American Journal of Speech-Language Pathology[113]

Each of the three factors consist of sub-elements that are rated on a scale from low to high. It is postulated that high ratings are more likely to result in successful implementation.

The framework has been widely used in implementation projects since its inception and a critical synthesis of the literature on the use of PARIHS was conducted in 2010 to gain greater understanding in to how it has been utilised and to identify its strengths and limitations[114]. The review included 24 empirical studies which were appraised, abstracted and summarised according to descriptive and interpretative themes. The study found that the PARIHS was mostly utilised retrospectively as an organising framework. None of the included studies used PARIHS prospectively despite the fact that the developers originally planned for the PARIHS to be used to guide the implementation process. The authors described the strengths of the framework as its flexibility and applicability to a range of settings, intuitive nature and explicit definition for successful implementation. However, the main limitation identified was the need for greater conceptual clarity of the sub-elements of the 3 factors (evidence, context and facilitation) and the relationships between them.

A recent conceptual study using qualitative methodology involving document reviews and interviews aimed to characterise the experiences of using the PARIHS at nine implementation research centres[115]. The study found that PARIHS was being used in many different ways and revealed similar strengths and weaknesses as the critical synthesis[114].

More recently a revised PARIHS guide[116] published in 2011 has been developed to enhance and optimise the use of the PARIHS framework in implementation trials and evaluations.

3.2.4 Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research[110] (CFIR) was developed and constructed from a synthesis of published implementation theories, pulling together an overarching list of constructs to help and guide implementation. The authors of the CFIR argued that whilst there were many implementation theories described in the literature, there was considerable overlap and all were missing at least one key component required for successful implementation. The CFIR consists of a menu of 39 constructs that have been associated with successful implementation. These constructs are ordered across five major domains (i) intervention, ii) inner and outer settings, iii) individuals involved and iv) process of implementation.

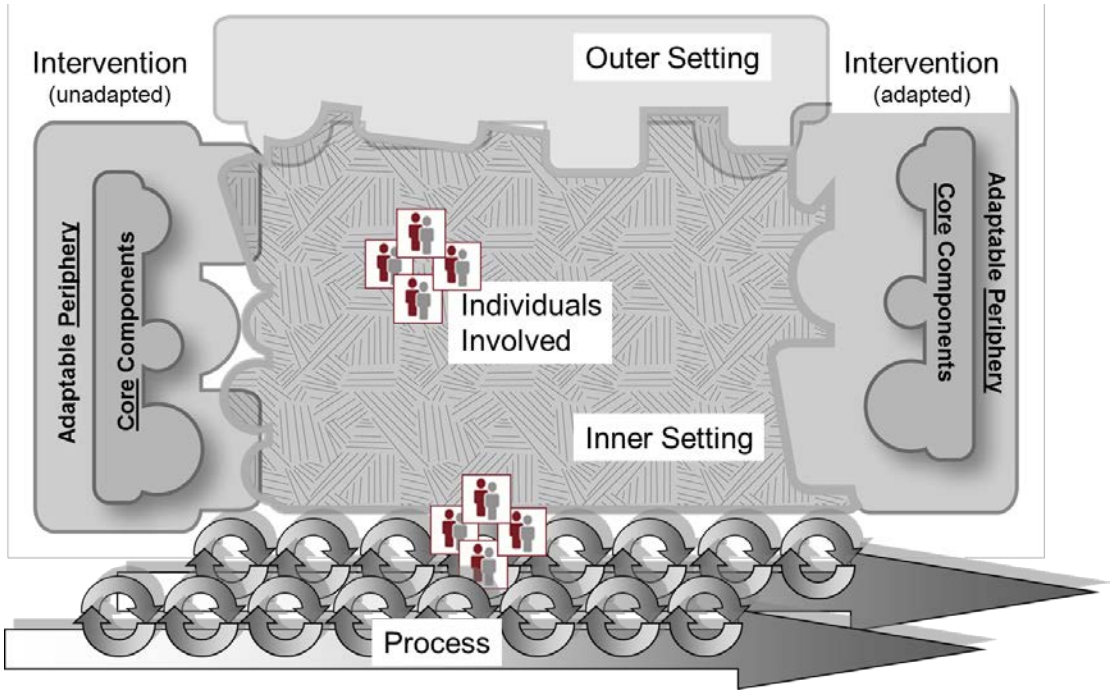
i) **Intervention**: The intervention domain is concerned with the characteristics of the intervention including perceptions about its complexity and adaptability to local context, its quality and validity based on evidence, and costs that could be incurred when implementing the intervention.

ii) **Inner and outer settings:** This domain describes the context in which the intervention is to be implemented. The **inner setting** refers to the cultural and structural features, networks and communications, and climate in which the implementation process will proceed, whilst the **outer setting** refers to the wider economic, political and organisational features of an organisation.

iii) **Individuals**: Bringing about change is also a function of the characteristics of individuals, including the individual behaviours of key stakeholders and the interplay between the individual and the wider organisation.

iv) **Process of implementation**: This domain includes the planning, engagement, execution and evaluation of an intervention and is aimed at both the individual and organisational level.

Figure 8: Consolidated Framework for Implementation Research



Reproduced from Damschroder 2009, Implement Sci[117]

The CIFR was designed to provide a 'common language' in implementation research and provide researchers with a comprehensive and standardised list of constructs that can be tailored to their individual research project or intervention[110]. It was designed to be applied at every stage of the implementation process, from developing an intervention through to analysing, interpreting and reporting related findings. A systematic review[118] of the use of the CFIR was conducted in 2016, 6 years after its initial publication. The aim was to assess the usage of the framework in implementation research, including the breadth and depth of use, and the contribution to implementation science. The study reviewed 26 empirical studies that met the

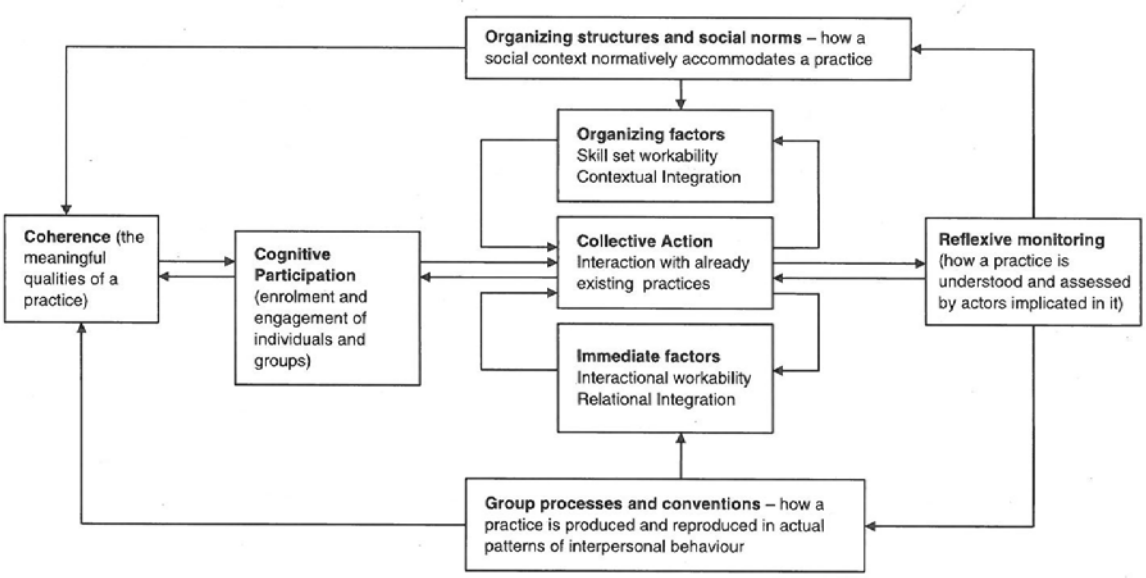
criteria for inclusion, and results suggested that the framework was widely used across a range of studies, although depth of usage was limited and only a small number used it pre-implementation. In addition, only half of the post-implementation studies reported investigating the link between outcomes of implementation and CFIR constructs, suggesting a gap in the implementation process.

3.2.5 Normalization Process Theory (NPT)

NPT is concerned with how processes become embedded in their social contexts. The first iteration of the theory was the Normalization Process Model in 2007 (NPM)[106] which was concerned with the processes around operationalising complex interventions, but did not seek to explain how complex interventions were formed, how actors engaged with the intervention and how they appraised the intervention. It was further developed in 2009 into NPT[5], a middle range theory with a wider scope to encompass these other considerations and provide a robust framework for analysing processes and relationships involved in implementation and change of practice.

The propositions of NPT are that new practices become routinised as a result of people working individually and collectively to enact them. The work of enacting a practice, or intervention, is facilitated though four 'generative mechanisms' or components (*coherence, cognitive participation, collective action* and *reflexive monitoring*). Producing and sustaining practice requires actors to invest in actions that carry forward in space and time. All of these processes are dynamic and are affected by play of power and by the social context. Figure 9 shows the relationship between the components.

Figure 9: Normalization Process Theory



Reproduced from May et al, Sociology 2009[119]

Each of the 4 constructs represents the kinds of work that people need to do to enact a new process.

i) **Coherence** is the work that people do both individually and collectively to make sense of a new practice (sense-making work). This includes differentiating the new intervention from current practice, building an individual and shared understanding of a new practice, and understanding its value and potential benefits.

ii) **Cognitive participation** is the work that people do to engage in a new practice (relational work), which includes people buying into and supporting a new practice and agreeing that the practice should be part of their work.

iii) **Collective action** is the work that people do to enact or operationalise a new practice (operational work) which includes whether people are able to perform the tasks required of them, and whether they have the right skills and are adequately supported by the host organisation.

iv) **Reflexive monitoring** is the work people do to assess and evaluate a new practice (appraisal work) including how they access information, individually and

collectively assess the practice as worthwhile, and how they modify their work in response to their appraisal.

Each of the 4 constructs of NPT are subdivided into 4 individual components (16 in total) which helps to define the individual and collective actions required for each of the constructs.

Since its development NPT has been widely used as a theoretical approach to implementation. A qualitative systematic review of studies using the theory was published in 2014 to understand how the theory was being used and operationalised in studies of healthcare implementation[120]. The study of 29 empirical research projects found that NPT was mainly used in qualitative research to study the implementation of complex interventions. It was being used as an organising framework for analysis and reporting, designing of new complex interventions, generating research questions for fieldwork and creating tools to investigate and support implementation and process evaluations. Challenges of using NPT included tensions about fitting data into pre-determined categories, understanding clearly the construct definitions and differences between the constructs, and 'getting it right' when data was seen to fit into one or more categories. Recommendations from the report suggest that researchers should justify their reasons for choosing a particular theoretical framework, and where possible, multiple stakeholders should be involved to gain a range of perspectives in the implementation process.

3.2.6 Selecting a theory for this research project

Each of the three theories reviewed here would have been suitable to underpin this research project, although all have their limitations and no single theory would cover all of the constructs required for implementation of the nasal balloon.

The PARIHS framework could provide a structure for consolidating evidence from the literature and different stakeholders (e.g. GPs, parents, nurses, audiologists), and help to understand the context of current management strategies for glue ear in primary care. However, the framework lacks a task-related focus to implementation which I

considered to be important for my research as nasal balloon autoinflation has a strong process element.

The CFIR could also provide a robust framework for implementation in this research project. It consists of constructs that focus on the intervention itself which would be important for such a novel intervention as the nasal balloon. The CFIR also focuses on context which includes a consideration of local factors, such as how GP might prescribe the nasal balloon and how parents/children might manage the intervention at home, to global factors such as the current NICE guidelines and NHS resources. The CFIR also highlights the importance of the individual including consideration of the relationships between the different stakeholders (e.g. between healthcare professionals and families) which is important to ensure the uptake of the nasal balloon, and process of implementation, including how wider use of the nasal balloon might be brought about and evaluated in the primary care setting.

NPT focuses on the process element of implementation and work that is required of the individual stakeholders to bring about 'normalisation' of a new intervention. I considered this to be particularly important as the implementation of nasal balloon autoinflation requires engagement and collaboration of different individuals including the healthcare professional, the parents/carers and the children themselves. Additionally, NPT was developed through the researchers work on the difficulties of implementing and integrating telehealth systems[5], the provision of health services through electronic and telecommunications technologies, and thus is particularly relevant to my PhD. The PARIHS was developed from health guideline implementation and practice improvement, and the CFIR was derived from a review of existing theory which appeared less directly relevant to my research project.

In summary, all three models were relevant to this research project and the final choice of theory was essentially pragmatic. Firstly, there was a lot of available evidence of the use of NPT in healthcare research which provided a good foundation and knowledge base with which I could approach my own research. In addition, there is a useful website outlining NPT (www.normalizatonprocesstheory.org) which includes an extensive reference list and a heuristic device which allows tailoring of the theory to

your own intervention. Also, I became familiar with the Normalization Process Theory during my masters studies and was fortunate to meet with Professor Carl May (a key developer of NPT) at an early stage to discuss how to use NPT to underpin research with the nasal balloon. These meetings provided expert guidance into how to use the theory appropriately and flexibly to inform my PhD research. Further work is being carried out by Professor May, working towards a more general theory of implementation[121] and the Burden of Treatment theory[122] which is also potentially highly relevant to my research project.

3.3 Using Normalization Process Theory to underpin implementation research

Published research has shown that NPT can be used in a number of ways to support the development, evaluation and implementation of complex interventions[123]. An interactive toolkit is available online (www.normalizationprocess.org) which can act as a heuristic device to help researchers think through the implementation process in more detail. A 23-item instrument has now been developed (NoMAD)[124] for measuring implementation from the perspectives of the healthcare professionals who are directly involved in the implementation process. NoMAD was not available at the time this project was conceived, but could have added an additional interesting, quantitative element to the process.

This section reviews how NPT has been previously employed in research, from the development of complex interventions to the process evaluation of clinical trials and discusses the implications for this research project.

3.3.1 NPT and qualitative research

It is reported that NPT can help with focussing and developing applied research questions. In the wider sense it can act as a stimulus to encourage researchers to think about their research in terms of the work and processes required to implement a new intervention and prompt both awareness and consideration of the context in which a new intervention is to be implemented. The constructs and components of NPT can be

used to shape research questions. For example, Gask and colleagues[125] used the four components of *collective action* to derive their research questions in a study looking at the implementation of collaborative care for depression, and concluded that components of NPT provided a useful structure for understanding not only barriers to wider implementation but also the work required in practice to make implementation of collaborative care models a success.

NPT can also facilitate the coding and analysis of qualitative data. For example, interview data can be coded directly to the constructs and components of NPT. Murray[126] used this method to code their data from a study exploring the difficulties around implementation of e-health initiatives. Interview data was directly coded to the 4 components of *collective action*. NPT can also be used as an analytical framework to guide the analysis. Open coding or labelling of the data can be refined and grouped under the constructs of NPT. Blakeman[127] used NPT as a framework for analysis of their study to understand the processes around management of early stage renal disease in primary care. Initial coding of the qualitative interview data was undertaken and then grouped under the 4 constructs of NPT. Finally, NPT can be used to recode or reanalyse qualitative data and facilitates the comparison between traditional qualitative analysis and results obtained from that guided by implementation theory. Gallacher[128] undertook a secondary analysis of qualitative interview data to help understand patient experiences of treatment burden in chronic heart failure. The authors designed a coding framework according to the core constructs of NPT and described how the components of treatment burden related to the NPT constructs.

NPT is also reported by the authors to be able to help guide the interpretation of research findings, providing a framework with which to make sense of the results and aid conceptualisation and reflection. It can be used in a less structured way simply to help with overall reflection, or a defined way in which conclusions and interpretations can be drawn across the theoretical constructs. Franx[129] used the constructs of NPT to help understand and interpret the research findings of a qualitative study looking at stepped-care design for depression in primary care. The authors conducted a thematic

analysis of group interview data with healthcare professionals and NPT was then used to frame their research findings through a lens of implementation.

3.3.2 NPT and the development of complex interventions

Most interventions in healthcare are comprised of more than one component, whether it involves interactions between elements of the intervention, targets different groups or organisational levels, requires different behaviours from those delivering/receiving the intervention, or results in a variety of outcomes[130]. Developing, evaluating and implementing interventions with different levels of complexity present practical, organisational and methodological challenges to researchers, practitioners and policy makers alike. The MRC developed broad guidance for developing and evaluating complex interventions[131] and recommend a systematic process of development using best evidence, a theoretical understanding of proposed intervention and modelling of the processes and outcomes, to identify potential weaknesses or areas for improvement. NPT provides a strong theoretical framework with which to underpin the development of complex interventions. Murray[123] describe using NPT to develop an intervention to support patients with back pain in primary care. Using NPT facilitates an understanding of the context in which the intervention was to be implemented and to analyse the intervention prior to testing in a full trial. In another topic area, Godfrey at al[132] used NPT to develop and implement a delirium prevention programme for elderly people in the hospital setting. The authors report that the successful theory-led research resulted in an intervention combining multiple components to introduce and embed a delirium prevention programme into routine clinical practice.

3.4 Using NPT in this research project

This research project involves the design and evaluation of an educational intervention to support the wider use of nasal balloon autoinflation in primary care. In order to discuss how I use NPT in this project I will firstly define what is meant by 'intervention'. In this project nasal balloon autoinflation is the key intervention. It can be defined as a *complex intervention* as it comprises multiple interacting components and a number of

stakeholders for use in everyday practice. The LittleEARS study website is an *educational intervention*, which is designed to support the wider implementation of nasal balloon autoinflation. It can be defined as an educational intervention, rather than purely an information website, as it has components to promote not only education but also self-management and self-monitoring. In order to make things clear, I will use the terms '**nasal balloon intervention'** and '**educational intervention'** to distinguish clearly between the two.

Table 3: NPT evaluation of nasal balloon autoinflation intervention

	Parents/families/children	***GPs and nurses***
Coherence	- How do parents make sense of glue ear including recognising symptoms and impact, diagnostic tests and available treatments? - Would families know what would be required? - Would families value the intervention? - Would they find it acceptable?	- How is glue ear currently managed? - What local facilities are available? - Is the intervention easy to describe and distinguish in current practice? - Would GPs know what would be required of them? - Would GPs value the intervention? - What would be the effect on service provision?
Cognitive participation	- Do parents think that the intervention is a good idea? - Would parents commit to autoinflation? - Are children happy to comply with autoinflation? - What do parents need to sustain the nasal balloon intervention?	- Do GPs think that the nasal balloon is a good idea? - What would GPs need to drive this forward? - What would GPs need to do to engage parents? - What do nurses think about taking on this role? - What organisational changes may be required? - What evidence do GPs need? - How will GPs sustain the intervention?
Collective action	- What training will be needed? - What will affect compliance?	- What training will be provided? - What resources are needed? - What effect will it have on consultations? - Will staff require additional training?
Reflexive monitoring	- How do parents know if the treatment is working? - What should parents seek further help and advice?	- How GPs determine effectiveness? - How can practices collectively appraise the intervention? - Can the intervention be improved on the basis of the appraisal?

In this project I used NPT to underpin the development and evaluation of the educational intervention (LittleEARS website) in accordance with the MRC guidelines. As a first step I used NPT as a heuristic device to review the context in which the nasal balloon intervention was to be implemented and identify questions associated to the implementation of the nasal balloon across the four constructs of NPT (Table 3).

To help address these questions two qualitative studies were conducted. Firstly, Chapter 5 describes a qualitative interview study of GP views and experiences of OME and use of the nasal balloon in primary care. This study was designed to help describe the context in which nasal balloon autoinflation was to be implemented (i.e. how are GPs currently diagnosing and managing OME), and to feed into the development the educational intervention (i.e. what are the enablers and barriers to active monitoring and autoinflation? What resources would support wider use in primary care?). I used NPT to help develop the study interview guide, using the 4 components of *coherence, cognitive participation, collective action* and *reflexive monitoring* to create interview questions relevant to the research aims with emphasis on context, work and processes required for implementation. Chapter 6 describes the secondary analysis of qualitative data from different stakeholders (parents, nurses, GPs). In this study I used NPT as a framework for analysis, coding and mapping data extracts to the four main components of NPT. The results of this study identified factors that promote or inhibit implementation and this was used to guide the development of the educational intervention (Chapter 7 and 8). Finally, I used NPT to guide the interpretation and evaluation of the results of the feasibility study (Chapter 9).

3.5 Summary

Dissemination of research evidence alone is rarely sufficient to facilitate the adoption of findings into clinical practice, and complex interventions often require careful consideration and substantial effort. Using a theory to underpin implementation research, whether in the development of a new intervention or evaluation of a new process or guideline, provides a framework within which to better consider facilitators and barriers to successful implementation, and helps to understand why implementation succeeds or fails. After a review of the most relevant theories I selected the Normalization Process Theory for this project, due to its emphasis on the work and process elements of an intervention, which I considered to be highly relevant for the implementation of a new technical treatment like the nasal balloon method. NPT provided a coherent, theoretically sound basis for the research undertaken in this PhD project. It has informed, sensitised and supported a rigorous research process throughout my PhD studies.

Chapter 4: Philosophy and methodology

4.1 Introduction

The research presented in this thesis involves exploring barriers and facilitators to wider implementation of the nasal balloon, and the development of an intervention to promote its wider implementation in the primary care and community settings. To answer these research questions requires selecting the appropriate methodology. Similarly it is important to recognise the philosophical assumptions of the different research methods selected, whilst identifying and recognising my own world views and how they can end up shaping my research. In this chapter I present my philosophical position and discuss the selection of a pragmatic approach using mixed methods to guide this body of research.

4.2 Philosophical stance

A research paradigm is the overarching philosophical belief system or set of assumptions of the researcher which underpins the research itself and provides a base from which knowledge is produced.[133] In healthcare research a researcher's paradigm relates to their ontological viewpoint (beliefs about the nature of reality) and their epistemological viewpoint (beliefs about the nature of knowledge). These philosophical assumptions guide the methodology (how knowledge is acquired) and methods of enquiry (tools and techniques used to acquire the knowledge)[134].

There are two main opposing research paradigms: positivism and interpretivism. The *positivist researcher* believes in an objective reality which is independent of the observer and that objective knowledge is produced deductively using rigorous methodology and experimentation. Quantitative research, or scientific enquiry, is generally based on the assumptions of post-positivism and involves collection of numerical data to explain a phenomenon. Conversely, the *interpretivist researcher* believes in a subjective reality which is individually or co-constructed and uses methodology to obtain knowledge inductively from the individual perspective. Qualitative research, or social enquiry, is based on the assumptions of interpretivism

and involves collecting contextual data about the 'how' and 'why' of a phenomenon. These underlying philosophies and worldviews of qualitative and quantitative researchers are diametrically opposed but in reality this is a simplification of the paradigms and most researchers subscribe to somewhere along the continuum between the two positions. In fact, in healthcare research, researchers often need to draw on a range of positions to achieve the best outcome for their research and to answer their research question.

My philosophical approach to this research was one of *critical realism*[135] . Critical realists believe that reality exists independently of our perceptions of it (ontological realism), whilst still accepting that our understanding of the world is constructed from our own perspectives (epistemological relativism). This philosophical approach departs from the tenets of positivism and provides an important way of studying the natural and social sciences. Assuming a critical realist position has allowed me to explore the important and relevant questions concerning management of children with OME in primary care and use of the nasal balloon. I have aimed to identify the truth or reality about active monitoring and nasal balloon autoinflation but acknowledge that this reality is constructed by the different stakeholders involved in the research and my own personal perspectives. An alternate but closely related approach is that of subtle realism[136], which also assumes an independent reality which is only known from our own perspective of it. A more critical approach seemed to be most relevant to my research which required naturalistic and scientific enquiry, whilst critically evaluating the research outcomes.

I have also taken a pragmatic approach to my research. Pragmatism, is a philosophical tradition based on the ideas of early American Philosophers such as Pierce[137], and is based on the idea that for something to be meaningful it must have a practical bearing or application. In research, pragmatism advocates that research methodology is selected for its appropriateness to answer the research question rather than because of its philosophical position. My philosophical position has been argued as a critical realist, whilst my methodological approach is one of pragmatism. Critical realism is concerned with the nature of reality and facilitates the question of *whether knowledge*

accurately reflects reality? Pragmatism, on the other hand, is a practical activity that allows us to question *whether knowledge serves our purpose*?[138] Assuming a critical realist philosophical stance and a pragmatic approach to frame my research has allowed me to use the most appropriate methods to answer my research question.

4.3 Methodology

Methodology is the '*strategy, plan or action, process or design*' underlying the choice and use of particular research methods[139]. Mixed methods research is based on the assumptions of pragmatism. In my research I employed mixed methods to address the research aims of improving management of OME in primary care and supporting wider use of the nasal balloon. Mixed methods research came about through discussions and debates between quantitative and qualitative researchers in the social and behavioural sciences. The following definition of mixed methods research was provided by Johnson in 2008[140]:

> *Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches for the broad purposes of breadth and depth of understanding and corroboration.*

There are three general strategies for mixed methods research, including sequential, concurrent and transformative designs. Sequential design is the use of one research method as an exploratory mechanism to inform or direct the next part of the research process. In this body of work I used qualitative research to inform the development of the educational intervention. Concurrent or embedded design is when both qualitative and quantitative data are conducted together to provide a comprehensive analysis of the research problem. In the final feasibility study I used qualitative and quantitative outcomes to assess overall feasibility, acceptability and uptake of the educational intervention. Finally, transformative design is when a researcher uses a theoretical perspective within a research project using both qualitative and quantitative data. In my research I used the lens of the Normalization Process Theory to frame the research question, select the appropriate methodology and analyse the outcomes.

4.4 Methods of enquiry

Research methods are the '*techniques or procedures used to gather or analyse data related to research question or hypothesis*"[139]. In this research I used both qualitative and quantitative methods to address the research aims and objectives.

Qualitative research was selected as the most appropriate method for gathering the views and experiences of the participants about OME and autoinflation in the primary care setting (chapter 5). Qualitative methods are often used to answer questions about the *what*, *how* and *why* of a phenomenon[141] and are useful when wanting to explore or find out more about, rather that quantifying or measuring a phenomenon. It is also useful when exploring previously un-researched areas. The objective of this study was to capture contextual data to understand potential facilitators and barriers to implementation of autoinflation from the perspective of the GP, something which cannot be collected in such a rich and in-depth way by quantitative methods. Chapter 6 describes a secondary analysis of qualitative interview data focusing on the work required for implementation of the nasal balloon treatment itself, using the Normalization Process Theory[5] to underpin the process. Again, contextual data and personal views and experiences were sought to understand promoting and inhibiting factors to wide implementation of nasal balloon autoinflation. Chapter 8 describes the pragmatic development and evaluation of the LittleEARS educational intervention. This part of the research employed qualitative methods (Think Aloud[142] interviews) to gain insight into real-world experiences of parents using the intervention.

Quantitative methods are concerned with objective measurements of a phenomena and often draw upon statistical techniques to analyse the data. I used quantitative research methods to further develop and evaluate the wTADAST-24 hearing disability test, which required analysis of test-retest reliability and correlation with previous versions of the test (chapter 7). In addition, I employed quantitative methods to analyse the feasibility study presented in chapter 9.

However, mixed methods research is not just about conducting qualitative and quantitative research within a research programme. A key component is the

integration of the results of both methods of enquiry to obtain a better and more contextual answer to your research question. In my PhD I integrated the findings of qualitative and quantitative work to develop and evaluate an educational intervention to support implementation of the nasal balloon method in primary care.

4.5 Summary

In this chapter I presented my philosophical stance as a critical realist and argued that pragmatism and mixed methods were the best approach to answer my research aims. Pragmatism advocates that research methodology is selected to answer the research question, rather than due to its philosophical position. I selected mixed methods, the integration of rigorous qualitative and quantitative enquiry, to address my research aim of promoting wider implementation of nasal balloon autoinflation. This required drawing on qualitative methods to explore the wider context for implementation and both qualitative and quantitative methods to develop and evaluate clinically-orientated tools to help monitor and manage children during a recommended 3 month active monitoring period.

Chapter 5: Qualitative research: exploring GP views and experiences of OME and nasal balloon autoinflation in primary care

5.1 Introduction

Embedding or normalising a new intervention in clinical practices requires more than simply dissemination of results. Chapter 3 discussed the factors concerned with successful implementation and presented theoretical constructs that can help guide the implementation process. One key factor identified for successful implementation is consideration of the political, historical, cultural and organisational environment or context in which a new intervention is to be implemented.[143] To support wider use of nasal balloon autoinflation in primary care, there is a need to better understand how GPs currently manage children with OME; the organisational processes involved; the current local and national guidelines for managing these children; referral pathways; and local experience and expertise. To date there has been no qualitative research exploring such issues as they commonly impact on day to day practice. This chapter describes a qualitative study exploring GP views and experiences of diagnosis, treatment and routine management of children with OME in primary care.

5.2 Aims and objectives

5.2.1 Aims:

The aim of this study was to determine how OME is currently diagnosed and managed in primary care in the UK and to explore the barriers and facilitators to active monitoring and nasal balloon autoinflation.

5.2.2 Objectives:

i) To explore how OME is currently diagnosed in primary care, including access to and use of tympanometry, clinical histories, and symptoms.

ii) To explore how OME is currently managed in primary care, including knowledge and application of the current NICE guidelines, access to local services, referral strategies, and medical treatments.

iii) To explore the views and experiences of GPs of the application of nasal balloon autoinflation treatment including barriers and facilitators to wider implementation.

iv) To explore GPs opinions about resources to support the wider implementation of autoinflation in primary care.

5.3 Methods

5.3.1 Research methods

Qualitative research was selected as the most appropriate method for gathering the views and experiences of the participants about OME and autoinflation in the primary care setting. Qualitative methods are often used to answer questions about the *what*, *how* and *why* of a phenomenon[141] and are useful when wanting to explore or find out more about, rather that quantifying or measuring a phenomenon. The objective of this study was to capture contextual data to better understand potential facilitators and barriers to implementation of autoinflation from the perspective of the GP, something which cannot be collected in such a rich and in-depth way by quantitative methods.

Semi-structured interviews were selected as the most appropriate way of collecting qualitative data in this case. This type of 'focused' interview uses open-ended questions to allow some flexibility and scope for participants to talk in detail about their opinions and experiences of diagnosing, treating and managing children with OME in primary care whilst ensuring that the data collected also includes areas highlighted in previous research as being important and relevant[144]. Focus groups would be an alternative method of data collection but I was interested in the first-hand personal views of the participants rather than capturing a group discussion. Additionally it was not practical to get GPs from different regions in one place for a focus group due to limited financial resources of this student project and NHS time constraints.

The Normalization Process Theory (NPT)[5] was used to guide this qualitative study. As described in chapter 3, NPT was constructed as a framework for developing, evaluating and implementing complex interventions and is a useful tool to help researchers understand the factors that affect wider implementation of their research findings[123]. In this study I used NPT to explore the context in which nasal balloon autoinflation would be implemented including current diagnostic and management strategies, availability of local services and resources, and views and experiences of the nasal balloon method. Understanding these factors will help towards embedding nasal balloon autoinflation in everyday primary care practice.

5.3.2 Rigour and trustworthiness

High quality research is essential if the findings are to be trusted and used to further understanding and improve healthcare. Establishing research quality has roots in scientific enquiry, where research is judged on its i) internal and external validity, ii) reliability and iii) objectivity/avoidance of bias. However, qualitative research is based on naturalistic enquiry i.e. focusing on how people behave in natural settings, and thus the scientific measures of quality are neither appropriate nor transferable. Lincoln and Guba[145], however, offer alternative criteria for trustworthiness and rigour in qualitative research including: i) credibility, ii) transferability, iii) dependability and iv)confirmability. Each of these criteria are discussed as follows in relation to this research project.

i) **Credibility in qualitative research** is demonstrating confidence in the truth of the findings. For example, does the given account of the findings logically and accurately represent the data itself and can the findings stand up against alternative explanations? Guba and Lincoln[145] suggest a number of methods to ensure credibility of qualitative research including constant comparison, triangulation, respondent validation, and negative case analysis. In this study I used a method of constant comparison during the analysis which involved comparing and checking data within and between interview transcripts to develop a strong understanding of the data. This also facilitated the identification of deviant or negative cases, which confirms the patterns emerging from the data

analysis. Credibility is also enhanced using multiple coders. This facilitates the inclusion of multiple perspectives which vary dependant on the background of the individual coder. Working closely as a team provides an opportunity to discuss coding disagreements and agree future coding decisions. In this study, Hazel Everitt and Ian Williamson who are general practitioners, and Caroline Eyles who is a qualitative expert, coded the first few transcripts and assisted in the development of a coding structure which was then applied to the rest of the data set. Responder validation, presenting the research findings back to the participants for confirmation, was unfortunately not possible for this study due to time and financial restrictions of the PhD research project.

ii) **Dependability in qualitative research** is the demonstration that the research findings are consistent. For example, are data coded in the same way throughout the data set, and do different researchers code the data in the same way? I used methods for dealing with this including being transparent in the analytical methods used, maintaining a meticulous audit trail and using multiple coders to ensure consistent coding of the data set. I also kept a reflexive journal which involved keeping notes and reflections after each interview and general thoughts and ideas during the analysis, which afforded further transparency of the research process.

iii) **Confirmability in qualitative research** is the extent to which the research findings are affected by the researcher's own motivations and preconceptions. It is impossible to disconnect the perspectives and experiences of the researcher from the project itself as the researcher is the research tool and integral to the data collection, analysis and interpretation of the findings. Reflexivity, is the acknowledgement of this interrelationship between the researcher and the project at all stages of the research process[146] and is an essential part of establishing confirmability of research findings. Researchers bring their own preconceptions to the research, including philosophical stance and theoretical underpinnings, prior experiences, personal beliefs, and motivations for conducting the research[147]. My philosophical stance is presented in chapter 4 and the theoretical underpinnings of this research are presented in chapter 3. I have a professional background as a

research manager for large multi-centre primary and secondary care studies, and I was the research coordinator for the AIRS study[3]. I therefore had personal views, experiences and assumptions about the topic area and the use of the nasal balloon which could potentially influence the analysis and results of this study. Also, some the GPs were aware of my role as the AIRS study manager and this may have affected their responses to the interview questions. I am also a parent of two children, and consequently have my own views of the GP consultation between parents and young children, and these views may have influenced the research interview and the analysis/interpretation of the study findings. My reflections are presented in the discussion section (section 5.5).

iv) **Transferability in qualitative research** is demonstrating the applicability of the research findings to other contexts. In scientific enquiry it is concerned with generalisability of findings, however in qualitative research samples are often small and consequently not considered representative of a wider population. Guba and Lincoln suggest instead to look for conceptual or theoretical transferability using thick description to describe the findings in sufficient detail to allow conclusions to be drawn as to whether the results are transferable to other settings. In this study I described the methods, analysis and findings in detail so the study could be readily evaluated with respect to relevance to the wider general practice.

5.3.3 Sampling and recruitment:

A purposeful sample[148] of GPs from 12 Clinical Commissioning Groups (CCGs) in three regions (Thames Valley, Wessex and Cheshire) were invited to take part in the study. These regions were selected as they were regions who had also participated in the Autoinflation Randomised study (AIRS)[3] and governance approvals were already in place in these areas. A maximum variety sample included sampling for a range of gender, practice list size, practice deprivation score and practice location (rural/semi-rural/urban). The sample also included some GPs who had previously participated in the AIRS study[3], although in most practices the day to day research was undertaken by a research nurse so GP involvement with parents/children and the nasal balloon was minimal. Including participants with previous experience of autoinflation provided

information-rich cases, whereas those who had no previous experience of autoinflation ensured a wider sample of participants with a broader range of views[148]. All interviews were conducted following the release of the AIRS trial results which may have affected their expressed views of the treatment method.

After approximately half of the interviews had been conducted, views were emerging about potential barriers to using autoinflation in areas of higher social deprivation. To ensure that the sample included some GP participants whose practice includes these demographics, an additional mail-out was conducted inviting participants from practices with the lowest deciles of social deprivation. This is an example of an iterative sampling process which is based on emergent themes and constructs, and allowed a rich understanding of concepts across a range of real life settings and circumstances[149].

An invitation letter, participant information sheet and consent form were mailed to the participants using DocMail, a secure online mail management system (Appendix B). Interested participants returned a reply slip and completed consent form to the researcher, and were subsequently contacted by email to make an appointment for a telephone interview. GPs were also sent a link to the Otovent™ nasal balloon video that was used as part of the AIRS study[2 3], to ensure that those who were not familiar with the nasal balloon had an opportunity to see the method before the interview.

5.3.4 Ethical approvals

With samples drawn from 2 different populations (AIRS and non-AIRS GPs), approval was obtained as follows:

i) The AIRS study was approved by the National Research Ethics Committee South Central (Southampton B) on 10th August 2009 (09/H0504/75). A substantial amendment (10) to include this qualitative evaluation was approved on 18th March 2014 (Appendix B).

ii) The wider qualitative evaluation of non-AIRS GPs was approved by the Faculty of Medicine Ethics committee on 28th April 2014 (appendix B).

Research governance approval was granted by the participating CCGs prior to commencing the interviews. A Letter of Access was granted to the researcher by each participating CCG.

The University of Southampton acted as sponsor for the study. The study was funded as part of the wider NIHR-HTA programme (09/01/27) and as part of my School for Primary Care Research (NSPCR) training studentship.

5.3.5 Data collection

An interview guide (Appendix B) was developed based on the research aims and objectives, and informed by the literature review presented in chapter 2, knowledge from the AIRS study[3] and underpinned by NPT[5].

For GPs to make sense of the nasal balloon intervention (*coherence*) it was important to ask questions concerning their views and experiences of treatments and current level of knowledge about glue ear. For GPs to commit and engage with the nasal balloon intervention (*cognitive participation)* questions were designed to help understand local policy and structure within the practice, and who might deliver the intervention. For operationalising the nasal balloon intervention, questions were included to explore current practices and skillset within the GP surgeries (*collective action*), and appraising the nasal balloon intervention (*reflexive monitoring*) includes how GPs manage and follow up children within their current practice. Questions were also included to elicit views and experiences of using the nasal balloon, and explore views about resources to support wider implementation of nasal balloon autoinflation in primary care.

I piloted the interview guide with a GP member of staff from University of Southampton. This helped to refine my qualitative interviewing skills as I had not conducted telephone interviews with GPs prior to this study. Piloting the guide also led to minor modifications to improve phrasing of the questions and general flow of the interview. I received ongoing support and advice from an experienced qualitative researcher (Dr Caroline Eyles) throughout this qualitative research study.

Data collection continued until data saturation was achieved in this selected group of participants. As the final interviews were conducted, no new or relevant information emerged with respect to the research question.

GPs were reimbursed £50 to cover their time for participation a qualitative telephone interview lasting 20-30 minutes.

5.3.6 Data management

All interviews were conducted by telephone at Aldermoor Health Centre and audio-recorded using a hand-held digital recorder (Olympus DM-650) attached by cable to the telephone handset. I listened back to the interview recordings immediately after the interview to ensure quality and completeness of the recording. The interviews were then professionally transcribed by Joe McGowan Transcription service and the transcripts were checked for accuracy and anonymity. Once complete, the audio recordings were destroyed in accordance with the ethics committee specifications.

The transcripts and summary field notes were then imported into NVivo 10 Computer-Assisted Qualitative Data Analysis Software (CAQDAS) programme to facilitate data management and analysis.

5.3.7 Analysis

CAQDAS has become an important and valuable tool in qualitative research, facilitating the organisation and sorting of large amounts of data, leading to transparency and repeatability of the analytical process. However, although CAQDAS can assist with the analysis, its primary role lies within data management, and the researcher must still engage with the interpretation and conceptualisation.

In 1994, Social Policy Researchers who were looking for a more pragmatic approach to qualitative analysis, developed Framework analysis[150] which was designed for real-world investigations where the analysis was more focussed towards *a priori* issues (towards the deductive end of the spectrum). This differs from the more inductive approach of Grounded Theory [149] which starts inductively then becomes more focussed leading to concepts emerging from the data itself. Framework analysis can

take a theme-based or a case-based approach. For example, a theme-based approach would allow the comparison of what all GPs in the study thought about grommet surgery for glue ear, whilst a case-based approach would look at whether GP access to local services affected how they managed or referred a child with glue ear.

I considered framework analysis to be particularly suitable in this study as the aims were to determine how OME is currently diagnosed and managed in primary care and explore the *a priori* themes of barriers and facilitators to active monitoring/watchful waiting and autoinflation from the perspectives of the GPs. A theme-based approach, rather than a case-based approach, facilitated the analysis of the data by the *a priori* themes, whilst allowing the comparison of individual cases from different sociodemographic regions.

Thematic analysis is a flexible method for identifying, analysing and reporting patterns within a dataset and would also have been an appropriate analytical method for this research project[151]. However, thematic analysis is a more inductive approach where the data collection is guided by initial research questions and themes are grounded in the dataset itself, rather than fitted into pre-existing models or frames. Using this method may not have answered all of the *a priori* questions that were driving this study.

Analysis of the study involved the five stages of Framework analysis: 1) familiarisation, 2) developing the framework, 3) indexing, 4) charting, and 5) mapping/ interpretation and was undertaken by myself with support from my supervisory team.

Stage 1: Familiarisation with the data

This stage of the analysis involved becoming immersed in the data, by reading and re-reading the transcripts, to gain an initial sense of what the interviews were about and to make preliminary notes about ideas and concepts. The field notes were also reviewed ensuring that any noted ideas, issues or contexts were taken into consideration. I coded the first transcript using open coding and then 3 co-supervisors also coded independently. This allowed codes to be compared and agreed, and an

initial coding framework developed. Table 4 demonstrates how the codes were agreed within the coding team.

Table 4: Agreement of codes

Example of quotation	***Individual coders***	***Agreed coding***	***Developing the theme***
"The diagnosis is normally on the history , so that's obviously the most important thing"	• Parent-reported history (*Jane Vennik*) • Importance of history (*Hazel Everitt*) • Collecting history – various sources (*Ian Williamson)* • History aids diagnosis (*Caroline Eyles*)	Clinical history taking	How GPs Diagnose Glue Ear

A tentative framework was then developed after the familiarising and coding of 5 interviews in order to inform the forthcoming interviews. Familiarisation with the whole data set prior to developing the framework would have ensured completeness and that no data overlooked, however, frameworks can be further developed and modified as analysis progresses and therefore early progression to creating a framework was not seen as a constraining factor in this study.

Stage 2: Developing the Framework

Working closely with the aims of the study, together with the codes, concepts and themes that emerged during the familiarisation stage, a framework was developed consisting of 27 codes grouped into 7 categories/themes (Table 5). Each code was described in such a way as to ensure that it was clear what the code meant to ensure that it could be applied consistently throughout the dataset.

Table 5: Coding framework

Category	***Code***
1. Diagnosis of glue ear (OME)	1.1 How GPs diagnose OME
	1.2 GP practice facilities
	1.3 Community facilities
	1.4 Epidemiology of OME
2. Guidelines and referrals	2.1 Local policy for referral
	2.2 National guidelines
	2.3 Decision making for referral
	2.4 Referral rates
3. Active monitoring/watchful waiting	3.1 Describing watchful waiting
	3.2 Employing watchful waiting strategy
	3.3 Acceptability to parents
4. Treatment and management	4.1 Treatment strategies
	4.2 Non-surgical treatments
	4.3 Surgical treatment
	4.4 Treating other conditions
5. Autoinflation	5.1 Perceptions of autoinflation
	5.2 Prescribing autoinflation
	5.3 Engaging families with autoinflation
	5.4 Training and supporting treatment
	5.5 Evidence for autoinflation
6. Information and resources	6.1 Patient information about OME
	6.2 Web based resources for families
	6.3 Online hearing test
	6.4 QOL and PROMS
7. Primary care management of OME	7.1 Nurse lead service
	7.2 GP management of OME
	7.3 Practicalities and limitations

Stage 3: Indexing

The coding framework was then applied to the subsequent interview transcripts using the theme and sub-theme codes. Each code was assigned a number for ease of identification. As indexing progressed, the framework was modified to include any emergent codes or themes, or to rearrange sub-themes.

Stage 4: Charting

Framework matrices were developed using NVivo 10 for all the major themes. The data were then charted or summarised into the matrix which reduced the text into brief summaries linked back to the original data. This reduced the data into an understandable format and afforded comparison across participants and themes. An example of this can be seen in Table 6.

Table 6: Example of charting

Interview excerpt from 'How GPs diagnose Glue Ear'	***Summarised test (charting)***
P7: "I tend to go on the history and the history might give me clues, as in the popping or variation in hearing and recent cold or something like that and I'd be looking at the duration"	Parent reported history and duration. History giving clues.

Stage 5: Mapping and interpretation

The final stage of the Framework Analysis involved the refinement and comparison of themes and sub-themes, referring back to the original data to ensure correct understanding and appropriate context. The original framework consisted of 27 codes across 7 themes (Table 5). I reviewed and refined these after coding was complete, and used mind maps to conceptualise how the themes and sub-themes inter-related.

The resultant conceptual framework consisted of 4 main themes with 10 sub-themes (Table 7).

Table 7: Themes identified in the analysis

Four themes identified from the thematic framework analysis
1. Making the diagnosis
1a How GPs make a diagnosis
1b Improving diagnosis
2. Decision making
2a Factors affecting decision making
2b Available services
3. Watchful waiting
3a Describing watchful waiting
3b Engaging families
3c Supporting watchful waiting
4. Management of OME in primary care
4a Management options
4b Autoinflation
4c Nurse–led services in primary care

5.4 Findings

5.4.1 Sample characteristics

Participants were sampled from the AIRS and non-AIRS cohorts and included GPs from Wessex, Thames Valley and Cheshire. Details are presented in Table 8.

Table 8: Identifying interview participants

	Invited by mail (n)	*Expressed interested (n)*	*Did not participate(n)*	*Participated (n)*
AIRS GPs	34	14	2*	12
Non-AIRS GPs	164	34	15**	19
TOTAL	**198**	**48**	**17**	**31**

**unable to contact, ** unable to contact or duplicate practices*

In total, 31 GPs (12 AIRS and 19 non-AIRS) participated in the study from 30 practices located in 12 CCG regions in the UK between April and September 2014. The length of the interviews ranged from 15 to 36 minutes with an average time of 23 minutes.

The purposeful sampling achieved a range of participant demographics including gender, experience and practice characteristics. Details are presented in Table 9.

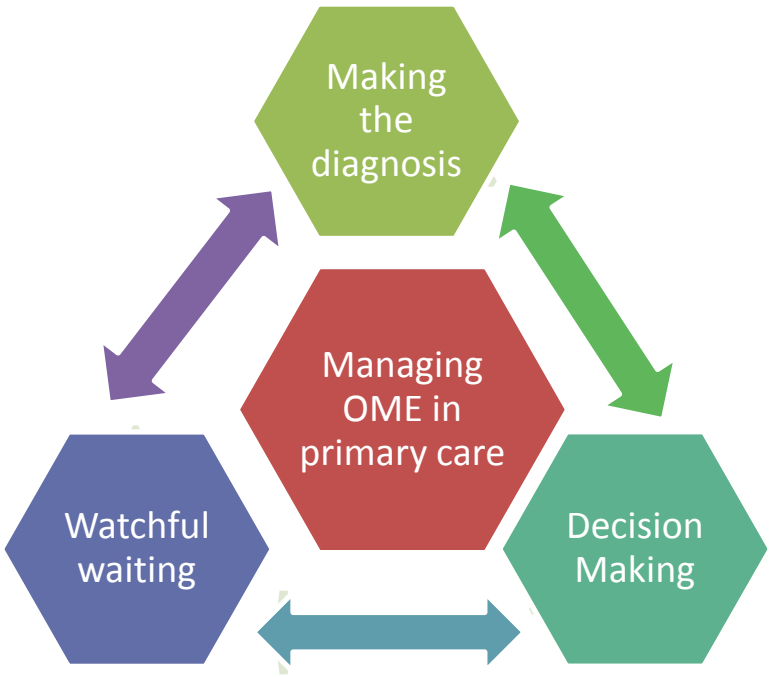
Table 9: Participant and practice characteristics

Participant Characteristics	***N=31***
Years in general practice (*Median,IQR*)	9 (7-22)
Male	24
Female	7
Practice demographics	***N=30***
Practice deprivation decile (where 1 is most deprived, 10 is least deprived) *median (range)*	9 (3-10)
Practice list size *mean (range)*	10742 (3164-28827)
Practice location	
- Rural town and fringe	3
- Rural village and dispersed	3
- Urban city and town	20
- Urban major conurbation	5
Clinical commissioning group	
- NHS Dorset	2
- NHS Eastern Cheshire	6
- NHS Fareham and Gosport	1
- NHS Milton Keynes	2
- NHS Newbury and District	1
- NHS North East Hampshire and Farnham	1
- NHS Oxfordshire	6
- NHS Somerset	2
- NHS South Eastern Hampshire	1
- NHS Southampton	3
- NHS West Hampshire	3
- NHS Wiltshire	3

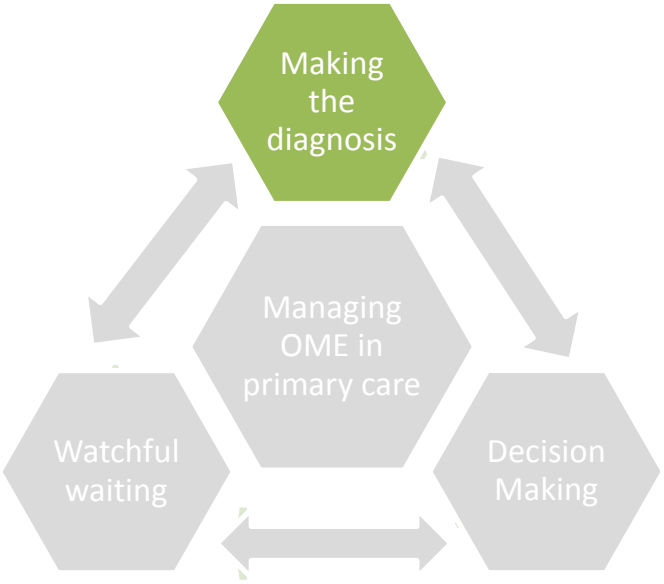
5.4.2 Main findings

Four themes were identified from the analysis and are presented in Table 7. Each theme has 2 or more sub-themes. These are not exhaustive of the information that arose from the interviews but represent those that were considered most relevant to the research questions. Figure 10 represents how each theme link together to explain the findings of the study.

Figure 10: Mapping of 4 key themes from the framework analysis



Theme 1. Making the diagnosis



This theme presents how GPs make a diagnosis of OME in primary care, including the common presenting symptoms, the facilities and resources available to GPs, and the factors that are taken into account when making a diagnosis. This provides the context within which GPs are managing children with OME in primary care.

1a: How GPs make a diagnosis

GPs described that a common reason for consultation in primary care is parental concern about a child's hearing. Typical symptoms reported include: not listening, mishearing, increasing the volume on the television, speech and language problems, and behavioural issues. Concerns often first come to light if the child's teachers suspects hearing problems when a child is inattentive or doesn't follow instructions in the classroom.

> ***P14:*** *Well usually it's because they can't hear at school, so they have to sit in the front in class; occasionally it's a pain, but it's usually just hearing loss on one side. Sometimes it's lack of balance but it's usually hearing loss.*

Good clinical history taking was described as important to GPs when identifying children with glue ear. GPs consider the age of the child, the duration of parental

concerns, the number of previous consultations, recurrent acute otitis media (AOM) and general wellbeing to build up a clinical picture before making a diagnosis.

> ***P26:*** *So, I might suspect a glue ear first of all because of a history of repeated ear infections, earaches, attendances with upper respiratory infections, possibly a complaint of blocked nose, mouth, breathing, speech development problems, that sort of thing. Then I'd have a look at the notes and look in the ears.*

GPs report using a range of diagnostic facilities within the practice for suspected OME. Otoscopy is most commonly used, although some GPs described limitations of otoscopy when the ear canal was full of wax and the tympanic membrane obscured.

> ***P24****: It can be quite difficult to see [the tympanic membrane] with the instrumentation that we've got, which is just a standard otoscope because children's ear canals are quite small and they don't like you pulling on them that much. It can be difficult to get a really good view.*

GPs described looking for a dull, retracted tympanic membrane and bubbles or fluid behind the eardrum as a sign of middle ear effusion.

Some GPs had a tympanometer in the practice following participation in the AIRS study[2 3] although only some were still in use, with GPs describing problems in maintaining them during periods when demand is relatively low, such as the summer months.

> ***P11:*** *So it's basically being used less and less now. I had a discussion with my colleagues and I did say, you know, we should think about keeping it [tympanometer] charged up in the winter months, if you think it's going to help. But, on the whole, they don't use my research nurse and me very much for tympanometry because for years we didn't have it and they've developed their own management approaches.*

Audiometry was available in some practices for testing hearing levels in older children. Some GPs described using the Whispered Voice Test[152] or a tuning fork in the process of making a diagnosis.

In summary, most GPs described themselves as confident in diagnosing OME with a combination of parental reported concerns, clinical history taking and physical examination with the facilities currently available to them at their practice.

> ***P20:*** *So diagnosis predominantly on history and examination findings. Because obviously a child, if they're particularly young, may just be inattentive, may be behaving badly, appears to be in a world of their own. Parents have often noticed that the TV gets turned up loud and that they shout. Maybe some behavioural problems at school? All those are sort of good indicators. And then just straightforward looking in their ears, and if they've got dulled tympanic membranes or attic retraction, I'm pretty confident they've got glue ear.*

Conversely, a few GPs reported a level of uncertainty about diagnosis, commenting that diagnosis was not always clear.

> ***P8:*** *often I think the diagnosis of a lot of the ear problems is sometimes a little bit difficult in terms of is it definitely an otitis media, is it definitely glue ear, is it a viral illness? I think sometimes I think it's not, you know, I wouldn't say that we might work with something but I think often you're not 100% sure*

1b Improving diagnosis

GPs were asked about how they diagnosed children with glue ear, and prompted about the use of questionnaire, symptom lists and PROMS. A quality of life questionnaire (OMQ-14[153]) was postulated as useful decision tool by a small number of GPs. They described it as having potential to improve the quality and consistency of referrals, and helping to differentiate which children could be managed appropriately in primary care and which children require immediate referral.

> ***P14****: it probably would be useful, you know, being able for them to score a baseline and then review it with a follow-up; okay, I can see a place for that and we have got used to tools which provide us with a score in lots of areas of primary care now.*

GPs reported that parents might find it reassuring to have a measure by which to report their child's hearing and the wider impact on their quality of life. However, other GPs described questionnaires as a "*tick-box exercise*", which would take too long to implement and impede the consultation process. It was suggested that questionnaires would require parental motivation to complete and return at the next visit. Some GPs reported a dislike of questionnaires finding them too subjective. In general, the OMQ-14 was described as unlikely to affect the management or referral of the child in general practice.

> ***P11:*** *I'm slightly against all this, these sort of clinical scorings, predictive scores, they are a bit sort of tick box medicine and they don't always pick up on the nuances that actually can influence you hugely as a clinician.*

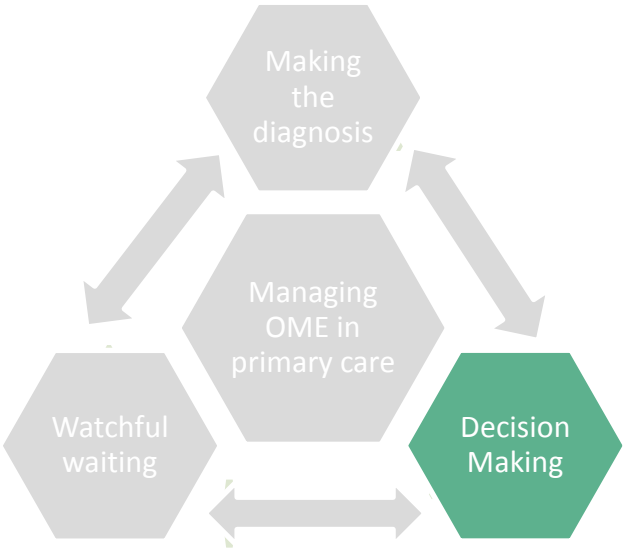
GPs generally described specific screening or targeted questions to be potentially useful for clinical questioning and could improve the diagnosis of OME. Such questions might help screen out the children who need further action taken, whilst deciding on which children could be monitored in primary care. Some GPs suggested that a set of simple criteria, analogous to the Centor Criteria[154] for bacterial infection in sore throats, would be an extremely useful tool for decision making and managing expectations of families.

> ***P31****: if we've made the clinical diagnosis and parents are sceptical, they're worried that we're missing an infection, it would also be useful evidence for us to say look your child is ticking all these boxes for glue ear, that's why I think that your child has this condition.*

Theme 1 summary

Most GPs described themselves as confident in diagnosing children with OME in general practice by conducting a full clinical history, a thorough physical examination using facilities available to them at the practice and by listening closely to parental concerns. There was mixed opinion about whether quality of life questionnaires would aid diagnosis and management or be a burden to the consultation process. However, specific screening or targeted questions to improve the precision of diagnosis were generally considered by GPs to be more useful in clinical practice.

Theme 2. Decision making



After the initial diagnosis of OME has been made, a decision needs to be made as to whether the child can be managed conservatively within primary care or requires further investigation or referral. This theme presents how GPs decide on the next steps for managing a child with suspected OME.

2a <u>Factors affecting GP decision making</u>

A number of GPs described OME as a self-limiting condition with the majority of children expected to resolve naturally within a few weeks.

> ***P27:*** *Most of the problems aren't persistent or recurrent and do resolve as expected, and therefore don't require a great deal of intervention or at least don't seem to require a great deal of intervention*

However others suggested that there may be long-term consequences if the short-term difficulties were not addressed.

OME was generally referred to as an uncommon condition in primary care, with one GP reporting no cases requiring referral within the past 3 years.

> ***P29*** *The problem we have with a lot of these conditions is you just don't see them very often. Therefore, your management isn't very up to date probably. Do you know what I mean? You just don't see them, you know.*

GPs reported taking a number of factors into consideration when deciding whether to refer for further investigation (audiology) or directly to ENT services. Parent-reported educational, developmental and language concerns were key prompts for onward referral, especially when combined with a history of persistent of recurrent ear-related problems

> ***P17****: I mean that's why I refer really, because if they've got persisting deafness, especially if it's affecting them at school or their development, language and development, then that's when, that's what I refer for.*

However, a number of GPs also considered the time of year to be important in the light of perceived higher rates of natural resolution in the summer months. Some GPs reported a lower threshold for referral if there was significant, persistent hearing loss; atypical hearing loss; significant impact at school; heightened parental anxiety; recurrent AOM; or where there was uncertainty about the diagnosis.

GP's reported that there were limited options for families in primary care and in some cases felt that they had no alternative than to refer. This was sometimes associated with heightened parental anxieties about their child's hearing.

> ***P8:*** *I'm quite a low referrer generally but I think if a mum was very anxious and very cross about it and very adamant that she wanted a specialist opinion and was concerned about hearing, I think if she felt that strongly, I probably would just get an opinion*

In some regions GPs reported that parents did not want to wait and monitor progress and often requested immediate referral.

> ***P31****: we've got a very highly affluent area and many people are privately insured and often people will push for an early referral to an ENT consultant with the view to having grommets inserted because they'll have heard that that's the done thing. So, that wouldn't be something that we would be encouraged, but it's something that we frequently get asked for.*

In a similar vein, a GP from an area of mixed cultural background reported that specialist referrals were often requested from other European nationals, where a more secondary-care led service is the norm.

GPs reported seeing their role as providing information, support and reassurance so the decision for future care is a collaboration between the families and the GP. Some GPs did not see it as their position to obstruct referral if that was what the family wanted.

> ***P2:*** *Some people are prepared to put up with a little bit of discomfort and are prepared to let their children put up with a little bit of discomfort and inconvenience, if it then saves them an operation. Other parents are kind of, 'Well he needs an operation straightaway doctor'. And you know, we're certainly not going to be in a situation where we stand in the way of a parent like that. I don't view that as our role.*

2b Availability of local services for OME

Participants reported a variety of local and secondary care services available for them to refer children with suspected OME. This included specialist GPs within the practice, community audiology, community paediatrics, paediatric ENT services and general ENT services. In most cases, the first referral would be for a hearing test which would commonly be conducted by a community audiology department. In many regions a health visitor (and occasionally a school nurse) could refer children directly into the services, bypassing the GP. Community audiology facilities were often reported as being accessible with relatively short waiting times. Most GPs were generally unaware of any local guidelines, policies or pathways for managing children with OME applicable to their practice. Despite this, most GPs had a clear understanding of where and how children should be managed.

GPs from some practices described a huge pressure to reduce referrals and this affected decision making to refer for further investigation.

> ***P11:*** *Massive, massive pressure to reduce unnecessary referrals. So, you know, broadly those are the principles but, of course, any individual case can swing it; so if a child is terribly compromised, then I might refer them earlier.*

Some GPs were aware of the NICE guidelines[35] for the surgical management of OME, but did not think it was particularly relevant to their day to day management of children with glue ear.

> ***P7:*** *Equally, the same thing applies to NICE Guidelines and so on; I might look it up but, actually, I have a plan in my mind as to what I would do. So the existence of the protocol doesn't necessarily change things. It's really nice to have a protocol in place that new doctors could refer to or we could refer to check current management, but I don't think there is one for glue ear.*

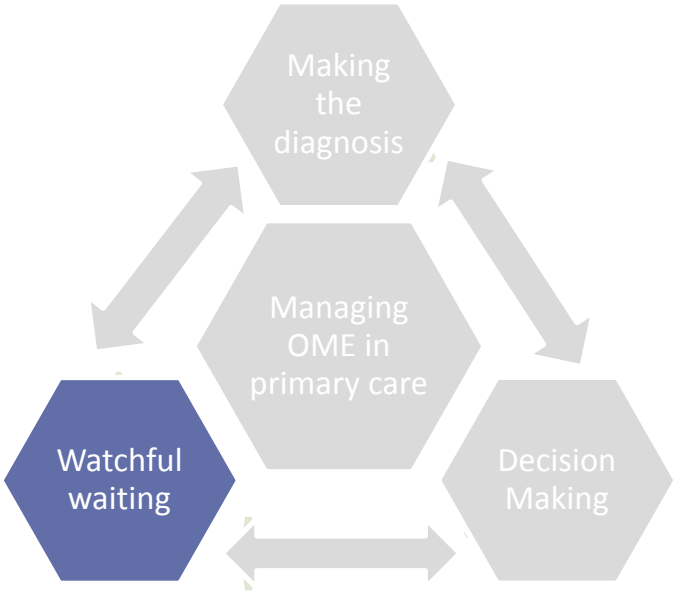
Referral directly to the ENT services, rather than via audiology, was described as the route for more children who were considered to potentially require grommet surgery. Surgery was seen as a "*good option*" by some GPs and "*as a last resort*" by others. Grommet surgery was described as having only a short-term benefit, effective for a minority of children, with associated risks and complications.

> ***P1:*** *For a lot of them my feeling is always avoid if possible because you have to have an anaesthetic and the results can be, or the effect can be over within, you know, six months which is, for an anaesthetic, is a short time and, for a child, if you're trying to improve their hearing, you do wonder how much different that makes, to be honest.*

Theme 2 summary

GPs described OME as a self-limiting condition, and they had a high expectation for natural resolution. However, parent-reported educational, developmental and language concerns in combination with ear-related history, were considered key reasons for rapid referral. Referral strategies were often based on availability of local services. Whilst most GPs were unaware of local guidelines, polies or pathways, most GPs described being clear about where and how children should be managed in their local area. Community audiology services were available in most areas, and were reported as easy to access with short waiting times. Direct referral to ENT services was described as appropriate for more severe children who were considered by the GP to require early surgical intervention.

Theme 3. Watchful waiting in primary care



This theme describes how active monitoring/watchful waiting is implemented in primary care, including how families engage with the process, and how children are monitored and managed during this period.

3a Describing watchful waiting

All GP participants were aware of the term 'watchful waiting' but a few did not think it was the correct term to use in relation to OME. Most GPs understood the term watchful waiting as a period of monitoring and waiting for improvement.

> *P19: Well it's, I suppose the term describes a period of non-intervention with the expectation that there may be a beneficial change or change in outcome with an agreed review. So it's not a dismissal it's more a sort of agreement that the ongoing management will be reviewed in future.*

GPs described monitoring as a period of active observation of the child's hearing levels, social and academic development, speech and language development, as well as their general health. This observation could be carried out by the parents, who spend the most time with the children, but could also be relatives, school teachers and health visitors.

> ***P17:*** *To me, I don't do the watching, I expect the parents to do the watching…. and to come back if it's not improved.*

Improvement was often described as natural resolution of the condition which could be assessed either objectively with the facilities available or improvement in terms of symptoms and concerns.

3b Engaging families

Before deciding on a period of watchful waiting, GPs described the importance of discussing options with families, describing the need for a good explanation of the condition, providing reassurance and addressing parental concerns. The period of watchful waiting was described as a period of time ranging from 4 weeks in some cases to 6 months in others. Some described 3 months as being too long especially when the child's schooling was being affected. Most practices offered an open follow up system where parents returned to see their GP within a specified time period if symptoms and concerns persisted. This was described as a type of '*safety netting'* for families.

> ***P11:*** *Waiting if the situation improves or doesn't improve and such is the pressure on appointments, as I say, I'm not in the habit of bringing people back to check that all is well and, I'm sorry, that is a luxury of the past. Now I say, come back if the situation hasn't improved.*

Other practices offered an active follow up where the GP would book a follow up appointment within a specified time, especially if there were significant hearing and educational concerns. One GP described watchful waiting as being overused by the commissioning boards to reduce referral costs, resulting in children not getting the timely assessment and treatment they required.

Some GPs described the watchful waiting as a period of non-intervention, whilst other GPs considered this time as a period where certain treatments could be applied, including medical and practical interventions.

> *P3: It's basically doing nothing and just giving parents tools to look out for any red flag symptoms to re-attend*

GPs observed that giving a good explanation to families improved acceptability of the watchful waiting period, although parents with a high level of concern were less likely to accept a potential delay to referral.

GPs reported a watchful waiting strategy would be used depending on the initial level of concerns, whether it was a newly presenting symptom and the perceived level of willingness of the parents to wait and see. It was reported that some parents often seemed to want a quick solution and waiting was not always acceptable.

> *P31: People around here don't like waiting, but we do encourage it because we say that at least half of children with this would have cleared within three months, so it's a good chance that with no intervention it will be fine.*

3c Supporting watchful waiting

Patient information, either written or online, was described by GPs as a way to help back up the verbal information given during a consultation.

> *P18: even when I first see them and I diagnose glue ear with the parents I would give them the patient information leaflet even from that visit itself really, because I think to go away with an information leaflet it's very valuable for them to understand the condition a bit more and give them more reassurance really.*

It was reported as helping parents to understand the condition, providing reassurance and encouraging self-management, although some GPs reported that information leaflets can be too generalised and can increase anxiety for some parents.

> *P27: A lot of patient leaflets are pretty – they say too much, they say more than the patients actually want to know and they show you all kinds of stuff, which often ends up increasing rather than decreasing anxiety.*

One GP from an area of high social deprivation commented that the people who struggle the most are often the least able to access information and self-help guidance. Low literacy levels could also be a barrier to good health information, and GPs need to rely more on the consultation to give information to patients in this case.

Websites were generally considered to be a good source of information for families and help self-management. A number of GPs reported signposting to online information, most commonly to www.patient.co.uk.

> *P1: I think people do respond to either websites, which are easily accessible because everyone has access now, don't they, or information leaflets, which I have to say I haven't used, so that would be good.*

However, in many cases information was being printed by the practice to give the families in the surgery, especially if the families had no access to the internet or there was a perceived lack of parental motivation to access a website at home. GPs suggested information websites should be evidence based and linked to the surgery website adding to the credibility to the resource and potentially taking pressure off the GPs as the only available information.

> *P3: But I'm just equally trying to say I think we need to start moving to utilisation of other resources, such that the final pathway is not always us, but there is a gateway to high quality information, and that's the thing that would make a big difference, because then they've got that with them every day to reinforce their technique.*

Suggestions for improved patient information websites included snappy and concise signposting, available for mobile devices as well as the computer and have charity endorsement or be linked to a charity website.

GPs reported mixed views about the use of an online hearing test for families to access at home. Some GPs suggested that it could improve self-monitoring of OME and could reduce pressure on primary care. It could be used during the watchful waiting period, and parents would feel that they are taking action, rather than just waiting for natural resolution.

> *P22: I think it would be, in our practice population, it would be very useful because it's an objective marker which removes the subjectivity and potential unnecessary concern on the part of the parents.*

However, other GPs suggested that an online hearing test may heighten anxiety for some families and would not affect their overall management or referral strategies. There were general concerns about validity, reliability and whether it would result in

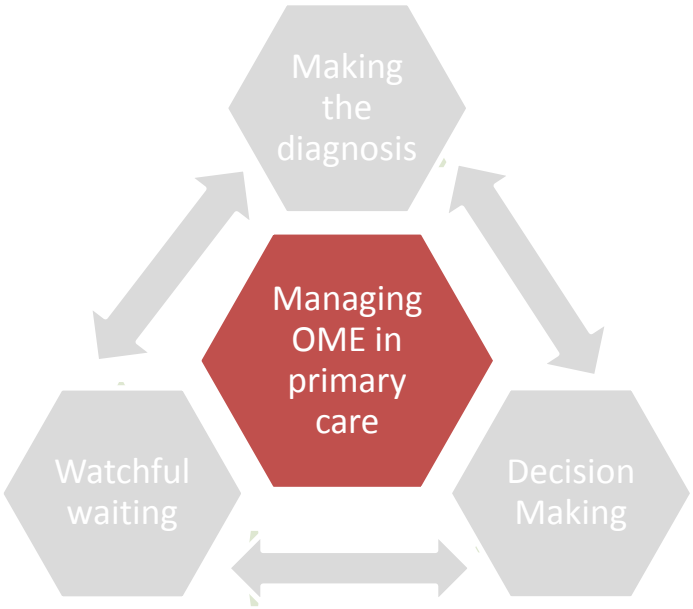
an increase in workload for GPs (by anxious parents requiring additional consultations).

> ***P16:*** *I'd be a bit dubious about something like that. I can imagine endless parents pouring in with, 'We've done the online test, blah blah blah'. - even if it's well validated.*

Theme 3 summary

For children who did not require early referral, GPs considered a period of active monitoring/watchful waiting to be appropriate. However, this required discussions with the family, including providing explanations, reassurance and addressing concerns to ensure that the family engaged with the monitoring process. Follow up for children was variable, with some GPs offering an open follow-up consultation if things didn't improve, whilst others booked a follow up appointment immediately. Most reported that the family monitored the child's progress rather than the GP, and therefore parental concerns and parental engagement were highly influential to how the children are managed and referred. Providing written information to families about glue ear was described by GPs as a good way of backing up the verbal information given at the consultation, although information leaflets were often thought to be too generalised with the potential to increase anxiety levels for some parents. The internet was considered a good source of information for families to promote self-management but there was a reported need for them to be credible and evidence-based.

Theme 4. Management of OME in primary care



This theme describes the management strategies employed in general practice for children with OME including the available treatments and a discussion of the roles within primary care concerning who is best placed to case manage children with OME.

4a Management strategies

GPs reported using a range of management strategies for children with OME in primary care. Many GPs use no treatment at all due to lack of evidence for an effective treatment, or consider that OME is a self-limiting condition which would resolve without any intervention. A number of GPs reported using antibiotics in children with OME, especially in the presence of a suspected infection. Nasal sprays, saline drops and decongestants were also used in some children for OME, together with steam/menthol inhalation and chewing gum as a self-help treatment, although some GPs commented that there was little evidence to support their use.

> *P2: the way it works is we tell them the simple, straightforward stuff first. You know, that you use a bit of Vic or use a bit of Olbas Oil and do the steam inhalations and do the Valsalva's and so on*

P10: I don't know if there's any evidence for that but it seems to help some of them.

Close monitoring and waiting for natural resolution was also described by some GPs as a treatment used for OME, together with some practical suggestions of moving to the front of the class and hand-washing to reduce transmission of infection.

Surgical intervention with grommets was described as having an immediate effect on symptoms of OME, generally acceptable and a good option for selected children. Other GPs described surgery as ineffective or only effective in the short-term, with associated risks and complications, and should be '*a last resort'* for children.

P3: It's an invasive procedure. We know that the grommets tend to fall out often fairly easily anyway. So most of us would say our impression is not overly, you know, successful for a condition that, in a lot of people will resolve on its own.

Many GPs reported using some techniques of middle ear insufflation in their current practice. The Valsalva manoeuvre itself was commonly suggested if the child was considered old enough to comply. Other techniques described included yawning, drinking whilst holding the nose, blowing the nose, chewing gum, sipping drinks, nasal balloon autoinflation and mouth inflation of a party balloon.

P 11*: just saying useless things like saying try and help them not to get more colds, remember basic hand washing measures, but you're on a hiding to nothing, really, with youngsters. So I remind them that sipping drinks and swallowing to open the Eustachian tubes and theoretically if you sip, sip, sip, that might help a little bit.*

4b <u>Autoinflation</u>

A sample of the GPs had previous experience of using nasal balloon autoinflation including those who had participated in the AIRS study (12 GPs) and others who prescribe the device in their routine clinical practice (3 GPs). For the remaining 16 GPs who participated in the study, 13 had never heard of the device or the technique of autoinflation. All GPs had received a link to the nasal balloon video that had been used as part of the AIRS study so views expressed by GPs were sometimes based on seeing the video rather than personal experience, and a copy of the AIRS study[2 3] abstract (Appendix A). The mechanism of action of autoinflation was described as easy to

understand and to explain to parents, and was generally considered to be a low-harm, low cost intervention.

> ***P1*** *It's easy to use, physiologically you can see how it could be helpful and it's something that's, you know, we talk about actively trying to drain or aerate the middle ear, et cetera, and you think well that's probably going to help it and the likelihood of it doing any harm is very, very low, so why not?*

The device was described as a non-surgical treatment to add to a GP's primary care "*toolkit*" and something that could either be prescribed or bought over-the-counter as an instant treatment. Some GPs expressed uncertainty about its effectiveness, whether it would make things worse, and when or how long to prescribe the treatment for. There were also some concerns about its credibility, being described as a '*gimmick'* or purely a placebo especially by the non-AIRS GPs were unfamiliar with the nasal balloon.

> ***P7:*** *Am I going to do more harm than good; is it something that's going to help or actually is just a placebo? Is it a short-term benefit or not and will the patient come back and complain that they've got ear pain with it or is it used inappropriately? I suppose those are the doctor's concerns.*

GPs identified that the treatment would require a level of parental motivation and suggested that there could be issues with compliance.

> *P17: I think a lot of parents wouldn't stick with it is the honest... I think they would just, because they're busy people, it's just something else to do. I don't know how long you're meant to carry it on for, but I imagine it's quite a long time.*

One GP described it being an unnecessary burden for families in what was considered a self-limiting condition. There were also concerns about medicalisation of what would be considered a normal childhood condition. However, some GPs described autoinflation as a way to empower parents by involving them in the management process and promoting self-treatment.

> ***P17:*** *I think some parents would love it, because they think they're doing something. I think some parents would be very keen for that, especially if they thought it might reduce the need for further medical intervention later on, or if they thought it was going to help their child.*

Some GPs reported the importance of carefully choosing which children/families to offer the device to. Nasal balloon autoinflation was described as more likely to be taken up in areas of higher education and lower social deprivation. Some GPs thought that there may be barriers to uptake in diverse cultural populations and areas of high social deprivation.

> ***P17**: I mean, we've got a real mixture here. I can think of patients' parents that would do it religiously, and then I've got one where they just wouldn't even open the packet.*

GPs identified the importance of a good demonstration when prescribing autoinflation to ensure the technique is mastered correctly.

> ***P30**: Because demonstrations are always really important. It's all about technique. All these things are about technique.*

Some GPs did not always see it as their role to demonstrate the nasal balloon, either due to time commitments or the practicality of keeping a demonstrator in their office.

> ***P30**: I honestly think I would struggle to teach it within a busy consultation because there are often other problems being brought or other kids running round the room and I don't think I would be the best person to teach it.*

Although other GPs described that demonstrating the technique themselves would improve credibility of the nasal balloon as a treatment and help to motivate the parents.

> ***P11**: demonstrating it and the fact that a GP is prepared to undertake this undignified procedure, probably helps the parents to keep motivating the child, although, as we know, the children actually quite enjoy it and see the fun side of it.*

However, GPs reported that there would be considerable time pressures if training to use the device took place within the normal consultation. There might also be an increase in workload with the potential need for follow up consultations or telephone consultations to check the technique.

An example pack or demonstration pack, like with asthma inhalers, was reported by some GPs as being very useful to help train the children to use the device.

> ***P24****: I think you'd have to show them how to do it, so I'd have a clean one in a drawer that you could demonstrate and then another one to give to the child, so you could check their technique and everything. Then give them a prescription to get their own new one on prescription.*

However, others reported that it would not be useful as they would be single use and or get lost amongst all the paperwork and equipment in their office.

There were suggestions about who else could deliver the nasal balloon training. Some GPs suggested that practice nurses could be trained to undertake this role within the practice as was done in the AIRS study.[2 3]

> ***P22:*** *So I think it would fit in perfectly with the nurse practitioners in our practice and I think it would be something that they relish and easily take on board.*

Some GPs suggested that there could be a role for pharmacists during dispensing of the device, which is reported to work well with the demonstrating and prescribing of asthma inhalers.

> ***P24****: We have an asthma nurse, so if it's an asthmatic, they all get seen and they have to bring their inhalers in with them and demonstrate……and then I say, 'When you get to the pharmacy and pick it up, please ask the pharmacist to show you with your own device how to use it'.*

Most GPs described the value of an online training video for families, which would save time for GPs, engages children and promotes self-management. However, they wanted it to be evidence-based and accompanied by a good verbal explanation.

> ***P25:*** *I think videos and tutorials and things like that are very useful, especially for children who seem to know an awful lot about YouTube and things like that. I think it is quite a useful resource to have, definitely*

To support the prescription of autoinflation in general practice, GPs described wanting a good evidence base, endorsement/support from local ENT colleagues and suggested that Otovent™ could be added to the local prescription formulary.

4c Nurse led services in primary care

Nurses were reported by GPs as being ideally placed to provide ear care for OME in the practice, being described as having more time to spend with children and the families than GPs.

> ***P1****: Yes, all the sort of chronic disease management is nurse led, well a lot of it is, certainly obviously asthma and chest stuff is nurse led. So, yes, I think I could see it working very well in primary care.*

However, some GPs reported that nurse time was as limited as the doctor's time and nurses may not have the capacity to take on additional responsibilities.

> ***P11****: Gone are the days where we passed work on to the nurses because they've got more time; their appointments are massively pressurised too.*

In some practices nurses were already providing some ear care services, but more commonly for adults and older children.

GPs identified that nurses could be trained up from within the practice, keeping the patient management in-house and result in the *"up-skilling of primary care"*.

> ***P22****: I think it would give them ownership of another skill which needs to be beneficial for all concerned.*

Tympanometry would be another skill for nurses, although there would need to be a level of ongoing training. GPs suggested that nurses were good at patient education and practical demonstrations, for example inhaler techniques, and would be in a good position to demonstrate the autoinflation device.

> ***P28****: I feel nurses are probably more appropriate in our surgery because they've got slightly – they've got nurse-consultation time and they do see lots and lots of minor things which we are not used to seeing anymore even because they deal with it and they've got slightly longer time. And I think they've got slightly more patience as well in terms of demonstrating techniques.*

Principal barriers to a nurse-led service were reported by GPs to be lack of demand, difficulty retaining skills within the practice and acquiring funding for additional services.

GPs reported that the demand within a single practice would be intermittent and that the service may not therefore be cost effective. However, there may be more demand over the winter periods and could be considered during this time. Demand would also depend on the availability of local services. Some GPs reported good access to community audiological services which would be the first step if OME was suspected.

> ***P10****: I mean I'm not sure that there would be a huge benefit to it because we do have reasonable local services that can do hearing assessments and diagnosis, so I'm not sure if it would have a sort of, you know, make a massive difference.*

Concerns were reported that skills would not be retained if the demand was intermittent. Additional time would be needed for nurses to undertake training and keep their skills current.

Funding was considered to be a main barrier and it was not clear who would fund a nurse-led service.

> ***P3****: They are a very rationed resource. We are incredibly stretched, we are getting increasingly stretched. So we are now talking about - primary care at the moment seems to be having to absorb everything. So we are under tremendous pressures*

Other services within general practice were considered to be more pressing. Some GPs suggested that the service may work on a locality or CCG level, or a practice providing the service for other practices in the locality, but there were uncertainties about this would work on a practical level.

Theme 4 summary

During the active monitoring period GPs prescribed a range of treatments and management strategies. Whilst some GPs relied purely on 'wait and see' others prescribed antibiotics, nasal sprays, saline drops' and decongestants. Self-help treatments included steam/menthol inhalation and middle ear inflation techniques, such as the Valsalva manoeuvre, blowing the nose, chewing gum, sipping drinks as well as nasal balloon autoinflation in some cases.

Some GPs had prior experience of nasal balloon autoinflation due to their participation in the AIRS study[2], but many had not heard about the treatment or did not routinely

use it in practice. The device was described as easy to understand and explain to parents and generally considered low-harm and low cost, but there was expressed uncertainty about its effectiveness and credibility as a treatment modality. Whilst some GPs thought it could empower parents and promote self-management, others thought it might be another unnecessary burden for families. It was generally agreed that it would be useful for a selective group of motivated parents. The demonstration of the technique of autoinflation was considered to be key to the uptake and compliance with the device, but GPs thought it might add considerable time pressures to the consultation. Nurses and pharmacists might be able to deliver the training if the funding permitted, and GPs suggested that online training videos would engage families and children, and promote self-management.

5.5 Discussion

5.5.1 Summary of main findings

The findings of this study found that GPs described themselves as generally confident in diagnosing children with OME in primary care, despite having limited access to objective tests such as tympanometry or audiometry. Most GPs consider OME to be a self-limiting condition with a high expectation for natural resolution and therefore consider that it can be effectively managed in the primary care setting for the majority of children. Most GPs were unaware of the local guidelines for management and referral for OME, or the applicability of the national NICE guidelines. However, all were aware of their own local referral pathways. Many GPs described referral to ENT services as often driven by parental pressure. A period of active monitoring/watchful waiting was described as an appropriate management strategy but parental engagement was seen as important as parents generally take on the role of monitoring. GPs report using a range of medical and self-help treatments for children with OME, with only the AIRS GPs and a few non-AIRS GPs having experience of using the nasal balloon in practice. The nasal balloon was described as low harm and low cost, but some concerns were raised about its effectiveness, the credibility of such a

treatment, and the potential burden on the GP consultation for training children and families to use the balloon.

5.5.2 Comparison to existing literature

Parental concerns and clinical history are the basis for most diagnoses of OME in primary care[155]. In this study, only a few GPs offer tympanometry in their practice and this was entirely due to having equipment previously provided for the AIRS randomised controlled trial[3]. The remaining GPs did not use tympanometry, which is consistent with previous research that suggests that less than 5% of GP practices have access to tympanometry at their practice[27]. Despite this, previous research has shown that general practitioners[156] and practice nurses[3 86] are confident and competent in undertaking tympanometry with training and support, which could considerably improve the precision of diagnosis of OME in primary care and referral accuracy of true cases.

Little direct information has until now been available about how GPs report managing children with OME in primary care. Some participants in our study had knowledge of the NICE guidelines[35] for surgical management of OME but described them as applicable to the secondary care setting, with little relevance to primary care. GPs may be unaware that the guidelines relevant to primary care are well hidden within the surgical guidelines[35] and thus supports Peter Burkes statement that glue ear is often regarded as a 'surgical condition' by many doctors.[157] There was limited knowledge of local guidelines, at either the practice or trust level, a symptom of general confusion about management. Thus, management provided by the GP was often *ad hoc* and based on their own current knowledge and what other partners in the practice were doing. However, a search of the corresponding Primary Care Trust (PCT)/Clinical Commissioning Group (CCG) websites found that many trusts in fact did have guidelines in place for managing children with OME appropriate to both primary and secondary care settings. For example, Cheshire and Merseyside CCG commission grommet surgery in children aged 3 years and above with a history of recurrent AOM or 3 months watchful waiting from the date of diagnosis of OME(by GP/audiologist/ENT surgeon) AND with delayed speech or persistent hearing loss[158].

Whereas Hampshire CCG commission grommet surgery after 6 months active monitoring (3 months in primary care followed by 3 months in secondary care). Oxfordshire PCT also commission grommet surgery following 3 months watchful waiting after diagnosis in primary care and at least 5 recurrences of OME, evidence of speech delay or educational/behavioural problems with hearing loss[159]. This suggests that whilst local guidelines are commonly based on the NICE guidelines, there is variation in commissioning of grommet surgery in different regions of the country, which will affect how children are managed in primary care. The more frequent diagnosis of AOM may also reflect under-diagnosis of OME or incorrect labelling of a more subtle condition.

Community paediatric audiology services were reported as being widely available to GPs in this study, and children are referred to these services when initial concerns are raised by parents and often prior to commencing any treatment. Audiology is a healthcare science service which provides excellent diagnostics and treatments for hearing problems, tinnitus and balance disorders in the NHS. Paediatric audiology services currently offer diagnostic testing, watchful waiting and assessment for speech, language and behavioural problems in children with glue ear[160]. These services are accessed by a large number of children with OME, and so constitutes a potential service where the nasal balloon treatment could be very usefully implemented, alongside general practice, although audiology services do not currently have the mechanism by which to prescribe the nasal balloon free at the point of need for children.

My study suggests that some GPs are individually using a range of medical treatments for managing glue ear. Antibiotics have a potential to improve resolution of OME but this needs to be balanced against the potential for causing harm, and in light of emerging antibiotic resistance. A recently updated Cochrane review[37] found that children treated with antibiotics were more likely to have a complete resolution of their glue ear at 2 to 3 months than a control group (NNTB – 5), although were also more likely to experience diarrhoea, vomiting or skin rash (NNTH – 20). The impact of antibiotic treatment on hearing, speech language and cognitive development and need

for grommet surgery has yet to be established. Parental expectations of antibiotics may be high and in turn influence inappropriate antibiotic prescribing[40 161]. Likewise, treatments with nasal steroid sprays[45], decongestants[47], and antihistamines[47] are also ineffective, and in the case of decongestants and antihistamines and have the potential to cause harm due to the side-effects[47]. A course of oral steroids may speed resolution of OME in the short term. An important HTA-funded trial is currently under way to assess effectiveness and potential harms of oral steroids before this treatment can recommended.[46]

Nasal balloon autoinflation is still, by all accounts, a relatively unknown treatment option in primary care. However, all GPs in this study received a copy of the AIRS study results abstract prior to taking part in the research interview, and this may have affected their response to the research questions. In this study, GPs described the nasal balloon as a low-cost, low-harm treatment option for some children, however, some GPs raised questions about acceptability to families. Previous small studies of autoinflation found that the technique was described as both '*fun'* and '*amusing'* to children[78 79 83] and parents have variously described the nasal balloon as a natural, holistic treatment with children reported enjoying the novelty of the technique[3]. However, usage of the nasal balloon over a longer period of time might be considered a burden for families, especially if the child refuses or is very reluctant[2].

Providing additional information to support the consultation is thought to help parent's understand the condition of OME, which can lead to joint decision making and encouraging self-management[162]. A qualitative study based in the UK of parental perceptions and understanding of information provision and management options in the treatment of children with glue ear found that parents were keen to receive supplementary printed information alongside verbal provision during consultation[65].

Web-based interventions have become an increasingly popular way of delivering health advice and information, and can also facilitate the delivery of child and parent tailored messages, provide immediate feedback and allow more accurate progress to be tracked over a period of time[163]. However, in this study, patient access to the internet was reported as varied and sometimes limited in areas of high social

deprivation. In other regions, GPs print out information for patients if it appears that the motivation for accessing information on the internet it low.

Patients who seek health information on the internet are generally more health-oriented than those who do not use the internet for health information[164]. This means that whilst web-based interventions are potentially important and valuable for many patients, certain at-risk populations may be disadvantaged. However, a qualitative study investigating parental knowledge in paediatric otolaryngology surgical consultations found that many parents used the internet as their primary source of information prior to their surgical appointment. Most parents wanted more information, with internet delivered information reported as the most desirable[165]. Providing web-based information together with options to print out might be the most appropriate option to ensure widest access to those who might benefit.

5.5.3 Strengths and limitations

This research successfully recruited GPs across broad sociodemographic regions of the UK and has allowed us to gain insight into how GPs manage OME in primary care, and the context in which they are diagnosing, managing and referring children. Semi-structured interviews were a good way to gain their detailed views and experiences, by asking open-ended questions focusing on the topics of interest. The full range of views, both positive and negative, expressed during the study suggests that GPs felt able to speak freely during the research interviews. Data collection continued until data saturation was achieved in this selected group of participants. As the final interviews were conducted, no new or relevant information emerged with respect to the research question. A range of GPs from different geographical and sociodemographic areas were interviewed as part of the study, but policy and guidelines were different between regions and therefore not fully reflective of how OME is managed in the wider UK setting. The sample did, however, include 'information rich' cases by including those GPs who had participated in the AIRS study and had previous experience of actually using the nasal balloon. All GPs had received a copy of the results of the AIRS study prior to participation, and this may have influenced their views and experiences of the nasal balloon method. The AIRS study found that the

nasal balloon was effective compared to usual care, and compliance overall was good[2 3]. This may have given GPs some confidence in the method and credibility to the treatment, which would have affected how GPs described and evaluated the nasal balloon treatment. Without this evidence, GPs may have reported less coherence with the nasal balloon method, and have less confidence of its potential use in primary care.

A strength of this study was the use of NPT to develop the interview topic guide. This ensured that the context of primary care monitoring and management was explored in such a way as to provide a good understanding of the local factors likely to be affecting implementation of the nasal balloon method.

I used rigorous methods to ensure the credibility and trustworthiness of this research, including constant comparison methods, multiple coders, a transparent audit trail and also maintained a reflexive journal to document and reflect on the influence of my own thoughts on the findings of this qualitative work. My preconceptions of the nasal balloon through my work on the AIRS study, was that GPs liked the idea but were not convinced of the practicalities of the treatment. I tried to ensure that I recognised my preconceptions whilst designing the interview questions and analysing the results to ensure that the findings were a true representation of the GPs views and not simply what I expected them to be. As a parent of two children, I also have views on the acceptability of medical and surgical interventions for childhood conditions. I have a strong preference to avoid surgery for myself and my family unless all other options have been explored. Additionally, in the light of emerging antimicrobial resistance, I would prefer to avoid antibiotic treatment especially if there are other options available. These views may have influenced my interactions with the GPs during the research interviews, and consequently the analysis of the results, as I may have an implicit bias toward non-surgical and non-antimicrobial interventions such as the nasal balloon.

To improve the credibility of the study, the results of the qualitative evaluation could have been presented back to a sample of the participants for their views on the findings (respondent checking)[166]. However due to time and financial constraints this was not possible for this study.

5.5.4 Future strategies

My analysis identified that developing tools to encourage and promote self-management may indeed be helpful and suitable for the early management of OME in primary care and the NHS (audiology). Online patient information with facilities for printing hard copies could facilitate better access to much-needed evidence-based information than is currently the case, and for a wider range of families.

The nasal balloon method has a strong practical component for children to learn the technique of autoinflation and comply with the treatment regimen. Providing tailored practical support for use of the nasal balloon is therefore pivotal, and could be delivered by GPs, nurses, pharmacists or audiologists, although this is dependent on available time and resources. An online video should be considered as a potentially useful method of training families, and could support the advice given by the healthcare provider to improve adherence and health outcomes from the perspective of both affected families and the NHS.

Paediatric audiology services were described as a relatively accessible service for the early diagnosis of children with hearing problems and are an interesting potential setting for developing the nasal balloon autoinflation treatment.

5.6 Conclusion

Primary care management of OME continues to present a number of practical challenges. GPs describe themselves as competent in identifying glue ear in primary care and base their diagnoses on clinical histories and physical examination. Management options often include watchful waiting and a range of temporising medical treatments. However, referrals are often *ad hoc* and driven by parental concerns, local services and available resources. Nasal balloon autoinflation is still a relatively unknown treatment option for the NHS and whilst many GPs could see its potential benefit, there remained concerns about the practicalities of its use in a primary care setting, and whether the treatment would be seen as an additional work for families. GPs identified alternative methods of training parents and children to use the balloon, suggesting the use of pharmacists as educators as part of their dispensing

routine. Likewise, GPs suggested that audiologists could signpost to online training videos which could significantly alleviate the pressures of this very common condition on already stretched primary care services. This qualitative study has provided new information about the context in which wider implementation of nasal balloon treatment is planned.

Chapter 6: Qualitative research: secondary analysis of existing qualitative data

6.1 Introduction

Implementation of a novel intervention such as the nasal balloon method requires multiple stakeholder involvement and engagement. As part of the development process it was important to gain a range of views and perspectives from those who were most likely to deliver and/or benefit from the intervention. This chapter reports the secondary analysis of existing qualitative interview data from GPs, practice nurses and parents of children with glue ear. The existing data is drawn from the GP qualitative study presented in the previous chapter, and a qualitative study of nurse and parent views and experiences nested in the AIRS study[3] which I undertook in my previous post. Unlike the primary research studies that explored the general context and experiences of treatment and management of children with glue ear, this secondary analysis focuses on the work required for implementation of the nasal balloon treatment itself, using the Normalization Process Theory[5] to explore the generative mechanisms of implementation.

6.2 Aims and objectives

The aim of this study was to evaluate the promoting and inhibiting factors to implementation of nasal balloon autoinflation from the viewpoint of the different stakeholders including GPs, practice nurses and parents of children with glue ear. The main objective was to develop guiding principles and identify key components for an educational intervention to support implementation of the nasal balloon method and better management of OME in primary care.

6.3 Methods

6.3.1 Research methods

Secondary analysis of qualitative data is a research method which allows the use of pre-existing data to investigate new research questions or to examine similar questions from a different perspective[167]. In this study, I was interested in exploring factors that might influence the implementation of the nasal balloon method into practice from the perspectives of the parents (and their children by proxy), practice nurses and GPs, to inform the development of an educational intervention for families of children with glue ear. Secondary analysis was chosen, in contrast to a meta-synthesis which is more concerned with reviewing and synthesizing existing evidence relating to a common research question.[168]

The Normalization Process Theory[5] was selected to guide this secondary analysis due to its relevance in designing and evaluating complex interventions and facilitating evaluation from the perspective of implementation (discussions about the choice of implementation theory for this project are presented in section 3.2.5).

6.3.2 Conducting a secondary analysis

There are a number of practical, methodological and ethical issues that need to be considered when conducting a secondary analysis[167]. These are discussed in the following sections with reference to how they were considered in this study and their potential effects on the study outcomes.

Compatibility of the primary data sets: It is important to ensure that the primary data sets are compatible with the secondary research question to ensure quality, transparency and credibility of the secondary analysis[167]. Assessing the data sets for extent of missing data, and a review of how the data was originally collected and analysed helps to ensure a good 'fit' with the secondary research question. The primary datasets included in this analysis are presented in chapter 5 and appendix C. Both datasets were considered of good quality, with both reporting negative case analyses to establish credibility, researcher reflexivity and audit trail to establish

confirmability and dependability according to Guba and Lincoln's evaluative criteria for qualitative research[169]. The original interview transcripts were available as NVivo10 files, but the original audio-recordings had been destroyed in accordance with the original ethical arrangements. Original field notes were also available.

Researcher presence and reflexivity: There is considerable discussion in the literature about the effect of the researcher on a secondary analysis[167]. Primary researchers have a specific relationship with the data that they generate. This includes the relationship they have with the participants and their research team, all set in the context of current social and political landscapes[170]. As a secondary analyst, it is argued that particular insights can be lost and findings can limited compared to the primary research[167]. Hammersley proposed that even the same researchers returning to reanalyse their own primary data can experience some distance from the original context[171]. For this study, I was the interviewer and primary analyst for both primary qualitative studies, meaning that I retained a contextual relationship with the original data. However, I also recognise that this may have led to a degree of overlap between the primary and secondary analyses.

Ethical considerations: Obtaining individual consent from participants for a secondary analysis is not always feasible or practical. Hinds[167] suggest that professional judgement should be used to determine whether the re-use of the data contravenes the original consent that was given by the participants of the primary studies. In this project participants gave their written informed consent for participating in the primary studies; for the interview to be audio-recorded and anonymous quotes from the interviews to be included in the reports of findings. Consent was not given explicitly for a secondary analysis to be conducted, however, I considered that the secondary research aims were sufficiently close to the original research questions, in terms of intentionality of usage, to trust that the re-use of data did not infringe the original consent. Also, as the same main investigator was handling and analysing the data, this was considered an extension of the original studies rather than a different research project.

6.3.3 Sampling/selection of primary qualitative data

The two primary datasets were generated by myself as part of this PhD project and from a nested qualitative study within the AIRS study[2]. A search of Medline OVID in August 2015 revealed no further published qualitative studies of nasal balloon autoinflation that could be included in this secondary analysis.

The following tables present a summary of the two primary data sets (Tables 10 and 11).

Table 10: Primary Data Set 1

Exploring GP views and experiences of OME and nasal balloon autoinflation in primary care
Aims: The aim of this study was to determine how OME is currently diagnosed and managed in primary care in the UK and to explore the barriers and facilitators to active monitoring and nasal balloon autoinflation. The study was conducted between April and September 2014.
Methods: 31 semi-structured telephone interviews were conducted with a purposeful sample of GPs. Interviews were digitally audio-recorded and transcribed verbatim. NVivo 10 was used to facilitate data management and a framework analysis was used to analyse the data.
Findings: The study found that GPs were generally confident in diagnosing glue ear although referral strategies varied dependant on clinical judgement and locally available services. GPs used a wide range of different treatment modalities including participating with active monitoring, various medical treatments, and active treatments such as the Valsalva manoeuvre and the nasal balloon. However, GPs expressed concerns about the practicalities of using the nasal balloon in the primary care setting and the potential burden to families. The demonstration of the technique was identified by GPs as an important component to help promote uptake and compliance with the device, but concerns remained about whether it may complicate and thus lengthen the GP consultation process.
Reference: Chapter 5 of this thesis

Table 11: Primary Data Set 2

A nested qualitative study of parent and practice nurse views of nasal balloon autoinflation and active monitoring for glue ear.

Aim: The aim of this study was to explore the views and experiences of parents (and their children by proxy) and practice nurses of the nasal balloon treatment method and active monitoring for glue ear in primary care. The study was conducted between January and September 2013.

Methods: Semi-structured face-to-face and telephone interviews were conducted with a purposive sample of 19 practice nurses and 14 parents whose children had participated in the AIRS study. The interviews were digitally audio-recorded and transcribed verbatim. NVivo 10 was used to facilitate data management and a thematic analysis was conducted.

Findings: The study found that parents described active monitoring as a passive approach of 'wait and see'. Where OME had been identified parents frequently wanted to 'take action' and waiting was often seen as unacceptable. Parents perceived the practice nurse as competent and appropriate in providing management of OME, and most nurses felt skilled and confident in this role. However, wider NHS implementation in primary care may be limited by workload and financial constraints. The three-way collaborative relationship between nurse, parent and child was central to ensuring that children mastered the autoinflation technique and that families engaged with the monitoring process. Making autoinflation part of the daily routine enhanced compliance, especially in the first month of treatment.

Reference: Appendix C, HTA report: Autoinflation in children with otitis media with effusion[3]

6.3.4 Data management and analysis

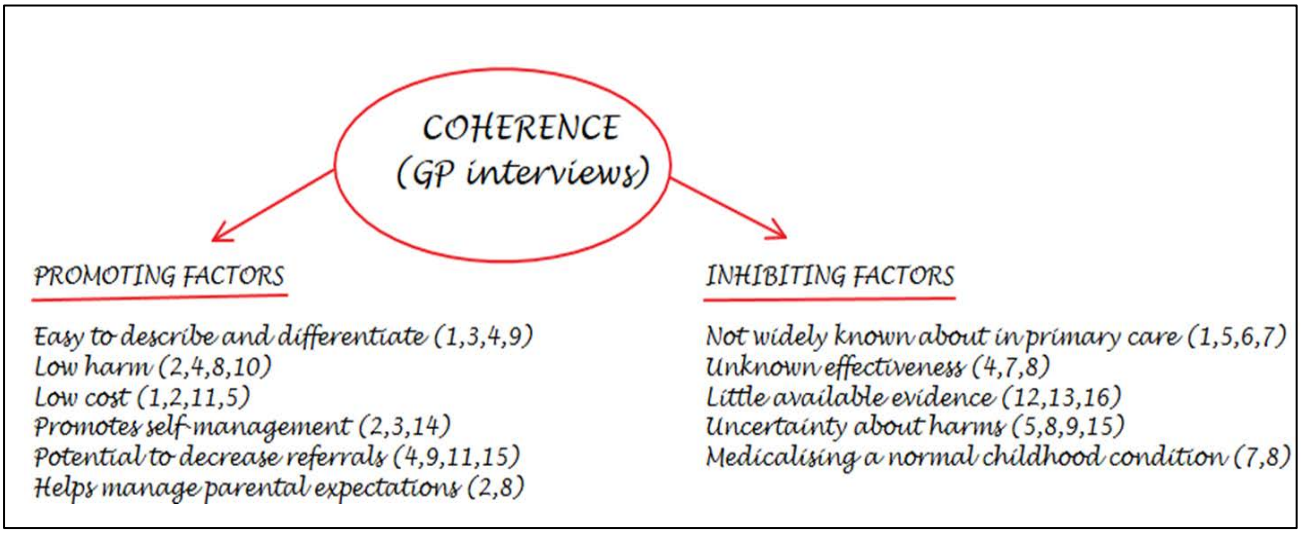
Individual transcripts from both primary studies were combined into an NVivo10 project file. A framework analysis[172], as described in section 5.3.7, was used to organise and analyse the data, using the four constructs of NPT[5] to define the analytical framework (*coherence, cognitive participation, collective action* and *reflexive monitoring*). Each construct is sub-divided into 4 individual components (section 3.2.5, page 44) and I explored the data using these 16 components as the theoretical framework for analysis. However, using the theory at this level on this dataset would have added significant complexity to this analysis. It would have required defining each theoretical component to the context of my research and making coding decisions based on correct interpretation of each component. After some exploratory

analysis and referring back to the aims and objectives of this analysis I decided that drilling down to such a theoretical level during this coding would not have added value but just increase complexity. Instead I decided to use the components to help with interpretation of the results, which is a suggested way of analysing data using NPT on their online tool.

At the outset of the analysis it became clear that some sections of the original interview data were not required for the secondary analysis. Much of the original interview data from both primary studies concerned contextual issues. The secondary analysis, however, was aimed at understanding issues around implementation of the nasal balloon and as such, only sections of the interviews concerned with the nasal balloon were identified and used in the secondary analysis.

After re-familiarisation with the interview data, every relevant section was coded to the four constructs of NPT (*coherence, cognitive participation, collective action* and *reflexive monitoring*). However, having only 4 codes resulted in a large amount of data under each heading. I therefore began by exploring individual stakeholders (i.e. GPs, practice nurses, parents) under each construct. For example, I collated all coded extracts for *coherence* from GP interviews and used a visual mapping technique to map out the factors that I considered would either promote or inhibit coherence with the nasal balloon method for GPs. At the end of each summarised extract I added a link back to the original data (see Figure 11).

Figure 11: Mapping promoting and inhibiting factors



The next step was to collate the results from the different stakeholders, comparing between groups and referring back to the original data to ensure correct understanding and appropriate context. A number of sub-themes emerged under each construct. The results have been written up under each NPT construct and sub-theme, using quotations from the original data to illustrate the results.

6.4 Results and findings

6.4.1 Sample characteristics

The sample comprised i) 31 GPs from 30 general practices ii) 19 practice nurses from 18 general practices and iii) 14 parents of children with glue ear from 10 GP practices. The general practices were in both urban and rural locations, and included areas of high and low social deprivation. The parents included in this analysis were from a range of socio-demographics as identified by the highest level of maternal education. Four of the 14 parent participants reported leaving school aged 16 with O' levels, whereas 7 parents had an undergraduate or postgraduate degree (Table 12).

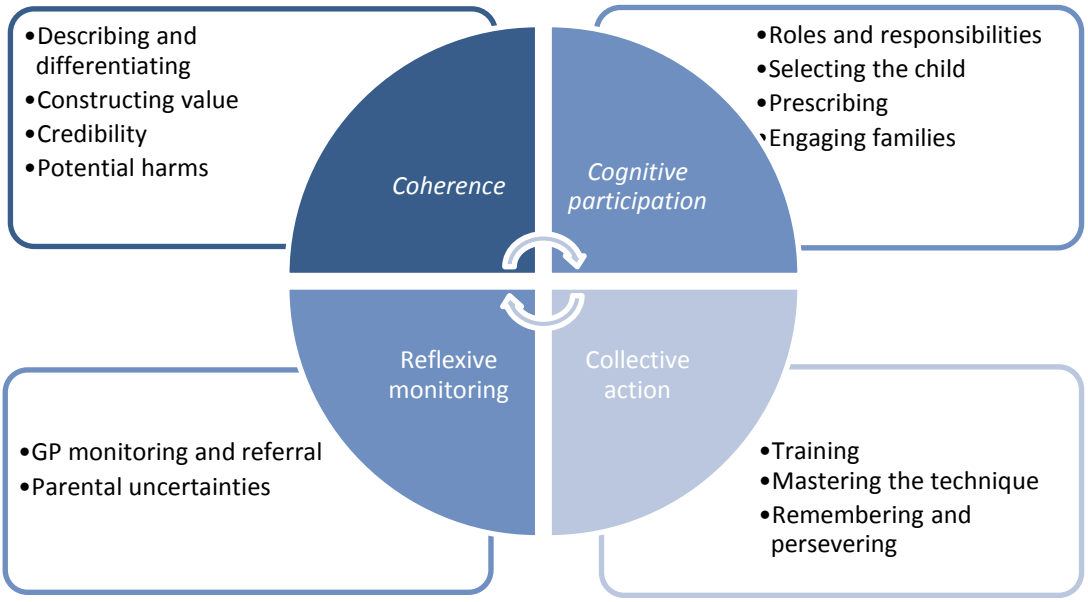
Table 12: Sample characteristics

	Dataset 1	***Dataset 2***	
	GPs (n=31)	Practice nurses (n=19)	Parents (n=14)
Female	7	19	14
Male	24	0	0
AIRS	12	19	14
Non-AIRS	19	0	0
Practice deprivation decile *median (range)*	9 (3-10)	9 (6-10)	-
Practice list size *mean (range)*	10742 (3164-28827)	11,032 (3378 – 28261)	-
Education level	-	-	
School to 16, GCSE's / O levels			4
Sixth form, A level			2
Highers, Scotvec or NVQ			1
University degree			3
Professional/postgrad. degree			4

6.4.2 Main findings

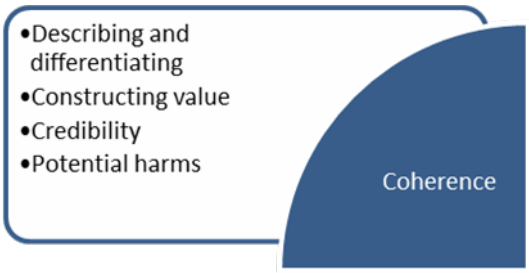
The findings detailed below allows conceptualisation of the work required by the different stakeholders (GPs, nurses, parents and children) for successful implementation of nasal balloon autoinflation into clinical practice. The 4 NPT theoretical constructs about the work required include *coherence* (sense-making work), *cognitive participation* (relational work), *collective action* (operational work) and *reflexive monitoring* (appraisal work). Figure 12 represents the main findings under each of the four constructs.

Figure 12: Main findings associated with the theoretical constructs of NPT



Construct 1: Coherence

Coherence concerns how GPs, nurses and parents make sense of the intervention. This includes differentiating from current practice, the individual and shared understanding of the intervention, and constructing value, benefit or importance of the intervention within their practice population. Four themes emerged under this construct: i) describing and differentiating from current practice, ii) constructing value, iii) credibility, and iv) potential harms. Quotations illustrating the themes of *coherence* are presented in Table 13.



1.1 Describing and differentiating from current practice

Nasal balloon autoinflation was reported by GPs as easy to describe and differentiate from current practice[1a], having a logical mode of action and similar to methods of middle ear inflation that were currently being recommended in some GP practices (e.g. Valsalva manoeuvre, mouth inflation of balloon, drinking whilst holding the nose). *Coherence* was inhibited in those who were not familiar with, or had not used the technique before[1b]. 10 of the 19 non-AIRS GPs had not heard of the Otovent™ nasal balloon prior to the GP study discussed in chapter 5 and, of the nine who were familiar with the device, only four had personally used it in their practice. Uncertainties about the nasal balloon treatment arose from concerns about how the treatment could be implemented in their practice and how it fits with the current management strategy and the local and national guidelines[1c]. GPs also raised questions about how they would access the evidence and be trained to use or demonstrate the nasal balloon.

Of the parents who took part in the qualitative interviews (dataset 2), 12 parents had children in the nasal balloon treatment group and 2 in the standard care group (watchful waiting). However, all parents had received information about the nasal

balloon as part of the study and the 2 children in the standard care group were offered autoinflation at the end of the 3 month trial period. In this analysis, parents generally described the balloon as a natural, holistic treatment, with a mode of action that was easy to understand. It was commonly described as a "*physical, practical solution*" to their child's hearing problem that was quick and simple to do, and appealing to children[1d].

1.2 Constructing value of the intervention

GPs and practice nurses described autoinflation as a low harm, low cost and easy to use intervention for primary school age children that had the potential to reduce referrals for grommet surgery[1e]. Nasal balloon autoinflation was described by GPs as able to promote self-management and enhance the watchful waiting process for families[1f]. GPs described that an active treatment option for families might help to manage parental expectations, especially when there is a high expectancy of prescription or immediate referral. However, some GPs expressed an opinion that the intervention was "*simply a distraction for anxious parents*" and an unnecessary burden of treatment for families.. Parents, however, described the nasal balloon as a '*clever idea'* which made sense as a treatment option for glue ear.

1.3 Credibility of the nasal balloon

Some healthcare professionals raised concerns about the credibility of prescribing or recommending such a treatment, with autoinflation being described as a '*gimmick'* or *'purely a placebo'* by both AIRS and non-AIRS GPs[1h]. However parents in the qualitative study did not identify problems with credibility, generally describing the treatment as acceptable, practical, holistic and fun for children[1i, 1j]. However, all parents had received detailed information about the treatment from a credible source (their GP or practice nurse) and were taking part in an ethically approved randomised controlled trial and this may have affected their perception of the nasal balloon.

1.4 Uncertainties about harms

Some parents raised concerns about the potential harms associated with inflating the nasal balloon. Parents noticed that some children went red in the face, whilst others

reported some pain, popping and clicking when using the balloon[1k]. Most GPs described the balloon as a low-harm treatment option, however some GPs described the potential for parental concerns about '*making things worse'* with increasing pressure whist inflating the balloon or an increased risk of acute ear infections or risks associated with not inflating the balloon correctly[1l]. GPs who were not familiar with the nasal balloon were concerned about the lack of available evidence of effectiveness or associated harms.

Table 13: Quotations illustrating *Coherence*

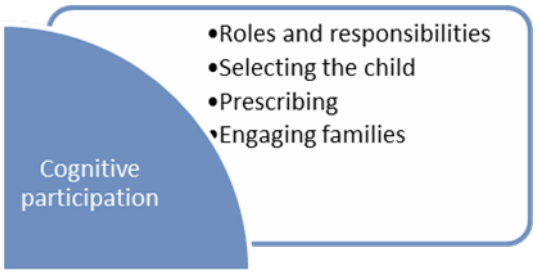
Theme	***Quotation***
1.1 Describing and differentiating	*[1a]GP1: It's easy to use, physiologically you can see how it could be helpful and it's something that's, you know, we talk about actively trying to drain or aerate the middle ear, et cetera, and you think well that's probably going to help.*
	[1b]Non-AIRS GP18: I'd never even heard of the name or never even seen any letters written from hospital, nor have I seen my colleague using it or seen in the consultation notes or find any prescription for it really, so it's completely new.
	[1c]Non-AIRS GP25: It has to be realistic and it has to be guidelines driven
	[1d]P6: it seems quite a simple procedure and quite acceptable I should imagine with children, quite a fun thing to do.
1.2 Constructing value	*[1e]N1: I think with the balloon, I would assume it's relatively inexpensive, it has to be a good process of elimination for glue ear and grommets, and I think a lot of referrals to consultants at - you know, secondary care - could be avoided by three months of trialling the balloon.*
	[1f]Non-ARIS GP31: I think it's got a lot of potential for several reasons. I think during that 'watchful waiting' period it would actually give the parents something to do so they wouldn't feel like they'd just been dismissed with nothing to do.
	[1g]Non-AIRS GP17: I think it's actually usually a self-limiting condition so I think it's an awful lot to ask someone to do on a daily basis, quite involved for a condition that will probably resolve itself anyway.

1.3 Credibility	[1h]*GP19: I think because it's such a simple intervention and perhaps it looks a bit unusual people may see it - I don't know how you'd describe it, but maybe a bit of quackery.*
	[1i]*P10: the balloon is wonderful because it's easy, it's quick and it seems to have, you know, it seems to have an impact*
	[1j]*P3: anything holistic that doesn't involve sort of medicine or drugs I think is brilliant.*
1.4 Potential harms	[1k]*P9: Sometimes I did kind of wonder thinking – you know – it puts a lot – it's what the pressure of it will be doing in your head, you know, his face would go quite red.*
	[1l]*Non-AIRS GP 18. Yes, because anything that generates pressure or releases pressure may give layman, or lay people, and indication whereby is that going to make it worse really?*

In summary, GPs and nurses reported good *coherence* for the nasal balloon intervention, however there were some reported concerns about credibility and the lack of widely available evidence about its effectiveness and potential harms. Likewise, parents also reported good *coherence* for the nasal balloon treatment, describing it as simple, practical and non-invasive treatment, potentially reducing the need for medications and invasive surgery. Parents did not recognise a potential credibility issue, and described it as an acceptable and logical treatment for their child's glue ear.

Construct 2: Cognitive participation

Cognitive participation is the engagement and commitment of GPs, nurses and parents in the implementation of the nasal balloon. This includes commitment to initiating the process, working together and 'buying in' or engaging with the nasal balloon treatment. In this analysis, four main themes were identified under the construct of *cognitive participation*: i) roles and responsibilities and ii) selecting the right child, iii) prescribing of the nasal balloon and iv) engaging families and children. Quotations illustrating the themes of *cognitive participation* are presented in Table 14..



2.1 Roles and responsibilities

GPs identified that a good demonstration would be required to ensure children mastered the technique of autoinflation and engage with the intervention. GPs described nasal balloon autoinflation as "*all about the technique*" like inhaler techniques for asthma and it was seen as important to get this right. However, whilst some GPs proposed that a personal demonstration would add credibility to the treatment and improve the technique[2a], others did not see demonstrating the balloon as their role, or considered that it would not be feasible during a routine consultation due to time constraints[2b]. Parents, however, described the importance of a good demonstration to help them understand exactly what the children needed to do.

Practice nurses described themselves as being capable of undertaking the role of patient education and patient management for OME in primary care if given the time and resources to do so[2c], and GPs generally agreed but often described nurse services as being as stretched as GP services[2d]. Parents described being satisfied with nurses providing ear care for their children and often described nurses as approachable and accessible[2e].

Some GPs suggested that pharmacists could demonstrate the balloon as part of their dispensing procedure, although there were uncertainties if they would be happy to fulfil this role[2f]. Another GP suggested a role for community audiology, rather than a nurse-lead service in primary care, which could be more effective and potentially alleviate pressure on primary care resources.

2.2 Selecting the right child

A common concern raised by GPs, especially those who did not have personal experience with the balloon, was how to select children for the nasal balloon treatment. There was a general perception that the treatment would be suitable for older children rather than the early school years where glue ear is most common, as the technique appeared to require a level of dexterity and cooperation[2g]. Nurses, however, found that children in the AIRS study were generally capable of inflating the balloon, and even some younger siblings (3 years old) were anecdotally reported as able to inflate the balloon.

GPs reported making judgments for who would be a suitable candidate for the nasal balloon based on cultural and sociodemographic factors. GPs generally perceived the nasal balloon to be suitable for *'middle class'* families, and that families of lower sociodemographic areas were considered less likely to engage with the nasal balloon due to competing commitments and responsibilities with other children. A nurse concurred with this view describing that when parents have other children to get to school, the nasal balloon treatment is not always prioritised[2h]. However, one parent from a low income, low education family with 2 young children, engaged really well with the nasal balloon treatment. The parent reported that her child managed very well, mastering the technique and remembering to inflate the balloon daily. She also described it as a '*clever idea'* and '*exciting'* for her child to try instead of '*more antibiotics'*. One GP from an urban, inner city practice reported potential language barriers which might affect uptake and cultural expectations of migrant families where parents expect early referral to secondary care[2i].

2.3 Prescribing

Some GPs were unaware that the Otovent™ nasal balloon was prescribeable. Those who did use the nasal balloon in practice either asked parents to source the nasal balloon themselves, or prescribed the balloon themselves. GPs and nurses reported that often parents preferred a prescription as prescriptions are free for children's medication[2j]. Prescribing, however, was limited if the nasal balloon was not listed on the prescribing formulary and one GP was unhappy about prescribing something without having access to enough evidence. However, another GP reported that providing a prescription would make them feel that they '*had done something'* rather than just dismissing the parental concerns and doing nothing[2k]. No parents or nurses commented about prescribing of the nasal balloon as the nasal balloons were provided as part of the AIRS randomised controlled trial[2 3].

2.4 Engaging families and children

GPs described the perceived need for a high level of parental motivation to ensure good uptake with the nasal balloon and some thought it could be a '*complete aggravation'* or *'a lot of effort'* for some families[2l]. Whilst some GPs proposed that this as a barrier to engagement, most parents in the study were happy to try the nasal balloon as part of the RCT and commit to the treatment regimen and children were generally engaged with the treatment especially in the first few weeks if it was made it fun or part of a game[2m].

Table 14: Quotations illustrating *Cognitive Participation*

Theme	***Quotation***
2.1 Roles and responsibilities	*[2a]GP12: When you look at it, it's just a load of balloons and a plastic device and they will probably think, well, what's the doctor telling me? … It might look a bit strange, but I think if you can practically show them, rather than just explaining it, then, you know, they sort of get the idea a bit better*
	[2b]GP31: I honestly think I would struggle to teach it within a busy consultation because there are often other problems being brought or other kids running round the room and I don't think I would be the best person to teach it.

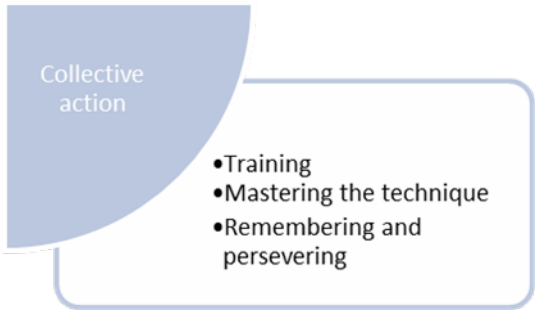
	[2c]*N17: The surgery is leading towards more nurse-lead services in the practice anyway. Nurses are very accessible to patients*
	[2d]*GP11: Gone are the days where we passed work on to the nurses because they've got more time; their appointments are massively pressurised too.*
	[2e]*P10: I suppose it just comes down to – you know – the skill set and the expertise they have, whether it's a doctor or a nurse; you know, nurses I think can be perfectly adequate in – carrying out those sorts of things.*
	[2f]*GP31: If the pharmacists are getting a prescribing charge out of this they can maybe show them and do a bit of a demo as well.*
2.2 Selecting the right child	[2g]*GP 16: you wonder what age onwards the child would be able to do that?....I would have thought a child under five might struggle*
	[2h]*N11: When you've got – you know – a mum, when you've got three children you've all got to get off to school*
	[2i]*GP 28: we are in an urban practice with lots of different migrants registered at our practice, so language is one barrier, cultural expectation is another barrier.*
2.3 Prescribing	[2j]*Non-AIRS GP 19: I know from when I've said, 'You can get this over-the-counter'. The first question that comes back is 'Can you prescribe it?'*
	[2k]*Non-AIRS GP31: They will like the fact that it's on prescription because they get to walk away with something useful. Yes and it would just make me feel like I've done something.*
2.4 Engaging families and children	[2l]*GP7: So the other barrier would be patient acceptance; do they want to take it up and they might go oh, I can't be bothered with this, sort of thing, it's too much of a faff.*
	[2m]*P5: Well, the girls thought that was great fun, anything to do with balloons isn't it? They think it's great and the gross factor of blowing it up with your nose is a real hit with the little ones. They love it*

In summary, whilst GPs regarded autoinflation technique training to be important most did not feel that it was an additional role that they could take on in clinical practice. Most considered that nurses or pharmacists could undertake this role if funding and training were available. Practice nurses from the AIRS study expressed confidence in their abilities to provide patient education and patient management but reported concerns about workload and financial considerations. GPs described the nasal balloon intervention as acceptable and achievable for most families with good training and support, although some considered that general public engagement could potentially be inhibited in certain socio-demographic groups. Parents whose children

had participated in the AIRS study, however, engaged well with the nasal balloon and found the method to be fun and acceptable to children.

Construct 3: Collective Action

Collective action is the work required by GPs, nurses and families to operationalise or enact the nasal balloon treatment, including working together, allocation of tasks, skills and training, and resources required to implement autoinflation in the primary care setting. Three themes were identified in the construct of *collective action*: i) Training to use the nasal balloon, ii) mastering the technique, and iii) remembering and persevering. Quotations illustrating *collective action* are presented in Table 15.



3.1 <u>Training parents and children to use the nasal balloon</u>

Operationalising the nasal balloon intervention requires the children and families to be trained in the use of the nasal balloon. '*Getting the technique right*' was seen as an important component to GPs with some GPs suggesting that patients can have problems with things that '*require a level of coordination*'[3a]. GPs identified that it would take time out of their normal consultation period to teach the children to use the balloon, and considered that this might complicate the consultation and not be good use of their time[3b]. Some GPs suggested that a demonstration pack (rather like an asthma inhaler demonstrator) may be useful to demonstrate the technique to families[3c].

Nurses proposed that either demonstrating the technique personally or involving the parents was an effective way of encouraging the child. Parents agreed that a good

demonstration by the nurse was really useful to understand exactly what was required and to give the child confidence to try themselves[3d].

An online video was described by all stakeholders as a potentially useful tool to support the training with the device[3e]. However, GPs described wanting it to be evidence-based, relevant to the UK population, and suitable for the NHS/primary care, rather than a '*marketing type'* video that was provided by the nasal balloon manufacturers for the AIRS study. They also felt that videos should also be supported by verbal information and instructions. Good verbal information was also described by GPs as being important to improve the self-management and compliance with the nasal balloon and this should include information about technique, directions about when not to use, and how to overcome difficulties with inflating the device. It was suggested that this could also be supplemented with good quality online information suitable for families and children.

3.2 Mastering the technique

For families, *collective action* are the practices and activities that are needed to help children master the technique of nasal balloon autoinflation and adhere to the treatment regimen over the longer treatment period.

Parents reported that some children have initial difficulties with inflating the nasal balloon, and can only get it slightly inflated to the size of a small plum in the early stages[3f]. Nurses described the importance of involving the children early in the consultation process and describing to them clearly what was required, using a good demonstration and giving lots of encouragement. Parents and nurses both reported that in most cases children mastered the technique quickly or got better over time with practice[3g].

3.3 Remembering and persevering

Treatment with the nasal balloon can typically last for 1-3 months during the recommended active monitoring period so requires an element of remembering to use and persevering with treatment. Parents reported a range of methods to help remind them and their child to use the nasal balloon. Some children were good at

remembering themselves whilst others were considered to be too young to take responsibility for the treatment[3h]. Making the nasal balloon part of their child's daily routine helped to ensure that children adhered to the treatment[3i]. Parents also reported that the use of incentives, such as sticker reward charts, improved compliance and motivated children to use the nasal balloon[3j].

However, children were described by GPs and nurses as less likely to comply if they found autoinflation difficult or uncomfortable to perform, or if they had a cold or blocked nose and often stopped treatment during those periods[3k].

The dynamics within some family groups, including single parent families and families with multiple siblings, were described by GPs and nurses as a potential for compliance problems. Single parents in the study also reported problems when children stay with the child's non-resident parent[3l], and also compliance could be a problem during the holidays when out of the normal school routine.

Most parents reported good compliance over the AIRS study period, however, the treatment did become a burden for some families if the child stopped cooperating[3m].

Table 15: Quotations illustrating *Collective Action*

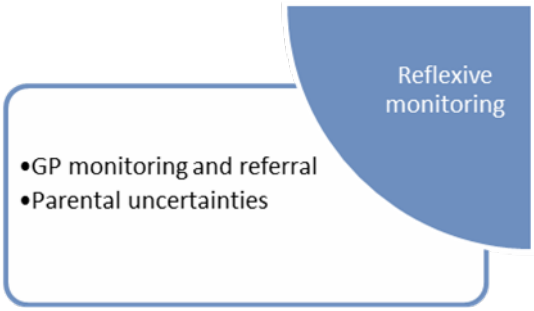
Theme	***Quotation***
3.1 Training	*[3a]GP30: Because demonstrations are always really important. It's all about technique. All these things are about technique.*
	[3b]GP13: My main concern is around the time to teach them. Who is going to teach them properly? 10 minutes is just not enough to do the regular things; this can take a good 5 – 10 minutes isn't it, to show them. I think I'm being very conservative with that estimate
	[3c]GP26: Yes, I think you'd have to show them how to do it, so I'd have a clean one in a drawer that you could demonstrate and then another one to give to the child, so you could check their technique and everything.
	[3d]P11: She [the nurse] gave us a very good demonstration; it was very clear and we understood completely what we needed to do.

	[3e]*GP5: I think it's a very visual thing and I think actually seeing a video of what it is and what it involves would be the most helpful thing.*
3.2 Mastering the technique	[3f]*N7: they would sit opposite me and we would do it. Some of them managed to cotton on quite quickly, others less so and some didn't find it very easy at all*
	[3g]*N2: even if they blew it up a bit, then we sort of said – oh that's brilliant. And then of course the next time you saw them they'd be blowing it up to the size of an orange.*
3.3 Remembering and persevering	[3h]*P11: At her age it came down to me, she'd completely forget – if left to her own devices.*
	[3i]*P3: …..just part of routine; brush your hair, brush your teeth, and we called it 'Balloon Practice.' So we would say, 'Let's do balloon practice.'*
	[3j]*P12: he was – really happy to be down here: let me mark off, let me put the sticker on – and so we never had no problems with it. In fact he was reminding me – mum, I haven't done it, I haven't done my balloon*
	[3k]*P5: It got trickier as the trial went on because she got fed up with it and she did get quite poorly a couple of times with really bad colds and blocked up nose and she just point blank refused because it hurt too much.*
	[3l]*N1: Sometimes the child would go to the other parent for the weekend because the parents were divorced or separated and then……I don't know how compliant the child was because they went to their father or vice versa.*
	[3m]*P4: So we staggered along for a few weeks with her not really trying to do it and yes it was just becoming such a pain really.*

In summary, GPs and nurses suggested that training families in the use of the nasal balloon would be enhanced with a personal demonstration of the technique which could be delivered by the GP, nurse or pharmacist and supported with an evidence-based online training video. They felt that the use of incentives and sticker reward charts had the potential to promote ownership and compliance with the nasal balloon and that making autoinflation part of the child's normal routine would be likely to improve adherence. However, some healthcare professionals expressed concerns that adherence could be affected by family circumstances and become more of a problem in the longer term.

Construct 4: *Reflexive monitoring*

Reflexive monitoring concerns how GPs appraise the intervention. This includes determining its effectiveness in the primary care population, by collecting information and evidence, individually and collectively evaluating the intervention and modifying practice as a result of the intervention. *Reflexive monitoring* also concerns how parents determine how long to continue treatment and when to seek further advice. Two themes were identified in the construct of *collective action*: i) GP monitoring and referral, and ii) parental uncertainties. Quotations illustrating *reflexive monitoring* are presented in Table 16.



4.1 GP monitoring and referral

GPs reported that they would appraise the effectiveness of the nasal balloon by a combination of reviewing published evidence, checking fit with local guidelines, and anecdotal evidence from their own clinical experience[4a]. Both AIRS and non-AIRS GPs reported positive experiences of using the nasal balloon in their patient population[4b]. However, for GPs who had not come across the balloon beforehand, appraisal would involve trying the treatment in practice and building up their own experience[4c]. Most GPs described the nasal balloon as low harm, or a '*low risk strategy*', however, sustainability of the intervention would be limited if the nasal balloon was seen to be ineffective[4d]. The fit with local and national guidelines for treating children with glue ear in primary care was described as important for wider implementation and sustainability[4e], and local support from ENT specialists was described as likely to facilitate local acceptance and uptake[4f].

4.2 Parental uncertainties

Parents reported being uncertain about the technique of nasal balloon autoinflation. Questions were raised concerning '*getting the technique wrong'* and how big to inflate the balloon for it to be effective? [4g]

Additionally, some parents were unsure about the length of treatment needed to be effective, whether it was a short or long term treatment, and how quickly they should expect to see results. Parents reported uncertainties about recognising if the treatment was working and when to return to the GP for further advice[4h].

Table 16: Quotations illustrating *Reflexive Monitoring*

Theme	***Quotation***
4.1 GP monitoring and referral	[4a]GP8: I guess seeing something which presented the evidence for it and that it worked and that it was cost-effective and that our formulary were supporting the prescription of it, I guess that's the other big thing.
	[4b]GP6: And certainly it's anecdotal that several mums have come in and said that it's been, not only effective, but dramatically effective and that's really nice to hear.
	[4c]GP31: From what I've seen so far I'd be happy just to have a crack at it and then build up my own little anecdotal group and get people's feedback to see how it's going, just because it seems like a low risk strategy. It's not like prescribing a brand new drug that nobody has ever tried.
	[4d]GP19: I think if it didn't seem to, you know if the vast majority were coming back with it not making any difference it would probably fall out of favour for me to be honest.
	[4e]GP25: I tend to go through guidelines rather than new evidence, to be honest with you. Simply because even though there's evidence out there, and then you start prescribing things according to evidence, and then you end up prescribing red and black listed devices or drugs and then you have to go back and go, 'Actually you can't use it anymore because it's against local guidelines.'

	[4f]*GP18: If you were to bring it out and implement locally I think it will probably give GPs more confidence if it's, at least, being endorsed locally by the consultant at the hospital really, if they are aware of their waiting list, if they will say right, you can consider trying the device in the meantime which may improve outcome and reduce surgical rates, then that will give confidence in the GP to use it really.*
4.2 Parental uncertainties	[4g]*P8: I always thought you had to blow it up completely. But she said as long as - which I didn't know, she said as long as you can blow it to I think it was a nut size and then an apple size and she said as long as you can blow it to a certain size, it will benefit him*
	[4h] *P7: Well, this is clearly not a short-term remedy it seems but is it medium to long-term? That wasn't made clear to me. So how long do you persist with this before you think okay, I need to take it to the next level? That isn't clear to me.*

In summary, GPs described that they would appraise the nasal balloon using available evidence and clinical experience of using the treatment in practice, although this would be inhibited if patients did not return for assessment. Sustained use within the practice would rely on a good fit with national and local guidelines for glue ear, and a positive response from families. For parents and children, *reflexive monitoring* may be inhibited due to parents being unsure about how long to continue treatment for, how to know if it is working and knowing when not use the nasal balloon.

6.5 Discussion

6.5.1 Summary of main findings

This study used secondary analysis of qualitative interview data, guided by NPT, to identify the promoting and inhibiting factors to implementation of nasal balloon autoinflation in the primary care setting. Parents from the AIRS study found the treatment to be acceptable and fun for children and were generally motivated to try a non-surgical treatment. GPs and nurses described the treatment as low harm, low cost and feasible in the primary care setting (*promoting factors*) although they thought it may be a potential burden for some families. However, the treatment is not widely known or used currently, and GPs considered that it may complicate the consultation

process which might limit engagement with the intervention. GPs also described difficulties appraising the intervention, and parents were uncertain about how to know if the treatment is working and how long to continue for (*inhibiting factors*).

6.5.2 Comparison to existing literature

Nasal balloon autoinflation is, at the time of writing, surprisingly still a relatively unknown treatment option in primary care with no published qualitative studies other than the nested qualitative study in the AIRS trial[3]. Both parents and healthcare professionals in this secondary analysis, much of which was gathered from participants of the AIRS study, viewed it as both an acceptable and worthwhile treatment. A shared understanding between stakeholders about the value of the nasal balloon is crucially important as divergent views may continue to cause a significant detrimental effect on the likelihood of successful implementation. However, a tension often exists between doctor's beliefs about suitability of treatment and what patient's themselves believe. In our study GPs thought that some families would find nasal balloon treatment a burden, however, parents who participated in this research did not identify this as a barrier. The included parents, however, were a cohort from the AIRS study and it could therefore be argued that they were already motivated parents who had taken part in a clinical trial and may have had a positive experience of using the nasal balloon in the trial setting. Parents whose children had not previously used the nasal balloon may have expressed different views, and therefore may have provided a differing perspective.

The key to mastering the technique of autoinflation necessarily relies on good instruction and demonstration. Previous studies have reported that children aged 4 years and above are generally able to master the technique[3 79] and children as young as 3 years can manage the technique with some instruction and encouragement[94]. In the AIRS trial[2 3] parents and children were taught the technique by the research nurse and supported by an instruction video provided by the nasal balloon manufacturer to view at home[3]. Similarly, instruction videos to teach children with asthma found that their inhaler technique improved when a video was used to back up the consultation[173]. An evidence-based video for demonstrating the nasal balloon has the

potential to reinforce the information provided by the healthcare professional and potentially reduce the ongoing burden to the consultation process. The current video, provided by the manufacturers, is 8 minutes in length making it too long to engage children and families. It also contains limited instruction for preparation of the balloon prior to inflation and is set in a hospital setting and thus less relevant for wider use in primary care.

The evidence-based treatment regimen involves nasally inflating the balloon three times a day for 1-3 months. After the child has mastered the initial technique there is the problem with longer term compliance, and this depends on the extent to which families are engaged in the process, their motivations for continuing the guidance they have been given and being able to monitor their child's progress. The self-regulatory model[174], or common sense model, was proposed by Leventhal to explain illness-related behaviour in chronic illness. This model theorises that illness perceptions determine treatment adherence[174 175]. However, Horne and Weinman[176] proposed that as well as illness perceptions, the patient beliefs about treatment also affect adherence to the treatment schedule, including beliefs about the value of the treatment and concerns about potential harms. Parental perceptions of the nature, severity and impact of glue ear together with their perception of the nasal balloon have the potential to affect longer term compliance. A study of factors affecting the prospective use of asthma inhalers found that illness perceptions and treatment beliefs were stronger independent predictors of inhaler use than clinical and socio-demographic factors[176]. Continuation of a behaviour has been found to be influenced by whether the intervention is seen to have worked.[176] With the nasal balloon it is difficult to determine if the treatment is working as it relies on subjective assessments by the families and teachers. Sustained usage of the nasal balloon may therefore be affected due to an apparent inability to appraise the intervention, both individually by the parents and by health professionals within the GP practice, as this study shows. The TADAST hearing disability test[177] was designed in primary care as an objective measure of impact of hearing loss associated with OME and has the potential to help parents monitor their child's condition during the 3 month recommended monitoring period (see chapter 7).

6.5.3 Strengths and limitations

A key strength of this study was the use of NPT to guide the secondary analysis resulting in a better understanding of the individual and collaborative work required to implement nasal balloon in general practice, and from the view of the different stakeholders. It facilitated the triangulation of emergent results and the identification of tensions between the different stakeholder perspectives.

However, it is recognised that the sample of participants were from only two primary datasets, and that most participants had been part of the AIRS study[2 3]. GPs and nurses were from research active practices and were familiar with the results of the AIRS study prior to participation, which may have affected their responses. Parent participants had children who participated in the AIRS study which may have influenced their expressed views and experiences of the nasal balloon treatment. Thus, limited conclusions can be drawn regarding the transferability of the results of the secondary analysis. However, the qualitative research paradigm aims to gain a rich understanding from the viewpoint of the participants rather than to ascertain the truth. The ontological position of this research was one of critical realism[135], where reality can only be known from the participants perspective and subjected to critical reasoning. In this study the perspectives of the different stakeholders were reviewed and critically examined, and have provided an insight into the different and shared views and experiences of the nasal balloon.

A limitation often cited for secondary analysis is the researcher distance from the data itself. In qualitative research, the researcher is the research instrument[148 169] bringing their own perspectives to the data collection and analysis which is often lost in a secondary analysis. However, in this study I was the primary and secondary data analyst and was therefore intimate with the primary data itself. Furthermore, I was also AIRS study manager which meant that I was intimate with the study itself but recognise that my relationship with the research nurses and AIRS GPs may have influenced the interviews and consequently the research findings.

Previous research has gathered views and experiences of other stakeholders, including parents and practice nurses[3], but it would also be of interest to gather information

from parents not involved in the AIRS study, paediatric audiology who are on the referral pathway for many families, and pharmacists who may have a role in dispensing and demonstrating the nasal balloon. Including other informants in the study would have allowed further data triangulation (multiple sources) and to be able to look at further interactions within the primary care setting.

6.5.4 Future considerations

The study has identified areas that might promote or inhibit wider implementation of the nasal balloon method. This section describes proposed strategies to address the relevant factors.

Firstly, strategies to promote *coherence* (sense-making work) for GPs and nurses could include a programme of wider dissemination of the AIRS study[2] results, an update to the Cochrane Review of Autoinflation for hearing loss associated with OME[60] and update to the NICE guidelines for Surgical Management of OME[35]. Since this study was completed, NICE have conducted a technologies assessment of the Otovent™ nasal balloon(2016)[61] and recommended autoflation as a treatment during the watchful waiting period. This should increase *coherence* in the use of nasal balloons for OME for GPs as NICE is a legitimate and respected source of guidance. Promoting *coherence* for parents could include the provision of evidence based, online information to support verbal information given in practice, with better signposting to available NHS resources.

Strategies to promote *cognitive participation* (engagement) could include resources to ensure parents have a better understanding of glue ear and the treatment choices available to them using assessable formats and appropriate language. Self-management is a vitally important aspect, giving parents the tools to identify and monitor their child's symptoms with help and advice about how to help their child hear better both in the social environment and in the classroom. Strategies to promote engagement of primary care health professionals include ensuring that GP surgeries have the tools and resources, with appropriately trained staff, to prescribe and support the uptake of the nasal balloon.

Collective action, or working together to use the nasal balloon would be enhanced for all stakeholders with a training video with an accessible format and step-by-step instructions with greater use of diagrams to ensure families and children know exactly what is required of them. This has the potential to reduce overall burden on the GP consultation.

Strategies to promote *reflexive monitoring* include symptom checklists and diaries to help parents monitor hearing-related symptoms, a newly formatted and evaluated hearing disability test (wTADAST-24) to assist with the monitoring period and easier signposting for parents about what to do if their child doesn't improve over the monitoring period.

6.5.5 Personal reflections

A question remains for me is whether a secondary analysis of qualitative data identified any additional information compared to the two primary studies and whether the Normalization Process Theory was useful in structuring the analysis. As I expected, there was some overlap between the primary and secondary analyses, with similar ideas emerging around differentiating and describing the nasal balloon, and requirements for operationalising the intervention in general practice. However, the secondary analysis highlighted new potential factors that might inhibit the engagement of all the stakeholders in the proposed treatment regimen including differences in views between what GPs think about the suitability of treatment and what parents are actually happy to try. The most prominent issue that emerged from the secondary analysis was associated with *reflexive monitoring* – how is treatment for glue ear sustained over a period of time and how do parents and GPs know if it is working? These identified factors need to be addressed to promote wider implementation of the nasal balloon method in the NHS. Using NPT to structure the analysis provided an interesting dimension and allowed me to look at the data from a different perspective. However, it did take considerable time to familiarise myself with the constructs and components of NPT and to consequently code the data. It was a challenge to code certain data extracts which might have fitted more than one construct, however, I decided that it was more important that an issue was

highlighted, rather than to which construct it was coded to. Using NPT facilitated a thorough interrogation of the data and I felt that I was fully immersed in the interview transcripts. It also allowed me to view the data through a 'lens' of implementation and I feel that the exercise was extremely valuable to identify the potential challenges for future implementation and facilitate the design of an online educational intervention.

6.6 Conclusion

Successful implementation of nasal balloon autoinflation in primary care requires addressing several identified factors thought to promote or inhibit wider implementation, both for the healthcare professionals and the families. These include i) providing good quality information to supplement information provided during the consultation to facilitate better engagement of families with the treatment plan, ii) high quality videos to supplement training with the nasal balloon minimising the burden on the GP consultation process, and iii) providing support to families over a longer period with methods to assess if the treatment is working and when to seek further advice. These aspects are important to families and have the potential to enhance effective use of the nasal balloon.

NPT proved useful in conceptualising the many issues around the implementation of nasal balloon autoinflation in the context of primary care, and is used to guide the development of a web-based educational intervention to promote self-management and ultimately achieve better NHS care for children and families impacted by OME.

Chapter 7: Further development and evaluation of a hearing disability test (TADAST)

7.1 Introduction

Successful implementation of nasal balloon autoinflation in primary care requires addressing several identified factors to promote implementation including a better structured active monitoring period and tools to monitor for improvement. Qualitative work presented in chapters 5 and 6 identified that monitoring is often undertaken by the parents at home, rather than by the general practitioner, with decisions to re-consult and seek further advice being, for the most part, delegated to the families. However, parents are often unclear about how to recognise if their child's condition is improving, and when further advice from a healthcare professional is really necessary. GPs also face the challenge of identifying which children can be managed appropriately in primary care and which children require expedited referral for further investigation and surgery. A hearing disability test (the Two Alternative Auditory Disability and Speech Recognition Test - TADAST) was first developed in primary care 20 years ago, and was used more recently within the AIRS study[2] as an outcome measure. The pilot web version of the test at the time of the AIRS study came into question due to reported poor reliability and consequently it was not available for use until towards the end of the study. The qualitative work presented in chapter 5 found that GPs thought an accessible online hearing disability test could improve self-monitoring for families and reduce the pressure on NHS services.

This chapter presents the necessary further development and evaluation of a shorter, updated TADAST hearing disability test in a new web format. The aim of this development is to improve web-reliability and usability to families and children in the primary care and community setting.

7.2 Background

Hearing impairment and hearing disability are different concepts. Impairment, as described by the WHO, is concerned with *abnormities of structure and organ/system function as a result of disease*[178] whereas disability reflects the *consequences of impairment in terms of functional performance and activity* of the individual. Pure tone audiometry (PTA), as described in chapter 2, is a measure of hearing impairment, i.e. the hearing threshold at which an individual can hear. However it is not a measure of the impact of hearing loss in everyday situations and on quality of life. Whilst impairment and disability are related, the relationship is subtle and complex, and there are considerable variations in impact or consequences of a hearing impairment, which can be due to both individual and societal factors. For example, a child with moderate hearing impairment may experience minimal disability with the correct hearing aids, whilst another child with similar impairment might experience much greater disability in a noisy classroom without hearing aids and being unable to lip-read or see the teacher. Screening and diagnosis of hearing loss in children currently relies mostly on objective measures of hearing including PTA and tympanometry. There are few measures of hearing disability that are applicable to the paediatric population in primary care and that carry a degree of objectivity.

7.2.1 Testing for hearing disability

Testing for hearing disability differs from testing for hearing impairment in as much as it aims to test for the consequences of impairment i.e. the functional performance and activity of the individual. There are two main types of testing that cover hearing disability; i) quality of life (QOL) questionnaires and ii) speech perception tests, both of which are discussed in the following section:

7.2.1.1 Quality of life questionnaires

There are only a limited number of published quality of life assessment tools for children with chronic health conditions and even fewer that have been designed for measuring impact of paediatric hearing loss. One of the first paediatric hearing QOL measures, the HEAR-QL questionnaire,[179] was developed at the Washington University

School of Medicine with adolescents with hearing loss. This test was designed to help identify challenges faced by this group of young people and to help evaluate interventions such as hearing aids and cochlear implants. As a child-reported measure however, it is not suitable or appropriate for young school children with hearing loss associated with glue ear which is most common in children under the age 7 years.

The OM8-30 (further refined to the OMQ-14) is an ear-related quality of life measure, developed within two large studies of OME in the UK[85 86] and validated using data sets from a large European study.[87] It is a functional health status measure completed by the parent (proxy measure) which is more appropriate for the younger child. The OM8-30 measures 3 main domains: i) reported hearing difficulties and speech concerns, ii) behaviour and developmental impact; and iii) ear-related physical ill health. This parent reported outcome measure (PROM) can be used at first consultation to determine the level of impact and consequently the need for treatment, and at follow up to assess the outcome of treatment or any natural resolution. However to date it has only been used in research studies and audits as an outcome measure and not yet available for clinical use due to its complex, weighted scoring system requiring calculations to obtain test scores.

7.2.1.2 **Speech-in-noise tests**

Speech-in-noise tests involve the ability to understand and discriminate speech in background noise. The first speech-in-noise tests were developed to assess hearing loss in adults. Early work was conducted by Kalikow[180] and Plomp & Mimpen[181] who developed the first sentence-in-noise tests which provided the foundation for numerous other tests in multiple languages and many different formats. The Pediatric Speech Intelligibility test was developed by Jerger and Jerger[182 183] in 1980-82 and comprised a test of 20 single syllable words and a 10-sentence procedure. The child is instructed to point to one of five pictures corresponding to the sentence or word that has been heard. The test can be conducted in the quiet or in background noise, representing a naturalistic environment. Further speech in noise tests have been developed: the Two Alternative Auditory Disability and Speech Recognition Test (TADAST)[177] test was developed at the University of Southampton in the early 1990s,

and this work was used to further develop a test in other languages, including the Galker-test (in Danish)[184] and the Wuerzburg Speech perception in noise test (in German).[185] The TADAST test (in English) is discussed in the following section and has been further developed and updated for use in this research project.

7.2.2 Two Alternative Auditory Disability and Speech Recognition Test (TADAST)

7.2.2.1 Development of the TADAST

The TADAST[177] was developed in general practice as a potential near patient test to inform parents, general practitioners and teachers of a child's hearing disability particularly in the normal learning environment. It was initially designed to complement existing evaluations and give a reliable test measure of hearing disability. The test has an audio-visual format and takes about 5 minutes to complete with 5 minutes of introduction sequence to enable self-completion. During the test, children identify the best picture of the word spoken by a presenter. Two pictures representing phonemic contrasts e.g. "rose" and "nose" appear at the bottom of the screen for the child to point to. The test relies on a built-in signal to noise ratio of 4dB (background white noise provided at 61dB and spoken test at 65dB), lessening the need for full soundproof conditions. Nearly all hearing tests in primary care are invalidated by high background noise,[33 186] so the ratio of sound signal strength to background noise strength built into the TADAST is crucial to its validity as a pragmatic community test and reflects usual signal to noise ratios in infant school classrooms[187].

The test has undergone a number of developmental phases (see Table 17). Initially a list of 160 word pairs was compiled from children's books and other speech perception tests, taking into consideration the vocabulary of 4-8 year old children. The word pairs were words that differed by one phoneme. Pictures were drawn to illustrate the words and then tested for recognition[177]. A pilot study with 40 children was undertaken and reduced the test to the 80 word pairs most discriminating between children with and without OME (as determined by tympanometry)[177]. The test was

then refined further to the 50 most discriminatory word pairs which were used in subsequent tests (TADAST-50).

Table 17: Developmental stages of the TADAST hearing disability test

Version	*Format*	*Reference/Paper*	*Description*
TADAST-50 (VHS format)	50 items (all audio-visual)	Sheridan and Williamson 1994[177]	Defined the TADAST test characteristics in a range of normal 5-8 year old school-children, and in a group of children with bilateral OME.
		Riley 1996[188]	Compared TADAST with the McCormick Automated Toy Discrimination Test to assess hearing disability in 5-8 year olds.
TADAST-36 (VHS format)	36 items 12 audio 12 visual 12 audio-visual	Worseley 1996[189]	Adapted TADAST to combine audio-visual, audio only and visual only modalities. Tested in a normative population of children aged 3-8 years
		Wyllie 1996[190]	Pilot study to assess hearing disability in children awaiting grommet surgery
wTADAST-36 (web format)	36 items 12 audio 12 visual 12 audio-visual	Beckett 2010[191]	TADAST adapted for online use for use in the AIRS study[3]using same word pairs as the TADAST-36. Pilot study to test performance, validity and feasibility in a normal population of 4-11 year olds.
		Williamson 2015 (AIRS)[3]	Outcome measure for autoinflation randomised trial in 4-11year old children with unilateral or bilateral OME.
wTADAST-24 (web format)	24 8 audio 8 visual 8 audio-visual	Vennik 2016 (current project)	Further refining and development of the TADAST for current technology, and a reduced number of word pairs to make the test more engaging, reliable and acceptable to families, whilst retaining face-validity.

The early test was conducted using a VHS video recorder and 21-23 inch TV with the child sitting 5ft away from the screen. Following a practice session, children listened to the words and pointed to the picture of the word on the screen and the researcher recorded the child's answer. The results of the pilot study demonstrated a significant difference between scores in children with OME compared to the control group (mean score (SD) 38.1 (3.2) for OME group compared to 42.6 (2.4) in control group, P=0.004 for 6 year olds).[177]

In a study by Riley[188] in 1996, the TADAST-50 was compared with the Automated McCormick Toy Test (ATT)[33] to assess hearing impairment in 5-8 year old children. Hearing impairment was assessed by audiometry and a (non-validated) hearing disability questionnaire. Results of the study showed no significant correlation between the TADAST-50 and the ATT. The ATT was significantly correlated with audiometry (best ear average) and the disability questionnaire score but the TADAST-50 was not correlated with either audiometry or the disability questionnaire. However, at the 10% significance level, the TADAST was correlated with parent-reported difficulties, vocabulary level, occurrence of first episode of OME and presence of OME. The results of the study are interpreted with much caution due to the very small participant numbers (n=20), and that there is no gold standard for auditory disability.

The TADAST-50 presented words in an audio-visual format only. However, the visual component of speech perception is also important in assessing hearing disability. The test was consequently adapted to combine audio-visual, audio and visual modalities (TADAST-36) to allow better diagnostic discrimination and comprised of 3 lists of 12 words, removing floor/ceiling effects and word pairs/pictures that were ambiguous to children.[189] A pilot study of 60 children aged 3-8 years studied the TADAST-36 in a normative population of children (with normal hearing and no history of OME[189]). The results showed that children scored most highly in the audio-visual group, and the least well in the visual only group. No gender differences were noted, but mean scores were significantly higher in older children (6-8 year olds) than younger children (3-5 year olds).

The TADAST-36 was then used in a pilot study to assess hearing disability in children with OME awaiting grommet surgery[190] (25 children with OME and 11 controls). No significant difference in total score or audio-visual score between the 2 groups was found, which reflected a significant ceiling effect in the test materials. However, the OME group had significantly lower audio-only scores (where children could not use lip-reading cues) suggesting a hearing disability which might not be picked by audiometry alone. Additionally, no difference in visual only scores (lip-reading scores) were noted

between the children with OME and the control group. There is little research about lip-reading abilities in this age group. It has, nevertheless, been established that adults with pre-lingual hearing loss are better lip-readers than those with normal hearing[192], and more recent research has found that children aged 7-15 years with hearing loss have better lip-reading abilities than those with normal hearing[193]. However, little is yet known about lip-reading abilities in younger children or the effect of intermittent hearing loss, such as when as child has OME, on a lip-reading ability.

A further development of the TADAST-36 took place in 2010 to make the test available online for use in the AIRS study (wTADAST-36). The study evaluated performance, validity and feasibility of the wTADAST-36 in a normal population of 4-11 year old children.[191] Fifty three children took the test on 2 occasions (1 week apart) in a supervised setting with the researcher, and in the home setting, in random order. Results showed poor levels of agreement between the test scores in the 2 settings suggesting the test in its current format could not be reliably used unsupervised by a researcher. However, numbers were again small and no repeatability testing was undertaken in the same test settings.

7.2.2.2 **Correlation with other measures of hearing disability/impairment:**

During its development, the TADAST has been assessed against objective measures of hearing impairment/OME (audiometry/tympanometry) and subjective measures (teacher and parent reported concerns, disability questionnaires). Williamson and Sheridan[177] found a significant correlation between the TADAST-50 and hearing threshold as measured by audiometry in 6-7 year old children (Spearman's rank correlation 0.60, $p>0.001$) but much lower and non-significant correlation in 5-year olds. However, Wyllie[190] found no significant correlation between TADAST-36 scores and PTA in a pilot study of children with OME. It is very likely that PTA and TADAST are measuring different domains of hearing. Audiometry measures levels of hearing impairment but cannot measure how children function in a naturalistic situation where cognitive and other mechanisms may affect the impact of hearing loss, e.g. social environment, communication skills etc. TADAST is potentially a better measure of

hearing disability, especially in the younger age group where audiometry is known to be less reliable.

In one study of the TADAST-50 in a cohort of 138 children aged 5-6 years, teachers were asked to identify which children they considered to have a hearing disability. The study found that the teacher-selected group for likely hearing disability had significantly lower TADAST-50 scores than the non-selected group.[187] A Danish cohort of 182 children aged 4-5 years, also found a significant but moderate relationship between the Danish TADAST-50 score and the parents and nursery nurse expectations of hearing problems, language problems and history of ear-related problems [187]. These correlations afford some important construct validity for the TADAST test.

A pilot study in 50 school children aged 4-11 years compared the wTADAST-36 [191] with OM8-30 scores (Medical Research Council (MRC) measure of parent-reported ear-related disability[86 194]). The study found a moderate, but significant correlation (Spearman's rank correlation, r=0.38, p=0.004) between the two measures, which increased when comparing sub-scores of the 2 tests. Some correlation would be expected between the two measures as they are both measuring audio-visual disability, but the OM8-30 is a parent/carer reported measure, whilst the TADAST is a functional test of the child and therefore measuring impact in a less subjective way. The wTADAST-36 may in fact have more face-validity and be a more naturalistic measure of function hearing ability than the OM8-30. The question remains about which measure is likely to be most accurate? Both parent-reported measures and functional testing of children appear to have a distinct place in identifying hearing disability.

7.2.2.3 **Repeatability**

Repeatability of the TADAST has been tested in early versions of the test. Significant correlation of the TADAST-50 total score over 4 weeks was reported in a sub-group of 10 children with normal hearing levels (r=0.77, p=0.01)[177] suggesting that the test has good level of test-retest reliability.

7.2.2.4 Summary

In summary there is no ideal validation for such auditory disability tests. Pure tone audiometry measures hearing loss rather than disability and while this is a useful and objective measure, it does not reflect the impact of hearing loss for children in their everyday settings. Reported measures, such as questionnaires, can assess hearing related health and quality of life, but are subject to reporting biases. The TADAST shows some correlation with teacher and/or parent assessment of hearing disability, and with actual OME status and hearing level, although correlation is overall moderate and sample sizes to date are small.

Further revision of the TADAST is desirable to provide a more accessible updated format, and that could potentially inform parents, teachers, school nurses and GPs of the child's holistic functional hearing disability in a simulated noisy classroom environment. As part of an active monitoring process the TADAST could clarify children most at risk of the condition of OME thus requiring early onward referral (often a difficult decision for school nurses, health visitors and GPs).

7.3 Aims and objectives

The aim of this study was to further develop this simple, accessible test with a new web format which is more stable and useable on current technology.

Objectives:

i) To update the wTADAST-36 with new visuals and graphics and reduce the number of discriminating word pairs (if possible) to improve acceptability and practicality, and allow ready use in the home/school environment (wTADAST-24).

ii) To test the reliability and usability of the wTADAST-24 in a cohort of young school children.

iii) To test the validity of the wTADAST-24 by assessing correlation with wTADAST-36 and with parent/teacher-reported concerns of hearing impairment.

7.4 Further development of the TADAST

Improving and updating of the TADAST test involved the following steps i) reducing the number of word/picture pairs to reduce test duration and improve discriminatory ability of the test ii) updating the images to improve picture recognition, iii) re-filming of the videos to have contemporary face validity and iv) developing a novel website to improve accessibility and reliability.

i) Reducing the number of word/picture pairs

Test duration is important in children's tests to retain test engagement and to reduce the likelihood of test fatigue. The TADAST has been continually modified and refined during its development (see Table 18) and previous refinements have reduced the number of test items, to improve discriminatory ability and reduce testing time. The discriminatory ability of tests can be improved by removing items that either always cause errors (floor effects) or never cause errors (ceiling effects). Previous studies of the TADAST[188] [177] found that certain word/picture pairs were often identified incorrectly (floor effects), whilst other pairs were always often identified (ceiling effects). The word/picture pairs that were previously identified in the Riley study[188] as least discriminatory are presented in appendix D. The final test items that were both included and removed from the wTADAST-36 to form the wTADAST-24 are presented in Table 18.

Table 18: wTADAST-24 final word/picture pairs

Audio only	***Visual only***	***Audio-visual***
Pen/Pig	Pond/wand	Boot/fruit
Pig/pin	Moon/spoon	Nose/Rose
Car/star	Tie/pie	Bin/pin
boot/boat	Bed/bell	Shell/bell
Sea/key	Arm/farm	Mouse/house
Bell/bull	Log/dog	Rat/bat
Ball/bowl	Socks/Clocks	Money/monkey
Pea/bee	Plug/plum	Birds/beads

Removed audio pairs	***Removed visual pairs***	***Removed audio-visual pairs***
Goat/Coat	Thin/pin	Man/fan
Chop/Shop	Queen/green	Two/tea
Ship/Shop	Dog/dig	Fountain/mountain
Comb/Coat	Pin/Pan	Well/wall

ii) Redrawing the pictures

New digital vector images were required for the wTADAST-24 as the original images were of poor digital quality and therefore unsuitable. In addition some images were unsuitable because they were not recognised by contemporary audiences (e.g. nappy pin) and required updating. New images, based on the original validated images, were drawn by myself and a graphics student and an example is presented in Figure 13.

Figure 13: Example of redrawing of 'boot' for the wTADAST-24

wTADAST-36

wTADAST-24

There were 45 images in total (some images were used for the practice test, whilst other words were repeated in the wTADAST-24 e.g. bell/bull and bell/bed). The new images were then checked with 5 children (aged 4-7 years) for word-picture association. Seven images were not identified correctly by 3 or more of the 5 children (*pin, boot, rose, farm, bull, money, beads*) and were consequently re-drawn, retested and included in the wTADAST-24.

iii) Filming of the wTADAST-24

The wTADAST-24 was filmed by Eyewitness Productions Ltd, Southampton under my personal direction. A new presenter was selected through personal contact. The presenter was a female native English speaker and was instructed to speak as if addressing primary school children. As the presenter can have an effect on test

outcomes[195] a female rather than a male presenter was chosen to be consistent with the original test. Recording took place in a recording studio using appropriate lighting and a microphone. Background speech-shaped white noise (61dB) was added retrospectively as for the original test. Whilst multi-babble background noise instead of white noise might improve face-validity of the test, it was considered to add too much variability to the test and had potential to affect the results[196]. Using speech-shaped white noise was also consistent with the original test.

iv) Development of the wTADAST-24 website

A new, interactive website was developed by David Pepper, iSolutions, University of Southampton in 2014 following extensive discussions and refinements. The new test retains the original format, but usefully includes a section for anonymously collecting demographic data and a results section to feed back to parents and children at the end of the test. The wTADAST-24 is hosted on the University of Southampton web platform at www.hearingtest.soton.ac.uk and is accessed using a unique login number (*the test can be accessed using the following log in number: TST999*).

7.5 Final format of the wTADAST-24

The wTADAST-24 test site includes the following 5 steps. Full details of the word/picture pairs and screen-shots of the test are presented in appendix D

Step 1: Setting the volume on the test computer or device.

The first step is to set the volume on the test device. There is an option to play a sample of the presenter's speaking voice and parents are asked to set the volume of their computer or device to normal speaking levels. Whilst this appears quite subjective, the inbuilt signal to noise ratio of the wTADAST-24 means that the computer or device volume is not absolutely critical to the performance of test, as increasing or decreasing the test sound (presenters voice) automatically increases or decreases the background noise with the same ratio. The test can be taken using speakers or headphones.

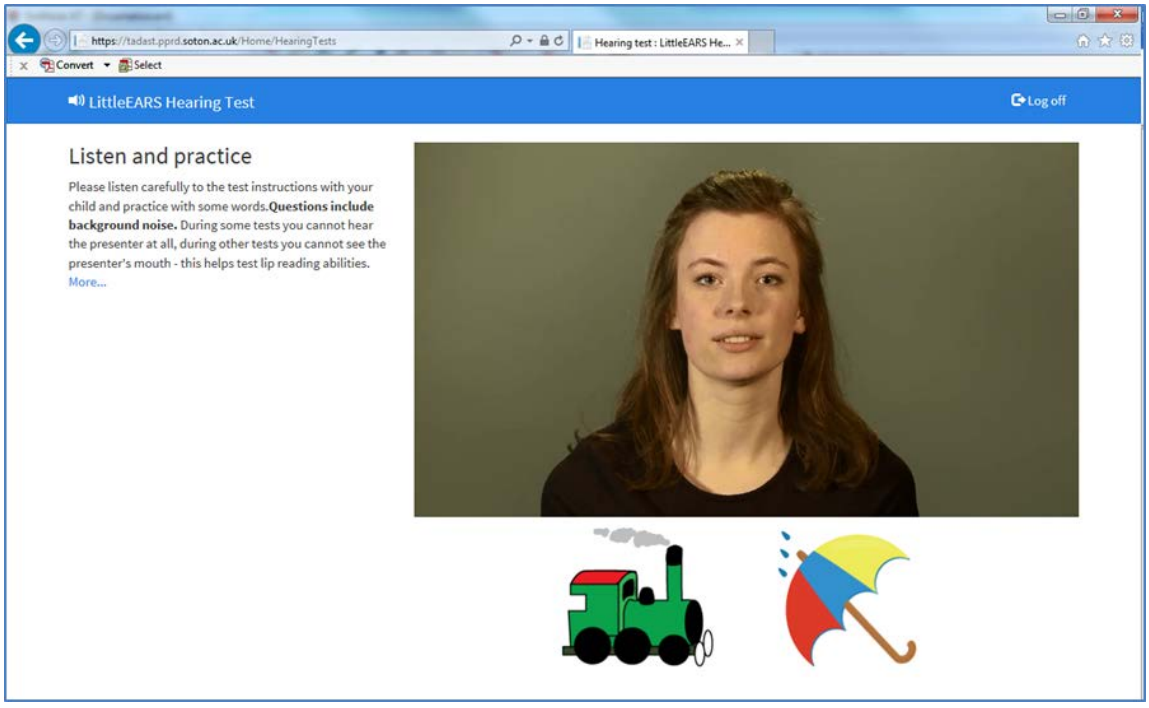
Step 2: Collecting information about the child and hearing symptoms

Information is then asked about a child's age, gender, history of ear related symptoms, concerns and visits to the GP. This was built in to the test with the future potential of using this information in combination with the wTADAST-24 score for giving an overall risk of hearing disability.

Step 3: Practising the test

Prior to taking the actual test children are given 4 sets of word/picture pairs as a practice. The integrated background noise is introduced during the practice session so children are not surprised by the sound during the actual test (Figure 14).

Figure 14: wTADAST-24 – computer screen shot



Step 4: Taking the test

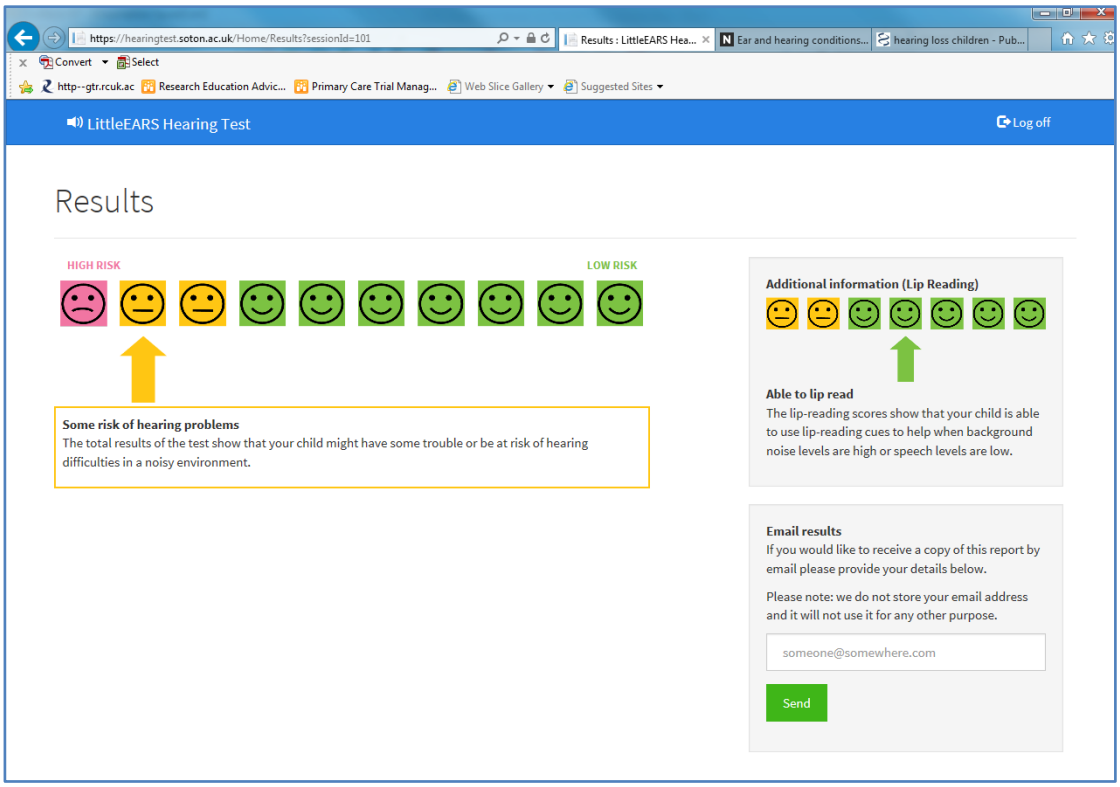
After practicing, children are directed to the main test. The presenter speaks a series of words and children need to select the best pictures for the word. Words are not repeated and the website prompts the child to make a selection (or their best guess) before moving on to the next question. The main difference with the wTADAST-24 compared to the previous version is that children have to select the next button to go

to the next test question. The wTADAST-36 automatically jumps to the next question and this means that questions are easily missed, not heard if the child is distracted or skipped over.

Step 5: Results of the test

After completing the 24 questions, results are presented on the screen for total score using colour-coding to identify risk of hearing disability: **low risk** (green), **some risk** (yellow), **high risk** (pink). (Figure 15)

Figure 15: Results page of wTADAST-24



Additionally, lip-reading scores (visual-only scores) are presented giving an indication to parents as to whether the child uses lip-reading cues for speech perception. Children who are unable to lip-read may be at higher risk of hearing disability.

Included in the test is the option of receiving the test results by email (the email addresses are not stored on the website, retaining anonymity).

When the website was available I arranged for in-house usability testing on different devices (personal computer, laptop, iPad, android tablet, Mac book) and using

different web browsers (Chrome, Firefox, Internet Explorer, Safari). Eleven independent testers (6 adults and 5 children with their parents), who were identified by email to colleagues within Primary Care and Population Sciences, took part and provided me with their written/oral feedback about the test. Think aloud interviews[197] would also have been a valuable method of assessing usability of the wTADAST-24. These are interviews where users verbalise their thoughts and actions as they perform a series of tasks, such as testing a website, and can give real insight into usability of a digital intervention. However, in-house user-testing provided sufficient information for the purposes of this research.

Overall feedback was good and the website was generally considered to be clear and easy to use. Some of the feedback is presented here with details about which device was used to access the test:

> *"Easy to follow and the site itself is a lovely little website" (**iMac user**)*
>
> *"Very nice and professional (and actually quite fun)" (**Laptop user with Internet explorer**)*
>
> *"Well put together and very clear instructions" **(Desktop computer user with Chrome**)*
>
> *"Some confusion about setting the volume to normal speech levels – but all became clear when actually following instructions" **(MacBook AIR user)***

The website was considered ready in the current format to undergo testing with a cohort of school children and is hosted by University of Southampton at www.hearingtest.soton.ac.uk

7.6 Methods

This section describes the evaluation of the wTADAST-24 compared to the wTADAST-36 in a cohort of 5-6 year old primary school children in Hampshire.

7.6.1 Setting and Recruitment

The study was set at Halterworth Community Primary School in Romsey. This school was selected as my own children went to this school and I have maintained a

relationship with the head and deputy head teachers. The school is also research active in the field of education and were willing to assist with this project.

An invitation pack was sent to all families of children in year 1 (aged 5 and 6 years) via the children's school bag. Each pack included a parent information letter, information sheet for children, a consent form and a reply slip (appendix D). Interested parents/carers indicated their agreement for their child's participation in the study by completing the reply slip and consent form, and returning these to the school office.

7.6.2 Ethical considerations

The research was approved by Southampton University Faculty of Medicine Ethics committee on 21/04/2015. (Appendix D) Written approval was obtained from the head teacher to undertake the research in the school. I obtained enhanced DBS clearance prior to the start of the study,

Parents/carers were given information about the study and had the opportunity to discuss the study with the researcher by telephone before deciding whether their child would participate. Interested parents/carers gave written informed consent for their child to participate and children were asked to give verbal assent to take part at each test session. Parents/carers were advised that they and their child could withdraw from the study at any time, without giving a reason.

The main ethical issue anticipated was raised anxiety if the child scored low on the hearing test. It was stressed to the parents that meaningful information could not be obtained from the research results until further validation had been completed. Parents who were concerned about their child's hearing were advised to contact their general practitioner for further advice.

The data collected as part of this study was fully anonymised and stored on the secure network at University of Southampton. Records will be kept for 15 years in accordance with GCP/MRC good practice guidelines and Faculty of Medicine research conduct guidelines.

7.6.3 Test schedule and data collection

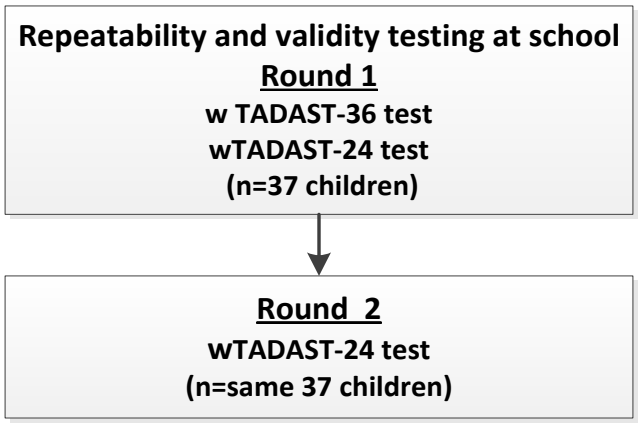
7.6.3.1 Baseline and demographic data

Baseline data was obtained from the returned parental reply slips which collected information about the child's gender, age, ear-related ear symptoms/concerns in the last 3 months and number of GP visits for any ear problem in the last year.

7.6.3.2 Test schedule

Testing of the wTADAST-36 and wTADAST-24 took place in 2 rounds (see Figure 16). During round 1, children took both tests in random order according to a pre-generated randomisation list to reduce bias due to learning effects. Round 2 of testing took place 2 weeks later and children took the wTADAST-24 only.

Figure 16: wTADAST-24 Testing Schedule



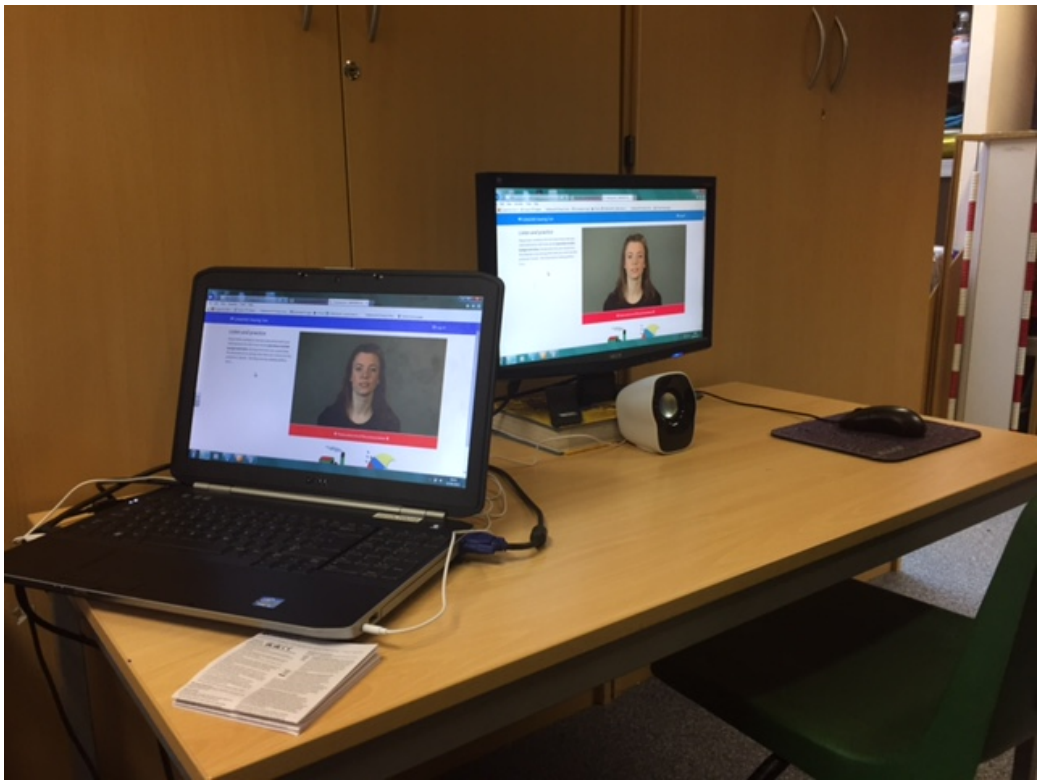
7.6.3.3 Test conditions

Testing took place in a quiet room close to the children's classroom and supported by the children's teacher. Background noise was measured before each test and did not exceed 50dB. The sound level was measured using the SPLnFFT web app on an iPhone 6. This application has been evaluated and shows good correlation with calibrated reference instrumentation [198]. The sound level for each of the two tests was calibrated individually as the internet sound level was lower on the old test. The background

noise for each test was measured and the speakers adjusted accordingly to ensure that they measured 64dB at 0.7m from the speaker.

For test conditions, the children were seated 0.7m away from the test screen (previously determined as the optimal distance for sound consistency [191]) . A single speaker was set up directly beneath the screen. The test screen was linked to a laptop computer, provided by the school, to facilitate access to the internet. The hearing test displayed on both the test screen (Figure 17– right hand screen) and the laptop (Figure 17– left hand screen) simultaneously so I could observe and administer the test with the children. Both the wTADAST-24 and wTADAST-36 were taken using the same equipment and with the same physical set-up.

Figure 17: Test set-up for wTADAST-24 and wTADAST-36 evaluation



7.6.3.4 **Test procedures**

During both rounds of testing I explained the study to each child and asked if they had any questions before starting the test. Verbal assent was obtained from each child prior to each test session. Children were asked to listen to the introduction and

practise with the introductory questions. Before starting the test, children were asked again if they had any questions or concerns about taking part.

The data was collected automatically on the website and I noted responses to ensure all data was captured. I also made field notes of remarks and comments made by the children and noted any difficulties encountered or prompts that were needed during the test. During testing, one child completed the test by choosing the opposite picture than the word that was heard. I discovered this by questioning the child and the test was repeated with the child saying out loud the word that they had heard the presenter say and the researcher noted their response. Some children tried to lean too close to the speaker to hear the words that were being spoken. However, the integrated background noise on the tests meant that the tests were not invalidated by proximity to the signal/noise source.

After each test session, children were given a sticker as a thank-you for taking part, and a card to notify parents of their child's involvement was sent home in their book bag. Parents were not notified of their child's test score as the TADAST-24 test had not undergone full validation. However, parents who were concerned about their child's hearing were advised to seek additional advice from their child's GP.

7.6.4 Statistics and Data analysis

7.6.4.1 Sample size calculation

Intraclass correlation coefficients (ICC) are commonly used to the determine test reliability of continuous variables. In order to detect a good reliability in the test conducted approximately 2 weeks apart in the same children under the same test conditions (where commonly 0.70-0.79 is considered good, and 0.80-1.00 is considered excellent reliability) a sample size of 20 children was required for a power of 80%. To detect a similar level of agreement between the original and updated test, a sample size of 20 was also required for a power of 80%.

7.6.4.2 Analysis

Mean, standard deviations and 95% confidence intervals were calculated for the total and sub-scores (audio, visual and audio-visual) of the wTADAST-24 and wTADAST-36. Test-retest reliability of the wTADAST-24 was assessed using intraclass correlation coefficient (ICC) and Cronbach's alpha, as a measure of internal consistency. Comparison of the wTADAST-36 and wTADAST-24 was based on total score and a sub-score of the 20 identical items on both tests. Bland-Altman plots were used to represent the results and correlation was assessed with Pearson's Correlation.

7.7 Results

The initial tests took place at Halterworth Community Primary School during 18-20th May 2015 (round 1). Repeat testing took place on 2nd and 5th June 2015 (round 2).

7.7.1 Sample characteristics

A total of 37 parents/carers (62%) responded to the invitation letter and gave consent for their child to participate in the research project. The sample children were all 5-6 years of age and 59% were girls. 5 (14%) children had 4+ symptoms from the glue ear symptom checklist (Table 1) and 6 (16%) children had consulted their GP concerning ear-related problems in the previous 12 months.

All 37 children were present for the 2 test sessions, and completed the 3 tests (round 1: wTADAST-36, wTADAST-24 and round 2: repeat wTADAST-24). This exceeded the number estimated by the power calculation of 20 children required to complete the tests, but it was considered appropriate to include all children whose parents consented to their participation. This also allowed for missing data due to known website problems with the original test.

Table 19: Sample characteristics

Number of children	**37**
Age of child	
5	12 (32%)
6	25 (68%)
Gender of child	
Female	22 (60%)
Male	15 (40%)
Ethnicity of child	
White British	37
Parent-reported symptoms associated with OME in the previous 3 months (symptom list from AIRS[2 3])	N=37
A prolonged or bad cold or ear infection	6 (16.2%)
Bad cough of chest infection	5 (13,5)
Appears to be lip reading	0
An earache	5 (13.5%)
Not doing as well at school as expected	3 (8.1%)
Often mishears what is said	4 (10.8%)
Has noises in the ear or is dizzy	2 (5.4%)
Hearing loss is suspected by anyone	4 (10.8%)
Snores, blocked nose or poor sleep	3 (8.1%)
Says 'eh what?' or 'pardon' a lot	8 (21.6%)
Speech seems behind other children's	4 (10.8%)
Needs the television turned up	4 (10.8%)
Any suspected ear problem	4 (10.8%)
May be irritable or withdrawn	2 (5.4%)
Number of children with 4+ symptoms in previous 3 months	5 (14%)
Number of children visiting the GP for ear-related problems over the previous 12 months	6 (16%)
Number of children that teachers identified with potential hearing loss in the classroom	3 (8%)

7.7.2 Test characteristics

Background noise (at the school) was assessed at the start of each test session and did not exceed 50dB. The sound level of the test materials was measured at the start of each test session and was found to be within satisfactory limits.

7.7.3 Missing data

Website problems with the wTADAST-36 (including videos slow to load, unresponsiveness/freezing and jumping forward questions) resulted in 19 out of 37 participants (51%) having incomplete data (Table 20).

Table 20: Missing data

Number of missing test item scores	*wTADAST-36 (n)*	*wTADAST-24 (n)*	*Repeat wTADAST-24 (n)*
1	11	1	-
2	3	-	-
3	2	-	1
4	-	-	-
5	3	-	-
TOTAL	**19**	**1**	**1**

In contrast, website problems with the new wTADAST-24 occurred on 2 occasions (freezing of the web page), resulting in just 1 out of 37 (3%) participants having incomplete data for either the wTADAST-24 or the repeat test.

There are a number of ways to manage missing data and I discussed the options with Dr Beth Stuart, statistician at Primary Medical Care. Dealing with missing data in statistical analyses depends on the reason for the data being missing. In this study, the missing data was due to the website problems which occurred at random and was completely unrelated and independent to the item test score itself. As such the data is classified as missing completely at random (MCAR) and a simple way of obtaining a non-biased result is to conduct a complete case analysis (i.e. only analyse cases where the complete data is available). This is because the subset of complete cases selected is assumed to represent an unbiased sample group[199].

If there is some uncertainty about the reason for missing data, there is a possibility of the results being biased. To deal with data that is not missing completely at random (i.e. the reason for being missing may be related to the variable itself), there are statistical techniques that can be employed to impute the missing data, which can

reduce uncertainty and improve the quality of the estimation. There are a number of techniques available including simple imputation, multiple imputation, and modelling techniques. In this study, I imputed the missing data using a simple imputation of scaling up the individual test scores, which assumes that the missing test items would be answered in the same way as the completed test items. For example, a score of 20/32 on the wTADAST-36 would be scaled up to 22.5/36. Whilst this is a crude method of imputation, the data was considered MCAR and it was considered a valid technique to use as a sensitivity analysis to explore whether the results were sensitive to some scores being artificially low due to missing items following website failures.

7.7.4 Main results

7.7.4.1 Descriptive statistics of the hearing disability tests

Table 21: wTADAST-24 and repeat wTADAST-24 Total Scores

	n	*Mean*	*SD*	*95% Confidence intervals*
wTADAST-24*	36	19.47	3.38	18.33, 20.62
Repeat wTADAST-24*	36	20.58	2.71	19.67, 21.50
wTADAST-36**	18	27.83	3.52	26.08, 29.58

** Maximum possible score 24, **Maximum possible score 36*

The descriptive statistics for the 3 tests (wTADAST-24, repeat wTADAST-24 and wTADAST-36) are presented in Table 21. There was one outlier in the wTADAST-24 test where the child scored 4 out of a possible 24 (a chance score by guessing each word would be 12 out of 24). This child had no history of hearing problems and no concerns had been raised by the teacher or the child's parents. The child subsequently scored 21/36 on the wTADAST-36 and 10/24 on the repeat wTADAST-24 which still lies in high risk group for hearing disability, but there is a possibility of other cognitive or developmental reasons why this child scored particularly low on the first test. Including the outlier affects the distribution of the test scores resulting in the wTADAST-24 test scores being not normally distributed.

Table 22: Sub-domains of the TADAST

	n	***Audio-only*** *Mean (CI)*	***Visual-only*** *Mean (CI)*	***Audio-visual*** *Mean (CI)*
wTADAST-24	36	6.78 (6.35, 7.21)	5.19 (4.65, 5.74)	7.50 (7.08, 7.92)
Repeat wTADAST-24	36	6.92 (6.54, 7.29)	5.92 (5.42, 6.41)	7.75 (7.50, 7.99)
wTADAST-36	18	9.67 (8.85, 10.48)	7.78 (6.71, 8.85)	10.39 (9.66, 11.12)

Table 22 presents the sub-scores for the three domains of the wTADAST-24, repeat wTADAST-24 and wTADAST-36. The maximum score for each domain of the wTADAST-24 was 8, with an expected chance score of 4/8. No statistical tests were performed on these sub-scores. The results show that children scored highest when both audio and visual cues were available (audio-visual domain), with a mean score of 7.50 suggests a ceiling effect with this domain. Children scored lowest on the visual only questions (mean score of 5.19) suggesting that not all children have good lip-reading abilities. The audio-only scores, which provided sound without the visual cues, is most likely to represent hearing ability, but does not account for how children use strategies such as lip-reading to function in a noisy environment.

When the wTADAST-24 was repeated there was a small improvement in total score (mean 19.54 to 20.51) although this was not tested for significance. The largest improvement was seen in the visual only domain which may represent a potentially important learning to lip-read effect.

7.7.4.2 **Internal consistency of the hearing disability tests**

Cronbach's alpha[200] is an estimate of internal consistency of a scale and can be used to measure scale reliability. The alpha coefficient ranges in value from 0 to 1 with the higher the score the more reliable the scale. Nunnally[201] in 1978 indicated an alpha of 0.7 to be an acceptable reliability coefficient. The wTADAST-24 had a Cronbach Alphas of 0.761 (n=36) suggesting that the wTADAST-24 has good internal consistency. The repeat w-TADAST-24 had a Cronbach's alpha of 0.689 (n=36) suggesting that internal consistency is not affected by repeat testing.

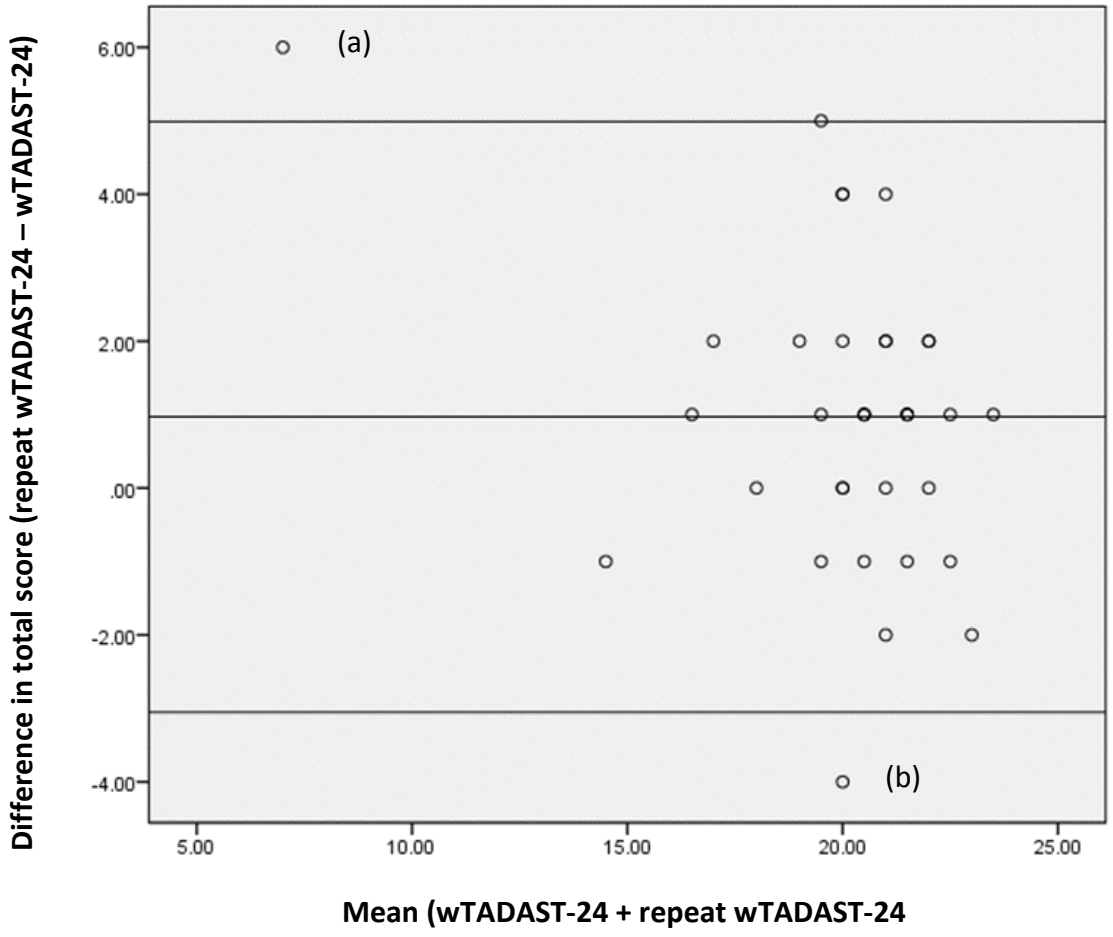
The wTADAST-36 had a Cronbach's alpha of 0.57 suggesting that the internal consistency of the original test was not as good as the updated test. Certain aspects can affect test performance including poor inter-relatedness between items or heterogeneous constructs.[202] With this test poor internal consistency may be a result of word/picture recognition. Also there was a large amount of missing data due to screen freezing which affects validity. The original test was developed 20 years ago and current children may have been unfamiliar with certain word/picture pairs and needed to guess the answer, thereby reducing the consistency of the test. In fact, some children asked for clarification of a picture before deciding which one to choose in the test (e.g. fountain and nappy pin).

7.7.4.3 Test-retest reliability of wTADAST-24

Test-retest reliability of the wTADAST-24 was assessed with 35 participants where a full dataset was available. The intraclass correlation coefficient (ICC)[203] for reliability was 0.78, with 95% CI 0.60, 0.88, suggesting that very good test-retest reliability was achieved.

The Bland and Altman plot for this data is given in Figure 18 which shows good agreement for most cases. However, there are two cases which lie outside the 95% limits of agreement. The first outlier (a) represents the boy who is described in the descriptive statistics section. The child scored particularly low on the first test (4/24) and then 10/24 in the repeat test resulting in an increase in test score of 6 points. However, both scores represent a high risk group for glue ear and therefore gave a consistent overall result. The second outlier (b) presents a girl who scored 4 points less on repeat testing, although both scores represent a low risk of hearing disability. A deterioration in score could represent a worsening in hearing levels due to AOM or OME, but no acute ear infection had been reported by the parents or teachers in the two weeks between the 2 rounds of testing. In addition, neither parents nor teachers expressed concerns about the child's hearing, and score difference may have been due to other factors such as fatigue (the child was the last one of the day to take the test).

Figure 18: Bland-Altman plot (test-retest reliability of the wTADAST-24)



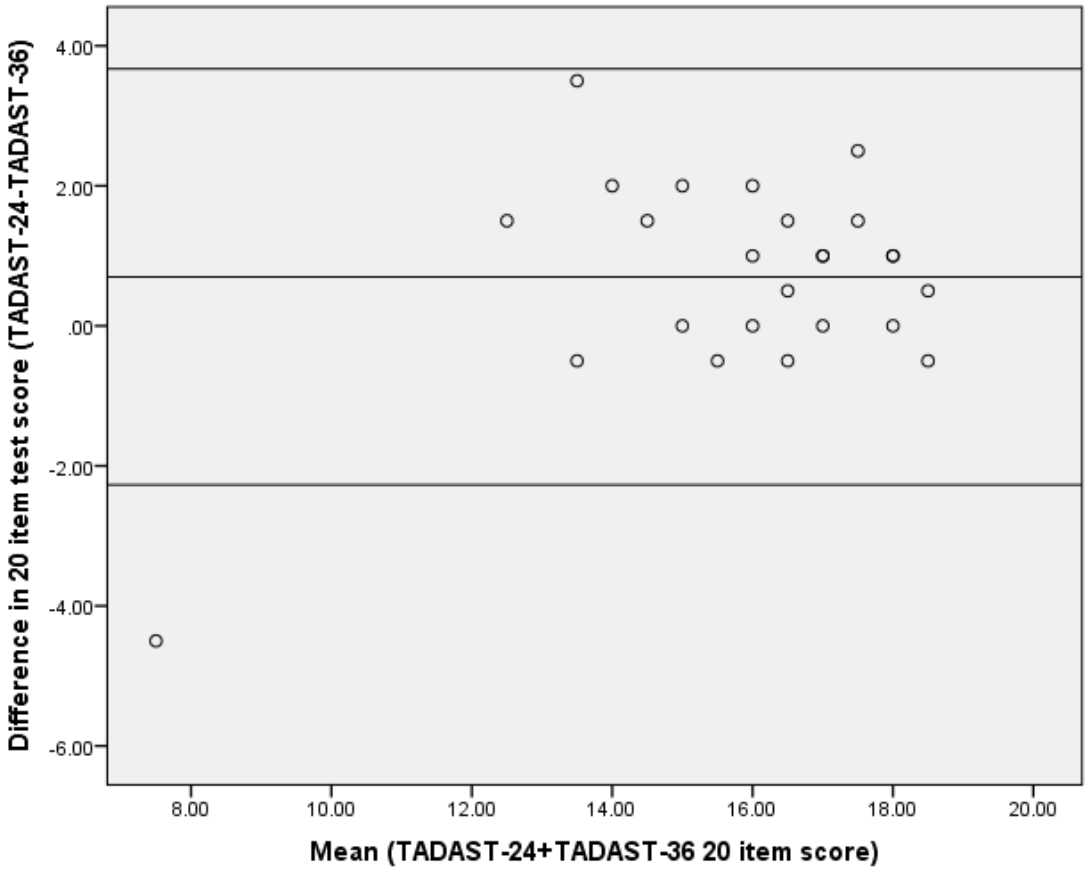
7.7.4.4 Correlation between wTADAST-24 and wTADAST-36

Due to the previously known reliability problems with the wTADAST-36 I only had a full dataset of wTADAST-24 and wTADAST-36 test scores for comparison in 18 participants. Using the datasets available I found a Pearson correlation between the two tests of 0.46 with borderline significance (p=0.052). This is only a moderate correlation, however what is more relevant is the ability of a test to identify children with a potential hearing disability. We would expect in a classroom of 5-6 year old children that ~3 would have glue ear and consequently score lowest on the hearing disability tests. Interestingly, 2 of the 3 low scorers on the wTADAST-36 were also the lowest scorers on the wTADAST-24 suggesting that both tests are measuring the same aspect of hearing disability and there is correlation between tests for this clinically important low score marker/action threshold. As a sensitivity analysis, I also conducted the

analysis with the scaled-up data set. The Pearson correlation between the two data sets was 0.41 (p=0.01).

I also looked at the correlation between the 20 matched word/picture pairs of both tests. To assess agreement the difference in total scores was plotted against mean score for each test, as described by Bland and Altman[204], n=25 where full data was available. The mean score difference was 0.70 (SD 1.5) indicating that the children performed slightly better on the wTADAST-24 than the wTADAST-36, but no systematic bias was indicated.

Figure 19: Bland-Altman plot of score difference against mean of wTADAST-24 and wTADAST-36 scores (20 items)



The 95% limits of agreement are presented on the graph (Figure 19) and the majority of points lie within these limits suggesting a modest level of agreement. Again the two outliers are the same children as discussed in the previous section.

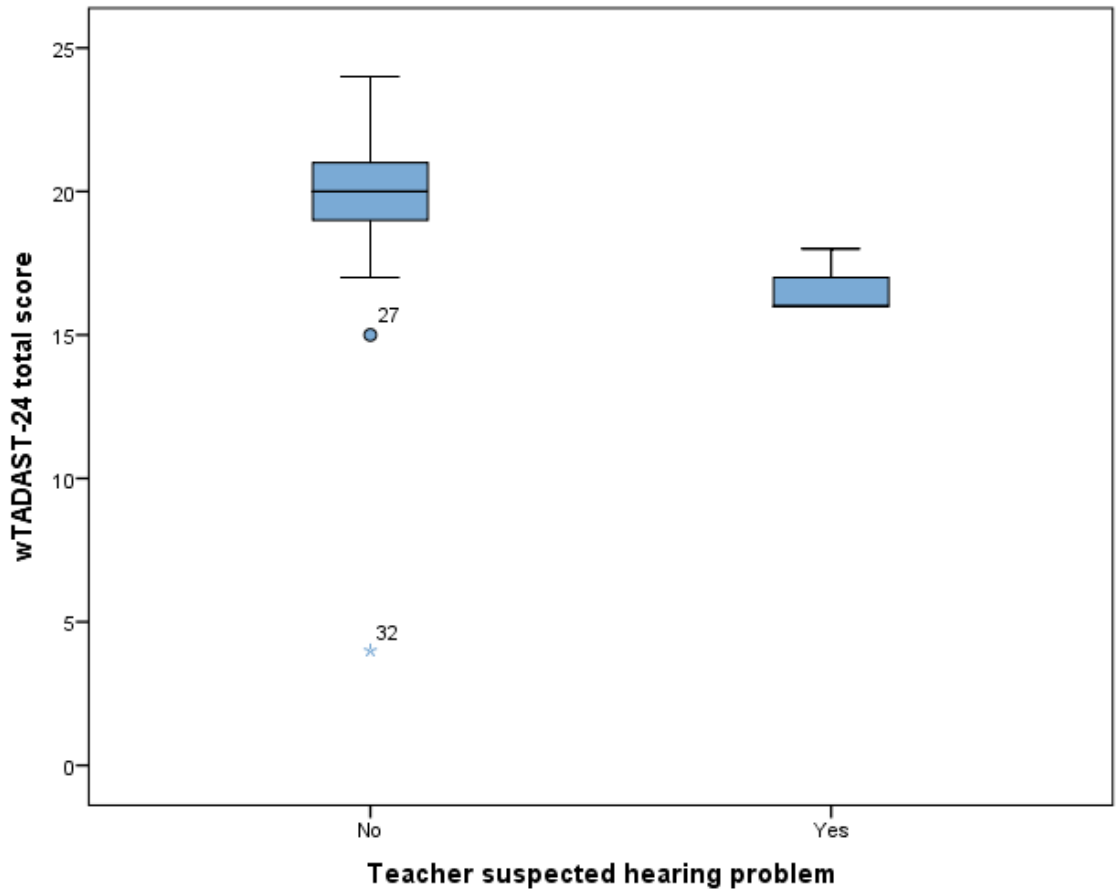
7.7.4.5 **Correlation with parent and teacher reported concerns.**

As this was a small sample and the sample was from a population of healthy school children, the number of cases where concerns were raised by parents or teachers was small, and therefore conclusions are limited.

Teachers identified 3/37 children with potential hearing difficulties in the classroom. Parents raised concerns in 9 children from a list of symptoms identified in the AIRS study[3] (concerns identified as 4 or more predictive symptoms of OME on the list of 12 symptoms used – Table 19).

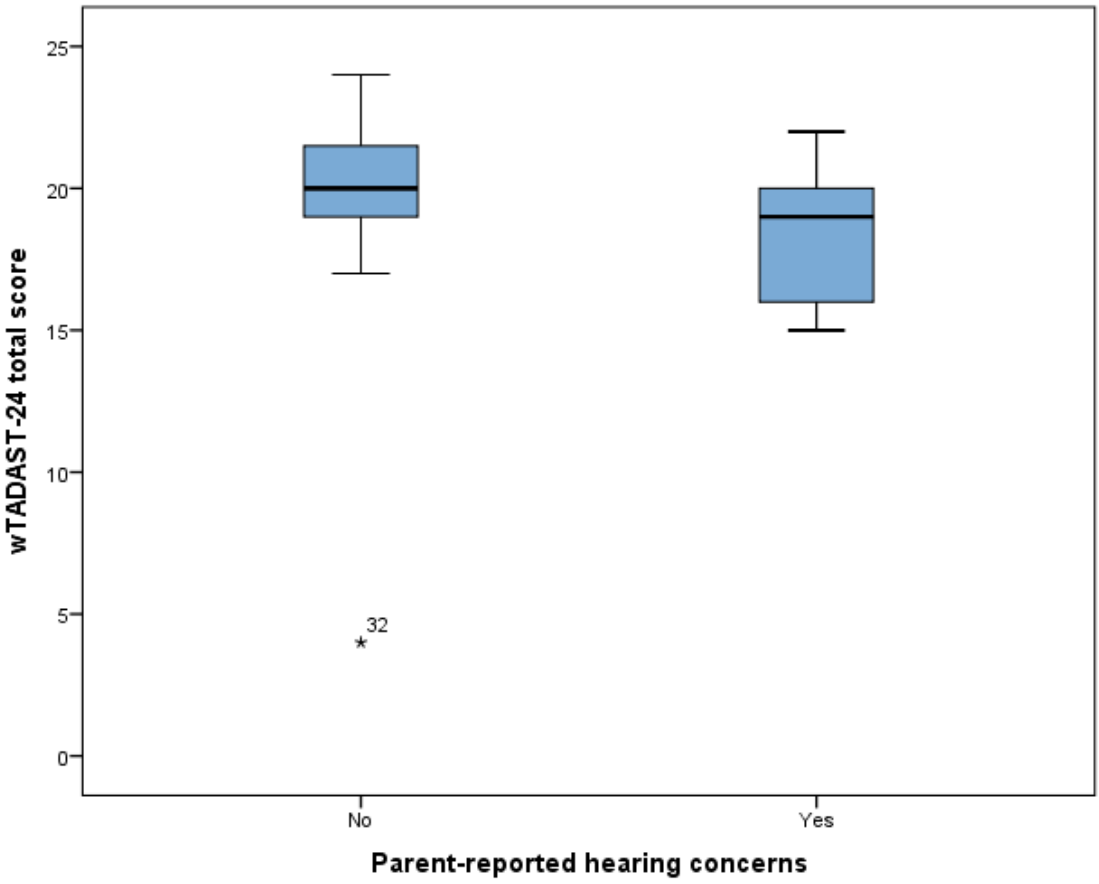
The mean wTADAST-24 score for the teacher identified at-risk group was 16.7(1.16) compared to 19.8 (3.34) in the group where no difficulties were identified. In addition, these 3 children all scored in the bottom five children on all three tests (wTADAST-36, wTADAST-24 and repeat wTADAST-24).

Figure 20: Box plot wTADAST-24 scores/teacher identified group



The mean wTADAST-24 score for the parent-identified group was 18.50 (2.41) compared to 19.85 (3.67) for the group where no concerns were raised.

Figure 21: Box plot wTADAST-24 scores/parent-identified group



7.7.4.6 Summary of reliability and validity of the wTADAST-24

Reliability of a test is the degree to which it is free from measurement error. This includes internal consistency (the interrelatedness between the individual test items), consistency over time (test-retest reliability) and consistency between different responders (inter-rater reliability). In this study, the wTADAST-24 showed good test-retest reliability (ICC 0.78, CI 0.60, 0.88) over a period of two weeks, and a relatively high internal consistency (Cronbach's alpha 0.76), suggesting that the overall reliability of the wTADAST-24 is good and suitable for further evaluation.

Validity of a test is the extent to which a test measure the attributes it purports to measure. This includes content validity, construct validity, and criterion validity. Content validity is a subjective assessment that the content reflects the attributes to be measured. The COSMIN checklist[205] recommend a judgement of the relevance and comprehensiveness of the items of a test. The content of the wTADAST-24 (i.e. pictures, videos and graphics) is relevant to the age of children where OME is most prevalent and is presented in a format that is easy for children to use. The test includes constructs to assess both visual, auditory and combined functions which reflects the components likely to contribute to hearing disability associated with OME. The words and pictures are age appropriate, and have been refined and re-drawn to reflect the current context. However, a sample of 10 children were asked to name the 24 picture pairs and some pictures were still named incorrectly (see appendix D) which might affect the content validity of the wTADAST-24 as children may not be correctly identifying the word/picture pair. The construct validity is defined was whether the test measures what it claims to measure. The wTADAST-24 has been developed to assess hearing disability, but to date there is no defined measure of hearing disability associated with OME (see section 7.2.1). In this study, correlation with teacher and parent-reported hearing disability was assessed, but numbers were small, so limited inference about construct validity can be drawn. The criterion validity is defined as whether a test reflects a 'gold standard'. However, no gold standard exists for hearing disability in children, and therefore criterion validity could not be established within this study.

7.8 Discussion

7.8.1 Summary

This study was designed to evaluate an updated form of the TADAST for a contemporary audience using updated technology. Results overall suggest that the wTADAST-24 website performed well and consistently better than the previously used web version (wTADAST-36). It also proved to be accessible to children and suitable for use in the classroom setting. The wTADAST-24 showed good repeatability and a

relatively high internal consistency and a showed a moderate positive correlation with the earlier version.

Test-retest reliability of the wTADAST-24 was good over the period of 2 weeks (ICC 0.78, CI 0.60, 0.88). A child's hearing level is not considered to change substantially over 2 weeks unless they develop an acute ear infection. None were reported during the study and therefore unlikely to affect the results. It has been acknowledged, however, that there might be a level of increased performance on the repeat test due to learning effects, which can lead to poorer test-retest reliability. However, a similar score of test-retest reliability was seen with the TADAST-50 when the test was repeated after 1 month.[177]

The mean (SD) wTADAST-36 score in this study was 27.3 (3.63), which compared well with previous studies in normative populations (Worseley 1996: mean (SD) 29.23 (2.54)[189] and Beckett 2010: 27.33 (3.75)[191]). It has yet to be determined what score level would indicate a functional hearing disability worth investigating further or referral on to different health professionals (*the action threshold*). There is a lack of validated measures for hearing disability and there is no definitive 'gold standard' by which to measure the TADAST. Because the TADAST is a two-alternative test, 50% would be expected to be answered correctly by chance, therefore 64% would be required to perform significantly above chance at the 0.05 significance level. This equates to a test score of 23 or more on the wTADAST-36 and a score of 16 or more on the wTADAST-24. In this study of a normal population of 5-6 year old school children in the spring term at school, the population point prevalence of bilateral glue ear is predicted to be ~5%, and unilateral glue ear ~6%[12]. This would mean that ~4/37 children may have current unrecognised unilateral or bilateral glue ear and be at higher risk of hearing disability in the classroom (children with bilateral glue ear probably at more risk than those with unilateral glue ear). In this study, 4 of the 37 children (~10%) scored 16 or below on the wTADAST-24 which supports the pragmatic selection of a score of 16 and below for identifying likely risk of functional hearing disability associated with OME requiring further action. Remediation here may take

the form of an alert to parents/teachers for more information on OME and other causes of low scores and possibly seeking medical opinion.

The TADAST has 3 subsets of questions: audio only, visual only and audio-visual domains. The results of the wTADAST-24 test agreed with previous work that children perform best with audio-visual questions and least well with visual only questions.[189] In this study, audio-visual questions produced the least number of errors and the mean score in this category was 7.5/8, representing a ceiling effect, and therefore is less useful to discriminate for hearing loss. The visual only scores represent lip-reading ability. MacLeod and Summerfield[206] described the difference between audio only and audio-visual scores as *audio-visual gain*, and hence is also a measure of lip-reading ability. In this study the difference between the audio and audio visual scores was 0.72 representing 9% of the total wTADAST-24 score attributed to lip-reading abilities, which is consistent with the Worsley study.[189] Lip-reading abilities in children is an under-researched area. Whilst lip-reading is thought to improve with age, and children with hearing loss are better lip-readers than children with normal hearing[193], it is not clear whether children can be taught to lip-read, or at what age is most significant for improving lip-reading abilities. This study, however, found a lip-reading effect which appears to be learnt.

7.8.2 Strengths and limitations

The study was conducted with school children aged 5-6 years, the age at which glue ear is highly prevalent[8] (the second bimodal peak of OME – see chapter 2), and therefore in a population where such a test of hearing disability is most applicable. The grommet surgery procedure is usually performed in children aged 3.5 to 8 years and thus the wTADAST-24 focuses on this group of children where resource use is high for the NHS. The setting for the study was a primary school, one of the places where the wTADAST-24 might have a potential use. Concerns about OME often relate to school performance and norm referencing (i.e. comparing abilities with other children)[20].

The updated test has proved to be significantly more consistent than the previous web version, with fewer problems with webpage freezes or missed/jumped questions. Children found the wTADAST-24 easy to complete and were engaged with the new user-friendly format that could be used in the home or school setting. The shortened test meant that the children remained well engaged and test results (with smiley faces) acted as a reward for the children. The wTADAST-24 website is available to access on different devices, including PCs, Apple Mac, android phones and tablets and Apple iPads. However, the test cannot currently be run on the iPhone due to internal iPhone architecture (i.e. inability to display videos and pictures at the same time).

The shortened test has the potential to improve test reliability due to reduction in test fatigue in very young children. It also retains the ability to measure hearing disability and moderately correlates with the earlier wTADAST-36. Reducing the number of test questions from 36 to 24 might reduce the test sensitivity but the most important aspect of the test is identifying the children with scores in lowest 5% of test score distribution, and this does not appear to be affected by reducing the number of test items. In my study, the children who scored the lowest on the wTADAST-24 were the same group who scored low on the wTADAST-36. A ceiling effect was noted for the audio-visual questions which reduces the discriminatory ability of this subset of questions but positively reinforces test engagement. The visual-only questions provide an important measure of how children manage in the noisy classroom environment by the use of visual cues to compliment audition.

Participant numbers were small and the study did not include any other measures of hearing impairment or hearing disability with which to correlate the wTADAST-24 scores. Whilst parental and teacher concerns were recorded, the number of children with parent or teacher reported hearing-related concerns were few and therefore limited conclusions can be drawn as to the construct validity in this study. However, construct validity has been found in the earlier versions of the test.[187]

The researcher administered the TADAST tests and supported the children during the testing process. This might have affected children's engagement with the test. In

addition, the study did not assess whether the test results were repeatable in the home environment, where the wTADAST-24 is likely to be used in practice.

It is important to note that many factors impact on a child's development including IQ, cognition, verbal reasoning, visual acuity, ability to attend and block out distractors as well as hearing ability and social factors such as communicating styles. All these factors have the potential to affect the test scores. This is both a strength and a weakness of the TADAST. If a child is confirmed to have OME by other tests e.g. tympanometry, then low scoring children are most likely to have the greatest impact from OME and constitute a degree of priority for referral or treatment. If identified by testing in a school environment but are found not to have confirmed OME, referral to an Educational Psychologist may be the most appropriate route for help.

7.8.3 Further validation of the wTADAST-24

The development work for the TADAST has included a certain amount of reliability and validity testing, however, further research could improve the overall quality of the test. The COSMIN checklist[205] was developed to evaluate the properties of such tests, and suggests standards for design and evaluation. I used the COSMIN checklist to review the development work to date for the TADAST as it seemed a relevant and clear way to evaluate outcomes of such tests, and suggest some further testing that could be undertaken:

Reliability testing: further work could be conducted to test the reliability of the test in different test settings, for example in the school and home settings. This would ensure that the test gives consistent results, independent of where the child takes the test.

Content validity could be further tested using a sample of school children, to confirm word/picture test recognition of the wTADAST-24. Some pictures were not named correctly by a small number of children in this study and further refinement of the content could improve the validity of the test. However, as children vary widely in their cognition, it is unlikely that a test could be developed where no errors in word/picture recognition occurred and thus this is recognised as a limitation of the test.

Construct validity: some testing has already been conducted, comparing the TADAST test scores with other measures of hearing disability. However, the lack of a 'gold standard' means that it is difficult to interpret correlation with other available forms of hearing tests. However, further work could be conducted comparing the TADAST with Pure Tone Audiometry (PTA), but this comparison may not provide useful information as PTA measures hearing impairment rather than disability. Comparing against the OM8-30/OMQ-14 may provide a more valid comparison, although the TADAST is an objective test, whilst the OM8-30/OMQ-14 is a proxy measure of hearing impairment. The OM8-30/OMQ-14 does, however, include a measure of different hearing domains including: reported hearing difficulties, behaviour, and speech/language domains. A comparison of the wTADAST-24 with these different domains of hearing may provide some further construct validity.

Responsiveness: the ability of the TADAST-24 to detect change over time has yet to be evaluated. It would be useful to use the wTADAST-24 as a measure of hearing disability before and after a treatment for OME (such as grommet surgery) to determine its ability to detect change in ear-related quality of life. Additionally it would be important to identify the minimal important change (i.e. the smallest change in score which patients perceive as important).

7.8.4 Implications for practice

Intermittent temporary hearing loss in school children can have a significant effect on a child's behaviour, speech, language and educational development, and hearing related quality of life. OME often goes unrecognised and many children are being disadvantaged, including potentially disproportionate numbers of those children who are most socially deprived. Having an age-appropriate tool to assess hearing disability in a naturalistic setting has the potential to help to identify those children who may have a functional hearing disability, for which remedial action can be taken.

It is envisaged however that the wTADAST-24 could be used as a pragmatic management tool, rather than a wider screening test, for use in the community, i.e. used at the point of need when concerns have been raised rather than blanket

screening of large cohorts of children. If potential OME hearing concerns are identified or suspected by parents, teachers, school nurses, health visitors etc., a child could take the online test with supervision to identify whether they are likely to be having difficulties learning in a noisy environment. A low score may indicate the need for further medical assessment for OME.

For children with a concurrent diagnosis of OME, and who may be undergoing active monitoring, parents may wish to monitor their child's hearing disability at home to assess progress using the wTADAST-24. This is analogous to keeping asthma diaries to monitor the progress of another chronic intermittent childhood condition and about which a great deal has been done and written.[207] Currently, no evidence is available as to whether the wTADAST-24 is sensitive to changes in hearing disability over time, and this is potential future research to further validate the usefulness of this test.

It is thus envisaged that the wTADAST-24 could complement existing assessments of hearing in children. Included within a package of information for families, it may be useful to support better overall management of glue ear in primary care and in the community setting.

The wTADAST-24 forms part of the new LittleEARS educational intervention described in chapter 8.

7.9 Conclusion

This chapter has described the further development, improvement and evaluation of the TADAST hearing disability test. The new shortened version (wTADAST-24) contains new videos and graphics, is accessible and reliable, and retains its face-validity as a naturalistic hearing disability test. The test forms part of the educational intervention for families of children in primary care and the community settings. The improved test has the potential to help families monitor hearing disability associated with OME, thereby promoting active monitoring and self-management.

Chapter 8: Development of an educational intervention for glue ear (LittleEARS)

8.1 Introduction

Recent research has found nasal balloon autoinflation to be an effective treatment for OME applicable to the primary care setting[2] and a recent NICE technologies assessment has recommended its use during the 3 month active monitoring period. However, the wider implementation of the nasal balloon relies on addressing the practical, organisational and behavioural challenges of such an intervention, some of which have been identified as part of the qualitative work (Chapters 5 and 6, and the AIRS study[3]). Through this work I have identified that provision of good quality, evidence-based information about glue ear and practical training/demonstration of use of the nasal balloon has the potential to improve active monitoring, promote self-management, and support the use of the nasal balloon.

Self-management is an important part of healthcare, [62] particularly with the increase in number of people living with a chronic condition and an ongoing squeeze on healthcare resources in the UK (NHS Five Year forward View[62]). One of the ten current priorities for healthcare commissioners in England is *Active Support for Self-Management*, which involves both tools and techniques to help patients choose healthy behaviours, and a move towards a collaborative partnership between patients and caregivers[208 209]. Supporting self-management involves educating people about their health condition, providing advice about treatment and what people can do themselves; making healthy choices; self-observation of changes in their condition; and knowing when to seek further help[64].

Routine self-management can improve quality of life for patients, result in better clinical outcomes and reduce health resource usage and associated costs[210]. There are a range of strategies to support better self-management including patient information leaflets and websites, one-to-one and group education sessions, telehealth, and digital psychological health interventions. However, different health conditions are likely to

benefit from different approaches[211]. In the case of children with OME, qualitative work in chapters 5 and 6 identified the need to focus on information provision for parents and technical skills to support wider implementation of the nasal balloon method.

Unfortunately few resources are currently available to support families in self-management of OME. Whilst there are some publically available health websites designed to provide information about glue ear, they contain little information about the nasal balloon method and limited direction about self-management and self-monitoring techniques. My work presented in this chapter concerns the development and evaluation of an educational intervention to encourage and facilitate self-management and support a pragmatic structured monitoring period for OME applicable in primary care.

8.2 Aims and objectives

The aim of this chapter was to develop and evaluate a web-based educational intervention (LittleEARS) for use by parents and children to support and promote wide implementation of nasal balloon autoinflation in children with OME.

Key objectives

i) To provide evidence-based information in an easily accessible format to parents of children with a recent diagnosis of glue ear in primary care and community settings.

ii) To provide support and advice to encourage self-management of glue ear in both home and school settings.

iii) To provide practical support for uptake and use the nasal balloon method for up to 3 months.

8.3 Methods

An educational intervention such as LittleEARS is considered to be a complex intervention as it consists of a number of interacting components, and requires new and different behaviours from those delivering and those receiving the intervention.

The MRC has developed broad guidance for developing and evaluating complex interventions[131] and recommends a systematic process of development using best evidence, a theoretical understanding of the proposed intervention, and modelling of the processes and outcomes. The involvement of end-users at all stages of development (the person-based approach[212]) focuses on the perspectives and understandings of the individuals who will use the intervention so ensuring that it is developed in such a way as to make it most acceptable, feasible and relevant. I have used the MRC complex intervention guidance and elements of the person-based approach to inform my methods as described below.

This section describes the pragmatic and systematic development of an educational intervention in three key phases:

i) Establishing the evidence base for the intervention.

ii) Describing the theoretical basis and approach to intervention development.

iii) Planning, developing and refining the intervention.

8.3.1 Establishing the evidence base for the educational intervention

The first step in development of the proposed educational intervention was to gather published and empirical evidence to inform both its content and components. I conducted a two-part literature review which included: a) a scoping literature review of available evidence and b) a review of existing UK patient information leaflets.

i) Full details of the literature review is presented in chapter 2 and represents the key published evidence on which the educational intervention was based.

ii) To identify and review the current resources available to families I conducted a search of existing UK patient information leaflets and websites using Google search engines and discussions with a range of primary healthcare professionals. I identified nine patient information sources in total (appendix E) and whilst not an exhaustive list, they covered those that appeared most frequently on search engines, and were mostly derived from reputable national sources including the NHS, NICE and leading hearing charities (National Deaf

Children Society and Action on Hearing Loss). The list also included those mentioned by GPs during the qualitative interviews (chapter 5). This search provided an insight into the format and content of the most commonly used or trusted information being provided to parents. It also provided insight into how information was being presented, the specific language used, and the extent of detail and instruction about the use of the nasal balloon.

The second step involved gathering empirical evidence from qualitative interviews with healthcare providers (GPs and nurses) and parents of children with glue ear, which is presented in chapters 5,6 and AIRS nested qualitative study[3]. I used this to gain an insight into the different stakeholder views of information needs about glue ear and the nasal balloon.

I drew on both the published and empirical evidence to develop the content of the educational intervention to ensure that it was evidence-based, relevant and practical for the end user.

An important consideration during the development of the LittleEARS educational intervention was to ensure that the information provided was accessible and understandable to a wide range of end-users. The WHO (2015) defined health literacy as '*the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health'*[213]. In the UK, 42% of working-aged adults are unable to understand current health information which can lead to health inequalities and poorer health outcomes (Public Health England: 2015[214]). Strategies have been proposed to improve health literacy both in broader terms of ensuring that all health information is clear and accessible to everyone independent of their individual ability, and also targeted towards improving health literacy of low literacy populations[215]. For the development of the LittleEARS educational intervention I used direct and plain language, together with good layout and web design, to ensure the widest accessibility and understanding.

8.3.2 Theoretical basis and approach to intervention development

Using theory in the development of a complex intervention offers a framework to enhance the better understanding of facilitators and barriers to implementation and to help understand when implementation fails[130]. In the development of this educational intervention I used Normalization Process Theory (NPT)[5] to underpin the process, informed by Behaviour Change Techniques (BCTs)[216] and elements of the person-based approach[212] to maximise the success of implementation and ensure that the intervention was relevant, feasible and acceptable to parents. These elements are discussed in the following sections in relation to this research project.

8.3.2.1 Normalization Process Theory

The Normalization Process Theory (NPT) was used to underpin the pragmatic development of the LittleEARS educational intervention. Chapter 3 described how theory is useful in the development and implementation of complex interventions and discusses why NPT[5] was selected for this research project. This section describes how I specifically incorporated the factors and components identified in chapter 6 in the development of this educational intervention for families of children with glue ear.

NPT is concerned with how processes become embedded in their social contexts and provides a robust framework for analysing processes and relationships involved in implementation and change of practice[119]. NPT proposes that new practices become routinised as a result of people working individually and collectively to enact them. The work of enacting a practice, or intervention, is facilitated though four 'generative mechanisms' or constructs (*coherence, cognitive participation, collective action* and *reflexive monitoring*). Each represent the kinds of 'work' that people need to do to enact a new process. *Coherence* is the work that people do both individually and collectively to make sense of a new practice (sense-making work); *cognitive participation* is the work that people do to engage in a new practice (relational work); collective *action* is the work that people do to enact or operationalise a new practice (operational work); and *reflexive monitoring* is the work people do to assess and evaluate a new practice (appraisal work).

The NPT constructs shown to be most associated with the **development** of an intervention are *coherence* and *cognitive participation*[120]. The factors found to promote *coherence* and *cognitive participation* in chapter 6 include: i) helping parents to understand about their child's condition, ii) understanding the care pathways and treatment options available, and iii) helping parents and children to engage with the active monitoring period and use of the nasal balloon.

The NPT constructs most associated with **implementation** of an intervention are *collective action* and *reflexive monitoring*[120]. Factors that promote the usage and compliance with the nasal balloon (*collective action*) identified in chapter 6 include a video demonstration of the nasal balloon to facilitate technique training and stepwise instructions to ensure families understand what is required of them. Factors to promote *reflexive monitoring* identified in chapter 6 include: i) symptom checklists and diaries to monitor hearing-related symptoms, ii) a newly formatted and evaluated hearing disability test (wTADAST-24) to assist with the monitoring period and iii) easier signposting for parents about what to do if their child doesn't improve over the monitoring period.

These factors were used to guide the choice of elements, or Behaviour Change Techniques, for inclusion in the educational intervention, and are described in the following section.

8.3.2.2 Behaviour Change Techniques

Behaviour Change Techniques (BCTs)[216] are components of an intervention designed to regulate or change behaviours. They are described as the 'observable, replicable and irreducible component' or 'active ingredient' of an intervention. Many behavioural change interventions have been developed, aimed at improving the health of the population, and most are complex with many interacting components. It can be difficult to determine which component or combination of components of an intervention are effective. Additionally, it can be unclear how future interventions can replicate similar effect if the active components are not identified. Behavioural change researchers have attempted to identify and categorise these active components, and

produced a taxonomy of BCTs to help in the design and development of new interventions. Michie *et al.* developed a taxonomy of 93 distinct BCTs in 16 clusters, through expert consensus, resulting in a comprehensive BCT taxonomy for designing, evaluating and implementing behaviour change interventions that is generaliseable to a wide range of healthcare settings.

Whilst this research presents the pragmatic development of an educational intervention, some behaviour change components were identified which were thought to act by promoting implementation of the nasal balloon. These active ingredients are discussed later in relation to the theoretical constructs of NPT and how they are thought to promote implementation. A formal behaviour change analysis process was beyond the scope of this work.

8.3.2.3 Person-based approach

The person-based approach *(PBA)* for the development of digital health interventions was first described only recently by Yardley in 2015[212] and has been used successfully in the development of other complex interventions such as asthma self-management[217], weight loss interventions[218] and self-management of dizziness[219]. The authors recognised a need to identify a way of applying theory and evidence-based models and techniques to the individuals who will be using them. The aim of the person-based approach is to focus on the perspectives and understandings of the individuals to ensure that the intervention developed is acceptable, feasible and relevant to end users.

The person-based approach recommends the use of end-users at all stages of the development and evaluation process, including the phases of planning, design, development/evaluation, and implementation.

I. **During the planning stage:** The PBA recommends the use of qualitative research to identify key behavioural issues and challenges that need to be addressed. This may include synthesizing previous qualitative work or conducting primary qualitative studies to elicit views of the end-users regarding

potential behavioural change. This will help to ensure that the intervention components are feasible and acceptable to the people who will use the intervention, and to exclude things are a particularly disliked or seen to be unhelpful.

II. **During the design stage:** The design stage involves the creation of 'guiding principles' to address the behavioural issues and challenges identified in the planning stage. This involves identifying key features aimed at addressing these objectives.

III. **During development and evaluation of an intervention:** This stage involves the evaluation and optimisation of the intervention through end- user involvement. This may include think-aloud interviews to iteratively develop the intervention and longitudinal case studies to evaluate and optimise independent use of the intervention.

IV. **During implementation:** finally, the PBA details the evaluation of the intervention in real-life contexts, using mixed methods approaches to further modify and improve the intervention for wider implementation.

I have incorporated aspects of the person-based approach into the development process, but it was not possible to fully implement the PBA due to time and cost limitations.

Firstly, during the planning of the LittleEARS educational intervention I used existing qualitative interviews with parents and nurses, and conducted primary qualitative interviews with GPs to identify the behaviours, information needs and challenges required to support the use of the nasal balloon (chapters 5 and 6). On reflection, I could have consulted more widely with experts (such as paediatric audiologists) at this stage which might have provided a wider perspective to the planning process.

During the design phase, I produced 'guiding principles' to focus the intervention development, detailing the design objectives and the key features of how the project

objectives would be met. I then mapped the components of the intervention to behavioural change techniques and the constructs of NPT to ensure that the features of the intervention address those issues identified for implementation.

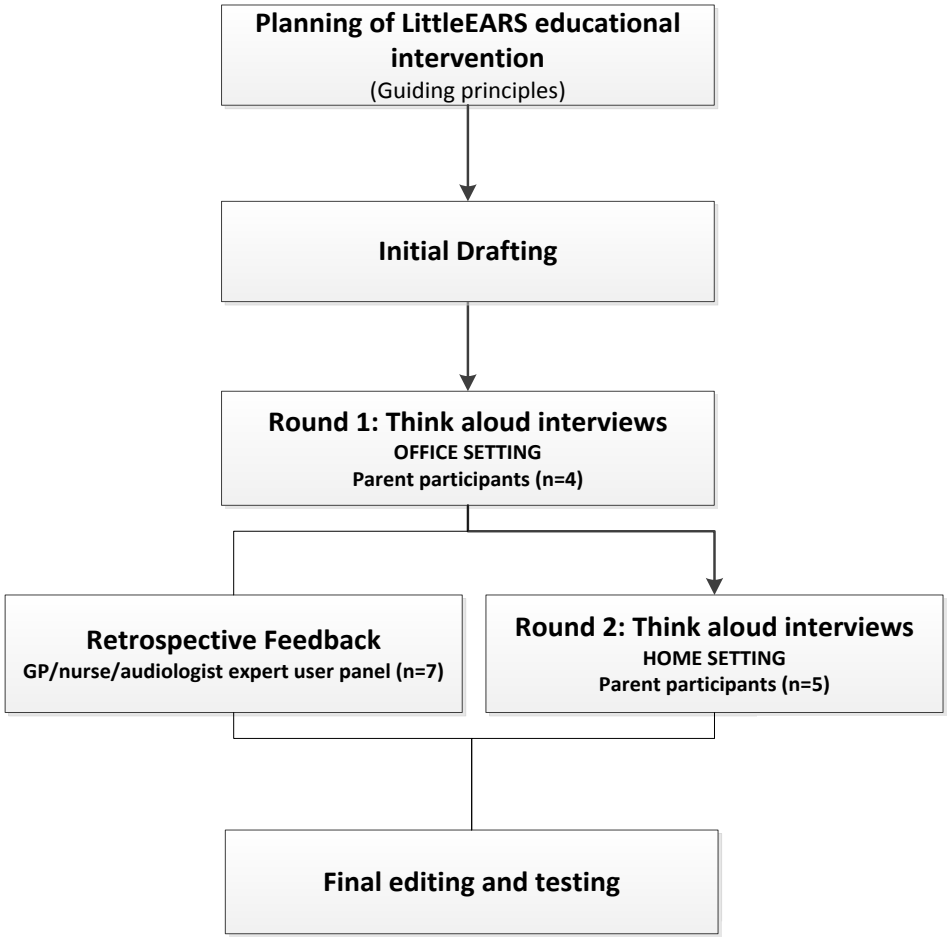
During the development and evaluation phase, I involved end-users (parents) in the evaluation and refinement of the intervention using think-aloud methods[142] which are particularly useful methods to obtain immediate feedback and allow direct observation of how the intervention is being used. I also included some testing in the home setting, for a closer evaluation of independent use which provided useful information. An additional option would have been the inclusion of parents of children who were currently being monitored for glue ear, but this would have required NHS ethics approval and I was limited in the time for development of the intervention.

Finally, I evaluated the intervention in a feasibility study (chapter 9), which included parents of children with a current diagnosis of OME. My evaluation could have also included qualitative interviews with the parents who participated in the feasibility study, but time constraints were a limiting factor for this PhD research.

8.3.3 Planning and developing the educational intervention

Figure 22 details the steps of planning, developing and refining the educational intervention, including developing guiding principles, drafting of the website, and evaluation and further refining using think aloud methods and retrospective feedback from expert users.

Figure 22: Flow chart of planning, developing and refining the LittleEARS educational intervention



8.3.3.1 Planning of the educational intervention

The first consideration when designing the intervention was deciding on the key message that the educational intervention would be giving to parents. The broad aims of the work overall is to support the wider implementation of the nasal balloon. However, for implementation to take place, parents need to engage with the active monitoring period and be able to monitor for improvement or identify when further medical advice is needed. The main message throughout the LittleEARS intervention was therefore as follows:

'Active monitoring is an appropriate early management strategy for children with glue ear in primary care and the nasal balloon method is an effective and practical treatment option that can be applied during the recommended 3 month active monitoring period'.

A key recommendation of the person-based approach is the development of guiding principles to focus the design objectives and identify key components of the intervention to ensure that the objectives are met[212]. For the LittleEARS educational intervention I identified 5 guiding principles from the published and empirical evidence, and the promoting factors for implementation detailed in chapter 6. From this I mapped Behaviour Change Techniques (BCTs) to help meet these objectives.

8.3.3.2 Guiding principles for developing the educational intervention

<u>Guiding principle 1:</u> To help families understand the causes and natural history of glue ear, the active monitoring period and treatment options available (promoting coherence)

Providing families with a good background information about the topic and the treatment options available for their child in a clear and easy format was a key objective. The BCTs identified to meet this objective were '*information about health consequences'* and '*credible source'*[216]. I included sections on the causes of glue ear, the natural history of the condition, diagnosis and care pathways within primary care and the community. I included references to the latest evidence for treatment options, giving parents the opportunity of finding out more if they wanted to. Chapter 6 identified strategies to promote *coherence* including providing evidence-based information in a user-accessible format. I ensured that the educational intervention was written in plain English so it was widely accessible and had print out options for those patients with limited internet access or expressed preference for that method of information delivery.

<u>Guiding principle 2:</u> To help families engage with the active monitoring process (promoting cognitive participation)

A key to improving early management of children with glue ear in primary care is by ensuring that parents are aware of the care pathways for glue ear, and also understand that active monitoring is the appropriate early management for most children as it is self-limiting. Engaging with the active monitoring process is facilitated by a good understanding of the natural history of the disease, and the associated symptoms and awareness of the self-management options during this period. The BCT component identified to support this was also '*information about health consequences'*[216]. In the design of the educational intervention I included clear information about the symptoms and natural history of glue ear to ensure that parents could more reliably monitor their child's glue ear. I also included sections on self-management methods including how to help children hear better at home and in the classroom. This aims to actively involve parents in the child's early management and helps minimise the impact of hearing loss whilst waiting for natural resolution. Additionally it has the potential to help manage parental expectations during the recommended 3-month active monitoring period.

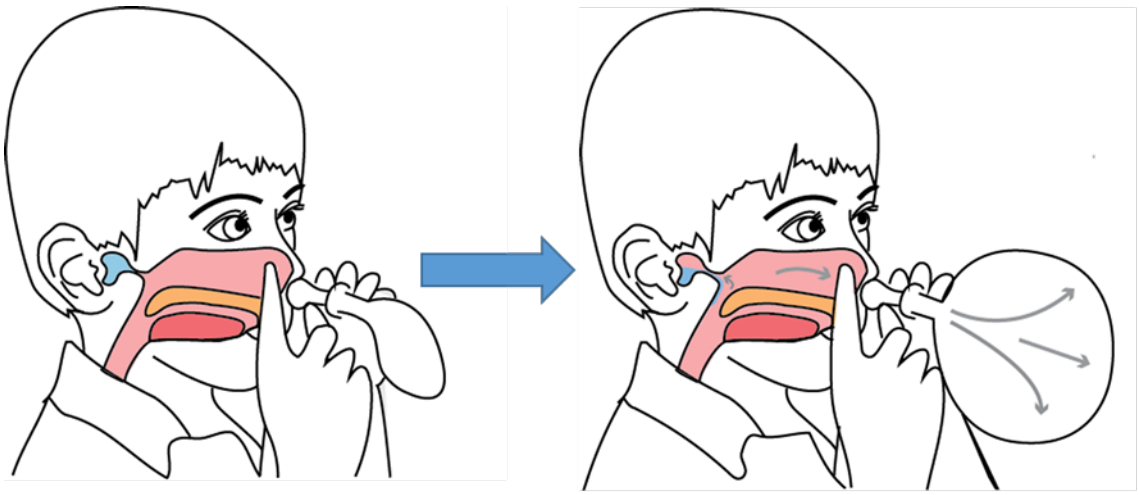
<u>Guiding principle 3:</u> To help families engage with the nasal balloon method (promoting cognitive participation)

As the nasal balloon method at the time of writing is a relatively unknown treatment option, it is important that parents identify the value and credibility of the treatment and the relevance to their child's health condition. The BCTs identified were '*credible source', 'information about health consequences', 'social reward'* and *'Information about other's approval'*[216]. I developed the LittleEARs educational intervention with sections describing the technique and evidence of the nasal balloon, together with some personal experiences from parents and children about using the nasal balloon (*cognitive participation*). The method requires a level of active cooperation by the child so I have included visual elements to ensure that children understand what is required of them and sticker charts to engage the children and encourage ownership of the treatment.

Guiding principle 4: To help children master the nasal balloon method (promoting collective action)

Nasal balloon autoinflation requires children to master the technique of inflating the balloon through their nose. This requires an element of demonstration and training, and feedback to ensure the balloon is inflated correctly. The BCT components identified were *'demonstration of the behaviour'* and '*verbal persuasion about capability'*[216]. I included diagrammatic instructions (Figure 23), detailed step by step instructions alongside a video to demonstrate the technique to families and children. The video draws on the emergent concepts from chapter 6 and previous qualitative work[3] which highlighted the importance of the triadic relationship between nurses, parents and children to help children try and master the technique of autoinflation. The video includes a nurse giving stepwise instructions of preparing the balloon and nozzle, pre-stretching the balloon, demonstrating to the parent and child, and finishes with a successful inflation of the nasal balloon by a 4 year old child.

Figure 23: Diagrammatic instructions for inflating the nasal balloon



Guiding principle 4: To support compliance with the nasal balloon over the treatment period (promoting collective action).

Supporting compliance with the nasal balloon requires continuing engagement with the treatment regimen and making the treatment part of the child's daily routine. The BCT components identified were '*prompts and cues'*[216]. Sticker reward charts are included in the educational intervention to help parents and children keep track of usage, and acts as a reward to children which in turn promotes engagement. Making the treatment part of the child's daily routine has been found to increase uptake and compliance, so details about how to include in the teeth cleaning routine, getting dressed and undressed routine, can help the treatment becomes embedded or routinised into the child's day.

Guiding principle 5: To help families know if the treatment is working and when to seek further help (promoting reflexive monitoring)

A key consideration for parents is how to know how long to continue treatment for, how to know if the treatment is working and how to know when to seek further advice. The BCT component associated with this was identified as '*self-monitoring of behaviour'*[216]. Included in the educational intervention is a symptom checklist of those most predictive symptoms of glue ear, a symptom diary to allow parents to record symptoms over a period of time, and access to an online hearing disability test (wTADAST-24) (chapter 7) for parents to monitor their child's hearing. In addition there is signposting to further information and advice about when to seek further help or support.

In summary, I identified a total of 5 guiding principles from the published and empirical evidence, and from the promoting factors for implementation detailed in chapter 6. Based on this I identified the components likely to help meet the intervention objectives and used these to outline the educational intervention.

8.3.3.3 Drafting of the educational intervention

Using the guiding principles to design and structure the educational intervention, I created a prototype draft using Microsoft Visio to describe the overall layout and navigation of this site and Microsoft PowerPoint to detail the content. This facilitated sharing and discussions with the other members of the research team.

The outline draft was then sent to the web developer (Mr Apostolos Tovletoglou) at iSolutions at the University of Southampton, who created a pre-production website using Drupal 7, an open source content management software programme. Drupal is widely used around the world for websites, internet forums and blogs, and is supported and hosted by the University system. I elected to use this platform as it was flexible enough to provide the overall structure that I wanted for the educational intervention whilst allowing me to retain editorial control of the menu structures, links and content. The Lifeguide software[220] developed by the University of Southampton would have also been a good platform for this educational intervention. Lifeguide enables the creation and evaluation of behavioural interventions without the need for extensive web development skills and has been widely used in Primary Medical Care for Behavioural Change Interventions. However it takes time and resources to learn such software and to develop an intervention, which I did not have as part of this PhD.

After the initial site was created with menus and sub-menus as specified in the original plan, I populated individual pages with content including written information, pictures and diagrams, video links (hosted privately on YouTube) and external links to other websites and sources of information. I retained complete control of the menu structures, links and content. iSolutions were responsible for site maintenance (updates and upgrades), structural, style and storage that required changes to html coding, and who also provided development support throughout.

Table 23 presents the initial structure and summary of the LittleEARS educational intervention.

Table 23: Structure and summary of LittleEARS educational intervention

Content of LittleEARS	*Behaviour change technique*	*NPT construct*
About glue ear (6 pages)		
Provides parents/carers with information about the causes of glue ear, the natural history, associated symptoms and how glue ear is diagnosed in the community.	**Information about health consequences** Information about the natural history of glue ear and evidence for using the nasal balloon during the watchful waiting period.	***Coherence***
	Credible source Information about glue ear and the nasal balloon given in video format by Dr Ian Williamson, GP[1].	***Coherence***
Self-help advice and information (3 pages)		
Provides information about what to do if a child has glue ear, how can they be helped to hear better and concentrate at home and at school, and how to recognise when to seek further help and advice. Printout information is available for teachers. A symptom diary also allows parents to monitor symptoms over the 3 month watchful waiting period.	**Information about health consequences** Information about self-help and monitoring	***Cognitive Participation***
	Habit formation Advice given to parents to make inflating the nasal balloon part of the child's daily routine like when cleaning their teeth.	***Cognitive Participation***
	Verbal persuasion about capability Parents are informed by video[1] that watchful waiting is the best option for children with glue ear and that nasal balloon autoinflation is a worthwhile treatment during this time.	***Cognitive Participation***
	Self-monitoring of behaviour Symptom diary to monitor symptoms of glue ear.	***Reflexive Monitoring***
Nasal balloon (4 pages)		
This section provides information, advice and instructions about how to use the nasal balloon, including a video with step by step instructions. A sticker chart is also available to allow parents/carers to monitor and remember to use the balloon.	**Social Reward** Sticker chart is provided for children as both a reward for inflation the nasal balloon and a reminder to keep to the treatment regimen of 3 times per day.	***Cognitive Participation/ Collective action***
	Prompts and cues Maintaining a sticker chart to remind them to use the balloon.	***Collective Action***

	Demonstration of the behaviour A video of a nurse and a child demonstrating the use the nasal balloon is included[2]. **Information about others' approval** Quotes from parents whose children have used the nasal balloon. Quotes from GPs and practice nurses about their experiences of prescribing the nasal balloon. **Verbal persuasion about capability** Difficulties with using the nasal balloon can be overcome with good demonstration and practice.	***Coherence*** ***Coherence/ Collective Action***
Other treatment options (2 pages) This section includes information about other treatments that are sometimes given to children with glue ear in primary care. Also discussed are surgical options for those with persistent bilateral glue ear.	**Information about health consequences** Information about other available treatments and outcomes.	***Coherence***
Next steps (1 page) This section gives parents information about how to monitor hearing, what to do if things worsen, or if symptoms return.	**Self-monitoring of behaviour** Symptom diary to monitor symptoms of glue ear. Hearing disability test to monitor impact of glue ear.	***Reflexive Monitoring***

[1] ***Information video about glue ear***

The information video is 2 mins in length and consists of Dr Ian Williamson providing some background information about the treatment and management of glue ear in primary care (https://youtu.be/XslCvLW29bk)

[2]***Demonstration video for use of the nasal balloon.***

The demonstration video is 1min 26 seconds in length and consists of a nurse demonstrating the nasal balloon technique to a mother and 4 year old child. The video gives clear stepwise instructions and also includes a clip of the child successfully inflating the nasal balloon following the nurse demonstration (https://youtu.be/dlDGiQ2rOt4)

Figure 24: Screen shot of LittleEARS educational intervention

8.3.4 Evaluating the educational intervention

The research was approved by Southampton University Faculty of Medicine Ethics committee on 21/04/2015 (Appendix E).

Following initial planning and drafting, a series of usability tests were undertaken to further develop and refine the educational intervention. Two complementary methods, namely 'think aloud' interviews[197] and retrospective feedback methods, were used to elicit views about the content and format of the educational intervention and evaluate user experiences and interactions with the intervention.

The 'think aloud' method has roots in psychological research and was developed from the early work of Ericsson and Simon[197] in 1980 who used a method of eliciting verbal reports from research participants. Think aloud studies involve participants, or users, verbalising their thoughts and actions as they perform a series of tasks or actions. This

gives an insight into their cognitive processes, i.e. not only what participants are doing, but also what they are thinking and feeling. The advantages of this method is that it is a quick and straightforward way to gather information and is particularly helpful to identify navigational issues and improve content of digital interventions. However, it is not a natural environment for the user i.e. being observed/recorded by a researcher and participants may not use the intervention in the same way as they would if they were alone. Technology now allows for remote user testing (e.g. Skype) which can be recorded and allow observation at a distance. This makes the environment more normal for the participants, however it was not possible in this project as it would have added to the complexity of the testing schedule and not considered necessary for the overall development of the LittleEARS educational intervention.

Retrospective interviews, where participants try the intervention alone and then give oral or written feedback, can complement the think aloud method[221]. It is a useful way to gain detailed information about user experiences of engaging with an intervention and thoughts about content but does not address the issue of usability to the same extent as the 'think aloud' method.

8.3.4.1 Qualitative think aloud interviews

Qualitative methods of think aloud interviews

Think aloud interviews were undertaken with a convenience sample of parent participants in two rounds. In the first round, parents of school-aged children were identified via email invitation to staff at Primary Care and Population Sciences, University of Southampton (appendix E). Three employees and one spouse took part in think aloud interviews lasting 45-60 mins at Primary Medical Care, Aldermoor Health Centre in December 2015.

The second round of the think-aloud interviews involved interviewing 5 parents of school aged children in their own home. Despite still not being a fully natural environment (as they were being observed by the researcher), it facilitated the use of the participants own devices for the test, in their home environment. Recruitment was through advertising on Facebook (Romsey News And Information Group with 1500+

local members, population of Romsey estimated 16,898 in 2015 (Office for National Statistics).

The purpose of the study was explained to the participants and written informed consent was received before the interview commenced. Baseline and demographic information was collected prior to the interview. The Single Health Literacy Question[222] was used to determine participants' health literacy. Participants received a shopping voucher to thank them for participating in the study.

All round 1 and 2 interviews were digitally audio-recorded using a hand held recorder (Olympus DM-650). During the interview participants were asked to verbalise their thoughts as they used the educational intervention. Prompts were used to elicit responses if appropriate (e.g. what do you think about this page? what made you choose that option?). At the end of the test session, participants were also asked about their overall views about content and ease of navigation, and were asked to comment on things that could be improved or added and their perceived usefulness of the intervention.

Small incremental changes were made to the educational intervention after each interview (e.g. minor layout issues, simplification of language) and larger changes were summarily made at the end of the round 1 (e.g. order of content, navigational changes). All changes and modifications were then tested in round 2 of the intervention development, after which minor amendments were made to create the final version. This process can be described as an iterative cycle which moves back and forth between feedback and testing.

Analysis of the think aloud interviews.

I transcribed the first 3 interviews to ensure I became familiar with the data and then used professional transcribing services (Joe McGowan Transcriptions) for the remainder of the recordings. The interviews were transcribed verbatim and the transcripts checked against the original recordings for accuracy, and to ensure that all identifiable data had been anonymised. Once this process was complete the audio recordings were destroyed in accordance with the ethics committee approval. Data

were managed using NVivo10, a computer assisted qualitative data analysis software package.

The data was then analysed using thematic analysis[151], a flexible method for identifying, analysing and reporting patterns within a data set that can be applied across a range of theoretical and epistemological approaches. Braun and Clarke described six phases of thematic analysis, presented in Table 24.[151]

Table 24: Thematic analysis of think aloud studies

Thematic analysis
Stage 1: Familiarisation with the data The first stage of thematic analysis involves familiarising and immersing yourself in the data, by listening to the auto-recordings and multiple readings of the transcripts. Additional notes are made at this stage to note any observations or interpretations.
Stage 2. Generating initial codes Coding is a method of reducing data whilst capturing both the semantics and concepts of the data itself [149]. This process can be carried out either inductively, where codes stay close to the original data, or deductively, where an existing coding framework is applied to the data (or a combination of both). This think aloud study aimed to improve usability and therefore I developed a coding framework to answer questions about content and navigation, relevancy and usefulness of the intervention. I then systematically coded the interviews according to the coding framework. Multiple coders maximise the reliability of qualitative results, however due to time constraints this was not done for this study.
Stage 3 – Searching for themes Codes were refined and then grouped into broad themes. In this case, themes were guided by *a priori* knowledge and a clear idea of the question that needed answering. In addition, extracts of the data were noted for whether they were positive about the intervention, or where they identified problems or suggestions for improvement.
Stage 4 – Reviewing themes The themes were then reviewed at the level of the original coded data extracts to ensure that they were a true representation of the data and that they were thought to form a coherent pattern [151]. When this was achieved, the themes were reviewed in the context of the whole dataset to ensure they fitted together and provided a meaningful story about the data.
Stage 5 – Defining and naming themes The themes were then defined to conceptualise the theme and to represent what each was telling about the data set.

Stage 6 – writing up

Finally each theme was described in relation to the research question and the existing literature. This involved integrating the original data extracts within each theme to represent the meaning of the data.

Quality and reflexivity

The reliability of the think aloud protocol is based on being systematic with the approach to the method, transparent with the study process, and reflexive in the reporting of the study findings. During this study I maintained a meticulous audit trail for data collection, coding and analysis ensuring that the research was transparent, consistent and reproducible[145].

I attempted to ensure that the environment was as natural as possible during the round 2 interviews, conducting the research in the participants' homes and on their own devices. One participant had 2 small children at home which disrupted the interview to some extent, but this gives a picture of the actual environment in which the final educational intervention may be used.

Almost all of the participants verbalised their thoughts well during the study; only one appeared to be slightly uncomfortable with the process despite reassurances from me. This discomfort is a potential disadvantage with this type of research, and is quite difficult to ascertain prior to the interview. However, overall I managed to collect very useful data.

Reflexivity is the acknowledgement that researchers bring their own preconceptions to the research study, including personal perspectives, beliefs and motivations for conducting the research [147]. In this study I recognise that as the author of the educational intervention that I had presumptions about how the intervention would be used and what parents would find interesting and useful. To improve the trustworthiness of the results I worked with an experienced member of my research team to evaluate the codes and interpret the results.

8.3.4.2 Expert panel feedback

An expert panel of 3 GPs, 1 health psychologist, 2 practice nurses and 1 audiologist reviewed the educational intervention in their own time and gave retrospective feedback either in person or by email of the final version of the educational intervention (after the think aloud interviews). Retrospective interviews may have given a more detailed and thorough insight into their views and experiences, however, I was limited by time and financial resources as part of this PhD project and I considered that oral or written feedback was sufficient in combination with the parent think-aloud interviews. GPs and nurses were identified via email to GPs and nurses who had participated in the AIRS study. The audiologist and health psychologist were identified through personal contact.

A link to the educational intervention, with login details, was sent to each participant via email. Participants were asked to comment on the questions presented in appendix E. Feedback was provided within 2 weeks to reduce recall bias.

The results of this feedback were summarised and compared with the results of the think-aloud interviews, providing user feedback from the different stakeholders.

8.4 Findings

8.4.1 Sample Characteristics – think aloud study

Nine think aloud interviews were undertaken either at Primary Medical Care, Aldermoor Health Centre (AHC) (n=3), Southampton General Hospital (SGH) n=1 or the participant's home (n=5).

Table 25: Sample characteristics for think aloud interviews

	Recruited from	*Sex*	*Children*	*Length of interview (mins)*	*Highest qualification*	*Place of Interview*
1	University	M	Child with glue ear (and grommets)	59	Degree	AHC
2	University	F	School-aged children (<7 years)	69	Post-doctoral degree	AHC
3	University	F	School-aged children (<7 years)	58	Degree	AHC
4	University	F	School-aged children (<7 years)	73	Post-doctoral degree	SGH
5	Facebook	F	Child had glue ear. No grommets	24	Degree	Home
6	Facebook	F	Daughter with glue ear	50	Degree	Home
7	Facebook	F	Child had glue ear. Now has grommets	31	Degree	Home
8	Facebook	F	Has 6 year old at school. Eldest child had glue ear	Not recorded	GCSE/O' Level	Home
9	Facebook	F	Child with previous ear problems (participated in AIRS)	62	GCSE/O 'level	Home

The sample contained a range of parents (1 father and 8 mothers) with good health literacy and a range of socio-demographics. No participants were included with poor health literacy, although one participant reported being dyslexic. Social media

(Facebook) was a particularly effective and efficient way of reaching participants for the study.

8.4.2 Sample Characteristics - expert panel

Seven healthcare professionals reviewed the educational intervention in their own time and provided written or oral feedback to the study team by email (Table 26).

Table 26: Sample characteristics for the expert panel

Participant number	*Sex*	*Profession*	*Location*
1	M	GP	Hampshire
2	F	GP	Hampshire
3	F	Health psychologist	Hampshire
4	F	Nurse	Berkshire
5	F	Nurse	Oxfordshire
6	M	GP	Buckinghamshire
7	F	Audiological scientist	Hampshire

8.4.3 Main findings

8.4.3.1 Developing and refining the educational intervention

Table 27 presents the main changes made to the educational intervention during and following the two rounds of qualitative think-aloud interviews. Minor changes to layout, navigation links, terminology and grammar were made as the interviews progressed, and major changes were made after each round.

Table 27: Summary of major changes after think aloud interviews.

Topic	*Summary of changes*
Home (1 page)	No major changes
Glue ear (6 pages)	• Symptoms were divided into sections of those most common (hearing loss and ill health) and those less common (persistent glue ear – speech, language, behavioural problems) • Preventing glue ear: Breast-feeding decreases the risk of children getting glue ear but is not a factor that could be changed for the individual child. This information is retained but moved to the section 'how common is glue ear?' • Links were added to the NHS childhood vaccination programme. • Diagnosis section: individual tests were described in terms of what the child would experience when taking the test rather than solely on how the test works.
Self-help (3 pages)	• The self-help section was renamed from watchful waiting to self-help, which more accurately described the section. • Mention of the nasal balloon was removed from this section and moved to its own section. • Lip-reading was removed as a sub-page and instead information included in the main page to improve navigation.
Nasal Balloon (4 pages)	• Nasal balloon autoinflation introduced and described first in this section. • Added details about who the treatment was suitable for and when the balloon should not be used. • Instruction video made more prominent and earlier on in the section. • Downloadable instructions removed as caused confusion as to whether different information to that on the screen.
Other treatments (2 pages)	• 'Other treatments' were moved to their own section and information separated into non-surgical and surgical treatments. • Grommet surgery section simplified as generally considered to be too much information and most children would not reach that stage. • Small section added about adenoidectomy • Hearing aids were redefined as temporary hearing aids for clarity.
Next steps (1 page)	• No major changes
Quick links (7 pages)	• No major changes

8.4.3.2 **Thematic analysis of think aloud interviews**

Thematic analysis of the think-aloud interview transcripts identified two main themes: i) content – comprehensiveness, relevancy and usefulness, and ii) layout/navigation:

how easy was the intervention to use? Quotations illustrating the themes of content and layout/navigation of the intervention are presented in Table 28.

Theme 1: Content of the educational intervention: how comprehensive and relevant was the intervention?

This theme describes the content of the educational intervention with respect to its comprehensiveness and coherency, its relevance to the end-user, and whether the content gives a consistent message throughout the intervention.

1.1: Comprehensiveness and coherency

Parents described the educational intervention as clear and concise, with the right amount of information which was pitched at the right level for parents of children with glue ear[1a]. However, some sections were described as being *too technical* and suggested that medical jargon should be avoided, or explained further to make it more accessible for a wider audience[1b].

Some sections were described as not giving a consistent message about what to do or expect with a child with glue ear, and this had the potential for causing confusion for parents[1c]. However, in general parents described the elements of the educational intervention as reassuring, and reinforced that watchful waiting was the best option for children at the early stage[1d].

Some parents offered suggestions about how to improve coherence of the educational intervention. These included clarifying terminology, simplifying content and instructions, and making the main message both clear and consistent throughout.

1.2: Relevance and usefulness

Parents described the educational intervention as a useful and practical resource for families of children with glue ear. Diagrams were described as being 'really helpful' to facilitate understanding of the condition, although a clearer comparison of a normal ear with a glue ear would enhance understanding[1e]. Parents liked the description of associated symptoms and potential treatment options. Symptom lists were described as relevant and helpful to allow parents to monitor their child's glue ear. Parents also

liked to understand what treatments were available for glue ear and the benefits and harms of the different options[1f]. Information for teachers was described as useful and many participants thought they would use it to inform their child's teacher of glue ear[1g].

The nasal balloon instruction videos were described as very useful with just the right level of instruction and overall length to retain attention[1h]. However, the NHS Choices video, which was embedded in the educational intervention, was considered to be too long and contained too much information about grommet surgery which was not considered relevant for the majority of parents/children.

Downloadable sticker reward charts were described as a particularly useful resource for parents to aid compliance with the nasal balloon[1i].

Some sections were considered less relevant to families, such as the section describing the diagnostic tests, but this depended on the individual children and how long they had been affected by glue ear[1j].

1.3: Main messages of the educational intervention

Parents described three key messages that they understood from the educational intervention: i) watchful waiting is the best management strategy for most children with glue ear as the condition clears up on its own in the majority of cases, ii) nasal balloon is an evidence-based treatment option during this period, iii) if you are particularly worried about your child, you can go back to see the GP when needed, rather than waiting until the end of the 3 month recommended monitoring period.

In summary, the content of the educational intervention was considered to be clear and concise, relevant and useful for families, but with suggestions about how to simplify some areas of content, and ensure the main message is consistent throughout the site.

Theme 2: Layout and navigation: how easy was the educational intervention to use?

Parents liked the overall presentation and layout of the site. The use of colour and images were considered appropriate for such an educational intervention. The

typeface was described as easy to read, with not too much writing on each page. The use of bold typeface was described as useful to draw attention to important issues or facts[2a].

The general order of the information provided in the site was described as logical although some suggestions were made about making certain information more prominent on a page, or come in an earlier section[2b].

The overall structure of the site was described as clear and simple. However, there was some confusion over navigation between pages and around the site. The site has a menu tab across the page, and also links between pages at the bottom of each page and parents weren't always certain about which ones to use. Parents were asked to use the site how they would if they were on their own, and consequently some parents followed the navigation buttons at the bottom to ensure they didn't miss anything, whilst others used the menu bar to quickly navigate to the area of interest[2c]. Occasionally pages or sections were missed by participants, due to navigation problems, but these were rectified as they were identified and did not cause an issue in subsequent interviews.

One of the main suggestions for improvement of navigation included opening of hyperlink pages or downloads in a new rather than the current tab. Opening in the current tab caused problems with parents unable to find the way back to the launch page, or inadvertently closing the web browser.

In summary, the interviews highlighted several issues that were addressed and participants managed to navigate well through the educational intervention, quickly getting used to finding their way around the site and locating the information that was most relevant to them.

Table 28: Quotations illustrating themes from the think aloud interviews

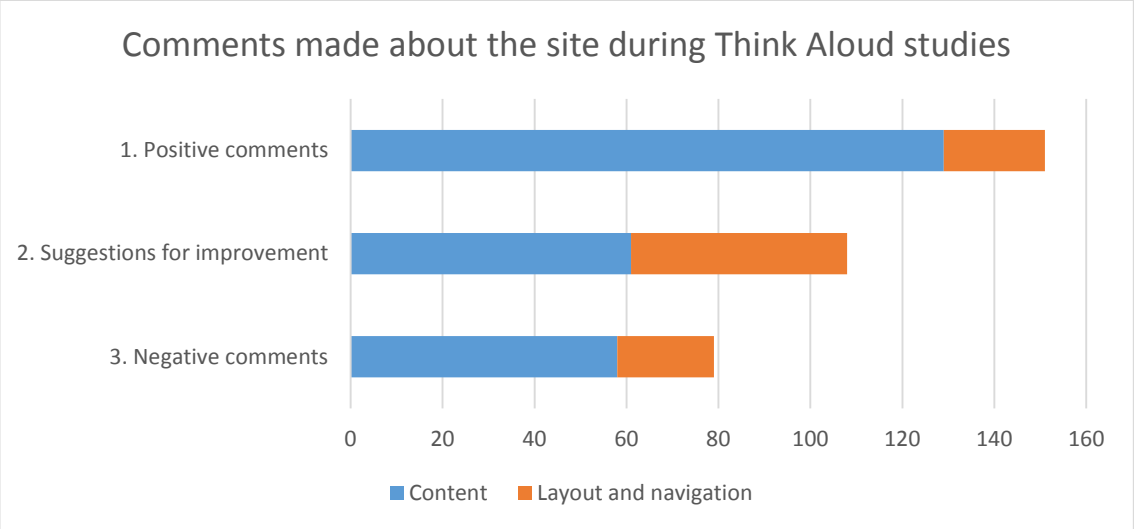
Comprehensiveness and coherence	*[1a]P9: It is really straightforward. To the point. There are no words that don't need to be there.*
	[1b]P5: There are a lot of medical words. Some people get confused.
	[1c]P4: On one hand you are clearly saying will clear up on its own, no treatment, but then you are saying there is a treatment!
	[1d]P3: There isn't any evidence for other treatments that work and these ones do have side effects so you are better off doing the watchful waiting and the nasal balloon. That was the message I got.
Relevance and usefulness	*[1e]P2 yes I think it was useful to picture what we were talking about – it being just behind the eardrum. Helps make this a bit more sense.*
	[1f]P2 and I think in my head, what should I be looking out for? And I think the way that it is written – is it immediately speaking to me? Ok this is what I need to look for.
	[1g]P5: Teachers obviously spend a lot of time with the children. You don't want them thinking that they are just ignoring you.
	[1h]P9: There is nothing better than actually seeing someone physically doing it, rather than just reading instructions.
	[1i]P5: and it would be good for me too with 4 children remembering when they had done it. It would be useful for me.
	[1j]P8 if I had a child who was not being referred for that particular test I would have probably or possibly looked over it, or if it is something they have already had and I knew what it is about I would have probably skimmed over it.
Theme and layout	*[2a]P7: I really like it. It is really nice and easy to look at. Not too crowded. Not too busy. There is not too much information on any given page or slide.*
	[2b]P3: I think it needs to come sooner on the page but I think as I said, you mentioned the nasal balloon and I had no idea what it is!
	[2c]P4: I saw the menu up there at the beginning and was maybe tempted at times to go and see what was around. Because I am working through it, my instinct is to go this way. But it is confusing.

8.4.3.3 Classification of comments made during the think-aloud studies

As NVivo was used to manage and code the data from the think-aloud studies, it was possible to make a count of the type of comments that participants made (see Figure 25). This method was described in a report of the development of an asthma internet self-management intervention[223] and I considered it to be useful and relevant to this study to identify whether participants in this study engaged with the testing process.

45% of the comments by parents overall were positive suggesting that participants liked the content and layout of the educational intervention. 23% of the comments were negative which suggests that participants felt able to criticise the site during the think-aloud interviews, and weren't just saying things to please the researcher. 32% of the comments were suggestions for improvement of the site meaning that participants engaged well in the usability testing and understood what was required of the testing process.

Figure 25: Comments made during Think Aloud studies (n=9)



8.4.3.4 Expert panel review

Overall the expert panel liked the LittleEARS educational intervention, describing it as *informative*, *easy to navigate* and *patient friendly* and thought it would be useful and valuable in clinical practice.

The content was described as *pitched at the right level* for most patients, although in some areas the language used was considered to be too academic, and that plain English[224] should be used. The site was described as containing good factual knowledge, clear instructions, useful videos and downloadable diaries and reward charts. One participant thought it would be useful to have a video of a mother and child speaking about their experiences and success with the nasal balloon. Unfortunately there was no time to film this and include in the final version, but this is a consideration for the future.

Most participants liked the layout of the site, and no problems were reported with navigation.

Participants described a potential value of the educational intervention to patients and their practice. One participant expressed a view that "*patients who understand more about their conditions are more likely to comply with treatment*" and LittleEARS was seen as being able facilitate this. Other participants described the value of presenting watchful waiting in a positive way. *"parents often don't see watchful waiting as a time of proactive management"* and other parents *"demand treatment straight away"* so it is valuable to have self-help things to do at home or at school during the watchful waiting period.

8.4.3.5 Final contents and structure of the LittleEARS educational intervention

Table 29 summarises the final content of the LittleEARS educational intervention. The final layout and additional content can be found in appendix E.

Table 29: Final contents of the educational intervention

Topic	*Summary of content*
Glue ear (6 pages)	Provides parents/carers with information about the causes of glue ear, the natural history, associated symptoms and how glue ear is diagnosed in the community *(promoting coherence)*
Self-help (3 pages)	Provides information about what to do if a child has glue ear, how they can be helped to hear better and concentrate at home and at school (*promoting cognitive participation*), and how to recognise when to seek further help and advice. Printout information is available for teachers. A symptom diary also allows parents to monitor symptoms over the 3 month watchful waiting period (*promoting reflexive monitoring*)
Nasal Balloon (4 pages)	This section provides information, advice and instructions about how to use the nasal balloon, including a video with step by step instructions (*promoting cognitive participation and collective action).* A sticker chart is also available to allow parents/carers to monitor and remember to use the balloon (*promoting reflexive monitoring*).
Other treatments (2 pages)	This section includes information about other treatments that are sometimes given to children with glue ear in primary care. Also discussed are surgical options for those with persistent bilateral glue ear *(promoting coherence and cognitive participation)*
Next steps (1 page)	This section gives parents information about how to better monitor hearing, what to do if things worsen, or if symptoms return (*promoting reflexive monitoring*). This section includes links to the wTADAST-24 hearing disability test*.
Quick links (7 pages)	The quick links section gives quick access to the wTADAST-24 hearing test*, videos and print sheets and links to other external useful information.

**The final intervention contains links to the wTADAST-24 hearing disability test which is hosted on a different site at the University of Southampton (www.hearingtest.soton.ac.uk). The wTADAST-24 was not evaluated as part of the think aloud protocol as the hearing test has been developed for children, and it was the parents alone who took part in the think aloud interview. Additionally, the wTADAST-24 has already been evaluated for usability during in-house testing, and with a group of school children (chapter 7). The hearing test can, however, be accessed easily by clicking the link in the educational intervention and the hearing test opens in a new webpage. After the test has been taken, the users can return directly to the educational intervention.*

8.5 Discussion

8.5.1 Summary

The LittleEARS educational intervention has been developed using empirical evidence, expert knowledge, and user feedback, underpinned by implementation theory and elements of the person-based approach, to support parents of children with glue ear in primary care and the community. The Normalization Process Theory identified key areas to promote or inhibit implementation which led to the development of guiding principles to focus the design objective and identify key components, or Behaviour Change Techniques[216], to address the main objectives of the intervention.

Feedback from the parent interviews helped to improve and refine the intervention. They described it as useful and relevant, and reported that it provided comprehensive information about glue ear, the treatment options available, and practical advice about self-help and use of the nasal balloon. Healthcare professionals, including GPs, nurses and audiologists, agreed that the educational intervention was coherent, comprehensive and relevant to their patient population and considered it to be a potentially valuable resource for use in practice.

8.5.2 Comparison with existing literature

Printed information leaflets were the mainstay of providing patient information prior to the digital age. They can facilitate consultations by increasing patient knowledge about their health condition, and promote the understanding of treatment options and self-management[225]. They are relatively cheap to produce, but their effectiveness is variable between health conditions[226]. They also only provide generic information with little ongoing support for patients. However, a recent study of parental perceptions and understanding of information provision in the treatment of children with glue ear found that parents valued supplementary printed information to support the information given during the consultation[65]. Parents in this same study also reported using the internet to clarify or supplement information given by the healthcare providers, suggesting that there is a need for good quality, accessible online information and support for families of children with glue ear.

Digital interventions can provide tailored, individualised support to patients with the possibility of reaching a wide appropriate population[227]. They have become more common, as access to the internet has become widespread, and are available for a wide range of topics and health conditions. Their effectiveness to promote behaviour change has been reviewed in a meta-analysis of 85 web-based behaviour change studies[228]. The results showed that the digital interventions had a small but significant beneficial effect on health behaviours. Such strategies have already been developed and are widely used in self-management of asthma[229]. Asthma is pertinent as it is another common chronic intermittent childhood respiratory condition, but where educational interventions have been demonstrated to reduce morbidity and reduce the utilisation on health resources in both children and adolescents[207]. The key ingredients of most of the asthma self-management interventions are *provision of information* and *self-management education/advice*. A digital educational intervention has the potential to provide such support and advice to families of children with glue ear, to promote engagement with the active monitoring period, and encourage wider use of the nasal balloon.

There are currently two main websites providing patient information about glue ear in the UK which appear to be commonly recommended by GPs (www.patient.co.uk and www.nhs.uk/conditions/glue-ear). Whilst they provide evidence-based information for families, they contain little information or instruction about the nasal balloon, and limited direction about self-help and self-monitoring of glue ear in primary care and the community. The LittleEARS educational intervention uses novel videos and pictures providing the first detailed demonstration and stepwise instructions for use of the nasal balloon. This contrasts with the range of videos currently available on the internet which give mixed messages and unclear instructions about usage of the nasal balloon.

The question remains about accessibility of such an intervention, and the qualitative work presented in chapters 5 and 6 highlighted potential inequalities of access to both the internet and to the usage of the nasal balloon. The internet is used in all aspects of public, private and work life today with 82% of the population in the UK currently use

the internet daily or almost every day compared to just 35% in 2006[230]. However there are sectors of the population who either do not have access or do not have the necessary skills to use the internet, and are therefore considered to be digitally excluded[231]. Factors such as age and socio-economic status contribute to this 'digital divide'. Older people are more likely to have never used the internet (32% aged 65+) compared to only 1% of those under the age of 35[232]. Social disadvantage, as described by lack of any formal qualifications affects access to the internet, with 55% of those with no formal education never using the internet compared with only 2% of those educated to degree level.[232] Staying with the traditional methods of delivering patient education and behavioural interventions in healthcare such as face-to-face consultations and printed information leaflets, could potentially help to mitigate this digital exclusion but deprivation and poor health literacy is also associated with poor access to GPs and engagement with primary care services.

With the ever-increasing pressure on healthcare resources, digital health interventions offer an additional useful complementary route of delivering healthcare and promoting self-management to the majority of patients. In the case of families with children with glue ear, the age demographic suggests that most parents will have some form of access to the internet. The LittleEARS educational intervention is available to access on a range of digital platforms such as mobile devices, laptops and computers, increasing accessibility for parents.

8.5.3 Strengths and limitations

The development of this educational intervention followed guidance from the MRC framework for developing a complex intervention using published and empirical evidence, underpinned by implementation theory and elements of the person-based approach to ensure end-user involvement throughout the process. Using a theory-based approach substantially improves the likelihood of wider implementation in real-world settings[130].

Think-aloud interviews were successfully used to refine and test usability of the site, and the number of comments and suggestions made during the interviews indicated

that the parents were engaged in the process of developing and improving the intervention. However, parents were not recruited from primary care, where this educational intervention is likely to be most widely used, which is a potential limitation to the study. However, all of the participants were parents of school-aged children and most of the participants had children with either a history of or current OME.

The expert user panel also provided a useful perspective from the position of healthcare provider. However, it was not possible to fully implement the person-based approach throughout the intervention development due to time constraints, and limited financial resources. Retrospective interviews with a wider base of healthcare providers would have given a more detailed feedback than oral and written communication provides.

As the researcher who developed the educational intervention, I also undertook the think aloud interviews and had direct contact with the expert panel. There were benefits to this in that rapid changes could be made to the intervention during and after the interviews. However, I recognise that my preconceptions and presumptions may have influenced the outcomes of this development. Efforts were made to improve reliability by ensuring the study was undertaken methodically and transparently, in collaboration with the rest of the research team, through constant discussion and communication.

8.5.4 Description of the final intervention using the TIDieR checklist

The reporting of healthcare interventions are commonly incomplete or not described in sufficient detail with which it can be replicated. The TIDieR guidelines[233], published in 2016, was developed through expert consensus, to improve the reporting of interventions, and also guide the development of future interventions. I have described, here, the LittleEARS Educational Intervention according the TIDieR standards, to assist in the reporting of my work.

Table 30: TIDieR Checklist for the LIttleEARS Education Intervention

Checklist item	***Description***
1. Name	LittleEARS educational intervention
2. Rationale	The LittleEARS educational intervention is designed to promote wide implementation of nasal balloon autoinflation in children with OME by: - Providing evidence-based information in an easily accessible format to parents of children with a recent diagnosis of glue ear in primary care and community settings. - Providing support and advice to encourage self-management of glue ear in both home and school settings. - Providing practical support for uptake and use the nasal balloon method for up to 3 months.
3. Materials	The intervention consists of the following sections: 1. Information about glue ear (6 pages) 2. How to help monitor and manage children with OME (3 pages) 3. Demonstration and usage of the Otovent nasal balloon (4 pages) 4. Information about other available treatments (2 pages) 5. Next steps – what to do if concerns remain about a child's hearing (1 page) Full details are presented in Table 23 and section 8.4.3.5
4. Procedures	The LittleEARS educational intervention combines background information about glue ear, with ways to help monitor and manage children with OME during the 3 month recommended active monitoring period. It also supports the uptake and usage of the Otovent nasal balloon during this period.
5. Intervention provider	The LittleEARS educational intervention has been co-developed with GPs, topic experts, researchers and end-users (parents).
6. Mode of delivery	Internet based designed for independent use.
7. Location	The intervention is designed to be used by parents independently in the community. The intervention can be used on mobile phones, tablets and computers.

8. Usage	The intervention is designed to deliver all of the information and instruction on a single visit, but allows parents to log back again in the future if required.
9. Tailoring	The intervention is designed for parents of primary school-aged children (4-11 years). No tailoring of the intervention was built in to the intervention.
10. Modifications	Modifications and refinements were made throughout the iterative development of the intervention. The final version from the development was used in the feasibility study (chapter 9).
11. Assessment/extent of adherence/ fidelity	Usage of the LittleEARS educational intervention and uptake/compliance with the nasal balloon method will be evaluated in the feasibility study (chapter 9).

8.5.5 Implications for practice.

The aim of the educational intervention was to support better early monitoring of glue ear in primary care and encourage uptake of the nasal balloon treatment during the active monitoring period, with the potential to reduce the associated detrimental effects of conductive hearing loss in school-aged children. This developmental work has resulted in an evidence-based resource which is widely applicable to the primary care setting. It could be used to support the information provided during the GP or nurse consultation, and offer parents self-help advice during the active monitoring period, whilst waiting for natural resolution or any onward referral to ENT. Additionally it has potential for use in community audiology or classroom settings where glue ear is commonly first identified.

8.6 Conclusion

This chapter has described the pragmatic development of LittleEARS educational intervention using evidence from the literature, qualitative enquiry, expert knowledge, and user feedback, to produce a resource that is considered acceptable, comprehensive and useful to parents. Using theory to underpin the development ensured that appropriate components were included that were most likely to promote wider implementation of nasal balloon autoinflation in real-world settings. Usability testing was carried out by parents of school-aged children and this ensured that the resource was relevant and accessible to the target user group. The next step is to evaluate the educational intervention with families of children with glue ear in a feasibility study.

Chapter 9: Feasibility study of the LittleEARS educational intervention to support nasal balloon autoinflation in primary care and audiology.

9.1 Introduction

The previous chapters in this thesis provide the foundation for evaluating the LittleEARS educational intervention to support management of children with glue ear and implementing the nasal balloon treatment more widely in primary care. Chapter 2 presented key aspects of the condition of glue ear including epidemiology and risk factors, impact on children and their families and current challenges to diagnosis, treatment and management. Also highlighted were the concepts of active monitoring/watchful waiting, with specific relevance to the potential use of nasal balloon autoinflation during this period. Chapter 5 identified particular challenges for GPs when diagnosing glue ear and when deciding which children to refer and which children can be managed more appropriately in primary care. This chapter also explored GP views about the use of the nasal balloon and its potential use within the context of available resources and local guidelines. Chapter 6 explored potential promoting and inhibiting factors to wider implementation of the nasal balloon method from the perspectives of both parents and healthcare professionals. A further development and evaluation of the wTADAST-24 hearing disability test was presented in chapter 7, to provide a more objective near-patient test of hearing disability to identify and monitor children with OME related hearing loss. This body of work used appropriate methodology (chapter 4) and was underpinned by implementation theory (chapter 3) and has been used to inform and guide the development of the LittleEARS educational intervention, presented in detail in chapter 8. This current chapter presents the next stage in the implementation process which involves evaluating feasibility and acceptability of the educational intervention in supporting a desirable active monitoring period and facilitating improved uptake of the nasal balloon in children with OME at the point of need.

9.2 Aims and objectives

The aim of this study was to assess the acceptability and feasibility of the evidence-based LittleEARS educational intervention in parents of children with glue ear.

The study objectives were as follows:

- To assess the degree to which parents find the proposed educational intervention to be acceptable, usable and relevant during a 3 month active monitoring period using self-assessment.
- To assess the uptake and actual use of the nasal balloon treatment in this sample population using parent-reported usage.
- To explore the acceptability and feasibility of using the wTADAST-24 for case-finding of children with OME in primary. This was done by measuring levels of uptake and usage of the online hearing test, and by evaluating the range of test scores in this screening population of children with parent-reported hearing difficulties compared to a normative population.
- To explore the feasibility of using the wTADAST-24 to monitor symptoms in children with OME in primary care and audiology by measuring the uptake and usage of the wTADAST-24 and evaluating difference in test scores before and after the 3 month active monitoring period.
- To evaluate the change in OMQ-14 test scores after 3 month active monitoring compared to baseline and to facilitate further validation of the test as a measure of ear-related quality of life in OME trials.
- To explore recruitment, uptake rates and follow up rates for the educational intervention in different community settings (primary care and paediatric audiology).

9.3 Methods

9.3.1 Study design

A feasibility study was selected as the most appropriate method to progress the concept of more supported self-management in primary care. Feasibility studies are necessarily exploratory and designed to determine whether a main study or useful future research can be done, and also whether an intervention is appropriate for

further testing[234]. Reasons for conducting a feasibility study may be to develop and evaluate research instruments; establish a suitable recruitment strategy; determine likely response, uptake, adherence and follow-up rates; and determine estimates of important outcome parameters. This contrasts with pilot studies that are defined as a smaller version of a planned main study, designed to test individual components and processes such as recruitment, randomisation, treatment and follow-up. They may also include a preliminary assessment of the primary outcome. I selected a feasibility study as the design for this evaluation as it seemed the most appropriate way of exploring acceptability and the practicality of delivery of the educational intervention, including response rates and uptake of the educational intervention and the nasal balloon treatment and use of the OMQ-14 and wTADAST-24 hearing test which may be used to assess and monitor hearing disability.

9.3.2 Ethical and research governance approvals

The study was reviewed and approved by the South Central – Hampshire B Research Ethics Committee on 30th November 2015 (appendix F). I attended the ethics committee meeting to answer any questions that arose. Further clarification was requested concerning the participant information sheet (PIS) and also importantly how I planned to ensure children were not delayed in accessing care if their condition worsened. I made minor changes to the PIS to ensure clarity of information and confirmed to the committee that parents/carers would be sign-posted on the website if they were particularly concerned about their child's hearing or progress.

The study was then reviewed by the lead CRN research governance office (CRN Wessex). Subsequent research governance approvals were received for independent contractors (GP surgeries) in Hampshire, Dorset, Wiltshire, Swindon, Oxfordshire and Gloucestershire to act as Participant Identification Centres for the feasibility study.

Local governance approvals proved more difficult to obtain for the audiology departments based in secondary care. Portsmouth Hospitals NHS Trust took 6 months of correspondence and negotiation to finally obtain approval, causing very long delays to the start of recruitment. In addition, seeking approval at Salisbury NHS Foundation

Trust was also subject to delays as it coincided with the introduction of the new HRA approval system in March 2016, delaying the start of recruitment in Salisbury audiology by more than 2 months.

9.3.3 Settings

This feasibility study was set both in both primary care and paediatric audiology, the two settings where the nasal balloon is considered particularly timely as an intervention.

Primary care is often the first point of contact for parents who are concerned about their child's hearing and therefore is a setting where the nasal balloon treatment is likely to be used. Recruitment of children for the AIRS study[2 3] was successful in primary care, with 30% of symptomatic children attending for screening found to have middle ear effusions. The nasal balloon treatment was also found to be effective in this cohort of children. I therefore consider primary care to be an appropriate setting for this feasibility study and recruitment methods have already been tested.

Paediatric audiology is also a potential setting for this study. It is recognised, however, that children presenting to audiology clinics may have a more severe or chronic hearing condition but nonetheless could still be appropriately managed with active monitoring in accordance with the NICE guidelines for surgical settings.[35] Additionally the nasal balloon has been shown to be also effective in several secondary care studies.[60] I consider audiology as an appropriate setting for this feasibility study due to the potentially large numbers of children attending with conductive hearing loss who may be eligible for the study.

Another potential setting for the study could have been primary schools. Glue ear is very common in 4-6 year old children[8], and hearing losses associated with glue ear often come to light in the classroom. However, I considered that there may have been some difficulties linking parents/children to a GP practice who were participating in the study, so I decided not to try and recruit children from this setting for this study.

9.3.3.1 Identifying GP practices

General practices were identified in Hampshire, Wiltshire, Dorset, Gloucestershire and Oxfordshire with help from the CRNs, and by personal contact. The networks in Wessex and West of England were asked to identify practices with a range of socio-demographics in an attempt to achieve a diverse sample for the study. I selected practices from a range of locations and different practice sizes, and included 7 practices who had previously participated in the AIRS study who I knew to be research active and also familiar with the nasal balloon method. I attempted to include practices from areas of higher social deprivation as a result of the findings from the qualitative work which suggested that GPs perceived family engagement with nasal balloon autoinflation may be inhibited in lower sociodemographic groups (chapter 6). I asked the CRNs to identify potential practices with a range of socio-demographics, however, no practices appeared currently available for participating in the study during the required time period.

9.3.3.2 Identifying Community Audiology Centres

I approached the paediatric audiology service at Portsmouth NHS Hospitals Trust through personal communication with Rosemary Scott, Audiological Scientist. The department has limited experience with recruitment to NHS trials but completed their Good Clinical Practice training and agreed to act as a Participant Identification Centre (PIC) for the study. Salisbury NHS Foundation Trust was contacted directly by Professor Mike Moore. The paediatric audiologists were already trained in GCP and research methods and agreed to act as a PIC for the study.

9.3.4 Participants

Study participants were defined as parents or carers of children with a recent diagnosis of glue ear and who met the inclusion/exclusion criteria for the study (Figure 26).

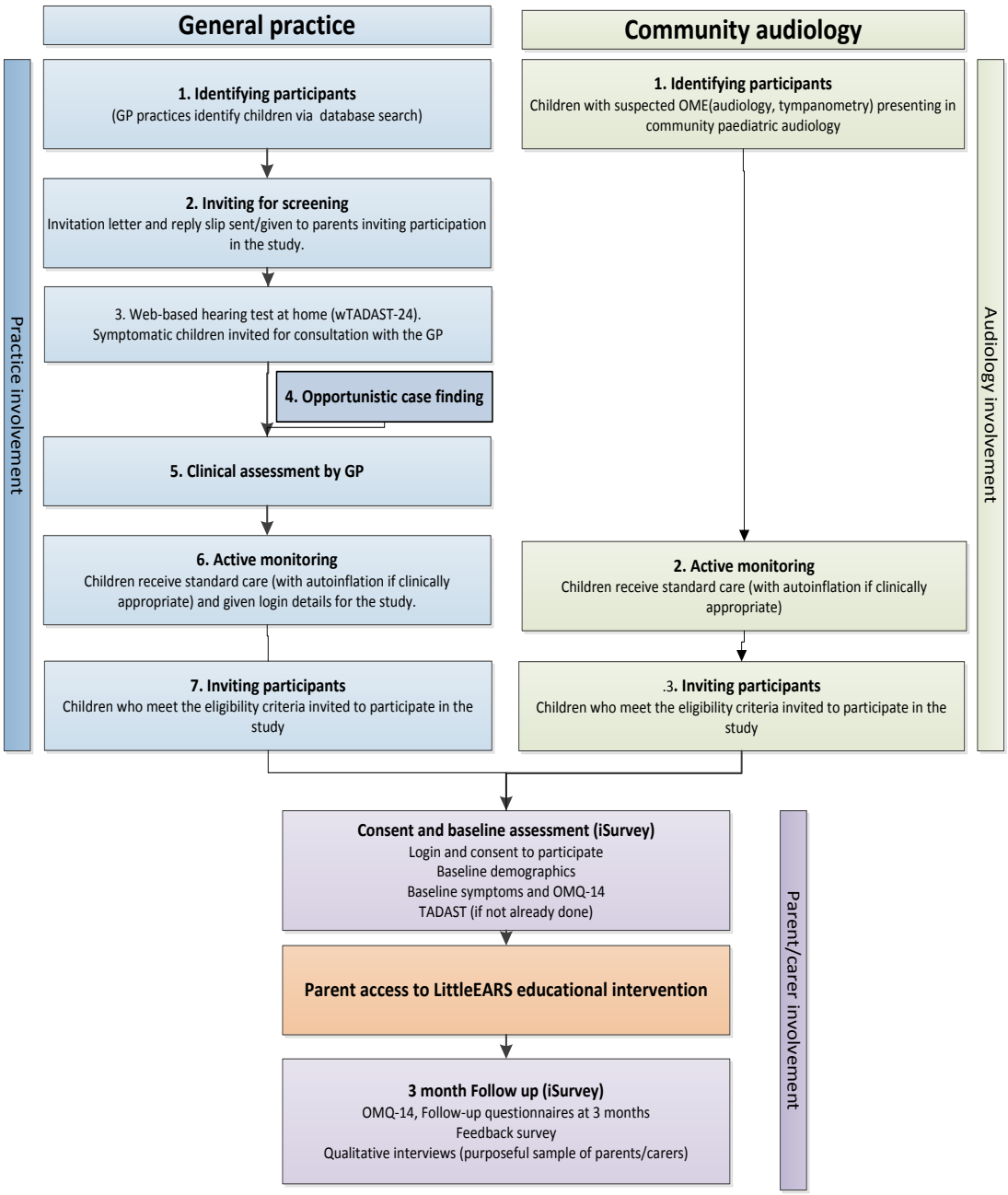
Figure 26: Inclusion/exclusion criteria for feasibility study

INCLUSION CRITERIA	**Parents/carers of** 1. Symptomatic children aged 4-7 years (with 2 or more symptoms from list 1 and a total of 4 or more symptoms from list 1 and 2 combined) **Symptom List 1 (Predictive of type B tympanogram)** • Appears to mishear what is said • Needs the television turned up • Any suspected ear problem **Symptom List 2 (other symptoms of glue ear)** • A prolonged or bad cold, cough or chest infection • An earache • Hearing loss has been suspected by anyone • Says 'eh what?' or 'pardon' a lot • May be irritable or withdrawn • Appears to be lip reading • Not doing so well at school as you or the teacher think e.g. with reading • Has noises in the ear or is dizzy • Snores, blocked nose or poor sleep • Speech seems behind other children's 2. Children with TADAST-24 score of <16 – (moderate to high risk of hearing disability) – (primary care group) **or** Children with unilateral or bilateral middle ear effusions (as diagnosed by tympanometry/audiometry) – (audiology group)
EXCLUSION CRITERIA	**Parents/carers of** 1. Children with grommets *in situ* or recent grommet surgery in the last 6 months. **2.** Children with uncommon conditions and syndromes at high risk of recurrent ear disease including those with cleft palate, Downs' Syndrome, Kartagener, Primary Ciliary Dyskinesia and immunodeficiency states for whom early referral is indicated.

9.3.5 Study procedures

Figure 27 represents the flow of participants through the study with details of what was required of the health professionals and parents at each stage of the process.

Figure 27: Flow chart for feasibility study



9.3.5.1 Identifying participants in general practice.

GP practices were asked to conduct a database search to identify children in the 4-7 year old age cohort. Prevalence of OME is high in this age group[8] and educational impact is particularly important and can lead to high grommet rates in this age group. In addition previous studies have shown a good rate of response to this method of recruitment[2]. GPs checked the list of identified children for suitability and excluded those children with grommet surgery in the last 6 months and any children with a condition or syndrome for whom early referral was indicated (Figure 26). A pack consisting of an invitation letter, a symptom checklist and a log-in number for the hearing disability test(wTADAST-24), was then sent using Docmail (an automated secure mailing service)(Appendix F).

Each practice was asked to send out 130 letters. This number was based on the AIRS[3] recruitment data which I used to estimate that each practice would need to invite 133 children, to screen 14 children and consequently identify 7 children and their families to be eligible for the study. If the practice identified more than 130 children, they were asked to start with the 4 and 5 year old children as glue ear is more common in the younger age group.[12]

On receipt of the invitation pack, parents/carers were asked to check their child's symptoms against the checklist. If parents had 4 or more concerns over the previous 3 months (Figure 26) they were invited to take the wTADAST-24 online hearing disability test with their child at home. The symptom list has been used in AIRS, but refined as a result of further analysis of the symptoms most likely to predict middle ear effusions in the AIRS cohort of screened and recruited patients (unpublished). The symptoms found to be most commonly associated with unilateral or bilateral OME were i) appears to mishear what is said, ii) needs the television turned up and iii) any suspected ear problem. In addition, children recruited to the AIRS study had a median number of 6 symptoms from the symptom checklist. Therefore, in this study I wanted to guide and refine the screening process to ensure those who attended for a consultation at general practice were those mostly likely to have OME. As a study team, based on the experience of the AIRS study, we agreed to use a refined symptom

list asking for parents to have 2 concerns from the most predictive list and a total of 4 symptoms/concerns in total (Figure 26).

A log in was provided for parents to access the wTADAST-24 hearing disability test which facilitated the first level of screening for glue ear in the home. The test data were anonymous, with no personal identifiable data collected. After the hearing test was complete, parents were given the test result indicating if their child was at *high*, *moderate* or *low risk* of hearing disability. Symptomatic children scoring moderate/severe risk ($\leq$16 total score) of hearing disability were then invited to make an appointment with their GP or practice nurse. Those children who scored $\geq$17 on the test were advised that they were at low risk of hearing disability from a learning perspective and no further action was needed at that stage. Parents were, however, informed in the invitation letter that they could consult the GP or take the hearing disability test again at any time if they were concerned about their child's hearing.

Cases were also identified opportunistically in practices by GPs, nurses and health visitors. Children with a clinical history and symptoms of suspected OME were informed about the study and given a study invitation pack. Posters were also placed in some of the GP surgery waiting rooms giving information about the study with instructions about who to contact regarding participation.

Children who were identified either through the practice mail out or opportunistically were subsequently assessed by the GP or practice nurse as part of routine clinical practice. Children suspected to have OME (based on conventional clinical history taking, physical examination and parent-reported symptoms) were informed about active monitoring/watchful waiting and given the Otovent™ nasal balloon if deemed to be clinically appropriate for the family and child. In routine practice, the GP could either prescribe or recommend the private purchase of the nasal balloon, but in this study I gave practices a supply of balloon packs to make things easier for parents. GPs and nurses were advised to make their own clinical judgment as to whether the nasal balloon method would be appropriate for the individual families. I advised the nurses/GPs to show the nasal balloon to the families and describe what to do. They

could also give a demonstration of the technique if they thought it appropriate, but this was not pre-specified so as to reflect normal clinical practice.

Parents/carers of children who met the inclusion/exclusion criteria (Figure 26) were then invited to take part in the feasibility study of the LittleEARS educational intervention. Parents who were interested and agreed to participate were provided with a study pack containing a participant information sheet and log in letter for the educational intervention (appendix F). A record of the study packs was kept by the GP surgery to determine uptake of the intervention.

Parents/carers of children who were considered not to have OME were advised that no further action was needed, however parents were advised that their child could retake the wTADAST-24 or consult the GP again at any time if they had ongoing hearing or OME-related concerns.

9.3.5.2 **Identifying participants in Paediatric Audiology Clinics**

Participants were also identified via paediatric audiology services in two hospitals in the south of England. Children presenting at paediatric audiology with either unilateral or bilateral OME (as determined by pure tone audiometry (PTA) and/or tympanometry) received routine care which usually included watchful waiting/active monitoring for 3 months. The audiology department at Salisbury District Hospital also received a supply of Otovent™ nasal balloons to offer to parents alongside active monitoring. Audiologists are not presently able to prescribe the nasal balloon and so could either recommend private purchase or ask the family to return to their GP to obtain a prescription. To facilitate this study I provided the departments with a supply of the nasal balloons to make things more straightforward for families. However, the audiology department at Portsmouth Hospital Trust declined a supply of nasal balloons because of expressed concerns about giving out free items to some patients but not to others. In this centre, therefore, parents just received the study pack and were advised to obtain the nasal balloon from their GP or from the internet.

Parents/carers of children who met the inclusion/exclusion criteria (Figure 26) were invited to take part in the study. Interested participants were provided with a study

pack with a unique log-in number and asked to visit the study site within 14 days (appendix F). A record of the study packs given to participants was kept by each audiology department to determine uptake of the intervention.

9.3.5.3 Consent and data collection

After having read the information in the study pack received from their GP or audiologist, parents/carers were invited to visit the LittleEARS educational intervention (www.littleears.soton.ac.uk). On the first visit to the site participants were redirected to iSurvey (a survey generation and research tool provided by University of Southampton) to facilitate the online consent process and collection of baseline information. The iSurvey website provided information about the study and contact details for the study team if potential participants had any questions prior to consent. After participants had given their online informed consent, they were asked to complete a baseline questionnaire about themselves (sex, relationship to the child with glue ear, age range, highest level of qualification achieved, SILS - Single Health Literacy Question[235]) and about their child (age, gender, ethnicity, hearing-related symptoms and concerns, OMQ-14[153]). When the baseline questionnaire was complete, parents/carers were then sent an automated email with log in details for accessing the full LittleEARS educational intervention using a unique log in number and password.

After 3 months parents/carers were emailed and asked to complete a follow-up questionnaire. If there was no response from the participant within 2 weeks of the email, another follow up email, together with a paper copy in the post. All participants were offered a £10 shopping voucher as a thank you for participating in the study.

9.3.6 Intervention

The intervention being evaluated in this feasibility study was the LittleEARS educational intervention that was developed through evidence from the literature, qualitative enquiry, expert knowledge and user feedback. Full details are described in chapter 8 and appendix E. The educational intervention is designed to educate parents about glue ear, and to help facilitate wider use of the nasal balloon intervention in primary care and community settings.

The educational intervention is accessed via a login page (details which were sent to participants automatically by email after they completed the consent process and baseline assessment). The home/welcome page gives information about how to navigate through the site and gives details about logging out and returning to the site again at any time. Parents were given the option of selecting one of the tabs along to top of the web page (i.e. glue ear; self-help; nasal balloon; other treatments; next steps; or quick links). There is also a '*click here to start'* button which directs parents to the information about glue ear and leads parents through the site. The intervention is designed to deliver all of the information and instruction on a single visit, but also allows parents to log back again in the future if required.

The site was hosted at www.littleears.soton.ac.uk and accessed via a unique login number and password.

9.3.7 Outcome measures

Screening numbers were collected through GP and audiology screening logs and electronically through the use of the hearing disability test. Demographic data, child baseline symptom/concerns and OMQ-14 scores were collected through the baseline questionnaires on www.isurvey.soton.ac.uk. The OMQ-14[153] is an ear-related quality of life PROM measure completed by the parent (proxy measure) which is described in more detail on page 136.

Outcome measures for this study were collected at 3 months using a self-reported online questionnaires on iSurvey. There is no standard way to measure acceptability or feasibility of interventions and no guidelines to determine what scores represent a good level of acceptability or indeed predict behaviour change. There are, however, certain concepts which are thought to be important including usability, user-friendliness, comprehensibility and readability.[236] I used these concepts, together with other examples of acceptability and feasibility testing[237] to design a questionnaire using 5 point Likert scales appropriate for this feasibility study (appendix F).

Google Analytics was used to assess parental engagement with the educational intervention. Google Analytics is a programme which monitors and analyses traffic to

websites and can give information about number of unique page views, how long people spend on the site and which are the most common 'leaving' pages when people have finished looking at the website. Google Analytics works by adding a piece of code (*page tag*) to each page of the intervention. The tracking code is activated when a page is visited and data is sent to a Google data collection server. The results are available for viewing and downloading from the Google Analytics Dashboard. The number of unique views of the information and demonstration videos were obtained through the hosting YouTube channel, and by parent report.

Self-reported use and experiences of the nasal balloon was recorded by asking participants to complete a follow-up questionnaire (appendix F). Changes in OMQ-14 score and wTADAST-24 hearing disability test score from baseline provided further information concerning the potential use of these scales in identifying and monitoring children with OME.

9.3.8 Sample size and analysis

As a study with primary outcomes of acceptability and feasibility of a digital intervention it was not appropriate or indeed possible to make a formal power calculation to determine sample size as there is no previous relevant data to base it upon. However, prior research has suggested that a target of 30-50 participants is generally appropriate for feasibility studies.[238] Based on the AIRS[3] recruitment data I estimated that each practice would need to invite 133 children, to screen 14 and consequently consent 7. I estimated therefore that I would need 8 primary care practices to invite 1064 children and consequently recruit 56 participants into the study. Potential recruitment from Paediatric Audiology was unknown, so the aim was to assess the feasibility of recruitment in 1-2 centres for this feasibility study.

Data were analysed using SPSS software. Summary statistics were presented for baseline and 3 month outcomes. The OMQ-14 standardised total scores at baseline and 3 months were calculated based on weightings provided by Prof Mark Haggard and Helen Spencer of the Eurotitis-2 Study Group and summary statistics for baseline

and follow up standardised OMQ-14 scores are presented together with mean change from baseline at 3 months.

9.4 Results

9.4.1 Recruitment and trial flow profile

Recruitment commenced in March 2016 and the last participant was recruited in to the trial in August 2016. A total of 9 general practices and 2 audiology departments took part in the feasibility study. The GP practice demographics are presented in Table 31.

Table 31: GP practice demographics

Practice demographics	***N=9***
Practice deprivation decile *median (range) (where 1 is most deprived and 10 is least deprived)*	9 (8-10)
Practice list size *mean (range)*	11107 (7804-16339)
Clinical commissioning group	
- NHS Dorset	1
- NHS North East Hampshire and Farnham	1
- NHS Oxfordshire	1
- NHS North Hampshire	1
- NHS South Eastern Hampshire	2
- NHS Gloucestershire	1
- NHS Wiltshire	2
AIRS practices	7
Non-AIRS practices	2

Eight of the nine GP practices conducted a search and mail out. A total of 1422 letters were sent to parents/carers of children who met the inclusion criteria inviting those with concerns about their child's hearing to take the online hearing disability test (wTADAST-24). Of the letters sent out, 56 children took the test (4%). One practice did not complete the search and mail-out but identified participants opportunistically in practice. Table 32 presents a breakdown of screening and recruitment in primary care.

Table 32: Recruitment in Primary Care

Region	***Number of practices***	***Number of letters sent***	***Number taking hearing test (% of those invited)***	***Number eligible and given study pack (% of those invited)***	***Number Consenting (% of those given a study pack)***
Hampshire	4	490	16 (2.7%)	5 (1.0%)	2 (40%)
Dorset	1	129	2 (1.6%)	1 (0.8%)	1 (100%)
Wiltshire	2	260	12 (4.6%)	6 (2.3%)	1 (16.7%)
Gloucestershire	1	-	1	3	1 (33%)
Oxfordshire	1	543	25 (4.6%)	5 (0.9%)	2 (35%)
TOTAL GP	**9**	**1422**	**56 (3.9%)**	**20 (1.4%)**	**7 (35%)**

Demographic details of the audiology departments are presented in Table 33

Table 33: Paediatric audiology demographics

	Type of hospital	***Population served by the hospital***
Portsmouth Hospitals NHS Trust	District General	675,000
Salisbury NHS Foundation Trust	District General	225,000

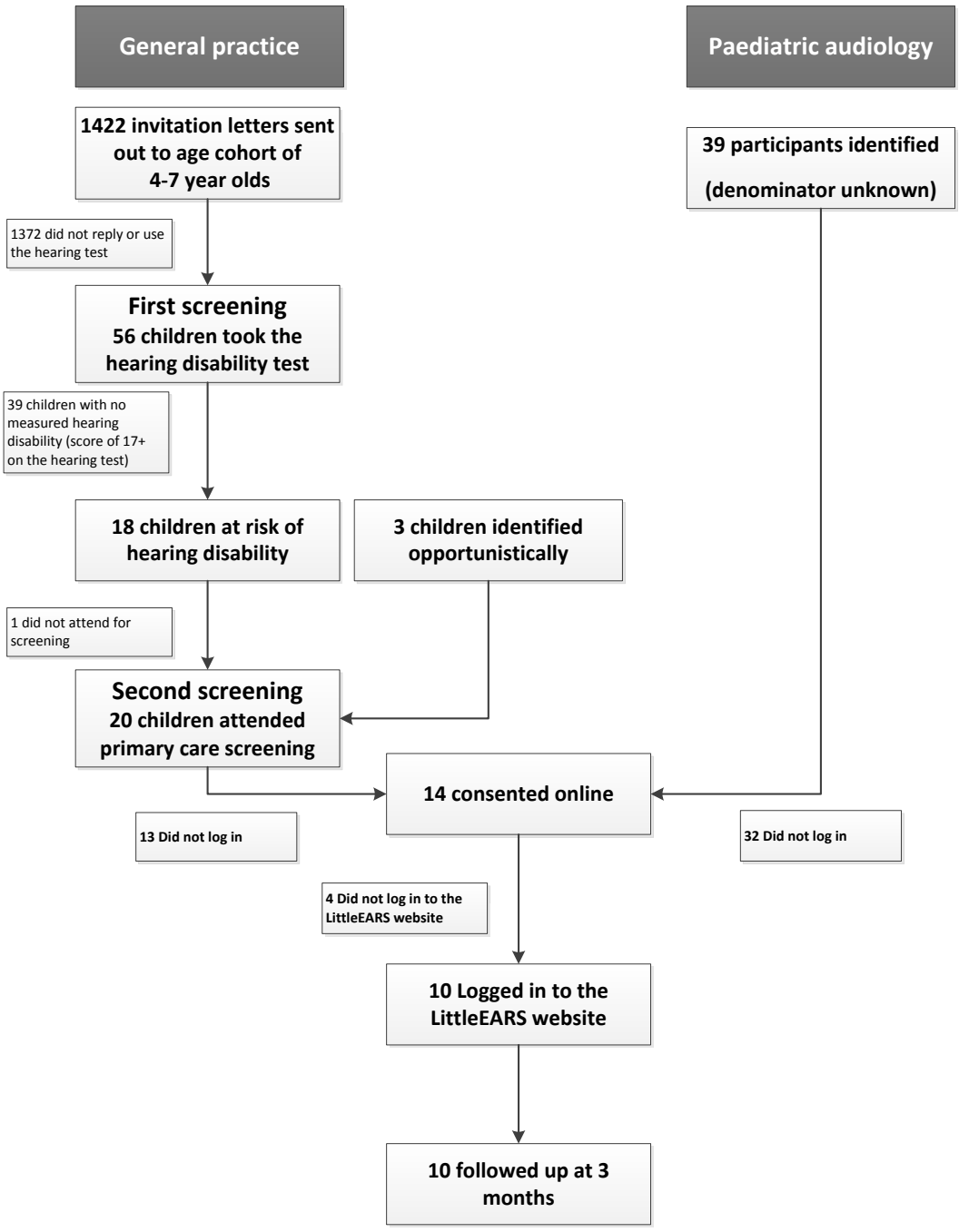
Audiologists gave out a total of 40 study packs between June and August 2016. Table 34 presents a breakdown of the number screened and recruited from audiology.

Table 34: Recruitment in paediatric audiology

Community Paediatric Audiology Site	***Number eligible and given study pack (% of those invited)***	***Number Consenting (% of those given a study pack)***
Portsmouth Hospital NHS Trust (Audiology)	19	2 (10.5%)
Salisbury NHS Foundation Trust (Audiology)	21	5 (23.8%)
TOTAL Audiology	**40**	**7 (17.5%)**

Figure 28 presents the CONSORT diagram detailing the flow of participants through the study.

Figure 28: CONSORT diagram



9.4.2 Screening hearing test

A total of 56 children took the wTADAST-24 hearing disability test as part of the screening and identification process for the feasibility study and child characteristics are presented in Table 35. One child was outside the age range for the study. Parents were invited for their child to take the test if they had 4 or more symptoms on the symptom list. Consequently, the number of reported symptoms or concerns was relatively high in this cohort of children, and a similar level of baseline concerns to parents of those children who participated in the AIRS study[3].

Table 35: Characteristics of screened children using the wTADAST-24 (First screening cohort on the CONSORT n=56).

Age of child	N (%)
4	15
5	25
6	15
8	1
Gender of child	
Female	30
Male	26
Parent reported symptoms in the previous 3 months	
Often mishears what is said	44 (78.6%)
Needs the television turned up	37 (66.1%)
Any suspected ear problem	20 (35.7%)
Appears to be lip reading	13 (23.2%)
An earache	25 (44.6%)
Not doing as well at school as expected	25 (26.8%)
A prolonged or bad cold or ear infection	31 (55.4%)
Has noises in the ear or is dizzy	10 (17.9%)
Hearing loss is suspected by anyone	17 (30.4%)
Snores, blocked nose or poor sleep	32 (57.1%)
Says 'eh what?' or 'pardon' a lot	45 (80.4%)
Speech seems behind other children's	8 (14.3%)
Any suspected ear problem	20 (35.7%)
May be irritable or withdrawn	15 (26.8%)
Number of symptoms (median)	6 (IQR 3)
Number of GP visits in last year for an ear-related problem	
No visits	28
1+ visits	28

The descriptive statistics for the total score and sub-scores of the wTADAST-24 are presented in Table 36. The mean total test score in this feasibility study was lower than that found in the normative population of school children presented in chapter 7 (18.27 vs 19.47 in normal population). This is likely to be because the cohort of children tested in this study were already identified by the parents as having symptoms of hearing loss. There was no difference in test scores between boys and girls (18.20 vs 18.35) indicating no gender difference in children's hearing disability associated with glue ear. Test scores were, however, affected by the child's age. Children aged 4 years had a mean total score of 17.07 (CI 15.87, 18.26) compared to a mean score of 20.20 (CI 19.03, 21.27) in 6 year old children which is consistent with results found with earlier versions of the TADAST.

Table 36: Baseline hearing test scores (n=56)

wTADAST-24 (n=56)	***Mean***	***SD***	***95% CI***
Total score*	18.27	3.30	17.38, 19.15
Audio only^	5.98	1.53	5.57, 6.39
Visual only^	5.41	1.41	5.03,5.79
Audio-visual^	6.88	1.27	6.54, 7.21

**Maximum score = 24, ^Maximum score = 8*

As has been reported previously in chapter 7, children generally score highest on the audio-visual questions and lowest on the visual-only questions. Children aged 4 years in this study scored particularly poorly on the visual only questions contributing to their lower test scores on the wTADAST-24 and suggesting that a reduced level of lip-reading in this age group contributes more strongly to their overall hearing disability.

The mean test score for children with 4 or more parental reported hearing symptoms/concerns was 17.88 (95% CI 16.94, 18.82) compared to 19.54 (95% CI 17.20, 21.87) for children with fewer than 4 symptoms or concerns from the symptom list (some families took the hearing test despite having fewer than 4 symptoms from the checklist as specified on the invitation letter). Figure 29 presents a box plot of the total wTADAST-24 scores versus parent-reported concerns from the symptom checklist.

Figure 29: Box plot wTADAST-24 scores/number of parent reported concerns

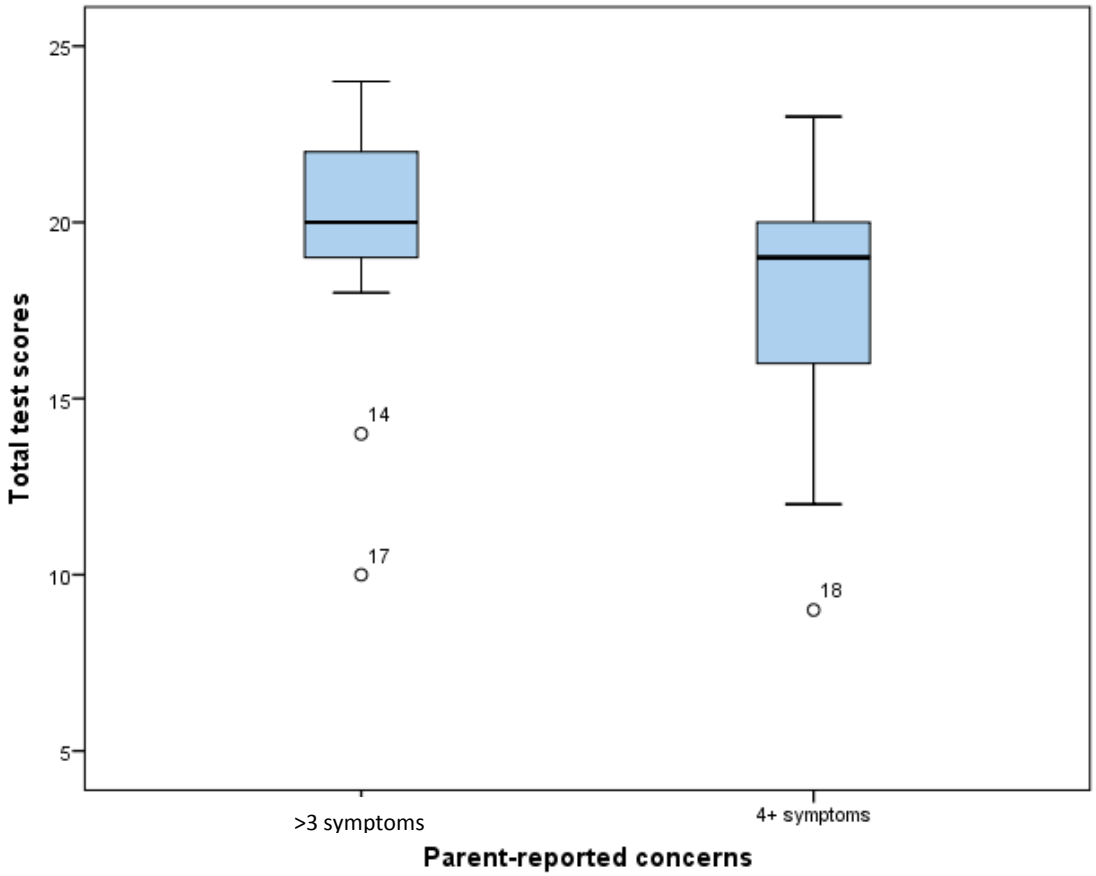
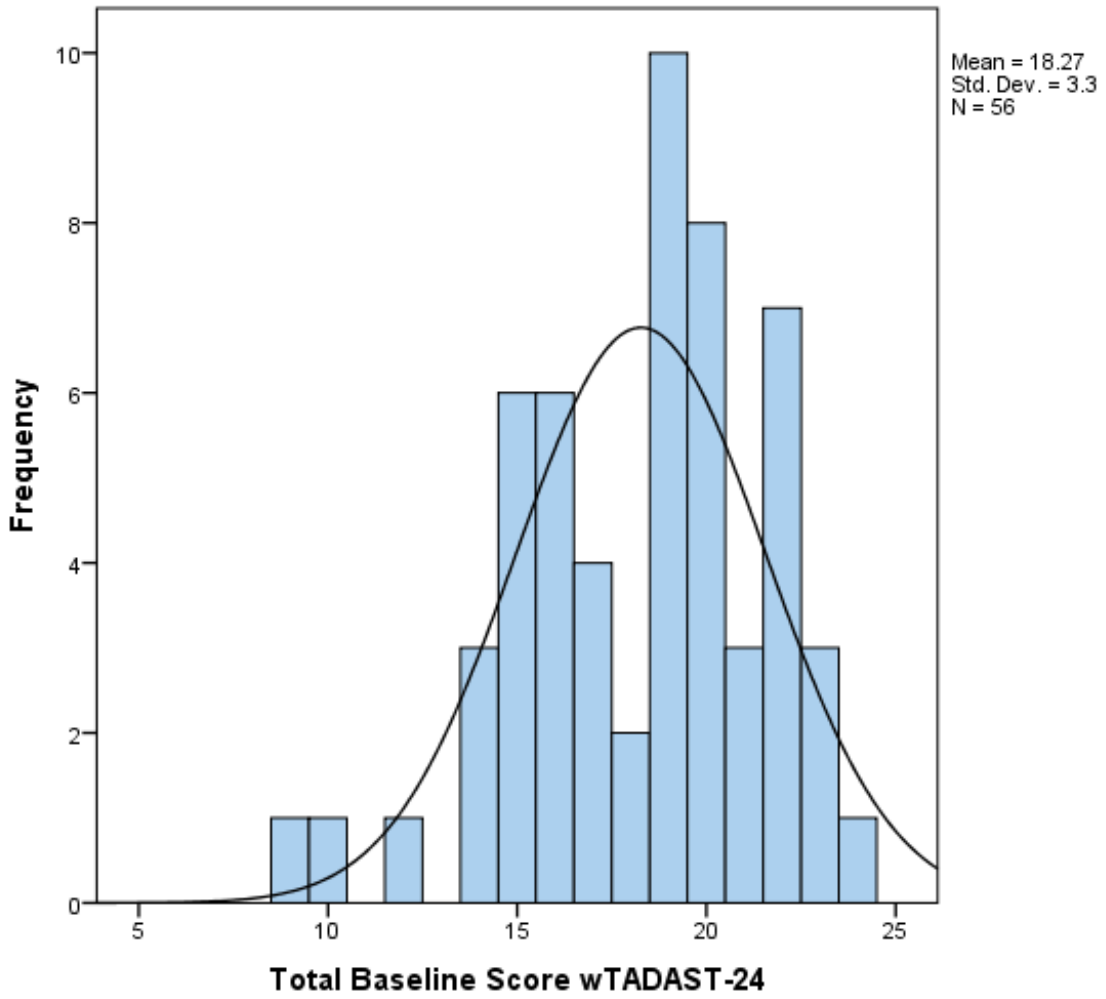


Figure 30 shows the distribution of test scores for the 56 children who were screened using the wTADAST-24 for hearing disability. Eighteen children scored 16 or lower on the wTADAST-24 and were identified as 'at risk' of hearing disability and invited for a consultation with the practice nurse. It is unclear whether these test results are normally distributed or whether there is a bimodal distribution. Preliminary investigations suggest that the sample is too small to draw any firm conclusions.

Figure 30: Distribution of test scores (maximum score 24)



9.4.3 Baseline characteristics of study participants

Table 37 presents the baseline characteristics for the 14 participants who gave consent for the study and completed the baseline questionnaire following screening by the GP, nurse or audiologist. All participants were female (mothers) with an educational level of A' level or above, with 4 having a professional or postgraduate degree. Most participants reported good health literacy (as measured using the single item literacy screener-SILS[235]) , however one participant recruited through audiology reported *sometimes requiring help to read health information from the doctor* on the Single Health Literacy Question[222] . This suggests a potential for reduced health literacy, which may have affected the parent's ability to understand or use the information presented in the educational intervention.

Attempts were made to include participants from lower sociodemographic groups, with specific requests to the Clinical Research Networks to identify GP practices from regions of higher social deprivation, but unfortunately none of the practices approached were interested in participating in the study within the timeframe of this research project. All the children of the participants were of white British ethnicity, with equal numbers of boys and girls. Parents reported a median number of 6 relevant OME symptoms/concerns from the checklist over the previous 3 months, and most children had visited the GP for an ear-related problem over the previous 12 months.

Twelve of the 14 participants received a nasal balloon directly from their healthcare provider. Two participants were recruited through Portsmouth audiology and consequently did not receive a nasal balloon and had to source the device themselves.

Table 37: Baseline characteristics (n=14)

Age group of parent/carer	Primary care (n=7)	Audiology (n=7)
18-24 year	0	1
25-34 years	1	2
35-44 years	5	3
45-54 years	1	1
Gender of parent/carer		
Female	7	7
Education level of parent/carer		
Sixth form school or college, A' level	1	2
Diploma or equivalent	0	3
University degree	3	1
Professional or postgraduate degree	3	1
Health literacy of parent/carer *(SILS[235] - how often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy? Never/rarely/sometimes/often/always)*		
Never	6	6
Rarely	1	0
Sometimes	0	1
Age of child with glue ear		
3	0	1
4	3	3
5	4	3

Gender of child		
Female	5	2
Male	2	5
Ethnicity of child		
White British	7	7
Parent reported symptoms in the previous 3 months	N=7 (%)	N=7(%)
A prolonged or bad cold, cough or chest infection	3 (42.9%)	2 (28.6%)
Appears to be lip reading	3 (42.9%)	1 (14.3%)
An earache	5 (71.4%)	4 (57.1%)
Not doing as well at school as expected	0	2 (28.6%)
Often mishears what is said	6 (85.7%)	6 (85.7%)
Has noises in the ear or is dizzy	4 (57.1%)	1 (14.3%)
Hearing loss is suspected by anyone	9 (64.3%)	9 (64.3%)
Snores, blocked nose or poor sleep	6 (85.7%)	5 (71.4%)
Says 'eh what?' or 'pardon' a lot	5 (71.4%)	6 (85.7%)
Speech seems behind other children's	2 (28.6%)	3 (42.9%)
Needs the television turned up	4 (57.1%)	5 (71.4%)
Any suspected ear problem	5 (71.4%)	4 (57.1%)
May be irritable or withdrawn	1 (14.3%)	5 (71.4%)
Median number of symptoms N [IQR]	6 (0.25)	7(3.5)
Number of GP visits in last year for an ear-related problem		
No visits	1	0
1+ visits	6	7
OMQ-14 standardised score*(SD)	0.37 (0.82)	0.60 (1.29)

**The OMQ-14 standardised score is a weighted score total of the 14 items on the parent-reported questionnaire, which measures 3 domains of i) reported hearing difficulties and speech concerns ii) behaviour and development impact and iii) ear-related physical ill health. The larger, or more positive the score, the worse impact. Better outcomes are represented by more negative scores.*

9.4.4 Uptake and usage of the educational intervention

In this feasibility study I was interested in the uptake rate of the educational intervention, the extent of interaction with the individual webpages, the views of the information and instruction videos and use of the wTADAST-24 hearing test to monitor progress.

9.4.4.1 Uptake rates

Of the 20 families who attended for screening for glue ear in primary care 7 (33%) gave consent to participate in the study and completed the baseline assessment. Similarly, in paediatric audiology 39 study packs were given out to families, with 7 (18%)

participants giving their consent to participate and completed the baseline assessment. As consent was only given later online at the time of logging in to the digital intervention, it was not possible to follow up why some parents did not participate in the study. In addition, it was not possible to determine the uptake of the nasal balloon or whether there was any difference in socio-demographics of the families who were given a study pack but did not participate in the study.

Fourteen parents/carers gave their consent and completed the baseline assessment, however 4 did not log on to the educational intervention. I contacted these parents by email as they had given consent to be contacted as part of the study. Three of the 4 parents reported not receiving the login details for the main LittleEARS site following completion of the baseline questionnaires. These emails were sent automatically from iSurvey and had potentially been redirected to a spam folder. New logins were created for the parents but none went on to use the LittleEARS educational intervention. No contact was received from the fourth parent.

Of the 10 parents who logged in to the LittleEARS educational intervention, all 10 were followed up at 3 months. One participant only provided limited follow up information, but the remainder completed the follow up questionnaires in full. Two of the participants completed the final questionnaires by post after an email reminder.

9.4.4.2 Extent of interaction with the educational intervention

Parents reported using a range of devices to access the educational intervention including laptops, tablets and iPads (Table 38). One participant reported having a problem using an iPad, but otherwise most participants reported not encountering any problems with the site.

Table 38: Devices used to access the educational intervention

Device	***Number of participants (n=10)***
Laptop	4
Tablet	2
IPad	2
Not specified	2

The extent of interaction with the educational intervention was assessed by counts of the page views of the individual site pages and time spent on each page. Whilst Google Analytics was able to provide information about number of unique page views, it could not determine if the same participant had viewed the same pages but from different devices (i.e. from their phone and then their computer). Therefore this data simply provides an overview of the interaction and a summary of the pages most commonly visited. Table 39 presents the unique page views during the study period and the average time spent on the individual pages. The most commonly visited pages were: i) about glue ear; ii) helping your child with glue ear; iii) nasal balloon treatment; iv) other treatments, and v) what to do next. Parents spent most time on the nasal balloon instruction page, followed by the quick links; what to do next; and how to help your child at home.

Table 39: Unique page views for the LittleEARS educational intervention

Section of educational intervention	***Unique Page-views***	***Avg. Time on Page (seconds)***
About glue ear | LittleEARS	17	57.32
Nasal balloon treatment | LittleEARS	16	44.47
Helping your child with glue ear | LittleEARS	13	14.75
Other treatments | LittleEARS	12	13.38
What to do next | LittleEARS	10	114.78
Nasal balloon instructions | LittleEARS	9	207.30
Quick links | LittleEARS	7	131.00
FAQ - nasal balloon treatment | LittleEARS	7	25.43
Helping at home | LittleEARS	7	82.38
What do parents say? | LittleEARS	7	43.63
What causes glue ear? | LittleEARS	7	21.71
Can glue ear be prevented? | LittleEARS	7	19.71
Helping at school | LittleEARS	7	17.43
How is glue ear diagnosed? | LittleEARS	6	35.67
What are the symptoms? | LittleEARS	6	25.17
How common is glue ear? | LittleEARS	6	12.50
Operations for glue ear | LittleEARS	5	25.20
About the LittleEARS website | LittleEARS	1	23.00
Contact details | LittleEARS	1	12.00

Four participants reported visiting the educational intervention on a single occasion, whilst the remaining 5 participants visited the educational intervention between 2 and 4 times during the 3 month period.

The data in Table 39 shows that participants did not visit all pages of the educational intervention. The structure of the site allowed parents to navigate their own way through the site and go to the area of most interest to them. This may have resulted in some useful information being overlooked but as an educational site I thought it most appropriate to let participants select their own area of interest.

There were 6 unique views of the glue ear information video suggesting that video information was interesting to some parents, but it cannot be determined if participants watched the video through to the end. There were 10 unique views of the nasal balloon demonstration video suggesting that most parents engaged with the online demonstration.

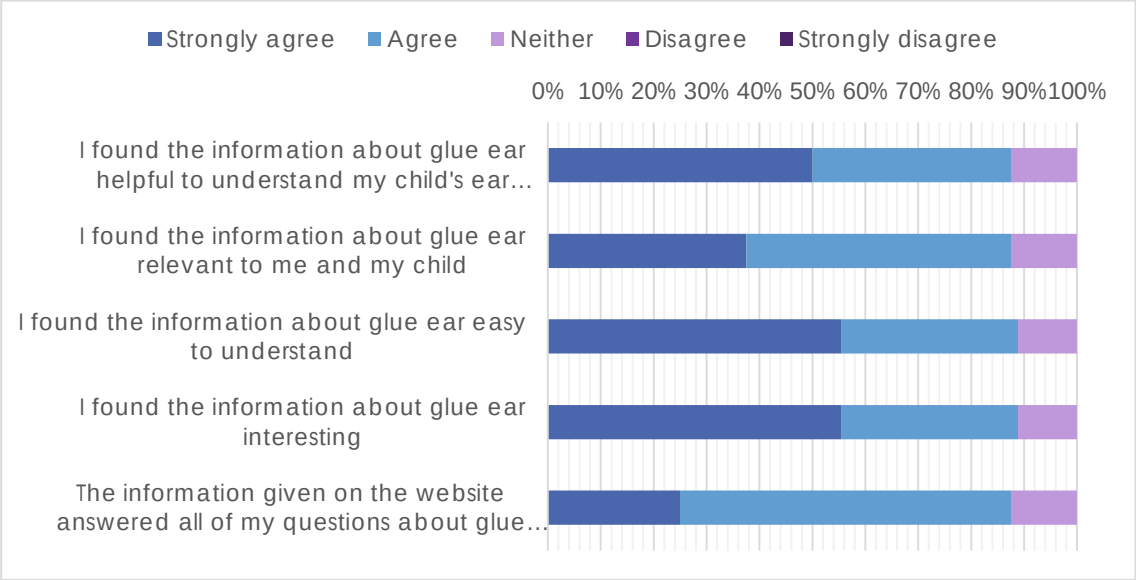
9.4.5 Acceptability of the educational intervention

Acceptability of an intervention is the extent to which it is suitable for purpose and acceptable to those for whom is it intended. In this study I was interested in the appropriateness of the LittleEARS education intervention for parents, whether it was useful to help understand their child's condition and whether it was accessible and easy to navigate through.

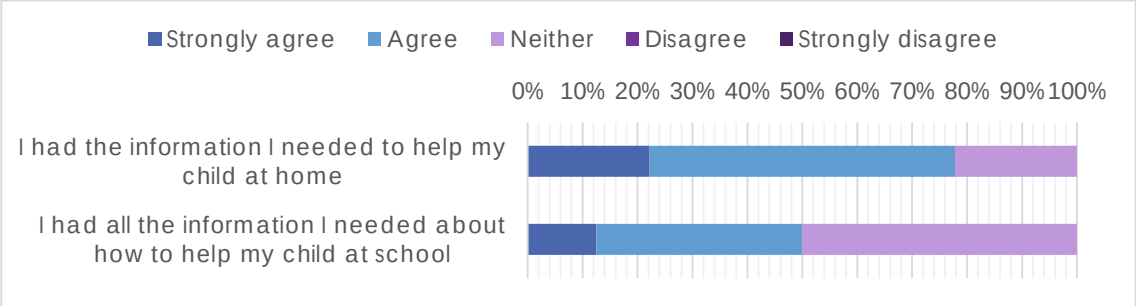
Error! Reference source not found. Figure 31 presents the data from the 5 point Likert scales completed by parents regarding acceptability, usefulness and usability of the LittleEARS educational intervention.

Figure 31: Parent views of acceptability, usefulness and usability of the educational intervention (5 point Liker scale) n=9

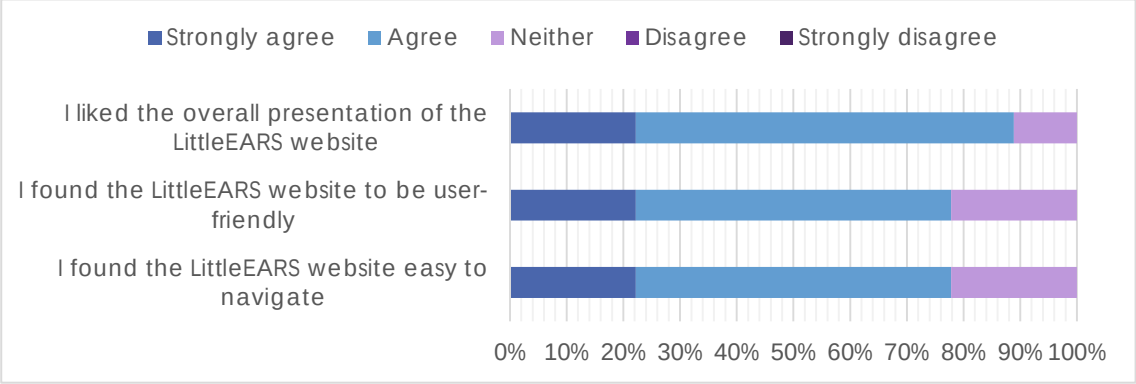
Usefulness – about glue ear (promoting *coherence*)



Usefulness – self-management (promoting *cognitive participation*)



Usability



Parents generally reported that the educational intervention was helpful, relevant, interesting and easy to understand. Information about glue ear was described in the free text boxes as '*good information and easy to read*', '*useful information*' and '*easy layout*'. Parents reported having enough information to help their child at home, although slightly lower scores were obtained about how to help children at school. This may be because not all parents visited this page of the intervention (Table 39). Parents reported liking the overall presentation of the LittleEARs educational intervention, found the interface useable and easy to navigate.

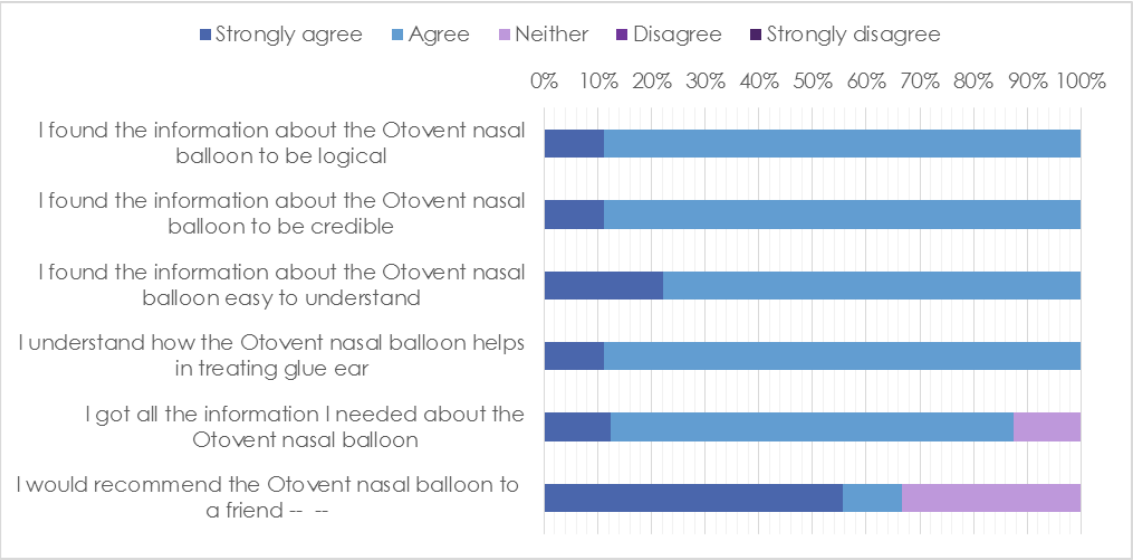
9.4.6 Uptake of the nasal balloon treatment

In this feasibility study 9 participants reported that their child had tried the nasal balloon during the 3 month period (no information was available for the 10th participant). Six children used the nasal balloon at least once a day for up to 3 months, one child used it for 2 weeks and two children only used the nasal balloon a few times.

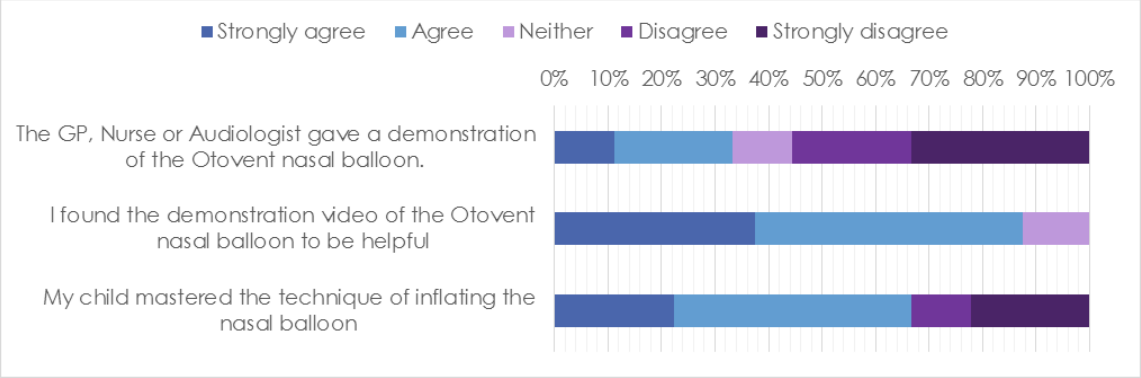
Parents were asked to describe their views on the information provided about the nasal balloon. All parents either agreed or strongly agreed that the information provided was logical, credible, coherent, easy to understand and provided everything that they needed to know about the nasal balloon (Figure 32).

Figure 32: Parent views of the Otovent nasal balloon (5 point Likert Scale) n=9

Usefulness – nasal balloon treatment (promoting *coherence)*



Demonstration of the nasal balloon (promoting *collective action)*



Five children mastered the technique of nasal balloon autoinflation, with four reporting problems with the technique especially at the beginning. Two of these children persevered and managed the technique, whilst the other two were unable to inflate the balloon and therefore only used it a few times. One parent suggested that problems were due to their child's age. '*She couldn't blow it up but is only 4 and still learning to blow through her nose'.*

Likert scores were low for the demonstration of the technique by the healthcare provider. GPs, nurses and audiologists were asked to describe the intervention to families and children, but demonstration was optional and was thus more likely to reflect normal clinical practice. However, video demonstration was generally agreed to be helpful to parents (Figure 32). No data was collected from the healthcare professional's viewpoint in this study.

9.4.7 Exploring use of the wTADAST-24 and OMQ-14

9.4.7.1 wTADAST-24

The wTADAST-24 hearing disability test was included as part of the LittleEARS educational intervention to allowparents to check and monitor their child during the active monitoring period. However, only 2 of the 10 participants reported using the hearing test again at the end of the study, following prompts during the final questionnaire.

9.4.7.2 OMQ-14 quality of life questionnaire

The OMQ-14 is a parent proxy measure of ear-related quality of life and was included in this study to evaluate hearing disability and as a validation for future implementation studies.

Table 40 presents the summary statistics for baseline and follow-up (three month) standardised OMQ-14 scores. Lower (more negative) scores represent better outcomes.

Table 40: Summary statistics for standardised OMQ-14 scores

	N	*Mean standardised score**	*SD*	*Min*	*Max*
Baseline	9	0.40	1.11	-1.90	1.84
3 month	9	-0.10	0.97	-1.75	1.54
Change from baseline	9	-0.49	0.87	-1.82	0.84

**The OMQ-14 standardised score is a weighted score total of the 14 items on the parent-reported questionnaire, which measures 3 domains of i) reported hearing difficulties and speech concerns ii) behaviour and development impact and iii) ear-related physical ill health. The larger, or more positive the score, the worse impact. Better outcomes are represented by more negative scores.*

There was a change in OMQ-14 score of -0.49 (0.87SD) compared to baseline which represents a modest overall improvement in the quality of life score over the 3 month active monitoring period.

9.4.7.3 Ongoing concerns and referrals

At the end of the 3 month study period, participants were asked whether they were still concerned about their child's hearing and what actions, if any, there were going to take.

Table 41: Ongoing parental concerns at 3 months

	N=9	*At 3 month follow-up*
I am still concerned about my child's hearing	4	2 ENT referrals (recruited from audiology) 1 audiology referral (recruited from primary care) 1 will continue to use the nasal balloon
I am no longer concerned about my child's hearing	4	4 will use the nasal balloon again if symptoms return.
Uncertain	1	1 uncertain about whether still a problem and what to do next.

Table 41 shows that approximately half of the participants were still concerned about their child's hearing levels after 3 months active monitoring and 3 of these had been consequently referred to ENT or audiology for further investigation and management. The relatively high level of ENT referral of those recruited from paediatric audiology may represent a more severe or chronic condition in children who are already on the referral pathway to ENT services i.e. standard compliance with the referral pathway. All participants who were no longer concerned about their child's hearing reported that they would use the nasal balloon again if the glue ear returned.

9.5 Discussion

9.5.1 Summary

This feasibility study recruited participants through primary care and audiology. However, recruitment proved to be difficult, hampered by research governance delays and seasonal prevalence rates. Additionally, the study design included complex case-finding procedures and a multi-step log-in/consent process and on reflection this is likely to have affected the uptake of the educational intervention which was lower than expected when compared to similar recruitment procedures used in the AIRS study. Additionally, many potential participants received the nasal balloon at screening and it was not possible to determine the use/uptake of the nasal balloon in those families who received the device but did not participate in the study. My reflections on the problems associated with the design of the feasibility study and suggestions for improvement if I were to design the study again are presented in section 9.5.3.

However, despite these significant limitations, parents who gave consent and logged on to the educational intervention generally found it to be acceptable and relevant, easy to navigate and provided the information that they required to support their child during the active monitoring period and use of the nasal balloon. Uptake of the nasal balloon treatment was good with most children attempting the technique. Very few parents reported receiving a personal demonstration by the healthcare professional, however most watched the video demonstration and found it to be very helpful. Difficulties with the technique were reported by some parents especially in the early stages. Nonetheless many children mastered the technique with more than half of children continuing usage for up to 3 months. The wTADAST-24 hearing disability test was used to help with case-finding but with limited use for monitoring purpose by families during the 3 month active monitoring period. The OMQ-14 standardised quality of life questionnaire was completed by parents at baseline and 3 months and showed improvement in total standardised scores similar to that found in AIRS study[2 3] over the 3 month period.

In summary, the objectives of the feasibility study were only partially met, with insufficient numbers to confirm acceptability and feasibility of the LittleEARS educational intervention. Therefore caution must be applied in interpreting the results with respect to the generalisability and applicability of the educational intervention to the wider population of families of children with OME and further feasibility work should be undertaken prior to implementation.

9.5.1.1 **Case-finding and recruitment**

This feasibility study used a broad strategy for case-finding and recruitment, although overall recruitment numbers were disappointingly small. The response rate to the mail-out for screening in primary care was 4% which is relatively low level when compared to the AIRS study[3] who reported a ~15% response rate to a mail-out to a similar cohort of families and children. There are a number of potential reasons for low uptake. Firstly the study asked for children to have 4+ symptoms on a refined symptom checklist (compared to 1+ symptoms for AIRS), although outcomes of the cohort were similar. This may have reduced overall numbers identified for screening.

Secondly, initial screening/case-finding was using the wTADAST-24 hearing disability test at home prior to consultation with the GP or nurse. Some parents may have had difficulties accessing the hearing test website or not had access to the internet, although it is likely that most parents in this age demographic do have access to a mobile device or a computer and the hearing test is accessible on most platforms. Another potential reason for low uptake for screening is seasonal variation. Invitation letters were sent in the spring rather than the autumn/winter season when glue ear is much more common.[13] Glue ear may also be perceived as less of a priority for parents at the end of the school term, compared to the beginning of term when parental and teacher concerns may be more evident particularly in the first year of school. Recruiting in the first school term (September to December) when children just start a new school year, and when glue ear is most common[12] may therefore have been a more successful strategy but was not possible due to the time restrictions placed on my PhD project.

For those children who took the wTADAST-24 hearing disability test, 32% were identified as being at moderate or high risk of hearing disability requiring further consultation. This is similar to the screening levels for middle ear effusions seen in two primary care studies using mail-outs to similar cohorts of children: The GNOME study[86] (nasal steroids for OME in primary care) reported 23% of children failed tympanometry at screening in primary care, whilst the AIRS study reported 26% of children failed tympanometry at screening and were diagnosed with unilateral or bilateral glue ear. This suggests that the wTADAST-24 has the potential to identify children with hearing disability in primary care, and best used when symptoms or concerns have already come to light, and so provides a new objective measure of hearing disability in the community setting to help with clinical management.

In paediatric audiology, despite being in the summer months, children were identified with more persistent OME and invited to participate in the study. Whilst it is not known how many potentially eligible children attended for audiological screening during the time period, recruitment was more effective than in primary care, although

it is recognised that these children may already be on the referral pathway to ENT services and represent clinical cases that are more severe or chronic.

In summary, this study was conducted first and foremost to explore the feasibility of the educational invention to support effective implementation of the nasal balloon method in primary care. We needed to identify families of children with glue ear to take part in the study and evaluate the educational intervention. Whilst such case-finding using a database search and mail-out has been successful in previous primary care studies[3 86] in everyday clinical settings it may not be the most appropriate or effective way of identifying children at risk of hearing disability associated with OME. In fact, my work suggests that case-presentation is likely to be the best point for delivery of the wTADAST-24 and LittleEARS educational intervention i.e. by signposting to the website and use of the nasal balloon if appropriate.

Paediatric audiology is also a potentially useful and appropriate setting for the nasal balloon treatment and the educational intervention. Rather than refining recruitment methods, this study has given insight into who and where this educational support intervention may be most useful and effective.

9.5.1.2 Uptake of the educational intervention

The uptake of the educational intervention following screening was also low (35% in primary care, 18% in audiology). Previous studies of online behavioural interventions have found that there can be a discrepancy between the numbers who agree to participate and the number who actually log in to a digital intervention. For example, in a childhood eczema study[239] 74/223 parents who originally expressed an interest in the study, did not log in to the intervention.

In this OME feasibility study it is possible that parents were interested in trying the nasal balloon but did not require any further information, advice or support for its use in the form of an educational intervention. At the screening visit, families were given verbal health information about glue ear and the Otovent™ nasal balloon and parents may have considered this sufficient to use the nasal balloon. Alternatively, parents might simply have not wished to take part in a research study. Barriers to research

participation have been identified previously in a systematic review of randomised controlled trials[240] which found that patients were often apprehensive about the additional demands of a trial, concerned about the information provided and the consent process, and worried about uncertainty. In summary, I was aiming to capture information on the uptake and usage of the nasal balloon, but unfortunately I didn't manage to fully achieve this during the feasibility study. My reflections on the study design and how I would approach things differently if I were designing the feasibility study now is presented in section 9.5.3.Intervention delivery and use

This study used two different sites for data collection and intervention delivery (iSurvey.soton.ac.uk and littleears.soton.ac.uk) which contributed to the loss of 4 participants after they gave consent for the study. Adding too many steps to the process or adding unnecessary demands has the potential to reduce engagement with an intervention. I tested the procedures myself prior to the feasibility study, but on reflection I could have tested them more widely with volunteers using different systems outside of the University prior to the commencing the study. This might have highlighted the problems that arose. For future research and clinical application it would be useful to have data collection and intervention delivery on a single platform to streamline the process for parents.

Despite these problems, parents who managed to log in to LittleEARS reported that the intervention was acceptable and relevant, easy to navigate and provided the information that they required to support their child during the active monitoring period. Engagement with a digital intervention is often categorised in terms of number of logins, duration spent on the intervention or individual numbers of pages viewed and visited[241]. Using Google Analytics facilitated an overview of the pages that participants visited in this study and the average time spent on the individual pages, but did not provide a detailed view of individual engagement. Engagement can be categorised into three phases: visiting for the first time; prolonging the first visit; and revisiting the intervention[242]. This educational intervention was designed to deliver all of the information on a single visit, but participants could revisit at any time. In this study, more than half of the participants revisited the intervention (self-report)

suggesting a moderate level of engagement with the educational intervention in this small sample of parents.

Follow-up questionnaires were again completed using iSurvey. Most participants completed them after an initial request and reminder email, with two cases completing the follow up by post. Employing other methods to ensure good follow up rates in trials of digital interventions is common. For example, a childhood eczema reported that 61% of participants completed the follow up questionnaires online, whilst 35% completed the key questions by telephone, with only 3.5% being uncontactable[239]. In this study, sending out the final questionnaire by mail resulted in really good follow up rates.

9.5.1.3 Uptake of the nasal balloon

Providing a supply of the nasal balloon to practices and to audiology meant that parents/children could be given a device during the consultation and have the opportunity to try it or discuss the technique with the healthcare professional. However, it is recognised that uptake of the nasal balloon may not have been so good if parents had to source the nasal balloon themselves. A practical treatment like the nasal balloon can take time to describe, and a demonstration can be a facilitator to mastering the technique. Qualitative work nested within the AIRS study[3] identified that the triadic relationship between nurses, parents and children was important to children mastering the autoinflation technique. However, personal demonstration by the healthcare professional is not always possible due to time constraints within a routine consultation and GPs don't always see this as their role (Chapter 5). In this educational intervention, the demonstration video comprises a nurse demonstrating the technique to a mother and young child and thus can fill this niche. Similarly, instruction videos to teach inhaler technique to children with asthma found that technique improved when a video was used to back up the consultation.[173] Due to the small numbers in this study it is not possible to determine whether watching the online video or having a personal demonstration affected whether the child could master the autoinflation technique. However, it is reasonable to suppose that either or both would be beneficial or no longer needed reassurance that the test provided.

9.5.1.4 Monitoring

The wTADAST-24 hearing disability test has provided a new way for parents to monitor their child's hearing impact although few parents repeated the hearing disability test either during or at the end of the 3 month monitoring period. This suggests that parents were either uncertain about the monitoring process, did not remember to use/have confidence in the test, or were monitoring their symptoms in other ways. Qualitative interviews with parent participants would have been valuable to explore the reasons forlimited use of the wTADAST-24 during the 3 month active monitoring period.

The improvement in OMQ-14 ear-related quality of life score between baseline and three months suggest that overall children improved during the 3 month active monitoring period. The level of improvement found was similar to the treatment arm of the AIRS study[3] suggesting that the OMQ-14 might have a potential role in helping clinicians assess and monitor the impact of hearing disability and quality of life in young children. However, the use of the OMQ-14 is rather less practical at the moment in the clinical setting due to its complex weighted scoring system. A future online version, with built in algorithms may however be useful to allow parents or healthcare professionals to monitor change in scores and consequently improve patient management.

9.5.2 Strengths and limitations

The evaluation of the LittleEARS educational intervention in this feasibility study was conducted with a range of parents of young school children recruited from primary care and community audiology in the south of England. The strength of this approach is that it has enabled assessment of the feasibility of the intervention in two different NHS settings. Confining a feasibility study to just one setting restricts the potential generalisability of the results particularly when considering the diverse care pathways for glue ear and may result in an intervention that would be limited to a single setting[243]. In this case the educational intervention has potential use in both primary

care and community paediatric audiology but numbers were too small to determine if there was any difference in usage and impact between the two settings.

Despite such a broad and NHS relevant recruitment strategy involving primary care and paediatric audiology, the study did not meet the proposed end point sample size of 30-50 participants for a feasibility study. Case finding in primary care screening was affected by the trial design and season of recruitment. Audiology recruitment was severely hampered by research governance procedures at Portsmouth. I highlighted the problem at an early stage and discussed potential strategies with my supervisory team. We agreed to approach another paediatric audiology department (Salisbury) to help with case-finding but unfortunately recruitment was also delayed at this site due to governance approvals. Consequently, overall recruitment was lower than expected and unfortunately I did not have enough time within this PhD project to continue recruitment for another winter season.

Another limitation of the study is not managing to recruit participants from as wide a range of socio-demographics as originally planned. Whilst GP practices with appropriate local population were approached by the CRN, none were interested in participating in the study, compounding the ongoing difficulty of recruiting hard-to-reach populations in clinical trials.[244] Recruitment in audiology clinics in Portsmouth and Salisbury had the potential to recruit participants from a wider range of socio-demographics, but the baseline data suggest that this was not successful. For future work, more Patient and Public Involvement is needed to identify how best to recruit and engage participants from lower socio-economic groups.

Uptake rates of the educational intervention were also fairly low, and this may have been due to a number of factors including the satisfactory provision of a nasal balloon together with verbal advice from the healthcare provider, or alternatively a potential unwillingness to undertake the extra demands of a research project. Conducting qualitative interviews or feedback questionnaires with non-participants would have given a clearer idea about reasons for low uptake.

9.5.3 Personal reflections on the study design

Recruitment rates were low and uptake of the educational intervention were also disappointing with only 24% of families logging in to the intervention following consultation with the healthcare professional. As such, it is important to reflect on the objectives of the study, whether the trial design was adequate to answer the study objectives, and how could the study design have been improved.

Study objectives

Firstly, on reflection, I think my original study objectives were not completely clear and this might have affected my study design. The main aim of the feasibility study was to assess acceptability and feasibility of the educational intervention to support wider uptake and usage of the nasal balloon in primary care and audiology settings. Development work of the educational intervention had involved parents of school-aged children, but had not included parents of children with OME. I was primarily interested in exploring whether the educational intervention was acceptable, useful and feasible in this parent population. However, my objectives included other aspects such as exploring the use of the wTADAST-24 for case-finding, which added an additional complexity to the study, and consequently affected recruitment.

An important consideration is to determine whether my feasibility study met its objectives. The low patient numbers and low uptake of the educational intervention means that the objectives were only partially met and that further feasibility work is required before a wider implementation study should be considered. This should also include some further qualitative work to determine reasons for poor uptake of the intervention and qualitative feedback on the intervention itself.

Study design

There are two main considerations for the study design for which, on reflection, I would make changes to.

<u>Recruitment methods</u>

Recruitment methods for primary care OME studies have been developed and used successfully in the AIRS[2 3] and GNOME[86] studies and I employed some of these strategies in my feasibility study. Firstly I included a database search and opportunistic case-finding to identify children with OME in primary care. This was successful in identifying a cohort of children who were most at risk of middle ear effusions. However, as this was a pragmatic study, I did not plan to include objective measures of OME such as tympanometry as most GPs do not have the facilities in primary care. Instead, I decided to include a more refined symptom checklist, developed through AIRS, with symptoms that were most likely to predict a type B tympanogram. Additionally, I decided to include the wTADAST-24, to improve case-finding for OME by giving parents the opportunity to take the test with their child at home, and potentially reduce unnecessary consultations in primary care by those children who were not found to have a hearing disability. However, this resulted in significant losses from the recruitment process prior to consultation with the GP or nurse. It is unlikely that the wTADAST-24 would be used for case-finding in wider clinical practice, and in hindsight I would not include as part of a future feasibility study.

Uptake of the educational intervention

It would be interesting to explore why a large number of parents did not log in to the educational intervention despite their child being given a diagnosis of OME and being provided with the log-in details for the educational intervention. As consent was not obtained until the parent logged in to the website, it was not possible to contact these parents to determine the reasons for this. This is an important question for assessing acceptability and feasibility any intervention, and capturing this information would help to guide future implementation. As such, as in previous OME studies, I would have the consent process completed by the healthcare professional during the consultation visit to allow follow-up of those who initially agree to participate and then fail to log in to the intervention.

Uptake and usage of the nasal balloon**.**

An objective of the study was to explore the uptake and usage of the nasal balloon, and to maximise the number of children able to try the nasal balloon, it was provided directly to the families by the healthcare professionals. However, this does not normally happen in clinical practice. In real world settings, parents would either receive a prescription from the GP or source the nasal balloon over-the-counter. On reflection of the process in this study, provision of the nasal balloon did not give a clear assessment of uptake in real world settings. It would have been more pragmatic for the nasal balloon to be prescribed, and this would have facilitated better assessment of uptake and usage.

9.5.4 Suggested improvements and further research

The log in procedure for the educational intervention caused difficulties for some participants, so the final intervention needs to be easier to access and combine data collection and intervention delivery on the same platform. This could be facilitated by the use of the Lifeguide software[220] or further developmental work to the current site. However, there are potential issues for collecting and retaining user identifiable information using the current University platform which would need to be explored. The alternative would be to make this purely a self-management tool thus avoiding the many issues around data collection.

Parents did not use the hearing disability test to monitor for improvement or worsening of symptoms Prompts or reminders have been found to improve engagement with digital interventions and behaviour change[228]. The LittleEARS educational intervention could be developed further and more tailored to the individual family and child, sending email reminders to retake the hearing disability test, complete the OMQ-14 or simply check symptoms against the predictive symptom checklist after 3 months. Collaboration with health psychologists would facilitate further development to address these issues and further qualitative work, as recommended by the person-based approach for intervention development, would ensure that the intervention was both relevant and acceptable to families, and improve the likelihood of implementation

This study has provided an initial insight into the feasibility and acceptability of the educational intervention to support implementation of the nasal balloon method. The results were promising but potential issues were highlighted and numbers were small so further work is necessary before its wider use in an implementation study. Recruiting further parents to evaluate the intervention would give a more comprehensive view of feasibility. However, recruitment via primary care was a lengthy and costly process, so further case-identification may be more successful and rapid via paediatric audiology. Further qualitative work was planned as part of the wider project but not possible during the time period of this PhD. Qualitative interviews with parents who have used the educational intervention would enable a better understanding of its use in everyday situations, and issues around need for and avoidance of NHS consultations.

9.5.5 Clinical Implications

The vast majority of young school children with glue ear are currently being managed by the GP in primary care, with many referred to paediatric audiology for further investigation and testing. It is appropriate to implement a period of 3 months active monitoring prior to onward referral for further assessment or treatment due to the high natural resolution rates and false positive diagnoses relating to parental concerns in the case of ENT referrals. Both settings could potentially benefit from the proposed educational intervention if proven to be successful in a larger implementation study.

In general practice, GPs use a range of monitoring strategies and treatments for children with glue ear, as described in chapter 5, and the LittleEARS educational intervention has the potential to inform general management and support the uptake of the nasal balloon in children while waiting for either referral or natural resolution. However, uptake rates in this study were low, and further research would be needed to establish acceptability and usefulness in the primary care and community setting.

The wTADAST-24 is a potentially interesting hearing disability test with good face-validity and reliability. However, its usefulness in the wider clinical or home setting has

yet to be established, and it is still unclear as to whether it can monitor change over time. Further work will be needed to assess these issues.

Audiology departments have a long established diagnostic role, and can differentiate those who require onward referral to ENT i.e. those most severely affected, or those who can return to general practice if symptoms resolve. However, audiologists are currently unable to prescribe treatments other than hearing aids, and are therefore limited in the treatment options they can offer children with glue ear. The nasal balloon, whilst not currently prescribeable by audiologists, can however be bought over-the-counter or prescribed by the GP, and is a potentially useful treatment option for families during the active monitoring period. The LittleEARS educational intervention has the potential to provide support to families during this time, and support the uptake and usage of the nasal balloon method. Qualitative interviews with audiologists regarding their views and experiences of using the nasal balloon and educational intervention would provide valuable information for future implementation.

9.6 Conclusion

This chapter has described a feasibility study to assess the acceptability and feasibility of an educational intervention to support active monitoring and the nasal balloon in children from both primary care and audiology. Recruitment was poor, and uptake of the educational intervention was lower than expected, so limited conclusions can be drawn as to applicability to the wider clinical setting. However, parents who did take part engaged well with the educational intervention and appeared to be enabled to support their child in the use of the nasal balloon. Further work is required to establish the usefulness and acceptability of the wTADAST-24, and whether it can monitor change over time.

Chapter 10: Discussion

10.1 Introduction

The aim of my PhD is to promote wider implementation of nasal balloon autoinflation for early management of otitis media with effusion in primary care. My work involved reviewing the evidence; conducting empirical qualitative work to better understand the context for implementation; further development of an objective measure for hearing disability (wTADAST-24); and the development of a novel digital educational intervention (LittleEARS) to support more structured primary care monitoring and use of nasal balloon autoinflation in primary care.

This final chapter presents an overview of my PhD, including a summary of the individual chapters, a discussion of the key findings in relation to the current literature, the strengths and limitations of my research and proposed future directions for my research. I present my personal reflections on the use of the Normalization Process Theory to underpin my research, and the selection of appropriate methodology and research methods to answer my research aims. Finally I discuss my own personal learning and development through undertaking this PhD.

10.2 Overview of this thesis

I began by conducting a literature review (chapter 2) to identify the key clinical aspects of OME including epidemiology and risk factors, challenges of diagnosis and management, impact on children and their families, and to systematically review current evidence for autoinflation as a treatment for OME. This identified gaps in current knowledge about accurate early diagnosis and management of OME in the primary care setting. In addition, the nasal balloon, despite being available for more than 10 years as a prescribeable treatment, is currently still surprisingly unknown in UK practice and yet to be widely used in the management of children with glue ear in the community setting. However, the Otovent™ device has recently been reviewed in a NICE Medtech Innovation Briefing (MIB59)[61] and identified as an effective treatment for OME during the active monitoring period, so its profile may be start to be raised.

In chapter 3 I discussed the importance of having a sound theoretical basis for researching implementation of the nasal balloon method and to underpin the development, evaluation and implementation of an educational intervention. I reviewed three relevant implementation theories for this research and discussed why I selected the Normalization Process Theory (NPT) to guide and inform my PhD. I identified that NPT puts emphasis on the work and process elements of implementation which I considered to be most relevant for the implementation of a new technical treatment like the nasal balloon.

My theoretical and methodological approach to this research is presented in chapter 4. I described my philosophical stance as a *critical realist* and argued that pragmatism using mixed methods was the best approach to answer my research aims. Pragmatism advocates that research methodology is selected to answer the research question, rather than due to its underlying philosophical position. In this PhD I planned a broad programme of work to include the exploration of stakeholder views and experiences of glue ear and the nasal balloon, together with the pragmatic development and evaluation of a hearing disability test and educational support intervention. This approach necessitated drawing on both qualitative and quantitative methods to address my research aims.

Key factors for successful implementation are the political, historical, cultural and organisational contexts in which any new intervention is to be successfully implemented[245]. My qualitative work presented in chapter 5 helps to better understand how GPs currently manage children with OME, the organisational processes involved, implications of local and national guidelines, referral pathways, and the major effect of local experience and expertise. The study found that GPs were generally confident in diagnosing glue ear although referral strategies varied dependant on clinical judgements and locally available services. GPs used a wide range of different treatment strategies including participating with active monitoring, various available medical treatments, and other active treatments such as the Valsalva manoeuvre[68] and the nasal balloon. However, GPs expressed some concerns about the actual practicalities of use of the nasal balloon in the primary care setting and identified a potential compliance burden to families. The demonstration of the

technique was identified by GPs as an important component to help promote uptake and compliance with the device, but some concerns remained about whether it may complicate and thus lengthen the GP consultation process.

Treating and managing children with such a common problem as OME requires the involvement and engagement of different stakeholder groups including primary healthcare professionals (GPs and nurses) and families (parents, carers and children). Chapter 6 of this thesis explores the facilitators and barriers to wider implementation of the nasal balloon method in primary care. A secondary analysis of qualitative interview data was undertaken using the Normalization Process Theory to guide the analysis. This study identified that both providing evidence-based information and an effective demonstration video of the nasal balloon method enhances engagement with the active monitoring process, promotes uptake of the nasal balloon and so has potential to reduce the burden on the GP consultation. The use of NPT to focus the analysis helped identify promoting and inhibiting factors to wider implementation of the nasal balloon, and these identified factors were used to guide the development of the final LittleEARS educational intervention.

A significant element for implementation identified in the qualitative work concerned *reflexive monitoring* or the ability of GPs and parents to appraise the outcome of monitoring and management. In chapter 5, GPs suggested that parents are often required to monitor their child for improvements, which in turn can affect consultation rates and onward referral to ENT. However, there are currently very limited resources available to measure hearing disability and support self-management. The TADAST hearing disability test was developed in general practice 20 years ago, but due to rapid technological advances became out-dated. Chapter 7 describes the further necessary development and evaluation of an updated shorter wTADAST-24 with new videos and graphics presented on a new platform. The developmental outcome was a naturalistic hearing disability test with good face-validity, which is both accessible and applicable to use in a wide community setting but that will need more work to assess potential to measure change and where it might be most usefully employed in the management and monitoring of children with OME.

Chapter 8 presents the pragmatic development of the LittleEARS educational intervention, which was underpinned by NPT and informed by elements of the person-based approach. Guiding principles for this were developed from the qualitative work presented in chapters 5 and 6. Existing evidence and the qualitative work was used to focus the intervention design objectives and mapped to key behaviour-change components. Usability testing was conducted with parents using the think-aloud method, and a panel of healthcare professionals and topic experts familiar with OME provided expert feedback. The resulting educational intervention was therefore developed from evidence in the medical literature, qualitative enquiry, multi-expert knowledge, and direct user feedback. A resource that was considered acceptable, comprehensive, useful to parents and applicable to the community setting was produced.

Chapter 9 describes a feasibility study that assesses the acceptability and usability of the LittleEARS educational intervention in support of active monitoring and the nasal balloon in children from both primary care and audiology. Whilst numbers were smaller than hoped, and recruitment problematic, the study found that participating parents engaged well with the new educational intervention and were able to support their child in the use of the nasal balloon. The LittleEARS educational intervention appears to be both appropriate and potentially useful in primary care and audiology settings. It has the potential to improve the active monitoring process for a great many affected school-aged children but needs further work to clarify optimum use and implementation.

10.3 Comparison with existing literature

This section presents the outcomes of my research in the general context of current clinical practice and up-to-date literature.

10.3.1 Primary care management of OME

At the start of this research very little information or evidence was available about how GPs actively diagnose and manage children with OME, which is surprising for such a common childhood condition. Recognising the main drivers for management and

referral is important to help understand the general context in which a new evidence-based treatment such as the nasal balloon method could be widely implemented. My research has attempted to shed light on these areas and so explored the general context for wider implementation of the nasal balloon treatment method.

Parental concerns are the basis for most diagnoses of OME in primary care[155] and most GPs do not have a sufficiently objective measure for diagnosing middle ear effusions such as tympanometry.[27] My qualitative work reports similar results and found that GPs used the child's symptoms, the age of the child, the time of year, and the number of previous consultations for ear related problems over the past year when making a diagnosis of more chronic glue ear. GPs in this study did not generally use or have access to tympanometry, but nevertheless remained confident in making a diagnosis of OME. However, there are previous anecdotal reports from GPs that there is professional uncertainty as to the nature and accurate diagnosis of glue ear in primary care.[20] A research paper by The Kings Fund in 2010[246] reviewed the quality of GP diagnosis and referrals for all conditions in primary care and described the role of the GP to be one of 'problem recognition' and 'decision-making'. The primary care objective is therefore not necessarily to reach a definitive answer, but to act as a gateway for further management whilst attempting to minimise delay for those who are most in need. In the particular case of glue ear, the objective for GPs is to both recognise the organic condition and its consequential impact rather than to provide definitive diagnosis. Thus children could be actively monitored for natural resolution or referred quickly in cases of 'high impact'.

One in 20 GP consultations in the UK results in a referral to secondary care services[246] with the main reasons for referral being to establish a diagnosis; for treatment or surgery; for further advice on management; and for reassurance. Decision for referral involves GPs balancing their concerns with the information that is available to them, whilst responding to patient expectations and pressure. In the case of OME management, the wTADAST-24 could provide useful information for GPs to help with the decision-making process in terms managing parental concerns, but it is not known whether it has the ability to detect changes over time. In addition, the more subjective OMQ-14[153] parent proxy measure of ear-related quality of life has a potential role in

helping clinicians assess and better monitor the impact of hearing disability in young children over the recommended 3-month monitoring, although in its current format it is not readily usable in normal clinical care due to its complex, weighted scoring system that requires calculation and interpretation.

Patient expectation and patient pressure can be important drivers for secondary care referral, and in the case of the very common condition of OME, parents are often and rightly concerned about potential impact of hearing loss on their child's quality of life and educational progress. A qualitative study nested in AIRS[3] found that that parents often wanted to take action following a diagnosis of OME, and that waiting was understandably not always acceptable to them. Another qualitative study of parental perceptions and understanding of OME reported that parents often described watchful waiting as unacceptable, especially if OME was impacting on a child's education.[65] However, OME naturally resolves in 50% of cases in 3 months, rising to 75% at 6 months [194] so there is a valid case for waiting for natural resolution. In a qualitative study of children with AOM, parents with more knowledge and who felt included in medical decisions were more likely to accept watchful waiting, rather than immediate antibiotic treatment[247]. However time scales are considerably different between AOM and OME histories. In the case of OME, parents are more likely to engage with the 3 month recommended active monitoring period if they are involved in decision making about management and referral, by receiving evidence-based patient information, and by being offered an evidenced-based non-surgical management option such as the nasal balloon. The LittleEARS educational intervention developed as part of my PhD has the potential to provide evidence-based information in an accessible format to support families during a desirable watchful waiting period.

10.3.2 Self-management of OME

The work described in this thesis has the potential to improve parent and child self-management of OME in primary care, by providing i) evidence-based information in an assessable format, ii) tools to help monitor the impact of hearing loss, and iii) self-help advice for helping children to hear and function better at home and in the school environment. Better understanding and self-management provides a more structured

environment in which the nasal balloon can be implemented as an additional self-management tool.

Self-management strategies in chronic childhood conditions have already been developed and are widely used in self-management of asthma.[229] Asthma is perhaps the main chronic intermittent childhood respiratory condition, and educational interventions have been well-researched to reduce morbidity associated with asthma and reduce the utilisation on health resources in children and adolescents.[207] Unfortunately, little work has been done to date to develop self-management strategies for families and children with glue ear, even though self-management is very probably the best way of helping and empowering patients to improve and manage their health[209]. It involves providing patients with the necessary tools and techniques with which to facilitate better health behaviours. It can also fundamentally change the relationship between patients and healthcare providers into a much more collaborative partnership. The impact of self-management could result in improved outcomes for patients, and increased satisfaction with healthcare provision. Additionally it has the potential to reduce unnecessary hospital referrals, by improving adherence to the active monitoring period and reducing parental pressure for referral. This is particularly salient for management of children with OME, where there are more than 27,000 surgical operations for grommets per annum[50]. At an estimated cost of £1359.00 per surgical case[51], even a small reduction in number of ENT referrals has the potential to provide significant cost-savings to the NHS.

The use of the internet to access health information is ever increasing, with the percentage of people seeking health-related information online in the UK increasing from 18% to 51% between 2007 and 2016[230]. Consequently, publicly available health information can strongly influence what patients understand about their health conditions and affect their decision-making about treatment and management. Parents of young children seek health information from a number of sources, and a study from the USA found that the internet was the second most preferred source of health information after the child's healthcare provider[193]. In the case of glue ear, there are numerous websites providing patient information in the UK with varying quality

and readability,[194] however they contain little information about self-help and self-monitoring or instruction about use of the nasal balloon.

Self-monitoring is another component that can improve patient self-management. The use of symptom diaries and peak flow meters have been widely used in self-management of asthma.[229] The development work on the wTADAST-24 has provided an accessible and naturalistic hearing disability test with good face-validity, which has the potential to help parents monitor the impact of their child's hearing loss associated with OME, although more research is needed to determine whether the wTADAST-24 can detect changes over time. Whilst it wasn't widely used in the feasibility study, the uptake was good in the wTADAST-24 development study (chapter 7) where parents gave consent for their child to evaluate the test in the classroom setting. Teachers also expressed an interest in using the test in the school setting once validation of the wTADAST-24 had taken place. Symptom diaries are also included as part of the LittleEARS educational intervention which can facilitate the monitoring of a child's symptoms throughout the 3 month recommended active monitoring period.

Effective self-management of conditions such as glue ear can reduce the burden on the healthcare services by increasing further joint-decision making with parents and also increasing uptake and satisfaction with the monitoring period. General practice is under considerable pressure with an ever growing workload, but this has not been matched by any increase in funding or workforce (Kings Fund 2016)[248]. Between 2011 and 2015, the number of face-to-face consultations grew by 13%, whilst GP workforce only grew by 4.75% and nurse workforce by 2.85%. The LittleEARS educational intervention together with an embedded wTADAST-24, provides an evidence-based information platform to support families of children with glue ear and has the potential to reduce the overall burden on primary and secondary care NHS services by improving self-management. It has the potential to support the use of the nasal balloon method and other self-directed treatments during the active monitoring period.

10.3.3 Implementation of the nasal balloon

Nasal balloon autoinflation has been shown to be an effective treatment option for children with OME during the 3 month active monitoring period[2 60]. Nonetheless it is not currently widely used in primary care, and there have been presumptive concerns raised as to whether children can master the technique, and whether treatment would constitute a significant burden to families. My research has offered some insight into the views and experiences of using the nasal balloon and resulted in an educational intervention which includes the first detailed demonstration and stepwise instructions for the use of the device in the primary care setting.

A practical treatment like the nasal balloon can be difficult to simply and quickly describe, whilst a demonstration can be key to children mastering such a technique. The qualitative work undertaken as part of this PhD found that GPs considered the demonstration of the technique to be key to its use, but thought it might add too much time to the GP consultation. However, improper use, or not mastering the technique, could lead to poorer outcomes for some children. In the case of childhood asthma, research has shown that children often do not use metered dose inhalers correctly and this can lead to poor asthma control, an increase in number of hospitalisations and increased associated healthcare costs.[249] If children can be shown how to use an inhaler and have time to practice during medical visits, the more opportunity there is to affect behavioural change and self-efficacy, and consequently improve outcomes.[250] In the case of the nasal balloon method, the most common problems arise with the first inflation due to the initial high tension in the balloon. The balloon universally needs to be pre-stretched either by hand or blowing up with the mouth, prior to trying nasal inflation. If families are unable to get past this first step, compliance with the nasal balloon is very likely to be poor, and children will be not getting any additional benefit of autoinflation during the waiting and monitoring period. Healthcare providers need to ensure that parents/children therefore receive good detailed instruction, preferably with actual demonstration of the nasal balloon, to enhance uptake and longer term compliance.

Practice nurses could potentially demonstrate the nasal balloon given the time and training to do so, although pressure on primary healthcare services also extends to the workload on nursing staff[248]. Previous research has found that nurses are very competent case managers for OME and the triadic relationship between nurses, parents and children was important to children mastering the autoinflation technique in a randomised controlled trial.[3] Similarly, asthma nurses are seen as central to training families and children in the use of their metered dose inhalers in primary care[251].

GPs also identified pharmacies as a potential place for the demonstration of the nasal balloon method. A study of the effect of community pharmacy delivered educational interventions to support correct inhaler technique found that a physical demonstration rather than written and verbal instructions alone significantly improved inhaler technique and compliance.[252] Pharmacists are particularly well place for this role as they are the last but immediate point of contact for patients before medication or devices are given, and they have more regular contact with patients (and patients can return easily without making an appointment if they need further advice or support). In Finland, the role of pharmacists in improving asthma control is thought to be an important element of improving care.[253]

Similarly, instruction videos to teach inhaler technique to children found that technique improved when a video was used to back up the consultation[137]. In my qualitative work, GPs suggested that demonstration videos had the potential to support the use of the nasal balloon, whilst reducing the burden on the consultation process. The LittleEARS educational intervention contains a demonstration video which draws on some the work done on teaching inhaler technique and on the triadic relationship between the healthcare professional, parent and children identified in the AIRS qualitative study.[3]

In the qualitative work presented in chapter 5, some GPs suggested that the nasal balloon treatment may be an unnecessary burden to families. Children are required to inflate the balloon three times per day for up to 3 months. Compliance with this treatment regimen was reported as good in the AIRS study[2 3], but participants who

take part in research trials are often more motivated and engaged patients. Making the treatment part of a child's daily routine has been found to help with compliance, especially in the longer term.[3] However, it is known that patients with chronic health conditions can be encumbered not just by their health condition but by the workload associated with it including taking their medication, attending medical appointments, and monitoring their symptoms. The Burden of Treatment Theory,[122] developed through the broader elements of NPT, refers to the interaction between the *capacity* of patients and the *work* that stems from healthcare. The potential burden to families of children with glue ear includes parents learning about the condition of glue ear, self-management activities, and compliance with the nasal balloon treatment regimen. This necessitates a level of acceptance of the tasks and an ability to carry them out. The feasibility study described in chapter 9 found that most parents and children engaged with the nasal balloon method. However, if children stopped using the balloon it was generally due to problems with mastering the technique rather than a longer term compliance problems. Nevertheless, the burden of treatment needs to be balanced against the ongoing burden of the disease itself. In the case of OME, the affected child may experience significant effects associated with hearing loss and this needs to be balanced against any additional work associated with treatment and management. Additionally, the burden of use of the balloon needs to be compared to the potential stress and ultimate burden of grommet surgery.

10.4 Use of NPT in this research

NPT facilitated the evaluation of current social, political and financial context and identified how this could affect the usage and uptake of the nasal balloon method in primary care. Through qualitative research guided by NPT I explored the work and processes required of families and healthcare professionals to implement the nasal balloon method. Finally I used NPT to explore levels of interaction with the LittleEARS educational intervention and uptake of the nasal balloon. The following describes the final NPT evaluation of the nasal balloon treatment and discusses where the work conducted as part of this thesis has the potential to promote wider implementation of the nasal balloon in primary care.

Coherence is the work that people do both individually and collectively to make sense of a new practice (*sense-making work*). This includes differentiating the new intervention from current practice, building an individual and shared understanding of a new practice, and understanding its value and potential benefits. My research found that parents generally report good *coherence* for the nasal balloon treatment, describing it as simple, practical and non-invasive treatment, potentially reducing the need for medications and invasive surgery.

Likewise, GPs and nurses reported good *coherence* for the nasal balloon intervention describing it as a logical, low harm, low cost intervention, but there were reported concerns about credibility and the apparent lack of widely available evidence about its effectiveness and potential harms for healthcare providers. Whilst individual understanding of the nasal balloon method was good, there were contrasting views about the suitability of the treatment for certain families. To improve *coherence* for families and healthcare professionals I developed the evidence-based LittleEARS educational intervention to provide information about glue ear and the nasal balloon treatment, in an accessible format which is applicable to the primary care and community setting.

Cognitive participation is the work that people do to engage in a new practice (*relational work*), which includes people buying in to and supporting a new practice and agreeing that the practice should be part of their work. In my research I found that families generally engaged with the nasal balloon method, although there was little data from the lower sociodemographic groups. Parents who participated in the feasibility study (chapter 9) engaged with the 3 month active monitoring process, using the educational intervention to improve their understanding of glue ear, to learn about self-management techniques and to support their child with using the nasal balloon. However, qualitative work suggested that GP engagement with the nasal balloon may be reduced as many did not consider it was their role to demonstrate the balloon method during the consultation. It was suggested that nurses or pharmacists could undertake this role if funding and training were available. GPs considered that the intervention was acceptable and achievable for most families with good training and support, although general public engagement may be somewhat inhibited in certain

socio-demographic groups. To improve *cognitive participation* for families, I developed the educational intervention to provide parents with a better understanding of glue ear and the treatment choices available to them using accessible formats and appropriate language. Self-management is a vitally important aspect of health and, by giving parents the tools to identify and monitor their child's symptoms, has the potential to help support their child with OME both in the social environment and in the classroom. As such I included self-management information and monitoring measures (symptom diaries and the wTADAST-24) to help parents monitor their child's hearing, although the wTADST-24 was not widely used in the feasibility study.

Collective action is the work that people do to enact or operationalise a new practice (*operational work*) which includes whether people are able to perform the tasks required of them, and whether they have the right skills and are adequately supported by the host organisation. My research found that *collective action* for the nasal balloon was enhanced with a practical demonstration of the nasal balloon method supported by an evidence-based online training video. I developed an online training video giving stepwise instructions for use of the nasal balloon treatment as part of the educational intervention, and parents who participated in the feasibility study reported it to be helpful to support the uptake of the nasal balloon method. The use of incentives and sticker reward charts promote ownership and compliance with the nasal balloon and making autoinflation part of the child's normal routine improves overall adherence. I included sticker reward charts for families to print out as part of the online educational intervention and information to parents about how to best engage children with the treatment regimen.

Reflexive monitoring is the work people do to assess and evaluate a new practice (*appraisal work*) including how they access information, individually and collectively assess the practice as worthwhile, and how they modify their work in response to their appraisal. One of the main issues that my research highlighted were the difficulties for monitoring the progress or improvement of glue ear in primary care. GPs often rely on parents to do the monitoring. However, parents are often unsure about how long to continue treatment for, how to know if it is working and when not use the nasal balloon. As part of my PhD I further developed and evaluated a simple user-friendly

hearing disability test (wTADAST-24, chapter 7). This is embedded in the educational intervention to promote monitoring and self-management. I also included symptom checklists, and the OMQ-14 ear-related quality of life questionnaire, which has the potential to improve management and precision of diagnosis, but is not currently available for use in the clinical setting.

In summary, the use of NPT has facilitated the understanding of the implementation work and processes required for wider use of the nasal balloon treatment. The result is an evidence-based accessible resource to support active monitoring and wider use of the nasal balloon method in primary care.

10.5 Strengths and limitations

My research set out to promote the wider implementation of the nasal balloon method in primary care. In order to address this, I initially focused on the uncertainties of current management and treatment strategies, and examining the broad context for implementation. This led to the development of tools to promote monitoring and better self-management of glue ear in primary care. A main outcome of my research is an evidence-based, educational intervention, co-developed by end-users and topic experts, which is accessible and relevant to parents in primary care. It has the potential to support the implementation of the nasal balloon method or other self-directed treatments for OME during a recommended three month monitoring period. However, participant numbers in the feasibility were small (chapter 9) and consequently the conclusion drawn must be viewed with caution.

My work has also resulted in a much needed update of a hearing disability test (wTADAST-24) that is applicable for use in the home or the classroom. As far as I am aware, it is the first objective measure of hearing disability applicable to primary care which has potential to better inform monitoring for glue ear as a near-patient test. However, it remains unclear whether the wTADAST-24 has the ability to detect change over time, particularly in the most vulnerable groups, which is a current limitation to its use.

A key strength of this research was using a theoretical framework and selecting a pragmatic methodological approach to answer the research aims. NPT was used to underpin the whole research process. As a generaliseable and flexible framework for implementation, I used it as a heuristic device to inform the overall research, as a conceptual framework for analysis, and to guide the development and evaluation of the educational intervention. The use of mixed methods allowed me to select the appropriate methods of enquiry and integrate the results to ensure the research aims were met. Further discussions and reflections on the use of theory and methodology in my PhD are presented in section 10.7.

Throughout my PhD I engaged families and children as research participants, both in qualitative interviews and for developing and evaluating interventions. However, I recognise that it might have been valuable to involve the public on a more advisory level, rather than just as research participants. Patient and Public Involvement[254] means that research is carried out as a collaboration with members of the public, rather than research being done for or about them. In my PhD I could have incorporated public involvement to advise on my overall research strategy, help develop research materials, or assist with the interpretation and application of the research outcomes.

One limitation of this work was not being able to adequately represent participants from lower sociodemographic groups in the evaluation of the educational intervention. However, my qualitative work (chapter 6) and the think-aloud interviews (chapter 8) did include some participants in the lower demographic groups as depicted by their highest educational level obtained, and who also contributed to the development of the educational intervention. For future work, it would be important to ensure fuller representation of socio-demographic groups including single parents, fathers and grandparents, to ensure that the nasal balloon and the educational intervention is not limited to those families who are already engaged and well-motivated. Further Patient and Public Involvement[254] would help explore how best to reach these target groups of parents.

Another limitation of this work is the age of child for whom the nasal balloon treatment is relevant. OME has a bimodal peak prevalence in children around the age of 2 years and then again in the early school years[8]. The work presented in this PhD has been conducted with school-aged children when hearing loss can impact significantly on their education and development. The hearing disability test was tested in children age 5-6 years and the educational intervention was evaluated in families with children aged 4-7 years. Limited evidence suggests that children as young as three years old may be able to use the nasal balloon with some training[95], however children aged 1-2 years are unlikely to be able to use the nasal balloon. For these children, OME still represents a considerable challenge if surgery is to be avoided. Other middle ear insufflation devices have been suggested for the younger age group, including the Politzer device[89] which requires less user-involvement than required for inflating a nasal balloon and research is planned in include children as young as 2 years. Additionally, the Moniri-Otovent™ device[90] may also be more suitable for the younger child, which can be used as a Politzer or Valsalva device although may not be suitable for the very youngest affected children.

Oral steroids are a potential treatment modality for this younger age group and a large randomised controlled trial[46] is underway to assess their effectiveness and may provide an important treatment option for this cohort of children in primary care. A modified educational intervention may also have the potential to support the families of younger children with OME, where a better, structured active monitoring period would be equally desirable.

10.6 Future research

The LittleEARS educational intervention has the potential to improve primary care monitoring of children with OME. It could be used to promote and support the use of the nasal balloon, and potentially support other medical interventions for OME, by providing better structured monitoring and self-management. However, further developmental work is still required.

Further work is needed to assess usability and acceptability of the educational intervention in a wider cohort of families of children with OME. Making the

intervention more widely available on the internet would facilitate the gathering of feedback and experience of use, prior to any further modifications or developmental work. Recent correspondence with Professor Paul Glasziou, however, has resulted in the inclusion of my Otovent demonstration video in The Royal Australian College of General Practitioners Handbook of Non-Drug Interventions (HANDI). This will facilitate collection of useful feedback from the general public in Australia concerning applicability and usefulness of the demonstration video itself. The LittleEARS educational intervention could be made more publically available, however with the ever-increasing number of health and self-management interventions it would be important that it was hosted correctly and linked to the evidence-based resources that are currently available to patients (e.g. current information sheets for OME and evidence-based websites such as patient.co.uk and NHS Choices).

To engage GPs in the use of the nasal balloon method it would be useful to identify what training or resources that GPs might need to support the prescription or recommendation for the nasal balloon in primary care. The LittleEARS educational intervention already has log in facilities for GPs and healthcare professionals (not evaluated as part of the PhD), but the content needs some further development and refinement. Providing GP training in OME and the nasal balloon, in terms of online modules and resources, may help further implement wider use of the nasal balloon in general practice.

Further work is also required to continue raising awareness of the nasal balloon method as a treatment for OME in the context of the wider NHS. Publicity of the AIRS study results by regional dissemination to the CCGs, and a further update to the Cochrane Systematic Review of Autoinflation[60] may help to address this.

In the longer term, an implementation study could be conducted to look at provision of the LittleEARS educational intervention to CCGs and subsequently assess outcomes and resource use, using large datasets, such as the Hampshire Health Records. Funding would be sought from the Collaborations for Leadership in Applied Health Research (CLAHRC) whose remit is to support applied health research which has a direct impact on patient health and well-being.

Audiology is a natural setting for the educational intervention and the nasal balloon. Currently, audiologists report that there is little to offer parents and children whilst they are waiting for natural resolution or onward referral. Further work could be undertaken by audiologists in implementing the educational intervention and the nasal balloon in the audiology setting.

The wTADAST-24 needs minimal developmental work to make it useable outside of a research setting. However, it does need to be made accessible without a login and requires proper signposting to ensure healthcare professional advice is sought if parents have continuing concerns about their child's hearing. Plans are underway to publish the results of the wTADAST-24 development and I aim to include links to the online hearing test to allow the public to try the test and provide feedback. This will facilitate the collection of anonymised data and allow assessment of usage, uptake and impact in the wider community setting, prior to any further developmental work or research. It would be particularly useful to gather some longitudinal data to assess sensitivity of the TADAST-24 to change over time. This could involve some further research using audiograms and quality of life measures before and after grommet surgery (or other medical treatment such as oral steroids), to validate the usefulness of the test in the wider clinical setting.

The wTADAST-24 also has potential to be used in the classroom setting where hearing concerns have been raised. Halterworth Primary School, who provided the setting for the further development and evaluation of the test, have expressed an interest in using the test once evaluation is complete.

10.7 Personal reflections

This section presents my reflections on the theory, methodology and research methods that I used for this PhD, and a personal reflection on my own learning and development during the past 3 years.

10.7.1 Reflections on the use of NPT to underpin the research process

NPT provided a coherent, theoretically sound basis for the research undertaken in this PhD project. It has informed, sensitised and supported a rigorous research process throughout my PhD studies.

In the early stages of my research I used NPT as a heuristic device to identify questions associated with implementation of the nasal balloon, and to explore the context in which implementation would be set. Using the four constructs of NPT allowed me to think about the work and processes that each of the stakeholders would be required to engage in if the nasal balloon implementation was to be successful. I used these thoughts and ideas to develop the interview guide for the GP interviews, which explored the practicalities of use in the clinical setting and its effect on the consultation process.

My secondary analysis of existing qualitative data used NPT to guide and frame the analytical process. Previous research has demonstrated the benefits of using the theory as an organising framework especially when exploring multiple perspectives (e.g. professionals and service-users).[120] Using it in this way allowed me to explore the views of parents and health professionals of the nasal balloon method and to explore differences in views between the different stakeholders with respect to suitability of treatment and potential treatment burden.

The secondary analysis of qualitative data also identified promoting and inhibiting factors to wider implementation of the nasal balloon and these were used to guide the development of the LittleEARS educational intervention. Using theory to underpin the development of a digital intervention is recommended in the MRC guidelines for developing and evaluating complex intervention.[130] NPT allowed me to focus the intervention on the components likely to engage families in active monitoring and the practical aspects of trying and complying with the nasal balloon treatment. It focused my thoughts on the components of *coherence* (what parents thought about glue ear and the nasal balloon treatment), *cognition participation* (what factors might promote or inhibit engagement with the treatment), *collective action* (what parents need to help their child master the technique) and *reflexive monitoring* (how will parents know

if the treatment is working). The resultant educational intervention was co-developed with experts and end-users, underpinned by an appropriate and relevant implementation theory.

Finally I used NPT to interpret the results and evaluate the processes of implementation of the nasal balloon treatment and discuss how this was used to develop and evaluate resources to support with wider implementation of the nasal balloon method in primary care.

Whilst NPT provided a relevant and usable theory to underpin my research, I did face some tensions and challenges whilst using NPT in my PhD. As reported by other users of the theory, I faced problems when making coding decisions in my qualitative work[120]. It was not always clear how to code sections of data, where it seemed that data could be coded to more than one construct. It required regularly revisiting the construct descriptions to try and understand the essence of each one and ensure that my coding was consistent. However, the authors of NPT state that the constructs are not in competition with each other but are intended to work together to explain causal mechanisms[5].

I also encountered problems with deciding the extent to which I should use the theory. Each of the four constructs of NPT has 4 sub-components, totalling 16 theoretical components in all. This is complex to understand and difficult to apply to your own work, especially when coding qualitative interview data and attempting to be consistent. In the end I didn't feel that using the 16 individual components would add additional value to my analyses so decided not to use the theory at that level in this particular research project.

Finally, I was concerned that using the theoretical model for every aspect and component of my research would constrain the results by trying to fit everything into a pre-defined framework. However, I used it in different ways for the different parts of my research to ensure that it guided the research process rather than acting as a 'theoretical straightjacket'.[120] This is consistent with NPT authors' views on the flexibility of using NPT.

Using NPT to underpin my PhD help me to recognise the value of using a strong theoretical framework for conducting research. I now have the tools and experience to use NPT in future research projects and would explore the use of other theoretical tools or frameworks as appropriate for future research.

10.7.2 Reflections on philosophy and methodology

I presented by own philosophical position as one of a critical realist, whereby I believe an independent reality to exist but recognise that my understanding of reality is neither perfect nor complete, and therefore requires critical examination. I also accept that views and understanding of the world is constructed from individual perspectives. I recognise, therefore, that the reality of use of the nasal balloon method for children with OME is individually constructed by healthcare professionals (GPs, nurses and audiologists) and families (parents and children). Taking a critical approach has allowed me to explore and examine the important questions around use of the nasal balloon in the primary care setting from the perspectives of the different stakeholders.

I selected mixed methods and a pragmatic approach to my PhD. John Creswell, a professor of educational psychology who has written widely on the subject of mixed methods, talks about the 4 main factors associated with mixed methods research[255]. I will discuss them here and reflect on how I employed mixed methods in my PhD research.

The first component of mixed methods research is the use of both qualitative and quantitative methods of enquiry. In my research I used qualitative work to understand GP views and experiences of diagnosing and managing OME in primary care which helped contextualise the setting in which the nasal balloon would be implemented. I also used qualitative research in the development of my educational intervention, which provided a better, more detailed understanding of how it might be used by the proposed end-users. Additional qualitative work may have helped understand more about what parents thought about the educational intervention. I used quantitative methods where the research question required answers associated with how much or how many. Importantly I used scientific enquiry to assess reliability and repeatability

of the wTADAST-24 hearing disability test and in the evaluation of usage and acceptability of the educational intervention.

The second component of mixed methods research is the use of rigorous research methods. In terms of qualitative work within my PhD I used Lincoln and Guba's criteria[145] for trustworthiness and rigour to ensure that the outcomes of the research were credible, transferable, dependable and confirmable. I used techniques such as multiple coders to ensure credibility. I maintained a meticulous audit trail and a reflexive journal to improve consistency and transparency of my research. I detailed my methods and outcomes to ensure that readers could assess whether the research was applicable or transferable to other settings. In hindsight I might have involved my supervisory team to a larger extent with the secondary analysis of my qualitative data, but as I was most familiar with the constructs and components of NPT I made most of the coding decisions and my supervisory team assisted more with the interpretation of the results. I could also have presented my findings back to the research participants for confirmation if time had allowed, and included Patient and Public Involvement in the interpretation of the outcomes of my qualitative work. In quantitative work, quality and rigour is measured in terms of internal and external validity, reliability and avoidance of bias. In my development work of the wTADAST-24 I recruited children from primary schools which is a potential and valid setting for the hearing disability test. I used objective measures to minimise measurement bias and had a 100% follow up rate and therefore reducing non-response bias.

The third, and arguably the most important, component of mixed methods research is the integration of the findings of both qualitative and quantitative findings. Simply reporting the outcomes of the different elements individually does not constitute mixed methods research. An important scheme describing integration of qualitative and quantitative findings was first presented by Greene[256] who suggested five types of integration: **triangulation** (convergence of results); **complementarity** (seeking elaboration or clarification from one method to the other); **development** (results from one method informs the next method); **initiation** (seeking new perspectives through the results of both methods; and **expansion** (seeking to extend the breadth and range of enquiry). In this work I integrated the qualitative findings presented in chapters 5

and 6 in the development of the educational intervention, and the think-aloud interviews were integral to the user-testing and evaluation.

My original plan was also to conduct qualitative interviews as part of the feasibility study presented in chapter 9. This would have facilitated triangulation of results from both qualitative and quantitative outcomes, adding confirmation of results and a better insight into the actual usage of the LittleEARS educational intervention in the everyday setting. However, this was not possible due to the time constraints of this PhD project.

The final component of mixed methods research is framing research within a theoretical framework. My reflections of this is presented in section 10.7.1 which discusses the use of NPT to underpin my PhD.

One of the key reported challenges of mixed methods research is the underlying epistemological dichotomy of qualitative and quantitative methods of enquiry. However, more recently, there has been a convergence of the two epistemological positions of positivism and interpretivism to a middle ground where mixing of methods has become possible. Pragmatism is a philosophical foundation which advocates that the research method is selected for the research aim, and provides a perspective with which both research methods produce findings that are both distinct but complimentary. I think that the outcomes of my PhD overall were enhanced by taking a pragmatic approach and using and integrating the results of both qualitative and quantitative methods which would not have been achieved by simply using one or other method of enquiry alone.

10.7.3 Reflections on methods of enquiry

My PhD has allowed me to further develop and refine my qualitative research skills. I have received training in qualitative research methods, including qualitative interviewing and qualitative thematic analysis which helped with the design and implementation of the qualitative elements of my PhD. In this body of work I have gained experience of conducting a framework analysis which I found to be more pragmatic and deductive than thematic analysis, but useful in situations where pre-

determined questions needed answering, or when organising results into a theoretical framework such as NPT as presented in chapter 6. I conducted telephone interviews rather than face-to-face interviews and found them to be less engaging than face-to-face, as sometimes interviewees became distracted by other things around them. Also it was less easy to build rapport with the interview participants. Whilst I acknowledge that in some qualitative research you may want to minimise the influence of the interviewer on the data collected, there is a balance between that and ensuring that you obtain full and descriptive answers to your interview questions. It is understandably also a question of time and resources to conduct interviews face-to-face, but in some groups such as healthcare professionals it might be preferable.

Quantitative work constituted a smaller element of my PhD research but I have really valued the opportunity of learning to use SPSS to analyse data from the wTADAST-24 (chapter 7) and the educational intervention (chapter 9). I have previously undertaken training in biostatistics as part of my MRes, but with the support of Beth Stuart, Statistician in Primary Medical Care, I have taught myself to use the SPSS software and analyse the outputs as part of my PhD.

10.7.4 Reflections on personal development

This PhD has helped me to develop a wide range of skills, techniques and a better understanding of research methods to pursue a career as an independent researcher.

I have enhanced my project management skills, ensuring that my research stayed on schedule and finished within the allocated time frame. However, it has been a fine balance between undertaking my PhD whilst supporting other projects and activities within Primary Medical Care.

During my 3 year candidature I was involved in a number of projects. I completed my MRes which I started in 2012 alongside my role as a trial manager for the AIRS study. This gave me a good foundation in research methods and academic writing, but I needed to set aside time to complete my final dissertation. Additionally, I co-authored the AIRS study HTA report and main publication with Dr Ian Williamson, which gave me valuable experience of academic writing, and managing multiple drafts and comments.

However it proved quite challenging to manage multiple tasks whilst keeping my own research on schedule.

During my PhD I have had the opportunity of further developing my presentation skills. I have had the opportunity of presenting my research at both national and international conferences, SPCR trainee meetings and the PCPS PhD conference.

My skills and experience has now led me to be part of the qualitative research group in Primary Medical Care and I am involved in teaching qualitative research methods to undergraduate and postgraduate student in the Faculty of Medicine. I am also involved in marking of qualitative assignments and exams within the faculty. Teaching a subject, and being challenged by students, helps to consolidate knowledge and ideas. My involvement in teaching of qualitative methods has helped me to understand my own philosophical viewpoint, given me a better understanding of methodology and research methods, and helped me to express my thoughts and ideas in a clear and coherent way.

In 2016 I had the opportunity to develop my grant writing skills, by securing a place on the SPCR Doctoral Research Training Camp at Ashridge Business School. Afterwards I wrote a blog for the SPCR website and spoke about the opportunity at the SPCR trainee day in September 2016. Overall the training camp was a great opportunity to learn new skills and network with other researchers from a range of disciplines, and has given me the confidence and skills to contribute to future funding applications.

10.8 Dissemination activities

The work presented in this thesis has been disseminated in a number of ways throughout my PhD candidature, and publications in the medical press are underway (**Error! Reference source not found.** 41).

Qualitative work

Dissemination of my qualitative work alongside the AIRS study was important to reach a number of stakeholders, including academic researchers, GPs, nurses, audiologists and the wider public.

I presented my qualitative work as an elevator pitch at the South West Society for Primary Care Research (SPCR) conference (Birmingham, March 2015). Additionally I also had the opportunity of presenting a summary of my qualitative work, including the work conducted as part of the AIRS study, at the North American Primary Care Research Group (NAPCRG) conference (New York, Nov 2014), which facilitated wider dissemination in the international arena.

In order to disseminate my research to GPs, I have submitted my research for publication in the British Journal of General Practice (BJGP) open journal.

As part of the dissemination activities for the AIRS study, I presented my qualitative work to a panel of media doctors who work in television, or who write for national newspapers and magazines. This provided an important role in getting our research known about in the public arena.

The findings of the AIRS study and my qualitative work have also been presented to the audiology department at Portsmouth Hospitals NHS Trust. This was an important way of informing and getting feedback from a potential future setting for the nasal balloon method and the educational intervention.

During my PhD I have also written a review on glue ear which was published in the British Journal of School Nursing in 2014[257] . This provides evidence-based information for school nurses about recognising children with OME in the classroom.

TADAST hearing disability test

I presented my development work on the wTADAST-24 as poster presentation at SW-SAPC (Cardiff, March 2016). Plans are underway to publish the study in the International Journal of Pediatric Otorhinolaryngology, which is the same journal who published the work on the early versions of the TADAST, and I hope will reach a wide audience of clinicians and audiologists.

LittleEARS educational intervention.

The development and evaluation of the LittleEARS educational intervention was presented at the School for Primary Care Research (SPCR) at 10Y conference (London, Nov 2016) as an oral presentation.

I was a non-specialist contributor to the NICE MedTech Innovations Briefing for the Otovent™ nasal balloon[61]. I have also written a guest blog entry for the Action for Hearing Loss charity concerning autoinflation and glue ear in children.

Table 42: Publication plans

Title	***Journal***	***Status***
A qualitative study exploring GP views and experience of diagnosis and management of glue ear in primary care. (chapter 5)	BJGP Open	Submission in progress
Development and evaluation of an online hearing disability test for children in primary care – wTADAST-24 (Chapter 7)	International Journal of Pediatric Otorhinolaryngology	In draft
Development and evaluation of an online educational intervention for families of children with otitis media with effusion. (Chapter 8 and 9)	TBA	In draft

10.9 Conclusion

Implementation of research findings into wider clinical practice can be challenging and complex. Nasal balloon autoinflation has been established as an effective treatment for young children with glue ear, however these results have yet to result in improved outcomes for children in the NHS. My research explored the context for implementation of the nasal balloon method and provided a better understanding of the management pathways, decision processes and treatment options used in primary care for children with OME. The further development and evaluation of the wTADAST-24 hearing disability test has provided a more objective measure of hearing disability applicable to use in the community setting. The LittleEARS educational intervention has potential to enhance the active monitoring process for families and improve engagement and uptake of the nasal balloon treatment in the primary care and audiology settings. Whilst some further developmental work is required to make them available for general use, these resources developed as part of my PhD provide an opportunity for the NHS to improve outcomes for children and reduce the more global impact of glue ear. In addition, the low cost of the nasal balloon together with an accessible educational intervention supports self-management, and thus has the potential to reduce the burden on NHS healthcare resources.

Appendix A Background and literature review

A.1 Autoinflation Randomised Trial: AIRS

CMAJ RESEARCH

Effect of nasal balloon autoinflation in children with otitis media with effusion in primary care: an open randomized controlled trial

Ian Williamson MD, Jane Vennik MRes, Anthony Harnden MBChB MSc, Merryn Voysey MBiostat, Rafael Perera DPhil, Sadie Kelly PhD, Guiqing Yao PhD, James Raftery PhD, David Mant MBChB MA, Paul Little MD

CMAJ Podcasts: author interview at soundcloud.com/cmajpodcasts/141608-res

See also page 949 and www.cmaj.ca/lookup/doi/10.1503/cmaj.150527

ABSTRACT

Background: Otitis media with effusion is a common problem that lacks an evidence-based nonsurgical treatment option. We assessed the clinical effectiveness of treatment with a nasal balloon device in a primary care setting.

Methods: We conducted an open, pragmatic randomized controlled trial set in 43 family practices in the United Kingdom. Children aged 4–11 years with a recent history of ear symptoms and otitis media with effusion in 1 or both ears, confirmed by tympanometry, were allocated to receive either autoinflation 3 times daily for 1–3 months plus usual care or usual care alone. Clearance of middle-ear fluid at 1 and 3 months was assessed by experts masked to allocation.

Results: Of 320 children enrolled, those receiving autoinflation were more likely than controls to have normal tympanograms at 1 month (47.3% [62/131] v. 35.6% [47/132]; adjusted relative risk [RR] 1.36, 95% confidence interval [CI] 0.99 to 1.88) and at 3 months (49.6% [62/125] v. 38.3% [46/120]; adjusted RR 1.37, 95% CI 1.03 to 1.83; number needed to treat = 9). Autoinflation produced greater improvements in ear-related quality of life (adjusted between-group difference in change from baseline in OMQ-14 [an ear-related measure of quality of life] score –0.42, 95% CI –0.63 to –0.22). Compliance was 89% at 1 month and 80% at 3 months. Adverse events were mild, infrequent and comparable between groups.

Interpretation: Autoinflation in children aged 4–11 years with otitis media with effusion is feasible in primary care and effective both in clearing effusions and improving symptoms and ear-related child and parent quality of life. Trial registration: ISRCTN, No. 55208702.

Competing interests: None declared.

This article has been peer reviewed.

Accepted: June 10, 2015
Online: July 27, 2015

Correspondence to:
Ian Williamson,
igw@soton.ac.uk

CMAJ 2015. DOI:10.1503/cmaj.141608

Otitis media with effusion, also known as glue ear, is an accumulation of fluid in the middle ear, without symptoms or signs of an acute ear infection. It is often associated with viral infection.[1–3] The prevalence rises to 46% in children aged 4–5 years,[4] when hearing difficulty, other ear-related symptoms and broader developmental concerns often bring the condition to medical attention.[3,5,6] Middle-ear fluid is associated with conductive hearing losses of about 15–45 dB HL.[7] Resolution is clinically unpredictable,[8–10] with about a third of cases showing recurrence.[11] In the United Kingdom, about 200 000 children with the condition are seen annually in primary care.[12,13] Research suggests some children seen in primary care are as badly affected as those seen in hospital.[7,9,14,15] In the United States, there were 2.2 million diagnosed episodes in 2004, costing an estimated $4.0 billion.[16] Rates of ventilation tube surgery show variability between countries,[17–19] with a declining trend in the UK.[20]

Initial clinical management consists of reasonable temporizing or delay before considering surgery.[13] Unfortunately, all available medical treatments for otitis media with effusion such as antibiotics, antihistamines, decongestants and intranasal steroids are ineffective and have unwanted effects, and therefore cannot be recommended.[21–23] Not only are antibiotics ineffective, but resistance to them poses a major threat to public health.[24,25] Although surgery is effective for a carefully selected minority,[13,26,27] a simple low-cost, nonsurgical treatment option could ben-

efit a much larger group of symptomatic children, with the purpose of addressing legitimate clinical concerns without incurring excessive delays.

Autoinflation using a nasal balloon device is a low-cost intervention with the potential to be used more widely in primary care, but current evidence of its effectiveness is limited to several small hospital-based trials[28] that found a higher rate of tympanometric resolution of ear fluid at 1 month.[29–31] Evidence of feasibility and effectiveness of autoinflation to inform wider clinical use is lacking.[13,28] Thus we report here the findings of a large pragmatic trial of the clinical effectiveness of nasal balloon autoinflation in a spectrum of children with clinically confirmed otitis media with effusion identified from primary care.

Methods

Study design and participants

We carried out an open, pragmatic randomized controlled trial in primary care. We examined the difference in effectiveness between autoinflation 3 times daily for 1–3 months plus usual care and usual care alone.

The study was piloted in 4 practices. The main study recruited children from 43 general practices from 17 primary care trusts (independent local groups) in the UK, between January 2012 and February 2013. Most (89%) children were identified by practice-based computer search, and the rest were recruited through opportunistic case finding by practitioners, nurses and health visitors. Tympanometry and recruitment were undertaken by practice-based nurses. The study protocol is available in Appendix 1 at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.141608/-/DC1.

The National Research Ethics Service gave ethics approval for this study. The 17 participating primary care trusts gave National Health Service approval.

Eligibility criteria

Children were eligible for inclusion if they were attending school and aged 4–11 years (deemed an age likely to be able to comply with autoinflation); had a history of hearing loss or other relevant ear-related problems in the previous 3 months; and had objective otoscopic and tympanometric confirmation of otitis media with effusion in at least 1 ear (i.e., had 1 or 2 type-B tympanograms using a modified Jerger classification) at the point of randomization (Table 1).[32,33] Children were excluded if they had current clinical features of acute otitis media (e.g., ear pain, fever or otoscopic features of acute inflammation), recent or planned ear surgery, a known latex allergy or a recent nosebleed.

Randomization and masking

An independent external agency provided a centralized Web-based computer-generated randomization system (www.sealedenvelope.com) for nurses to access while recruiting children. The Oxford Primary Care Clinical Trials Unit independently managed, coordinated, analyzed and checked the data validity. The randomization involved an algorithm with minimization based on 3 variables: age, sex and baseline severity (bilateral v. unilateral type-B tympanograms).[9] Because of the nature of the intervention, use of placebo was not possible, and therefore nurses, children and families were not masked to treatment allocation.

Procedures

All participating parents and children received information sheets, and parents gave written informed consent for screening to the research nurse. Children were invited to give written assent.

Table 1: Tympanometric classification*† (based on a modified Jerger classification[32,33]) and interpretation[34]

Type	Middle-ear pressure, daPa	Tympanogram	Interpretation
A	200 to −99	Peak in this range	Normal
C1	−100 to −199	Peak in this range	Normal
C2	−200 to −399	Peak in this range	Positive predictive value of 54% for otitis media with effusion
B	≥ −400	Flat trace without a discernible peak	Positive predictive value of 88% for otitis media with effusion

Note: daPa = decapascal.
*As used in primary care trials[9,10] and a Cochrane systematic review.[28]
†With normal canal volumes. Excessive wax, perforation and grommets excluded.

The simple autoinflation method involved inflating a purpose-manufactured balloon (Otovent) by blowing through each nostril into a connecting nozzle[31] (Figure 1). Children receiving treatment were instructed by watching the nurse or parent demonstrate the procedure after stretching the balloon. The schedule involved inflating the balloon 3 times daily for an initial period of 1 month. Children still recording a type-B tympanogram in either ear at 1 month were advised to continue with autoinflation for a further 2 months. At the end of the study, affected children in the arm receiving usual care were offered a 1-month treatment pack.

All nurses received training in the study methods, including tympanometry and interpretation (from an audiologist), updates on otoscopy and ways of maximizing study compliance. Hand-held calibrated MTP10 tympanometers (with printout facilities) were used.

Study outcomes

We assessed outcomes at 1 and 3 months after randomization, during which time natural resolution effects would be expected to occur for some children.[7,9]

Our main outcome was the difference between groups in the proportion of children showing definite tympanometric resolution (i.e., normal middle-ear pressure, defined by a type-A or -C1 tympanogram) in at least 1 affected ear per child at 1 and 3 months. Intermediate type-C2 tympanograms showing negative pressure were considered insufficiently stringent for resolution of fluid (Table 1).[32,34] We chose tympanometric outcomes because they allowed blinding, have been well validated previously,[2,34] are regarded as a good choice for primary care studies[13,35] and are used in meta-analysis.[28] Two members of the trial team, trained in tympanometry and masked to allocation, independently reviewed anonymized tympanometry printouts. The expert interrater agreement was 89%, and disagreement was settled by a third independent audiologist. We found a Cohen κ of 0.7 for the level of agreement between nurses and masked experts.

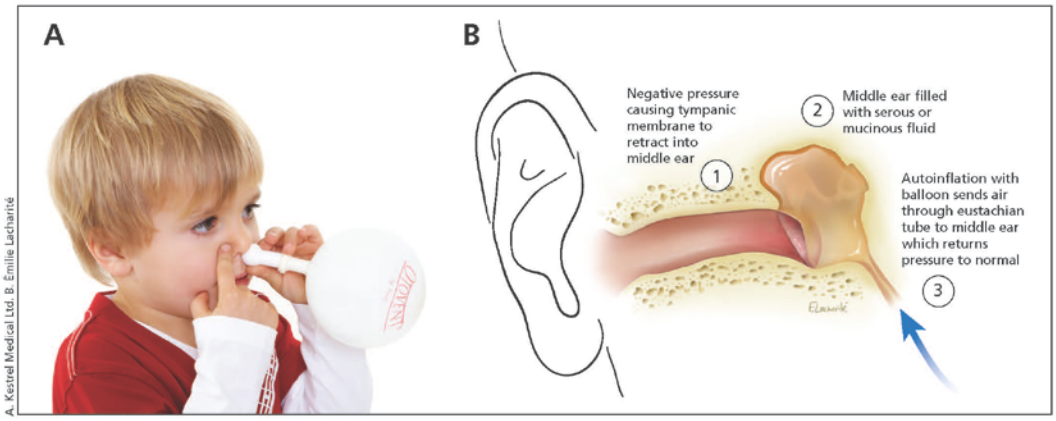
Ear-related quality of life was measured at 3 months using the OMQ-14, an instrument developed by a process of refinement and iteration from large clinical and trial datasets of otitis media with effusion that optimized item mapping onto the Health Utilities Index.[7,9,15,36] In addition, parents completed weekly diaries to record symptoms, adverse events and compliance. Days during which parents reported their child had hearing loss, earache, days off school, days requiring pain relief and sleep disturbance were summarized as days with any problem. We did not conduct pure tone audiometry because it cannot be done with adequate precision in non-specialist settings.

Sample size

A total sample of 295 children was required to provide 90% power (5% α) to detect a treatment effect (odds ratio [OR]) of 2.4, and allowing for 15% loss to follow-up at 1 month.[28] The study was also powered to detect a clinically important difference of 0.3 of a standard deviation (SD) in total OMQ-14 score.

Statistical analysis

We performed a modified intention-to-treat analysis, ignoring reported compliance but excluding children for whom no outcome mea-



A. Kestrel Medical Ltd. B. Émilie Lacharité

Figure 1: (A) Child demonstrating use of the Otovent device. Reproduced with permission. (B) Illustration of otitis media with effusion and the mechanism of autoinflation.

surement could be made. The relative effect of autoinflation on the primary outcome at 1 month and at 3 months was estimated using a generalized linear model for binary data with log-link function, and adjusted for baseline covariates (tympanometric baseline severity, age, sex and primary care trust). We conducted an ear-based analysis at 1 and 3 months using generalized estimating equations.

We compared change from baseline quality of life (standardized OMQ-14 scores) using a linear mixed-effects model. Data from weekly symptom diaries of days with symptoms related to otitis media with effusion were summarized according to categories of the number of days with symptoms. Groups were compared using an ordinal logistic regression model.

Analyses were conducted using SAS version 9.3 and Stata version 13.0 according to a prespecified analysis plan.

Results

Between December 2011 and February 2013, 1235 children were screened for eligibility and 320 (26%) were randomly assigned to standard care alone or autoinflation plus standard care (Figure 2). The main reasons for ineligibility

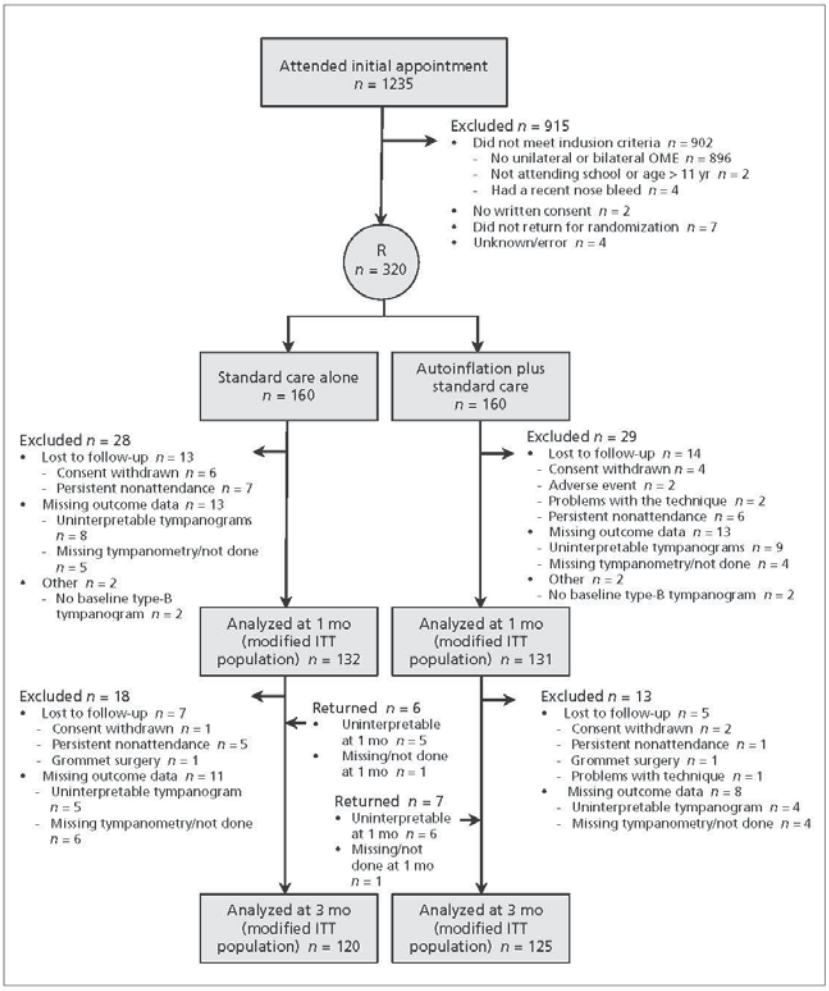


Figure 2: Enrolment, allocation and follow-up of patients. Note: ITT = intention-to-treat, OME = otitis media with effusion, R = randomization.

Table 2: Baseline characteristics of participants, by treatment group

Characteristic	No. %*	
	Standard care $n = 160$	Autoinflation $n = 160$
Age, yr, mean ± SD	5.4 ± 1.04	5.4 ± 1.24
Male sex	83 (51.9)	84 (52.5)
Severity of otitis media with effusion		
No type-B tympanogram	2 (1.3)	2 (1.3)
Type-B tympanogram, 1 ear	91 (56.9)	90 (56.3)
Type-B tympanogram, 2 ears	67 (41.9)	68 (42.5)
Month randomly assigned		
October to March	107 (66.9)	107 (66.9)
April to September	53 (33.1)	53 (33.1)
Ethnicity		
White	144 (90.0)	152 (95.0)
Bangladeshi/Indian	2 (1.3)	2 (1.3)
Mixed race	3 (1.9)	1 (0.6)
Other group	2 (1.3)	2 (1.3)
No information	9 (5.6)	3 (1.9)
Education level of parent or caregiver		
Attended school to age 16 yr; no certificate or diploma	11 (6.9)	6 (3.8)
Attended school to age 16 yr; secondary school diploma	28 (17.5)	33 (20.6)
College or nonuniversity certificate	56 (35.0)	63 (39.4)
University degree	37 (23.1)	31 (19.4)
Professional/postgraduate degree or certificate	17 (10.6)	22 (13.8)
No information	30 (18.8)	31 (19.4)
Parent-reported child characteristics		
Asthma†	19 (11.9)	16 (10.0)
Eczema†	15 (9.5)	20 (12.5)
Hay fever†	40 (25.0)	42 (26.3)
Antibiotics in previous month†	12 (7.5)	21 (13.1)
Parent-reported symptoms in the previous 3 mo (children aged 4–6 yr only)	$n = 135$	$n = 130$
A prolonged or bad cold, cough or chest infection	113 (83.7)	119 (91.5)
Appears to be lip reading†	27 (20.0)	27 (20.8)
An earache	74 (54.8)	77 (59.2)
Not doing as well at school as expected†	32 (23.7)	39 (30.0)
Often mishears what is said	98 (72.6)	112 (86.2)
Has noises in the ear or is dizzy	29 (21.5)	30 (23.1)
Hearing loss is suspected by anyone†	56 (41.5)	67 (51.5)
Snores, blocked nose or poor sleep	93 (68.9)	101 (77.7)
Says "eh what?" or "pardon" a lot	107 (79.3)	114 (87.7)
Speech seems behind other children's	22 (16.3)	31 (23.8)
Needs the television turned up	78 (57.8)	82 (63.1)
Any suspected ear problem	48 (35.6)	55 (42.3)
May be irritable or withdrawn	43 (31.9)	38 (29.2)
No. of symptoms, median (IQR)	6 (4–8)	7 (5–9)
OMQ-14 (quality of life)‡	$n = 153$	$n = 153$
Standardized score (SD)	−0.04 (± 0.95)	0.07 (± 1.00)

Note: IQR = interquartile range, SD = standard deviation.
*Unless stated otherwise.
†Missing data for children in the standard care and autoinflation groups on the following variables: asthma and eczema ($n = 9, 4$), hay fever and antibiotics in previous month ($n = 9, 3$), appears to be lip reading ($n = 1$ in autoinflation), not doing as well at school as expected and hearing loss is suspected by anyone ($n = 1$ in standard care).
‡Lower scores represent better global ear-related health (range of scores −2.1 to 3.8).

were that children lacked a type-B tympanogram (2 children from each arm were subsequently withdrawn because of this), were not currently attending school or reported a recent nosebleed. Ineligible children reported fewer symptoms associated with otitis media with effusion in the preceding 3 months, and had fewer consultations for otitis media in the previous 12 months.

Baseline characteristics of children who were randomly assigned were balanced between the 2 groups (Table 2). Trial demographic data are comparable to national figures, but 33% of participating parents (v. 27% nationally) had a university or postgraduate degree.[37]

Main results

Retention was good, with 8.4% lost to follow-up at 1 month and 12.2% at 3 months. Uninterpretable tympanograms due to poor technique (leakage or low canal volume), and clinical problems (wax or perforation) were similar between groups, leaving 131 children in the autoinflation arm and 132 in the usual care arm in the modified intention-to-treat analysis.

Compared with standard care, children receiving autoinflation achieved tympanometric resolution more often at 1 month (adjusted relative risk [RR] 1.36, 95% confidence interval [CI] 0.99 to 1.88) and at 3 months (adjusted RR 1.37, 95% CI 1.03 to 1.83, number needed to treat [NNT] = 9) (Table 3). Sensitivity analyses using multiple imputation for missing data yielded similar but slightly smaller RRs that did not achieve statistical significance. Analyses for individual ears, adjusted for correlation between ears within child, showed that tympanometric resolution was significantly more likely with autoinflation at 1 month (adjusted RR 1.38, 95% CI 1.01 to 1.87) and at 3 months (adjusted RR 1.41, 95% CI 1.05 to 1.88), consistent with our per-child (primary) analysis (Table 3).

Table 3: Tympanometric resolution at 1 month and 3 months, by study group

Variable	No. (%) of children* Standard care *n* = 160	Autoinflation *n* = 160	Adjusted RR or OR† (95% CI)
1-month analysis	*n* = 132	*n* = 131	
Tympanometric resolution of ≥ 1 type-B ear per child at 1 mo‡	47 (35.6)	62 (47.3)	RR 1.36 (0.99–1.88)¶
			RR 1.27 (0.95–1.71)**
Tympanometric resolution, by ear, at 1 mo,‡§ *n* = 263 children	*n* = 187 ears 52 (27.8)	*n* = 188 ears 73 (38.8)	RR 1.38 (1.01–1.87)
Days with any symptom or problem	*n* = 138	*n* = 136	OR 0.66 (0.41–1.05)††
None	9 (6.5)	18 (13.2)	
1–7	47 (34.1)	49 (36.0)	
≥ 8	82 (59.4)	69 (50.7)	
3-month analysis	*n* = 120	*n* = 125	
Tympanometric resolution of ≥ 1 type-B ear at 3 mo‡	46 (38.3)	62 (49.6)	RR 1.37 (1.03–1.83)¶
			RR 1.22 (0.92–1.63)**
Tympanometric resolution, by ear, at 3 mo,‡§ *n* = 245 children	*n* = 166 ears 52 (31.3)	*n* = 182 ears 74 (40.6)	RR 1.41 (1.05–1.88)
Days with any symptom or problem	*n* = 139	*n* = 139	OR 0.58 (0.37–0.90)††
None	4 (2.9)	9 (6.4)	
1–7	29 (20.9)	30 (21.6)	
8–28	57 (41.0)	73 (52.5)	
≥ 29	49 (35.3)	27 (19.4)	

Note: CI = confidence interval, OR = odds ratio, RR = relative risk.
*Unless stated otherwise.
†ORs adjusted for age and sex.
‡Adjusted for baseline severity (1 or 2 type-B ears), age and sex (not adjusted for centre effects due to nonconvergence).
§Generalized estimating equation model adjusting for correlation between ears for each child.
¶Primary analysis: adjusted for baseline severity (1 or 2 type-B ear), age, sex and primary care trust.
**Sensitivity analysis: multiple imputation of all missing data using baseline variables (use of antibiotics, eczema, hay fever, asthma, age, sex, baseline severity, baseline OMQ-14 and follow-up OMQ-14 weighted scores).
††From ordinal logistic regression.

Subgroup analyses

We conducted prespecified subgroup analyses of effects of age (< 6.5 yr v. ≥ 6.5 yr), severity (1 v. 2 type-B ears at baseline), OMQ-14 standardized total score (< 0 v. ≥ 0) and sex on the primary outcome. In all cases we found no differences in treatment effects between subgroups. *P* values for the interaction term (treatment by subgroup) in the model ranged from 0.3 to 0.5 (Appendix 2, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.141608/-/DC1).

Ear-related quality of life and diary symptoms

At 3 months, the mean change from baseline in the standardized OMQ-14 total scores was greater in the autoinflation arm than in the control arm by –0.33 points (95% CI –0.59 to –0.07). The adjusted difference between groups was –0.42 points (95% CI –0.63 to –0.22) (Figure 3). This score difference represents a treatment effect size of 0.48 of an SD. The mean improvement in baseline score was –0.69 (0.84 SD) points at 3 months for the treatment arm. Effects were consistent across individual OMQ-14 items (Appendix 3, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.141608/-/DC1). Overall, children in the autoinflation arm had fewer days with any symptom or problem than children in the control arm at 1 month (median [interquartile range] 8 [2–16] v. 9 [4–17] d; OR 0.66, 95% CI 0.41 to 1.05) and at 3 months (median [interquartile range] 14 [6–28] v. 22 [8–35] d; OR 0.58, 95% CI 0.37 to 0.90) (Table 3).

Compliance

A total of 89% of parents reported using the device "most" or "all of the time" during the first month of treatment, consistent with the daily compliance sticker charts. This level of compliance appears to be maintained in those continuing treatment up to 3 months (80%).

Adverse events

We found very little difference between study arms in the number of children with nosebleed (15% v. 14%), but there were more reported respiratory infections in the treatment group (15% v. 10% of children). Most of the respiratory infections were mild afebrile rhinorrhea. Eight children receiving autoinflation (compared with 2 receiving usual care) reported otalgia (Table 4). Five children in the treatment group and 4 in the control group had an episode of acute otitis media. Two children in the treatment arm were withdrawn: 1 was admitted to hospital with mild/early mastoiditis and made a full recovery, and a second was withdrawn due to otalgia.

Interpretation

In this study, we observed that autoinflation in young, school-aged children with otitis media with effusion is feasible in primary care and effective in clearing middle-ear effusions and improving symptoms and ear-related child and parent quality of life. Autoinflation is a simple, low-cost procedure that can be taught to young children in a primary care setting with a reasonable expectation of compliance. With an NNT of 9, it is a relatively noninvasive option that can add benefit by helping to fill the current gap between either doing nothing effective or referring for surgery.[13] Wider use of this device has considerable potential to address the present lack of treatment options for most symptomatic children, and the frequency with which inappropriate antibiotics continue to be used to fill this gap.[9,12,13,21,24,25] Because fluid in the ear does not completely clear in many instances even after 3 months, and with a tendency to recur, clinical vigilance with the option for surgery remains crucial to evidence-based management.

Best evidence suggests there are currently no proven nonsurgical interventions for glue ear. Parents often see temporizing strategies as causing unreasonable delay, and this can also lead to use of ineffective treatments, such as antibiotics. The most recent Cochrane Review of autoinflation[28] highlighted the need for a large primary care study. The small hospital-based trials available[29–31] for meta-analysis did not assess autoinflation in a primary care setting and lack both power and generalizability to the majority of affected children. Adding our data (and unpublished pilot, $n = 20$) to the meta-analysis more

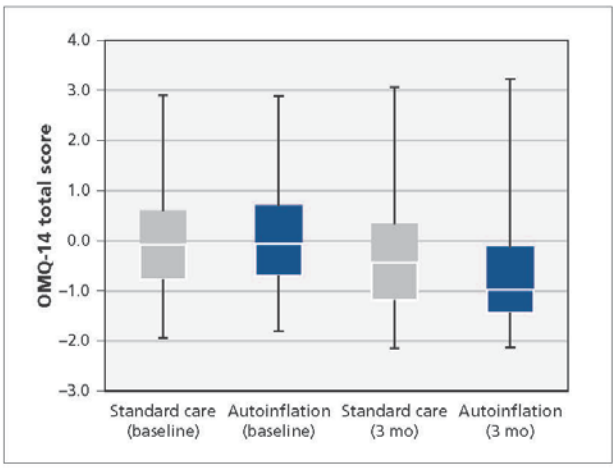


Figure 3: Standardized total scores on the OMQ-14 (an ear-related measure of quality of life) at baseline and at 3 months. Lower scores represent improvement.

Table 4: Adverse events, by study group

Adverse event	Standard care $n = 160$		Autoinflation $n = 160$	
	No. of events	No. (%) affected children	No. of events	No. (%) affected children
Nosebleed	26	24 (15)	26	22 (14)
Upper respiratory tract infection	6	6 (4)	20	13 (8)
Unspecified respiratory tract Infection	4	4 (3)	9	9 (6)
Lower respiratory tract infection	4	4 (3)	2	2 (1)
Acute otitis media	4	4 (3)	6	5 (3)
Otalgia	2	2 (1)	8	7 (4)
Headache	—	—	2	2 (1)
Hay fever	—	—	1	1 (1)
Hospital admission*	1	1 (1)	1	1 (1)

*Costovertebral angle pain (standard care), acute mastoiditis (autoinflation).

than doubles the available sample size with an estimated aggregate effect size of 1.61 (95% CI 1.26 to 2.06, I^2 heterogeneity 0.0%) (Appendix 4, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.141608/-/DC1).

For the child, parent and professional, the main issue is the impact caused by otitis media with effusion.[38,39] From this consequential perspective, moderate improvement in the total OMQ-14 score is important and encouraging (e.g., in terms of reduced days with hearing difficulty over 3 mo) (Appendix 3). Published data on ear-related quality of life from other trials of otitis media with effusion are currently very sparse.[9,15,26]

Limitations

The main limitation of this study is that the intervention cannot be blinded, and Hawthorne effects are possible.[40] However, concealment issues are unlikely to affect tympanometric outcomes, because Web-based randomization was used for allocation, and all printouts were anonymized and assessed by experts who were unaware of allocation. Even if symptom and mapped quality of life (OMQ-14) scores were affected by performance bias, the effects observed would still be likely to reflect routine practice. The study population included children who were likely to be able to reliably perform autoinflation (i.e., age ≥ 4 yr). Although children of all ages frequently present to primary care, in the UK the most common age for referral for otitis media with effusion is between 3.5 and 8 years.[7,9,26] This study does not address treatment for the youngest group of children affected. However, children as young as 3 years have been found to be able to use the device in hospital settings.[29,31]

Conclusion

We have found use of autoinflation in young, school-aged children with otitis media with effusion to be feasible, safe and effective in clearing effusions, and in improving important ear symptoms, concerns and related quality of life over a 3-month watch-and-wait period. Autoinflation may not be suitable for all children, especially those under 4 years of age, and does require ongoing commitment to treatment. Further research is needed for very young children, and to inform prudent use across different health settings. The method has scope to be used in many symptomatic children, and is capable of producing better management and outcomes in primary health care systems. Wider use of nasal balloon autoinflation could address the present lack of treatment options for children with symptomatic otitis media with effusion.

References

1. Zielhuis GA, Rach GH, van den Broek P. Screening for otitis media with effusion in preschool children. *Lancet* 1989;1:311-4.
2. Stool SEBA, Berman S, Carney CJ, et al. *Otitis media with effusion in children*. Rockville (MD): Agency for Healthcare Research and Quality; 2013.
3. Fry J, Sandler G. *Common diseases*. 5th ed. New York: Kluwer Academic Publishers; 1993.
4. Williamson IG, Dunleavey J, Bain J, et al. The natural history of otitis media with effusion — a three-year study of the incidence and prevalence of abnormal tympanograms in four South West Hampshire infant and first schools. *J Laryngol Otol* 1994;108:930-4.
5. Higson J, Haggard M. Parent versus professional views of the developmental impact of a multi-faceted condition at school age: otitis media with effusion ('glue ear'). *Br J Educ Psychol* 2005;75:623-43.

6. Maw AR. *Glue ear in childhood.* London (UK): Mac Keith Press; 1995.
7. Browning GG. Two-year outcome of ventilation tubes in a randomized controlled trial of persistent childhood otitis media with effusion. *Clin Otolaryngol Allied Sci* 2001;26:342-4.
8. Browning GG. Watchful waiting in childhood otitis media with effusion. *Clin Otolaryngol Allied Sci* 2001;26:263-4.
9. Williamson I, Benge S, Barton S, et al. Topical intranasal corticosteroids in 4–11 year old children with persistent bilateral otitis media with effusion in primary care: double blind randomised placebo controlled trial. *BMJ* 2009;339:b4984.
10. van Balen FA, de Melker RA, Touw-Otten FW. Double-blind randomised trial of co-amoxiclav versus placebo for persistent otitis media with effusion in general practice. *Lancet* 1996; 348:713-6.
11. Casselbrant ML, Brostoff LM, Cantekin EI, et al. Otitis media with effusion in preschool children. *Laryngoscope* 1985;95:428-36.
12. Williamson I, Benge S, Mullee M, et al. Consultations for middle ear disease, antibiotic prescribing and risk factors for reattendance: a case-linked cohort study. *Br J Gen Pract* 2006;56:170-5.
13. *Surgical management of otitis media with effusion in children.* London (UK): National Collaborating Centre for Women's and Children's Health; 2008.
14. Marchisio P, Grasso D. Using differences and similarities between centres for power and generality. Helsinki (Finland): ESPO Conference; May 27, 2010.
15. Dakin H, Petrou S, Haggard M, et al. Mapping analyses to estimate health utilities based on responses to the OM8-30 Otitis Media Questionnaire. *Qual Life Res* 2010;19:65-80.
16. American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. *Pediatrics* 2004;113:1412-29.
17. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States 2006. Hyattsville (MD): National Center for Health Statistics; 2009.
18. Desai SN, Kellner JD, Drummond D. Population-based, age-specific myringotomy with tympanostomy tube insertion rates in Calgary, Canada. *Pediatr Infect Dis J* 2002;21:348-50.
19. van Dongen TM, van der Heijden GJ, Freling HG, et al. Parent-reported otorrhea in children with tympanostomy tubes: incidence and predictors. *PLoS ONE* 2013;8:e69062.
20. *Grommet insertion and adenoidectomy for otitis media with effusion.* Dublin (Ireland): Health Information and Quality Authority; 2013.
21. van Zon A, van der Heijden GJ, van Dongen TM, et al. Antibiotics for otitis media with effusion in children. *Cochrane Database Syst Rev* 2012;9:CD009163.
22. Simpson SA, Lewis R, van der Voort J, et al. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2011;CD001935.
23. Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database Syst Rev* 2011;CD003423.
24. Davies S, Grant J, Catchpole M. *The drugs don't work: a global threat.* New York: Penguin; 2013.
25. *Antimicrobial resistance: global report on surveillance.* Geneva (Switzerland): World Health Organization; 2014. Available: www.who.int/drugresistance/documents/surveillancereport/en (accessed 2014 May 6).
26. Browning GG, Rovers MM, Williamson I, et al. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2010;CD001801.
27. Williamson I. Otitis media with effusion. *BMJ Clin Evidence* Jan. 12, 2011 [Epub ahead of print]. Available: www.clinicalevidence.com/x/systematic-review/0502/overview.html (accessed 2014 May 6).
28. Perera R, Glasziou PP, Heneghan CJ, et al. Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database Syst Rev* 2013;5:CD006285.
29. Blanshard JD, Maw AR, Bawden R. Conservative treatment of otitis media with effusion by autoinflation of the middle ear. *Clin Otolaryngol Allied Sci* 1993;18:188-92.
30. Ercan I, Cakir B, Kayaoglu S, et al. Long term effect of autoinflation in the treatment of otitis media with effusion. *KBB Forum* 2005;4:166–70.
31. Stangerup SE, Sederberg-Olsen J, Balle V. Autoinflation as a treatment of secretory otitis media. A randomized controlled study. *Arch Otolaryngol Head Neck Surg* 1992;118:149-52.
32. Jerger J. Clinical experience with impedance audiometry. *Arch Otolaryngol* 1970;92:311-24.
33. Fiellau-Nikolajsen M. Epidemiology of secretory otitis media. A descriptive cohort study. *Ann Otol Rhinol Laryngol* 1983;92: 172-7.
34. Cantekin EI, Bluestone CD, Fria TJ, et al. Identification of otitis media with effusion in children. *Ann Otol Rhinol Laryngol Suppl* 1980;89:190-5.
35. Browning GC. Paediatric otolaryngolgy. Chapter 72. In: *Scott-Brown's otorhinolaryngology, head and neck surgery.* Vol 1, pt 12. 7th ed. London (UK): Hodder Arnold; 2008.
36. Feeny D, Furlong W, Torrance GW, et al. Multiattribute and single-attribute utility functions for the health utilities index mark 3 system. *Med Care* 2002;40:113-28.
37. *Qualifications and students, local authorities in the United Kingdom.* London (UK): Office for National Statistics; *2011.* Available: www.ons.gov.uk (accessed 2014 Jan. 8).
38. Rosenfeld RM, Goldsmith AJ, Tetlus L, et al. Quality of life for children with otitis media. *Arch Otolaryngol Head Neck Surg* 1997;123:1049-54.
39. Hearing and balance disorders. *Achieving excellence in diagnosis and management.* London (UK): Royal College of Physicians; 2007.
40. McCarney R, Warner J, Iliffe S, et al. The Hawthorne effect: a randomised, controlled trial. *BMC Med Res Methodol* 2007;7:30.

Affiliations: Primary Care and Population Sciences (Williamson, Vennik, Little), Faculty of Medicine, University of Southampton, Aldermoor Close, Southampton, UK; Nuffield Department of Primary Care Health Sciences (Harnden, Voysey, Perera, Kelly, Mant), University of Oxford, Oxford, UK; Faculty of Medicine (Yao, Raftery), University of Southampton, Southampton General Hospital, Southampton, UK

Contributors: Ian Williamson conceived and designed the study, led protocol development, funding application, analysis and interpretation. Jane Vennik provided day-to-day management, coordinated recruitment, and contributed to the data collection, analysis and interpretation. Anthony Harnden contributed to protocol development, funding application and data interpretation. Merryn Voysey led the statistical analysis and interpretation of the study findings. Rafael Perera contributed to protocol development, funding application, statistical analysis and data interpretation. Sadie Kelly supervised the randomization process, and coordinated data collection, cleaning and validation. Guiqing Yao and James Raftery led the health economic analysis. David Mant contributed to protocol development, funding application and interpretation of findings. Paul Little contributed to protocol development, funding application and interpretation of findings. All of the authors contributed to drafting the article. Ian Williamson and Jane Vennik revised the article, with particular support from Merryn Voysey and Anthony Harnden. All of the authors gave final approval of the version to be published and agreed to act as guarantors of the work.

Funding: This project was funded by the Health Technology Assessment program of the National Institute for Health Research and will be published in full in *Health Technology Assessment* (www.nets.nihr.ac.uk). The funders had no role in the design or conduct of the study, the analysis or interpretation of the results, or the decision to submit the manuscript for publication.

Acknowledgements: The authors thank the following: the Health Technology Assessment and National Institute for Health Research funders; the Oxford Primary Care Clinical Trials Unit, especially Sarah Benge for protocol development, logistical help and pilot work; Sharon Charnock of Starkey Laboratories Ltd. for audiological review and assistance with nurse training; Mark Haggard and Helen Spencer for use of the OMQ-14, with advice and supply of a scoring system; and Sven-Eric Stangerup, the inventor of Otovent, for advice on use. The authors also thank the regional primary care research networks and all participating practices and Kestrel Medical Ltd. for the trial supply of Otovent and providing the photograph in Figure 1. Finally, and most importantly, the authors thank all the children and families who took part in the study.

See the following video online:
Demonstration of nasal balloon autoinflation. www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.141608/-/DC2

A.2 Literature search criteria for update to autoinflation systematic review.

1. exp *otitis media/
2. ((otitis adj media) or (glue adj ear)).tw.
3. ((secretory or serous) adj otitis).tw.
4. (SOM or OME).tw.
5. exp Ear Disease/
6. (otitis or inflam* or effusion* or infect* or suppurat* or secret* or pressure).tw.
7. 5 or 6
8. exp Middle Ear/
9. ((middle and ear*) or (eustachian and tube*)).tw.
10. 8 or 9
11. 7 and 10
12. 1 or 2 or 3 or 4 or 11
13. middle ear ventilation/
14. aeration/
15. valsalva maneuver/
16. (autoinflat* or ((auto or ear* or ME or air) and (inflat* or aerat*))).tw.
17. (valsalva or politzer*).tw.
18. ((nose or nasal) and balloon).tw.
19. (open* and eustachian*).tw.
20. (insufflat* or popper or earpopper).tw.
21. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
22. 12 and 21
23. 22 and 2013:2017.(sa_year).

Appendix B GP qualitative study (chapter 5):

B.1 Invitation pack to participants.

<GP name & practice>

Date

Dear

A qualitative study exploring GP experiences of managing glue ear in primary care

We are writing to invite you to take part in a research study led by the University of Southampton. The study will help us to understand more about current management and referral strategies for glue ear (otitis media with effusion) and explore GP views of active monitoring and autoinflation in primary care.

The enclosed Participant Information Sheet tells you about the study. We are asking for you to take part in a 30 minute telephone interview, for which you will be reimbursed £50 for your time. If you feel that you would like to participate, please complete the reply slip and consent form and return them to the research team in the freepost envelope provided.

If you have any questions about the study please do not hesitate to contact me.

Yours sincerely

Jane Vennik
Primary Medical Care, University of Southampton
Aldermoor Close,
Southampton. SO16 5ST
j.vennik@soton.ac.uk
Telephone 023 8024 1088

Participant Information Sheet
V2 25/4/2014

A qualitative study exploring GP experiences of managing glue ear in primary care

Researcher: Jane Vennik **Ethics number:** ERGO 9617

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the purpose of this research?
The purpose of this research is to explore how glue ear (otitis media with effusion) is currently managed in primary care, and to identify the barriers and facilitators to active monitoring and autoinflation during this period. The information collected will help towards the development of an intervention to support general practitioners and parents in a more structured, early management of glue ear in primary care. This research is part of an HTA-funded programme of autoinflation for OME (HTA: 09/01/27) and a PhD student project (Jane Vennik).

Why have I been chosen?
You have been chosen because you are a practicing general practitioner in the UK.

What do I have to do?
You will be asked to take part in a 20-30 minute by telephone at a time to suit you. You will need to sign a consent form to confirm that you understand what taking part in the study will involve and that your questions about the research have been answered.

If you are interested in taking part please return the reply slip and consent form in the **FREEPOST** envelope provided. A member of the research team will then contact you to arrange a suitable time for the interview. You will have at least 24 hours to decide whether or not you wish to take part in the research once you have had the opportunity to discuss the study with the researcher.

What are the advantages and disadvantages of taking part?
There are no direct advantages or disadvantages to you. We hope the information gained from the study will help us to understand more about the current management of OME in primary care which will help towards the wider implementation of active monitoring and autoinflation in primary care.

You will be reimbursed £50 to cover your time for taking part in the interview.

Will my taking part in the study remain confidential?
With your permission the interview will be audio-recorded to make an accurate record of what is said and then the recording will be transcribed. This written record will not include any names or other details that can identify you, to ensure confidentiality. The recordings will be held in a locked cabinet in the University of Southampton to which only the research team will have access. Once the recordings have been transcribed, they will be destroyed. The findings from this study will be used in research reports but no names will be included in the report so any quotes from the interview will be anonymous.

What happens if I change my mind?
Taking part in this research is voluntary. It is up to you to decide whether to take part. You can decide not to continue at any time without giving a reason.

What happens if something goes wrong?
If you have any concerns or feel that you have been placed at risk you can contact a member of the research team – Dr Ian Williamson on igw@soton.ac.uk / 023 8024 1071 or Head of Research Governance at the University of Southampton – Dr Martina Prude on mad4@soton.ac.uk / 023 8059 5058. If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure.

What will happen to the results of the research study?
The results will be published in scientific journals and presented at scientific meetings. A summary of the findings will be sent to all participants who would like to see the results and the full report can be made available on request.

Where can I get more information?
If you would like to take part in the study or if you have any further questions please do not hesitate to get in touch with Jane Vennik using the contact details below.

Contact details of the Researcher:

Name: Jane Vennik
Address: University of Southampton, Aldermoor Health Centre, Southampton, SO16 5WB
E-mail: j.vennik@soton.ac.uk
Telephone: 023 8024 1080

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION

Jane Vennik (AIRS Study)
Licence Number SO2912

FREEPOST

Primary Medical Care
Aldermoor Health Centre,
Aldermoor Close
Southampton, SO16 5WB

Reply Slip

A qualitative study exploring GP experiences of managing glue ear in primary care

Name of GP _____

GP Surgery _____

Phone number: _____

Email address: _____

The best day(s) and time(s) to contact me is:_____

Demographic information:

Year qualified as a GP: _____

GP practice: Rural/semi rural/urban

I am willing to take part in an interview

Signed: _____ Date: _____

Please return the **reply slip** and **consent form** to the researchers at University of Southampton using the **FREEPOST** address above or **Fax to 023 8070 1125.**

Study ID number ERGO 9617
Researcher: Jane Vennik

CONSENT FORM

A qualitative study exploring GP experiences of managing glue ear in primary care

Please initial each box

1. I have read and understood the information sheet dated 25/4/2014 version 2 and have had the opportunity to ask questions that have been answered satisfactorily. ☐

2. I agree to take part in this research study and understand that all my details will be kept confidential and my name will not appear on any reports or documents. ☐

3. I understand that the interview will be audio-recorded and that no one but the research team will hear the recording. ☐

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

5. I give permission for anonymous quotes from the interview to be included in reports of the findings from the research ☐

6. I agree for the research team to contact me to arrange an interview ☐

Name of General Practitioner _____ Signature _____ Date _____

Name of Researcher _____ Signature _____ Date _____

PLEASE RETURN THE CONSENT FORM IN THE ENCLOSED FREEPOST ENVELOPE

Primary Medical Care, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5WB

B.2 Ethics committee approval.

From: ERGO
To: Vennik J.
Subject: Your Ethics Submission (Ethics ID:9617) has been reviewed and approved
Date: 28 April 2014 08:41:20

Submission Number: 9617
Submission Name: Managing Glue Ear in Primary Care

This is email is to let you know your submission was approved by the Ethics Committee.

You can begin your research unless you are still awaiting specific Health and Safety approval (e.g. for a Genetic or Biological Materials Risk Assessment)

Comments
1.Dear Jane, Re: 9617: Managing Glue Ear in Primary Care Thank you for submitting your revised application relating to the above study. I am pleased to inform you that full approval has now been granted by the Faculty of Medicine Ethics Committee. Approval is valid from today until 30.09.14, the end date specified in your application. Please note the following points: â¢ the above ethics approval number must be quoted in all correspondence relating to your research, including emails; â¢ if you wish to make any substantive changes to your project you must inform the Faculty of Medicine Ethics Committee as soon as possible. Please note that this email will now constitute evidence of ethical approval. Should you require a paper signed copy of this approval, please contact the FoMEC Administrative Team via email at: Medethic@soton.ac.uk. We wish you success with your research. Yours sincerely Dr Catherine Hill Chair of the Faculty of Medicine Ethics Committee

Click here to view your submission

ERGO : Ethics and Research Governance Online
http://www.ergo.soton.ac.uk

DO NOT REPLY TO THIS EMAIL

B.3 Interview topic guide.

A qualitative study exploring GP experiences of managing glue ear in primary care

Interview guide
V1.3 8 April 2014

Introduction

- *Thank participant for agreeing to the interview.*
- *Check continued consent to participate in the study.*
- *Remind participant that the interview will last approximately 30 mins*
- *Check that they are in a suitable place where they are unlikely to be disturbed.*

For the AIRS participants:
As you are aware we have undertaken a large trial of autoinflation for glue ear in primary care. The results are in the process of publication, however, we can say that the results reinforce the current evidence that autoinflation is a feasible and effective treatment, which is applicable to primary care. An important part of research is the wider implementation of study findings. We are hoping that these interviews will help towards firstly finding out what is currently happening in primary care and secondly what sort of resource or intervention may support a better management of glue ear for families in the primary care setting. So you thoughts and ideas would be much appreciated. There are no right or wrong answers, it is just your views and experiences that we are keen to obtain.

Everything said will be kept confidential and any quotes used will not identify them as an individual and you can stop the interview at any point.

Do you have any questions at this stage.

If you are happy to continue I will switch on the recorder.

Part 1: Managing glue ear in primary care	NPT construct
i. Can you tell me how you'd manage a child with glue ear in your practice, starting with the diagnosis? *Prompt:* *What concerns are normally raised by parents? (hearing, behavioural, speech and language?)* *Clinical history?*	**Context** **Coherence** • Differentiation
ii. What facilities are available to you for diagnosing OME at your practice or in your locality? *Prompt: Otoscopy, Tympanometry, Audiometry (where?)Prompt: ENT specialisation?*	
iii. What treatments, if any, do you regularly use in your practice to treat glue ear? *Prompt:* *Do you have any preferences?* *Are there any treatments that you avoid using or are uncomfortable with?*	
iv. Do you have a local policy for managing children with glue ear? *Prompt:* *Within the practice?* *From the CCG?*	**Context** **Collective action** • Contextual integration
v. Are you aware of any national guidelines for managing glue ear? *Prompt: NICE guidelines for surgical management of glue ear*	
vi. What are your thoughts about surgical intervention with grommets for glue ear?	
vii. Do you consider your referral rates to be higher or lower than average? What do you think influences your referral rate?	
Part 2: Watchful Waiting	

viii.	Could you please describe what you understand by **watchful waiting** for glue ear?	**Context** **Coherence** • Differentiation
ix.	Do you use a watchful waiting strategy before referring children to ENT? *Prompt:* *What do you currently recommend to families during this period?*	
x.	What do you think would improve watchful waiting for children and their families?	**Coherence** • communal specification
xi.	Do you use any current patient information for glue ear?	**Cognitive participation** • Initiation • Enrolment • Legitimation • Activation
Part 3: New treatment for glue ear		
xii.	What do you think about autoinflation for treating glue ear? *Prompt: from what you have heard or from personal experience?*	**Coherence** Individual specification
xiii.	What are your thoughts about using autoinflation in your practice?	**Collective action** • interactional workability
xiv.	What do you think might facilitate the use autoinflation in your practice population with glue ear? *Prompt: facilitators for both the practice and for families*	**Cognitive participation** • Enrolment
xv.	Can you describe any potential barriers for using autoinflation in your practice population with glue ear? *Prompt: barriers for both the practice and for families*	**Cognitive participation** • Enrolment
Part 4: Resources to support management in primary care		
xvi.	What sort of educational information would you find useful to support a more structured monitoring period in your	**Collective action** • relational

	practice? *Prompts:* *Practice training modules in otoscopy, tympanometry, audiology, general ear care?*	integration • skill set workability **Cognitive participation** • Activation
xvii.	What sort of resources would you find useful? Simple quality of life impact measure? Simple online hearing test? Information leaflets to support parent/child self-management Web information for families and teachers?	**Collective action** • relational integration • skill set workability **Cognitive participation** • Activation
xviii.	What do you think about a nurse-led service in primary care? *Prompt:* *What would you see as the benefits?* *What would you perceive as the barriers?* *What would be the enablers?* *Would it work in your practice?* *What would the training needs be?* *What would support this over a longer time period?*	**Collective action** • interactional workability • relational integration • skill set workability
Part 5 : Any other topics or questions		
xix.	Are there anything other issue or topics that you would like to raise about the diagnosis and management of glue ear?	

End of the interview

Tell the participant that the interview is completed and the recorder is switched off
Thank the participant for taking part in the study.
Remind the participant of confidentiality and anonymity
Ask the participant if they had any further questions

Demographic questions:

Gender	Male/female				
Age bracket	21-30	31-40	41-50	51-60	61-70
Year qualified as GP	_____				

Appendix C Secondary analysis (chapter 6):

DOI: 10.3310/hta19720 HEALTH TECHNOLOGY ASSESSMENT 2015 VOL. 19 NO. 72

Chapter 6 Qualitative evaluation

Background

Autoinflation is a promising non-surgical treatment for OME, which has potential to improve natural resolution rates and QoL for children with OME-related concerns and symptoms, some of whom may be considered for ENT referral. The reliability of children inflating the nasal balloon and longer-term compliance with treatment has remained a concern regarding whether or not it could be a suitable treatment in primary care.[35] Although overall compliance has been assessed in the main trial, no previous qualitative work has been carried out with families or health-care professionals to explore facilitators and barriers to UK primary care management of OME, and the practicalities of use of autoinflation during this period.

This chapter reports a nested qualitative study, which is designed to inform the wider implementation of autoinflation in the primary care setting, including the monitoring process.

Objective

The qualitative study aims to explore the views and experiences of parents and practice nurses of both autoinflation and monitoring in primary care.

Methods

Participants and procedures

Participants were identified and recruited from general practices that participated in the main trial. A maximum variety sample[95] of practice nurses were invited to participate, including nurses from high- and low-recruiting practices, career RNs and practice nurses who undertake research alongside their normal duties. A maximum variety sample of parent participants ensured a range of child characteristics including age, sex, baseline severity of OME and GP practice location. This sampling was carried out to select a wide variety of 'information-rich cases', to obtain in-depth information about the issues relevant to the study.[95]

Interviews

Interviews were conducted either face to face or by telephone by a trained interviewer (JV), each lasting approximately 30 minutes. An interview guide was used to steer the interview while remaining sufficiently flexible to allow participants to raise issues that were important to them (see *Appendix 8*). Participants were asked about their views of screening and monitoring of glue ear in primary care, experiences of autoinflation including enablers and barriers to its use, and overall experiences of participating in AIRS. The interviews were digitally audio-recorded and transcribed verbatim, removing any identifiable data to ensure anonymity.

Analysis

Data were managed using NVivo 10 software and analysed using thematic analysis.[96] After initial familiarisation, the transcripts were systematically and comprehensively coded using open coding, a method of reducing the data while capturing the semantics and concepts of the data itself. The first three transcripts were coded by multiple coders and a coding framework agreed, improving the reliability of the study. Codes were refined into broad themes both inductively and guided by a priori knowledge of the topic area. Themes were then defined and described in relation to the research questions and existing literature.

Findings

Participants

A total of 33 participants took part in a research interview. Of these, 19 were practice nurses recruited from 18 GP practices across 10 former PCTs in the South West England, Thames Valley and Cheshire regions. Registered practice populations ranged from 3378 to 28,261, with the Index of Multiple Deprivation decile ranging from 6 to 10 (mid to low deprivation). Nurses variously described their employment status as practice nurses ($n = 11$), RNs ($n = 7$) and secondary care RNs ($n = 1$). The 14 parent participants were recruited from 10 practices in South West England and Thames Valley. All parents were the mothers, reflecting the usual carer who brought the child to the AIRS appointments.

Themes

Three key themes emerged from the analysis (*Table 37*). These themes are not an exhaustive account of the findings, but represent the major themes interpreted as relevant to the research question. Each theme is described in the following section and exemplar quotations are given to illustrate the subthemes.

Rationalising

This theme is defined as how parents seek information about OME and use their knowledge, experience and concerns to rationalise decisions about their child's management.

What parents knew about otitis media with effusion

Parents used a range of information including tacit knowledge, personal experience and information gathered from friends, family and health professionals to make sense of glue ear and understand the implications for their child. There was a mixed knowledge base, with some parents having a good insight into the causes and natural history of the condition, while others had not heard of glue ear before. Referencing to normal childhood behaviours, including ignoring instructions and misbehaviour, often meant that hearing impairment was not always recognised.

> *I mean I thought sometimes it was sort of a bit like a, you know, a normal child at that age, they don't want to answer you, sort of thing, they just ignore you anyway.*
>
> *Parent participant 13*

TABLE 37 Themes indentified in the analysis

Theme	Subtheme
Rationalising	What parents knew about OME
	Rationalising treatment decisions
Primary care management	Screening for OME
	Practice nurse as OME case manager
	Referral expectations
Engaging with monitoring and treatment	Interactions between nurses and families
	Compliance with autoinflation

DOI: 10.3310/hta19720 HEALTH TECHNOLOGY ASSESSMENT 2015 VOL. 19 NO. 72

Parents gathered information from various sources including the internet, friends and family, charitable sources, ENT departments and their GP practice. Nurses signposted parents to online information, often to the website Patient (www.patient.co.uk), which was considered a useful source. However, many parents relied solely on the information provided by their GP surgery, finding the information on the internet somewhat overwhelming.

> *We were given a lot of websites to look at and sometimes you can go information overload on them can't you?*
>
> *Parent participant 8*

Rationalising care decisions

Routine care [or active monitoring (AM)] was seen as a passive period of 'wait and see' rather than taking action, and this was unacceptable to some families. There was a general preference for non-surgical management of OME, although most parents would consider surgery if that was the only option or if the glue ear was considered to be particularly severe.

> *The grommets seem to be quite a good idea if . . . if, obviously, then if he had real bad problems.*
>
> *Parent participant 14*

Medical treatments such as antibiotics and steroids were not perceived by parents to be effective for OME, although there was some confusion with the diagnosis of AOM, for which antibiotics were seen as effective and acceptable. Autoinflation was described as a natural, holistic treatment that enables parents to feel that they are taking action, rather than waiting passively, as in the case with routine care.

> *Some parents don't want to stick pills into their children; they don't want to squirt stuff into their ear, they want to say, well, what else is there?*
>
> *Nurse participant 9*

Primary care management of otitis media with effusion

This theme is defined as how families and nurses understand the role of primary care in the early diagnosis and management of OME.

Screening for otitis media with effusion

Being invited for screening was viewed as positive by parents, although some nurses described certain parents as 'overly worried' rather than having real concerns about their child's hearing. Parents were advised one way or another if glue ear was present or absent and this helped with their future treatment or management decisions.

> *If it was – if it showed that they did have glue ear, possibly, the parents were quite relieved. I said, oh, you know, there could be – and they said, thank goodness, you know, there is something wrong.*
>
> *Nurse participant 12*

Practice nurse as case manager for otitis media with effusion

Nurses were sufficiently informed and skilled to screen children with tympanometry as part of the study, although some nurses reported anxiety with interpretation of the results. Nurses were considered by parents to be competent in screening and managing OME. They were described as accessible to families and, while knowing the whole family, could provide continuous, co-ordinated management in the wider family context. Nurses reported that it was feasible to provide screening in primary care, although workload management and financial constraints were suggested as potential barriers.

> *There's always a huge time pressure and more and more and stuff is being moved from hospital into general practice; we are all up-skilling all the time, so it would be a financial consideration.*
>
> *Nurse participant 17*

Some nurses also reported a need for additional training in tympanometry and interpretation to provide ongoing screening at their surgery. Others reported concerns about not seeing sufficient children with glue ear to maintain their skill level.

> *I think if it's just basic tympanometry I'd be happy to do it. I think – on having said that – I think if I am doing it, I would like more training just so – because – you know – it's nice to tell people – have information and knowledge so that you know what you're telling them.*
>
> *Nurse participant 18*

Referral expectations

Having their concerns listened to by GPs was very important to parents. Some parents reported that their concerns were not always recognised, and this resulted in repeat consultation and requests for onward referral.

> *Quite often they expected to be referred . . . and, you know, often – not often, but a few times I would get – the GP to come in just for – for reassurance, to say this is the glue ear season and even if we referred now, then maybe we would wait for a few months to see if things cleared naturally.*
>
> *Nurse participant 2*

Engaging with monitoring and treatment

This theme is defined as the importance of engaging parents and children in the screening process, AM and autoinflation for OME in primary care.

Interactions between nurses and families

Nurse–parent–child interactions were important for engaging families with primary care screening and compliance with the nasal balloon. Nurses reported good relationships with the children and their families. Parents often reported nurses to be more accessible than their GP colleagues, and having more time to spend with the children.

A good demonstration by the nurse, together with involvement of the parents, ensured that the children engaged with autoinflation treatment.

> *I demonstrated and they would then have a go and they – obviously weren't particularly good at it so I said to the mum – oh – you have a go and if you can do it, that helps the child.*
>
> *Nurse participant 12*

Some children had initial problems inflating the balloon, but in most cases this was overcome quickly and almost all children mastered the technique within a few days.

> *A couple were just scared of the idea but once they were shown whatever – and even if they just blew it a bit, then we sort of said – oh that's brilliant. And then, of course, the next time you saw them, they'd been blowing it up to the size of an orange.*
>
> *Nurse participant 2*

The 'fun' element of the balloon was often reported as appealing to the children. This led to the children taking ownership of the treatment:

> *Well, the girls thought that was great fun, anything to do with balloons isn't it? They think it's great and the gross factor of blowing it up with your nose is a real hit with the little ones. They love it.*
>
> *Parent participant 5*

DOI: 10.3310/hta19720 HEALTH TECHNOLOGY ASSESSMENT 2015 VOL. 19 NO. 72

Compliance with autoinflation

Overall, compliance was good during the first month of treatment. Making the balloon part of the daily routine made it easier for families to adhere to the treatment regimen.

> *in the morning whatever we were doing, and then at bedtime, so it was just like cleaning your teeth, just brought it in as an extra thing to do as part of the routine.*
>
> *Parent participant 6*

Positive feedback with reward sticker charts and the 'fun' element of the nasal balloon helped towards adherence over a longer period.

> *I think the sticker chart – I mean that definitely – having their reward book and different bits and pieces, I think that was – yes – that was a bit of an incentive.*
>
> *Nurse participant 2*

By contrast, some parents reported the novelty wearing off and others became frustrated with their children for not continuing. Unlike a medication that needs to be swallowed, autoinflation requires the child's active participation and this could become a battleground for parents.

> *So we staggered along for a few weeks with her not really trying to do it and, yes, it was just becoming such a pain, really. It was so painful to try and get her to do it and my husband was very supportive and we were both trying to encourage her to do it and I tried everything.*
>
> *Parent participant 4*

Discussion

This nested qualitative study of primary care monitoring and autoinflation in children with OME highlights the potential for an improved and more proactive role for general practice in the earlier diagnosis and treatment of this common childhood condition.

Primary care management of glue ear

The first point of contact for parents who have concerns about their child's hearing is usually primary care; they often present with a range of concerns, background knowledge and expectations for the diagnosis and treatment of their child.

This study found that parents wanted to take action once they had received a diagnosis, and that waiting was not always acceptable to them. For them, action involved taking medications, surgery and autoinflation. In a study of AOM, parents with more knowledge and who felt included in medical decisions were more likely to accept watchful waiting, rather than immediate antibiotic treatment.[97] OME naturally shows some improvement in ≈50% of cases by 3 months, rising to 75% at 6 months depending on the health-care system and on tympanometric criteria used to define improvement,[30] so there is a valid case for waiting for natural resolution of OME to occur.

Access to good-quality information about the natural history, causes and risk factors, treatments and preventative measures may help parents to rationalise and make informed choices concerning the management of their child. Written information has been found to increase the trust in verbal medical advice and reduce the need to obtain additional information elsewhere.[98] Ensuring that information fulfils the needs of parents with children with OME may be of particular importance considering the evidence of a link between parent views and treatment-seeking behaviours.[99]

Nurses were competent and skilled in managing children with glue ear, providing information, diagnosis with otoscopy and tympanometry, monitoring during the initial 3-month period and managing their treatment with the nasal balloon. It has been argued that nurses do not have the skills or sufficient training to conduct tympanometry.[100] Most of this research has been conducted in secondary care, where tympanometry diagnosis has been compared directly with the best relative standard of myringotomy ('relative' because of substantial dry tap rates at myringotomy), giving a direct measure of specificity and sensitivity for detecting middle ear effusions.[101] In the secondary care environment, multiple rigorous measures of bilateral OME causing persistent hearing loss are required as part of the AM process prior to undertaking grommet surgery, a requirement of the NICE guidelines.[1] However, in primary care, it is more useful to improve the early diagnosis of glue ear, to be able to start treatment as problems arise rather than allowing the condition to develop to the point of needing an operation. The latter may be considered a more substantial intervention from the child and family perspective.

Interactions

Building alliances in health care is an important part of helping towards a positive outcome and an important element of self-care.[102] Therapeutic alliances, most commonly reported in psychotherapy, may be a useful way of looking at the relationships between the nurse, parent and child in the case of primary care monitoring of OME. The model of therapeutic alliance was developed from the early work of Bordin,[103] who described the relationship between the practitioner and patient in terms of personal and collaborative relationships, and the effect they have on patient outcomes.[104] Our study has shown that the personal relationships between nurses and families can affect parental confidence in the information and diagnosis they receive and, consequently, the care that their child is receiving in primary care. The nasal balloon demonstration draws on the task element of this collaborative relationship and the combination of the nurse demonstration, parental involvement and engaging the child in the process has been shown to be important in children mastering the technique of autoinflation. The triadic relationship between the nurse, parent and child has been explored in asthma review consultations, which found that the individual dyadic relationships between nurse–parent, nurse–child and parent–child needed to be taken into account where there could be potential areas of conflict and lack of co-operation.[105] In this study, nurses reported focusing their attention on the relationship with the child, and seeing that co-operation at an early stage would be important for compliance with the procedure.

Acceptability and compliance

There have been both trial and anecdotal concerns from ENT centres that children may not be able to reliably perform autoinflation and that adherence to the treatment regimen may be a problem, especially in younger children. This study reported that the nasal balloon was perceived as an acceptable technique. School children mastered the technique relatively quickly, and adherence over the period of a month was achievable for most parents.

Acceptability to families of the nasal balloon has been reported in three previous secondary care studies, in which the technique was described as 'acceptable'[58] and 'fun' or 'amusing' for the children.[56,61] This is consistent with the findings of this study, where parents described the nasal balloon as a natural and holistic treatment, found it acceptable as a treatment and children are reported to enjoy the novelty of the technique. However, some children reported initial anxieties around the use of the balloon that were overcome with parental support and encouragement.

Previous studies have reported that young children had difficulty in mastering the technique of autoinflation, especially at the beginning. One study, which evaluated the use of Otovent after flying, found that just 53% of children aged 2–6 years could inflate the balloon.[106] However, the authors suggested that the children could have learnt the technique from their parents if they had commenced training 1–2 days before the flight. Accounts from this qualitative study suggest that most children became proficient at autoinflation after some practice. Stretching the balloon beforehand by oral inflation (by child or parent) helped with initial inflation, together with the encouragement and support of the parents.

DOI: 10.3310/hta19720 HEALTH TECHNOLOGY ASSESSMENT 2015 VOL. 19 NO. 72

Parents reported that the key to remembering to use the nasal balloon was to make it part of the child's everyday routine, such as after cleaning their teeth or using their asthma inhaler. Routines and rituals are important organisers of family life.[107] Children naturally adopt routines such as eating meals, daily homework and bedtime routines. It has been theorised that adopting good routines can improve the likelihood of compliance with certain medical treatments[108] and minimise the burden to families.[109] Adopting autoinflation as part of a routine may be very important for the longer-term use of the nasal balloon up to 3 months.

Strengths and limitations of the qualitative study

This research is the first to provide pragmatic, experiential data about use of autoinflation from a primary care setting, and includes both nurse and parent participant perspectives. It covers screening, AM and the use of the nasal balloon from the views of both the parents and primary care nurses. Using more than one data source to obtain different perspectives allows triangulation of the findings to check and establish study validity.[110]

The study has also given insight into day-to-day, real-life experiences of children using the nasal balloon, which has not hitherto been formally captured in previous studies of autoinflation. This study information should help identify the common enablers and barriers to the wider implementation of autoinflation in a community setting.

It was not possible to recruit parents of children who withdrew or dropped out of the AIRS. Their experiences of screening, monitoring and treatment may well have differed to the study group, such that possible problems associated with AM and compliance with the autoinflation treatment may be missing. It might have also been useful to gather views and opinions from the participating GPs, especially regarding primary care-led services. Also missing were the direct voices of the children themselves. Including children in research can enhance the scope and findings of a study;[111] however, in this instance the children were individually considered too young to be able to separately contribute to this study (predominantly 4–6 years).

Implications for clinical practice

The findings suggest that primary care professionals are eminently capable of engaging families early on in the process of AM with autoinflation and can provide good-quality information while drawing in parents and children in co-operative management decisions. Good demonstration/training with the autoinflation method, together with positive reinforcement by the health professional, will enhance child co-operation and improve overall adherence to the treatment schedule. Parents reported autoinflation to be acceptable to their children and compliance was improved by making the treatment part of the daily routine. However, the sample of parents had a somewhat higher than average educational level and were from areas of low social deprivation. Therefore, it would be of much interest to explore the potential barriers to autoinflation in lower socioeconomic groups where OME may have disadvantageous impacts.

Parents viewed practice nurses as accessible, local and able to provide continuity of care for OME. However, it remains uncertain as to exactly how a nurse-led service would work in the wider context of general practice, and this requires further research.

Appendix D Development of the wTADAST-24

D.1 Floor and ceiling effects identified in previous versions of the TADAST – TADAST-50 (Riley, 1996)[188]

Floor effects: word pairs that were too difficult for children to discriminate between in the wTADAST-50. Some of which were removed previously to form the wTADAST-36.

Word/picture pairs	***Number of errors (n=16)***
Goat/Coat	6
Fountain/mountain	6
Thin/pin	6
Socks/clocks	6
Bull/wool	7
Bee/pea	7
Van/fan	8
Hairy/fairy	9
Clock/block	10
Queen/green	12

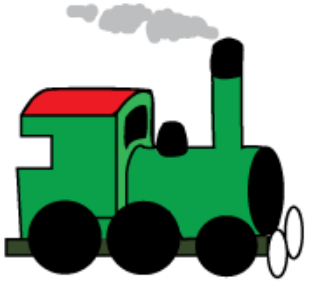
Ceiling effects: word pairs that were easy for children to discriminate between. Some of which were removed previously to form the wTADAST-36.

Word/picture pairs	Number of errors (n=16)
Nose/rose	0
House/mouse	0
Pin/pen	0
Birds/beads	0
Car/star	0
Pin/pan	0
Van/fan	0
Man/fan	0
Bell/bull	0
Log/dog	0
Two/tea	***0***
Comb/coat	0
Moon/spoon	0
Boot/fruit	0

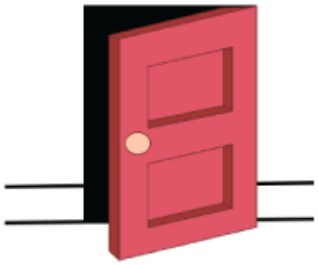
D.2 wTADAST-24 word/picture pairs

wTADAST-24 Practice sequence

VIDEO CLIP	Hello. I'd like you to look at some pictures with me. I will say a word. Remember to look at me and listen carefully. Then look at both pictures and chose the best picture of the word. Let's try some. Point to ….**train**

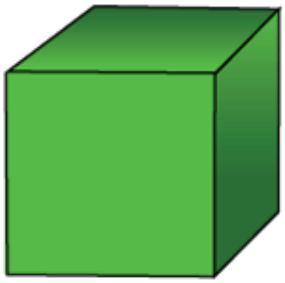



VIDEO CLIP	That's fine. Remember to look at me and listen carefully Now point to ….**door**

VIDEO CLIP	Very good. Now….**leaf**


VIDEO CLIP	Now I would like you to look at some more pictures with me. Remember to look at me and listen carefully. Then look at both pictures and chose the best picture of the word. **Block**

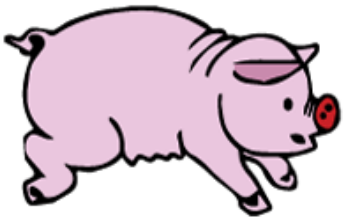
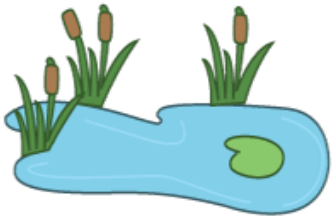
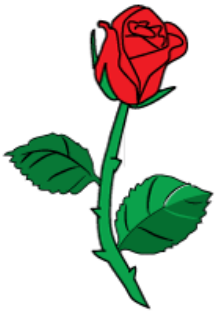


VIDEO CLIP	**Pen**

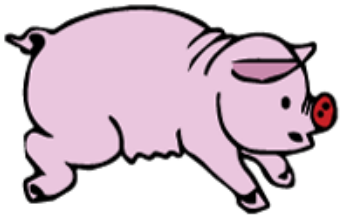
Pen/pin

VIDEO CLIP	**House**

wTADAST-24 Actual Test

Word pairs	Question type	Left picture	Right picture
1	Audiovisual	Correct answer: Boot	
			
2	Audio	Correct answer: Pig	
			
3	Visual	Correct answer: Wand	
			
4	Audiovisual	Correct answer: Nose	
			

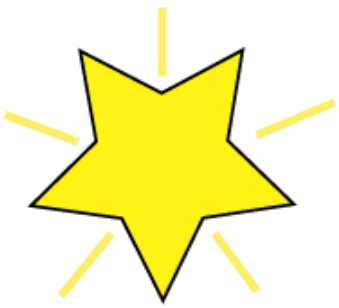
5	Audio	Correct answer: Pin



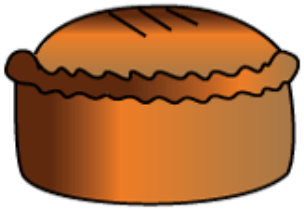
6	Visual	Correct answer:Spoon

7	Audiovisual	Correct answer: Bin

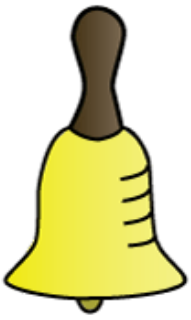
8	Audio	Correct answer: Star



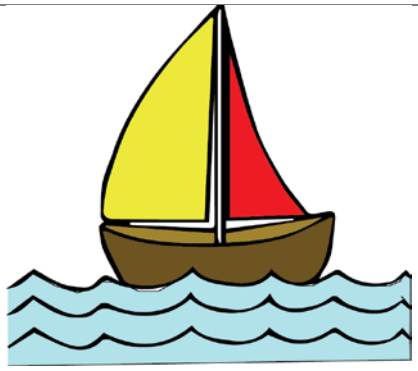
9	**Visual**	**Correct answer: Tie**



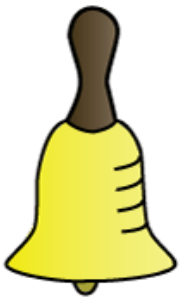
10	Audiovisual	Correct answer: Bell



11	Audio	Correct answer:Boot



12	Visual	Correct answer: Bed



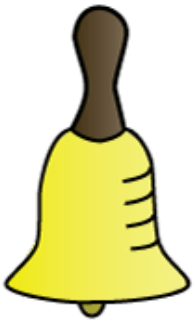
13	**Audiovisual**	**Correct answer: Mouse**

14	Audio	Correct answer: Sea

15	Visual	Correct answer: Farm

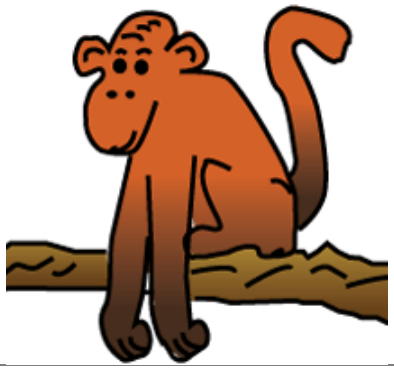
16	Audiovisual	Correct answer: Bat

17	**Audio**	**Correct answer: Bell**



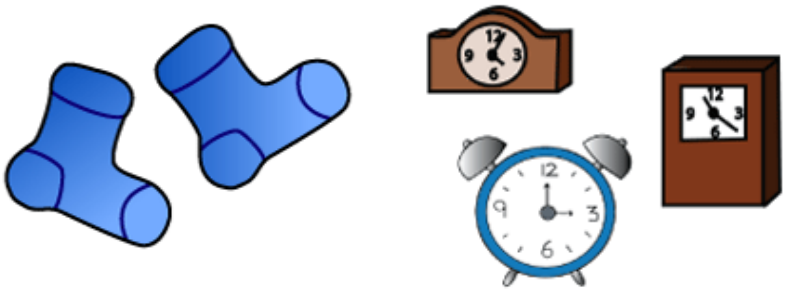
18	Visual	Correct answer: Log

19	Audiovisual	Correct answer: Money



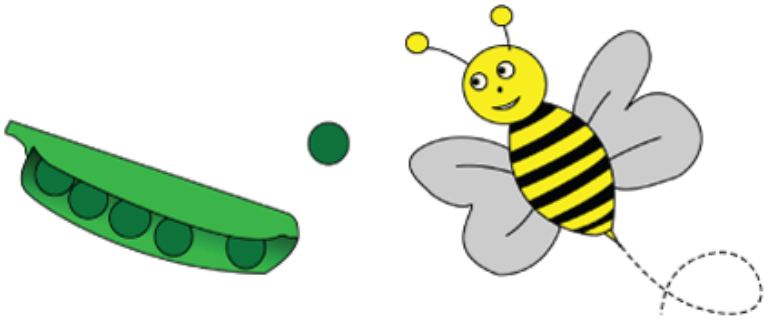
20	Audio	Correct answer: Bowl

21	**Visual**	**Correct answer: Socks**

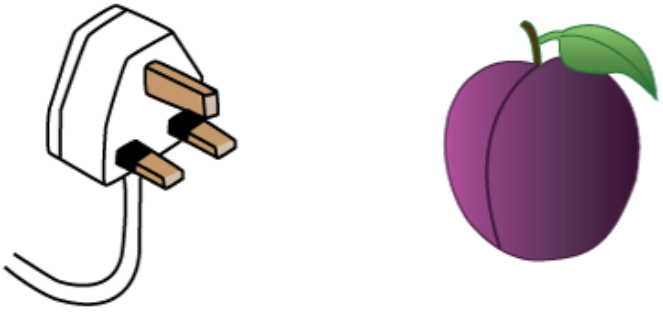


22	Audiovisual	Correct answer: Beads

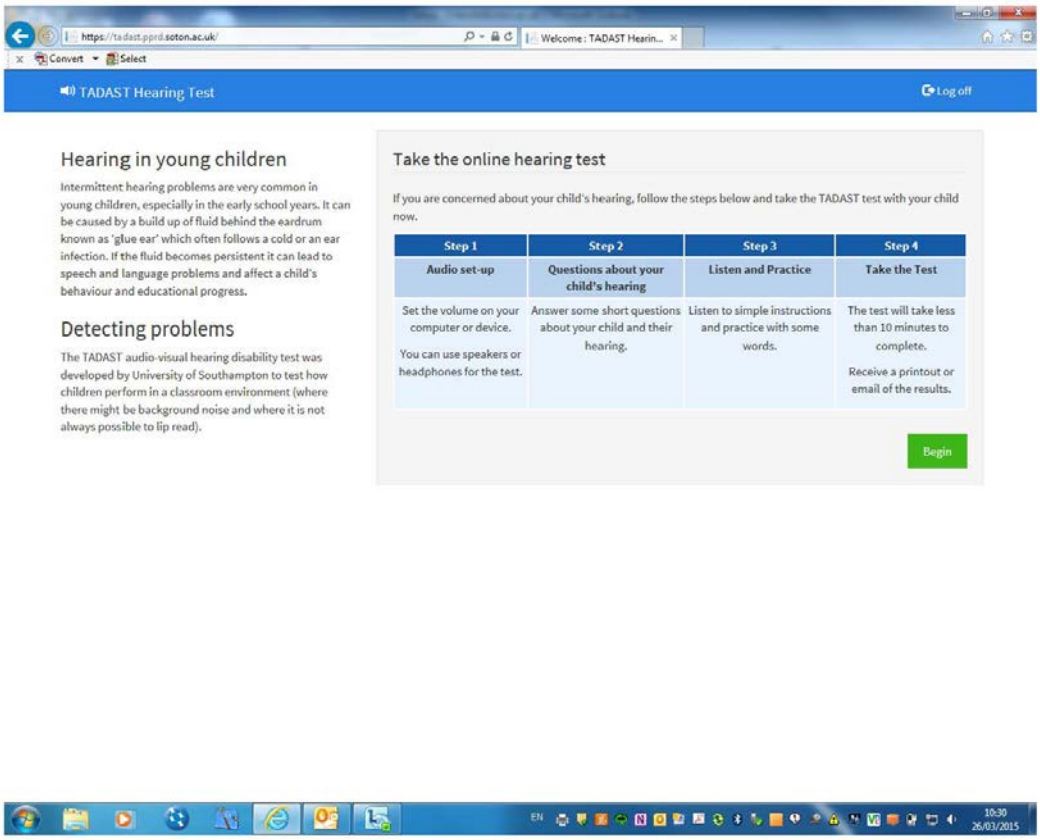
23	Audio	Correct answer: Bee

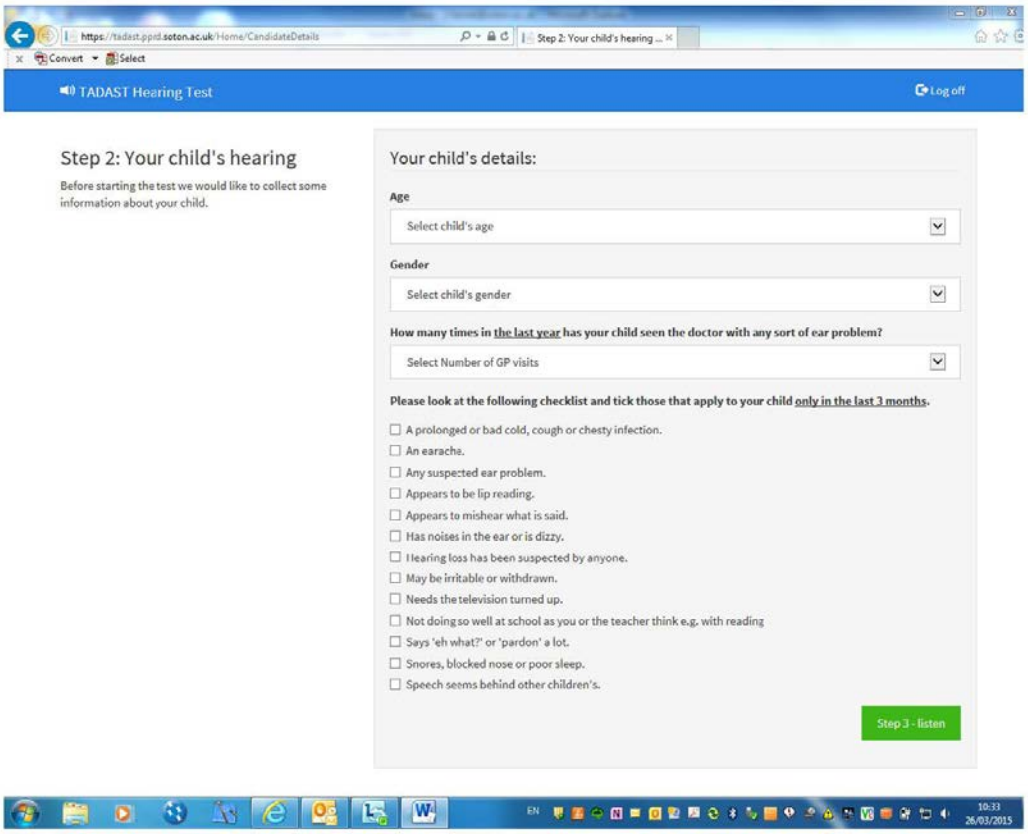


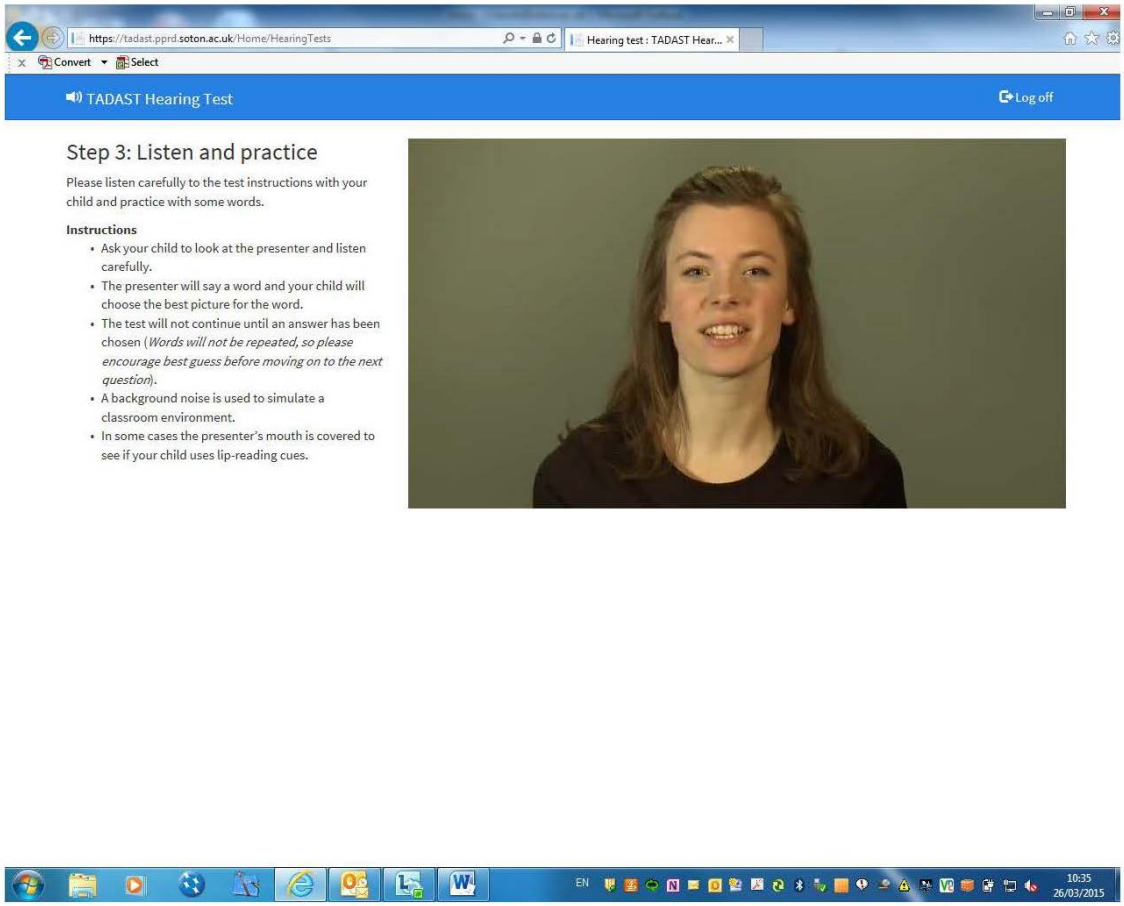
24	Visual	Correct answer: Plug



D.3 wTADAST-24 Screenshots






https://tadast.pprd.soton.ac.uk/Home/HearingTests
Hearing test : TADAST Hear...
Convert
Select
TADAST Hearing Test
Log off
Step 3: Listen and practice
Please listen carefully to the test instructions with your child and practice with some words.
Instructions
• Ask your child to look at the presenter and listen carefully.
• The presenter will say a word and your child will choose the best picture for the word.
• The test will not continue until an answer has been chosen (Words will not be repeated, so please encourage best guess before moving on to the next question).
• A background noise is used to simulate a classroom environment.
• In some cases the presenter's mouth is covered to see if your child uses lip-reading cues.
EN
10:35
26/03/2015

Ethics committee approval

From: ERGO
To: Vennik J.
Subject: Your Ethics Submission (Ethics ID:13620) has been reviewed and approved
Date: 25 March 2015 09:37:14

Submission Number: 13620
Submission Name: Web support intervention for glue ear
This is email is to let you know your submission was approved by the Ethics Committee.

You can begin your research unless you are still awaiting specific Health and Safety approval (e.g. for a Genetic or Biological Materials Risk Assessment)

Comments
1.Dear Jane, Re13620 - Web support intervention for glue ear Thank you for submitting your revisions relating to the above study. I am pleased to inform you that full approval has now been granted by the Faculty of Medicine Ethics Committee. Approval is valid from today until 30.11.2015, the end date specified in your application subject to the following stipulations: â¢ the above ethics approval number must be quoted in all correspondence relating to your research, including emails; â¢ if you wish to make any substantive changes to your project you must inform the Faculty of Medicine Ethics Committee as soon as possible. Please note that this email will now constitute evidence of ethical approval. Should you require a paper signed copy of this approval, please contact the FoMEC Administrative Team via email at: Medethic@soton.ac.uk. We wish you success with your research. Yours sincerely Dr Catherine Hill Chair of the Faculty of Medicine Ethics Committee

Click here to view your submission

ERGO : Ethics and Research Governance Online
http://www.ergo.soton.ac.uk

DO NOT REPLY TO THIS EMAIL

D.4 Participant information pack

Medicine

UNIVERSITY OF Southampton

Participant Information Sheet v2.0 23/03/2015

Phase 2: Development of an internet information pack to support primary care management of glue ear (Parent/carer Interviews)

Researcher: Jane Vennik ERGO number: 13620

Dear parent/guardian

My name is Jane Vennik, a doctoral research student at University of Southampton. I am conducting a research project concerned with managing young children with glue ear in the community. I am asking if you would consider taking part in a project to develop a website with advice, support and information for families of children with glue ear. Before you decide whether to take part it is important for you to understand why we are doing the study and what is involved. If you have any questions please feel free to contact me on 023 8024 1088.

What is the purpose of the study?

Glue ear is a common problem of childhood which can lead to intermittent hearing loss in young school children. This can affect a child's educational development and quality of life. Half of affected children will get better naturally within 3 months, but some may go on to have longer term problems. We are designing a website that can deliver advice, support and instruction for monitoring and managing glue ear in the home during the government recommended 3 month watchful waiting period. The purpose of this phase of the study is to find out what parents of children of this age group think about our new website.

Why have I been chosen?

You have been invited as a parent/carer of a young child in the age group where glue ear is most common.

Do I have to take part?

It is completely up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time and you do not have to give a reason.

What will happen if I take part and what do I have to do?

The researcher will arrange to meet with you at a time and place that suits you. When you meet with the researcher will be asked to look through the newly designed website and let the researcher know what you think. Sessions will last for 30-60 minutes. If you are agreeable, you may be asked to take part in an additional interview at the end of the website development.

What are the advantages and disadvantages of taking part?

There are no direct advantages or disadvantages to you. However, you will get the opportunity to contribute to a process that may improve the information, advice and support available for families of children with glue ear. You will be reimbursed £25 to cover your time for taking part in the research interview.

Will my taking part in the study remain confidential?

With your permission the interview will be audio-recorded to make an accurate record of what is said and then the recording will be transcribed. This written record will not include any names or other details that can identify you, to ensure confidentiality. The recordings will be held in a locked cabinet in the University of Southampton to which only the research team will have access. Once the recordings have been transcribed, they will be destroyed. The findings from this study will be used in the development of the website and also in research reports. No names will be included in the report so any quotes from the interview will be anonymous.

What happens if I change my mind?

Taking part in this research is voluntary. It is up to you to decide whether to take part. You can decide not to continue at any time without giving a reason.

What happens if something goes wrong?

If you have any concerns or feel that you have been placed at risk you can contact Research Governance Manager at the University of Southampton on telephone 02380595058 or email Rgoinfo@soton.ac.uk.

What will happen to the results of the research study?

The results will be published in scientific journals and presented at scientific meetings. A summary of the findings will be sent to all participants who would like to see the results and the full report can be made available on request.

Who is organising the funding of the research?

The University of Southampton is the sponsor of this study and the National School of Primary Care Research is the funder.

Where can I get more information?

If you would like to take part in the study or if you have any further questions please do not hesitate to get in touch with Mrs Jane Vennik using the contact details below.

Contact for further information

Researcher: Jane Vennik Tel: 023 8024 1088. Email: j.vennik@soton.ac.uk

Department of Primary Care, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton, SO16 5ST.

This study has been reviewed and given favourable opinion by Faculty of Medicine Research Ethics Committee.

Thank you for reading this document and for any help you decide to give

If you do choose to take part in the study please keep this information sheet and you will also get a copy of your signed consent form

YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANYTIME

Medicine

UNIVERSITY OF Southampton

Information for Children: Hearing test study

It can sometimes get a little sticky inside children's ears. This is called 'glue ear' and it is quite common in young school children. Glue ear can make it hard for children to hear whispers and people speaking – especially when there is a lot of noise being made all around, like in the classroom.

We have a new computer hearing test to help find out which children might have glue ear and not hear very well.

Helpers for our new hearing test

We need helpers to see if our new hearing test works. You will be helping other children who might not hear very well.

What will you need to do?

If you say yes you will do a short hearing test at school on the computer. You will sit in front of a computer screen, listen to some instructions and then a presenter will say a word and you will choose the best picture to fit the word. There will be 36 words altogether and the test will take about 10 minutes.

Do you have to take part?

No, you don't have to take part and you can stop at any time.

If you have any questions about helping us please ask the researcher Jane and she will answer them for you.

YOU CAN STOP WHENEVER YOU LIKE

Version 2, 23/03/2015

Primary Medical Care
University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST, United Kingdom
Tel: +44 (0)23 8024 1050 Fax: +44 (0)23 8070 1125 pmc1@soton.ac.uk

Medicine

UNIVERSITY OF Southampton

REPLY SLIP

If you agree to your child taking part in this study, please complete the attached **consent form** and the brief **questionnaire** below and return it in the enclosed envelope to your child's school teacher who will pass on to the researcher. If you would like to have access to the hearing test at the end of the study, please enter your email address so the relevant log in details can be sent to you directly. Your contact details will not be used for any other purpose.

If you have any questions or concerns in the meantime, please contact Jane Vennik, 023 8024 1088 or j.vennik@soton.ac.uk

Information about you and your child.

Your Name: …… Your email address: ……

Your child's name:…… Your child's age: ……..

1. Is your child experiencing a cold or trouble with their ears **today**? ☐ Yes ☐ No
2. In the **last 3 months** has your child had any of the following symptoms or concerns?

• A prolonged or bad cold, cough or chesty infection	☐ Yes	☐ No
• An earache	☐ Yes	☐ No
• Appears to mishear what is said	☐ Yes	☐ No
• Hearing loss has been suspected by anyone	☐ Yes	☐ No
• Says 'eh what?' or 'pardon' a lot	☐ Yes	☐ No
• Needs the television turned up	☐ Yes	☐ No
• May be irritable or withdrawn	☐ Yes	☐ No
• Appears to be lip reading	☐ Yes	☐ No
• Not doing so well at school as you or the teacher think *e.g.* with reading	☐ Yes	☐ No
• Has noises in the ear or is dizzy	☐ Yes	☐ No
• Snores, blocked nose or poor sleep	☐ Yes	☐ No
• Speech seems behind other children's	☐ Yes	☐ No
• Any suspected ear problem	☐ Yes	☐ No

3. In the **last 12 months** how many times have you seen your child's GP with any sort of ear problem?

☐

1

Medicine

UNIVERSITY OF Southampton

Study Number .....

Study ID number: 13620

CONSENT FORM

Phase 1: Development and validation an audiovisual hearing disability test

(Version 2, 23/03/2015)

Name of Researcher: Jane Vennik
Academic supervisor: Dr Ian Williamson

Please initial box

1. I confirm that I have had the chance to read the information sheet dated (version 3 dated 15/4/2015) and ask questions that have been answered satisfactorily. ☐
2. I confirm that I have spoken to my child about the study and they have had the opportunity to look at the child's information sheet (version 2 dated 23/3/2015) and ask any questions that have been answered satisfactorily. ☐
3. I confirm that my child has indicated their willingness to participate and understand this will be confirmed again by the researcher with my child on the day. ☐
4. I understand that all my child's details will be kept confidential and their name will not appear on any reports or documents. ☐
5. I understand that our participation is voluntary and that we are free to withdraw at any stage without giving reasons and without my child's school provision being affected. ☐
6. I agree to my child taking part in this study. ☐

Name of Parent/guardian	Signature	Date
Name of researcher	Signature	Date

Please return the questionnaire and consent form in the enclosed envelope to your child's school.

2

D.5 Identification of pictures from the wTADAST-24

Picture	*Number of children*	*Alternative words used*
Pond	7	Lake Water
Bull	6	Cow
Plug	5	Wire Charger Switch Not recognised(1)
Log	2	Tree Wood
Ball	2	Bowling Not recognised (1)
Pea	1	Beans
Pen	1	Pipe
Arm	1	Hand
Rat	1	Mouse
Birds	1	Chicks
Rose	1	Flower

Appendix EDeveloping the LittleEARS educational intervention (chapter 8):

E.1 List of patient information leaflets

1. Action on hearing loss: Glue Ear – The Facts. April 2012
2. BMJ: Glue Ear – BMJ Publishing Group Limited 2014
3. Bupa: Glue ear. Online accessed May 2015
4. ENT-UK: Glue Ear. Online accessed May 2015
5. NDCS: Factsheet: Treatments for Glue Ear. February 2008
6. NHS choices: Glue Ear. August 2013
7. NHS inform Scotland: Glue Ear. Online accessed May 2015
8. NICE Surgical Management of Glue Ear in Children. February 2008
9. Patient.co.uk: Glue Ear – November 2014

E.2 Invitation pack

Medicine

UNIVERSITY OF Southampton

Participant Information Sheet v2.0 23/03/2015

Phase 2: Development of an internet information pack to support primary care management of glue ear (Parent/carer Interviews)

Researcher: Jane Vennik ERGO number: 13620

Dear parent/guardian

My name is Jane Vennik, a doctoral research student at University of Southampton. I am conducting a research project concerned with managing young children with glue ear in the community. I am asking if you would consider taking part in a project to develop a website with advice, support and information for families of children with glue ear. Before you decide whether to take part it is important for you to understand why we are doing the study and what is involved. If you have any questions please feel free to contact me on 023 8024 1088 or Dr Williamson on 023 8024 1077. When you have had chance to read this we would be pleased if you would detach the reply slip at the end and return it to us in the FREEPOST envelope.

What is the purpose of the study?

Glue ear is a common problem of childhood which can lead to intermittent hearing loss in young school children. This can affect a child's educational development and quality of life. Half of affected children will get better naturally within 3 months, but some may go on to have longer term problems. We are designing a website that can deliver advice, support and instruction for monitoring and managing glue ear in the home during the government recommended 3 month watchful waiting period. The purpose of this phase of the study is to find out what parents of children of this age group think about our new website.

Why have I been chosen?

You have been invited as a parent/carer of a child at *{insert name of school, nursery or group}*. Please be assured that you have not been chosen because you child has any hearing problems at school.

Do I have to take part?

It is completely up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time and you do not have to give a reason.

What will happen if I take part and what do I have to do?

If you do decide to take part you should keep this information sheet and return the enclosed reply slip and consent form to the research team in the FREEPOST envelope (no stamp is required). You will be then be contacted by a member of the research team to make sure that you are still willing to take part and who will also answer any queries that you may have.

The researcher will arrange to meet with you at a time and place that suits you; this may be at the University, in your home or at the school – wherever is most convenient for you. When you meet with the researcher will be asked to look through the newly designed website and let the researcher know what you think. Sessions will last for 30-60 minutes. If you are agreeable, you may be asked to take part in an additional interview at the end of the website development.

What are the advantages and disadvantages of taking part?

There are no direct advantages or disadvantages to you. However, you will get the opportunity to contribute to a process that may improve the information, advice and support available for families of children with glue ear. You will be reimbursed £25 to cover your time for taking part in the research interview.

Will my taking part in the study remain confidential?

With your permission the interview will be audio-recorded to make an accurate record of what is said and then the recording will be transcribed. This written record will not include any names or other details that can identify you, to ensure confidentiality. The recordings will be held in a locked cabinet in the University of Southampton to which only the research team will have access. Once the recordings have been transcribed, they will be destroyed. The findings from this study will be used in the development of the website and also in research reports. No names will be included in the report so any quotes from the interview will be anonymous.

What happens if I change my mind?

Taking part in this research is voluntary. It is up to you to decide whether to take part. You can decide not to continue at any time without giving a reason.

What happens if something goes wrong?

If you have any concerns or feel that you have been placed at risk you can contact Research Governance Manager at the University of Southampton on telephone 02380595058 or email Rgoinfo@soton.ac.uk.

What will happen to the results of the research study?

The results will be published in scientific journals and presented at scientific meetings. A summary of the findings will be sent to all participants who would like to see the results and the full report can be made available on request.

Who is organising the funding of the research?

The University of Southampton is the sponsor of this study and the National School of Primary Care Research is the funder.

Where can I get more information?

If you would like to take part in the study or if you have any further questions please do not hesitate to get in touch with Mrs Jane Vennik using the contact details below.

Contact for further information

Researcher: Jane Vennik Tel: 023 8024 1088. Email: j.vennik@soton.ac.uk
Associate Professor: Dr I.G. Williamson Tel: 02380 241071. Email igw@soton.ac.uk

Department of Primary Care, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton, SO16 5ST.

This study has been reviewed and given favourable opinion by Faculty of Medicine Research Ethics Committee.

Thank you for reading this document and for any help you decide to give

If you do choose to take part in the study please keep this information sheet and you will also get a copy of your signed consent form

YOU ARE FREE TO WITHDRAW FROM THE STUDY AT ANYTIME

REPLY SLIP

If you do decide to take part you should keep the information sheet and return this reply slip and consent form to the research team in the FREEPOST envelope (no stamp is required). You will be then be contacted by a member of the research team to make sure that you are still willing to take part and who will also answer any queries that you may have.

Information about you

Your Name: ..... Email address: .....

Tel: .....

Preferred method of contact: ..... Email/text/phone

Please return the questionnaire and consent form in the enclosed FREEPOST envelope.

Medicine

UNIVERSITY OF Southampton

Study Number .....

Study ID number: .....

CONSENT FORM

Phase 2: Development of an internet information pack to support primary care management of glue ear. (Parent/Carer Interviews)

(Version 2, 23/03/2014)

Name of Researcher: Jane Vennik
Academic supervisor: Dr Ian Williamson

Please initial box

		Please Initial each Box
1.	I have read and understood the participant information sheet dated..... version..... and have had the opportunity to ask questions that have been answered satisfactorily.	☐
2.	I agree to take part in this research study and understand that all my details will be kept confidential and my name will not appear on any reports or documents.	☐
3.	I understand that the interview will be audio-recorded and that no one but the research team will hear the recording.	☐
4.	I understand that my participation is voluntary and that I am free to withdraw at any stage without giving reasons and without my medical care or legal rights being affected.	☐
5.	I give permission for anonymous quotes from the interview to be included in reports of the findings from the research and used in the glue ear website.	☐

Name of Participant	Signature	Date
Name of researcher	Signature	Date

Primary Medical Care
University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton SO16 5ST, United Kingdom

Tel: +44 (0)23 8024 1050 Fax: +44 (0)23 8070 1125 pmc1@soton.ac.uk

E.3 Expert panel questions

LittleEARS website feedback

1) Overall, what did you think about the website?

2) What are your views about the look and feel of the website?

3) What did you think about the general content of the website? Including:

- About glue ear
- Watchful waiting/self-help
- Nasal balloon autoinflation

4) What did you think about the information and instruction videos?

5) What did you think about the downloadable/printable information?

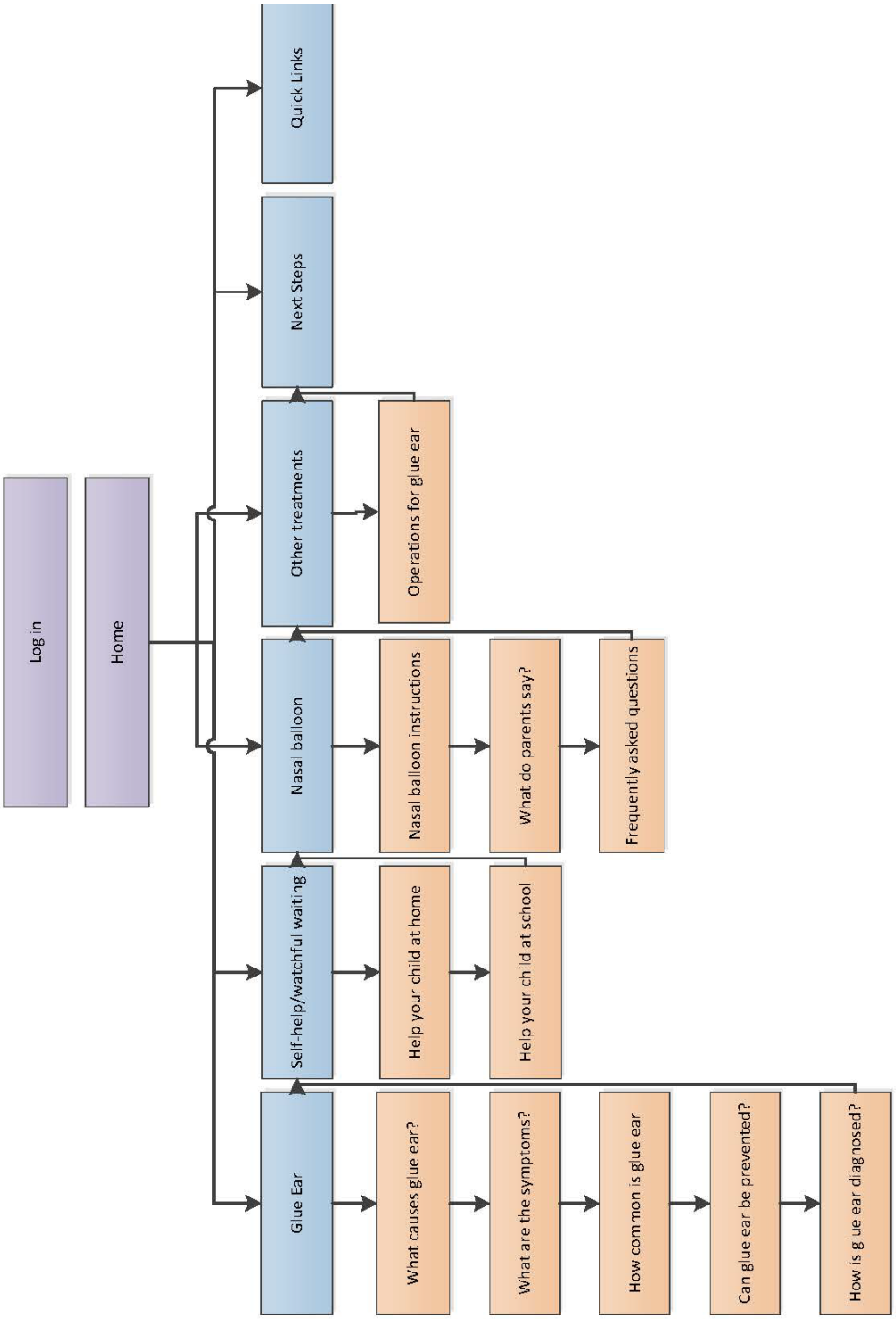
6) What do you think was good about the website?

7) What do you think could be improved?

8) Is there anything you thought was missing?

9) How relevant/useful do you think the website would be for your particular patient group?

E.4 Final layout of the LittleEARS educational intervention

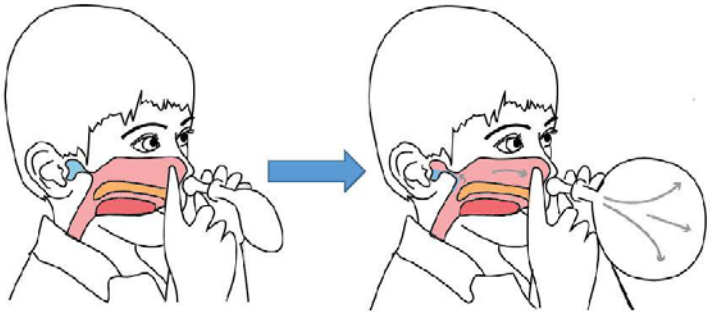


E.5 Instructions for using the nasal balloon

Instructions for using the Otovent nasal balloon

1. Take one of the balloons and stretch it by hand or blow it up with your mouth to release some of the tension, otherwise the first inflation may be quite difficult.
2. Attach the balloon to the connecting nozzle. If you can get your child to do it themselves, it does help with their confidence and cooperation.

3. To ensure your child understands the treatment it is a good idea to demonstrate it first or show them the instruction video. This will give them confidence to try themselves.
4. Ask your child to hold the nozzle up to one nostril and close off the other nostril with their fingers. Instruct them to keep their mouth closed, slowly blow out of the nose and inflate the balloon to about the size of a grapefruit.



5. Don't worry if they only achieve a small inflation. Most children get better with some practice and a small inflation is often enough to be effective.
6. Give your child lots of feedback and encouragement. Using a sticker chart can act as a reward for inflating the balloon and help with compliance over a longer time period.
7. Your child needs to inflate the balloon 3 times per day in each nostril (eg in the morning, after school and before bed) until the fluid clears (normally 2-4 weeks).
8. The balloon should be changed every week, or when it seems to have lost tension (your child may report that it is no longer working). The nozzle can be wiped with an antiseptic/baby wipe or washed in warm soapy water if needed.

E.6 Symptom Diary

LittleEARS

Glue ear symptom diary

You can print this diary and monitor your child's symptoms of hearing loss and physical health during the watchful waiting period.

Example

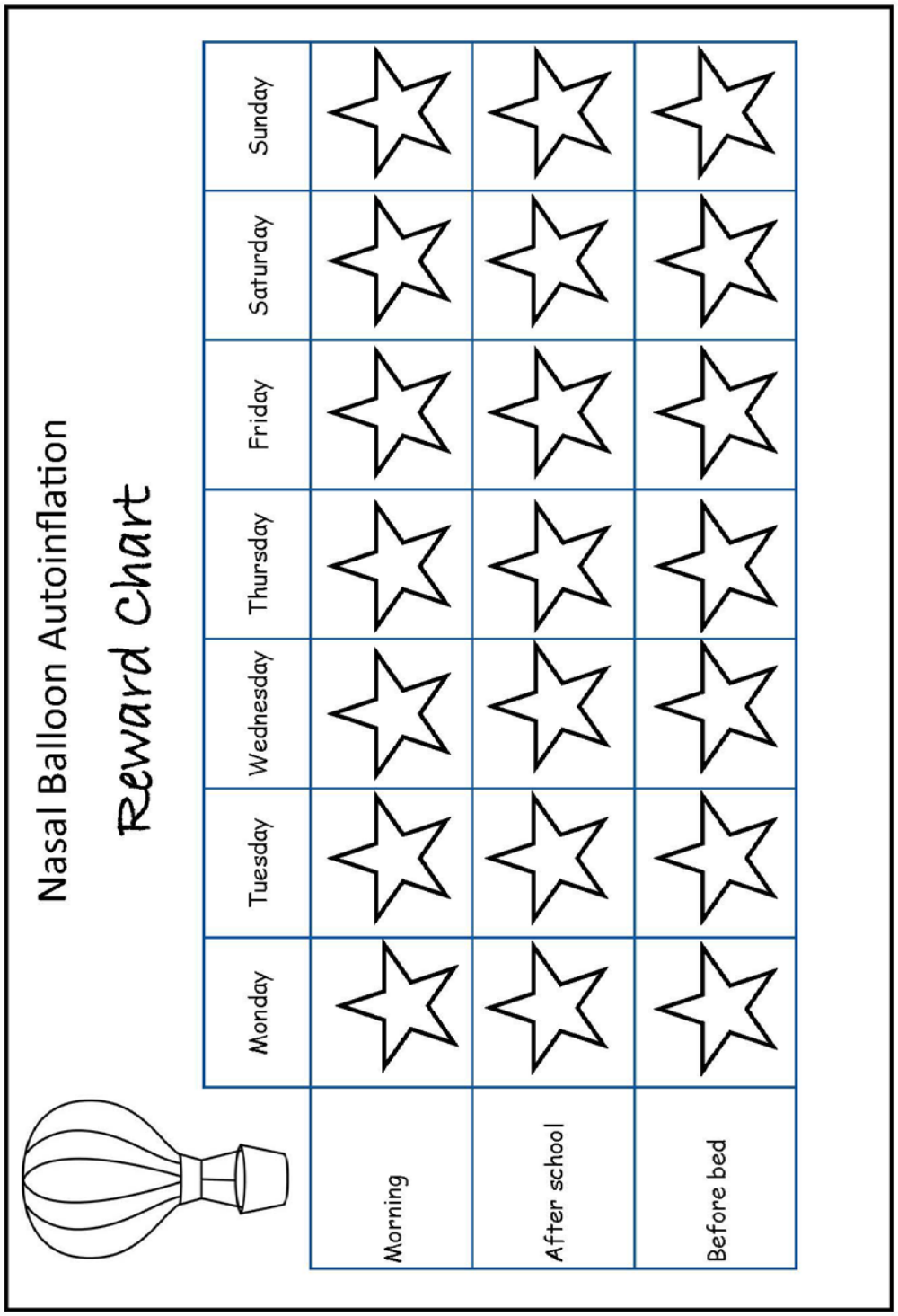
Month	e.g. December																															
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Comments
Hearing loss																							X	X								
Earache/ear infection																X	X	X														
Unwell/high temperature																	X	X														
Disturbed sleep																		X	X	X												
Visit to the GP surgery																																

Month																																
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Comments
Hearing loss																																
Earache/ear infection																																
Unwell/high temperature																																
Disturbed sleep																																
Visit to the GP surgery																																

Month																																
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Comments
Hearing loss																																
Earache/ear infection																																
Unwell/high temperature																																
Disturbed sleep																																
Visit to the GP surgery																																

Month																																
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Comments
Hearing loss																																
Earache/ear infection																																
Unwell/high temperature																																
Disturbed sleep																																
Visit to the GP surgery																																

E.7 Sticker reward chart



E.8 Printout for teachers

Information for teachers about glue ear

About glue ear

Glue ear is a condition where there is a build-up of fluid in the middle ear (the part of the ear just behind the eardrum). Normally it is filled with air which allows the eardrum and small ear bones (ossicles) to vibrate in response to sound. However, when the middle ear fills with fluid, the vibrations are dampened and hearing is reduced.

Glue ear is extremely common in young children and often goes unrecognised. There is a peak prevalence in 5 year olds coinciding with the start of primary school education, where the spread of upper respiratory infections is high. It is estimated that one in five children will be affected by glue ear in the first year of primary school and 80% of children will have had at least one episode by the time they are 10 years old. Glue ear is most common in the winter months.

Fortunately most children will resolve naturally within 3 months. However, for some children the fluid becomes persistent impacting on their speech and language development and educational progress.

What to look out for

Hearing loss: The extent of hearing loss varies between children and can depend on whether one or both ears are affected (hearing levels are similar to wearing ear plugs or putting fingers in ears).

You may notice one or more of the following symptoms:

- Often mishears what is said, especially in noisy environments
- Needs the television volume turned up
- Says ‘eh what’ or ‘pardon’ a lot
- Appears to be lip-reading

Physical ill health: Symptoms of glue ear can include ear-related and global symptoms of ill-health. These include:

- Recurrent ear infections (glue ear commonly follows acute ear infections and upper respiratory tract infections)
- Snoring, blocked nose or poor sleep

- Noises in the ear or dizziness
- Clumsy or off-balance.

Behavioural and educational development: If glue ear has been present for a while, you might notice behavioural changes. Children may become frustrated about not being able to hear or be included in activities. Children with glue ear can also become quiet, irritable and withdrawn. You may notice that children start falling behind at school.

Speech and language problems: Problems with speech and language have been associated with persistent glue ear in both ears. You might notice that a child's speech and language appears to be behind other children of similar age

How can teachers help?

There are a number of measures that some teachers find helpful to use in the classroom to help children with glue ear:

- Reducing excessive background noise in the classroom, especially when giving instructions
- Ensuring children with glue ear are sat in the class where they can see you clearly. This can help with lipreading.
- Gaining their attention before giving instructions and checking they have understood instructions.
- Using short, concise sentences for instructions.
- Writing key words/and or instructions on the board
- Speaking clearly, at normal speed.

Further information about glue ear can be found on the NHS choices website:

http://www.nhs.uk/conditions/glue-ear/Pages/Introduction.aspx

Appendix F Feasibility study (chapter 9)

F.1 Ethics committee approval

NHS
Health Research Authority

South Central - Hampshire B Research Ethics Committee
Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1384

08 June 2016 – corrected letter
30 November 2015

Mrs Jane Vennik
Primary Medical Care
Aldermoor Close
Southampton
SO16 5ST

Dear Mrs Vennik

Study title:	**Web-based support intervention to enhance management of children with glue ear in the community: a feasibility study.**
REC reference:	**15/SC/0592**
Protocol number:	**ERGO 17404**
IRAS project ID:	**190192**

Thank you for your letter responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Siobhan Bawn, nrescommittee.southcentral-hampshireb@nhs.net .

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

A Research Ethics Committee established by the Health Research Authority

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster for GP surgery]	1	10 September 2015
Covering letter on headed paper	1	19 November 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity and insurance]		11 September 2015
Interview schedules or topic guides for participants [Interview topic guides parents and HCPs]	1	11 September 2015
Letter from funder [Funding for PhD letter]		
Letter from sponsor [Sponsor letter]		11 September 2015
Letters of invitation to participant [Invitation letter]	1	10 September 2015
Letters of invitation to participant [Parent log in letter]	1	10 September 2015
Non-validated questionnaire [Self administered questionnaire]	1	11 September 2015
Other [Website screenshots]	1	19 November 2015
Participant consent form [Online consent form]	1	03 September 2015
Participant consent form [Parent interview consent form]	1	10 September 2015
Participant consent form [HCP consent form]	v1	10 September 2015
Participant information sheet (PIS) [HCP information interviews]	1	10 September 2015
Participant information sheet (PIS) [Parent information GP surgery]	2	13 November 2015
Participant information sheet (PIS) [Parent information audiology)	1	10 September 2015
REC Application Form [REC_Form_19112015]		19 November 2015
Referee's report or other scientific critique report [Peer review A Geraghty]	1	03 September 2015
Referee's report or other scientific critique report [Peer review S Williams]	1	04 September 2015
Research protocol or project proposal	2	13 November 2015
Summary CV for Chief Investigator (CI)		11 September 2015
Summary CV for supervisor (student research)		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study summary]	1	11 September 2015
Validated questionnaire [Questionnaire]	1	11 September 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at
http://www.hra.nhs.uk/hra-training/

15/SC/0592	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Andrew Scott
Acting Vice Chair

Email: nrescommittee.southcentral-hampshireb@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Mrs Diana Galpin
Ms Clare Rook, NIHR - CRN Wessex

South Central - Hampshire B Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 04 December 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Julie Brinton	Speech and Language Therapist	Yes	
Dr Andrew Scott (Acting VC)	Course Leader, M.Sc. Clinical Exercise Science	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Siobhan Bawn	REC Manager

F.2 GP invitation pack

Invitation letter v1 (*10.9.15*)

PRACTICE HEADED PAPER

Date

Dear parent or carer

Invitation to take part in study about glue ear

Our practice is taking part in a research project looking at a new website with information and support for families of children with glue ear. We are writing to you because your child, *<first name>* is in the age group where glue ear is most common (4-7 years).

If you have any concerns about your child's hearing, please complete the enclosed SYMPTOM CHECKLIST and take the ONLINE HEARING DISABILITY TEST with your child (see attached for details).

If you would then like an appointment with the GP to review your child for glue ear, [please complete the attached reply slip and return it in the enclosed envelope to the practice. A member of staff will be in contact to arrange an appointment] or [please ring the practice to make an appointment with Dr .....].

If the doctor thinks that your child has glue ear, your child will receive usual care which may include treatment and/or active monitoring. You will then be invited to take part in the research study of the new website. Please read the information leaflet to find out more about the study.

Taking part in the study is completely up to you. If you decide not to take part it will not affect the care that you or your family would receive from the practice in any way.

Yours sincerely

Dr .....

Screening number: | | | | | | |

1. Symptom checklist

Please use this checklist to identify any ear concerns in the **last 3 months**:

Appears to mishear what is said	☐ Yes	☐ No
Needs the television turned up	☐ Yes	☐ No
Any suspected ear problem	☐ Yes	☐ No
An earache	☐ Yes	☐ No
A prolonged or bad cold, cough or chesty infection	☐ Yes	☐ No
Hearing loss has been suspected by anyone	☐ Yes	☐ No
Says 'eh what?' or 'pardon' a lot	☐ Yes	☐ No
May be irritable or withdrawn	☐ Yes	☐ No
Appears to be lip reading	☐ Yes	☐ No
Not doing so well at school as you or the teacher think *e.g.* with reading	☐ Yes	☐ No
Has noises in the ear or is dizzy	☐ Yes	☐ No
Snores, blocked nose or poor sleep	☐ Yes	☐ No
Speech seems behind other children's	☐ Yes	☐ No
Total number of symptoms	☐	

2. LittleEARS hearing test:

If your child has had 4 or more symptoms in total (with at least 2 symptoms from the grey box) on the symptom checklist, please visit the website below and take the **LittleEARS hearing test** with your child. Please log in with the number below. Full instructions will be given on the website.

www.(.....).soton.ac.uk Login number: xxx000 (*unique three letters/three numbers*)

Results of LittleEARS hearing test (please circle one): High Risk Moderate Risk Low Risk

3. Next steps:

If your child has 4 or more symptoms and is at moderate or high risk of glue ear on the hearing disability test, [please complete the reply slip and return it in the pre-paid envelope] or [or please make an appointment with Dr ..... and take this form with you to your child's consultation].

Screening number: | | | | | | |

Reply Slip

Practice address

If your child has had 4 or more symptoms in the last 3 months, scored as 'high risk' on the hearing test and you would like consultation with the GP to discuss treatment and management, please complete the details below and return in the pre-paid envelope. A member of staff from the practice will be in contact with you to make an appointment.

I would like an appointment with Dr (.....) and agree to be contacted as follows:

Your name: .....

Your child's Name: .....

Tel: .....

Email address: .....

Medicine

UNIVERSITY OF Southampton

LittleEARS study Participant Information Sheet. V2.0 (13-11-15)

Web-based support intervention to enhance management of children with glue ear in the community: a feasibility study. *IRAS number:*

What is the research about?

You are being invited to take part in a study looking at a new website with information and support for families of children with glue ear.

Glue ear is a common problem of childhood which can lead to intermittent hearing loss in young school children. This can affect a child's educational development and quality of life. Half of affected children will get better naturally within 3 months, but some may go on to have longer term problems. We have designed a website to deliver advice, support and instruction for monitoring and managing glue ear in the home during the government recommended 3 month watchful waiting period. The purpose of this study is to find out what parents of children with glue ear think about our new website.

Why have you been chosen?

You have been invited because your child has been diagnosed with glue ear.

Do you have to take part?

It is completely up to you to decide whether or not to take part. If you do decide to take part you are still free to withdraw at any time and you do not have to give a reason.

What will happen if you take part and what do you have to do?

- If you decide to take part you will be asked to log in to the LittleEARS website at home.
- When you log in we will ask you to give your consent to take part in the study and to complete some online questionnaires about you and your child. This will take around 15 minutes.
- You will then be given access to the LittleEARS website to use where and when is appropriate for you and your child. It contains information about glue ear, diagnosis treatment and management options and information and instructions about using nasal balloon autoinflation, a treatment for glue ear.
- After 3 months we will ask you to complete some further questionnaires on the website which will take approximately 10 minutes to complete. If you would prefer, you can complete the final questionnaires over the telephone with a researcher.
- To find out what parents/carers think of the website we will ask if you are happy to be interviewed about this – but you do not have to. If you are happy to be interviewed we will contact you to arrange a time that suits you to conduct the interview by telephone. We will record the interviews and it is likely to take between 20-30minutes.

What are the advantages and disadvantages of taking part?

The main advantage is that you will have the opportunity to use a website that was developed by experts containing up to date information about glue ear, diagnosis and treatment options based on research evidence. The main disadvantage of taking part if the time it takes to complete the questionnaires at the beginning and end of the study.

Will your taking part in the study remain confidential?

All information which is collected about you and your child during the course of the study will be kept strictly confidential. Any quotes that arise from your interview will be anonymised and your name will not appear on any publications. We will handle, process, store and destroy data following procedures in keeping with the Data Protection Act 1998. Data from this study will be kept for 15 years and then disposed of securely. Your contact details will only be used whilst the study is running and to send you a summary of the research findings.

What happens if you change your mind?

Taking part in this research is voluntary and it is up to you to decide whether to take part. You can decide not to continue at any time without giving a reason. This will not affect the medical treatment that you or your child receive in any way.

What happens if something goes wrong?

If you wish to complain, or have any concerns about any aspect of this study please contact Jane Vennik (j.vennik@soton.ac.uk. Tel 023 8024 1088). If you are still unhappy and wish to complain more formally, please contact the Research Governance Office for the University of Southampton, who sponsor the study (phone: 02380 598848; email: rgoinfo@soton.ac.uk) or through the NHS complaints procedure (details are available from your doctors surgery).

What will happen to the results of the research study?

The results will be published in scientific journals and presented at scientific meetings. A summary of the findings will be sent to all participants who took part in the study. Additionally, everyone will have access to the website for 6 months after the end of the study.

Who is organising the funding of the research?

The University of Southampton is the sponsor of this study and the National School of Primary Care Research is the funder.

Where can you get more information?

If you have any further questions or queries please contact Jane Vennik: Tel: 023 8024 1088.
Email: j.vennik@soton.ac.uk
Department of Primary Care, University of Southampton, Aldermoor Health Centre, Aldermoor Close, Southampton, SO16 5ST.

F.3 Participant login pack

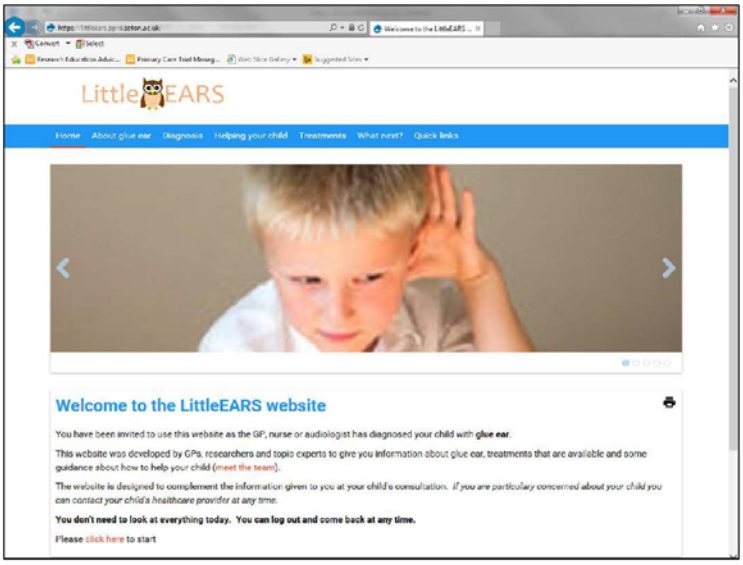
LittleEARS study Parent login letter. V1.0 (10-9-15)

Web-based support intervention to enhance management of children with glue ear in the community: a feasibility study. *IRAS number: 190192*

Thank you for your interest in taking part in the LittleEARS study to support the management of your child's glue ear. Please be assured that taking part in the study will not affect the normal clinical care that your child will receive from the surgery.

Please read the information sheet carefully (v2.0, 13-11-2015) and if you are still interested in participating in the study, please go to the following website where you will be given full instructions.

Web address: littleears.soton.ac.uk



If you have any questions or problems with the website please contact Jane Vennik, Researcher at University of Southampton on 023 8024 1088 or email j.vennik@soton.ac.uk

Taking part in this research is voluntary. It is up to you to decide whether to take part. You can decide not to continue at any time without giving a reason.

F.4 Outcome measures - follow up questionnaire

About the LittleEARS website

Please could you indicate what computer or device you used to access the LittleEARS website?

☐ Computer ☐ Laptop ☐ Macbook
☐ iMac/Mac mini/Mac pro ☐ iPad ☐ Tablet
☐ iPhone ☐ Android phone ☐ Other_____

Did you have any problems accessing the LittleEARS website?

☐ No ☐ Yes Please describe_____

How many times did you visit the LittleEARS website during the last 3 months?

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5+ ☐

Please rate how you found the **layout, navigation and presentation** of the LittleEARS website

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I found the LittleEARS website easy to navigate	☐	☐	☐	☐	☐
I found the LittleEARS website to be user-friendly	☐	☐	☐	☐	☐
I liked the overall presentation of the LittleEARS website	☐	☐	☐	☐	☐

Please describe what you liked best about the LittleEARS website

_____

_____

Please describe what you think would improve the LittleEARS website

_____

_____

About Glue Ear

Please rate **the information provided on the LittleEARS website** with respect to your child's glue ear.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I found the information about glue ear helpful to understand my child's ear problems	☐	☐	☐	☐	☐
I found the information about glue ear relevant to me and my child	☐	☐	☐	☐	☐
I found the information about glue ear easy to understand	☐	☐	☐	☐	☐
I found the information about glue ear interesting	☐	☐	☐	☐	☐
The information given on the website answered all of my questions about glue ear.	☐	☐	☐	☐	☐

Please give you opinion about the **self-help** information

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I had the information I needed to help my child at home	☐	☐	☐	☐	☐
I had all the information I needed about how to help my child at school	☐	☐	☐	☐	☐

About the Otovent nasal balloon

Did your child use the Otovent nasal balloon?

☐ No

- ☐ My GP/nurse/audiologist did not suggest the nasal balloon for my child
- ☐ I did not think it was an acceptable treatment option
- ☐ My child did not want to use it
- ☐ I did not think that my child would be able to manage the nasal balloon
- ☐ Other _____

☐ Yes (even if only once)

How often did your child use the nasal balloon?

- ☐ Only once
- ☐ Only a few times
- ☐ A lease once per day

How long did your child use the nasal balloon for?

- ☐ Less than a week
- ☐ 1-2 weeks
- ☐ 2-4 weeks
- ☐ 1-2 months
- ☐ 2-3 months

Please describe any problems that you or your child had with the Otovent nasal balloon

_____

_____

Please give your opinion on the **information given** about the Otovent nasal balloon

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I found the information about the Otovent nasal balloon to be logical	☐	☐	☐	☐	☐
I found the information about the Otovent nasal balloon to be credible	☐	☐	☐	☐	☐
I found the information about the Otovent nasal balloon easy to understand	☐	☐	☐	☐	☐
I understand how the Otovent nasal balloon helps in treating glue ear	☐	☐	☐	☐	☐

I got all the information I needed about the Otovent nasal balloon	☐	☐	☐	☐	☐
The GP, Nurse or Audiologist gave a demonstration of the Otovent nasal balloon	☐	☐	☐	☐	☐
I found the demonstration video of the Otovent nasal balloon to be helpful	☐	☐	☐	☐	☐
My child mastered the technique of inflating the nasal balloon	☐	☐	☐	☐	☐
I would recommend the Otovent nasal balloon to a friend	☐	☐	☐	☐	☐

Your child's glue ear

Could you tell us if you have any concerns about your child's hearing today?

☐ I am **no longer concerned** about my child's hearing

If your child's symptoms returned, would you use the nasal balloon again?

☐ yes
☐ no
☐ possibly

☐ I am **still concerned** about my child's hearing

If you are still concerned, please could you tell us what you plan to do now with respect to your child's hearing?

_____

_____

Has your child taken the hearing disability test AGAIN during in the last 3 months?

☐ No You can take the test again after completing this questionnaire using your unique ID number (three letters/three numbers).

☐ Yes

Thank you very much for completing this questionnaire and taking part in the LittleEARS study.

F.5 Outcome measures – OMQ-14

3 MONTH MEASURES *Date of completion˅* d d m m y y y y

Study ID Number˅

OMQ-14: Quality of Life in children's ear problems

Questionnaire on impact of ear problems in children 3-9 years*

How parent/caregiver should complete this questionnaire

Some children are more affected than others, and in differing ways. Help can best be given, and improvement best assessed, when this impact is measured in a standard way that bridges these differences. The following 14 questions cover some of the most important ways in which ear problems affect children's quality of life. For some questions an interpretation may be involved, not just an observation, so an "unsure" response is permitted. But please try to avoid this, by choosing the response that best describes just how affected your child has been over the last 3 months, and placing a tick-mark (√). On finishing, please check that you have answered all questions. The answers will be kept confidential to the clinic or research team.

All questions refer to the period of the last 3 months.

		FOR OFFICE USE ONLY
1. Over the last three months, taking everything into account, how has your child's health has been ?		
Very good	☐	
Good	☐	
Only fair, or poor	☐	
2. How many times has he/she had trouble with his/her ears ?		
Not at all	☐	
Once	☐	
2-3 times	☐	
4 or more times	☐	
3. How many ear infections has he/she had ? *(i.e. severe pain in his/her ear, possibly with a temperature, smelly discharge in ear canal, or hole in eardrum)*		
0	☐	
1	☐	
2-3	☐	
4 or more	☐	

*. Exceptionally, the questionnaire can be used after a child becomes 9 years old (see User Manual)

Page 1

All questions refer to the last 3 months.

		FOR OFFICE USE ONLY
4. How many times has he/she had an earache ?		
0	☐	
1	☐	
2-3	☐	
4 or more	☐	
5. How would you describe your child's hearing ?		
Normal	☐	
Slightly below normal	☐	
Poor	☐	
Very poor	☐	
Not sure	☐	
6. Has he/she mis-heard words when not looking at you ?		
No	☐	
Rarely	☐	
Often	☐	
Always	☐	
Not sure	☐	
7. Has he/she had difficulty hearing when with a <u>group</u> of people ? ***(ie not one-to-one)***		
No	☐	
Rarely	☐	
Often	☐	
Always	☐	
Not sure	☐	

All questions refer to the last 3 months.

		FOR OFFICE USE ONLY
8. How long can he/she concentrate on a game or a task <u>you have given him/her to do</u> ?		
Up to 2 minutes	☐	
Up to 5 minutes	☐	
5-10 minutes	☐	
10-15 minutes	☐	
More than 15 minutes	☐	
9. How often does he/she seek your attention unnecessarily ? *(e.g. in an unusually dependent way, asking for help for a task he/she can do alone, demanding to be carried, demanding you play with them, following you around)*		
Less than once a month	☐	
Once a month	☐	
Once a week	☐	
Once a day	☐	
Two or more times per day	☐	
10. How often is he/she unhappy for no apparent reason ?		
Less than once a month	☐	
Once a month	☐	
Once a week	☐	
Once or more per day	☐	
11. Has he/she mispronounced the beginnings or ends of words ?		
No	☐	
Rarely	☐	
Often	☐	
Always	☐	
12. Has his/her speech been behind (less developed than) that of children of similar age ?		
No	☐	
A little	☐	
Moderately or a lot	☐	
Not sure	☐	

		FOR OFFICE USE ONLY
13. Have you often felt tired ?		
Yes	☐	
No	☐	
14. Has your child needed more attention than other children ?		
Yes	☐	
No	☐	

Responding person providing information

A. Would you describe your educational qualifications as:				Score 1
Left school before age 15 years	☐	Usual school exams for 15-16	☐	
Usual school exams for 17-18	☐	Further qualifications, but not university degree	☐	Score 2
University degree	☐	Not applicable	☐	

B. Are you:				Score 3
Child's mother	☐	Child's father	☐	
☐ Other (please specify).....				
Your own age.....| Age of child:.....				

C. If any impacts from the ear problems of your child which you think important have <u>not</u> been covered above, please mention up to 4 here:

1. .....

2 .....

3 .....

4 .....

List of References

1. Daniel M, Kamani T, El-Shunnar S, et al. National Institute for Clinical Excellence guidelines on the surgical management of otitis media with effusion: are they being followed and have they changed practice? *Int J Pediatr Otorhinolaryngol* 2013;77(1):54-8.

2. Williamson I, Vennik J, Harnden A, et al. Effect of nasal balloon autoinflation in children with otitis media with effusion in primary care: an open randomized controlled trial. *Cmaj* 2015.

3. Williamson I, Vennik J, Harnden A, et al. An open randomised study of autoinflation in 4- to 11-year-old school children with otitis media with effusion in primary care. *Health Technol Assess* 2015;19(72).

4. Cooksey D. *A review of UK Health Research Funding*. London: The Stationary Office; 2006.

5. May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: Normalization Process Theory. *Implement Sci* 2009;4:29.

6. Stool SE BA, Berman S, Carney CJ, Cooley JR, Culpepper L, Eavey RD, Feagans LV, Finitzo T, Friedman EM et al. . Otitis Media with Effusion in children. *Guideline Technical Report No 12. AHCPR.* . Rockville MD: US. Dept. of Health and Human Services, 1994.

7. Browning GC. Scott-Brown's Otorhinolaryngology, Head and Neck Surgery. Vol1.pt 12. Paediatric Otolaryngolgy . Chapter 72. OME.7th edn. Hodder Arnold: London. 2008.

8. Hoffman HJ, Daly KA, Bainbridge KE, et al. Panel 1: Epidemiology, natural history, and risk factors. *Otolaryngol Head Neck Surg* 2013;148(4 Suppl):E1-E25.

9. Zielhuis GA, Rach GH, van den Bosch A, et al. The prevalence of otitis media with effusion: a critical review of the literature. *Clin Otolaryngol Allied Sci* 1990;15(3):283-8.

10. Fiellau-Nikolajsen M. Epidemiology of secretory otitis media. A descriptive cohort study. *Ann Otol Rhinol Laryngol* 1983;92(2 Pt 1):172-7.

11. Zielhuis GA, Rach GH, Van den Broek P. The occurrence of otitis media with effusion in Dutch pre-school children. *Clin Otolaryngol Allied Sci* 1990;15(2):147-53.

12. Williamson IG, Dunleavey J, Bain J, et al. The natural history of otitis media with effusion--a three-year study of the incidence and prevalence of abnormal tympanograms in four South West Hampshire infant and first schools. *J Laryngol Otol* 1994;108(11):930-4.

13. Rovers MM, Straatman H, Zielhuis GA, et al. Seasonal variation in the prevalence of persistent otitis media with effusion in one-year-old infants. *Paediatr Perinat Epidemiol* 2000;14(3):268-74.

14. Bruce I, Harman N, Williamson P, et al. The management of Otitis Media with Effusion in children with cleft palate (mOMEnt): a feasibility study and economic evaluation. *Health Technol Assess* 2015;19(68):1-374.

15. Barr E, Dungworth J, Hunter K, et al. The prevalence of ear, nose and throat disorders in preschool children with Down's syndrome in Glasgow. *Scott Med J* 2011;56(2):98-103.

16. Zhang Y, Xu M, Zhang J, et al. Risk factors for chronic and recurrent otitis media-a meta-analysis. *PLoS One* 2014;9(1):e86397.

17. Uhari M, Mantysaari K, Niemela M. A meta-analytic review of the risk factors for acute otitis media. *Clin Infect Dis* 1996;22(6):1079-83.

18. Kum-Nji P, Meloy L, Herrod HG. Environmental tobacco smoke exposure: prevalence and mechanisms of causation of infections in children. *Pediatrics* 2006;117(5):1745-54.

19. Martines F, Bentivegna D, Maira E, et al. Risk factors for otitis media with effusion: case-control study in Sicilian schoolchildren. *Int J Pediatr Otorhinolaryngol* 2011;75(6):754-9.

20. Black N. The 'health culture' of families as an influence on the use of surgery for glue ear: a case-control study. *Int J Epidemiol* 1985;14(4):594-9.

21. Bennett KE, Haggard MP. Behaviour and cognitive outcomes from middle ear disease. *Arch Dis Child* 1999;80(1):28-35.

22. Silva PA, Kirkland C, Simpson A, et al. Some developmental and behavioral problems associated with bilateral otitis media with effusion. *J Learn Disabil* 1982;15(7):417-21.

23. Silva PA, Chalmers D, Stewart I. Some audiological, psychological, educational and behavioral characteristics of children with bilateral otitis media with effusion: a longitudinal study. *J Learn Disabil* 1986;19(3):165-9.

24. Keles E, Kaygusuz I, Karlidag T, et al. Prevalence of otitis media with effusion in first and second grade primary school students and its correlation with BCG vaccination. *Int J Pediatr Otorhinolaryngol* 2004;68(8):1069-74.

25. Bradley RH, Corwyn RF. Socioeconomic status and child development. *Annu Rev Psychol* 2002;53:371-99.

26. Williamson I, Benge S, Mullee M, et al. Consultations for middle ear disease, antibiotic prescribing and risk factors for reattendance: a case-linked cohort study. *Br J Gen Pract* 2006;56(524):170-5.

27. Bennett K, Higson J, Haggard M. Do GPs have the techniques for 'watchful waiting' in glue ear? *Br J Gen Pract* 1998;48(428):1079-80.

28. Rosenfeld RM, Shin JJ, Schwartz SR, et al. Clinical Practice Guideline: Otitis Media with Effusion (Update). *Otolaryngol Head Neck Surg* 2016;154(1 Suppl):S1-S41.

29. Takata GS, Chan LS, Morphew T, et al. Evidence assessment of the accuracy of methods of diagnosing middle ear effusion in children with otitis media with effusion. *Pediatrics* 2003;112(6 Pt 1):1379-87.

30. Audiology services: A guide for health commissioners and health boards. In: British Academy of Audiology, editor, 2014.

31. England PH. NHS newborn hearing screening programme. 2013.

32. Bamford J, Fortnum H, Bristow K, et al. Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen. *Health Technol Assess* 2007;11(32):1-168, iii-iv.

33. McCormick B. The toy discrimination test: an aid for screening the hearing of children above a mental age of two years. *Public Health* 1977;91(2):67-73.

34. Kendall D. Audiometry for young children. Part II. The Teacher of the Deaf. LI 307, 18-23. 1954.

35. NICE. *Surgical Management of Otitis Media with Effusion in Children. Guideline 60*. London: National Collaborating Centre for Women's and Children's Health; 2008.

36. Williamson I, Benge S, Mullee M, et al. Consultations for middle ear disease, antibiotic prescribing and risk factors for reattendance: a case-linked cohort study. *The British Journal of General Practice* 2006;56(524):170-75.

37. Venekamp RP, Burton MJ, van Dongen TM, et al. Antibiotics for otitis media with effusion in children. *Cochrane Database Syst Rev* 2016(6):CD009163.

38. Macfarlane J, Holmes W, Macfarlane R, et al. Influence of patients' expectations on antibiotic management of acute lower respiratory tract illness in general practice: questionnaire study. *BMJ : British Medical Journal* 1997;315(7117):1211-14.

39. McNulty CAM, Nichols T, French DP, et al. Expectations for consultations and antibiotics for respiratory tract infection in primary care: the RTI clinical iceberg. *The British Journal of General Practice* 2013;63(612):e429-e36.

40. Hansen MP, Howlett J, Del Mar C, et al. Parents' beliefs and knowledge about the management of acute otitis media: a qualitative study. *BMC Fam Pract* 2015;16:82.

41. Jonsson H, Haraldsson RH. Parents' perspectives on otitis media and antibiotics. A qualitative study. *Scand J Prim Health Care* 2002;20(1):35-9.

42. Russell D, Luthra M WJ, Golby M, Plastow L, Marshall M,. A qualitative investigation of parents' concerns, experiences and expectations in managing otitis media in children: implications for general practitioners. *Primary Health Care Research and Development* 2003;4:85-93.

43. Rosenfeld R. New concepts for steroid use in otitis media with effusion. *Clinical Pediatrics* 1992;31(10):615-21.

44. Lack G, Caulfield H, Penagos M. The link between otitis media with effusion and allergy: a potential role for intranasal corticosteroids. *Pediatr Allergy Immunol* 2011;22(3):258-66.

45. Simpson SA, Lewis R, van der Voort J, et al. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2011(5):CD001935.

46. Francis N. HTA - 11/01/26: Oral STeroids for Resolution of otitis media with effusion (OME) In CHildren: the OSTRICH study http://www.nets.nihr.ac.uk/projects/hta/110126. 2013.

47. Griffin G, Flynn CA. Antihistamines and/or decongestants for otitis media with effusion (OME) in children. *Cochrane Database Syst Rev* 2011(9):CD003423.

48. MRC Multicentre Otitis Media Study Group. Adjuvant adenoidectomy in persistent bilateral otitis media with effusion: hearing and revision surgery outcomes through 2 years in the TARGET randomised trial. *Clin Otolaryngol* 2012;37(2):107-16.

49. Bennett K, Haggard M, Churchill R, et al. Improving referrals for glue ear from primary care: are multiple interventions better than one alone? *J Health Serv Res Policy* 2001;6(3):139-44.

50. Hospital Admitted Patient Care Activity, 2015 to 2016. In: NHS Digital, editor, November 2016.

51. Payment by Results in the NHS: Tariff for 2012-2013. In: Department of Health, editor, 2013.

52. Browning GG, Rovers MM, Williamson I, et al. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2010(10):CD001801.

53. Rosenfeld RM, Bhaya MH, Bower CM, et al. Impact of tympanostomy tubes on child quality of life. *Arch Otolaryngol Head Neck Surg* 2000;126(5):585-92.

54. Hellier WP, Corbridge RJ, Watters G, et al. Grommets and patient satisfaction: an audit. *Ann R Coll Surg Engl* 1997;79(6):428-31.

55. Johansen EC, Svendstrup B, Schonsted-Madsen U, et al. [Parents satisfied with the grommet treatment in ear, nose and throat practice]. *Ugeskr Laeger* 2010;172(37):2530-4.

56. NICE. http://www.nice.org.uk/newsroom/news/ChildrenWithGlueEar.jsp (accessed March 2014).

57. Jardine AH, Griffiths MV, Midgley E. The acceptance of hearing aids for children with otitis media with effusion. *J Laryngol Otol* 1999;113(4):314-7.

58. Tierney S, O'Brien K, Harman NL, et al. Risks and benefits of ventilation tubes and hearing aids from the perspective of parents of children with cleft palate. *Int J Pediatr Otorhinolaryngol* 2013;77(10):1742-8.

59. Mohiuddin S, Schilder A, Bruce I. Economic evaluation of surgical insertion of ventilation tubes for the management of persistent bilateral otitis media with effusion in children. *BMC Health Serv Res* 2014;14:253.

60. Perera R, Glasziou PP, Heneghan CJ, et al. Autoinflation for hearing loss associated with otitis media with effusion. *Cochrane Database Syst Rev* 2013;5:CD006285.

61. NICE. Otovent nasal balloon for otitis media with effusion. *Medtech innovation briefing (MIB59)* March 2016.

62. NHS Five Year Forward View. In: NHS England, editor, 2014.

63. May C. Self-management of chronic conditions: re-engineering patient-hood. *Chron Illness* 2006;2.

64. Bodenheimer T, Lorig K, Holman H, et al. Patient self-management of chronic disease in primary care. *JAMA* 2002;288(19):2469-75.

65. Gkiousias V, Butler CC, Shepherd V, et al. Parental perceptions and understanding of information provision, management options and factors influencing the decision-making process in the treatment of children with glue ear. *Int J Pediatr Otorhinolaryngol* 2016;89:6-12.

66. Ritchie L, Tornari C, Patel PM, et al. Glue ear: how good is the information on the World Wide Web? *J Laryngol Otol* 2016;130(2):157-61.

67. Feldmann H. [The Eustachian tube and its role in the history of otology. Images from the history of otorhinolaryngology, presented by instruments from the collection of the Ingolstadt German History Museum]. *Laryngorhinootologie* 1996;75(12):783-92.

68. Nishimura RA, Tajik AJ. The Valsalva maneuver and response revisited. *Mayo Clin Proc* 1986;61(3):211-7.

69. Stangerup SE, Sederberg-Olsen J, Balle VH. [Treatment with the Otovent device in tubal dysfunction and secretory otitis media in children]. *Ugeskr Laeger* 1991;153(43):3008-9.

70. Arick DS, Silman S. Treatment of otitis media with effusion based on politzerization with an automated device. *Ear Nose Throat J* 2000;79(4):290-2, 94, 96 passim.

71. Fraser JG, Mehta M, Fraser PA. The medical treatment of secretory otitis media. A clinical trial of three commonly used regimes. *J Laryngol Otol* 1977;91(9):757-65.

72. Shea JJ. Autoinflation treatment of serous otitis media in children. *J Laryngol Otol* 1971;85(12):1254-8.

73. Schwartz DM, Schwartz RH, Redfield NP. Treatment of negative middle ear pressure and serous otitis media with Politzer's technique. An old procedure revisited. *Arch Otolaryngol* 1978;104(9):487-90.

74. Kaneko Y, Takasaka T, Sakuma M, et al. Middle ear inflation as a treatment for secretory otitis media in children. *Acta Otolaryngol* 1997;117(4):564-8.

75. Arick DS, Silman S. Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part I: clinical trial. *Ear Nose Throat J* 2005;84(9):567-8, 70-4, 76

76. Silman S, Arick DS, Emmer MB. Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part II: Validation study. *Ear Nose Throat J* 2005;84(10):646, 48, 50 passim.

77. Hunt-Williams R. A method for maintaining middle-ear ventilation in children. *J Laryngol Otol* 1968;82(10):921-6.

78. Brooker DS, McNeice A. Autoinflation in the treatment of glue ear in children. *Clin Otolaryngol Allied Sci* 1992;17(4):289-90.

79. Stangerup SE, Sederberg-Olsen J, Balle V. Autoinflation as a treatment of secretory otitis media. A randomized controlled study. *Arch Otolaryngol Head Neck Surg* 1992;118(2):149-52.

80. Lesinskas E. Factors affecting the results of nonsurgical treatment of secretory otitis media in adults. *Auris Nasus Larynx* 2003;30(1):7-14.

81. De Nobili E BA. A comparative evaluation of efficacy of crenotherapeutic Politzer with sulphurous water versus crenotherapeutic Polister and audotinflation (OtoventO in patients with tubaric dysfuntion and secretory otitis media. *Medicina Clinica e Termale* 2008;20(64):30-34.

82. Blanshard JD, Maw AR, Bawden R. Conservative treatment of otitis media with effusion by autoinflation of the middle ear. *Clin Otolaryngol Allied Sci* 1993;18(3):188-92.

83. Ercan I, Cakir B, Kayaoglu S, et al. Long term effect of autoinflation in the treatment of otitis media with effusion. . *KBB Forum 2005;4 (4):166–70.* 2005.

84. Jerger J. Clinical experience with impedance audiometry. *Arch Otolaryngol* 1970;92(4):311-24.

85. Browning GG. Watchful waiting in childhood otitis media with effusion. *Clin Otolaryngol Allied Sci* 2001;26(4):263-4.

86. Williamson I, Benge S, Barton S, et al. Topical intranasal corticosteroids in 4-11 year old children with persistent bilateral otitis media with effusion in primary care: double blind randomised placebo controlled trial. *BMJ* 2009;339:b4984.

87. Marchisio P, Grasso D, Eurotitis-2 Study Group. Using differences and similarities between centres for power and generality. Special Eurotitis -2 session. ESPO Conference Proceedings. 2010.

88. Cohen J. Statistical power analysis for the behavioral sciencies. Routledge. 1977.

89. Banigo A, Hunt A, Rourke T, et al. Does the EarPopper((R)) device improve hearing outcomes in children with persistent otitis media with effusion? A randomised single-blinded controlled trial. *Clin Otolaryngol* 2016;41(1):59-65.

90. Bidarian-Moniri A, Ramos MJ, Goncalves I, et al. A new device for treatment of persistent otitis media with effusion. *Int J Pediatr Otorhinolaryngol* 2013;77(12):2063-70.

91. Bidarian-Moniri A, Ramos MJ, Ejnell H. Autoinflation for treatment of persistent otitis media with effusion in children: a cross-over study with a 12-month follow-up. *Int J Pediatr Otorhinolaryngol* 2014;78(8):1298-305.

92. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;343.

93. Hanner P. Non surgical treatment of otitis media with effusion. *Indian Journal of Otology* 1997;3(3):101-07.

94. Stangerup SE, Tjernstrom O, Harcourt J, et al. Barotitis in children after aviation; prevalence and treatment with Otovent. *J Laryngol Otol* 1996;110(7):625-8.

95. Stangerup SE, Tjernstrom O, Harcourt J, et al. [Barotrauma in children and adults after flying. Prevalence and treatment with Otovent]. *Ugeskr Laeger* 1998;160(12):1794-6.

96. Bossard J, Boll E. *Ritual in family living.* Oxford, England.: U. Pennsylvania Press.; 1950.

97. Fiese BH, Wamboldt FS, Anbar RD. Family asthma management routines: connections to medical adherence and quality of life. *J Pediatr* 2005;146(2):171-6.

98. Sackett DL, Rosenberg WMC, Gray JAM, et al. Evidence based medicine: what it is and what it isn't. *BMJ* 1996;312(7023):71-72.

99. Eccles MP, Armstrong D, Baker R, et al. An implementation research agenda. *Implement Sci* 2009;4:18.

100. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *The Lancet* 2003;362(9391):1225-30.

101. Mickan S, Burls A, Glasziou P. Patterns of 'leakage' in the utilisation of clinical guidelines: a systematic review. *Postgrad Med J* 2011;87(1032):670-9.

102. Cabana MD, Rand CS, Powe NR, et al. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA* 1999;282(15):1458-65.

103. Eccles MP, Armstrong D, Baker R, et al. An implementation research agenda. *Implementation Science* 2009;4(1):1-7.

104. Tabak RG, Khoong EC, Chambers DA, et al. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med* 2012;43(3):337-50.

105. Weiner BJ. A theory of organizational readiness for change. *Implementation Science* 2009;4(1):1-9.

106. May C, Finch T, Mair F, et al. Understanding the implementation of complex interventions in health care: the normalization process model. *BMC Health Serv Res* 2007;7:148.

107. Atkins S, Lewin S, Ringsberg KC, et al. Provider experiences of the implementation of a new tuberculosis treatment programme: A qualitative study using the normalisation process model. *BMC Health Serv Res* 2011;11(1):1-12.

108. Michie S, Johnston M, Abraham C, et al. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality & Safety in Health Care* 2005;14(1):26-33.

109. Gray-Burrows KA, Day PF, Marshman Z, et al. Using intervention mapping to develop a home-based parental-supervised toothbrushing intervention for young children. *Implement Sci* 2016;11:61.

110. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50.

111. Kitson A, Harvey G, McCormack B. Enabling the implementation of evidence based practice: a conceptual framework. *Quality in Health Care* 1998;7(3):149-58.

112. Kitson AL, Rycroft-Malone J, Harvey G, et al. Evaluating the successful implementation of evidence into practice using the PARiHS framework: theoretical and practical challenges. *Implementation Science* 2008;3(1):1-12.

113. Douglas NF, Hinckley JJ, Haley WE, et al. Perceptions of speech-language pathologists linked to evidence-based practice use in skilled nursing facilities. *Am J Speech Lang Pathol* 2014;23(4):612-24.

114. Helfrich CD, Damschroder LJ, Hagedorn HJ, et al. A critical synthesis of literature on the promoting action on research implementation in health services (PARIHS) framework. *Implement Sci* 2010;5:82.

115. Ullrich PM, Sahay A, Stetler CB. Use of Implementation Theory: A Focus on PARIHS. *Worldviews on Evidence-Based Nursing* 2014;11(1):26-34.

116. Stetler CB, Damschroder LJ, Helfrich CD, et al. A Guide for applying a revised version of the PARIHS framework for implementation. *Implement Sci* 2011;6:99-99.

117. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci* 2009;4.

118. Kirk MA, Kelley C, Yankey N, et al. A systematic review of the use of the Consolidated Framework for Implementation Research. *Implement Sci* 2015;11:72.

119. May C, Finch T. Implementation, embedding, and integration: an outline of Normalization Process Theory. *Sociology* 2009;43.

120. McEvoy R, Ballini L, Maltoni S, et al. A qualitative systematic review of studies using the normalization process theory to research implementation processes. *Implement Sci* 2014;9:2.

121. May C. Towards a general theory of implementation. *Implement Sci* 2013;8:18.

122. May CR, Eton DT, Boehmer K, et al. Rethinking the patient: using Burden of Treatment Theory to understand the changing dynamics of illness. *BMC Health Serv Res* 2014;14(1):1-11.

123. Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* 2010;8:63.

124. Finch TL, Girling, M., May, C.R., Mair, F.S., Murray, E., Treweek, S., Steen, I.N., McColl, E.M., Dickinson, C., Rapley, T. Nomad: Implementation measure based on Normalization Process Theory. [Measurement instrument]. Retrieved from http://www.normalizationprocess.org. 2015.

125. Gask L, Bower P, Lovell K, et al. What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalization Process Model. *Implementation Science* 2010;5(1):1-11.

126. Murray E, Burns J, May C, et al. Why is it difficult to implement e-health initiatives? A qualitative study. *Implementation Science* 2011;6(1):1-11.

127. Blakeman T, Protheroe J, Chew-Graham C, et al. Understanding the management of early-stage chronic kidney disease in primary care: a qualitative study. *Br J Gen Pract* 2012;62(597):e233-42.

128. Gallacher K, May CR, Montori VM, et al. Understanding patients' experiences of treatment burden in chronic heart failure using normalization process theory. *Ann Fam Med* 2011;9(3):235-43.

129. Franx G, Oud M, de Lange J, et al. Implementing a stepped-care approach in primary care: results of a qualitative study. *Implement Sci* 2012;7:8-8.

130. Anderson R. New MRC guidance on evaluating complex interventions. *BMJ* 2008;337.

131. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.

132. Godfrey M, Smith J, Green J, et al. Developing and implementing an integrated delirium prevention system of care: a theory driven, participatory research study. *BMC Health Serv Res* 2013;13(1):1-15.

133. Kuhn T. *The Structure of Scientific Revolutions*. Chicago: University of Chicago Press 1962.

134. Guba E, Lincoln Y. *Competing paradigms in qualitative research. In Handbook of Qualitative Research.*; 1994.

135. Collier A. *Critical Realism: An Introduction to Roy Bhaskar's Philosophy*: Verso; 1994.

136. Hammersley M. *What's Wrong With Ethnography? Methodological Explorations.* London: Routledge; 1992.

137. CS P. The Collected Papers of Charles Sanders Peirce, eds. C. Hartshorne, P. Weiss (Vols. 1-6) and A. Burks (Vols. 7-8). (Cambridge MA: Harvard University Press). . 1931-58.

138. Rorty R. Philosophy and Social Hope. London: Penguin Books. 1999.

139. Crotty M. *The foundations of social research: Meaning and perspective in the research process*: Sage; 1998.

140. Johnson B, Christensen L. Educational research: Quantitative, qualitative, and mixed approaches: Sage, 2008.

141. Green J, Thorogood N. Qualitative Methods for Health Research. 2011:219-28.

142. Fonteyn ME, Kuipers B, Grobe SJ. A Description of Think Aloud Method and Protocol Analysis. *Qualitative Health Research* 1993;3(4):430-41.

143. MRC. A framework for development and evaluation of complex interventions to improve health. 2000.

144. Rubin H, Rubin I. *Qualitative Interviewing: The Art of Hearing Data*. Thousand Oaks, California: SAGE; 1995.

145. Lincoln Y, Guba E. Naturalistic Inquiry. Newbury Park, CA: Sage Publications. 1985.

146. Finlay L, Gough B. *Reflexivity: a practical guide for researchers in health and social science, Oxford, Blackwell Publishing.*; 2003.

147. Malterud K. Qualitative research: standards, challenges, and guidelines. *Lancet* 2001;358(9280):483-8.

148. Patton M. *Qualitative evaluation and research methods (pp. 169-186). Beverly Hills, CA: Sage*; 1990.

149. Glaser B, Strauss A. *The Discovery of Grounded Theory: Strategies for Qualitative Research,*. Chicago: Aldine Publishing Company; 1967.

150. Ritchie J, Spencer L. *Qualitative data analysis for applied policy research, in A. Bryman and R.G. Burgess (eds.), analyzing qualitative data. London: routledge. pp173-194*; 1994.

151. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology, 3, 77-101. 2006.

152. Swan IR, Browning GG. The whispered voice as a screening test for hearing impairment. *The Journal of the Royal College of General Practitioners* 1985;35(273):197-97.

153. Dakin H, Petrou S, Haggard M, et al. Mapping analyses to estimate health utilities based on responses to the OM8-30 Otitis Media Questionnaire. *Qual Life Res* 2010;19(1):65-80.

154. Centor RM, Witherspoon JM, Dalton HP, et al. The diagnosis of strep throat in adults in the emergency room. *Med Decis Making* 1981;1(3):239-46.

155. MacClements JE, Parchman M, Passmore C. Otitis media in children: use of diagnostic tools by family practice residents. *Fam Med* 2002;34(8):598-603.

156. Rosenkranz S, Abbott P, Reath J, et al. Promoting diagnostic accuracy in general practitioner management of otitis media in children: findings from a multimodal, interactive workshop on tympanometry and pneumatic otoscopy. *Qual Prim Care* 2012;20(4):275-85.

157. Burke P. Otitis media with effusion: is medical management an option? *J R Coll Gen Pract* 1989;39(326):377-82.

158. . *Cheshire and Merseyside Commissioning Policy*. http://moderngov.cheshireeast.gov.uk/documents/s32480/DRAFT%20CM%20CommissioningPolicy%206th14V14v.pdf (accessed 27 Sept 2016).

159. Oxford CCG Commissioning Policy. http://www.oxfordshireccg.nhs.uk/wp-content/uploads/2013/03/ps101-myringotomy-in-children.pdf.

160. Department of Health. Transforming Services for Children with Hearing Difficulties and their families: A good practice guide. August 2008.

161. Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations--a questionnaire study. *BMJ* 1997;315(7107):520-3.

162. Trevena LJ, Davey HM, Barratt A, et al. A systematic review on communicating with patients about evidence. *J Eval Clin Pract* 2006;12(1):13-23.

163. Bennett GG, Glasgow RE. The delivery of public health interventions via the Internet: actualizing their potential. *Annu Rev Public Health* 2009;30:273-92.

164. Dutta-Bergman MJ. Primary Sources of Health Information: Comparisons in the Domain of Health Attitudes, Health Cognitions, and Health Behaviors. *Health Communication* 2004;16(3):273-88.

165. Gorodzinsky AY, Hong P, Chorney JM. Parental knowledge in pediatric otolaryngology surgical consultations: A qualitative content analysis. *Int J Pediatr Otorhinolaryngol* 2015;79(7):1135-9.

166. Strauss A, Corbin J. *Bascis of Qualtitative Research: Techniques and Procedures for Developing Grounded Theory*. USA: SAGE Publications; 1998.

167. Hinds PS, Vogel RJ, Clarke-Steffen L. *The possibilities and pitfalls of doing a secondary analysis of a qualitative data set. Qualitative Health Research. 7(3): 408-24.*; 1997.

168. Walsh D, Downe S. Meta-synthesis method for qualitative research: a literature review. *J Adv Nurs* 2005;50(2):204-11.

169. Lincoln YS, Guba EG. *Naturalistic Inquiry. Newbury Park, CA: Sage Publications.*; 1985.

170. Irwin S, M W. Debates in Qualitative Seconday Analysis: Critical Reflections. A timescape Working Paper. 2011.

171. Hammersley M. Can we re-use qualitative data via secondary analysis? Notes on some terminological and substantive issues. *Sociological research online* 2009;15(1).

172. Gale NK, Heath G, Cameron E, et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.

173. Carpenter DM, Lee C, Blalock SJ, et al. Using videos to teach children inhaler technique: a pilot randomized controlled trial. *J Asthma* 2015;52(1):81-7.

174. Leventhal H, Diefenbach M, Leventhal EA. Illness cognition: Using common sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy and Research* 1992;16(2):143-63.

175. Leventhal H, Cameron L. Behavioral theories and the problem of compliance. *Patient Educ Couns* 1987;10(2):117-38.

176. Horne R, Weinman J. Self-regulation and Self-management in Asthma: Exploring The Role of Illness Perceptions and Treatment Beliefs in Explaining Non-adherence to Preventer Medication. *Psychology & Health* 2002;17(1):17-32.

177. Williamson I, Sheridan C. The development of a test of speech reception disability for use in 5- to 8-year-old children with otitis media with effusion. *Eur J Disord Commun* 1994;29(1):27-37.

178. World Health Organization. International classification of impairments, disabilities and handicaps. Geneva: WHO, 1980. .

179. Umansky AM, Jeffe DB, Lieu JE. The HEAR-QL: quality of life questionnaire for children with hearing loss. *J Am Acad Audiol* 2011;22(10):644-53.

180. Kalikow DN, Stevens KN, Elliott LL. Development of a test of speech intelligibility in noise using sentence materials with controlled word predictability. *J Acoust Soc Am* 1977;61(5):1337-51.

181. Plomp R, Mimpen AM. Improving the reliability of testing the speech reception threshold for sentences. *Audiology* 1979;18(1):43-52.

182. Jerger S, Jerger J, Lewis S. Pediatric speech intelligibility test. II. Effect of receptive language age and chronological age. *Int J Pediatr Otorhinolaryngol* 1981;3(2):101-18.

183. Jerger S, Lewis S, Hawkins J, et al. Pediatric speech intelligibility test. I. Generation of test materials. *Int J Pediatr Otorhinolaryngol* 1980;2(3):217-30.

184. Lauritsen MB, Kreiner S, Soderstrom M, et al. A speech reception in noise test for preschool children (the Galker-test): Validity, reliability and acceptance. *Int J Pediatr Otorhinolaryngol* 2015;79(10):1694-701.

185. Kraus F, Steigenberger C, Volter C, et al. [Speech perception in noise with the "wuerzburg speech test for children"]. *Laryngorhinootologie* 2014;93(2):100-6.

186. Hickson F. The Manchester Picture Test: A Summary. . *Journal of British Association of Teachers of the Deaf* 1987;11(6):161-66.

187. Williamson I, Sheridan C, Galker E, et al. A video-based performance in noise test for measuring audio-visual disability in young school children: test development, with validation by trained teachers, parents and audiometry as relative standards for disability. *Int J Pediatr Otorhinolaryngol* 1999;49(2):127-33.

188. Riley A. *MSc Thesis: Comparison of TADAST and IHR-McCormick automated toy discrimination test to assess hearing disability for speech in young children.* , 1996.

189. Worsley L. MSc Thesis: A normative study of an adapted version of the Two Alternative Auditory Disabilty and Speech Reception Test. University of Southampton, Faculty of Engineering and Applied Science, ISVR 1996. 1996.

190. Wyllie F. MSc Thesis: Audio-visual speech perception in children with mild to moderate hearing loss, ISVR, University of Southampton. 1996.

191. Beckett K. A pilot study to evaluate feasibility, performacne and validity of an internet-based audiovisual disability test in healthy volunteer children (aged 4-11 years). 4th year BMedSci project, School of Medicine, University of Southampton., 2010.

192. Auer ET, Jr., Bernstein LE. Enhanced visual speech perception in individuals with early-onset hearing impairment. *J Speech Lang Hear Res* 2007;50(5):1157-65.

193. Tye-Murray N, Hale S, Spehar B, et al. Lipreading in school-age children: the roles of age, hearing status, and cognitive ability. *J Speech Lang Hear Res* 2014;57(2):556-65.

194. Browning GG. Two-year outcome of ventilation tubes in a randomized controlled trial of persistent childhood otitis media with effusion. *Clin Otolaryngol Allied Sci* 2001;26:342-44.

195. Theunissen M, Swanepoel de W, Hanekom J. Sentence recognition in noise: Variables in compilation and interpretation of tests. *Int J Audiol* 2009;48(11):743-57.

196. Wilson RH, Carnell CS, Cleghorn AL. The Words-in-Noise (WIN) test with multitalker babble and speech-spectrum noise maskers. *J Am Acad Audiol* 2007;18(6):522-9.

197. Ericsson KA, Simon HA. How to study thinking in everyday life: Contrasting think-aloud protocols with descriptions and explanations of thinking. *Mind, Culture, and Activity* 1998;5(3):178-86.

198. Kardous CA, Shaw PB. Evaluation of smartphone sound measurement applicationsa). *The Journal of the Acoustical Society of America* 2014;135(4):EL186-EL92.

199. Sterne JA, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ* 2009;338:b2393.

200. Tavakol M, Dennick R. Making sense of Cronbach's alpha. *International Journal of Medical Education.* 2011;2(53-55).

201. Nunnally J. Psychometric theory. New York: McGraw-Hill. . 1978.

202. M T, R D. Making Sense of Cronbach's Alpha. *International Journal of Medical Education. 2011; 2:53-55* 2011.

203. Bartko JJ. The intraclass correlation coefficient as a measure of reliability. *Psychol Rep* 1966;19(1):3-11.

204. Bland JM, DG A. Measuring agreement in method comparison studies. *Stat Methods Med Res* 1999;8:135-60.

205. Mokkink LB, Prinsen CA, Bouter LM, et al. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and how to select an outcome measurement instrument. *Braz J Phys Ther* 2016;20(2):105-13.

206. MacLeod A, Summerfield Q. Quantifying the contribution of vision to speech perception in noise. *Br J Audiol* 1987;21(2):131-41.

207. Guevara JP, Wolf FM, Grum CM, et al. Effects of educational interventions for self management of asthma in children and adolescents: systematic review and meta-analysis. *BMJ* 2003;326(7402):1308-9.

208. The Kings Fund. *http://www.kingsfund.org.uk*

(accessed May 2014).

209. de Silva D. Evidence: Helping people help themselves. In: Health Foundation, editor. London, 2011.

210. Challis D. Self-care and Case Management in Long-term Conditions: The Effective Management of Critical Interfaces. 2010.

211. Michie S, Abraham C. Interventions to change health behaviours: evidence-based or evidence-inspired? *Psychology & Health* 2004;19(1):29-49.

212. Yardley L, Morrison L, Bradbury K, et al. The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions. *Journal of Medical Internet Research* 2015;17(1):e30.

213. Health literacy toolkit for low and middle-income countries: A series of information sheets to empower communities and strengthen health systems. 2015.

214. Public Health England. Improving health literacy to reduce health inequalities, 2015.

215. Improving health literacy to reduce health inequalities. In: Public Health England, editor, September 2015.

216. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med* 2013;46(1):81-95.

217. Morrison D, Mair FS, Chaudhuri R, et al. Details of development of the resource for adults with asthma in the RAISIN (randomized trial of an asthma internet self-management intervention) study. *BMC Medical Informatics and Decision Making* 2015;15(1):57.

218. Little P, Stuart B, Hobbs FR, et al. Randomised controlled trial and economic analysis of an internet-based weight management programme: POWeR+ (Positive Online Weight Reduction). *Health Technol Assess* 2017;21(4):1-62.

219. Essery R, Kirby S, Geraghty AW, et al. The Development of Balance Retraining: An Online Intervention for Dizziness in Adults Aged 50 Years and Older. *Am J Audiol* 2015;24(3):276-9.

220. Williams S, Yardley L, Wills GB. A qualitative case study of LifeGuide: users' experiences of software for developing Internet-based behaviour change interventions. *Health Informatics J* 2013;19(1):61-75.

221. Bradbury K, Watts S, Arden-Close E, et al. Developing Digital Interventions: A Methodological Guide. *Evidence-based Complementary and Alternative Medicine : eCAM* 2014;2014:561320.

222. Morris NS, MacLean CD, Chew LD, et al. The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. *BMC Fam Pract* 2006;7(1):21.

223. Morrison D, Mair FS, Chaudhuri R, et al. Details of development of the resource for adults with asthma in the RAISIN (randomized trial of an asthma internet self-management intervention) study. *BMC Med Inform Decis Mak* 2015;15:57.

224. . www.plainenglish.co.uk.

225. Arthur VAM. Written patient information: a review of the literature. *J Adv Nurs* 1995;21(6):1081-86.

226. Harris M, Smith B, Veale A. Printed patient education interventions to facilitate shared management of chronic disease: a literature review. *Intern Med J* 2005;35(12):711-6.

227. . *http://www.health.org.uk/sites/default/files/HelpingPeopleHelpThemselves.pdf*.

228. Webb TL, Joseph J, Yardley L, et al. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *J Med Internet Res* 2010;12(1):e4.

229. Morrison D, Wyke S, Agur K, et al. Digital Asthma Self-Management Interventions: A Systematic Review. *J Med Internet Res* 2014;16(2):e51.

230. Office for National Statistics (ONS). Internet access - households and individuals, 2016.

231. National Telecommunications and Information Administration (NTIA). Falling through the net: Defining the digital divide. Washington, DC: US Department of Commerce. 2000.

232. Office for National Statistics (ONS). *Internet Access - Households and Individuals*. http://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/bulletins/internetaccesshouseholdsandindividuals/2015-08-06.

233. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.

234. Bowen DJ, Kreuter M, Spring B, et al. How We Design Feasibility Studies. *American Journal of Preventive Medicine* 2009;36(5):452-57.

235. Morris NS, MacLean CD, Chew LD, et al. The Single Item Literacy Screener: Evaluation of a brief instrument to identify limited reading ability. *BMC Fam Pract* 2006;7:21-21.

236. Brug J, Steenhuis I, van Assema P, et al. The Impact of a Computer-Tailored Nutrition Intervention. *Preventive Medicine* 1996;25(3):236-42.

237. Vandelanotte C, De Bourdeaudhuij I. Acceptability and feasibility of a computer-tailored physical activity intervention using stages of change: project FAITH. *Health Education Research* 2003;18(3):304-17.

238. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65(3):301-8.

239. Santer M, Muller I, Yardley L, et al. Supporting Self-Care for Families of Children With Eczema With a Web-Based Intervention Plus Health Care Professional Support: Pilot Randomized Controlled Trial. *J Med Internet Res* 2014;16(3):e70.

240. Ross S, Grant A, Counsell C, et al. Barriers to Participation in Randomised Controlled Trials: A Systematic Review. *Journal of Clinical Epidemiology* 1999;52(12):1143-56.

241. Danaher BG, Seeley JR. Methodological issues in research on web-based behavioral interventions. *Ann Behav Med* 2009;38(1):28-39.

242. Brouwer W, Kroeze W, Crutzen R, et al. Which Intervention Characteristics are Related to More Exposure to Internet-Delivered Healthy Lifestyle Promotion Interventions? A Systematic Review. *J Med Internet Res* 2011;13(1):e2.

243. O'Cathain A, Hoddinott P, Lewin S, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and Feasibility Studies* 2015;1(1):32.

244. Bonevski B, Randell M, Paul C, et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Med Res Methodol* 2014;14(1):42.

245. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;82(4):581-629.

246. Foot C NC, Imlson C,. The quality of GP diagnosis and referral. *The Kings Fund* 2010.

247. Finkelstein JA, Stille CJ, Rifas-Shiman SL, et al. Watchful waiting for acute otitis media: are parents and physicians ready? *Pediatrics* 2005;115(6):1466-73.

248. Understanding pressures in general practice. In: The Kings Fund, editor, May 2016.

249. Giraud V, Roche N. Misuse of corticosteroid metered-dose inhaler is associated with decreased asthma stability. *Eur Respir J* 2002;19(2):246-51.

250. Sleath B, Ayala GX, Gillette C, et al. Provider demonstration and assessment of child device technique during pediatric asthma visits. *Pediatrics* 2011;127(4):642-8.

251. Wooler E. The role of the nurse in paediatric asthma management. *Paediatr Respir Rev* 2001;2(1):76-81.

252. Bosnic-Anticevich SZ, Sinha H, So S, et al. Metered-dose inhaler technique: the effect of two educational interventions delivered in community pharmacy over time. *J Asthma* 2010;47(3):251-6.

253. Haahtela T, Tuomisto LE, Pietinalho A, et al. A 10 year asthma programme in Finland: major change for the better. *Thorax* 2006;61(8):663-70.

254. Stewart D, Wilson R, Selby P, et al. Patient and public involvement. *Annals of Oncology* 2011;22(Suppl_7):vii54-vii56.

255. Creswell JW. *Research design: Qualitative, quantitative, and mixed methods approaches. (2nd ed.) Thousand Oaks: Sage.*; 2003.

256. Greene JC, Caracelli VJ, Graham WF. Toward a conceptual framework for mixed-method evaluation designs. . *Educational Evaluation and Policy Analysis,* 1989;11:255-74.

257. Vennik J, Williamson I. An overview of the symptoms and management of glue ear. *British Journal of School Nursing* 2014;9(7):335-38.