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Supporting families with unsettled babies: Development of a digital intervention

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Abstract

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Background

Unsettled baby behaviours, such as crying and vomiting, are common but distressing for families. Unsettled behaviours are increasingly attributed to medical causes such as reflux or cows' milk allergy. When inaccurate, this causes unnecessary harm to families and healthcare systems. Existing interventions to support parents managing unsettled babies are costly and often biased by conflicts of interest from the formula milk industry.

Aims

To co-design a person-, theory- and evidence-based behavioural intervention supporting families with unsettled babies.

Method

Qualitative interviews and the person-based approach (PBA) were combined with innovative methods including partnership working with underserved communities. Firstly, a systematic review and thematic synthesis explored parent experiences of unsettled babies, with an emphasis on parents' thoughts and feelings about medical labels. An explanatory, conceptual model was proposed summarising parent experiences when faced with a baby they perceive as unsettled. Next, a qualitative interview study aimed to deepen understanding of parent attitudes to medical labels using an ethnically diverse sample of 25 mothers. Hybrid inductive & deductive analysis was used, including reflective thematic analysis, negative case analysis and framework analysis. Themes were presented and the conceptual model was refined. Finally, an intervention was developed using behaviour change theory and the PBA. This was optimised through qualitative 'think-aloud' interviews with 22 parents, analysed through thematic analysis and a table of changes.

Findings

Key findings from the systematic review and qualitative interviews offer a new insight into the thoughts, feelings and motivations of parents with unsettled babies. Findings suggest parents report a sense of guilt or failure, driving a search for an external, medical cause of unsettled behaviour. A novel intervention was developed. This aims to help parents distinguish normal baby behaviour from medical red flags; increase parent self-efficacy and give tools to self-manage unsettled behaviours.

Discussion

The results of this work are put in the context of wider literature on medically unexplained symptoms, the transition to parenthood, parenting self-efficacy and bonding. Limitations and strengths of the research, suggestions for future research and clinical practice are discussed.

Conclusion

The resulting intervention, if nested within a wider system of support, may provide help to families of unsettled babies, reducing unnecessary medicalisation.

Table of Contents

Table of Tables

Table of Figures

Research Thesis: Declaration of Authorship

Print name: Amy Dobson

Title of thesis Supporting families with unsettled babies: Development of a digital intervention

I 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.

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. Unless where stated otherwise and referenced (see appendix G), none of this work has been published before submission

Signature: Amy Dobson ..... Date: 21.06.2023 .....

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My family showed me how to parent with unconditional love, something I hope echoes through these pages.

Ada, you made me a mummy and you showed me how to be **your** mummy. I love you so much.

To my husband Rich, thank you for being my rock, my anchor and my safe place for the past twenty years.

To my partner Cressida, thank you for being my constant cheerleader and bringing me so much joy.

… and finally, thank you to 'Boo'; my bearded dragon and co-author; for her ceaseless (sometimes smelly) presence on my desk!

Definitions and Abbreviations

HV..... Health Visitor. A specialist community nursing role caring for families from antenatal to five years

RQ ..... Research Question

CMA..... Cow's Milk Allergy

FGID..... Functional Gastro Intestinal Disorder

PPIE ..... Patient and Public Involvement and Engagement. A research activity which includes patients or members of the public with personal experience of the condition or phenomena of interest in the research process.

PBA..... Person Based Approach. A methodological framework to guide the design of a behavioural intervention.

CSM ..... The Common Sense Model of health and illness. A theoretical model of how people perceive and understand illness and how they self-manage illness.

PSE ..... Parental Self-Efficacy. The belief of a parent that they have the ability to influence their child and the environment and thereby influence the child's development or success

RTA..... Reflexive Thematic Analysis

TA ..... Thematic Analysis

SCT ..... Social Cognitive Theory

SEO..... Search Engine Optimisation

IBCLC ..... International Board Certified Lactation Consultant

FSMP ..... Foods for Special Medical Purposes

MOSCOW ..... 'Must, Ought, Should, Could, Would' a change decision tool

IMD ..... Index of Multiple Deprivation

BCT ..... Behaviour Change Techniques

Parent..... Used inclusively throughout this thesis to refer to biological and non-biological parents and carers, of all genders and family configurations.

Definitions and Abbreviations

Breastfeeding ..... Lactation, since all the parents interviewed in my research use the term breastfeeding, I have used this as a general term. I intend also to include those who prefer the term ‘chestfeeding’ or who use alternative language for lactation.

Chapter 1 Outline and research aims

1.1 Scenario

The work presented in this thesis was designed to meet a clinical need which I experienced in my practice as a Health Visitor (HV) in the UK from 2016-2020. I wrote the following in 2020 before starting my PhD to summarise my experiences and initiate a conversation with colleagues. I have reproduced it here as a practical introduction to a clinical scenario which I believe is common in primary care:

> "I frequently see families where the baby is a few months old but somehow things have just never been quite right. Baby is unsettled, cries a lot, maybe they vomit or seem gassy, they don't sleep well…often there are co-occurring feeding problems like nipple pain, fussiness at the breast or poor weight gain. There are diagnoses of tongue tie, reflux or allergies and sometimes it feels like these cause more problems than they solve. Parents' mental health has often deteriorated and there are complicating factors like anxiety and sleep deprivation which make getting a clear history difficult. There are also often bonding or attachment issues, since it is hard to build a happy relationship between a baby who is crying all the time and a parent who is at the end of their tether. These relational issues then compound parents' mood problems, as they cause feelings of guilt and shame. Developing mental health issues also complicate any intervention or assessment, as disorders of thought or cognitive distortions can colour parents' ability to think clearly. In this situation parents are often desperate to be listened to and to be taken seriously, are looking for quick solutions or diagnoses which will make sense of their experience, or are so desperate to exert some control over the situation that they are likely to see a placebo improvement from any intervention we do. I find these situations extremely difficult to work with effectively as a practitioner and often come away feeling unsatisfied or like I haven't really met the need"
>
> **Amy Dobson, UK Health Visitor 2020**

1.1.1 Thesis structure

In this thesis I will firstly critically examine research on the parent experience of unsettled babies in Chapter 2 and demonstrate that this is a growing and significant issue with potentially serious

implications for babies, parents and carers (hereafter referred to as parents) and healthcare systems. I will demonstrate that this parent need is increasingly being labelled and treated as a medical problem and discuss the possible consequences and impacts of inaccurate medicalisation. My PhD research will then be outlined, including underpinning theory, methodological frameworks and methods in Chapter 3 and partnership working with parents in Chapter 4. Chapter 5 presents a systematic literature review, exploring how and why parents come to illness-related interpretations of unsettled babies. Following on from this, Chapter 6 will report my analysis of the findings from a qualitative interview study which extends the understanding gained through the systematic review and includes previously underserved groups. In my intervention development, Chapter 7, I will outline how I have used the Person Based Approach [2] to guide development of a digital intervention which aims to meet the needs I have identified in the previous chapters. Chapter 8 will then report qualitative think-aloud interviews which refined and optimised the acceptability and engagement of this intervention. Finally, Chapter 9 will discuss the learning from this thesis, possible directions for future research and clinical practice.

1.1.2 Research aims and scope

1.1.2.1 Aim and questions

Overall research aim: To develop a person-, theory- and evidence-based behavioural intervention to support parents of unsettled babies.

- Research Question (RQ) 1: What are the experiences, thoughts and feelings of parents/carers of unsettled babies, with particular reference to medical labels?
- RQ 2: What is the underlying need of parents with unsettled babies that leads them to medicalise behaviours and/or seek medical help?
- RQ 3: What purpose are diagnostic labels and / or medications serving for families of unsettled babies?
- RQ 4: Can I develop an explanatory, conceptual model of the parent experience when faced with an unsettled baby?
- RQ 5: Does this model fit with new data? What refinements can be added?
- RQ 6: Can I build a supportive, digital intervention for parents which aims to meet their needs appropriately?
- RQ 7: Can I include a diverse range of parent voices?

1.1.2.2 Scope and limitations

This PhD aims to understand the needs of parents with unsettled babies and then to produce a digital behavioural intervention to meet those needs. In doing this, I recognise that this digital intervention will need to sit within the existing landscape of support for parents, including more intensive support given face-to-face and healthcare professional education.

Pre-conception and antenatal expectations of parenthood as well as antenatal mental health are likely to have an impact on parents' perceptions of their unsettled babies [3-6]. Emerging evidence suggests the intergenerational transmission of emotion dysregulation [7]. However; covering both antenatal and postnatal audiences is beyond the scope of this PhD. Therefore, for pragmatic reasons, this research will be limited to the early postnatal period (first year after birth). There is possibility that future research could extend this research to the antenatal context.

The question of the cause of baby crying, feeding or sleep difficulties has been presenting a dilemma to research for many decades [8]. We are still far from a conclusive solution [9] and the answer is likely to be complex, multifactorial and interactional; as well as individual to each baby [10]. This PhD is not attempting to uncover the cause of unsettled behaviour in infancy, rather it is attempting to take a pragmatic approach at reducing the harm it causes.

The resulting product from this PhD will be a digital intervention. The goal is that in many cases this will meet parent's needs without requiring a diagnostic label or medication. Testing the effectiveness of this intervention will require a clinical trial; which is beyond the time or budget limitations of this PhD. The strength of this research is in the depth and nuance of insight which the qualitative work brings to the understanding of parent needs and worries.

Chapter 2 Background

2.1 The problem

2.1.1 Defining 'Unsettled Babies'

Researchers have been interested in temperamental or behavioural differences between 'easy' or 'difficult' babies for many years [11]. Different names have been given to this group of babies including diagnoses such as 'colic' [8, 12] or 'failure to thrive' [13, 14]; as well as psychological terms such as 'orchid babies' [15, 16]; 'difficult temperament' [17, 18] or 'emotionally negative' [8]. Authors have also described 'unsettled infants' [19] as demonstrating 'problem crying' or 'irritability' [20], the 'fussy' or 'high needs' [21] or 'highly sensitive baby' [22, 23]. Parent-facing groups might describe babies who are unsettled and sleep less than their peers as 'little sparklers' [24] or 'low sleep needs' babies [25]. More recently research has focused on possible neurological differences and refers to babies with 'regulatory problems' [26] or 'hyperarousal' [27]. It could be argued that these are all the same babies under different names, and the proliferation of research into each gives an insight into the scale of this distressing experience for families.

Attempts have been made in the past to operationalise excessive crying (to inform a diagnosis of 'infantile colic') in formal criteria; the most significant of which was Wessels Rule of Three (crying for three hours per day, three days per week, under three months of age) [8] or more recently adapted to the Rome III Criteria [28]. However, these attempts have been met with criticism as they have been perceived as too prescriptive and, in practice, unhelpful for families [29]. My PhD focuses on how we can better understand and support families who consider themselves to have an unsettled baby. I am defining this as parents who are worried about their baby's behaviour, rather than restricting the definition to a list of symptoms or criteria.

For the purposes of this thesis, an unsettled baby is therefore defined as an infant under the age of one year, with a parent who perceives their crying, vomiting, sleep behaviour or stools to be problematic, or who otherwise worries that their baby is 'unsettled'. This is likely to include babies of parents who are considering a medical explanation, such as allergy or reflux.

2.1.2 Medicalisation of unsettled baby behaviours

In clinical practice, primary care practitioners such as GPs and Health Visitors regularly see families with unsettled babies who are in great distress; babies with behaviours such as crying, sleep

problems, vomiting, unusual stools or rashes [19, 30]. Practitioners report that families often consult many times without finding the help they need [31], and parents report they often feel dismissed or ignored when they seek help [32].

There is a growing concern that babies' unsettled behaviours are being increasingly attributed to medical causes such as reflux, cows' milk allergy (CMA) and other functional gastrointestinal disorders (FGID) (see Figure 1) [30, 33-39]. These labels are often used not only to describe and categorise unsettled behaviour, but also to try to understand it; sometimes with the implicit goal of changing it. These labels can include opinion-based judgements such as 'spoilt' or 'clingy', can include conditions which are within the range of normal such as 'dyschezia' (crying for a period of time before defecating) and 'foremilk-hindmilk imbalance' (excessive gas and frothy, green stools caused by a fat imbalance in breastmilk). For a small number of babies, unsettled behaviours can be indicative of a rare medical issue such as Food Protein Induced Enterocolitis Syndrome (FPIES) [40]. However, the most recent Lancet breastfeeding series focused on the possible detrimental public health implications of mislabelling unsettled baby behaviours as allergy [41, 42]. This series highlighted that the prevalence and vague nature of unsettled behaviours leaves room for understandable misinterpretation. This is compounded by the misleading bias introduced by the formula milk industry, who have invested heavily in healthcare professional training and funding for clinical guidelines [30]; as well as marketing directly to parents with social media adverts attributing common baby behaviours to underlying health conditions [30, 34, 41, 42]. For a full discussion of commercial bias see Chapter 2.5.3.

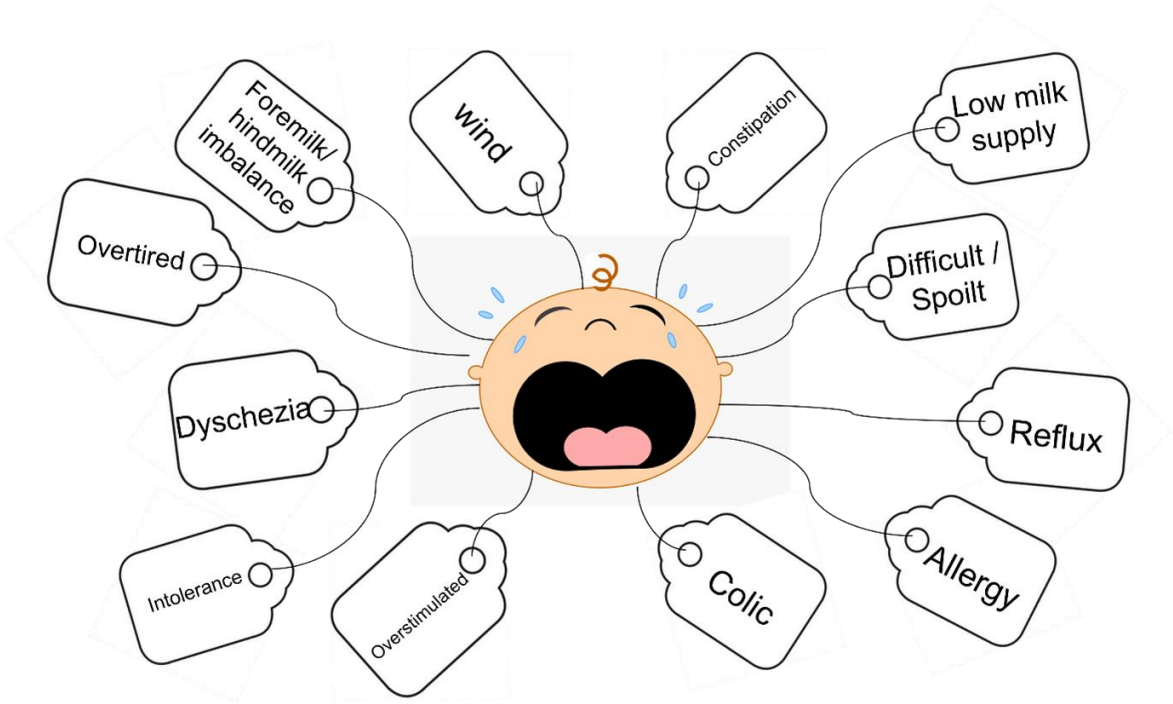


Figure 1: Potential labels that can be assigned to babies' unsettled behaviours

It is possible that societal myths and misconceptions about normal baby sleep, feeding, behaviour and development may also increase medicalisation, by framing evolutionarily normal and adaptive baby behaviour; such as waking frequently, feeding often and wanting to be held; as a 'problem' that needs to be 'fixed'. In one example of this, qualitative focus group research demonstrated differences in the group-reported perceptions of infant sleep behaviour as problematic between formula feeding and breastfeeding parents [43]. In a second example, clinicians and researchers present the argument that modern social expectations of normal infant sleep are unrealistic when compared with biologically normal patterns of sleep behaviour [44]. Normal baby behaviours are juxtaposed with unattainable societal expectations of parents and a routine-driven 21st century lifestyle; making responsive parenting challenging [45-48]. The result of this can be that parents feel inadequate, like a failure or as if their baby is somehow 'wrong'; and it is possible that these feelings may contribute to parental health anxieties when their baby displays behaviour like fussiness, crying or disturbed sleep [49].

2.1.3 Impacts of inaccurate medicalisation

2.1.3.1 Physical health impacts

Medical labels increase parents' and healthcare professionals' likelihood of medicating babies; even when told the medication is likely to be ineffective [50]; introducing potentially harmful side effects.

It is therefore important on an individual level to support parents and clinicians in recognising conditions requiring medical intervention and distinguishing this from normal infancy [36, 38].

Aside from risks introduced by medication side effects; a recent qualitative research paper demonstrated that a loss of confidence in breast/chestfeeding (hereafter referred to as breastfeeding) is an important negative impact of parent anxiety around unsettled symptoms [51] and researchers have suggested that labels such as CMA may decrease confidence in breastfeeding at a vulnerable time [39]. This has clear relevance for public health, since it has been estimated that the scaling up of breastfeeding to a near universal level could prevent 823,000 annual deaths in children under 5 years and 20,000 annual deaths from breast cancer; in addition to the range of additional well-established physical and mental health benefits to the parent and child from breastfeeding [52]. This finding was the result of a global meta-analysis conducted as part of the 2016 Lancet breastfeeding series [52]. To reach this figure, authors working with the World Health Organisation (WHO) completed a large scale meta-analysis of outcomes postulated to be associated with breastfeeding and then used a statistical modelling tool - 'the Lives Saved Tool (LiST)' [53] - to apply relative risks for all known infectious disease causes of death in children under two years and to the 15% of deaths caused by complications of prematurity after the first week of life, resulting in this significant mortality figure [52]. The authors used data from low and middle income countries for this calculation; but argue that high income countries stand to benefit to a comparable level due to the extremely low levels of breastfeeding at 12months of age and the high rates of breast cancer [52]. It is clear therefore, that increasing breastfeeding for those who want to in the UK is a high public health priority.

Aside from the mortality and physical health benefits of breastfeeding, there are a range of well-established psychological, emotional and developmental benefits to the child and parent [54]. We also know that there can be a significant psychological impact of stopping breast/chest-feeding earlier than planned, causing long term guilt and trauma for some parents [55], harm which may be preventable with improved management of parent anxiety about unsettled behaviour [39].

Additionally, there are dietary impacts of inappropriate labelling for both the parent and the baby, across the short and long term. Firstly, exclusion or elimination diets are prevalent in breastfeeding parents of unsettled babies. These are often recommended in clinical guidelines [30, 39], underpinned by anecdotal evidence, clinical experience and a small number of case studies [56] and empirical studies suggesting human milk can trigger 'allergic type' reactions [57]. However, contrasting recent research estimates that for more than 99% of babies with proven CMA, breastmilk does not contain sufficient antigen to trigger a reaction [39] and a recent meta-analysis

concluded that the probability of an IgE-mediated reaction as a result of a breastfeeding parent consuming wheat, peanut, egg or cow's milk is less than 1 in 1000 [58]. Research suggests the inclusion of possible allergens in the diet may in fact reduce symptoms over time [59] and may reduce the risk of allergy [60]. A recent Cochrane review also found there was insufficient evidence to recommend dietary alterations for babies with colic [61] and there is no clinical rationale to justify elimination diets in babies with reflux [62].

Dietary manipulation in the breastfeeding parent leads to potential negative effects on the parent's own nutritional status [63] as well as resulting in baby outcomes such as altered childhood eating habits [64], growth restriction, insufficient micro/macro nutrients, food avoidance and altered satiety responsiveness at the age of 2-6years [65]. In a recent cohort study, babies who had been on elimination diets for non-IgE mediated CMA were found to have worse quality of life and family functioning than matched cohorts with sickle cell disease and intestinal failure [66]. It is suggested therefore that exclusion diets should be implemented only where necessary. New guidance developed independently of commercial influence advises against dietary exclusion for breastfeeding parents except in specific, rare circumstances [67]. This aims to prevent some of the unintended physical health consequences of inaccurate medicalisation.

2.1.3.2 Emotional health impacts

Having a baby who is unsettled is highly distressing [31]; with review studies documenting the impacts on parents' wellbeing, sleep and family strain [68], as well as a negative impact on the parents' relationship [69]. At its extreme, excessive crying is thought to be a trigger of abuse and non-accidental injury [70].

Qualitative research into parent experiences of unsettled babies highlights that health professionals are perceived to focus on medical or physical aspects and neglect psychological factors and the parent-baby dyad [32, 71]. Prominent academics in the field are also now making a case for considering unsettled behaviours in infancy in an emotional and relational context [72].

Where primary caregivers are struggling with mental health problems, babies too manifest more negative emotionality [73, 74], are more likely to have labels of colic, reflux or dyschezia [75, 76] or early FGID [77] and there are differences in their dyadic interactions with their parent [78-81]. It is difficult to untangle causality and the effect is likely to be bidirectional and multifactorial - with unsettled babies having a negative impact on parental wellbeing; as well as poor parental mental health leading to baby negative affect, increased perception of unsettled behaviours or more difficulty coping with an unsettled baby [82, 83]. This is perhaps unsurprising, given the

interdependence, synchrony and mutuality of emotions in this sensitive perinatal period [84-86]. Fathers and coparents' emotional health is also vital to this unsettled family dynamic, creating the emotional environment in the home [87].

Parents often report presenting repeatedly to multiple practitioners with the same problem; often feeling dismissed or ignored when they seek support [31, 32]. Although there is likely to be a degree of selection bias in the sample reporting this experience; this may suggest that there remains an important unmet need for these parents driving repeated help seeking [31]. It is possible that inaccurate medicalisation of unsettled baby behaviours may lead to the emotional dynamics of the family being overlooked [32].

2.1.3.3 Economic impacts

Unsettled babies are known to have a high rate of service use in Western, Educated, Industrialised, Rich and Democratic (WEIRD) societies [19] and represent large and rapidly increasing costs to the NHS [30]. Cost for crying and sleep problems in infancy was estimated at £65 million in 2001 [88]. In a commercially funded piece of research calculating the Cost of Illness (COI) of infant FGID placed the lowest conceivable COI at £72.3 million per year in 2017, which the authors judged a significant underestimate [89]. This figure is likely to have increased significantly since 2017, an analysis piece for the British Medical Journal published in 2018 highlighted a strong upward trajectory of diagnosis and treatment for CMA [30]. NHS spending for specialist milk formula alone increased by 700% from £8.1 million to £60 million between 2006 and 2016, without evidence of any increase in allergy prevalence [30]. Prescribing rates of medications for reflux have all also increased between 2010 and 2016 [90].

2.1.3.4 Long term impacts

The evidence of long term impact, either of unsettled baby behaviour, or of the inaccurate medicalisation of unsettled babies, is as yet limited and unclear. It has been noted that the population prevalence rates for unsettled babies and behavioural difficulties in older children are similar, with similar stability ratings [72]. A meta-analysis published last year found a link between unsettled behaviours in infancy and later externalising, internalising difficulties and/or attention deficit hyperactivity disorder [91]. Additionally, longitudinal analysis published last year found that combined regulatory problems in infancy are linked with mental health outcomes in childhood [92].

One interpretation of this data could be that infant unsettled behaviour is an early behavioural manifestation of ADHD [93]. Alternatively, some authors postulate that the mechanism for this link

could be due to variation in parenting behaviour and negative impacts on parent-infant relationships [91, 94]. A recent review of the impacts of crying on parent-baby relationships found that babies who are unsettled are often perceived more negatively by their parents, with potential implications for their developing relationship [95]. A baby's early attachment relationships determine brain architecture [96, 97] and are formative for a range of later developmental, health and behavioural outcomes [98].

Researchers have proposed that some babies might be more vulnerable to parenting or bonding issues than others in the 'differential susceptibility hypothesis' [99, 100]. Others have suggested a 'mutual exacerbation hypothesis' – that babies who are thought to be 'difficult' both elicit and are more vulnerable to negative responses; and that this might be predictive of later conduct problems [101].

This school of thought has led to a proposed 'neurobiological model' of unsettled behaviour in infancy [26]. This model suggests that specific patterns of neurological stress-response mechanisms; developed during infancy in response to relational interactions with caregivers; may underpin later behavioural difficulties in childhood [26]. The theory further posits that neuroprotective interventions influencing parenting practices may be able to reduce risk for neurodivergent disorders in the long term by nurturing healthy attachment relationships and associated brain development in unsettled babies [26, 102, 103].

However, research testing these theories has had mixed results [104], and whilst some studies have shown support for differential susceptibility [105-107] or mutual exacerbation hypotheses [18]; others have not. In their study attempting to test the mutual exacerbation hypothesis, Lorber and colleagues failed to find evidence of infant 'difficultness' being linked to later conduct problems [108]. In addition, qualitative work with parents of four-year old children who had colic as babies describes early difficulties in relationship development which were short-term; with parents reporting close and strong family relationships and no long term impact [109].

There is a further concern with theories that include parenting and parent-infant relationships as a causal or mediational factor in infant unsettled behaviour. This is the risk of 'parent blame'. This is the perception of parents that they are seen by healthcare professionals, or others, to be at fault for problems in their child [110]. In the feminist literature this has been argued to be a gendered experience for parents socialised as women [111] and fits within literature demonstrating significant harm of 'intensive mothering' in a context of dichotomised sociocultural ideals [112]. For further discussion of this see Chapter 2.3.

Even if it were established to be the case that unsettled babies develop into children with behavioural difficulties and that the mechanism for this was through neurodevelopmental changes due to parenting style and bonding issues; this does not speak necessarily to inaccurate medicalisation. There is, as yet, no evidence about labelling unsettled behaviours as a medical issue and whether this might make a difference (positive or negative) to parenting and relationships or to long term child behavioural problems.

From a pragmatic perspective, it is therefore clear that babies who are unsettled in infancy and parents who are worried about this unsettled behaviour are suffering; and that they may have difficulties in their relationship [113]. In terms of clinical care; it is reasonable to conclude that greater emphasis on emotional and relational issues for these families is important [72].

2.1.3.5 Summary

Taken together, this evidence suggests parents increasingly seek medical explanations for unsettled behaviours. Without intervention, this could have physical and emotional health impacts for the parent and baby, negative impacts on breastfeeding and significant economic cost. There is a possibility that there may be long term psychosocial impacts of unsettled behaviour in infancy for the family, however evidence regarding this is mixed.

2.2 What's in a label?

A recent systematic review looking at the consequences of a diagnostic label synthesised 97 qualitative studies from a wide range of illnesses and perspectives; individual patients' voices as well as those of family and friends, healthcare professionals and the lay community were included [114].

The synthesis covered the psychosocial impact of a label, impact on support, future planning, behaviour and treatment expectations [114]. Given the range of conditions included in the analysis, prognoses, severity and treatment pathways were very different and therefore there were many contrasting experiences reported; including both positive psychosocial impacts of a label such as feeling believed and validated; as well as the negative impacts such as feeling reduced to a label and dehumanised. Similarly, future planning was impacted by a label; either allowing patients to be informed and plan for the future; or leading to fear or uncertainty about prognosis. Finally, labelling was found to be helpful where it allowed for treatments, offering a sense of hope and control [114]. Alternatively, labels could also impact treatment negatively, where there were harmful side effects or withdrawal of support services [114]. A second systematic review of quantitative research recently found that receiving a diagnostic label may increase anxiety levels in patients from sub-

clinical to clinical levels [115]. However; once again there was a wide range of conditions studied, likely reflecting diverse patient experiences. These differences make it difficult to apply either of these systematic reviews to a specific field. In addition, the studies synthesised were mostly about people's perspectives on their own label, rather than parents' perspectives on their baby's diagnostic labels.

There are, however, qualitative studies of people with contested or controversial disorders, which may give some insight into the experiences of families with unsettled babies. Where there are medically unexplained symptom, people often face scepticism in the discourse surrounding their condition and report difficulty finding supportive healthcare professionals [116]. In addition, a qualitative study into patient views and relationships found that people felt a diagnostic label validated their symptoms as being real rather than imaginary or fraudulent [117]. These findings appear similar to the experiences of parents with unsettled babies who report feeling dismissed or 'fobbed off' [118].

Qualitative work has described that in conditions where a label cannot be found, the uncertainty causes distress [119]. In this way, the receipt of a diagnosis may increase a patient's perceived control [117]. However, the treatment options and specificity of the diagnosis determine this sense of control. In cases where the diagnosis is seen as a 'catch all' or where there are few pharmacological treatment options this sense of relief and control over symptoms may be missing or weaker [120].

Within qualitative literature on parent experiences of diagnosis for their child; parents reported feeling a sense of responsibility and guilt regarding their child's symptoms [121]. They describe that it is their job to not 'miss anything' and reported that they took on the search for an explanation for the symptoms as part of their parental role [120], feeling fearful that in the future they will realise they 'failed their child' by missing a possible diagnosis [122]. This was also found in a review of studies looking at the impact of a diagnosis of developmental disability in children, where diagnosis often served to assuage parent guilt [123]. It is plausible, therefore, that this sense of guilt and responsibility may be similar for parents of unsettled babies.

Some authors have theorised that diagnosis or labelling for 'medically unexplained symptoms' is partially attributable to sociocultural factors and could be self-reinforcing, resulting in worsening symptoms [124]. According to this theory, the internet, online forums and media promote the labelling of symptoms as an illness [125]. On being given a medical label there is often an element of relief and catharsis, which is self-reinforcing [124]. Hearing about the label may also result in the

reinterpretation of earlier symptoms being integrated into the concept of illness, thereby heightening awareness and perpetuating illness beliefs [124]. This concept has many parallels with the interpretation of unsettled baby symptoms as allergy or reflux; since this medical interpretation is reinforced strongly in the media and online forums [126], the vague nature of the symptoms leaves room for misinterpretation [41] and the act of labelling itself may provide some form of relief which could be considered self-reinforcing [124].

In contrast, an additional important consideration when researching controversial or contested diagnostic labels is the potential for harm which may be caused by taking a psychological approach to a potentially physical problem [127]. Researchers have cautioned against ignoring physical symptoms when dealing with conditions which have a psychosocial component, as it is possible that the psychosocial component may be over emphasised at the expense of understanding the biological element [127]. A further critique of this psychosocial approach is that it often is against the patient voice and takes a top-down, prescriptive approach to care, whilst ignoring the clinician's own biases [124]. It is clear therefore that any approach which seeks to apply the learning from bio-psycho-social models to the field of unsettled babies needs to be mindful of the parent voice, ensuring that reflexivity, parent involvement and engagement are central to the research process.

It is therefore possible to imagine, from drawing on related literature, that the labels of reflux and allergy may be considered helpful and beneficial by providing parents with a sense of control and assuaging guilt. The use of a label may also reflect patient-centred care and taking a partnership approach by including the parent's views. However, the decision to label a baby needs to be balanced by consideration of the risk of self-fulfilling prophecy and concerns about the social propagation of a medical label. It is unclear as yet whether these ideas can be applied to unsettled babies. My research aims to explore this.

2.3 Transition to parenthood: 'Good Babies' and 'Good Parents'

In their 1978 paper "failure to thrive or failure to rear"; O'Callaghan and Hull show professional tendency to blame parents of young babies for infant weight gain issues, particularly those from marginalised groups or lower classes. This blame culture is also exemplified historically in attachment research with particular focus on mothers breastfeeding and working outside the home in Bowlby's original theory of 'maternal deprivation' [128]. Feminist authors have critiqued this approach emphasising the importance of the social and political climate of misogyny which contributes to our understanding of motherhood [129, 130].

There is significant evidence for idealised norms of motherhood, known as the 'motherhood myth' which causes feelings of judgement, shame and guilt and underpins the experience of the transition to parenthood for many women [111, 131]; even in some cases resulting in 'parenting burnout' [132]. In her book 'the cultural contradictions of motherhood' [133], Hays proposes the term 'intensive mothering' and describes how these idealised beliefs become a set of impossible standards by which mothers are judged and judge themselves. A study of women in midlife [134] further suggests that the emotional and psychological cost of intensive mothering may persist in the long term. It is likely that intensive mothering myths also perpetuate inequalities, as they discriminate against mothers from different racial or socio-economic groups who may face additional challenges in the resources needed to meet the 'ideal' [112].

Winnicott, in 1960, coined the term 'good enough' in relation to parenting by suggesting that there is a minimum standard for parenting required by infants to allow for healthy development [135]. This concept has been very influential in the health and social care space, particularly in relation to safeguarding and child protection and has informed a proliferation of parenting assessments and surveillance interventions [136].

Social narratives about motherhood are deeply contentious, as is explored in the 2014 film 'The Babadook' [137]. This film highlights the potential value of normalising taboo feelings (such as the desire for an independent identity separate from one's child) and suggests that the real monster may be the "pressure to be the perfect mom that comes from ideologies of intensive mothering" [138] pp. 1. In addition, O'Reilly, in her 2019 book [139], explores the concept of 'maternal regret' (the feeling that you wish you had never had children) as the final taboo of motherhood and suggests that by discussing this taboo we may be able to reframe normative motherhood. In one final example, a recent paper presenting a qualitative analysis of social media blogs and their comments discusses the characterisation of a 'bad mother' as the new normal, as the polarised dichotomy between 'bad' and 'good' parenting continues.

In a recent paper, Budds [140] argues for continued challenge to the western ideal of 'intensive mothering'; prioritising instead family access to social support without sacrificing the 'good mother' identity. Capitalist society may also contribute to the problem, as an interview study with direct marketing consultants revealed the tendency of commercial industries to exploit intensive mothering ideologies [141]. This may have particular relevance to parents of unsettled babies, as a recent Lancet series highlighted how formula industry marketing is exploiting unsettled behaviours as a commercial opportunity [41].

It is not only parents who face idealised norms. Independence and self-sufficiency in the baby is valued as evidence of competent parenting [142], which is in contrast to normal, healthy and evolved infant behaviour such as frequent waking, proximity seeking, dyadic emotional regulation and frequent feeding [47, 143, 144]. In this way, babies are seen to be 'good babies' or 'bad babies' according to how commonly they exhibit these normal, adaptive behaviours [145].

2.4 Sense of control and parents' thoughts about their baby: The role of internalising and externalising

Parent's thought patterns and attributions about their child are crucial in determining a range of long term outcomes for the child such as psychological, temperamental and relational functioning [146, 147]. In optimal, securely attached parent-baby relationships, parents typically attribute babies' negative behaviour to external or situational causes (such as being tired or hungry) and positive or desirable behaviours to internal ones (such as personality) [148]. Cognitive psychological literature suggests that parent's attributing baby negative behaviour to internal causes may be linked to harsh or insensitive parenting and abuse [149-152]. Research into baby temperament found that parents' perceptions of their baby was the strongest predictor of behavioural problems [153, 154] and was associated with less responsive parenting interactions [155]. Research has further found that parental attributions minimising the emotional significance of their baby's distress was an important predictor in determining parenting behaviours [156]. In infant crying research, studies have found that parents sometimes believe that their baby is manipulating them or purposely trying to upset them [157]. These attributions may be linked to more negative parenting behaviours and difficulty bonding [149].

In our population of interest, studies show that parents perceive babies with suspected CMA [158] and colic [159] as more demanding and temperamentally 'difficult', parents with colicky babies are more likely to be bothered by their baby's negative emotionality [159] and parents who are worried about 'spoiling' their baby by keeping them close are more likely to struggle with colic symptoms [160]. These findings are supported by wider literature which finds significantly more dysfunctional parent-child interaction patterns in families with suspected CMA [161], colic [162], reflux [75, 163, 164] and 'non-organic failure to thrive' [165]. Taken together, these studies appear to suggest a complex interplay between infant temperament, parenting behaviour, parent thoughts or attributions about their baby and bonding.

However, this research is far from clear cut. Studies are correlational and therefore it is difficult to unpick a causal direction to understand whether a baby's unsettled behaviours may be at the root of the difficulty bonding, or whether the parent's negative attributions about a baby could be manifesting as baby unsettled behaviours, or perhaps through a complex interaction. It is also unclear what role parent internal or external attributions may have in the unsettled baby context; since these internal processes present inherent difficulty in operationalising.

Research on 'locus of control' is a similar field to internal and external attributions. Based in social learning theory, 'locus of control' was proposed by Rotter in 1966 and remains an influential concept in psychology [166]. In this theory, parents who exhibit a high 'internal' locus of control believe they are able to control their child's behaviour and development [167]. High internal locus of control is significantly associated with higher confidence, self-esteem, self-efficacy and parenting satisfaction, after controlling for confounding factors such as family structure and social support [167, 168]. Recent research demonstrated that increased parent internal locus of control (through an 8week parenting programme) predicts better child behavioural and coping outcomes [169]. Alongside the concepts of internal/external attributions and internal/external locus of control; there is also the related concept of parenting self-efficacy, based in Bandura's seminal work [170]. This is based on similar principles and considers the parents' own confidence in their ability to manage their baby's behaviour and development [171]. Parenting self-efficacy is one of the theories underpinning this PhD and is discussed in Chapter 3.5.

Therefore, whilst the exact mechanisms and relationships between these related factors are as yet not fully understood, it is plausible that parent sense of control and internal or external attributions about their unsettled baby may be important for family relationships; and for interpreting and managing unsettled behaviour.

2.5 Research context

2.5.1 Epistemology and ontology

In developing and planning the research for this PhD I considered the ontological and epistemological position of both myself as the researcher and the most appropriate philosophy to apply to the phenomenon of interest. Discussion of these considerations is presented in this section and applies to the entire thesis.

Firstly considering ontology, on a continuum of realist to relativist or irrealist [172], instinctively I find the concept of a single 'reality' to be reductionist and indeed universal 'laws' are likely to be impossible to find in a complex social issue such experiences of unsettled babies. There are likely instead to be multiple perceptions of 'unsettled'; multiple different experiences of parents in a variety of different contexts. However, on the other end of the spectrum, my desire to improve outcomes for parents with unsettled babies and to do this by understanding the mechanisms behind my planned intervention clearly demonstrates an underlying assumption that there is a 'reality' which I can alter, meaning that irrealism is not pragmatic in this case. This leaves me closest to an overall ontological position of realism, with a need to be mindful of complexity and context [172].

Epistemology is the other dimension I considered, on a spectrum from objectivism to subjectivism [172]. When attempting to understand the unmet needs of families with an unsettled baby, I recognised that the perception of the baby's behaviour is constructed as a product of the parent's experiences. These experiences occur in complex social context which is likely to influence their own narrative, my perception of and interpretation of their words and my own opinions and perspectives. It could be argued that this lends itself to a more subjectivist viewpoint, which recognises the difficulty in measuring something accurately within the social world. In terms of the methodological approaches throughout my PhD I was balancing my desire for scientific rigour and trustworthiness [173] alongside the need for pragmatism and a respect for the qualitative nature of the research and the topic area [174]. I decided to transparently report analysis methodology, engage in a thorough critical analysis and regularly reflect on my own position and opinions on the issue to maximise research trustworthiness within a subjectivist perspective.

In conclusion, as a clinician I am practical and pragmatic in my approach to research and I am interested in translational research which aims to have a direct clinical impact. As such my ontological and epistemological standpoints are influenced by this. I believe that the best fit for both myself as a researcher and for the topic at hand is a realist and subjectivist approach. In particular, the practical and pragmatic nature of this PhD relies on the concept that there is a 'reality', although I do not believe that this reality can be objectively observed in itself. Societal structures exist which shape our perspectives. I therefore decided to adopt an overall approach of Critical Realism which encourages me to understand the causes and structures underpinning observable events in the world [175, 176]. This approach recognises the subjectivity of observation, but remains positive that we as social scientists are able to both understand and impact the world by making justifiable, realistic claims about reality [175, 176].

2.5.2 Reflections on researcher position

In addition to this, my personal experience as a parent and my professional experience as a health visitor are relevant to this PhD topic.

As a health visitor, I have had significant training in breastfeeding and in attachment. Both these topics were special interests of mine, therefore I sought out professional development opportunities in lactation, parent-baby relationships, perinatal and infant mental health. In practice, I frequently found myself seeing families with unsettled babies who were highly anxious and feeling that, as a service, we were not able to meet their needs adequately. Infant feeding service limitations, in my experience, were insufficient to support parents to recognise feeding issues, and these were often mislabelled as other health problems. Often these families appeared to me to have poor outcomes in terms of their feeding journey or emotional relationship and so I believed that helping them to manage the unsettled baby behaviours would have a strong positive impact on their transition to parenthood. As such, I entered this PhD topic with the idea that both feeding and parent-baby relationships would be central to the topic of unsettled babies and this perception could influence my interpretation of the literature and the data.

In addition, while conducting qualitative interviews and reflexive thematic analysis I have reflected that my background as a clinician means I am often reading transcripts and trying to understand a family's story with some attention focused on trying to get to the bottom of the symptoms and find a cause, so that I can better support the parent. This is perhaps different from how a non-clinical researcher might approach the transcripts. Discussions with my supervisory team and other researchers involved with the study have supported my personal reflections on how this background may affect my analysis and interpretation of the data.

From a personal perspective, I had a baby who could have been described as 'unsettled'. I was not unduly worried about her need to be held constantly, fed frequently and her inability to settle on her own in a cot; my clinical training gave me information which prepared me for this and gave me the confidence to parent in the way I wanted to. I do empathise, however, with parents who are struggling in these early months and I understand on a personal level how emotionally challenging and exhausting it is. I also feel passionately about breastfeeding, as I am currently breastfeeding my own five-year-old daughter to 'natural term' (when she chooses to stop feeding herself; on average between five and seven years). I suspect that without my knowledge about infant feeding and attachment; I may have doubted my ability to feed her or lost confidence with my parenting style. Had this been the case our journey could have been very different.

I therefore have approached this topic from both a personal and professional standpoint passionately committed to helping other parents who wish to breast/chestfeed their baby and to parent responsively to do so with confidence. I am aware that there is considerable debate in the field in particular about attachment based or responsive parenting and that there are critics who feel that responsive parenting may hinder the development of self-soothing mechanisms in the child [177]. I have considered this argument critically from a scientific and academic perspective in Chapter 3.6; however whilst I aim to be as objective as possible in my reading and synthesis of the evidence base, I acknowledge that my personal position may have a subconscious influence on my work. I aim therefore to be as transparent and reflective as possible throughout my research to increase the trustworthiness of my findings. In addition, I discussed my findings and analysis with my supervisors regularly including discussion of our differing personal viewpoints and how these impact on our interpretation of qualitative data.

Finally, I have a sibling who is transgender and I therefore feel strongly about inclusion of marginalised groups through inclusive language. As such I will be choosing to use non-gendered language such as 'parent' wherever possible throughout this thesis. When I refer to breastfeeding, I am also including chestfeeding for the same reason.

2.5.3 Formula industry bias

There is important commercial context to this PhD, which may contribute to understanding why there might be an increase in medicalisation of unsettled babies and how industry influences families and healthcare professionals. This section explores this context.

Recent concern over the influence of 'Big Formula' [178] has led to a widespread interest in the behaviours of Human Milk Substitute companies ('formula companies') in the UK and worldwide [179-181]. Formal analyses conclude that this industry is powerful and influential to the point of ubiquitous across clinical education, professional publications, training and national professional associations [182, 183]. It is suggested that CMA may be providing a 'Trojan Horse' by which companies can influence the medical field [30] and the recent Lancet breastfeeding series highlighted some practices of formula companies as concerning [41]. Specifically, some are inaccurately positioning unsettled baby behaviours as 'problematic', further implying they are 'fixable' with specialist formula [41]. A recent report from the Baby Feeding Law Group UK; in partnership with First Steps Nutrition; summarises how formula companies are commonly practicing outside the law and are misusing the category of 'Foods for Special Medical Purposes' (FSMP) for

financial gain [184]. It is noteworthy that, in an observational study of the advertising by formula companies in UK health professional journals, 64.5% were found to be targeting CMA [182].

Research has found that companies are placing themselves in competition with breastfeeding, competing for a 'share of the [infant] stomach' [180] and that advertising techniques compare a specific branded formula with breastfeeding more often than they compare it with an alternative brand [182]. Multiple research studies including reviews, observational research and interviews with industry professionals [180, 182] [185] [186] show formula companies using marketing techniques to position breastfeeding as one minority option; promote mixed feeding; highlight problems with breastfeeding and offer advice on breastfeeding which is likely to undermine its success [180, 182] [185] [186]. This represents a public health concern.

It further argued that formula companies frequently use misleading techniques to advertise directly to parents, particularly targeting parents with unhappy babies and first-time parents [180]. There is concern that existing inequalities in health (such as lower breastfeeding rates amongst low income families, ethnic minority parents and adolescent parents) may be perpetuated by marketing campaigns which position breastfeeding supporters as aggressive, judgemental or antagonistic [187]. Authors believe there is a risk that formula marketing may introduce doubt or fear about breastfeeding at a sensitive time for the parent-baby dyad [188].

Digital marketing campaigns, including social media, are gaining popularity as industries learn how effective these can be [189, 190]. A review of social media practices of formula companies concluded in 2012 that their media presence was widespread and violations of the International Code of Marketing for Breastmilk Substitutes (The Code, World Health Organisation) were common [186]. It is clear that digital marketing and social media campaigns by formula companies are now globally prevalent and influential.

It has been proposed that the overdiagnosis of CMA and over-prescription of hydrolysed/amino acid formulas may be attributable in part to inaccurate information circulating on social media [191]. For example, both the domains 'isitcowsmilkallergy.com' and 'cowsmilkallergy.co.uk' are managed by formula companies [30]. Apps run by formula companies and specifically focused at babies with diagnosed or suspected food allergies have already emerged [186]. When searching for support on internet search engines, the top results are commercially funded 'symptom checkers' which frequently direct parents to consult their GP about the possibility of an allergy. In a world where new parents are increasingly turning to the internet and social media for feeding support [192]; there is

concern that this may present an opportunity for formula companies to take advantage of parents in a hard-to-police domain [180, 185] [193].

Advertising directly to parents additionally makes it extremely difficult for primary care clinicians to manage concerns from parents about unsettled baby behaviours in an unbiased way, potentially increasing pressure on them to prescribe without meeting the real need [30, 194]. This, combined with the subconscious bias of formula marketing to clinicians could also provide a possible contributory explanation of overdiagnosis [30].

Given this context, I conclude that independent research providing evidence-based and unbiased advice and support for parents is needed. In my PhD work, I will therefore need to be aware of the challenges and dominance of the commercial industry in the digital space, particularly in relation to CMA. There is a need for all research in the field of unsettled babies; including my own research; to maintain independence from industry and avoid any possible conflicts of interest in funding and research activities. The digital intervention resulting from my PhD will need to exist in a space which is significantly biased by commercial industry competitors.

2.5.4 Equality, diversity and inclusion

Despite the breadth of literature across fields as diverse as psychology, interpersonal neurobiology, primary care, medicine, attachment, parenting, nursing and public health; much of the research in the field of unsettled babies has been with white, middle class, affluent women; with ethnic minorities, other genders and low income families conspicuously missing. I will consider here three minority groups whose views have been largely absent from research and for whom the topic of unsettled babies has particular relevance. I will summarise why the voice of this group specifically is needed and briefly discuss the existing research with each group to date. I will also consider the context of a digital intervention from the perspective of equality, diversity and inclusion by looking at digital illiteracy and inequalities in access to digital media.

2.5.4.1 Low family income

A recent systematic review attempted to pinpoint parental factors related to differences in incidence rates of colic [195]. This review found that higher socio-economic status is related to higher incidence of colic, however this finding was based on just one research paper of two hundred and nineteen babies conducted in 1990, therefore it is unclear whether this continues to be relevant [196]. Data from Chile has suggested a similar result, however this may not be transferrable to our UK population and had methodological flaws in the blinding [197]. Given the recent increase in

medicalisation of unsettled behaviours, it is plausible that this is no longer a problem experienced only by more affluent families; but rather has spread to vulnerable groups as the medicalisation narrative has become more prevalent [198].

In addition, there are good reasons for including families of low socio-economic status in unsettled babies research. There is a compelling argument that babies born to families living in poverty are at higher risk of struggling with many other complex social issues [199, 200]. In some cases, babies may be more vulnerable, in need of responsive parenting interventions to buffer negative impacts of accumulated stressors or adverse childhood experiences [201]. Families on a low income may also be disproportionately affected by the impacts of misdiagnosis, such as premature cessation of breastfeeding and the need to purchase formula milk [39]; and this has the potential to widen the health inequality gap [200].

2.5.4.2 Cultural differences

Few studies have looked at differences in prevalence of unsettled baby behaviours across cultures, however the scarce data available appears to suggest culture is important in the interpretation of unsettled behaviours. Research in a Malaysian population suggested significantly lower rates of FGID than have been seen in Caucasian populations [202]. One study compared three cultures across the UK and South Africa and found differences in child emotion regulation and aggression, relating this to differences in parenting such as responsiveness to distress [203]. Another found that parents in the US, Sweden and China had different opinions on the temperament characteristics that were interpreted as positive and negative [204]. Some limited additional data from a PhD thesis is available suggesting Hispanic parents may differ from Caucasian parents in their interpretation of the causal factors for their baby's colic, with Hispanic parents being more likely to believe that colic was related to the way they cared for their baby and Caucasian parents associating physical complaints such as wind with their baby's colic [205].

Cultural and social constructions of 'normal' influence the way parents perceive their baby's sleep and therefore the way they respond to differences in sleeping patterns [145]. Cultural emphasis on independence versus interdependence may influence parenting goals, expectations and behaviour in relation to feeding, soothing and sleeping arrangements [206]. Specifically, western ideals and cultural values prioritising independence, return to work and the child's ability to cope with separation from an early age may mean that parents in the UK are ill-prepared for the biologically normal, adaptive baby behaviours such as wanting to be held close constantly, sleeping in close contact and feeding frequently [43, 44].

Researchers have explored temperamental differences across cultures and postulated that these could be due to differences in customs and parent belief systems which create the baby's daily environment [207]. It is also possible that the cultural milieu surrounding a parent may impact not only the baby's behaviour but also the parent's framing or interpretation of that behaviour [207]. The parent's perception of their baby's symptoms is thought to be of foremost importance in providing meaningful and effective support to families of unsettled babies [208]; highlighting the need to capture and include cultural differences in unsettled babies research.

2.5.4.3 The family system

Despite mounting evidence of the importance of fathers and other co-parents in the perinatal period, in relation to baby emotional expression and baby colic [5, 87, 209]; they remain largely underserved in intervention studies about unsettled babies. Research which has included them has focussed largely on the prevention of abusive head trauma [210-212].

Historically, fatherhood and the involvement of a father in baby development has been studied from a range of perspectives, reflecting the society and cultural factors at the time [213, 214]. Fathers were considered to play a key role in baby development by using a different style of play, with research suggesting this may be more boisterous, boundary pushing and thereby increasing the baby's confidence; although recently these ideas have been updated to reflect modern changing gender constructs [215]. Fathers have also been recognised as important support for the primary caregiver (traditionally seen to be the mother) [216, 217].

More recently, however, an increased recognition of the complexity in family dynamics and a reduced emphasis on traditional gender roles has led to a more thoughtful analysis of the father or co-parent role as an equal part of the family dynamic; in particular contributing to the household emotional climate [218] or as part of a co-parenting 'triad' [219-221]. Most recently, researchers have discussed the development of infant emotion regulation (such as in unsettled babies) as happening in the context of scaffolding within a triadic or family-level subsystem, in which each member of the family contributes to the overall atmosphere and dynamic [222].

2.5.4.4 Digital inclusion

As the reliance on technological interventions within healthcare settings increases, there is a risk of growing inequity in the gap between families living with social disadvantage, risk or complexity and those from more privileged backgrounds [223]. This underlines the importance of including underserved groups in health technology research and design; including through engagement or co-

production strategies. I also acknowledge that my intervention does not aim to provide a solution for every family; but rather to offer an accessible, free resource to efficiently support those who are able to use it. This resource must sit embedded within a larger network of face-to-face and relational support for those who require this approach. There are other projects underway which offer a more intensive level of non-medical support for parents of unsettled babies – for example Cognitive Behavioural Therapy through the Surviving Crying Programme [224], multidisciplinary expert care through the Possums programme [225], telephone helpline and home visits through the 'Fussy Baby Network' [208] and social support, music therapy and a group health education intervention through a collaboration between Alder Hey children's hospital and University of Liverpool [226]. It is hoped that the current research project can add to this body of research by adopting a pragmatic and cost-efficient approach using a digital intervention. This may allow for funding to be targeted on those who need more intensive support.

2.6 Existing interventions

2.6.1 Support for parents with unsettled babies

Face-to-face interventions have been used effectively to address parent concern around their baby's health; but are often costly and resource intensive to implement. In one example, parent reassurance and nutritional advice helped to manage baby FGID and parent concern [37]. Researchers have presented evidence that a face-to-face parent educational intervention with reassurance and teaching settling techniques can replace medication (medication was ceased prior to starting intervention) [227]. Similarly, it has been established that colic symptoms and parental concern can be improved by education and modifying parent-baby interactions [228].

In particular, a significant body of research has developed resources known as the 'Surviving Crying' approach [229] [230] [231] which has been shown to improve parent mental health and wellbeing with a combination of a website, printed materials and Cognitive Behavioural Therapy (CBT) with a trained health visitor. While effective, these materials are specifically focussed on crying and may not include detail about other unsettled behaviours such as vomiting and stool changes which cause health related anxiety in families. It is unclear whether these resources provide adequate support for families worried about the possibility of a medical cause for their baby's unsettled behaviour. More research would be needed to evaluate whether or not these materials might lead to reduced healthcare service use, reduced diagnosis and prescriptions or increase in breastfeeding.

While the overall paradigm in the literature advocates supporting parents to cope with unsettled behaviours, rather than attempting to change baby behaviour; this approach is not without critics. In particular there is a concern about dismissing and patronising parents [232, 233]. This highlights an important truth that many parents fear judgement in their parenting choices [187] [192]. In recognition of these issues, it is important that any future intervention must seek to provide validation and allay fears of judgement.

A digital intervention is likely to be a cost effective, accessible and time efficient way of supporting a large number of families [88]. There is also evidence that increasingly parents are looking to the online arena for advice on parenting and infant feeding and that this is a powerful and influential tool in parent's lives [234]. A systematic review looking at the efficacy of parenting training on child emotional and behavioural problems has demonstrated good effect sizes and concluded that this is a promising arena for new interventions [235]; although the interventions were focused on an older age range than my PhD and included parenting education to respond appropriately to child behaviour issues [235]. A second, more recent systematic review into digital parenting interventions found similar success for parents experiencing social disadvantage, with significant improvements in child behaviour and parenting, and approaching significant improvement in parent psychological well-being [236].

With the proliferation of digital resources for parenting, there are a high number of biased and commercially influenced resources specifically targeting parents of unsettled babies and reinforcing a medicalised narrative [41]. For a more detailed discussion of this issue, see Chapter 2.5.3. There is, therefore, a need for an accurate and trustworthy resource to counteract this effect.

2.6.2 Existing online resources

At the outset of my PhD, I completed a scoping search looking for existing online resources for parents. This was done firstly using a Google search, entering phrases such as 'crying baby', 'baby in pain', 'unsettled baby' and 'something wrong with my baby'. I scoped academic literature using Google Scholar searches such as 'regulatory disorder infancy intervention', 'colic intervention' and 'crying baby resource'. Additionally, I posted on a health visitor professional social media forum asking what resources professionals use with families or signpost families to. Finally, my own experience as a practicing paediatric nurse and health visitor also helped me to identify a number of available resources with which I was familiar.

I collated details of each resource I had identified, including both overt and covert commercial marketing, NHS information pages, parenting support charities, educational interventions and

parenting advice pages. Very few of these resources appeared to be evidence based or produced with service users. Many had elements of bias due to formula industry involvement (also see Chapter 2.5.3). Many interventions also included majority or exclusively face-to-face components and were therefore considered to be materially different from my anticipated digital intervention.

In order to assess the existing field of interventions I developed a list of criteria which I felt were key characteristics of a digital resource to support parents of unsettled babies. In developing this criteria, I used the principles of the Evidence Based Intervention Programme [237]; which is a partnership project between the National Institute of Health and Care Excellence (NICE), NHS England, NHS Confederation, the Patients Association and 'Getting it Right First Time' (GiRFT). The project is led by the Academy of Medical Royal Colleges and seeks to improve the quality of care while reducing harm from unnecessary and inappropriate procedures or treatments. In addition to these basic principles, when creating these criteria I have also drawn upon recommendations from an international workshop on the development of digital behaviour change interventions [238].

In addition I have added several criteria which are based in my professional clinical experience or in my conversations with parent partners as part of PPIE. The first of these is inclusion of a dyadic or relational approach (considering both parent and infant mental health) with a foundation in attachment theory [239, 240]. This is due to the increasing body of evidence which recommends the consideration of baby unsettled behaviours from a relational perspective, presented briefly in Chapter 2.1.3.2 (emotional impacts) and then further discussed in Chapter 3.6. Secondly, I have included a criteria that the intervention should cover the spectrum of severity from normal infancy through to medical red flags and should be free and accessible to parents. These requests came from multiple conversations with parents and professionals through my PPIE work as part of my PhD (summarised in Chapter 4). Finally, given the overlap with feeding issues and the potential public health impacts on breastfeeding; I have included a criteria which specifies that the resource should provide explicit informed and skilled support for infant feeding [41]. This includes, as a minimum, the involvement of an International Board Certified Lactation Consultant (IBCLC) in the design or review of the materials.

Table 1 contains a curated list of the most relevant resources I identified and their key characteristics. I have rated each resource as either 'yes' (if it meets this criteria), 'no' (if there is evidence that it does not meet it) and 'unclear' (if I am unable to find evidence that it meets it). Please see Appendix A for a full summary table of existing digital resources and evidence-based interventions for unsettled babies.

Table 1: Existing digital resources and their characteristics

Resource	Tested in peer reviewed research?	Independent of commercial influence?	Designed to help parents identify medical red flags?	Dyadic approach, consistent with attachment theory?	Covers the spectrum of problem severity?	Underserved populations included in testing?	Supportive of parent mental health?	Accessible, freely available or easy to implement?	Informed support for breastfeeding? [41]	Co-produced or using 'effective engagement' with parents? [238]
Little orange book	No	No[1]	Yes	No	Yes	Unclear	No	Yes	Unclear	Unclear
NHS Choices	No	No[1]	Yes	No	Yes	Unclear	No	Yes	Unclear	Unclear
Healthier Together	No	No[1]	Yes	No	Yes	Unclear	No	Yes	Unclear	Unclear
CrySis Helpline	No	Unclear	No	No	No	Unclear	Yes	Yes	No	Unclear
ICON Programme	Yes	Unclear	No	No	No	No	Yes	No[2]	No	No
BabyBuddy App	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Unclear	Yes
Latch Aid App	Yes	Yes	No	Yes	Yes	Unclear	Yes	No[2]	Yes	Unclear

Resource	Tested in peer reviewed research?	Independent of commercial influence?	Designed to help parents identify medical red flags?	Dyadic approach, consistent with attachment theory?	Covers the spectrum of problem severity?	Underserved populations included in testing?	Supportive of parent mental health?	Accessible, freely available or easy to implement?	Informed support for breastfeeding? [41]	Co-produced or using 'effective engagement' with parents? [238]
Surviving Crying	Yes	Yes	No	Unclear	Unclear	No	Yes	No[2]	Unclear	Yes
Purple Crying	Yes	Yes	No	No	No	Yes	Yes	No[2]	Unclear	Yes
Fussy Baby Network	Yes	Yes	No	Unclear	Yes	Unclear	Yes	No[2]	Unclear	Unclear

1. Resources use recommendations from existing allergy guidelines, which have been demonstrated to have commercial influence [30].
2. These interventions are free at the point of access; but require local area commissioning for funding; meaning there is large geographical variation in accessibility.
3. Searches were completed between November and December 2021 and were conducted on google using keywords such as 'crying baby', 'unsettled baby'.

2.6.3 The evidence gap

There is a limited evidence base on how illness-related decisions are made in the context of unsettled baby behaviours, attributing symptoms to allergy or reflux [32, 241-243]. There are as yet no qualitative systematic reviews synthesising this evidence and attempting to understand the evidence collectively. Without thoroughly understanding this unmet need it will be difficult to effectively support parents. A systematic review of parent experiences of unsettled babies is therefore required. This systematic review represents the first research chapter of my PhD.

As outlined in the previous sections, it appears that families with unsettled babies require more support [31, 32]. There is a need for an intervention to help parents manage unsettled baby related health concerns and access accurate, unbiased information on colic, reflux and allergy to prevent misinterpretation and unnecessary medicalisation. This could take the form of a digital intervention to maximise cost efficiency and accessibility, as well as to fit with parents' growing reliance on technology to support parenting [235]. This resource needs to take account of infant feeding issues, help to identify where these are the likely underlying cause and signpost to effective, high quality support. The intervention should be rooted in attachment theory and supportive of the dyadic and developing parent-baby relationship. It should be evidence based and co-produced, or produced using extensive partnership with parents, including groups typically underserved by research [238]. The development of this intervention represents the remainder of my PhD.

Chapter 3 Methodological framework and theories.

In the following chapter I discuss three theories which underpin my PhD research. In addition, the person-based approach is presented as the methodological framework I am using for the intervention development.

3.1 Methodological framework: The person-based approach (PBA)

The main framework to underpin the research in this thesis will be the person-based approach (PBA), as outlined by Yardley and colleagues [2, 244, 245]. This approach offers a structure to develop a person, theory and evidence-based intervention incorporating behaviour change techniques. The PBA will help me ensure the research is grounded in the real-life experiences of families of unsettled babies. It will therefore help to ensure the resulting intervention is maximally engaging and acceptable to the target audience.

It is becoming increasingly clear that there is both a moral imperative and a logical imperative to include parents in the development of an intervention designed to support them [246]. Healthcare researchers who aim to have real-life impact from their work are advised to ensure partnership with the target audience is pursued throughout the scientific process [247]. The PBA is a well-accepted and well-evidenced way to achieve this goal, since it uses co-production techniques, embeds the intervention in user experience and blends well with related techniques such as public involvement and engagement [248]. There has been pragmatic and successful application of the PBA to develop online behavioural interventions in a wide range of health areas, demonstrating that this approach has a track record of usefulness in a broad range of subjects [2, 249].

The PBA is also rooted in health psychology and therefore considers the underpinning mechanisms to support behaviour change to improve the likelihood of efficacy of an intervention [2, 244, 245]. There is growing emphasis on understanding how an intervention works, rather than simply accepting that it does or does not [250]. This understanding of process is now seen to be important alongside outcome measurement in the design of new complex healthcare interventions [251]. Understanding exactly what works, for whom and in what circumstances makes the knowledge more practically transferable in the real world [252]. It also allows for replication and increased efficacy making it vital to intervention development [253]. The PBA offers a structured and systematic way to approach this [2, 245]. In my research I will therefore be using the PBA as a methodological framework to create a complex digital health intervention with applied behavioural science techniques.

As part of this methodological framework, there are a number of key aspects which are recommended for the development of digital behaviour change interventions in the field of healthcare. Firstly, the PBA suggests that within the planning phase of research, there is a need to understand the key behavioural issues, needs and challenges of the target population [2]. In my research this understanding will be gained throughout the systematic review and subsequent qualitative analysis and summarised in the Intervention Development Chapter 7.2.1 – user context. Secondly, guiding principles for the intervention are recommended, which will show how the unique features of the intervention will meet the needs identified in the user context [2]. In my case, this will be summarised in Chapter 7.2.4, guiding principles. In addition to these key features, the PBA often uses 'think-aloud' interviews as a form of intervention optimisation, where the intervention materials are presented to the target user and data are gathered about their engagement and acceptability as well as changes which need to be made. This process will be reported in Chapter 8 - Intervention Optimisation.

In this way, this thesis uses the Person Based Approach (PBA) as a methodological framework for intervention development.

3.2 Self-efficacy theory

Self-efficacy theory, originally based on the work of Bandura in 1977 [170], is one of the most powerful and influential theories in behaviour change psychology [170]. It functions best when it is domain specific, and has been successfully applied to the domain of parenting babies by many researchers [171, 254]. In the context of my PhD; it is particularly relevant to unsettled babies as it provides underpinning theory to help me understand the degree of confidence parents may feel in their ability to manage their infant's unsettled behaviours.

Parental self-efficacy (PSE) has been defined as the 'beliefs or judgements a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child' [171] PSE is a complex concept, explored in a concept analysis by de Montigny and Lacharite in 2005 [171] and distinguished from similar and related ideas of parenting confidence; which was described as a broader term, non-specific to situation or task [171]. 'Parental self-esteem' is another similar term; however this is believed to be connected to self-worth; rather than purely a judgement of personal capability [171]. It seems likely however that the two things are connected. Finally, parenting competence was highlighted as a related term, which is occasionally used interchangeably with PSE. The authors propose that parenting competence could be construed as a judgement of another person's abilities, rather than one's own [171], however measurement of the two concepts is often flawed and conflated across papers, contributing to a lack of clarity in the literature [255].

PSE can function in multiple ways within one parent-child dyad [255]. For example, PSE may be a precursor or a consequence, depending on the situation. High PSE can be seen as an antecedent or good starting point for acquiring strong parenting skills; low PSE as a consequence of either environmental challenges such as socioeconomic disadvantage or as a result of a particularly challenging parenting scenario such as a child with a developmental disorder [255]. This theory of PSE as a consequence could provide insight into the field of unsettled babies, as these could be considered to be particularly difficult babies to parent; thereby resulting in low PSE. Alternatively, or for some parents; it may be that an existing low PSE may lead them to perceive their babies as more unsettled due to a lack of confidence in their own soothing abilities.

As well as a precursor and a consequence; PSE could also be viewed as a mediator, where the environment impacts parenting confidence or child outcomes by reducing or increasing PSE. One such example of this is a classic paper which proposed that PSE could buffer the effects of maternal depression and child temperament on parenting sensitivity [256]. The mediation hypothesis has been tested in a number of studies and appears to have merit as an explanatory process [257, 258]. A further option is a positive or negative feedback loop. In this theory, parents with high PSE may have greater perceived success in parenting, which reinforces their high PSE, leading to a virtuous circle. In contrast, parents with low existing PSE may struggle with parenting, perceive themselves as failing or perceive poor child outcomes; leading to lowered PSE even further in a vicious cycle [255]. It is likely that all these mechanisms are in place to some extent in various ways across different parent-infant dyads.

Independently of the specific mechanisms and processes; two comprehensive review studies completed in 2005 and in 2019 consistently find that PSE is important for parent and child wellbeing [255, 258]. In the first review, PSE is linked to parent mental health and parenting satisfaction or enjoyment, although the causal direction of this is unclear and likely bidirectional [255]. There is also good evidence for a link between PSE and various child outcomes including child behaviour problems, socio-emotional functioning (including self-regulation) and child school performance [255]. Although less clear, PSE is considered to be a risk factor for maltreatment; since parents who feel confident in their parenting may be less likely to resort to harsh or abusive punitive measures [255]. This is particularly relevant in the field of unsettled babies as crying is considered a trigger of non-accidental injury in childhood [70].

The second review in 2019 updated the previous review [258], finding similar results and linking high PSE with a range of positive outcomes for parent and child including parenting skills, family functioning, bonding and relationship outcomes [258]. As previously discussed, it has been found to often function as a mediator in areas such as parent well-being, child temperament, attachment and

positive parenting styles and to have a strong link with parent mental health [258]. This second review also confirmed the findings of the first review in relation to child outcomes, in particular finding that child emotional and regulatory behaviours were strongly linked to PSE [258].

Specifically applied to the topic of unsettled babies, there was a study into PSE which found that higher PSE was correlated with lower ratings of baby fussiness, although the direction of this relationship is once again unclear [259].

Research into parent experiences unanimously finds that parents with unsettled babies feel that they are dismissed or minimised when they seek healthcare support [13, 71, 260]. This undermines their sense of self-efficacy and parents feel it worsens the presenting problems [32]. There is also a strong body of laboratory based research which positions coping with baby crying through a self-efficacy model, suggesting that higher PSE increases parents' ability to cope with baby crying [261].

Babies with negative temperaments have been noted to be at higher risk of obesity and inappropriate weight gain, and it is believed that this effect is moderated by parent self-efficacy [262]. There is therefore also good reason to believe that nutrition related outcomes can be altered by increasing parent self-efficacy [263, 264]. This is suggestive that the theory could have utility when applied to feeding patterns for unsettled babies, especially when considered alongside research suggesting the possible negative impact of medicalisation on breastfeeding outcomes by undermining parent confidence [39, 42, 51].

Overall, PSE is conceptually complex and difficult to define or operationalise. However, pragmatically it appears that PSE is a clinically important variable for the transition to parenting and for coping with and self-managing unsettled babies. It is likely that it is also important for a wide range of child and parent welfare outcomes.

3.3 Attachment theory

Based on the seminal work of Bowlby [239, 240], attachment theory is one of the most powerful and influential theories in the parenting and infant development literature. Bowlby suggested that babies used interactions with their primary caregiver in the early months of life to form an adaptive, relational blueprint which would predict their strategies to resolve emotional distress later on. Building on this theory, Mary Ainsworth developed a measure of attachment relationship known as the 'strange situation' which tested baby's responses to being left alone with a stranger and then reunited with their parent [265]. Ainsworth proposed categories of secure and insecure attachment which distinguished between babies who were distressed on separation, approached their parent on their return and were easily soothed and those who did not exhibit these positive social behaviours

[265]. These attachment styles have been found to be powerful predictors of a wide range of social, emotional, behavioural, relational, cognitive and psychological outcomes for the baby [266]. Whilst the methodology of the original strange situation technique has been critiqued and the attachment categories have been challenged, it is now almost universally accepted that a secure attachment relationship, or relationships, with a caregiver(s) is the optimal goal for child development [267] and that dyads at risk of or with attachment difficulties should be offered interventions to improve their attachment relationship [268].

To achieve optimal attachment relationships, parenting programmes advise parents to aim to be a secure base for the baby to explore the world from, and a safe haven for them to return back to when distressed [269]. The current dominant paradigm in modern psychology is that a sensitive, responsive parenting style that is highly attuned to and acts on baby cues is the best way to achieve positive outcomes and healthy social and emotional development [270]. This approach informs the UK's approach to health and social care and major governmental policies [267] as well as UK health visiting practice [271] and guidance for all frontline health, social care and education practitioners [272].

Attachment theory is supported by a wide variety of related research fields including evolutionary psychology, anthropology and neuroscience. Evolutionary psychology suggests that human babies are born highly dependent on their caregivers for both their survival and their emotional regulation [273, 274]. Anthropology research makes the argument that babies who woke frequently and cried when not held close to a caregiver were more likely to survive and therefore these behaviours which can be viewed as 'unsettled' should perhaps be reframed as evolutionarily adaptive and normal, although difficult to manage in modern society [274, 275]. Early neuroscience research built on this foundation to demonstrate how the human brain adapts on an individual level in response to our experiences, with synapses and neural connections strengthening based on environmental cues [276-278]. Researchers then supported this work by demonstrating that brain changes are linked to differences in attachment relationships with caregivers, subsequently connecting this with infant mental health [266] and a specific field of social, attachment based neuroscience has now emerged [279].

Coined by Daniel Siegal, 'Interpersonal Neuroscience' specifically builds on this foundation to further demonstrate how our early relationships interact with brain changes to shape personality and behavioural patterns in the long term [96, 280]. This research suggests that through sensitive, responsive parenting interactions, positive neural pathways are established and self-regulation or independence is learned [266, 281]. For the newborn baby, everything happens in the context of their relationship with their primary caregiver, and it is this relationship which helps to structure and

organise their developing understanding of the world around them [96, 240, 280]. Babies who are responded to in a sensitive, responsive way the majority of the time are therefore more likely to grow up to be more confident, independent and secure, with the neurophysiology to underpin this [97].

It is hoped that the intervention developed through this thesis may help to alter the interpretation of crying on the part of the parent in order to support attachment relationships and improve both parent and child wellbeing [156, 208]. Studies suggest that parent temperament ratings at 4-6weeks predict attachment security at age five years [282] and parent temperament ratings appear to moderate the relationship between excessive baby crying and parenting stress [283]. Parents who understand and rationalise their baby's crying as developmentally appropriate and as expressing a real need are more likely to develop healthy and useful strategies for supporting their baby; and are more likely to empathise with their child's distress rather than developing negative, temperament related attributions of their behaviour such as 'they're just doing this to annoy me' [208]. These negative attributions are common in the field of infant crying and are considered likely to be harmful [156]. Attachment theory may therefore offer a useful theory for an intervention attempting to help parents better understand infant crying.

Attachment theory has already been applied very effectively with interventions seeking resolution to the problem of difficult baby temperament, early crying, feeding and sleeping problems [225]. 'Possums' is a face-to-face, 'neuroprotective' support programme to help families with unsettled babies. It has been found to be effective and has its theoretical roots in attachment theory and interpersonal neuroscience [284]. Whilst the Possums programme is resource-intensive, it has demonstrated therefore that attachment theory may be a useful tool to support understanding of unsettled babies and to underpin the design of a supportive intervention. This suggests that attachment theory may be similarly useful in my research.

However, the most significant and enduring critique of attachment theory; particularly of the attachment style categorisations and the strange situation procedure; is that it is culturally relative. Attachment theorists claim that the attachment styles hold true across cultures and that the fundamental tenants of the theory are universal [285]. However, critics argue that the concept of a 'secure' attachment places too much emphasis on western ideals of attachment such as independence [286] and that the theory minimises multiple caretaking models of parenting, and emphasises instead individual, primary attachment relationships which are more common in Western, Educated, Industrialised, Rich and Democratic (WEIRD) societies [287]. A recent review and meta-analysis of 20,000 babies taking part in the strange situation across the world revealed that the categories were stable across cultures, although there were distribution differences between the

USA and other regions such as Asia, the Middle East and South America [288]. However, the review also found that there were higher proportions of insecure attachment in populations where this would be anticipated by the theory, such as populations with sociodemographic risk factors, parental psychopathology, maltreatment or institutional care [288]. This may suggest that there is a degree of cultural bias inherent in the theory, however that there is at least some degree of value in the underpinning concepts behind attachment security.

In addition, the proposition that parenting should be sensitive, attuned and responsive to produce optimal developmental outcomes; as suggested by attachment theory; is not universally accepted. Some researchers argue that it has yet to be empirically supported [177, 289]. This critique points out that there is an evidence gap and that research is yet to demonstrate that parenting which ignores or deliberately doesn't respond to a baby's cues is harmful to their relationships or outcomes in the long term. This is primarily because of ethical and pragmatic concerns with design of this research. There are also a number of methodological weaknesses with studies of controlled crying, such as the absence of baseline stress measures, insufficient longitudinal data and inadequate sample sizes [177].

In two recent studies, researchers aimed to test the impact of 'cry it out' parenting techniques on parent mental health, baby stress and child development, researchers recently found no significant evidence of harm [289, 290] including at a five year follow up [291]. However; these results have been contested. Proponents of attachment theory point out that there are significant concerns in the conduct of both these studies in the measurement instruments used and statistical flaws introducing potential for bias [292]. Particularly, in the 2020 paper [289], there was significant concern raised around a lack of clarity in the definition of 'cry it out' [292]. In this paper authors asked the question 'have you ever tried leaving your baby to cry it out during this time'. They did not stipulate or measure whether this was while the baby was awake, during sleep times, the length of time they were left, whether it was while the parent was unable to get to the baby such as in a car or as part of a deliberate parenting strategy, whether the parent was present or not, whether it was similar or different to parenting style in general at other times. All these factors may be important for determining outcomes and could introduce significant heterogeneity in the groups. Furthermore the measurement of child development used scales which were created for the study, unvalidated and aimed to measure 'easiness', 'task persistence', 'attention and activity levels' and 'social referencing' rather than the more broadly accepted domains measured by available and widely used child development scales [293].

When applied to the unsettled baby field, critics of attachment theory argue that the message that 'crying is harmful' is unsafe because it may push parents to breaking point and lead to non-accidental

injury; or because it causes unnecessary and unfounded worry for parents [177]. This is an important concern to be mindful of. It is possible that parents who internalise the importance of responsive parenting may interpret this to mean that they must constantly and perfectly respond to their crying baby without regard for their own needs [294]. Therefore the resultant intervention from this PhD; whilst rooted in attachment theory; also must consider and mitigate against this important caveat.

Furthermore, the proposed intervention resulting from this PhD aims to support parenting confidence and self-efficacy, helping parents to recognise their own parenting strengths rather than attempting to enforce a fixed set of rules or dichotomised ideals [294]. In this way, it is hoped that parent feelings of guilt may be reduced as their success as a parent depends not on their ability to successfully stop their child crying; but rather on their attempts to support their child while they do and their recognition of crying as a normative, healthy and evolved behaviour [295].

Modern attachment researchers have noted that there is still a large degree of uncertainty around many key questions relating to attachment theory [296]. Some have cautioned that there is concern around replicability with many of the seminal studies, and that this should be sought consistently before theories are taken from science to application in practice [297]. There is an important ethical issue to balance here; since translational medicine aims to have a positive impact in the real world; but it is important to make the impact proportionate and accurate [297]. In their analysis of the application of attachment theory to the child courts, Forslund and colleagues recognise this problem and address several misinterpretations of the theory [298]. In a pragmatic approach, they outline key principles which can guide practical applications of the theory – namely:

> "the child's need for familiar, non-abusive caregivers; the value of continuity of good-enough care; and the benefits of networks of attachment relationships"
>
> **Forslund et al 2022, pp 25-30 [298]**

It is clear that parenting and child development are highly emotive topics and are likely to lead to points of disagreement between researchers. However, I would argue that a review of the literature base as a whole including areas such as psychology, anthropology and neuroscience would be broadly supportive of attachment theory as the current dominant paradigm; useful as a way of supporting and promoting parent and child wellbeing in the transition to parenthood. Other successful interventions with similar aims have found attachment theory helpful in understanding families with unsettled babies [208, 225]. This is therefore one of the theories I will be using to guide intervention design in this PhD.

3.4 The Common Sense Model of Self-Regulation of Health and Illness (CSM) [299, 300]

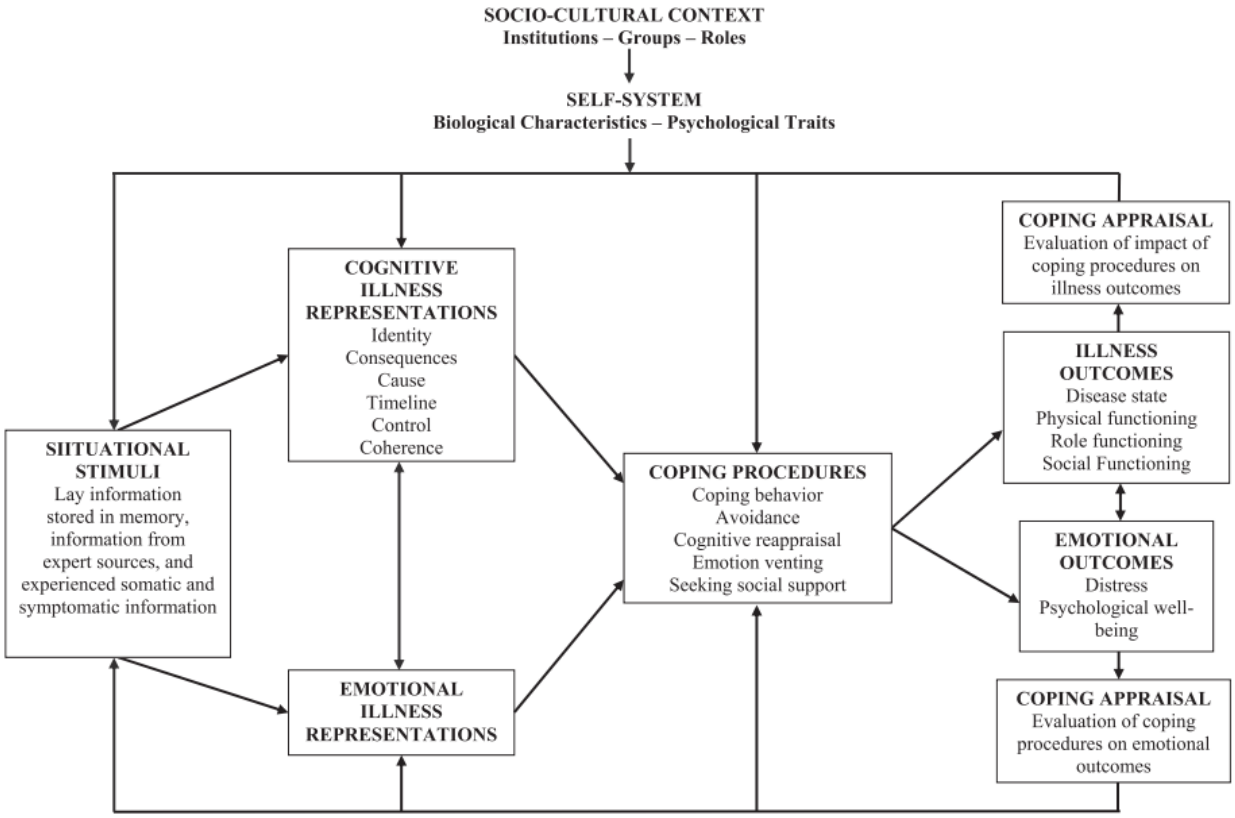


Figure 2: The Common Sense Model (CSM) [1]. Image reproduced from [2].

Throughout this thesis the goal is to understand how parents may perceive and interpret baby unsettled behaviours in order to support them to make accurate judgements of whether they need medical support and help them to confidently self-manage where appropriate. In doing so, it is helpful to look towards theories which may offer an insight into lay interpretations of symptoms and health threats [299].

The CSM proposes an understanding of how people understand, perceive and self-regulate illness. It includes cognitive psychology which attempts to describe how beliefs are formed about health threats as well as how these beliefs may influence coping and help seeking behaviours [300]. In this model (see Figure 3), a stimuli (eg. crying or vomiting) leads to an internal cognitive representation of the possible threat and the emotions associated with it. These representations then lead to coping behaviours and ultimately to appraisal behaviours which then focus attention on the stimuli again

[300]. It further includes emotional responses and sociocultural context and takes an individualised approach, illustrating how people may process illness differently from one another [300].

Although initially intended as a model to understand how patients perceive and self-manage their own health and illness, the CSM has been previously applied to parents of children with success and used to illuminate how mothers may make decisions about the health of their child [301] and to understand how parents may understand developmental delay in their young toddler [302]. In summary, the CSM may offer a useful theoretical basis for understanding and supporting unsettled babies and their families.

3.5 Schematic of Research

The schematic which follows is a visual representation of the contents of this PhD research and where in the thesis you can find it. 'Ch' refers to Chapter.

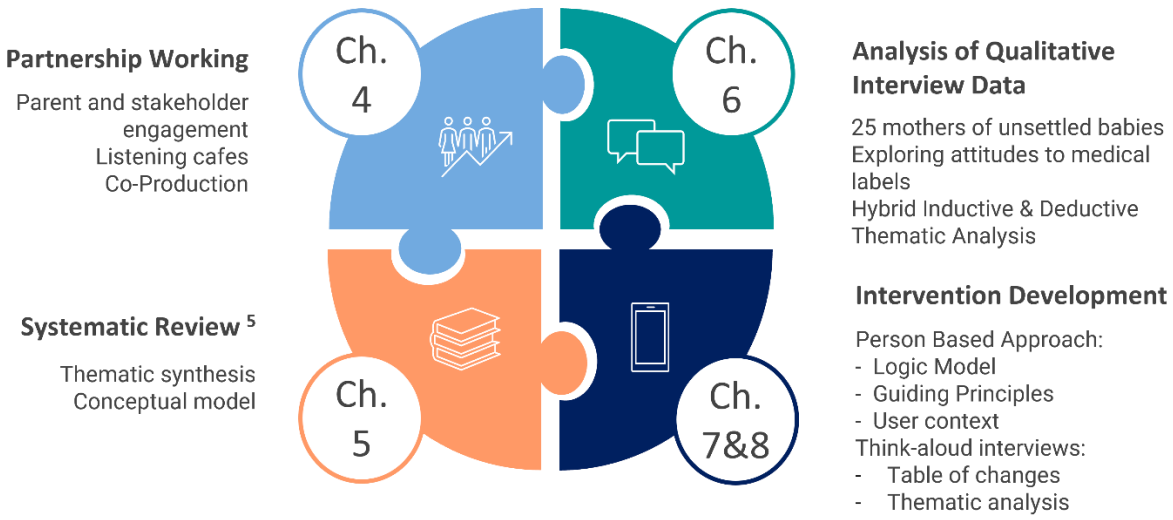


Figure 3: Schematic of research

3.6 Summary

In sum, this chapter has outlined the key methodological framework of the Person Based Approach and the rationale for using it. I also present three theories, the CSM, attachment theory and self-efficacy theory. These theories underpin the concepts throughout my thesis. Finally, I share a schematic of the various work throughout my PhD and how this fits together.

Chapter 4 Partnership with families and hearing the perspective of under-served groups

This chapter describes the Patient and Public Involvement (PPI) and Engagement work which I have completed to support this PhD. I will discuss my own learning in relation to inclusion of and partnership with underserved groups, how I planned and conducted a range of partnership activities and how this has changed or influenced my research.

The NIHR defines Public or Patient Involvement (PPI) as research which is conducted 'with', 'by' or 'in partnership with' members of the public or patients; rather than 'to', 'about' or 'for' them [303]. Engagement is when information or knowledge about research is distributed or disseminated [303]; although it is recognised that this process can be two way and that conversations through engagement work may influence research in a collaborative way [304]. Together, patient and public involvement and engagement (PPIE) are central throughout this body of research. This is due to the nature of the topic, being a common and highly emotive experience and the need for my intervention to understand and gently challenge existing beliefs or misconceptions which may be contributing to inaccurate medicalisation of unsettled babies. The perspective of parents who are not currently experiencing unsettled baby behaviours, but may have in the past or may have seen friends or family members experiencing this will be invaluable in helping me to learn an appropriate 'tone' or 'language' through which to do this. Furthermore, the PBA has the user voice at the centre and therefore fits well with other coproduction and parent led types of research [305]. The following chapter will detail how different forms of PPIE were conducted throughout this PhD and the key outputs of each. Impact of PPIE directly on elements of the resulting intervention are summarised in the intervention design Chapter 7. The reporting of PPIE in this thesis has been checked against the GRIPP-2 checklist to ensure comprehensiveness [306]. Over the course of my PhD, I have prioritised training and learning in this area and this has contributed to my confidence and enthusiasm for PPIE.

I developed a plan for PPIE early in my research journey which I regularly updated throughout the process (see Appendix B for version 6). This allowed me to have clear goals and planned outcomes from engagement and involvement activities. These are detailed in Table 2. My completed PPIE activities are then summarised in the text below. I did not complete all the activities planned in Table 2, and other activities were included opportunistically which had not been planned.

Table 2: Planned public and clinician involvement and engagement activities and their aims (taken from PPIE Plan V6 see Appendix B)

Type of Engagement	Aim/Purpose/Goal
Informal community group engagement	How is the language we are using perceived?
Informal community group engagement	What is the most acceptable term? “unsettled infant” / “common infant symptoms” / “unhappy baby”?
All	Gain a breadth of understanding of the Phenomenon of Interest (PoI)
Listening cafes, PPIE on research materials, informal community engagement	Get a sense of how to pitch the emotive or potentially contentious issues, start thinking about future impact and implementation.
Listening cafes, informal community engagement	Understand where the intervention fits within the wider community from a parent perspective
Stakeholder engagement, IBCLCs[1], HVs, GPs	Expert review of content
Stakeholder engagement, IBCLCs, HVs, GPs	Spot inaccuracies
Stakeholder engagement, IBCLCs, HVs, GPs	Identify any missing information
Stakeholder engagement, IBCLCs, HVs, GPs, service leaders, policy makers.	Consider impact and where the intervention could practically fit into and complement existing services.
PPI forum	Diverse recruitment strategies
PPI forum	Study materials review
PPI forum	First review of the logic model
Listening café; research Participants – in co-production (think-alouds)	Website content feedback – shaping and tweaking
Research Participants – in co-production (think-alouds)	Website navigation and layout feedback
Research Participants – in co-production (think alouds)	Website design feedback

1. International Board Certified Lactation Consultant (IBCLC)

4.1 Informal community group engagement

With permission from the group organiser I attended three ad-hoc, drop-in parent and baby groups in different areas to discuss my research with parents. This engagement was opportunistic and

informal, so data was not gathered about specific parent demographics and numbers; however I spoke with parents with a wide range of cultural heritage and attended groups run in areas of relative affluence as well as deprivation. I aimed to get feedback on how the research topic was received, what language parents were comfortable with using in referring to unsettled babies. From other research, 'common infant symptoms' had been used in the literature; however parents felt this sounded too dismissive. Unsettled babies seemed to convey a clear meaning, although some parents were slightly hesitant to talk about it, perhaps suggesting the term has slightly negative or judgemental connotations. Parents offered suggestions of terms such as 'highly sensitive' or 'orchid baby'; however others felt that these terms were not descriptive or clear enough.

In general, when asked what they understood by unsettled babies, all parents mentioned sleep, wanting to be held a lot and crying frequently. Some also mentioned vomiting and colic or gas. Many parents instantly related to the term, the below quote is an example of the type of thing many people have said to me informally over the course of my PhD.

> *'[unsettled baby]…oh yes, I've got one of those!'* ***Parent***

In these engagement sessions, parents frequently talked about comparison with other babies, social support and the importance of a strong social network, postnatal depression and feelings of guilt or failure. All the parents I spoke to were enthusiastic about the research topic and said they would value an app or a website. Parents said they would want access to the intervention antenatally, but when asked about where they had looked for similar support all the information volunteered was about postnatal baby information sources.

Two parents at different groups mentioned the idea of having regular prompts or notifications from the app, perhaps about baby health or development, to encourage them to use it.

In addition to organised parent and baby groups, I also took part in a community Research Café run by the Public Engagement and Research Unit at University of Southampton. This was held in a city centre café and included myself and two other researchers talking about their topic with five members of the public. There were interesting and thought provoking conversations relating to involvement of trusted and experienced older family members in the raising of children and the role this may play in parent confidence and reassurance with common symptoms like crying and vomiting. In particular, one member of the public reflected on the differences and challenges in two social settings between China and the UK. We discussed the tradition of family 'wisdom' being passed down in China and contributors suggested that the helpfulness of this is not necessarily the content of the advice but rather the person delivering it. If they have lived experience this was thought to be likely the most helpful characteristic. We talked about how being given advice from family members can be difficult if you know that it was not accurate or evidence-based, or when you

don't agree with it yourself. This prompted discussion about the proliferation and growth of technology and industry, both in terms of commercial parties biasing research or information families receive and also in terms of moving away from more 'natural' or 'traditional' approaches to healthcare. The tension between this industrial or technical approach and the relational, familial 'wisdom' was the main focus of the conversation at this event.

4.2 PPI forums

Two presentations at an existing PPI forum run by the University of Southampton Primary Care Research Centre were completed to get general public contributor thoughts on my research topic and research plans.

The first, in February 2022 was attended by four experienced public contributors and a PPI co-ordinator and took place at an early stage of my research. It allowed me to give them an overview of my research topic and early research plans and ask for contributor ideas on how to fund PPIE, how to access diverse groups of parents and how PPIE might best be used in this research. All four contributors in attendance felt the topic was important and worth researching, all citing examples from their personal life where parents had struggled with babies. We discussed the expectations or desire for 'perfection' and how this may not be met when parents are faced with a baby who struggles to sleep or has other medical concerns such as asthma or eczema, or where the parent faces additional social or emotional challenges. Underlying guilt as a common experience amongst new parents was raised as a relevant consideration. We discussed funding for involvement and engagement work and how I might reach parents from underserved communities, both as participants in my research and as possible PPIE contributors, and the members of the public on the forum were able to offer some useful suggestions (such as through early intervention keyworkers, children centres and NCT groups). In terms of the research plans to develop an intervention, the contributors offered advice on the use of the term 'intervention' in my parent-facing materials, thinking that this may be confusing and unclear. They further suggested that PPIE work may be helpful for understanding what type of intervention parents would use and how it might be accessed.

The second forum was organised by Wessex Public Involvement Network (PIN) and attended by four public contributors and a PPI co-ordinator on the 14th June 2023. All the contributors were older people and all had personal experience of a baby they would describe as 'unsettled' between 40 and 50 years previously. At this forum I presented results of my systematic review and all the contributors found these highly relatable. As such this offered an entirely new perspective on my research topic and underlined the importance of the issue; since all four contributors reported still

feeling significant emotional impact from the experience even four or five decades later. The following quote is from an email following the forum, shared with consent.

> *"It was actually consistent with what I believe often makes for the best PPI...People [with lived experience]…are often motivated to get involved in research because they want to be a part of making sure that people in the future don't have to go what they went through… it was clear from the group this morning that your research…unlocks this motivation, even in people who had children decades ago...I have had a couple of emails since emphasising how important they think your work is."* ***PPI Co-ordinator***

At this forum we discussed the importance of the older generation in terms of bringing confidence and experience for the new parent, described by contributors as their 'granny role', they felt it was partly to reassure parents of 'normal' baby behaviour. We also discussed the 'evolutionary normal' contrast with today's culture and how contributors had seen that culture change across their lifespan. Finally we discussed parents experiencing a fear of judgement. Interestingly, contributors suggested that this was worse back when they were parents, than in modern society. They felt that neighbours and peers genuinely were judging them, wondering what they were doing wrong; whereas they felt this was unlikely for parents today. They suggested that it would be useful to have something available online so that you don't have to admit to anyone that you're struggling, in order to prevent fear of judgement becoming a barrier to accessing help. There was a repeated and strong universal opinion that the intervention needs to be based around parents' own voices in order to be relatable.

We discussed timing of the resource or intervention, and opinions were divided on this. Some felt that an antenatal resource might be helpful. Others suggested that sometimes people don't know what they need until they need it.

Contributors suggested specific groups of parents who may be more vulnerable such as older parents, single parents or those without a good social support network. They also felt that 'successful' people who have perfectionist tendencies and feel in control in other areas of their life might struggle with having an unsettled baby.

4.3 Listening cafe

In addition to the informal methods and the PPI forums I have described so far, I additionally organised more formal partnership and engagement work in the form of listening cafes. These are described below in more detail than the previous sections, to reflect the additional time commitment and organisation.

4.3.1 Methods:

Together with the Primary Care Research Centre PPI officers and supported by my supervisor (IM) I led a series of three 'listening cafés' for eight mothers with unsettled babies, all of whom came from economically disadvantaged areas. The mothers were identified by children's centre key workers who were familiar with the needs of the local community. The sessions were held weekly on the 7th, 14th and 21st October 2022 for two hours each. They included a creche for the babies, an icebreaker, food and a craft activity to share as a group. The same families attended each week which provided an opportunity to build a trusting relationship and create an open, non-judgemental atmosphere to allow families to engage confidently with the research topic and offer their perspectives freely. This opportunity to build trusting relationships has been shown in PPIE literature to be key in working with underserved communities [307]. Each week I prepared topic starter questions and prompt stock photo images which gave an opportunity for families to share their experiences of unsettled babies as well as to discuss their thoughts about my research findings and their support needs for a digital intervention. Throughout, and where relevant, I shared some early findings and themes from my systematic review to get parents' views and opinions on these. On each occasion there was a significant degree of overlap in the themes emerging from the systematic review and the experiences reported by the contributors at the listening café.

We had a flexible approach to planning for the sessions; which involved reflection between myself and my supervisor IM after each session and adaptation to the plans for the subsequent week if needed. In the first week we did a gentle 'getting to know each other' session. We used a series of photos of unsettled babies and a list of topic starter questions to allow parents to begin sharing their experiences of unsettled babies and the challenges they had faced. Topic starters are listed below and the photo prompts are available in Appendix C.

Topic Starters:

1. Digital
    a. Did you use any online resources?
    b. Did you go looking for them yourself? Did someone recommend them to you?
    c. Did you have any trouble accessing them or using them?
2. Listening
    a. Do you remember ever feeling understood or listened to?
    b. Do you remember any websites, books, apps or resources that you felt were written by someone who understands? What did they have in common?
3. Finances

   a. Sometimes people talk about having an unsettled baby being expensive, because they felt like they had to buy more teats, bottles, medicines etc. Did you find that?
   b. How about with buying formula milk or stopping breastfeeding, was money ever a factor for you?
4. Self-efficacy
   a. Did you find that your baby's symptoms knocked your confidence at all?
   b. Were there times when you felt super confident, like 'I've got this.'?
   c. Is there anything that you think would have helped to make you feel good about yourself as a parent?
5. Healthcare professional advice.
   a. Would you see a HV/GP/nurse, anyone else?
   b. What do you want from a HCP?
   c. What makes you feel supported / listened to?

In the second week we explored attitudes towards medical labels, discussing diagnoses of allergy, reflux as well as treatments such as specialist milks and reflux medications. I prepared some quotes from parents taken from the systematic review and inspired by previous informal engagement work with parents at drop-in baby sessions and children's centres. These provided talking points and an opportunity to raise more difficult issues such as feelings of guilt and failure, bonding problems and feeding grief and trauma. The quotes were printed onto large paper and put on the table as open discussion starters. They are available in Appendix D.

In the third week I used flip chart paper with some key headings at the top focusing on specific challenges parents had talked about (eg. feeling judged, not having the facts on medical conditions, feeling dismissed and not listened to, feeling guilty and out of control). Together we discussed possible features of a digital intervention which might help to resolve some of these concerns. The suggestions parents made are summarised in Chapter 7. At the end of the three weeks the parents were given a thank-you gift bag with some self-care items.

Twelve months later I returned to the same venue and invited the same parents to come back for an update. I shared the progress of the project and some video content I had developed since the listening cafes, the slides from this session are available in Appendix E. I shared a leaflet which summarised the key messages I had got from the listening cafes and the progress made on the research topic since the end of the three sessions. This leaflet is available in Appendix F. Parents were very positive about their experiences in the listening cafes and resulting resources and expressed great enthusiasm about the project as a whole.

4.3.2 What did parents say?

4.3.2.1 The impact of unsettled symptoms

Parents shared the intense impact their infant's symptoms have had on a huge range of factors including their quality of life, relationships with family and friends, daily life and activities, mental health and their bonding with their baby. All parents had experienced very significant impacts on their emotional well-being during this period and many felt that although the worst of it was behind them, it had had some lasting impacts on their mental health and/or their relationship with their baby.

4.3.2.2 Financial implications

Parents described how expensive having an unsettled baby had been. They talked about experimenting with different milks and how expensive formulas are; different bottle types, teats and over the counter medications. They said that when their baby was on a specialist milk which was prescribed; this definitely helped with the cost because then the milk was free. When I asked whether they thought this impacted their decision to give the prescribed milk rather than buying normal formula they said this wasn't the case. Most said that next time they would prefer to continue breastfeeding for longer so as not to have to buy formula or use a prescription.

4.3.2.3 Infant feeding

As soon as unsettled symptoms were raised; infant feeding was a topic of conversation. All the parents connected the symptoms with feeding instantly. Multiple parents reported dreading feeding and all connected crying behaviour, vomiting or other behavioural cues with pain; the root cause of which was related to feeding in some way.

Parents talked about how they felt they had missed out on feeding as a bonding experience, or even that they felt rejected by their baby when they tried to feed them. They described how baby would arch their back or push away from them while feeding, crying and uncomfortable and how this had felt like the baby was pushing them away, or like they were failing as a parent.

Many of the parents in the group had stopped breastfeeding earlier than they planned or wanted to. Some had struggled for several weeks with difficulties breastfeeding. All parents had an implicit understanding that the foods they ate 'went into their breastmilk' in some way; and many had tried exclusion diets. Many described difficulties with weight gain in the early weeks which could explain infant symptoms; however they did not connect these two things, believing instead that there had been something in their milk causing the unsettled behaviour rather than a milk transfer or latch issue.

All the parents reported feeling immense judgement around infant feeding, typically this was described as being anticipated or perceived rather than experienced directly. One reported still feeling upset (her child was over 1yr) at having 'failed' to breastfeed. When describing their early breastfeeding experiences parents often appeared to want to emphasise how hard they had tried, or how difficult it was, or to justify or explain their decision to switch to formula.

Some of the parents had heard of responsive feeding techniques and tried them. None had had a discussion with a healthcare professional about milk quantities and how to tailor or titrate the amount of formula a baby might need to that individual baby.

One parent was in the process of getting an allergy diagnosis and had been advised to reintroduce normal formula to see if the symptoms re-emerged (as per NICE guidelines) but was very reticent to do this. She felt that it was unnecessary and didn't want to cause the symptoms to get worse again; so she was planning to continue on the specialist milk.

4.3.2.4 Experience of help seeking

Parents had all sought medical help for their baby's unsettled symptoms. All had been given a label of reflux or allergy, or were in the process of diagnosis for this. All parents had felt fobbed off, dismissed or not listened to by healthcare professionals, particularly specifying GPs and Health Visitors when they had tried to discuss their concerns.

Parents described feeling uncertain about when to ask for help from a healthcare professional. They said they 'couldn't win', since they would feel guilty, judged and criticised if they didn't ask for health advice about their child's symptoms; but equally when they did ask for advice they felt they were written off or seen as 'time wasters' or labelled as an 'overanxious first time mum'.

All parents described a desire to feel as if the healthcare professional understood how hard it was to have a baby with these symptoms. They felt that professionals were looking only at the physical needs and not recognising the emotional impact, which they knew to be significant.

Parents reported openly that they felt distrustful of professionals and said they often felt more comfortable talking honestly about their parenting experiences with other parents. They said that professionals might judge them, think that they 'weren't coping' or refer them to social care. There was a fear that admitting that they were finding it hard might ultimately lead to their children being removed from their care. Many parents stated that they were anxious whenever they attended A&E because they were aware of a '3 strikes' rule, which meant an automatic social care referral if there were 3 attendances in 1 month. Parents stated that awareness of this rule might mean that they ultimately didn't seek HCP support from A&E when they otherwise might have, because they were

scared of the referral to social care. I expressed my surprise that a discussion about social care had emerged when we were talking about unsettled babies; the parents reported that they often worried about this. Many of them reported having had personal experience, or had friends and family who had had experience with children's services.

4.3.3 Feedback:

Evaluation forms were collected from all parents in attendance. The parents who attended the group expressed finding it enjoyable and cathartic. They reported they liked having a space to themselves which was a break while they knew their baby was well cared for in the creche. They also enjoyed the opportunity to share experiences with other parents and to feel validated in knowing they were not alone. Finally, they reported feeling a sense of satisfaction and pride that they were contributing to research which might help future parents with unsettled babies. The accessibility and non-judgemental atmosphere of the sessions was reported to be important to creating the safe space needed to address some of the more emotive topics. Quotes from the evaluation forms are shared here with consent.

> *"I love the level of honesty in the room"* ***PPI co-ordinator***
>
> *"Fridays are always the best day of the week now. It has been so nice to hear other mums saying the same stuff"* ***Parent***
>
> *"It's so much better now to know I'm not the only one who can't stand their kid sometimes!"* ***Parent***

4.3.4 Impact on research

The listening café had numerous influences on my PhD research. Specifically, their ideas input into the content and nature of the intervention through particular features such as a 'symptom checker' (see Chapter 7 intervention design for more details). The experience of discussing unsettled babies with these parents also gave me a thorough sense of how strongly these parents feared judgement, particularly from professionals. This was instrumental for intervention development to inform the tone and 'voice' of the intervention content. The opinions of the parents attending the listening cafes was also strongly influential in the 'parent quotes' which were used throughout the intervention; since they emphasised the importance of the website having a 'genuine' voice from other parents who had lived experience. Many of the comments and conversations I had with these parents informed the content of the quotations on the resulting intervention.

4.4 Public involvement in preparing study materials

In addition to outreach PPI and engagement already described, I also utilised more traditional approaches in asking parent contributors to review study materials. Two PPI contributors reviewed public facing documents for think-aloud interviews, as well as the lay summary in the study protocol and their comments were integrated before submission to the University of Southampton Research Ethics Committee. As a result of their input significant changes were made to the wording to make it simpler, more inclusive, more appealing and less emotive.

The contributors were chosen to reflect different perspectives. One parent is an experienced public contributor (now a PPI co-ordinator) with an older child who had previously been unsettled as a baby. She brought this experience to her review of the materials and was generally very positive in her feedback about them. I made some small changes to the wording to make it clearer based on her recommendations.

The second parent is a mother of a toddler who has food allergies and maintained a strict exclusion diet throughout her feeding journey. She strongly believes in the importance of the parent voice and often felt dismissed by healthcare professionals. Her feedback was extremely helpful as it reflected this sensitivity to feeling dismissed or patronised and the changes I made to the materials as a result of her comments were to make them less emotive, more friendly and non-judgemental.

The second PPI contributor also designed the think aloud study posters to be shared on social media. These included a range of images depicting families with different ethnicities.

4.5 PPI with European parents

I was aware of the importance of considering cultural influences on the perception of unsettled babies (see Chapter 2.5.4.2); and thus far in my PPIE work I had not been able to reach many parents with diverse cultural heritage. After posting on social media asking for volunteer parents of unsettled babies with cultural heritage and identity different from my own (white British) to speak to me about their experiences parenting and differences in parenting beliefs and norms across cultures; I received contact from three parents who wanted to speak to me about this research and one-off individual phone calls were arranged. All three parents were reimbursed for their time in line with NIHR recommended PPI payments [308]. These were all mothers and all were first generation immigrants from Russia (Moscow), Romania and Spain. All had been in the UK less than ten years. One parent had two children, one of whom had been born in the UK and one in their country of origin. The other two had both given birth to and raised their babies in the UK. Although the UK is within the European continent, all three parents viewed the UK culture as being different from that of their country of

origin. All three parents had relatives living abroad and reported feeling strong cultural connection to their birth country.

There were some differences in their experiences but overall more commonality than difference. This may possibly have been because by co-incidence all three women were European.

4.5.1 Healthcare Systems

All three women reflected on the experience of the healthcare system in the UK being very different to their birth country, where healthcare (especially childbirth) was more medicalised, appointments and 'check ups' were more frequent and specialist advice from private practitioners was easier to access. This cultural experience or knowledge was seen as a form of expectation setting; determining what they expected and wanted from the UK system.

Two of the mothers mentioned continuity as a specific difference, since private providers allowed them to choose an individual they preferred and build a relationship. They felt this continuity was important to help them feel cared for.

When worried about their baby, each of them expressed feeling scared, anxious and worried that they were 'missing out' on important health checks and the guidance and reassurance they needed. One mother found she missed the more paternalistic approach in their birth country, saying she 'just wanted the doctor to tell me what to do and when'. Another mother felt her GP had been dismissive of her baby's problems and she should have been seen more promptly and that more 'thorough' tests or investigations should have been conducted to get to the 'cause' of the problems – this was what she would have expected and what she ultimately sought out in her birth country. She said that she perhaps should have exaggerated the problems to get seen here in the UK and wondered whether this was what other parents did. One parent recognised that the downside of increased medicalisation was that they might get unnecessary treatment and expressed that she worried about using up NHS resources in this way.

All three parents mentioned that they felt reluctant to trust the UK health system; either because of the lack of continuity of care; or the absence of regular 'check ups'; or both.

In the context of unsettled babies; this might be relevant for parents who are worried about behaviours which are within normal range as they find it difficult to access the reassurance they need. This reassurance when given may be less effective due to the lack of trust in the healthcare system as a whole.

4.5.2 'Traditional' parenting views

All three parents expressed that early days of parenting were difficult with less support network than they would have had in their birth country because family members were abroad. However, all three also described differences in views between themselves and their parents about how to raise babies. All three reported their parents had more 'traditional' or 'strict' views on parenting; saying that babies should be left to cry and not responded to immediately. It was difficult for us to separate whether this was a generational issue or a cultural one – with all three parents feeling that there was a 'modern' generation of parents in their birth country who were trying to parent in a different way, influenced by research (in particular they mentioned breastfeeding in public; routine childhood vaccinations and consistently responding to their baby's cries). As one parent put it 'there's a whole generation of mums having the same argument with their own parents right now'. Parents also discussed key political or social issues in their birth countries which may have had impacts on cultural parenting norms.

Finally, one parent discussed how her cultural identity and sense of belonging became very important to her when she became a mother herself. She described how becoming a parent was a big step or change in her life and when she was pregnant she was very keen for her baby to grow up experiencing a mix of cultures and retaining a sense of cultural identity. She felt her baby's arrival had encouraged her to make an active effort to engage with her heritage to give her child this opportunity. This might suggest that cultural identity is of particular importance to parents in the transition to parenthood.

4.6 Conclusions

4.6.1 Strengths and Limitations:

Not all my planned PPI activities took place in the way I had intended, mostly for pragmatic reasons of time and funding. This had both positive and negative impacts. Whilst I was unable to build a PPI panel as I had initially planned; this was altered in favour of one-off PPIE work with two contributors and some additional 1:1 engagement work with parents from European cultures (outside the UK) which had not been previously anticipated. I also took unexpected opportunities whenever they were available to increase my public involvement and engagement and gain new perspectives and opinions on my research. Examples of this included discussing my research at two PPI forum events and volunteering with the 'life lab'. The PPI forum is an online group session which brings together public contributors with researchers to stimulate discussion on research topics. The 'life lab' offers students from local schools the chance to meet researchers, learn about research and scientists to

learn about communicating their research effectively and hear a whole new perspective on their work. Although neither the older members of the public attending the PPI forums nor young people were a planned target population for my PPIE, each had new and different perspectives to offer on my research which I believe have strengthened the overall quality of the research.

One limitation of my PPIE work was that I could have had more explicit or objective measures of impact and of outcomes. Aside from the listening cafes, which had a short evaluation form, there was very little formal evaluation of my PPIE activities. This is something I would change in future PPIE work.

4.6.2 Research context

In the course of my PPIE work I have learnt about the differences, similarities and relationships between patient and public involvement, stakeholder engagement, parent engagement, co-production, participatory research and qualitative research. In their 2019 paper, Locock and Boaz discussed the overlaps and differences between these similar methods and recognise that they have similarities in their fundamental principles of inclusion, as well as similar potential downfalls of becoming tokenistic, despite good intentions [309].

In my PhD research, I have tried to maintain clear boundaries between PPIE and research data. Specifically PPIE has been used to inform mostly the conduct of the research itself, with contributors as partners in the research process, rather than as research participants contributing findings [310]. However, there are occasions where some part of the discussion in a PPIE context was then echoed in research findings. One example of this is the conversations with members of the public about balancing traditional cultural wisdom with modern evidence-based advice, which were similar in concept to findings from several qualitative interviews which discussed the challenges of balancing commonly practiced cultural solutions with NHS advice (examples in Chapter 6.4.2.2.3). It is interesting perhaps to consider that my previous conversations with PPI contributors on this topic may have underpinned my interpretation or understanding of this research data.

Considering the role of PPIE and how it functions alongside qualitative research also raises important issues of power and ethics in research. According to UK Health Research Authority guidelines, full ethical approval was sought and given for all the research data gathered in this research, however for the PPIE this was not required [311]. Theorists have argued that needing ethics for every piece of PPIE work puts unnecessary barriers in place, particularly for the participation of underserved communities and may make research less accessible to the public [312]. In my own PPIE practice, I have noted the value of being able to recognise and include the contributions and ideas from informal conversations, opportunistic discussions with parents and the public about my research

which had not been pre-planned. PPIE gave me a space to be able to acknowledge the contribution these conversations made to my research and to my positionality. In addition, it has been argued that where true partnership is achieved, paternalistic ideas about participants requiring ethical protection from researchers appears to imply a power imbalance that should not exist in, for example, participatory action research [309].

A thoughtful discussion is emerging in the literature about the extent to which the clear delineation between these related fields is beneficial and required; and the possible benefits which could come from recognising where they overlap, interact and may complement each other [309]. In my PhD work, I have tried to draw clear lines between the roles of public contributor and research participant; however I acknowledge how these two approaches could work harmoniously together in community-based or activist research methods such as participatory action research [309]. It could be argued that the label used to describe the activity is less important than the authenticity [309], roles, outcomes and enablers of the partnership interaction [313]. It is possible that future work will consider how the patient voice may be more powerfully harnessed by these related approaches collaborating their efforts [309].

Chapter 5 "There must be something wrong or else I'm just a terrible parent": Systematic review and thematic synthesis of parent experiences of unsettled babies.

5.1 Introduction

Upon starting my PhD it became clear that parents of unsettled babies currently have unmet needs within our healthcare system. This is exemplified by their frequent presentation to services, high and increasing service use and the impact of unsettled baby behaviour on family life (see Chapter 2). It is possible that the parent unmet needs could be part of the reason for the escalating medicalisation of unsettled baby behaviours, however there is no systematic review considering parent perspectives and attitudes towards unsettled baby behaviours that focuses on medical labels. It is possible that these labels are serving a purpose for families. Without understanding the parent perspective, any attempts to reduce medicalisation may remove the label without meeting the need, leaving parents and babies without the strategy they have been relying on thus far. Therefore my first task of my PhD is to understand the parent need and what purpose the label serves within the family context, so that my subsequent intervention can be supportive and helpful for families. This chapter therefore summarises my first original piece of work - a systematic review. This systematic review has been published in the Journal of Advanced Nursing. A copy of the published article is publically available [314] and is also available in this thesis as Appendix N.

5.1.1 Study aims

The aim of this review was to explore parent experiences of unsettled babies, with a particular emphasis on their thoughts and feelings about medical labels for their baby's behaviours (such as allergy or reflux). I also hoped to produce a thorough understanding of the parent experience which could be clearly communicated and articulated in the format of a conceptual model.

- RQ 1: What are the experiences, thoughts and feelings of parents/carers of unsettled babies, with particular reference to medical labels?
- RQ 2: What is the underlying need of parents with unsettled babies that leads them to medicalise behaviours and/or seek medical help?
- RQ 3: What purpose are diagnostic labels and / or medication serving for families of unsettled babies?

- RQ 4: Can I develop an explanatory, conceptual model of the parent experience when faced with an unsettled baby?

5.1.2 Study design

When developing the research question for the systematic review, I considered several potential options. One option was to complete a systematic review of interventions for unsettled babies including a review of their behaviour change components. Upon carrying out a scoping search, I discovered that a very similar review was registered on Prospero [315]. On contacting the author and discussing each of our research plans and her progress with her systematic review so far; I decided not to pursue this research question as it was likely to lead to duplication.

On reflection and discussion with my supervisory team I decided to explore qualitatively the parent experience of unsettled babies as I felt this would offer an opportunity to obtain a rich, deep understanding of parent perceptions, thoughts and views. I was hoping by understanding the parent perspective in this way to gain an insight into what function the medical labels are serving for parents and therefore how we might meet that need through a non-medical route in the intervention development phase of the PhD.

I created a protocol for the review and registered it on Prospero (CRD 42022355249).

5.2 Methods

ENTREQ guidelines were followed in reporting this research [316]

5.2.1 Eligibility criteria

Primary, qualitative research studies with data about unsettled babies less than 12months of age were included in this review. Unsettled behaviours were defined as perceived excessive crying with one or more additional issue such as vomiting, skin problems or stool problems. Studies about baby crying alone were only included where the findings or results section contained discussion of other symptoms e.g. gastro-intestinal symptoms or discussion of how parents construct medical-or illness-related narratives of the crying. Studies looking at IgE-mediated allergy were excluded as this presentation is markedly different and can have potentially life-threatening implications and as such represents a different experience for parents. Studies aiming to evaluate an intervention or tool were excluded if these did not focus directly on parent experience of unsettled babies. There is a well-established concern around commercial influence on academic publication, particularly in the field of unsettled babies, reflux and CMA (see Chapter 2.5.3). Therefore studies which reported involvement

or funding from the formula milk industry were excluded to protect against possible commercial bias of the results.

5.2.2 Information sources:

5.2.2.1 Databases

The search was written for the most relevant database. Following discussion with a specialist librarian and in light of its value for locating qualitative research [317], this was determined to be CINAHL; then adapted for replication in Medline, Embase, PsychINFO and Cochrane clinical trials register (for mixed methods trials). Searches were run from inception, completed on the 23.03.2022 and rerun on 14.04.2023. I did not apply any language restrictions.

5.2.2.2 Grey literature

In addition to database searching I completed a grey literature search and a hand search for relevant reports and literature. This comprised searching relevant grey literature databases (Social Science Research Network, ClinicalTrials.gov). I completed Google Scholar and Google searches of key free text terms (see Table 3) and using the filter filetype:pdf to identify policy or guidance documents. I reviewed academic conference proceedings, parent blogs, charity, commercial, news outlet and other organisation websites which appeared using the google search terms (Table 3) and considered relevant articles for inclusion. I screened articles if they appeared in the first five pages of google search and had titles which appeared relevant to the review topic. I took the decision in the interests of making the best use of time not to screen online forum posts, since there are two recent studies of online forum data which met the inclusion criteria for this systematic review [126, 242]; so this would have been unnecessary duplication.

My grey literature search identified 27 additional pieces of data or literature which appeared relevant. One of these was unpublished research which was relevant and therefore included [126]. I recognised that some of the remaining 26 articles may provide interesting additional perspective. However I was unfortunately unable to include these in my thematic synthesis primarily because they were not directly reporting parent voices, they were written directly by or accepted funding from a commercial industry or because they were individual parent blogs and therefore unsuitable for thematic synthesis or quality assessment. I noted a significant difference in the content of the articles on formula industry websites; observing that these articles tended to discuss common baby behaviours from a medicalised standpoint and starting from the position of assuming there was a medical concern. I feel that the exclusion of these articles on the basis of bias was therefore justified.

Additionally, I completed forwards and backwards citation searching from included studies to identify any additional eligible papers. I used google scholar 'cited by' results to identify studies which had cited the included articles, I also hand searched reference lists of included papers; however I did not find any new eligible papers in this way. Please see PRISMA Flow Diagram (Figure 4) for a summary of inclusion decisions.

Table 3: Free text terms for grey literature search

Google Scholar	**Google**
Unsettled infant parent experience	Baby crying parent experience
Reflux infant parent experience	Unsettled baby parent experience
Allergy infant parent experience	Baby vomit parent experience
Crying infant parent experience	Baby reflux parent experience story
Qualitative baby crying	Baby allergy parent experience story
Qualitative baby reflux	Baby won't be put down
Qualitative baby allergy	Baby poo allergy parent experience
Interview reflux infant	Baby rash allergy parent experience
Interview allergy infant	

5.2.3 Search strategy

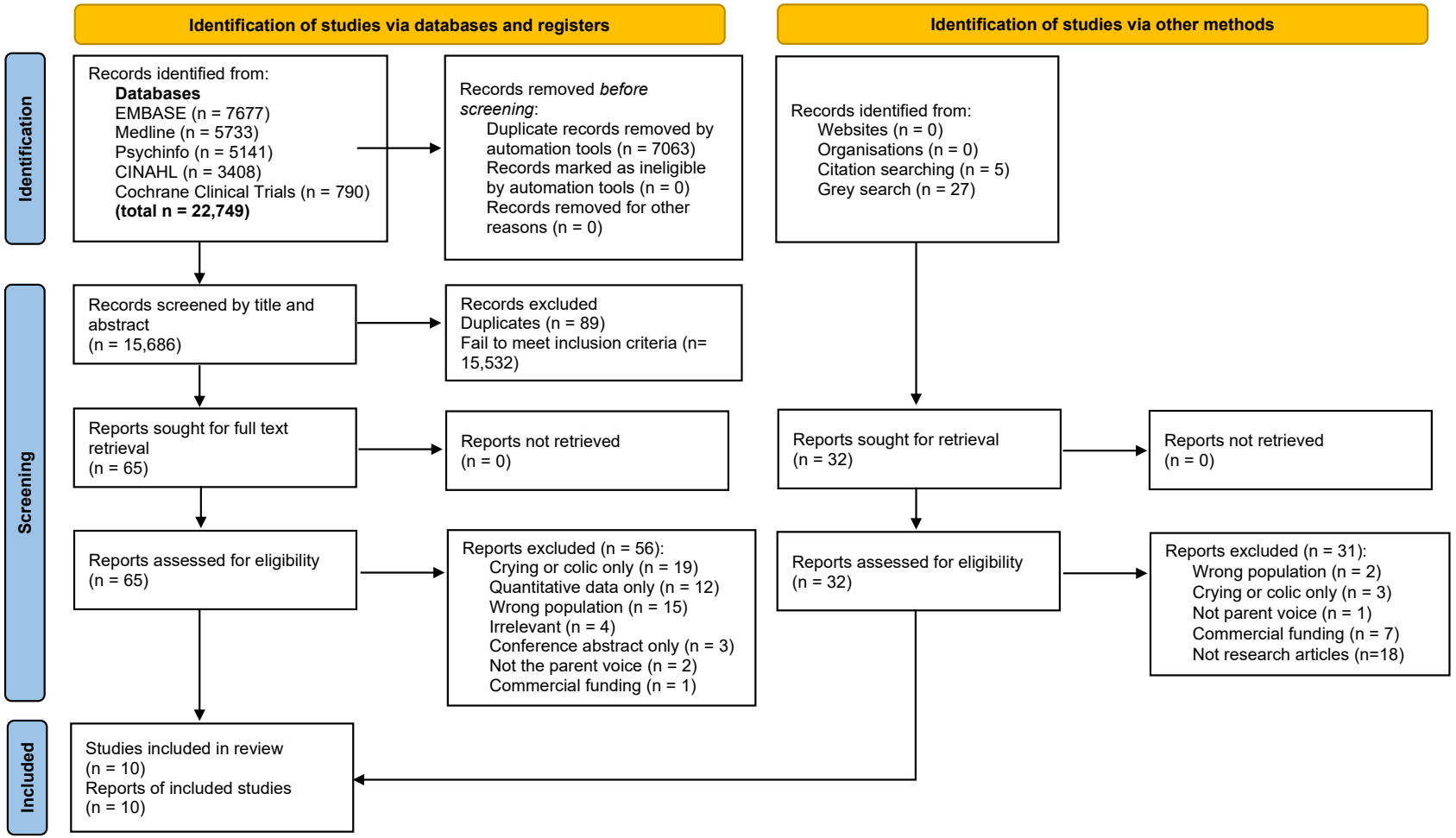
I used the SPIDER search tool (Sample, Phenomenon of Interest, Design, Evaluation, Research type)[318] to structure a clear search strategy as summarised in Table 4. I selected this tool as it is appropriate and widely used for qualitative research questions and offers a way to clearly delineate the different strands of my search, as well as helping to clarify my thinking in defining search terms [318]. I also used the PICOS tool (Population, Intervention, Comparison, Outcomes, Study Design) [319] when thinking about and planning my research question, however in practice I found that SPIDER offered a better fit for the topic area. I also noted from early scoping searches that the research topic was excessively broad, due to the nebulous nature of the topic 'unsettled babies'. For this reason I felt that a tool which was higher in specificity than sensitivity would be a strength. In a comparison study of search results using PICOS and SPIDER, SPIDER was found to offer this greater specificity [319].

I devised a search strategy to identify qualitative research relating to parent experiences, beliefs, thoughts, or attributions about and relationships with their baby; where the baby is 'fussy',

unsettled, perceived to have 'difficult temperament'; has a label of CMA, colic or reflux; or is exhibiting non-specific gastrointestinal symptoms. I deliberately adopted a broad search strategy to allow for inclusion of all articles potentially relevant to this wide topic area; and also to reflect the exploratory nature of the research questions. I identified additional search terms through use of a mixed methods search filter resource [320] and a qualitative search filter resource [321]. I identified MESH terms to include by searching the database and by looking at subject headings used by relevant articles. I completed all searches (including all iterations) on title, abstract and keywords. My initial search (iteration 1) was conducted on 22.02.22 and resulted in 86,294 results. This required refining due to time and resource constraints. I therefore refined the search with advice from a specialist librarian to reduce sensitivity and enhance specificity. This included adding adjacency qualifiers, removing some more general free text terms (such as 'diagnos*', 'label' and 'medical' which were too broad, only exploding MESH terms where the subheadings were all relevant and combining the parent and baby search terms together with AND). When satisfied with the level of specificity I checked the results for the key papers I was already aware of, all of which had been picked up by my search strategy. I was therefore satisfied that an acceptable balance between sensitivity and specificity had been achieved. For a full list of final search terms see Appendix G.

Table 4: SPIDER search strategy

S	Parents of babies <1yr
P of I	Unsettled babies
D	Interviews, focus groups, free text responses in surveys/ questionnaire, case study, observational study
E	Experiences, perceptions, beliefs, thoughts, opinions, relationships, bonding, attributions, attachment
R	Qualitative, mixed-method (to use the qualitative element only)



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Figure 4: PRISMA flow diagram of included studies. Searches re-run on 14.04.2023. These numbers are inclusive of the second search. Figure reproduced from [314].

5.2.4 Screening

Initial searches resulted in 21,102 results, reducing to 14,039 after automatic removal of duplicates in Endnote. I selected Endnote for deduplication as this has been found to be highly effective and there is a publically available evidence based methodology for completing deduplication [322]. Following deduplication I imported the records into RAYYAN [323] where I completed title and abstract screening. I screened all of the papers. A random 10% of studies were also second screened by a second researcher (SH) with a concordance rate of 100%.

This resulted in 64 records sought for full text retrieval. Full text review resulted in nine included studies for synthesis. See PRISMA flowchart (Figure 4).

Specifically, one academic study was excluded on the basis of commercial bias alone [324]. On reading this study for the first time, not knowing the funding source, I was surprised by the results which seemed to be suggesting that GPs should be diagnosing allergy more frequently and quickly. The tone and emphasis of the paper stood out to me as being unusual in the field. On closer inspection I concluded that this was at high risk of commercial bias. Firstly, this was an online survey funded by Mead Johnson Nutrition UK (a leading infant formula manufacturer) and was conducted without ethical approval as it was deemed unnecessary for an anonymous survey. The study had the stated goal of understanding delays in diagnosis of CMA. Although it claims no conflict of interest (stating no involvement of the funder in the design of the study, collection, analysis or interpretation of data, or the decision to publish); it also states that the survey questions were designed and written through a partnership between Opinion Health (a company specialising in patient insight into healthcare) and Mead Johnson Nutrition UK. Furthermore, several of the authors report receiving funding from multiple formula industry partners. The paper reported very limited qualitative data – just a few quotes from a free text question in the survey. I therefore concluded I was justified in excluding the study from my systematic review on the grounds that the limited data offered was not worth the high risk of bias.

On rerunning the searches on 14.04.23 in preparation for publication using an identical search method, I identified one new article which met inclusion criteria.

5.2.5 Quality appraisal and data extraction:

Prior to synthesis, I extracted data and appraised the quality and the comprehensiveness of reporting of each study. I used the CASP (Critical Appraisal Skills Programme [325]) checklist to enable the reader to assess the trustworthiness and quality of the studies. Individual CASP checklists for each

included study can be found in Appendix H. IM also completed quality ratings for each study and we resolved any disagreements through discussion.

In addition to CASP, I had planned to use the COREQ (Consolidated Criteria for Reporting Qualitative Studies [326]) checklist to assess the quality of each study's reporting; however I felt that the 'gender' category in the reporting guidelines was insufficiently clear to enable an accurate assessment of papers and following discussion with supervisors I chose to appraise quality using CASP alone.

Table 5: CASP quality assessment results. Table reproduced from [314].

Study Reference	Was there a clear statement of aims for the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	How valuable is the research?	Comment
Harskamp-Van Ginkel et al (2023)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	High	Very high quality paper
Ghio et al (2022)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	High	Very high quality paper
Nuyts et al (2021)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	High	Very high quality paper
Jurich (2021)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	High	High quality paper
Kidd et al (2019)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	High	Very high quality paper
Megel et al 2011 [327]	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Can't tell	High	Moderate quality paper

Study Reference	Was there a clear statement of aims for the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	How valuable is the research?	Comment
Gunnarsson & Hyden (2009) [243]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	High	High quality paper
Cox & Roos (2008)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	High	Very high quality paper
Lauritzen (2004)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Moderate	High quality paper
Long & Johnson (2001)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	High	High quality paper

5.2.6 Selection of synthesis method

Chapter 2.5.1 outlines the overall epistemological and ontological position for this thesis as critical realism. This formed the foundation for the selection of my synthesis method in this systematic review. The following discussion presents the rationale for my choice of synthesis technique in this specific study.

Firstly, I planned to take an interpretive approach to synthesis, allowing for synergy in the analysis – the whole to be 'greater than the sum of its parts' and building a layer of understanding extending beyond the conclusions of the primary studies [174]. I was aware that the approach selected would therefore require an iterative and reflexive approach to analysis, to allow for exploration of the issues and ideas arising from the primary research and for the construction of 'analytical themes' or 'second and third order constructs' [328].

Examples of methodologies which share these features are the recent iterations of meta-ethnography or some forms of thematic synthesis [328]. I also considered options such as critical interpretive synthesis, realist review, grounded theory and narrative synthesis. A realist review may be better suited for studying interventions and helping to illuminate what works for whom and how [329].

The data in the included studies used diverse methods, crossed many contexts and found sometimes conflicting results. I reflected that some approaches are more flexible to include qualitative studies conducted using different methodologies than others; for example thematic synthesis is traditionally used to allow for inclusion of diverse methods, whereas meta-ethnography traditionally synthesises only ethnographic research [328] (although there are more recent examples of meta-ethnography including a variety of methods [330]). In addition, I gave thought to the heterogeneity in the findings and the number of studies I had to synthesise. Thematic synthesis, for example, attempts to explain differences in results by looking at the context or types of participants; whereas meta-ethnography in contrast subsumes findings from primary research and 'translates' them into a unified higher order construct. Meta-ethnography theory describes a technique of 'refutational synthesis' which involves exploring and explaining differences [328]. However it may be that meta-ethnography is better suited to a smaller number of less diverse papers for synthesis [316].

Although the data were diverse in terms of qualitative methodology – some including interviews, some focus groups and some content analysis of forum posts – all the included studies were peer-reviewed research and centred around the parent voice. As such thematic synthesis is appropriate. Other approaches such as critical interpretive synthesis, rapid realist reviews and realist synthesis

may be more appropriate where the data is mixed and includes content from commentaries, news articles, policy articles and blog posts [331]. This may be more appropriate for aggregating and reporting the results of my grey literature search which was excluded from the current review due to methodological approaches which made them inappropriate to synthesise with academic studies.

In addition to the diversity of the data, it was all qualitative in nature and ranged from some very rich and deep data to other papers which were rather 'thin', containing less contextual and situational information. Techniques such as realist synthesis and narrative synthesis typically lend themselves to aggregating mixed methods data; and thematic synthesis may be particularly useful where the data is considered "thin" (p47) and other synthesis methods cannot be easily sustained [332].

Additionally, pragmatic factors such as time, resources available such as expertise and experience of my supervisors and the training available to me were considered [332]. Both meta-ethnography and grounded theory techniques are considered time-intensive [332]. In my case, my supervisors are very experienced in thematic synthesis, although they also have expertise in a range of other qualitative synthesis methods. Given that the resources for thematic synthesis are freely available and widely used within the department, access to appropriate training, knowledge and expertise was also taken into account in my decision making process.

The final factor to consider was the planned outcome of synthesis, or the 'synthetic product' [328]. Namely, whether this is production of an overarching theory or picture of the whole phenomena (which then requires additional interpretation to apply), or producing a more practical output useful for intervention design and policy makers [328, 332]. In this area of research, both seemed useful. Firstly I was in need of a cohesive 'picture of the whole' in defining the unmet need of parents with unsettled babies. This would also help to more accurately describe the group of families I was targeting with my intervention. Secondly, however, I was in need of a set of practical recommendations to inform an applied approach to the problem which can lead to rapid development of an intervention to support these families. Balancing the tension of these two priorities was key in selecting the appropriate methodology.

I acknowledged therefore that the advantage of approaches such as meta-ethnography and grounded theory is that they produce as their synthetic product one unified theory, which would be beneficial in understanding and defining this group of families. However, given the applied nature of this PhD and the clinical relevance of the phenomenon of interest it was vital to produce a synthetic product which can be used in intervention design, policy recommendations and in clinical practice, for which thematic synthesis is recommended to be highly useful [332].

As a result I decided that for my systematic review the best fit for the phenomenon of interest, research question and progression of the overall PhD goals was thematic synthesis. This process will initially use an inductive approach to data coding and then allow for interpretation of the resulting themes into analytical themes. As such the method is influenced both by grounded theory and meta-ethnography. This process resulted in a narrative similar to the 'line of argument' in meta-ethnography, but with the advantages of the applied lens of thematic synthesis. This synthetic product could inform practice recommendations and my intervention guiding principles in later parts of the PhD.

5.2.7 Coding and synthesis methods

In completing my thematic synthesis I followed the Thomas & Harden [333] method which comprises three key steps, firstly line-by-line coding; then grouping or reducing codes into descriptive themes and finally development of analytical themes which add a layer of interpretation and thought beyond the original data. I uploaded full texts into NVivo software and read through to identify data and findings to code. As proposed by Thomas and Harden; I coded any text presenting results of the study line by line to capture meaning and context, regardless of where this might appear in the paper. I included all text labelled as 'results' or 'findings'; both the data itself in the form of direct quotes from parents and the authors' findings or summaries of the data. Some of this text I found in the abstract as well as results sections of the papers. I built and edited a detailed code book reflexively through the coding process, adding new codes and consolidating others where necessary. I discussed the code book with my supervisors (SL, MS and IM) at regular intervals through the coding process to ensure rigour and get multiple perspectives and interpretations of the data. I ensured the code book contained illustrative quotes from the data to allow for exploration and comparison.

I initially organised these inductive codes in a hierarchical structure, with conceptual codes nested within broader conceptual codes. This had the advantage of allowing for 'translation' of the concepts across studies whilst maintaining the detail and granularity of the data [333]. By looking for similarities and differences between the codes I refined this hierarchical codebook into eight descriptive themes. I did this through a process of reflexive revision and discussion with my supervisors, again seeking out alternative interpretations and explanations to ensure rigour.

In the third stage of analysis, I considered how the descriptive themes related and interacted to each other and what relationships could be inferred from the data within each theme. Common concepts which underpinned multiple descriptive themes emerged which could be considered to be 'going beyond' the original findings of the included studies. I wrote these up as analytical themes.

Whilst in the analysis stage, I as the lead author made notes in the form of frequent recurring phrases or imagery. Through the process of analysis and discussion with collaborator DG, I developed these notes into a model. I have presented this model in the findings section (Figure 6) in addition to the descriptive and analytical codes as a way of concisely synthesising and summarising the analysis in this review. The model also allows for greater understanding of the proposed processes involved in parents' construction of an illness-related narrative of their baby's behaviours. I describe this as a conceptual model, distinguishing it from a theory or a theoretical framework. Whilst these are similar tools, a conceptual model is usually more practical, focuses on specific key findings or ideas and is produced from inductive rather than deductive analysis. It is also typically in a visual format, in contrast to a 'theory' or a 'conceptual framework', which can be described in text alone [334].

There is existing literature on the production of conceptual models from thematic synthesis which helps to inform the process used in the development of this model [335]. In their recent paper in 2023, Naeem and colleagues propose a method to develop a conceptual model from thematic analysis [333]. They lay out a six step model, the first four steps of which are a typical thematic analysis as follows. Step one is transcription and familiarisation with the data, step two is selection of keywords, patterns or ideas which are derived from the data, step three is coding and step four is theme development, where codes are grouped together in analytical ways to answer the research question [333].

In my own work, the initial stages differ from steps 1-4 as outlined by Naeem and colleagues, in that mine was a thematic synthesis as opposed to a thematic analysis [333]. The choice of thematic synthesis was made as being the closest method to thematic analysis, whilst taking account of the data being a systematic review of studies rather than primary individual participant findings. However, steps 5 and 6 are a good indication of how the model was subsequently developed using the themes from my thematic synthesis. In step 5, conceptualisation, key concepts are interpreted from the themes often through use of tools or visual representations of the main ideas in the analysis. These are then refined in step 6, involving a focus back on the research questions and consideration of the broader body of scientific knowledge, as well as representing the key sense of the main themes. Step 6 results in a visual representation which captures all the findings and insights derived from the systematic review [335]. In my case step 5 resulted in the visual representation of a 'cycle' or pattern of failed attempts to search for an explanation for unsettled behaviour and step 6 produced the final model, encapsulating the main findings of the systematic review.

Following development, this conceptual model was then refined through the hybrid inductive & deductive analysis in Chapter 6, described in Chapter 3.3.

5.3 Findings

5.3.1 Study characteristics

Nine studies met eligibility criteria from the initial search and I identified one additional study meeting eligibility criteria when rerunning the searches in preparation for publication. In total ten studies were therefore included. These studies were published between 2001 and 2023 and conducted in UK (n=2), Sweden (n=2), Turkey (n=1), South Africa (n=1), Canada (n=1), USA (n=1), Belgium (n=1) and Amsterdam (n=1). Table 6 reports the key study characteristics. Of the included studies, eight completed interview or focus groups with parents directly, whilst two collected online data from relevant online parenting discussion forums. Three studies did not report number of participants. The remaining seven included 103 mothers and 24 fathers.

Table 6: Characteristics of included studies. Table reproduced from [314]

Reference	Authors (year)	Country	Parent Participants (n)	Parent characteristics	Principle focus	Format of data	Method of data analysis
[336]	Harskamp-Van Ginkel, Klazema, Hoogsteder, Chinapaw & van Houtum (2023)	The Netherlands	Mothers (10), fathers (10)	Medium to highly educated, all parents worked 3 or more days per week	Parent experiences of healthcare support for excessively crying babies	Interviews	Thematic analysis
[126]	Ghio, Muller, Vestergren, Mandangu, Dennison, Sykes, Boyle & Santer (2022)	UK	Users of online discussion forums on baby crying (n= not known)	Not given	To explore online parent discussions about baby crying	Online forum posts	Thematic analysis and discursive psychology analysis
[32]	Nuyts, Van Haeken, Crombag, Singh, Ayers, Garthus-Niegel, Braeken & Bogaerts (2021)	Belgium	Mothers (n=13)	Caucasian, born in Belgium. Majority professional, well educated, living with a partner. Some had mental health treatment during the study	Mothers' experiences and needs around accessing an infant mental health facility for persistent, severe infant regulatory problems	In depth interviews	QUAGOL coding
[242]	Jurich (2021)	Turkey	Members of a social media allergy group (n= not known)	Unknown	How parents manage risk and make decisions on infant food allergy	Online forum posts	Ethnographic analysis
[51]	Kidd, Hnatiuk, Barber, Woolgar & Mackay (2019)	Canada	Mothers (n=21)	Majority highly educated, white, food-secure households well above the poverty line	Parents' perceptions of maternal diet in baby cry-fuss behaviour	Focus groups and interviews	Content analysis
[327]	Megel, Wilson, Bravo, McMahon & Towne (2011)	USA	Mothers (n=12)	Middle class women with partners. White (n=11) and Hispanic (n=1)	Mothers' experiences of parenting an irritable baby	In depth interviews	Grounded theory

Reference	Authors (year)	Country	Parent Participants (n)	Parent characteristics	Principle focus	Format of data	Method of data analysis
[243]	Gunnarsson & Hyden (2009)	Sweden	Mothers (n=18), father (n=1)	Not given	How child allergy is constructed and organised by parents in a moral everyday context	Interviews	Narrative analysis
[71]	Cox & Roos (2008)	South Africa	First time mothers (n= not given)	Urban, white, married, professional women between 25-35yrs	Experiences of first-time mothers with colic babies	In depth interviews	Descriptive analysis
[337]	Lauritzen (2004)	Sweden	Mothers (n=15) and fathers (n=7)	Varied Socioeconomic Status, Swedish origin (n=22) other origin – not given (n=1)	How parents experience and understand allergy diagnosis in their young children	In depth interviews	Narrative analysis
[118]	Long & Johnson (2001)	UK	Mothers (n=14) Fathers (n=6)	Majority white	Parents' experiences of excessive crying	Questionnaire, interviews and observations	Grounded theory

5.3.2 Quality assessment

Table 5 presents results of the CASP analysis. All studies were rated very high or high quality, with the exception of Megel et al [327] which was rated moderate quality. I deemed all papers to be of sufficient quality for inclusion, without weighting by CASP score.

5.3.3 Thematic synthesis

This paper presents two analytical themes and eight descriptive themes derived inductively from the data (Figure 5). It further presents a conceptual model which proposes the process parents may go through when faced with an baby they perceive to be unsettled (Figure 6).

Only one of the papers contained every descriptive theme [338]. The numbers of descriptive themes in each paper ranged from three to eight. All but one paper contained both analytical themes. Jurich [242] was the exception to this, with no theme of 'Identity as a good parent' emerging from this paper. This disconfirming case could be because of the narrow focus of the paper on descriptions of a physical symptom – primarily an analysis of forum posts about baby stools. Themes contained in each paper are mapped out in Table 7. Quotes are labelled as 'Author quote' when they are the author's interpretation or analysis, or 'Parent quote' when directly from parents. All quotes are referenced with their source study.

Table 7: Analytical and descriptive themes mapped onto included studies. Table reproduced from [314].

	[336]	**[242]**	**[118]**	**[71]**	**[337]**	**[51]**	**[32]**	**[327]**	**[243]**	**[126]**
'Identity as a parent'										
Transition from 'me' to 'me as a parent'	✓			✓	✓		✓	✓		
Guilt and Failure	✓		✓	✓			✓	✓		✓
Feeling responsible and wanting control	✓		✓	✓	✓	✓	✓	✓	✓	✓
'Searching for an explanation'										
Expectations	✓	✓		✓			✓	✓	✓	✓
Feeding is linked to unsettled behaviour	✓	✓		✓		✓				
Finding help	✓	✓	✓	✓		✓	✓	✓	✓	✓
Lack of certainty	✓	✓		✓	✓	✓	✓	✓	✓	✓
Hypervigilance and desperation	✓	✓			✓				✓	

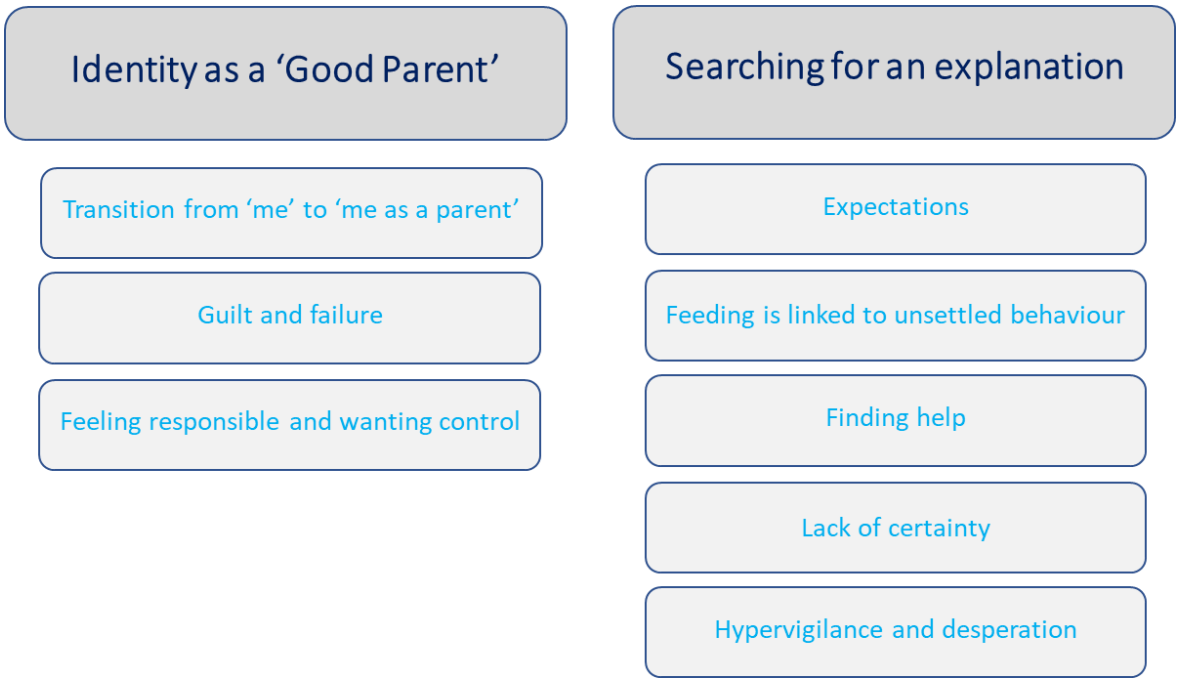


Figure 5: Analytical themes (dark blue) and descriptive themes (light blue). Figure reproduced from [314].

5.3.3.1 Analytical theme 1: Identity as a 'good parent'

Parents' experiences of unsettled babies and the actions they took to help their babies appeared to relate to endeavouring to construct an identity for themselves as a 'good parent'. This analytical theme included the descriptive themes of 'transition from 'me' to 'me as a parent'', 'guilt and failure' and 'feeling responsible and wanting control'.

5.3.3.1.1 Transition from 'me' to 'me as a parent'

Some studies described a sense of transition into a new identity as a parent. This was experienced in a variety of ways. Some parents described feeling that they were losing a sense of their own identity and feeling consumed entirely by their baby's needs. Although a 'change in' or 'loss of' one's own identity is not unique to the experience of parents of unsettled babies, parents in these studies often described the all-consuming nature of their baby's behaviour as not allowing space for themselves.

> *Parent quote: "you, as anything more than a mother, takes a backseat. There was no differentiation of me as a person" [71]*

Many also described how their self-image of who they thought they would be after the baby was born was challenged by the reality they faced after the birth.

> *Parent quote: "I never thought I wouldn't cope" [71]*

Parent quote: "I have always thought I'm going to have a child and nature will prepare you for it" [32]

Some studies also found that parents spoke about their expectations of themselves and their baby as being shaped by their own parenting experiences (both good and bad) and role models for parenting around them.

Author quote: "Expectations were also influenced by their own parenting experiences as a child. When mothers experienced a problematic parenting situation as a child, they were determined to be better parents for their children"[32]

5.3.3.1.2 Guilt and failure

The majority of the papers described parents' anxiety about being 'good enough'. This was a prevalent theme that presented in a variety of complex ways throughout the data set. Often parents of unsettled babies spoke about feeling like a failure and experiencing extreme guilt, in part because they sometimes experienced negative feelings about their baby, negative feelings about being unable to 'help' their baby or both. Many also expressed a fear of judgement from others because of their baby's behaviours, perhaps reflecting their own internal sense of guilt.

Author quote: "It seems that even though parents may have known that they had acted in a proper and responsible manner, exhausting every opportunity to help the baby, they could not rid themselves of thoughts of having failed" [118]

Parent quote: "My baby is telling me I am not a good mother" [327]

Parent quote: "I felt like the worst mother ever because what kind of mother can't comfort their own child" [32]

Parents also found it difficult to bond with their baby, which further added to their sense of guilt and failure.

Parent quote: "There are times when you feel: 'leave me alone, I don't even want to hold you', and then you feel so bad." [71]

Parent quote: "There were times when you want to throw him against the wall…[sometimes I feel] like 'running away'." [71]

The complexity of the parent-baby relationship was clear, since within the same study parents expressed both feelings of rage (as above) whilst also demonstrating empathy for their babies.

Parent quote: "'It's terrible to see her in pain'… '[it's like] having really bad heartburn'." [71]

In one study, this parent expressed explicitly that they hoped for a medical cause for the crying as a way to assuage their feelings of guilt and failure.

> *Parent quote: "For a long time I thought… It cannot be just the crying, there has to be something wrong with my child. Somehow I even wanted it to be cow's milk intolerance, so I knew that I wasn't doing anything wrong. I felt like I was failing as a mother because I could not help him." [338]*

Some papers described a fear of judgement, where parents said they felt other people (observers, family members or healthcare professionals) felt that they as a parent were responsible for their baby's crying. Parents reported that at times this led to them isolating themselves at home and added to their existing feelings of being alone in their suffering.

> *Parent quote: "[I want others to] think that my baby was perfect and not that he cried all the time"…"People would look at you like 'what are you doing to that kid?'" [327]*

> *Parent quote: "I just felt like nobody understood where I was coming from, what I was experiencing and what my child was really like" [71]*

5.3.3.1.3 Feeling responsible and wanting control

Many studies described parents expressing explicitly or implicitly that they felt they should be in control of their baby's behaviours. A few also reflected on the challenge their baby's behaviour presented to their own self-control. Authors noted that parents felt responsibility lay with them to uncover the cause and find a solution to the problem.

> *Parent quote: "For as long as he carries on crying I can't help feeling that I ought to be trying something else. I'm sure it's all to do with being a mother. A mother ought to be able to make things better. But you can't. There's nothing to be done. I do know it, inside. But that doesn't stop the guilt" [118]*

> *Author quote: "caregivers perceive themselves as advocates for the crying infant. It felt as though parents perceived themselves responsible completely, and therefore should know and understand the meaning behind every move and sound the infant makes, thereby knowing when something is wrong" [243]*

Some parents spoke about the lack of control over their babies' behaviours as being extremely distressing and debilitating.

> *Parent quote: "I felt that it would never end, the total utter helplessness to the point where you feel that you can't make this better and then losing hope that it would ever come to an end'. 'I reached breaking point and I gave up - this feeling of, 'I can't do anymore for you'." [71]*

Some parents reported a feeling of 'living on the edge' [118] and said they were scared of losing their own self-control and harming their baby, as in this example:

> *Parent quote: "I think you get used to a level, even though it's a very low level. Then, when you get too much aches and pains, and the pressure is too much, it takes you over the edge. And it might not take much to send you over that edge, either. You start thinking `I shouldn't be picking the baby up because I'm starting to lose control'." [118]*

Data from several studies suggests that the search for an explanation - especially when it ended in a diagnosis or in medication - appeared to be useful for parents as a way to exert some control over the baby's behaviours, thereby empowering the parents to be able to 'do something about it'. The need for a firm plan was important for parents in regaining a sense of control.

> *Parent quote: "The first thing she said was: "How are you holding up?" And then, yes, I started crying, because I was just so exhausted. But she gave me hope: "You are not leaving here without us making a plan that you can use and hold on to." [36]*
>
> *Author Quote: "The mothers' search for information on the causes of and treatment for colic offered hope that understanding and control could be gained" [71]*

Some studies also found examples where both relentless advocacy to healthcare professionals and suffering a personal hardship (e.g. through dietary restriction) were valuable to parents. These appeared to be being used as opportunities to construct an image of themselves as a good parent; both to themselves and to others perceived as judging them.

> *Author quote: "responses included encouragement that the original poster (OP) should go back again, seek further assessment and advice and 'fight' for the infant" [43]*
>
> *Parent quote: "when it's for your kid, it's easy to do" [discussing a heavily restricted diet while breastfeeding] [41]*
>
> *Parent quote: "He told me that as long as the baby is gaining weight and growing, peeing normally and there is nothing different with his poop, I have nothing to worry about. It was not what I wanted to hear, because my baby is in pain and I want him to feel better ASAP. Anyway he told me to take him to the GP tomorrow and have him checked again. Will do! As many times as I need!" [43]*
>
> *Author quote: "Having control means for many parents in this study being able to help their children (to relieve their 'suffering'), and at the same time presenting and maintaining oneself as a good, morally responsible, parent. For instance, food avoidance is a way for parents to try to control the*

child's well-being and health in terms of preventing illness, as well as a means of defining the situation and interpreting symptoms." [243]

5.3.3.2 Analytical Theme 2: Searching for an Explanation

This analytical theme comprised five descriptive themes. The search for an explanation was underpinned by parents' 'Expectations' of themselves, parenthood and their baby. It often centred around 'Baby feeding' and involved 'Help seeking'. The search was characterised by a 'Lack of certainty' and 'Hypervigilance and desperation'.

All papers described parents searching for an explanation for their baby's behaviours and four papers described this as a repeated 'cycle' or 'pattern' of failed attempts [71] [118] [327] [337].

Parent quote: "We started our cycle of chiropractors, reflexologists, homeopaths, medication for reflux; we changed his formula a hundred times; we have a hundred bottles, a hundred teats; it was this desperate clinging to something" [71]

Author quote: "repeated attempts had to be made to establish a diagnosis and to find a cure. Such attempts failed, leading to a repeated cycle of hope and disappointment" [118]

Author quote: "Searching involved cycles of seeking potential causes of the crying and treatments to soothe the baby, seeking help, isolating self and baby as protection from judgmental others (stigma), and experiencing hope followed by discouragement. Consequences of the cyclic search processes included exhaustion, frustration, guilt, helplessness and disappointment on the part of the mother" [327]

5.3.3.2.1 Expectations

This descriptive theme includes data with parents describing their own expectations of themselves as parents or of parenthood, their expectations of their baby and their expectations of what constitutes 'normal' baby behaviour. All of these had an impact on their overall search for an explanation. Where parents had expected a very settled, happy baby whom they could easily soothe and these expectations did not match with their experience; their certainty that the behaviours were abnormal was heightened and the search for an explanation was intensified.

Parent quote: "I thought it's all going to be wonderful and I'm not going to have a crying baby so when she came out and it was just this screaming all the time I really had a rude awakening" [71]

Parent quote: "I had a lot of preconceived ideas of how I was going to bring this baby up, then he ended up being colicky and I felt like burning [the parenting book]" [71]

Author quote: "The thematic analysis identified a tension between interpreting what is 'normal' crying and when crying is a sign of an 'underlying problem leading to the search for a diagnostic label. This tension seemed to be heightened when expectations that infancy should be a 'happy time' were threatened by excessive crying" [43]

5.3.3.2.2 Feeding is linked to unsettled behaviour

Parents' accounts almost universally linked to unsettled baby behaviours to feeding and parents were often quick to blame breastmilk for these behaviours. In many studies, this manifested implicitly in the data – parents seemed to immediately assume that the baby's tolerance of their milk feed was the cause of behaviours. Negative emotions were expressed around baby feeding and repeated changes were made to the parent and baby diet in a bid to reduce unsettled behaviours.

Parent quote: "it's a vicious cycle; you feed him and it calms him for a few minutes and then he gets more cramps, then he screams some more, so you can't keep on feeding, but then he doesn't get enough food." [Another mother reflected] "I just wished we didn't have to feed him" [71]

Parent quote: "Even my husband was like, 'Seriously now, when are we going to have that conversation about you not breastfeeding anymore?' and I said 'We are not going to have that conversation. I am determined to work through this.' He was like 'OK, I guess if you want to keep going, but I am serious. When are we going to stop hearing a screaming baby? When are we going to get him formula?". [41]

Parent quote: "Could it be a dairy allergy? My lo [little one] had reflux and it was caused by an allergy to dairy and soy. The crying was one of our first clues. You will be prescribed special formula if you're bottle feeding… if you are breastfeeding cut dairy and soy out of your diet. It will take about 2weeks for the dairy and soy to come out of their system so won't work straight away. Very common to be allergic to both. Good luck!'" [43]

5.3.3.2.3 Finding help

Parents reported they were often driven to seek medical help in their search for an explanation and that their experiences of healthcare professionals were largely negative. Parents felt dismissed and fobbed off and there was a sense of disillusionment with the healthcare system as a whole.

In contrast, when discussing helpful interactions parents talked about needing reassurance and emotional containment from a person they trust. In these supportive interactions, they were able to feel validated and listened to and supported to understand that their baby's unsettled behaviours were not their fault.

Author quote: "Parents scrutinise the children's problems carefully before seeking medical aid, and seek professional help with the 'social baggage' of an already constructed and organized illness". [42]

Parent quote: "A lot of the time they all said the same thing. It's just like a fob-off isn't it? To me, that's an easy way out for them. I don't think they're interested really. They don't believe what you say. They think you're exaggerating." …"it's because they don't know. They just fob you off. The doctor was a waste of time." [118]

Parent quote: "I think probably it was reassurance [thinking]. Yes. That was it. Reassurance. Because I was a first time mother I needed things explaining and I always thought it was just me. But [named health visitor] kept telling me it wasn't my fault. That was good. I needed that." [118]

5.3.3.2.4 Lack of certainty

Many of the studies found that the search for an explanation is complicated by a lack of certainty and clarity. This manifested in a variety of ways including the behaviours themselves being difficult to measure or describe, the different uses of different medical labels, the conflicting advice received and the different definitions of 'normal' baby behaviour.

Across the dataset there was a lack of certainty about what constituted a 'normal' level of unsettled behaviours such as crying and vomiting; where those behaviours indicated a medical problem and exactly what medical label or term might be most appropriate.

Even amongst cases where medical labels had been applied, the nature of the unsettled behaviours and the search for an explanation meant that uncertainty often remained in the parent's mind.

Author quote: "at times reflux was not described as a label but as a symptom indicating that the baby had an allergy. Colic sometimes seemed to be viewed as a label itself but most times colic was perceived as a 'gateway' to another label such as 'silent reflux' or 'acid reflux'. Terms such as allergy, intolerance or 'lactose overload' were used interchangeably." [43]

Author quote: "There remained at least some diagnostic uncertainty even after a diagnosis had been made." [42]

5.3.3.2.5 Hypervigilance and desperation

It appeared to some parents that as their desperation increased to find a solution and a cause for their baby's symptoms, so too did their level of vigilance and worry. This introduced additional difficulty for parents in separating normal behaviour from symptoms of illness.

Author quote: "It was common that parents in their interviews referred to an increased 'awareness' in terms of stating that they 'had to' become like 'detectives' to discern what the causes of the children's problems were. It was more than merely 'awareness' in that sense. Once the children's problems had been interpreted as abnormal, what was salient in the parents' stories was their problem readiness. Being detectives meant for the parents being able to help their children through finding out what was wrong." [42]

Parent quote: "The quest for an explanation and a cure came to be all-important. 'It rules my life!'…'There have been times when my whole life revolved around seeking explanations for the crying'" [118]

Parent quote: "I think that's probably where I got it wrong, though, or at least made it worse for myself. I couldn't stop trying to find the cause. I mean, you don't stop until well, in my case until he'd grown out of it. Doing at again makes you really think hard. I'm already looking for the cure before he's even born" [118]

5.4 Illness-related interpretations of unsettled baby behaviours: A conceptual model.

Through analysis and discussion with the supervisory team (IM, MS, SL) and a collaborator (DG) the following model was developed to summarise the findings of this review and illustrate the experience parents may go through when faced with an baby they perceive to be unsettled.

In this model (Figure 6) it is suggested that the search for a medical explanation for their baby's behaviours might be motivated by parents' need to create and maintain their identity as a 'good parent'. It may do this by requiring parents to sacrifice themselves for their baby (through dietary exclusion or advocacy to health professionals) and/or by allowing parents to regain a sense of control over their baby's behaviours, reducing their sense of guilt.

Further to this; the search for a medical explanation may provide some relief from uncertainty and offer an opportunity for parents to assuage feelings of guilt they have internalised when faced with their own perception that they have failed. This could be being provided by the attribution of an external cause or medical explanation for the unsettled behaviour.

It is argued that parents can become trapped in a cycle of anxiety and guilt while searching for the explanation, which ends when the child grows out of the behaviours, or when the parent reaches a sense of validation, control and external attribution for their baby's behaviours. This can be achieved either through medical diagnosis or through an experience of being validated and listened to,

acquiring understanding and acceptance of their baby's behaviours as normal and the self-confidence to recognise unsettled behaviours are not their fault.

The following quote provides an example to support the model:

> *Parent quote: "For a long time I thought… It cannot be just the crying, there has to be something wrong with my child. Somehow I even wanted it to be cow's milk intolerance, so I knew that I wasn't doing anything wrong. I felt like I was failing as a mother because I could not help him" [36]*

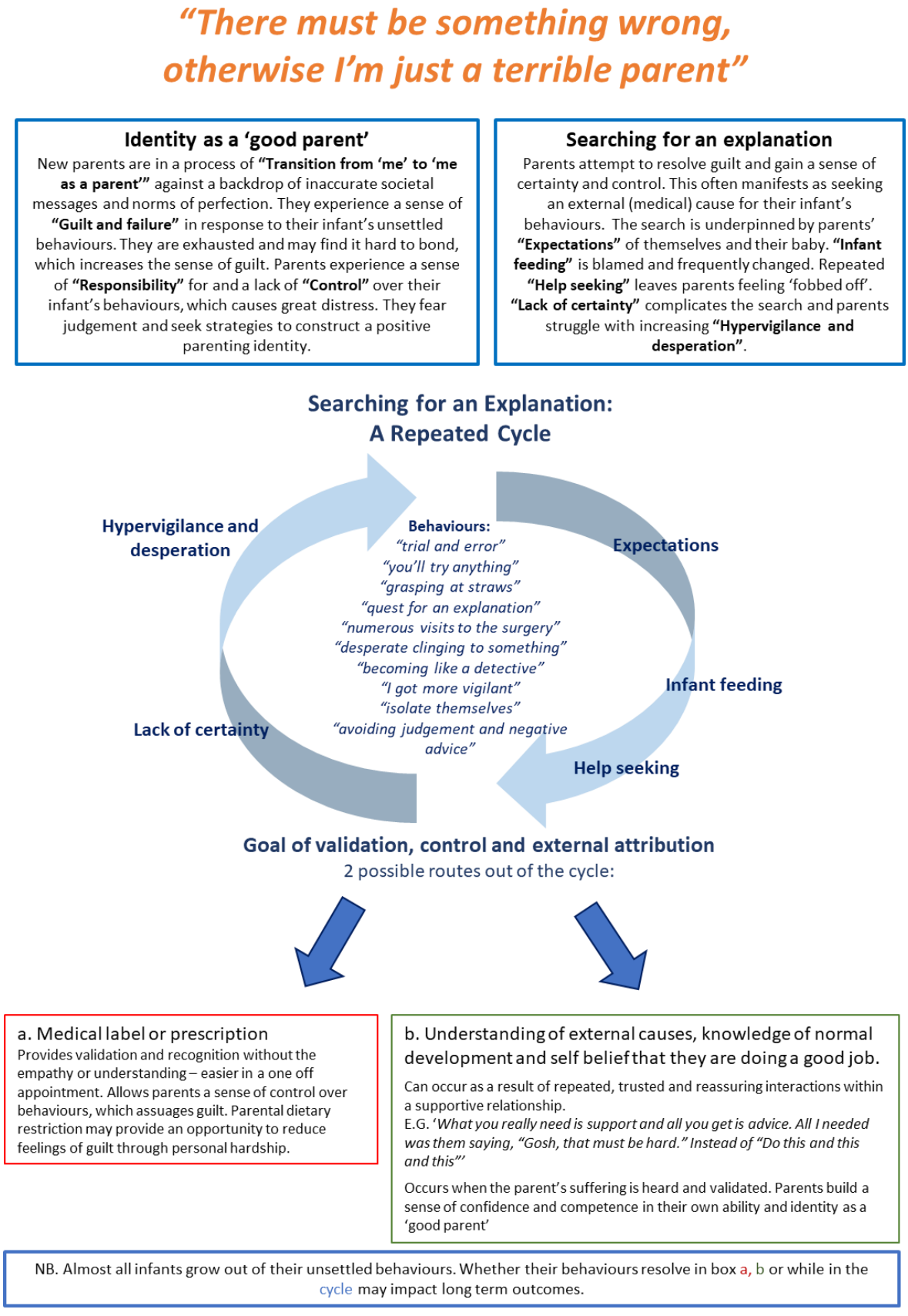


Figure 6: Proposed conceptual model of how and why parents reach illness related interpretations of unsettled baby behaviours. Figure reproduced from [314].

5.5 Discussion

5.5.1 Summary of findings

In this review I identified two analytical themes and presented a possible conceptual model of how and why parents may reach an illness related interpretation of their unsettled baby's behaviours.

In the first analytical theme 'identity as a good parent'; parents are in a process of 'transition from 'me' to 'me as a parent' against a backdrop of inaccurate societal messages and norms of perfection. They experience a sense of 'guilt and failure' in response to their baby's unsettled behaviours. They are exhausted and may find it hard to bond, which increases the sense of guilt. Parents experience a sense of 'responsibility' for and a lack of 'control' over their baby's behaviours which causes great distress.

The second analytical theme captures the parents' 'search for an explanation'. In this theme parents attempt to resolve guilt and gain a sense of certainty and control. This often manifests as seeking an external (medical) cause for their baby's behaviours. The search is underpinned by parents' 'expectations' of themselves, their baby and what is normal. 'Infant feeding' is blamed and frequently changed. Repeated 'help seeking' leaves parents feeling dismissed or ignored. A 'lack of certainty' complicates the search and parents struggle with increasing 'hypervigilance and desperation'.

This review proposes that in their search for an explanation for their baby's unsettled behaviour parents are attempting to gain validation for their experiences, seek control over their baby's behaviour and find an external cause to blame for their baby being unsettled.

5.5.2 Strengths and limitations of the review

This is the first systematic review to provide an understanding of the experiences and perspectives of parents of unsettled babies in relation to medical labels such as allergy and reflux.

In an attempt at clarity and due to the overlapping and complex nature of the research topic a decision was made to single code the data – applying only one code to each quote. For much of the data, multiple codes or themes could have been applied since the concepts were so closely entwined and indeed this layered coding approach is recommended in the Thomas and Harden methodological paper [33]. This may account for the relatively low number of studies which contained data relating to the themes of 'Hypervigilance and desperation' and 'Feeding is linked to unsettled behaviour'. There were, for example, many quotes which could have been coded as 'desperation', but were more appropriately situated elsewhere. Similarly, for feeding (which perhaps surprisingly maps onto

only four studies), parents often assumed that feeding was a factor rather than explicitly stated this, meaning that the quote was coded elsewhere. In future research layers of codes could be applied to each quote to account for this depth of insight in the data and more easily spot connections and overlaps between themes.

Due to capacity restraints this review was unable to consider parents' thoughts, attitudes and expectations about unsettled babies in pregnancy. Future research could synthesise research in the antenatal period, since this time is likely to be important particularly for expectation formation [50, 51].

5.5.3 Limitations of included studies

The included studies were limited by a lack of diversity in the samples - limited data from fathers and no data from parents of other genders, low numbers of ethnic minority parents and no known data for non-biological parents or other primary caregivers. In many cases this data was not gathered or reported in the papers. Where it was reported, sample demographics such as education levels or employment status were used as proxy indicators of socioeconomic status. The inclusion of these families must be a high priority for all future research.

Sample diversity is particularly relevant in this area since families on a low income may be disproportionately affected by the impacts of misdiagnosis, such as premature cessation of breastfeeding and the need to purchase formula milk [8]; and this has the potential to widen the already worrying health inequality gap [53]. Additionally, it is widely accepted that different cultures have very different beliefs, perspectives and practices in relation to baby feeding, sleep and behaviour [54]. The parent's perception of their baby's symptoms is thought to be of foremost importance in providing meaningful and effective support to families [55]; highlighting the importance of capturing and including cultural differences in unsettled babies research.

Despite the systematic search identifying ten studies with useful data for inclusion, there are very few which focus entirely on parents' perceptions of medical labels in relation to their unsettled baby, meaning there is a scarcity of data. In many cases data are often included in studies of parent experiences of their unsettled baby more broadly, or parent experiences of healthcare interactions for their unsettled baby. Future research attempting to generate data providing in-depth insight into the opinions, thoughts and feelings of parents of unsettled babies in relation to medical labels such as allergy and reflux is needed. This would provide an important opportunity to consider the conclusions of the current review in the light of new data as well as address some of the deficits in the sample demographics.

5.6 Conclusions

This review presents a new explanatory conceptual model which proposes the possible process parents may go through when faced with a baby they perceive to be unsettled.

Parents of unsettled babies are often struggling with feelings of guilt, failure and struggling to construct an identity of themselves as a 'good parent'. This may manifest as a search for a medical explanation for the unsettled behaviours. This search may provide an opportunity for parents to advocate for the baby, regain a sense of control and reassure them that their baby's behaviours are not their fault.

This suggests that in building an intervention to support families with unsettled babies there is a need to focus on validating parent experiences, building confidence, empowerment and reducing feelings of guilt. This may reduce the inaccurate medicalisation of unsettled baby behaviours, by meeting the underlying parent need for a positive parenting identity.

Chapter 6 Hybrid inductive & deductive analysis of interview data

6.1 Introduction

A key aspect of the person based approach to intervention development is to understand the user experiences and needs in detail [245]. This involves synthesising the available data in the area, as I did in my thematic synthesis in Chapter 5 [314]. In addition it often involves additional qualitative research to gain a deeper understanding of the issues and to fill gaps in the available research to date [245]. This is why I have chosen to include the following qualitative interview analysis as part of this PhD thesis.

6.2 Context and contribution

This chapter is based on data from a study that was completed as part of an external, NIHR School of Primary Care funded qualitative interview study about parent experiences of unsettled babies, which was separate to my PhD and has produced one published paper to date [113]. I was on the study team for this research and attended all study meetings. I contributed to all stages of the research process including establishing research questions, obtaining ethical approval, study design, writing the interview guide and recruitment. I also conducted one of the interviews. Once transcripts were obtained, I was part of the team discussions on the coding and analysis for the first paper from this data.

While this was a separately funded research project, the aims and data collected aligned closely with the objectives of my PhD. In the published paper there was a focus on the views and experiences of help-seeking, which was reflected in the research questions addressed in the published paper [113], but leaving a proportion of the data around parent perceptions of unsettled behaviours and ideas about medical labels unexplored. For the purposes of my PhD I wanted to address these unanswered elements of the original research questions (see Appendix I for original interview topic guide) which we were unable to cover within the published article due to time and space constraints.

In addition, I wanted to use a different method of analysis; applying both inductive and deductive techniques in a hybrid thematic analysis; and using the theoretical model resulting from my systematic review. This involved firstly completing an inductive, reflective thematic analysis to explore themes arising from the data. Secondly it involved looking for disconfirming cases, additional detail or depth of knowledge which I could use to expand or refine my model. This hybrid inductive &

deductive method is discussed in more depth in Chapter 3.3. I also wanted to take a more interpretive approach to initial inductive coding than the first paper, which used largely descriptive analytical themes [113]; to allow for a deeper and richer understanding of parent experience.

I therefore decided, after discussion with my supervisory team, to create a new NVivo file and start with the transcripts from the interviews we had already completed, coding them myself without reference to the previous coding structure. I took a reflexive approach to thematic analysis [339].

This chapter reports the team study process methods including design and data collection, some of which has also been described in the first published paper [113] and then the analytical methods and findings from my own analysis.

6.2.1 Aims and research questions

The original team research study aimed to explore how parents experience unsettled baby behaviours. In this analysis, I am to focus on how parents think and feel about unsettled baby behaviours with a particular focus on parent perspectives on a medical label.

This study builds on the findings of the systematic review and looks for deeper and richer understanding of research questions 1-4 (listed below). It also seeks to complete deductive analysis, examining the model to answer RQ 5. Finally, this study aims to contribute to the literature by exploring any similarities and differences in parent experiences of unsettled babies with a more ethnically diverse sample.

- RQ 1: What are the experiences, thoughts and feelings of parents/carers of unsettled babies, with particular reference to medical labels?
- RQ 2: What is the underlying need of parents with unsettled babies that might lead them to medicalise behaviours and/or seek medical help?
- RQ 3: What purpose might diagnostic labels and / or medication be serving for families of unsettled babies?
- RQ 4: Can I develop an explanatory, conceptual model of the parent experience when faced with an unsettled baby?
- RQ 5: Does this model fit real-world data? How can it be refined?

6.2.2 Qualitative approach and research paradigm

This study was rooted in an exploratory qualitative approach and used reflexive thematic analysis (RTA) [340]. Given the plurality of RTA, it is necessary to reflect on the theoretical underpinnings and philosophical assumptions of the research. The broad paradigm that RTA typically fits within is an

interpretivist and constructionist one, assuming that reality is subjective, multiple and socially constructed. However, attempts are made through use of researcher reflexivity to take a pragmatic approach to this real world problem of unsettled babies in an attempt to contribute to the literature, and support the evolution of supportive and helpful interventions which may help families. In this way the research paradigm also has realist influences [172]. This chapter is therefore positioned as within a critical realist paradigm, similarly to the rest of this thesis. Ontology and epistemology are discussed more fully in Chapter 2.5.1.

In particular, effort was made in striving to be a 'knowing' researcher [339] and efforts included keeping a reflexive diary which was used throughout the process of analysis to understand researcher position, experiences, emotions and perspectives which provide the backdrop to my interpretation of the data. A summary of this reflexivity is described in Chapter 6.2.3.

Themes were conceptualised in a latent, meaning-based, interpretive way; as opposed to a descriptive, topic summary approach. In this way, the resulting themes are interpretive stories based around a common united meaning. This allows for interpretation of the data to understand implicit as well as explicit meaning, multiple meanings for the same quote and is the approach which fits best with reflexive, thematic analysis [339]. It also supports the development of a deep understanding of a specific phenomenon, which is what I am attempting to do in understanding the needs of parents with unsettled babies.

6.2.3 Researcher characteristics and reflexivity

I am both a parent with personal experience of a baby who could be described as 'unsettled' and a clinician who until recently worked with families worrying about unsettled behaviours. For a discussion of my position, perspective and background more broadly as it relates to this research topic please see Chapter 2.5.2.

Specifically while coding and analysing the data for this study, I was aware of my drive as a clinician to unpick the parent's story to look for the clinical issue or problem. Without intending to, I was reading the transcripts and looking for the facts in a bid to understand the baby's behaviour from a clinical perspective so that I can advise the family appropriately. I therefore needed to exercise effort to put these thoughts to one side in order to hear the parent experience and the underlying needs that they were communicating.

There were times at which my experience as a clinician enabled me to see meaning that a non-clinical researcher may not have been able to interpret. For example, when a parent referred to 'doing everything you're supposed to do' and related that to baby massage; I understood her to

mean she was trying hard to bond with the baby. There were occasions where my knowledge of lactation and breast/chestfeeding relationships enabled me to understand implied meaning from the transcripts. I believe this helped contribute to the latent coding and fits well with an interpretive style of analysis because my experience as a clinician and a parent means I understand some of the 'language' parents used in the study.

6.3 Methods

6.3.1 Sampling strategy

Participants were recruited firstly from GP practices via a letter mail out. The practices were selected because they were in areas of high deprivation (according to Index of Multiple Deprivation IMD postcode data) to encourage a more diverse sample. Contact was made with parents via a GP mail out and through social media (Twitter and Facebook) paid adverts targeting areas of deprivation and ethnic diversity, through two local Sure Start centres (also selected because they were in areas of high deprivation). Some participants were also recruited by two health visitors from one NHS Trust opportunistically signposting parents with unsettled babies to the study information website and displaying study posters in baby clinics. Adverts and study information leaflet is available in Appendix J.

An online reply form asked optional additional questions to allow us to complete purposive selection of under-represented groups particularly ethnic minorities. Participants were over-recruited to allow for this selective strategy. The online reply form also included questions about what labels and unsettled behaviours the baby was experiencing and we attempted to interview parents reporting a range of unsettled behaviours and a range of medical labels. We also recruited some parents whose baby had not acquired a medical label.

We met the maximum sample target of 25 participants. The concept of 'saturation' does not apply within reflexive TA as the researcher is seen as the limiting factor on the meaning they can extract from the data, rather than the data itself being limited in its richness or diversity [341]. We therefore limited the sample number for practical reasons of time and funding, ensuring sufficient information power (detail, depth and richness in the data [341]) to allow for thematic analysis.

6.3.2 Inclusion and exclusion criteria

Parents/carers of babies aged up to 12 months were included if they had experienced unsettled behaviours in the first 4 months of life OR if they had considered their baby had had CMA, reflux or colic (regardless of whether or not a diagnosis had been given) [113]. By doing this, we included

some parents who had experienced the unsettled symptoms but had not sought any medical label. The model developed from my systematic review illustrates that parents are likely to seek a medical label for their baby's behaviours; so these examples contributed to the negative case analysis by providing 'disconfirming cases'.

Unsettled behaviours included symptoms such as excessive crying, vomiting, fussing unless being held, rash, changes in stool consistency/colour, gas/wind or nasal congestion.

Parents/carers of babies with serious or life-limiting conditions were excluded as these conditions are likely to have an influence on parents' perception of illness or health.

6.3.3 Ethics

The study was approved by the University Research Governance office and the Health Research Authority (with a proportionate review from the North East – Tyne & Wear South Research Ethics Committee) [113]. Parents had an information sheet and gave verbal informed consent before beginning the interview. They were fully debriefed afterwards including contact details for support organisations in case discussing their experiences had caused distress. Possible identifiers were removed from the transcripts during transcription to maintain confidentiality.

6.3.4 Data collection

Data were collected through semi-structured in-depth interviews between February and June 2022. These were conducted by SH (24 interviews) and AD (1 interview). Neither interviewer had any personal or professional connection with any of the interviewees. The interviews were conducted by video call or telephone call and lasted between 30-60minutes. Notes were taken during the interview and all but one interview was audio recorded and transcribed verbatim by a professional transcription service. In the one case that the participant did not consent to recording, detailed notes were taken and these contributed to the analysis.

An interview topic guide (Appendix I) was created with input from the research team of academics and clinicians in the field and a parent public contributor. Questions explored parent feelings about and experiences of their unsettled babies, perceptions and thoughts about medical labels, help seeking and baby feeding. Previous analysis has focused on data relating to help seeking [113]; meaning the other areas of the topic guide are largely unreported to date.

6.3.5 Data Analysis: Hybrid inductive & deductive analysis

Blending inductive and deductive qualitative analysis is a technique which has been proposed by some researchers as a method of examining complex and multifaceted phenomena [342]. This has the advantage of allowing for both a bottom up (inductive) perspective, where themes and new ideas can be generated in an open way, remaining closely aligned to the parent voice; and a top down (deductive) perspective which could utilise and build upon existing theory. Proponents have suggested that the two approaches used together may also offer increased rigor through mutual reinforcement [343], in a similar concept to triangulation [344]. It has also been proposed that using a hybrid inductive & deductive analysis may be useful in cases where researchers are looking to apply theoretical frameworks in a way which continues to generate new ideas or concepts; rather than seeking to confirm existing theory [342].

In my case; unsettled infants is an undoubtedly complex topic which has been relatively unexplored to date, therefore benefiting from inductive analysis. However, the body of knowledge may also benefit from deductively applying a preliminary framework or theory, such as the conceptual model I developed through my systematic review (see Chapter 5) but in a flexible way, maintaining the opportunity for new insight, generation of new ideas and enrichment. The goal throughout the deductive analysis will be to search for disconfirming cases, gaps or additional details which may update, improve or strengthen the existing model. In this way, the deductive analysis will have the goal of increasing the real-world explanatory power of the model, rather than taking a positivist perspective in assuming the model to be reflective of objective truth.

I am therefore utilising some elements of the hybrid inductive & deductive method proposed by Fereday and Muir-Cochrane [343] and recently clarified and illustrated by Proudfoot [342]. This new method is a reflexive, iterative process which helps to identify similarities and differences between the inductive and deductive codes using the critical realist concepts of abduction (the identification of gaps in the literature or in the theory) and retroduction (reformulating theory to account for new data) [342].

Firstly I conducted a reflexive, inductive thematic analysis (RTA) [339] which can be viewed as a stand-alone analysis of the interview data. Secondly, I then conducted a deductive analysis considering this interview data in the light of the themes and conceptual model resulting from my systematic review (Chapter 5). This deductive analysis used elements of framework analysis - specifically a theme by participant matrix [345] - and then negative case analysis [346] to identify parents whose stories did not fit the themes I had developed in my systematic review (Chapter 5). I summarised what new insight can be gained from my qualitative interview data to enrich the themes from the systematic review in relation to how the data 'supported, contradicted, refined or

expanded' the conceptual model [347]. Finally I pulled together insight from the inductive RTA and the deductive analysis and reviewed how this should build on and adapt the conceptual model from my systematic review.

Importantly, my analysis has a difference from the blended method outlined by Fereday & Muir-Cochrane [343] in that I was unable to produce a deductive 'codebook' apriori. This was for two reasons. Firstly, RTA was the method judged to be the best choice for this topic and interview data. In this method, Braun & Clarke [339] recommend against the use of a codebook in order to allow an authentic voice for the data to 'speak for itself'. Secondly, given that I am completing both inductive and deductive analysis myself, as well as being involved with the data collection phases of this study, I am unable to be independent of the data and therefore cannot produce an 'apriori' codebook as would be suggested for Fereday & Muir-Cochrane's blended deductive/inductive approach [343]. I am therefore flexibly applying the principles of hybrid thematic analysis whilst forgoing an apriori codebook.

Reflexivity remains vital throughout; and is key to providing trustworthiness and transparency to qualitative analysis both deductive and inductive. In my case, a reflexive diary was kept throughout the study and used actively while coding and analysing data. Given my level of subjectivity with regard to the model I produced and the fact that the inductive analysis has also been completed by me; reflexivity and transparency becomes even more important. The focus on negative case analysis within the deductive approach is as a direct result of this reflexivity. One of the strengths of negative case analysis is that it encourages the researcher to question or scrutinise their previously held beliefs and preconceptions [346, 348]. The overall goal of my hybrid inductive & deductive analysis should be not to prove or disprove the model but rather to "evaluate, revise and reconceptualise on the basis of the findings" [342] and the negative case analysis offers a structured way for me to achieve this.

6.3.6 Trustworthiness

Field notes were taken throughout the interviewing process. Regular meetings were held with supervisors where I discussed the developing themes and looked for different interpretations or understandings of the data. These discussions included reflection on personal experiences and stance in relation to the findings. A reflective diary was kept throughout the research and regular reference was made to this in the analytical process. These are all important principles of being a 'knowing', reflective qualitative researcher [339].

The consolidated criteria for reporting qualitative research (COREQ) [326] was used in reporting this paper.

6.3.7 PPI

KHS is a public contributor and parent with personal experience of an unsettled baby. KHS was involved at all stages of study design, attended study meetings and gave crucial insight into the research from the parent perspective. KHS supported with the design and wording of participant facing materials and in facilitating the listening cafes (see below).

In addition a group of eight local parents with lived experience of caring for unsettled babies and living in an area of relative socio-economic deprivation were involved in this research as part of a 'listening café' engagement project with a children's centre. A series of three two-hour morning sessions, across three weeks, where we built trust with each parent and discussed experiences of unsettled babies as well as their thoughts about their support needs. This work is described in more detail in Chapter 4.3.

6.4 Findings

6.4.1 Participant characteristics

Characteristics of included participants are summarised in Table 8 (baby) and Table 9 (parent). 25 female participants between the ages of 24-39 years were interviewed. There was an ethnically diverse sample, with 52% being white British. Babies were between 6weeks and 11months of age and all had experienced unsettled behaviours including excessive crying (22/24), vomiting (12/24) and perceived pain (12/24). Parents reported healthcare professional diagnoses including colic (4/24), reflux (9/24) and silent reflux (2/24). Many additional parents had labelled the behaviours themselves as being caused by one or more medical conditions, such as allergy (14/24) or 'intolerance' (10/24).

Table 8: Participant characteristics (baby). Table reproduced with formatting changes from [113]

Age range (at date of interview)	6 weeks – 11months	
Age range (at onset of unsettled behaviours)	Birth – 1.5months	
Problem identified by parents ('as quoted by parent')	Crying	22

	Discontented behaviour ('fussiness', 'unsettled', 'moody')	17
	Stool issues ('Explosive nappies', 'diarrhoea', 'green poo', 'constipation', 'blood in poo', 'mucous in poo', 'nappy rash')	15
	Body movements ('Stiff body', 'back arching', 'clenched fists' / 'wriggling around', 'putting knees up')	13
	Wind	13
	Perceived pain	12
	Being sick	12
	Proximity seeking ('will not be put down', 'clingy')	9
	Short sleep duration	8
	Congestion ('snotty nose')	5
	Feeding issues ('not wanting to feed', 'crying after a feed')	5
	Weight problems	2
	Digestive sounds ('tummy sounds', 'gurgling')	2
	Not wanting to be held	1
	Lethargic	1
	Cough	1
Parent label (self-diagnosis or explanation of symptoms)	Colic	13
	Allergy	15

	Reflux	13
	Intolerance	10
	Tongue Tie	5
	Silent reflux	2
	Under/overstimulation	2
	Developmental leaps	2
	Eczema	1
	Constipation	1
	Cranial misalignment	1
	Asthma	1
	High needs baby	1
	Overtired	1
	Immature digestive system	1
	Foremilk/hindmilk imbalance	1
Healthcare Professional Label (as reported by the parent)	Reflux	9
	Colic	4
	Silent reflux	2
	Allergy	7

Table 9: Participant characteristics (parent) Table reproduced with formatting changes from [113]

Age range (mean)	24-39 years (29.68 years)	
Gender	Female	25
Ethnicity (self identified)	White British	13

	Indian	3
	British Pakistani	2
	Black African	2
	Black British	1
	Black Caribbean	1
	White and Black Caribbean	1
	White Mixed	1
	Asian	1
Number of children	1	15
	2	6
	3	3

6.4.2 Hybrid Reflexive Thematic Analysis

A map of the five themes and subthemes identified in the hybrid reflexive thematic analysis is shown in Figure 7. The analysis found four key themes which describe the parent experience. These were Ignored vs Validated; Helpless vs. Empowered; Aware vs. Vigilant and Individual vs Connected Identity. The titles of the themes are framed as two contrasting experiences to capture the sense of transition through the journey to parenthood, the effect the medical labels were described as having on the parents and the different experiences represented by different parent stories. The 'vs' further represents the sense of conflict between parent and healthcare professional expressed throughout many of the parent stories. Each theme will be described in turn below Figure 7.

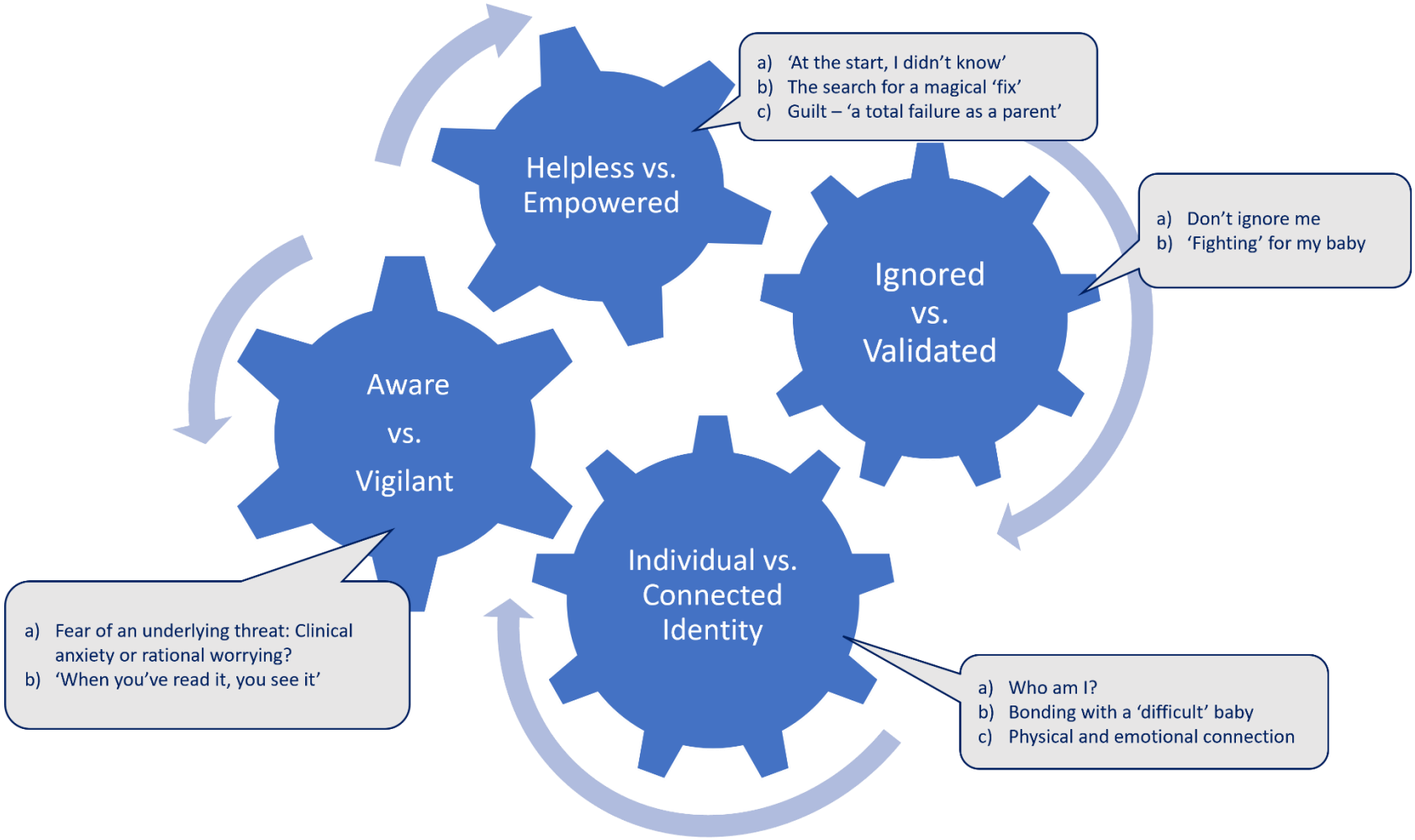


Figure 7: A map of themes (in cogs) and subthemes (in speech bubbles)

6.4.2.1 Ignored vs. validated

This theme reflects the parent journey to reach a sense of validation, feeling heard, believed and understood by healthcare professionals. In many cases, the sense that they were being listened to and the ultimate receipt of a medical label or a prescription appeared to validate their parenting experience and their ability as a parent to recognise their baby's problems – seen by parents in this study as a key aspect of 'good' motherhood. It additionally functioned to reassure the parent that the difficulties they may have had with bonding, with their own mental health or with feelings of frustration with their baby were valid and understandable, because there was something objectively 'wrong' with their baby, something any parent might experience in their position. In this way, feeling ignored or feeling validated may be linked to each parent's image of themselves as a 'good mother'.

6.4.2.1.1 "Don't ignore me"

Most parents described feeling dismissed or patronised, often by healthcare professionals. Parents often described that they felt they needed to provide evidence for their experience so that the professional wouldn't think they were "going loopy" or "just a paranoid first-time mum". They were relieved when babies cried in front of professionals because this ensured they were believed.

Parent narratives were often creating a story of being initially ignored and dismissed and subsequently developing their own confidence as a parent who 'knows their baby'. This journey further contributed to their developing sense of identity as a 'good mother'.

Parent descriptions of feeling dismissed often co-occurred with descriptions of their own youth or inexperience; adding to the picture that 'knowing your baby' is a state you 'grow into'.

> *"I had some doctors who were very dismissive, particularly when I told them I was a first-time mum…it felt really patronising"* **P12**

For many parents, this feeling of dismissal was experienced as upsetting, disempowering and unhelpful. One parent said that feeling her concerns weren't being heard by healthcare professionals caused her harm by contributing to perinatal mental health problems.

> *"I got postnatal depression…I think because I just felt like I wasn't being listened to"* **P18**

Often this was because they felt like the consultation followed a 'tickbox' process or as if the health professional 'didn't really care'. Parents reported valuing interactions where they felt the professional was patient or empathetic. Running tests, investigations or trialling formula milk or

medications were also usually interpreted as being listened to and being taken seriously. These actions were experienced as validating the parents' perspective and supporting the baby, even when the symptoms did not resolve.

> *"They tried everything that I think could be tried, to help ease the reflux, but unfortunately nothing that we tried did help, but…they explored the avenues…each of them…took it seriously"* ***P13***

> *"at the back of my head I knew that something is just not adding up…it just didn't seem normal to me…I just kept on pursuing to make sure the GP understands the seriousness of the issue."* ***P19***

Parents expressed their attempts to find validation for their experience and through this to reassure themselves that they were able to correctly identify when there was something wrong with their baby. When healthcare professionals normalised the baby's behaviour, parents seemed to feel that their expertise as a mother was not being credited or taken seriously. When they received a diagnosis, in contrast, this was validation that they were right to have been worried, and reassurance that they were therefore a good parent with an accurate 'mother's instinct'.

> *"the one that said everything was normal, I just thought their advice was pointless, because I knew that it wasn't normal, but when I spoke to the other doctor, her advice was very helpful. She kept reassuring us that we're doing a great job, and if it was her, she would get him, go to the hospital and everything, just to make sure that it's nothing more serious."* ***P11***

For two parents, they described feeling dismissed even when they had been given a prescription, because they were hoping for more investigations or assessments to discover the cause of their baby's unsettled behaviours.

> *"to be honest we lost a lot of faith in them, with the fact that the GP was just prescribing us medicine, prescribing us medicine, and then the hospital was just prescribing us medicine instead of running any tests or whatever…That's why we did it all ourselves."* ***P29***

6.4.2.1.2 'Fighting' for my baby

Some parents described trying to manipulate the system in order to access the help they needed. They did this by booking an appointment to discuss their own mental health, when they really wanted a GP to assess their baby; by saying they had already tried the first-line solutions or by feigning lack of knowledge:

> *"In the end I had to lie…I had to kind of say, 'I don't know whether she's gaining weight. I don't know any of this.' I had to pretend to be more kind of dismissive of her to get the attention that I needed."* ***P8***

The more parents needed to 'fight' to be listened to, the stronger the sense of pride through advocating for their baby appeared to become, and the stronger the ultimate sense of validation when a medical diagnosis or prescription was given, reassuring the parent that they were right all along. Again, this knowledge of their baby alongside the persistence and effort it had taken to be listened to was evidence of their 'good' parenting.

> *"it's quite a lot of work really trying to make them understand the whole situation, but, er, I wasn't going to give in."* ***P19***

> *"when it's your baby, you're going to need to do everything you can for them."* ***P10***

When asked what advice they might give other parents, mothers in this study often talked about needing to trust their gut instinct and push back against healthcare professionals to force them to listen. This appears to support the narrative of a journey from being ignored to feeling validated and to illustrate how 'good' parents know their baby and advocate for them when needed.

> *"trust your mother's instinct…and just push…for…what you think…because I think you know sort of as a parent that when something's right and not right with your child."* ***P18***

The journey to becoming a good parent was found through adversity and protecting their baby.

> *"Sometimes I feel like…I'm a lioness. I need to…take care of my little cub."* ***P23***

6.4.2.2 Helpless vs. empowered

The word 'helpless' was frequently expressed across all the interviews and was associated with extreme emotions and distress. The journey to becoming a good mother, for many parents in this study, was interpreted as a growing sense of control and empowerment gained through finding increased confidence and resolving uncertainty in relation to their baby's unsettled behaviours, through diagnosis and finding a solution, usually in the form of a medication or other healthcare related intervention. This journey was then often shared widely on social media with other families.

> *"I take our health in my own hands now"* ***P22***

When this journey was experienced, this allowed mothers to express a narrative in which they felt proud of their ability to manage the health of their family. Where the experiences did not fit this

journey, this caused further distress and for some mothers led to them questioning their abilities as a parent and also whether their baby was 'wrong' or 'broken'.

> *"it was after the [medication brand name] hadn't worked, because that was supposed to be the magic thing, that resolved everything. So that's when we got a bit desperate…You had to be careful there not to be, my child is fundamentally wrong."* ***P29***

In addition, being unable to control their baby's unsettled behaviours caused feelings of extreme guilt and failure. This challenged women's ability to form an identity as a 'good mother'.

In this theme, the transition to parenthood can be understood as developing an identity as a 'good parent' through a gradual journey from feelings of helplessness and uncertainty to feelings of control and empowerment.

6.4.2.2.1 "At the start, I didn't know"

Many parents described a sense of confusion and uncertainty about their baby's unsettled symptoms, and in distinguishing these from 'normal behaviours'. Parents who had found a medical label helpful reported that this had given them a sense of confidence which came from feeling that they knew what was wrong. This uncertainty felt worrying to some of the mothers in this study because they felt it reflected a failure in them as a mother. The transition from a place of uncertainty to a place of confidence was perceived as demonstrating that the parent was learning about their baby and becoming a competent parent. This confidence was sometimes gained through time and experience, other times through conducting their own research and gaining expertise in related illnesses such as allergy and reflux. In this way, the journey to becoming a good parent was interpreted as increasing confidence in the cause and solution for the unsettled behaviours.

Many parents talked about how their transition to parenthood was characterised by worries because they were a 'new mum' or a 'first time mum'.

> *"As a new mum, it panics you and it worries you. You don't realise that…you're going to get through it and it can change"* ***P6***

Parents described feeling doubt and uncertainty about whether a behaviour was normal or worrying, framing this as a feature of early or inexperienced parenthood.

> *"I think that's the hardest bit when you're first a parent is, should my baby be doing this, … should I be worried about this, or is this normal?"* ***P1***

> *"initially obviously…'cause it's my first baby I didn't know…countless amounts of research I had to do, just to really understand what's going on"* ***P19***

Parents described their growing certainty that their baby's unsettled behaviours were not normal. This seemed to bring with it confidence in themselves as a parent and in their own knowledge and experience.

> *"I just, I felt more confident that this isn't actually just normal. It's not just how normal babies should be, you know, I've seen babies in the rest of the family who are quite content when they're newborns. They're supposed to sleep a lot…they shouldn't be in that much discomfort."* ***P22***

Many parents described trying many different things at once and then feeling unclear about what had helped; or overwhelmed by different strategies. Some parents linked this to their cultural background.

> *"sometimes I think trying too many different things is a bit overwhelming, even… for the baby as well…'cause you're chopping and changing constantly…even now, I don't really know exactly what it is. I've just done 1000 things at once and something has worked…"* ***P22***

> *"culturally… You don't really ask for help…people just offer advice…having a baby in the kind of family dynamic that I live in…a really big family…and culturally, usually women…there's so much advice given to you… often in a very critical way…I just ignored most of it, to be honest, just filtered through, for my own sanity...I think too much advice sometimes is a bad thing, you know.* ***P12***

Here, parents were expressing how their experience of uncertainty was overwhelming. It seems also possible that not knowing exactly what had worked was contributing to their overall sense that they were not good enough. The 'good mother' appears to some of the interviewed mothers to be someone who is confident in their strategies and knows for sure what will work to resolve the unsettled behaviours.

In contrast to the uncertainty and confusion, for many parents being given a medical label was a moment of certainty that created confidence in itself.

> *"To put a label on it was kind of a, right, that's what it is, then. I'm not just sitting there going…Is it this? Is it that?…just the relief of knowing what it was, really."* ***P15***

6.4.2.2.2 The search for a magical 'fix'

For many parents, helplessness was associated with feelings of extreme negative emotionality such as guilt, exhaustion and desperation.

> *"Absolutely awful… I felt so handicapped because I just couldn't do anything…And it used to make me feel really horrible 'cause as a mum…I'm trying everything and nothing's helping… that's when I'd feel so helpless and handicapped… I went through depression …To a point where I'd tell my husband, 'I'm really fed up. I just want to run away somewhere. You take care of the baby and I just want to go away. I don't – I can't do this.'* ***P23***

For most parents, coping was sought through being empowered to try strategies to mitigate or reduce the unsettled behaviours. Other people were considered helpful if they were willing to suggest or try something new.

> *"I think because I was trying something that I had heard, I think it also made me feel more in control, because I was like, right, I'll try this… rather than feeling helpless"* ***P26***

Often parents framed the usefulness or accuracy of a medical label in the context of whether it offered new solutions to try, including medication or specialised formula milk. This was in contrast to labels of exclusion which left parents with few options.

> *"GP, they, they diagnosed colic but I'm quite sceptical about the term colic in general anyway, you know…I suppose there's nothing you can do really…so no, I didn't find it helpful."* ***P20***

Many parents described searching or hoping for a 'quick fix' to their baby's unsettled behaviours. For some, they found this solution in a diagnosis or a medication and wanted to share this with other parents.

> *"Pretty much just the [medication brand name] . It was kind of a miracle cure. We had it for about three days, and it stopped, really good…I know I keep on saying it, but it was the [brand] that really was like a miracle cure for her."* ***P8***

For others, the 'magical solution' remained elusive and this caused continued distress; especially when they had been convinced by other parents' stories that a particular medication would be the 'fix'.

> *"I guess I went to the GP expecting, like a, a fix, a magical wand to make everything okay, and the reality was, they didn't have it."* ***P12***

Some parents described the moment that they realised there was no 'magic fix' as a relief. However, even while acknowledging that, parents still struggled to let go of the idea that there could be a solution in the future.

> *"It was quite good to kind of just see that, yes, there's no cure for it. I think that was quite reassuring to know that there isn't a cure out there that's just gonna fix her, the baby having reflux…I would just say wait it out, enjoy the small moments, erm, just remember that it's only happening for a short amount of time, then hopefully there'll be something out there that will make it easier for us in the future."* ***P24***

6.4.2.2.3 Guilt – 'A total failure as a parent'

For many of the parents interviewed, the transition to parenthood was strongly characterised by feelings of guilt. Almost every parent interviewed described feeling like a 'bad mum' for having no control over their baby's unsettled symptoms.

> *"you just get this sense of, like, am I not, am I not doing it right by them?…am I getting this wrong…I'll be really honest, there was a couple of times I thought maybe I'm, like, the worst mum ever… I should know what I'm doing…maternal instincts should just kick in, and they didn't, and my baby just continuing to cry, and I just don't know how to fix it."* ***P12***

For many parents this was associated with guilt around their own diet, around stopping breastfeeding before they felt they 'should' or around not being 'good enough' at an exclusion diet.

> *"That's when I, I was, kind of, leaning towards the cow's milk protein allergy, especially because I was literally eating so much chocolate at that point. I thought if it is, I've probably poisoned him if he's got any allergies"* ***P20***

Medical labels or explanations helped to alleviate some of the guilt they experienced, because they were an independent cause which the parent could not have been expected to control.

> *"If I'd have known she definitely has reflux… I would have known it's an actual thing, it's not what I've caused, I couldn't cause it, she had it anyway, and, yeah, that would have helped. Or I would have then been able to say, 'Oh, it wasn't because I couldn't breastfeed her, it was because she has reflux.'"* ***P21***

One parent described how the unsettled baby behaviours impacted her identity as a mother, her bonding with her baby and her own mental health. Ultimately she described feeling she did not deserve her baby because she could not control the unsettled behaviours.

> *"I just assumed that she had a problem with me and didn't like me… it instantly…took a toll 'cause just didn't know what was going on or how to fix it, and just felt really inadequate and like we weren't the right parents for her, if we couldn't make it better… I felt like [baby] hated me … if she didn't suffer so much… me and my husband wouldn't have got quite so rundown… so I think it was different… slightly more resentment there"* ***P14***

6.4.2.3 Aware vs. vigilant

Many parents reported high levels of vigilance or watchfulness about their baby's unsettled behaviours which they found difficult to disentangle from their increased awareness and knowledge about illnesses which they had gained through their own research. For many, this was directed specifically at awareness of food allergy as a possible cause for the unsettled behaviours. Parents' accounts paint a picture of struggling to disentangle clinical symptoms of allergy or reflux from their own perceptions of their baby's behaviour, which they recognised as being characterised by worry and fear. Mental health difficulties in the transition to parenthood also contributed to the complexity of this for many parents, who struggled to separate what was 'sensible' from what was a sign of clinical or 'irrational' anxiety.

6.4.2.3.1 Fear of an underlying threat: Excessive anxiety or rational worrying?

For many parents, this feeling of vigilance was underpinned by a sense of looming or unknown threat which caused great anxiety. Parents were worried that there was something underlying which had been 'missed'.

> *"I think deep down there might still be something else, but I think that it is just hard getting somebody to actually do anything for her. Just because, obviously where she's still got some of the diarrhoea, and the sickness, even though she is [dairy free]… I just think that underlying, there might be something else, but I just feel like that nobody will listen, and actually do any tests on her"* ***P10***

Often distinguishing between 'serious' and 'normal' symptoms was difficult. Commonly it was perceived pain which concerned parents the most and prompted thoughts of an underlying medical explanation. Thinking their baby was in pain was understandably extremely anxiety provoking for parents, contributing to their vigilance about health concerns.

> *"It's quite upsetting to watch him…because you could see the pain…he would scream and he'd have his fist clenched and arms lifted…he was frowning all the time…I thought maybe…there was underlying issues, so I took him to the GP, and he said, 'No, it's absolutely fine. Kids cry so it's fine, it's normal...So I was like yes, yes, but what's, what's the reason?... There must be an underlying reason,'" P25*

Part of the vigilance experience was the challenge in separating the differences between clinical anxiety and rational worry. One parent described:

> *"The health visitor said, 'You know what? … they're not completely unhealthy thoughts you're having… because you're trying to get her looked after, not that you're being overly paranoid or anything. You're just…at the end of your tether, and you just want answers.' So..." P15*

However, shortly afterwards, this same parent described how her anxiety had become debilitating to a level she felt, looking back on it, was concerning and indicative of a problem.

> *"It just - when I look back I think, God, I was so worried about going anywhere with her or doing anything, especially on my own… I was very on edge for a long time…Now I look back on it I think, why was I so worried about that? What was wrong with me?" P15*

These examples demonstrate how parents were wrestling with their own perception of unsettled behaviours as symptoms of underlying health problems and the judgement of this as reliable or irrational.

6.4.2.3.2 'When you've read it, you see it'

When asked about their baby's symptoms, many parents mentioned possible food allergy or reflux. There was a reported vigilance about allergy and awareness of the symptoms of allergy amongst almost all parents interviewed.

> *"Sometimes that's what made me think it could be an allergy because most of the time he was fine, but there was the odd time where he really looked like his tummy was in pain and he would cry and cry and cry until he'd be sick." **P13***

Many parents noted that they would frequently read things online and then notice these problems in their baby. For some this represented a possible self-fulfilling prophecy or provoked new anxiety. Many parents reported continuing reading and searching until they found something that "felt right" for their baby.

> *"And then, um, I was doing a lot of research online and it was saying that, you know, the peak of it is around six weeks, so I kind of expected it to get worse before it got better, which kind of filled me with some dread 'cause I thought, how could this possibly get worse, and it did."* ***P20***

These parent stories exemplify the experience of increasing awareness of health related concerns and how this knowledge became increasingly difficult for parents to disentangle from fear and worry.

6.4.2.4 Individual vs. connected identity

The development of an identity as a 'mum' for the women in this study was described as spanning across pregnancy, birth and the early perinatal period; often complicated by health issues, birth trauma, mental health difficulties and other factors, as well as their baby's unsettled behaviour. Challenges were associated with the maintenance of their personal identity, including gender, religion and ethnicity whilst faced with new roles for their infant and their changing relationships with others in their lives (such as partners).

In the journey to becoming a 'good parent', parents of unsettled babies reported feeling a transition in their identity from a personal, individual identity to an identity as a mother, intrinsically connected to their baby. At times this was reportedly difficult to achieve because of the unsettled behaviours. Some parents coped with this by framing 'difficult' behaviours as being early signs of strength or courage. In other cases, medical labels or diagnoses were useful to frame the unsettled behaviour as being separable or distinct from the baby's personality, providing an external cause distinct from the baby themselves. This made the development of a connected identity easier for parents to build.

Physical and emotional connectedness were described as contributing to bonding and therefore to the overall transition to a parenting identity. Independence and interdependence were in tension, as the women described trying to maintain a sense of themselves while integrating their new bond with a physically and emotionally connected other.

6.4.2.4.1 Who am I?

For some mothers interviewed, they discussed difficulties in maintain their sense of self and personal identity whilst trying to manage unsettled behaviour. Many valued their social network and connections to others as vital in helping them to cope. Motherhood was seen as a new identity that you develop gradually.

> *"a bit surreal…it's really weird, I don't feel like a parent…of course I've taken onboard the role, but…it's a weird one, I feel like it's something that you grow into, isn't it?* ***P26***

Aspects of their personal identity, such as gender, were also described as playing a role in their experience of the unsettled behaviours. One interpretation of this is that parents viewed close proximity for the majority of the time as the key aspect of their identity development as a parent. Another interpretation could be that the parent's gender or socialisation as a female was important for understanding how the unsettled behaviours impacted their identity development as a 'mother'.

> *"Erm, my husband was at work all day so, like, when he's coming back on the evening he, he's, like, trying to help but, I don't know, I just think as a mum, it, it's just so much more overwhelming for us."* ***P20***

> *"The same for the partner as well, he, 'cause he works from home as well, so he's, I know some dads go out to work, but he's been here all the time as well. So he's experienced every step of it and he's, he felt the same"* ***P29***

In contrast, some parents described a difficulty discovering their identity as a parent, or integrating their new identity as a mother with their previous self before having a baby.

> *"I just felt like a milk machine. I didn't feel like mum, I felt like milk. I am the milk lady. Then we tried pumping, and I'm like, I just feel like a cow now…I felt quite robbed of me. I lost me for a while…I was just – I was just mum. That's all I was. That's all I could be at that time. I'm – I'm just mum. I'm not [name], I'm not wife, I'm not – I'm not even doing my housework properly at the minute. I'm just – I'm just mum, that's all I do."* ***P15***

For one parent, new responsibilities as a parent disrupted her personal religious identity, causing tension and emotional distress

> *"When he's crying I can't sort of – 'cause I've got, er, my prayers to pray and everything…before I, I could pray, you know, within the time whenever I…wanted, but now I have to sort of see when he's settled, then I have to sort of quickly pray before he starts crying again…sometimes – it makes me – it, it, it makes me sort of feel like giving up, you know? Being, you know, being a parent is really, really hard..."* ***P28***

Another had experienced racial abuse and described how this could have affected her view of herself or her baby:

> *"…whilst I was pregnant, I went through racial abuse... and lucky for me I didn't let that…impact how I treated myself, how I treated my baby, at all."* ***P23***

6.4.2.4.2 Bonding with a 'difficult' baby

Some parents reported that their experience of connection to their baby was harder or slower than it might have been without the unsettled behaviours. This was an intrinsic part of their transition to parenthood.

> *"I struggled to bond with her because she just kept crying all the time, and I kept thinking to myself, am I doing something wrong? Is it me?…if your baby is… not crying, it makes that bonding much quicker doesn't it? You get to bond with your child more, you get to create all these beautiful moments from the beginning. Whereas if you've got a child who's fussy… the onus is on you to try and sort this bab-, help this baby out… … Then obviously that's a very different experience to a parent who's having a beautiful time"* ***P12***

Parents appeared uncomfortable when discussing their own view of their baby's behaviour as being part of their temperament or personality; worrying that they were 'just a difficult child'. In some cases, this was described as making it harder for parents to connect with their baby and to be the 'mum' they wanted to be.

> *"How his temperament is… I've kind of just come to terms with the fact that he's just generally quite a cranky baby. I don't actually think there's anything wrong…I love being a mum, like, it's who I am. It's who I was, I felt I was made to be… sometimes… I wish that it, that he was different in, in terms of the crying, I'm not going to lie… I just think… why couldn't he just be a nice, easy baby"* ***P20***

Some parents interviewed, talked about their baby's character in relation to their future development. In this way, they were able to reframe the 'difficult' behaviours as being indicators of positive personality traits to come.

> *"Having had an exceptionally tricky first baby, who is an adorable toddler now. He went down the Demon Drop on his own yesterday…an absolute firecracker. I think had I not have had a tricky baby first, then I would have found this much, much harder."* ***P21***

In the journey to connect, other parents found the use of a medical label or illness related interpretation of their baby's unsettled behaviours was useful as it gave an external cause for the baby's behaviour, external both to themselves as a parent and to the baby's character. In this way a medical diagnosis could be seen as something they and their baby could work together against. It therefore appeared much more comfortable for parents to frame and discuss their baby's unsettled behaviour as something which was externally caused.

> *"I do feel like sometimes… I'm worried that I'm not enjoying her. I don't want to brand her as a fussy baby, but she is a fussy baby…I don't want to really be negative about her, but at some points I think I was feeling like I wasn't enjoying spending time with her. I just was constantly dealing with her being sad like her crying or her being uncomfortable…It's not her fault is my main thing. She can't help it, which has helped me, because I'm just like she's not deliberately being unsettled."* ***P5***

6.4.2.4.3 Physical and emotional connection

Many parents discussed experiences of being connected and separate from their baby both physically and emotionally. For some, the experience of being connected in pregnancy carried over to the early days of parenthood and often this was linked to feeding and to medical interpretations of unsettled behaviours.

> *"I try to limit any foods that are bad anyway…I know they say diet doesn't…impact your breastmilk, erm, but I don't know, just in cas'. …while I was pregnant…I tried to eat as clean as possible…I felt like if I…eat something that could negatively impact her, then it's really not fair on her."* ***P26***

For one parent, breastfeeding her baby was inextricably linked to her personal identity of who she wanted to be as a mother.

> *"breastfeeding, that's something that I always wanted to do and thought that I'd be a mum that did breastfeed, but that didn't come to fruition..."* ***P29***

Similarly, one parent described that the physical skin-to-skin experience of breastfeeding without a nipple shield made her feel proud. In this example it was not just that she was providing the milk with her body, but the absence of a physical barrier between them which was experienced as an achievement.

> *"I think when she was about three months old…she started latching on to my breast directly without any nipple shields, and it was the best moment ever. I literally felt like I've achieved something, which is so weird. It was like, I've won a gold prize! Oh my God! It made me feel so much better, because it felt like, you know what? I'm giving all the nutrition to my baby."* ***P23***

For many parents the connectedness to their baby was a challenge and there was a desire to accelerate the separation between them. This was either because of practical difficulties juggling daily life demands or because they were worried about their baby learning independence. Their

baby's unsettled behaviour was viewed as challenging because it meant extended periods of physical connectedness.

> *"Exhausted. Sometimes, yes, I am irritable because I just feel like, come on, I need to get up and go to toilet or I need to get up and have a shower….He was always a little bit in discomfort, and mum is the source of comfort, so he used me as a dummy as well as obviously he liked to hold and embrace with mummy…It's just extremely challenging because baby likes to be attached like a baby koala, 24/7."* ***P9***

For one parent, the unsettled symptoms had led to increased physical proximity and connectedness between her and her son. She felt that this had strengthened their emotional bond:

> *"because he was so fussy, he only ever wanted me…it's made me more of an overbearing parent…he's very much mummy's boy…I've mollycoddled him more than anything. I, I never did as much with my daughter, but I have been more overbearing and more overprotective of him because of these issues…our bond is perfect… I have times where I just get frustrated but not with him, with the situation. If anything, it's ma'e him less likely to leave me and me less likely to leave him"* ***P18***

Many parents described a symbiotic link between their own emotional state and their baby's. They described how the emotional climate was infectious. One parent articulated that her and her baby's emotional state were attuned and connected. She felt that finding the solution to her baby's unsettled behaviours would "fix" them both.

> *"From the day of having her I just cried, most days I just – I howled. And that was even before this reflux started… I did talk to the GP about it… Then they're, 'Well, do you need more antidepressants?' 'No, I need you to fix her, because if you fix her it'll fix me.'"* ***P15***

6.4.3 Deductive Negative case analysis

Overall the themes and model from the systematic review were supported by the data from these qualitative interviews. The central concept that parents experience feelings of guilt and failure which are connected to them searching for a medical explanation for their baby's unsettled symptoms was clearly visible in this data. The model overall provided a good explanation for the data and appeared to be a 'good fit'. The themes from the systematic review are listed in Table 10, which maps these themes against the interview participants. Ticks are given to participants whose stories closely mirror the theme from the systematic review. Those whose experiences did not match the systematic review theme are considered in turn in the following negative case analysis.

Taking the two analytical themes from the systematic review separately, the theme of 'Searching for an Explanation' was more strongly represented in this data than the theme of 'Identity as a Good Parent'. This was largely due to the first descriptive theme of 'transition from 'me' to 'me as a parent'; which only mapped well onto five of these parents stories. Negative case analysis offers an opportunity to learn from the stories of the parents who did not fit the systematic review themes. In this analysis, each of the systematic review themes is taken in turn and the cases which do not fit the systematic review themes are considered one by one. Suggestions of how the previous theory is supported, contradicted, expanded or refined are considered [347].

Table 10: Matrix maps the themes from published systematic review [13] against the new data from participants in this qualitative study.

		P1	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15	P18	P19	P20	P21	P22	P23	P24	P25	P26	P28	P29
Identity as a 'good parent'	Transition from 'me' to 'me as a parent'								✓			✓			✓										✓	✓
	Guilt and failure			✓	✓	✓	✓	✓	✓			✓		✓	✓	✓			✓	✓	✓	✓		✓	✓	✓
	Feeling responsible and wanting control		✓	✓	✓	✓	✓	✓				✓		✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓
Searching for an explanation	Expectations	✓	✓	✓	✓	✓	✓			✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓		✓
	Feeding is linked	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Finding help	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓
	Lack of certainty	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypervigilance and desperation			✓		✓	✓			✓		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓		✓

6.4.3.1 Identity as a good parent:

6.4.3.1.1 Transition from 'me' to 'me as a parent':

Supporting:

A minority of the participants did fit with this theme as it was expressed in the systematic review, these five parents are ticked in the matrix above. Specifically they expressed feeling like they had 'lost themselves' or else their expectations of who they would be as a parent did not match up to the reality they experienced.

Contradicting:

The theme of transition to 'me as a parent' as captured in the systematic review was not identified within 20 parents' interviews in this data. There were no examples of parents building their own parenting identity on their childhood experiences; as was described in the systematic review; however the interview guide did not explicitly ask about this so this could reflect a limitation of the study design rather than a disconfirming case.

One case was broadly positive when discussing the transition to parenthood and did not talk about any difficulty in assimilating her identity. This is in contrast to almost all the other stories. In this case, however, the participant describes herself as always having been 'maternal'; so it is possible she had already thought of herself in this role before conceiving her baby. In a minority of other cases parents had already thoroughly assimilated the role of 'mum' into their own identity through having had older children. These parents described their transition to parenthood this time as being easier because they were 'not a first time mum'.

> *"I'm very, like, maternal and whatnot anyway…and because I've been through it before"* ***P22***

Expanding:

Furthermore, the qualitative interviews suggested some elements to the transition to parenthood which were not captured by the systematic review and may reflect important additions to the existing theory.

Firstly there was one parent for whom her identity as a mother was not fully developed at the time of the interview, saying that the word 'mother' didn't really feel like her yet.

> *"A bit surreal…I don't feel like a parent…I obviously look after my baby; but it's such a weird word…I'd always thought of other people as parents, but not me…I feel like it's something that you grow into, isn't it?...I guess it'll feel more real when she starts calling me mum."* ***P26***

Secondly, those who volunteered information about their difficulties with conception, pregnancy or birth reported that this trauma pervaded their transition to parenthood. Their descriptions of the emotional transition to being a parent in the early days were interwoven with the physical or emotional trauma they had been through immediately before and this impacted their level of worry about unsettled baby behaviours.

> *"We took three years to conceive our little boy, so we were going through fertility treatments. That was really difficult…The pregnancy wasn't easy. I had quite a lot of complications…I had to have a c-section…I think because we had other stuff going on there was... other things we had to worry about…"* ***P1***

One parent also noted that she felt the experience was more overwhelming for her than for her partner because she was a mother (as opposed to a father). This was something which had not previously come out of the systematic review, possibly because of the general absence of parents of other genders in the literature. Future research would be needed to explore whether the emotions of early parenthood affect genders differently for parents of unsettled babies.

> *"I just think as a mum, it, it's just so much more overwhelming for us."* ***P20***

Secondly, connectedness and bonding was interwoven into many parents' stories of their transition to parenthood and their personal identity as a mum. This was an important part of the story for many parents and was complex and multifaceted. It included the relationship with their baby; through both physical connection (an embodied relationship - breastfeeding, skin-to-skin and massage) and emotional connection (through the family emotional climate and through the perceived 'clinginess' of the baby). It also included relationships with their intimate partner and wider social support, particularly in the context of the COVID pandemic, suggesting that the transition to parenthood was easier when these support networks were strong.

> *"It's made me more of an overbearing parent…he's very much mummy's boy…I've mollycoddled him... I never did as much with my daughter, but I have been more overbearing and more overprotective of him because of these issues"* ***P18***

> *"When … we first got her home, erm I did have a lot of help like from my boyfriend, my mum, my partner's mum, my friends and stuff…a lot of*

> *visitors for the first few weeks. So I feel like it took the first few weeks for me to realise that it's a lot harder, because I wasn't doing it all on my own…I did have quite a, a bad pregnancy, a traumatic birth and then all this [unsettled behaviours] came as well. So there was a time where I was a bit like, struggling to connect with her. Struggling to war-, I did wonder sometimes whether it was the right thing that we'd done, but…things got easier. [Now] I love her to pieces…I feel like I've got into the routine of being a mum now." **P29***

Refining:

In one case, the transition to being a mum is described as spanning her journey across her three babies' early years. With her first she feels she 'failed', then with later babies she was progressively more confident at advocating for them and challenging the professionals until with her third she was 'telling the GP what to do'. In her description she is describing that she now sees herself as a parent because she was finally able to understand the symptoms and advocate for the baby. Similarly in another case, a parent talks about 'mothers instinct' and states that as a parent you know what's wrong with your child. She equates identifying the cause as central to her identity as a parent.

> *"trust your mother's instinct…because I think you know sort of as a parent that when something's right and not right with your child." **P18***

In another example, transition to parenthood identity was entwined with being a 'good' parent. This parent expressed believing she was not a good enough parent and not worthy of her baby. She said she worried that her body was not good enough for baby, that her baby was angry with her breasts and implied that she doesn't deserve her baby because she (the mother) was not selfless enough to change her own diet. She believed her baby didn't like her and described herself as 'fumbling through parenthood'.

These cases appear to support the conceptual model as a whole and refine the concept of the transition to parenthood, or being a 'good parent', positioning it in the context of their birth experience, social network and describe 'growing into' a new role, rather than the feeling of loss captured by the systematic review.

6.4.3.1.2 Guilt and Failure

Supporting

The feelings of guilt and failure described by the theme in the systematic review were very closely mirrored by the experiences of the parents in this study. Almost all parents said that they felt like a

'bad mum' at times or like the symptoms were in some way their fault. These participants are ticked in the matrix above.

Contradicting

There were a few disconfirming cases and closer inspection of these allowed for greater understanding. For two parents they had moments of doubt when they began to feel guilty, suspecting they had caused their baby's symptoms by something they had eaten. However, these moments were fleeting and did not develop further because they described receiving high quality reassurance from professionals they had a strong relationship with and trusted.

> *"The breastfeeding group that I'm in… I was in it when my daughter was a baby…There's some, like, um, accredited breastfeeding lactation consultants in there, so their advice tends to be really, really good… I wondered if it was something that I was eating or drinking that was maybe upsetting him, that was causing him to cry, but they give really good evidence-based advice on that"* ***P20***

In one participant, only handwritten notes were available as the parent did not consent to recording, the richness of the data therefore suffered and this could be why the theme was absent from their story.

Expanding

Three further cases appeared to have fully internalised the viewpoint that they were good parents because they had fought for the diagnosis which ultimately 'fixed' their baby's unsettled symptoms. They believed that they had advocated for their baby and made themselves heard and as such they were left with the experience of feeling vindicated, angry or frustrated at what they perceived as being dismissed by professionals and proud of themselves as caregiver. This appeared to negate any feelings of guilt they may have experienced.

> *"I think that again, if I hadn't phoned the doctors every single time, then she could have still now been drinking that milk, still with bad stomachs, with me just going, oh well, it's nothing, like it's fine."* ***P10***

> *"I mean initially obviously they were like, 'Don't worry about it, it's just reflux and colic,' but at the back of my head I knew that something is just not adding up…it just didn't seem normal to me…I just kept on pursuing to make sure the GP understands the seriousness of the issue…obviously it's quite a lot of work really trying to make them understand the whole situation, but, er, I wasn't going to give in…[Later]…once it is actually diagnosed properly, then it does get better."* ***P19***

Overall, the theme of guilt and failure from the systematic review fit very well with this data. The cases which did not fit the theme appear to be because they have internalised the belief that they advocated successfully for their baby, supporting the model as a whole, which suggests that the search for a medical label may function to alleviate some feelings of guilt and failure.

6.4.3.1.3 Feeling responsible and wanting control

Supporting:

In the main, parents described wanting a strategy to resolve their baby's distress or symptoms and feeling unarmed and unprepared for the unsettled episodes because they felt that nothing they were doing was working. This lack of control was extremely distressing. In this way, most of the parents in this study described stories which fit very closely with the SR; however the language used by parents very consistently was 'helpless'.

Expanding:

There were some negative cases in which professionals had led the diagnosis of allergy or reflux and this had not been driven initially by parent concern; therefore the parent had felt in control from the start because they had a clear strategy as prescribed by the doctor.

> *"I think at the time I put it down to normal baby digestive issues with it being so immature. I hadn't really considered the fact that it could be something more… I was still very dubious when the doctor said try this milk. I did it because obviously you're being advised to do so by a doctor and it's clearly their field, but I was a little bit like, could it be that, or is it just we're reading too much into his symptoms? But you know after the months where his symptoms cleared up it was very evident…I think that it's more of an intolerance rather than allergy, so I've not been that worried."* ***P1***

There was a further group of three parents who believed strongly that their child had an allergy or reflux and that they were being ignored by medical professionals; in these cases they did not feel helpless because they took control of the situation and positioned themselves as an advocate for their child, fighting on their behalf and, as one parent put it, 'told the GP what to do'.

> *"I had to tell the GP what to do basically. I called and asked for a referral and she agreed, because I just said, 'This is my third child, I know what I'm struggling with. Could you refer me to dietitian?' and they did"* ***P9***

Finally, two parents had children who had been given a label of 'colic'; rather than a medical label (eg. allergy or reflux); but had felt well supported and listened to by professionals. They trusted the professionals and felt they had listened to them, empathised and tried everything they could. Both parents felt that they were 'waiting it out' and were using this as a conscious strategy. In these cases the parents had found a plan and a sense of control without the medical label.

> *"we went to the GP and then their advice was really helpful. And they tried everything that I think could be tried, to help ease the reflux, but unfortunately nothing that we tried did help, but, um, I, yes, I did think they, they explored the avenues so, so we saw a few different doctors, um, along, across a few weeks, um, and each of them was, was really nice, and took it seriously."* ***P13***

> *"initially I thought [there might be a medical cause] but then when everyone kept saying the same message I thought no, it's probably just colic and he'll grow out of it."* ***P25***

Overall these cases suggest that feeling helpless is central to parent experience of unsettled babies. This fits well with the theme described in the systematic review as 'feeling responsible and wanting control'. Cases which did not fit this theme offer supporting examples for the theory, suggesting that parents may find a sense of control through interactions with empathic and trusted professionals.

6.4.3.2 Searching for an explanation

6.4.3.2.1 Expectations

Supporting

Most of the parents had moments of wondering what was normal. Many parents also talked about expecting the newborn period to be 'perfect' and enjoyable and of early relationship building with their baby to be easy and natural, but then found that it was much harder than they had thought. Often this was linked to the unsettled symptoms and parents reported thinking that was an indication to them that something must be 'medically wrong'. In these respects, the theme from the previous systematic review was largely supported. Parents in this group are highlighted with a tick on the matrix.

Expanding:

For three parents, they discussed how the medical label itself had been functionally useful to them because it helped them to *"set my expectations accordingly"* ***P25.***

Refining:

Often parents felt that they had been expecting their baby to vomit or to cry but felt that the severity of these behaviours was so much more than they had expected that it couldn't possibly be normal.

> *"I was told it's only reflux, every baby suffers reflux. Um, and yeah, I just knew that it just didn't add up, because I understand every baby suffers reflux, but how much do they suffer? Like not with every feed, literally 99 per cent comes out. Like, what's going on?"* ***P19***

Contradicting:

For two parents, they were expecting an allergy before their baby was born (due to a previous baby having had an allergy diagnosis) and so were expecting to have to fight and advocate for their baby when they arrived to get the diagnosis they needed. In this case they did not fit the theme developed from the systematic review. One possibility may be that this is a more recent study and the increase in diagnoses in recent years has led to parents now having had this experience once already with older children.

> *"Being the third baby with cow milk allergy, I was pretty much certain that…I knew prior to him being born."* ***P9***

In one case, the parent was convinced that the symptoms were because her baby didn't like her. Sadly, she did not express being surprised about this or that it was different from what she had expected. In this case it appears that she was struggling with mental health problems and bonding issues and these were at the forefront of her mind.

Overall, the theme of expectations from the systematic review fit well with this primary data. Negative cases highlighted additions which can be made to the theory in terms of the severity of the behaviours, the function of the medical label to set expectations and experiences with previous children.

6.4.3.2.2 Feeding is linked

Supporting:

Every parent interviewed had connected their baby's unsettled symptoms to feeding in some way, there were no negative cases. Almost all parents who had done any breastfeeding had adjusted their own diet to try to control their baby's symptoms. Those who were formula feeding had often at least tried hydrolysed formula and many were on specialist prescribed formula full-time. Many of those

who had initially been breastfed but switched to formula described how their baby's symptoms had been a factor in this decision. In some cases this was because they felt their baby was 'too fussy' or 'too hungry' to breastfeed. One parent described switching to exclusively formula feeding because she had found it too difficult to administer colic drops while breastfeeding. Another described the challenges of giving Gaviscon while breastfeeding. The theme 'feeding is linked' from the systematic review was strongly supported by the data in these interviews.

Expanding:

In addition to supporting the theme, some further insight may be gained. Many parents felt that they had stopped breastfeeding before they wanted to and for some this had caused significant emotional distress. Parents often reported knowing that the transition to formula milk was 'harder on [baby's] tummy' or reporting that the symptoms had emerged only after they had introduced formula; but feeling that they had not had sufficient high quality feeding support to enable them to continue breastfeeding. Other parents reported that their baby was unsettled while breastfeeding and that this had been a factor in their decision to switch to formula. In these cases, it appears likely that resolving the breastfeeding difficulties may have provided a solution to some of the unsettled behaviours and prevented the transition to formula. Finally, two parents reported that the dietary changes they had implemented had made them consider switching to formula. Most parents reported that they would have benefitted from better breastfeeding support.

> *"at first it was like oh, should I just stop breastfeeding her all together so we're sure that it's not the dairy and that she's not getting any dairy from me or anything like that"* ***P5***

> *"when he, when he's being really fussy and he won't take, er, the boob…then I give him bottle instead, even though I prefer breastfeeding…But if he's, if he's being, you know, impossible, I can't, I can't deal with it, then I just put it in a bottle…In the beginning I wanted to just solely breastfeed, um, but because of, you know, because of how he fed and everything I started, um, formula feeding when he was, you know, when he was being a bit fussy and stuff"* ***P28***

Overall, the theme of 'feeding is linked' from the systematic review was strongly supported by this data. Although there were no negative cases, since every parent connected the unsettled behaviours with feeding at some point in the interview; the data builds on existing theory to add that feeding difficulties may be misinterpreted as medical problems and that parents both want and need better breastfeeding support.

6.4.3.2.3 Finding help

Supporting:

In almost all cases, the theme of finding help from the systematic review was mirrored in the data from these qualitative interviews. Parents reported feeling dismissed, patronised and not listened to. Where they were happy with their experiences of finding help, this was because they had felt listened to.

Refining:

In this data, additional detail was available on what constituted feeling 'listened to' which can enhance existing theory. Parents reported that they wanted their children to be seen in person and 'properly assessed' and felt that often they were 'fobbed off' with quick diagnoses with no possible action (like colic) or by being told their baby was normal. In two cases, the parents felt dismissed even despite being given a medication on prescription because they felt this had been done too hastily and without proper investigation. On a few occasions, parents described positive interactions with healthcare professionals. In all cases the common thread between these was that the parent felt that the healthcare professional had listened to them, taken their worries seriously and properly 'investigated' their concerns. Even when the symptoms hadn't subsequently resolved parents were accepting of that, as long as they felt the HCP was kind and empathetic.

Contradicting:

There were three exceptions who did not describe experiences similar to the above. In one case the interview data was limited because it was handwritten notes only as the parent did not consent to recording. In the other two cases they had not sought medical help for their baby's symptoms. Instead they had looked online or talked to family and friends and got a consistent message that it was most likely colic and they did not view this as a medical label so they were able to manage it at home with good support from their social network.

Overall, the theme of finding help fit well with the data from these interviews. It can be refined to better describe parents definition of being 'listened to' to include an empathic professional who takes considered action following a thorough assessment. Help may also be provided through a reassuring social network.

6.4.3.2.4 Lack of certainty

Supporting

All parents in these interviews reported feeling a level of confusion or uncertainty. Just as in the systematic review, this manifested in terms of confusion with what was normal and what was not normal; differences in the different medical labels or uncertainty as to what was causing the behaviours. Even after a HCP had given a diagnosis the parent was left with a lingering sense of uncertainty or confusion as to how to manage the symptoms and whether the diagnosis was accurate or not.

Expanding

In addition, some parents mentioned confusion because of conflicting advice they had received from professionals, or from reading different messages online. In contrast consistency of advice had made them feel less confused and more confident.

> *"I think after going to so many GPs and seeing so many different doctors and the lactation consultant, and all of them just saying, no, this is normal, I guess that kind of reassured me that, actually, there is no medical reason behind it."* ***P12***

Overall, the data from these interviews strongly supported the theme of 'lack of certainty'; with the additional confusion described as coming from conflicting messaging. Where messaging was consistent, this improved parent confidence.

6.4.3.2.5 Hypervigilance and desperation

Supporting:

Many of the parents we interviewed talked about feeling like they were constantly worried, watchful or anxious about their baby's health. They described being in a state of high alert. This also manifested as almost constant searching for new solutions, often through online forums or web searches. In this way, the theme of hypervigilance and desperation from the systematic review was echoed in this data.

Contradicting:

For those parents whose stories did not fit the theme of 'hypervigilance and desperation' from the systematic review, two had diagnoses of allergy which had been driven by a professional, so the parents said they hadn't been watchful or anxious about the behaviours pre-diagnosis.

> *"The GP said it sounds like reflux, when I was saying she was arching on the bottle and throwing herself back and screaming whilst in the middle of a feed. She said, 'It sounds to me like it's reflux.' I'm like, but she's not*

> *being sick. Not being sick, not beyond what I would call the norm for a baby. It was like tiny possets here and there."* ***P15***

For one parent there was limited data available as we had only handwritten notes for her interview. For another parent, she had an existing relationship with a HCP she trusted who was able to reassure her. For the final parent, she felt confident she knew her baby had reflux but was aware from her reading and from repeated interactions with HCPs that there was no medical worry in relation to this because her baby was otherwise well and gaining weight.

> *"Actually, I did speak to his, er, doctor…after his surgery he went for… they checked him and said if I had any concerns, so I told them about the burping and stuff and he said, 'Oh, do you know, some babies are just colicky… it sort of made me feel a bit relieved, in a way, because, um, at least there's nothing wrong with my baby."* ***P28***

Refining:

Some parents described being aware of symptoms before their baby was born and already knowing what to look for, in these cases there was often a very high level of vigilance and a sensitivity to symptoms such as nappy rash, skin irritation or nasal congestion. Many parents specifically mentioned allergy as a possible worry and there was a sense of 'problem readiness' in relation to allergy, often parents were watchful for particularly bad bouts of crying or gassiness after they had eaten specific foods. These parents appeared to be primed to look for things in their own diet which might cause their baby to be unsettled. The would find it difficult to shake their concerns about allergies, even when they had received reassurance from healthcare professionals it remained a worry in the back of their mind. In this way, the theme of hypervigilance and desperation can be refined.

Expanding:

The qualitative interview data appear to offer a pattern within this theme which may help to enrich the theoretical model developed through the systematic review. In this data there appear to be a group of eight parents who were interviewed who reported levels of vigilance, panic or anxiety which were suggestive of mental health difficulties or who explicitly described having mental illness which was diagnosed. For these parents, the anxiety about their child's symptoms were inseparable from their anxiety and appeared to interact with and exacerbate each other.

> *"I was so worried about going anywhere with her or doing anything, especially on my own. It was like, the thought of walking to town and back*

> *was like, but what if - what if she needs to feed? What if she needs this? If I don't get back in time she's going to start screaming….I was very on edge for a long time"* ***P15***

It is unclear whether in these cases the unsettled symptoms caused anxiety, or the anxiety made parents more vigilant and so more watchful for unsettled symptoms, or how else they may interact to cause parent distress. Future research could look into this dynamic in more detail.

Overall, the concepts described in the theory of 'hypervigilance and desperation' fit well with many of the cases in this interview data. The data can offer expansion of the theory to include additional vigilance from parents who have had experience with a previous unsettled baby and to show how the feelings of vigilance overlap and interact with anxiety or other mental health problems. Negative case analysis may offer insight that positive interactions with healthcare professionals offering consistent advice may mitigate these feelings.

6.4.4 Discussion and Proposed changes to the conceptual model

I have presented in this chapter the detailed analysis of 25 in-depth interviews with mothers of unsettled babies, including a hybrid inductive & deductive reflexive thematic analysis and a negative case analysis incorporating a framework matrix and case-by-case revisiting of the transcripts of disconfirming cases. This has enabled me to significantly strengthen the conceptual model proposed in my previous study, a systematic review. Hybrid thematic analysis has allowed greater insight to expand the model and consider how it applies to a more ethnically diverse group of parents. Negative case analysis then assesses directly how well the themes from my systematic review (Chapter 5) fit this new interview data (see matrix in Table 10). In the main, the model appears to fit most of the data and disconfirming cases have given additional insight into how it should be updated and enriched.

The model has been refined to include the findings of this study and this will inform the later chapters which show intervention development and optimisation. Proposed changes to the model as a result of the analysis in this chapter are summarised in Table 11 and the updated model can be viewed in Figure 8. The most significant change to the model is in the theme of "transition from 'me' to 'me as a parent'". Hybrid RTA and negative case analysis suggested that parents experiences described in the systematic review may be expanded to include the parent's level of social connectedness and bonding as well as their pregnancy, birth and parenting experiences.

It has been important to ensure that the changes made are proportionate to the findings (for example, evidence from multiple studies within the systematic review was given greater weight than

one parent's interview transcript); whilst remaining inclusive of a variety of parent experiences (such as in presenting more culturally diverse data) and ensuring data which might lead to practical or changes in practice was included (such as in the case of data about infant feeding). This was achieved by individual judgement of the importance of the change for inclusivity or practical value and was made on a case-by-case basis. Consideration of single cases and how they may expand or contribute to existing theories in the literature have been explored by other authors; who have highlighted their contribution to methodological rigour and the value of including single cases to expand and contribute to broadening the scope of future research [348].

A strength of this research is in the level of detail which has been obtained through multiple analysis of the same interview data. In particular, this is most evident when considering reflexive RTA alongside a negative case analysis. In thematic analysis, codes are typically given to concepts at an early stage and the data is organised or grouped into categories according to coding. The analysis then mostly takes place within these coded groups of quotes, with some reference back to the full transcript for context when desired. In this way, it is easy to miss contradictions within a narrative, or changes to the perspective of the parent throughout the interview. When combined with the negative case analysis, however, I found that this allowed for a fuller view of the individual parents' 'story' as a whole.

Limitations of the research which may have impacted the results include the absence of a question in the interview guide about parents own childhood experiences and how this impacted their transition to parenthood. This was deemed important in the systematic review but was absent from this data. It is therefore unclear whether the absence of parents' own childhood experiences in the findings was due to the absence of a question relating to it directly in the interview guide or whether this was due to a lack of support for the theory in this respect. Secondly, one of the parents did not consent to recording and transcription, which limited the richness and depth of the data available in her specific case. Finally, there was an absence of father's voices or parents of other genders in this data set. Future research could consider this theory in the context of father's experiences and consider whether the model fits well for other genders; or if the experience is specific to 'motherhood'.

In conclusion, hybrid inductive & deductive reflexive thematic analysis is supplemented by negative case analysis of this qualitative interview data. Through this I have developed a series of themes and refined the existing conceptual model to capture additional experiences and voices. This model was overall a good fit for the interview data, suggesting it may be a helpful resource to base intervention development around.

Table 11: Summary of proposed changes to the conceptual model from the hybrid RTA and the deductive negative case analysis

Systematic review theme	**Themes and subthemes from hybrid reflexive thematic analysis**	**Deductive negative case analysis findings**	**Specific changes to conceptual model**
Transition from 'me' to 'me as a parent'	Individual vs. connected identity: • Who am I? • Bonding with a 'difficult' baby • Physical and emotional connection	Expanded, Refined, contradicted	+ existing maternal identity + 'growing into' parenthood + entwined with birth trauma + physical and emotional connectedness to and separation from baby + connectedness to social network + religious or cultural identity
Guilt and failure	Helpless vs. empowered • Guilt – 'a total failure as a mother'	Supported, Expanded	+ positioning the mother's role as an advocate, martyr (eg. sacrifice through elimination diet), with the perfect body (for birth and breastfeeding), a perfect knowledge of and 'instinct' for their baby.
Feeling responsible and wanting control	Helpless vs. empowered: • 'At the start, I didn't know' • The search for a magical fix • Guilt 'a total failure as a parent'	Supported, Expanded	+ waiting it out with support as a conscious strategy

Systematic review theme	**Themes and subthemes from hybrid reflexive thematic analysis**	**Deductive negative case analysis findings**	**Specific changes to conceptual model**
Expectations	Aware vs. vigilant: • Fear of an underlying threat: excessive anxiety or rational worrying? • 'When you've read it, you see it'	Supported, Expanded, Refined	+ label can set new expectations + perception of severity contrasting with 'normal' amounts of unsettled behaviour
Lack of certainty	Helpless vs. empowered: • 'At the start, I didn't know' • The search for a magical fix	Supported	+ Conflicting advice causes more confusion
Feeding is linked	No explicit theme – integrated throughout	Supported, Expanded	+ I know switching to formula made it worse, but I didn't have enough support to BF + breastfeeding difficulties were misinterpreted as medical labels + exclusion diet was a reason for switching to formula
Finding help	Ignored vs. validated: • 'Don't ignore me' • 'Fighting' for my baby	Supported, Refined	+ being listened to means being thorough, taking carefully considered action and being empathic. + reassurance from a strong social network is important

Systematic review theme	**Themes and subthemes from hybrid reflexive thematic analysis**	**Deductive negative case analysis findings**	**Specific changes to conceptual model**
Hypervigilance and desperation	Aware vs. vigilant: • Fear of an underlying threat: excessive anxiety or rational worrying? • 'When you've read it, you see it.'	Supported, Refined, Expanded	+ Primed with a problem readiness to allergy + Scrutinising diet (own and baby's) + Persistent niggling doubts about allergy + Difficulty in identifying clinical anxiety

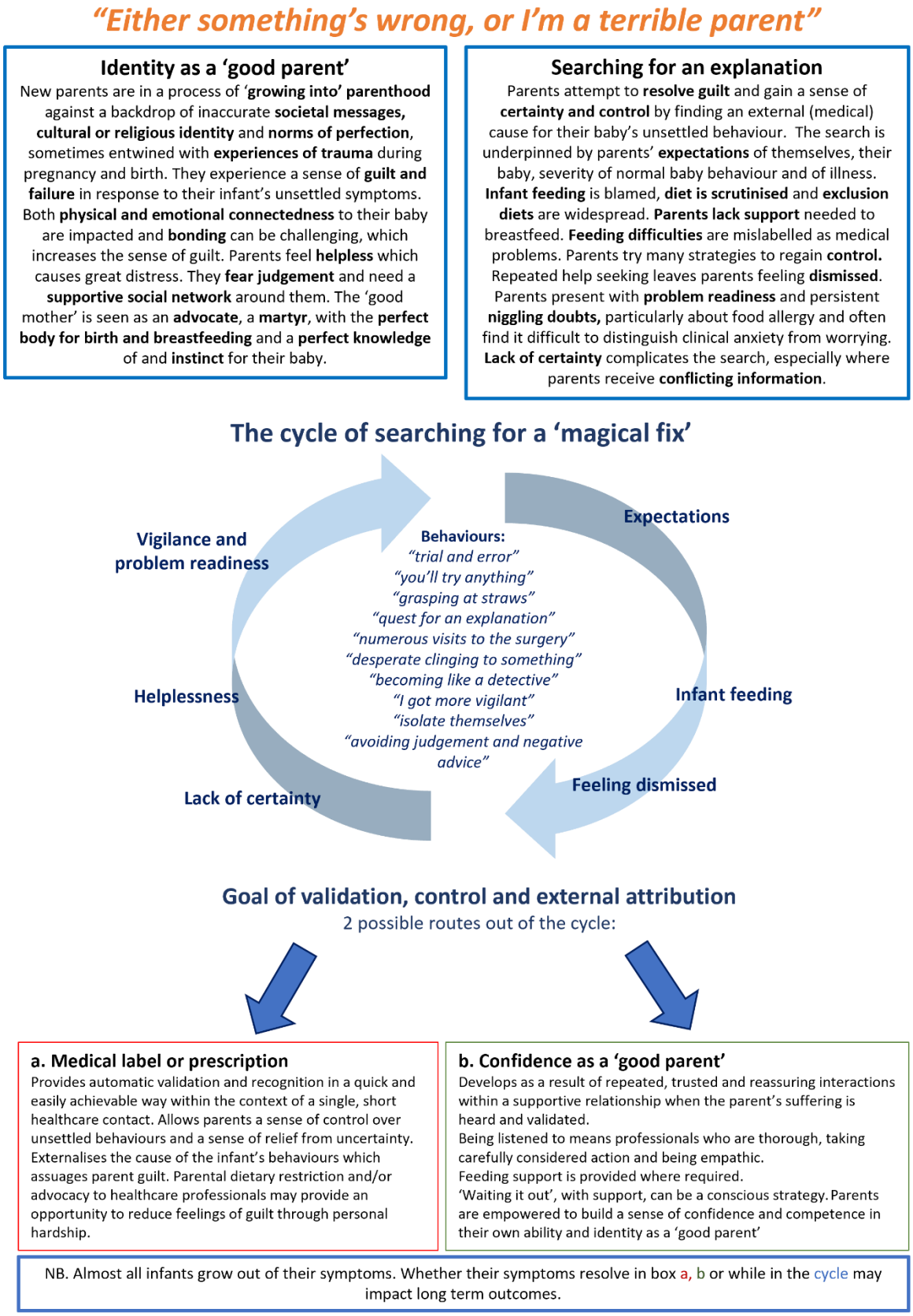


Figure 8: Proposed new conceptual model of how and why parents come to illness related interpretations of unsettled baby behaviours. Adjusted and updated from[314]

Chapter 7 Intervention development

7.1 Introduction

In the first two research chapters; Chapter 5 and Chapter 6; a detailed and rich understanding has been gained of the parent needs, thoughts, feelings and experiences. This was achieved through a systematic review and qualitative thematic synthesis and then extended to include some more diverse voices through the analysis of a series of qualitative interviews. Parent contributors and members of the public have engaged with outreach work and given their opinions and perspectives on the research design as well as contributed thoughts and ideas for the intervention, summarised in Chapter 4. The knowledge from this has now been carried forwards into intervention design, which is summarised in this chapter.

7.1.1 Study aims

This study aims to develop a person-, theory- and evidence-based intervention using behaviour change techniques. It will use the understanding of the parent need underpinning medicalisation of unsettled babies in order to answer the following remaining research questions:

- RQ 6: Can I build a supportive, digital intervention for parents which aims to meet their needs appropriately?
- RQ 7: Can I include a diverse range of parent voices?

7.1.2 Development process

In line with the PBA [2], I will firstly articulate the context of the intervention, including the following aspects:

- intervention objectives in terms of target behaviour and target outcomes;
- a detailed understanding of the relevant aspects of users and their psychosocial contexts;
- key behavioural issues, needs and challenges the intervention must address, problems with the current solutions or user behaviours which are challenging to manage.

I have then used these user characteristics and contextual details to develop a set of guiding principles to express the unique points about my proposed intervention and how it will overcome the anticipated challenges. Guiding principles are outlined in Table 12.

I have anticipated what thoughts and attributions parents may have before the intervention in relation to a range of topics such as 'when should I worry' and 'understanding and acceptance of normal' and articulated what thoughts or attributions should be targeted post intervention.

I have used a logic model, Figure 10, to summarise how we anticipate the intervention to work to achieve the target outcomes in terms of intervention target behaviours, techniques, processes, purported mediators and core behaviours.

Intervention content was then developed and translated into PowerPoint slides. These will then be refined using think-aloud interviews, reported in Chapter 8.

7.1.3 Goals of the intervention

Qualitative research to date, alongside existing evidence explored in the background of this thesis suggests the need for a supportive intervention to help parents who are worried about their baby's unsettled behaviour. The goals of this intervention are summarised in Figure 9 namely to meet the three needs identified by the qualitative work thus far – the need to develop a positive parenting identity and to support parent-infant bonding; the need for accurate and unbiased information on medical issues; and the need for a sense of control.

Firstly, the intervention will help parents in distinguishing red flags or signs of serious illness; identifying when and where to seek medical support or assessment. Secondly it will support the development of a positive parenting identity, helping parents to reframe their idea of a 'good parent' to allow for a baby who is unsettled. Thirdly, it will support parents in making a personalised plan including soothing strategies which do no harm. These strategies are supported by attachment theory and include things like responsive cues-based techniques, baby wearing and safer co-sleeping.

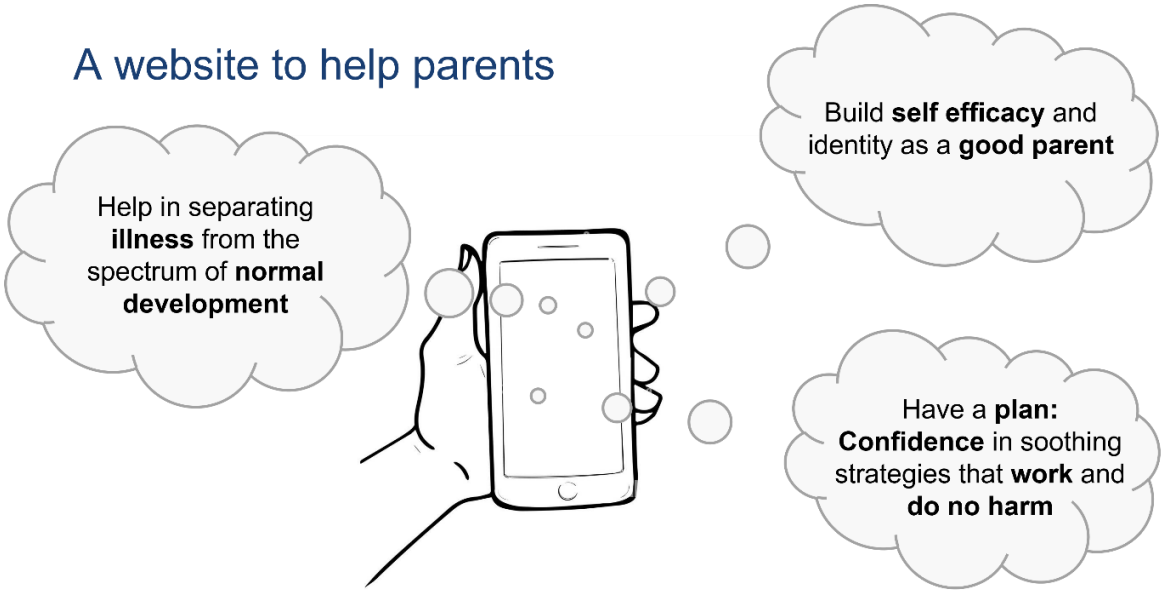


Figure 9: Goals of the intervention

7.2 Programme theory development

7.2.1 User context

Users of this intervention will be parents of young babies who are displaying unsettled behaviours such as crying, sleep disturbance, vomiting, gas/wind, rashes and stool problems. These parents will be tired with minimal mental capacity. They will have a very small amount of time to access the intervention during which they may have a crying baby vying for their attention. Whilst they are highly motivated to advocate for their baby and likely desperate for a solution; they have likely already been bombarded with too much conflicting information and advice. Their emotional resources are likely running low – they are likely feeling stressed, anxious, vulnerable, guilty and are worried they are failing at being a 'good parent', meaning they are highly sensitive to feeling judged. They may have already sought medical advice and felt dismissed or 'fobbed off' and so will be alert for any signs that their experience is being minimised. They may have low confidence in their own ability to meet their baby's needs.

Given the pressure on parents' time they are likely to forget to use the site, be pulled away from looking at it halfway through and not be able to find it again. Additionally, parents often look to unreliable sources for information (eg. search engines, formula funded websites, social media such as Facebook forums and TikTok) and this intervention will be required to function in a space which is occupied in the majority by commercially funded resources.

In addition to the contextual and situational difficulties, there are a number of user behaviours or perceptions which are likely to be challenging to manage. The most significant of these is that parents of unsettled babies are often convinced there is something wrong and will keep looking until they identify a medical label that they believe fits. They are primed to think no-one is listening to them (by reading the experiences of other parents online or through their own experience of being 'fobbed off') and they are expecting to find that healthcare professionals aren't interested in their child's problem and won't take it seriously enough. Commercially funded resources (websites, leaflets, advertising) as well as other parent stories may lead parents to believe their baby's behaviour is abnormal and needs to be 'fixed' using products or medical interventions. This is an attractive proposition for a tired parent, who is looking for a quick solution.

The most challenging aspect of the context, therefore, is that some of the fundamental messaging around reassurance of normal development and evolved healthy newborn behaviours is likely to be difficult for parents to hear or accept.

7.2.2 Digital interventions

I anticipate that a web app (i.e., website that is designed fluidly and responds to being viewed on a smartphone) is more accessible than a mobile app, as a web app works across a range of platforms and devices. Furthermore, a web app can generally be updated more readily than mobile apps and is accessible from any device without the need for an account 'log in'.

The intervention content was intended to be developed using the 'LifeGuide' software. This allows the researcher to easily change and update content as feedback is received from the participants. However, due to time constraints and software development delays it was necessary to find a different alternative. Instead, I developed the content in PowerPoint, using the 'live' features. This allows the slides to function as a website. The user can navigate the site as they would on a 'real' website, clicking links and embedding videos within the slides.

Audio-visual features (e.g. short videos and images) were incorporated to encourage engagement. Personal narratives were included from other parents (anonymised) as these have been a particularly popular feature in previous research and are likely to increase parents' sense of validation and relatability of the content.

7.2.3 Theoretical framework

Intervention development was informed by the self-efficacy construct from Social Cognitive Theory (SCT) [170] as this provides valuable suggestions for intervention elements likely to be effective (e.g. self-demonstrations, modelling) and has proven highly predictive of patient behaviour in other interventions [349-351]. The soothing strategies included are underpinned by attachment theory [239, 240] and the PBA was the methodological framework used to provide a systematic approach to intervention design [2]

7.2.4 Guiding principles

One aspect of the PBA is developing guiding principles which combine the objectives of the intervention with specific features of the intervention designed to achieve these aims. These also take consideration of the context specific user characteristics or behavioural challenges that are anticipated. The guiding principles are available in Table 12. These underpin intervention design and act as a coherent set of priorities that give focus and clear purpose to the intervention content [2].

The guiding principles (Table 12) are based on the knowledge of the target users gained through the qualitative research synthesised in Chapter 5; the results of the qualitative interviews with parents in Chapter 6; the extensive PPIE work which has been completed as part of this PhD and is summarised in Chapter 4, discussion with health visiting, primary care and academic colleagues and my own clinical experience.

Table 12: Guiding principles

User Characteristics	**Intervention Design Objective**	**Key Feature(s)**
New parents are tired; with minimal mental capacity	To provide information in ways that can be accessed quickly, navigated easily, digested and retained	Provide opportunities for planning/goal setting and prompts or reminders Use simple, concise and accessible language Break information down into small chunks Use memorable ways of delivering information, including a range of mediums (images, videos, text, interactive features) Use personalisation with simple steps to allow for parents to navigate through a 'symptom checker' to get personalised advice. Email this advice to them so it is not lost
Parents are likely to be distracted halfway through; and may have a crying baby vying for their attention	To provide support for parents to access the intervention in brief windows, perhaps on multiple occasions	Use personalisation with simple steps to allow for parents to navigate through a 'symptom checker' to get personalised advice. System saves their progress if they stop midway. Email the resulting advice to them so it is not lost Break the content down into small chunks. Make everything positive and rewarding to increase repeated engagement Design the content to be easily used on a phone
Parents are overwhelmed, bombarded with conflicting information	To provide clear, consistent advice which is evidence based and parents can trust	Demonstrate credentials Offer the opportunity for parents to 'check the science' for themselves Make advice clear, simple and evidence based

User Characteristics	Intervention Design Objective	Key Feature(s)
Parents feel 'dismissed', 'fobbed off' or 'minimised' when they seek support	To support parents and ensure they feel listened to and their concerns are taken seriously	Use lots of quotes from other parents which may resonate and help parents feel heard and understood Use the symptom checker to offer evidence based, personalised advice based on their own baby's symptoms Do lots of engagement, PPI and think-aloud interviews to ensure the intervention feels 'real' and grounded in the experiences of other parents who can relate to the users own experience
Parents have low confidence in their ability to meet their baby's needs and to be a 'good parent'	To increase parent's self-efficacy and confidence in their ability to self-manage where this is appropriate	Tools to help parents cognitively re-frame their perception of a 'good parent' and to remind themselves of the things they are doing well Practical, useable strategies that work to soothe babies Pragmatic advice on things like co-sleeping Signposting to where parents can get high quality further support Offering reassurance and information on 'normal babies'
Parents have low emotional resources and are highly sensitive to feeling 'judged'	To support parents in a way which builds their confidence and feels safe and welcoming	Demonstrate empathy for how hard this is to go through as a parent and offer support around mental health & wellbeing, coping strategies, feeling like a 'good parent' Trigger warnings for sensitive content if necessary Personalising content to user's own needs (eg. with feeding advice) Take a personal, relational approach – use videos, consider using 1st person in the text, accompany advice with a photo

User Characteristics	Intervention Design Objective	Key Feature(s)
Parents often go to unreliable sources for advice and support on unsettled babies (eg. Facebook forums). Qualitative research suggests this is because it is personalised and available instantly	To offer a personalised, instant support for parents of unsettled babies	Use an accessible digital format, which works on a mobile phone Personalise advice Make the resource easy to use, free to access and readily available Use existing services and networks to ensure parents are aware of this resource Use search engine optimisation (SEO) to help the site to rate on common searches (eg. Google)

7.2.5 Logic Model

A logic model is a widely used visual representation of how an intervention is anticipated to work [352]. It includes key target behaviours for an intervention and the techniques planned to reach short and long term outcomes [352]. It is a key element of intervention development within the Person-Based Approach [245]. The logic model I developed as part of my intervention design process can be viewed in Figure 10 and captures three key targets of the intervention (confidence/reassurance; self-efficacy/identity and control) and the problems believed to be associated with each one. It then describes the techniques and processes planned to be used within the intervention in order to achieve the long term outcomes of increased parent well-being, bonding and feeding satisfaction and reduced inaccurate medicalisation. This is anticipated to happen via the short-term outcome of increased parenting self-efficacy.

The PROBLEM Parents of unsettled babies experience:	Intervention TARGETS	Intervention TECHNIQUES	Intervention PROCESSES	Short Term OUTCOMES	Long Term OUTCOMES
1 ❖ Inaccurate medicalisation ❖ Not achieving personal feeding goals ❖ Uncertainty or confusion about what is 'normal'	**CONFIDENCE / REASSURANCE** Accurate health related information - Access to high quality help with feeding - Reduction in inaccurate medical diagnoses - Confidence in self-identification of concerns (including medical red flags) - Access to mental health support - Knowing what is normal development	❖ Trustworthy, evidence based information about the continuum of normal (including a 'symptom checker' with medical red flags) ❖ Signposting to quality feeding support and evidence based information on elimination diets. ❖ Information and signposting to perinatal mental health resources. ❖ Myth-busting	❖ Increased knowledge of normal and red flags	**Increased Parent Self-Efficacy**	Leads to: ❖ Increased parent well being ❖ Increased bonding ❖ Reduced inaccurate medicalisation ❖ Increased feeding satisfaction
2 ❖ Initial bonding difficulties ❖ Negative parenting identity (feeling like a bad parent)	**SELF EFFICACY / IDENTITY** Parenting self-efficacy - Self identity as a good parent - Positive feelings about their baby (bonding)	❖ Supporting parent-infant relationship and enjoyment of parenting through "bonding games" ❖ Activities to encourage reframing of 'good parent' including relatable quotes from other parents.	❖ Positive interactions with baby ❖ Reframing of 'good parenting' supporting the development of a positive parenting identity		
3 ❖ Poor emotional wellbeing (linked to feeling helpless / out of control)	**CONTROL** Sense of control - Having a plan - Feeling of doing something to help	❖ Toolkit of parent recommended practical strategies that WORK and DO NO HARM.	❖ Having a personalised strategy to try		

Figure 10: Logic Model: An intervention for families of unsettled babies to improve parent wellbeing, bonding, feeding satisfaction and reduce inaccurate medicalisation by increasing parenting self-efficacy.

7.2.6 Intervention Content

Intervention content was developed and divided into three core modules and some additional optional resources (see Figure 11 for a diagrammatic representation, and Figure 12 for screenshots of homepage content). These modules fit broadly with the three areas of the logic model (Figure 10). Module one comprised a symptom checker and included a list of red flag symptoms, possible medical concerns and normal baby behaviours for each of the most common parent concerns (crying, vomiting and unusual stool). It also included optional informative content on reflux, allergy, weight gain and crying.

Module two focussed on building parenting self-efficacy and included two videos 'you are a good parent' and 'bonding' which emphasised that good parents can have crying babies and that bonding may not always be easy and instant. Module two also included an interactive feature which prompted parents to make a list of the things they believe they are doing well as a parent and a list of 'bonding games' which they could try to increase the fun and enjoyment of the time they spend with their baby; including options to enter an email address or contact number and receive a copy of their answers. It also included a feature where parents could list their top parenting priorities and some informative 'top tips' about bonding.

Module three offered a list of practical strategies that might work to soothe a crying baby and prompted parents to tick the ones they would like to try and save them to a 'personalised toolkit'. The strategies were divided into sections such as 'feeding', 'sensory', 'physical', 'emotional' and 'sleep'. Module three also included a prompt to enter contact details to receive a copy of their toolkit.

In addition to these core modules there were a series of informative articles and signposting to external resources about infant feeding (including a basic feeding assessment tool) and perinatal mental health as well as 'myths and facts' about normal baby behaviours. Finally, there was a 'meet the team page' which included information about the study, myself and my supervisors and the logos of the NIHR as funder and the University of Southampton. There was also an 'I need help now' banner on the homepage, which included a crisis disclaimer and a link to the toolkit of strategies.

7.2.6.1 Content map

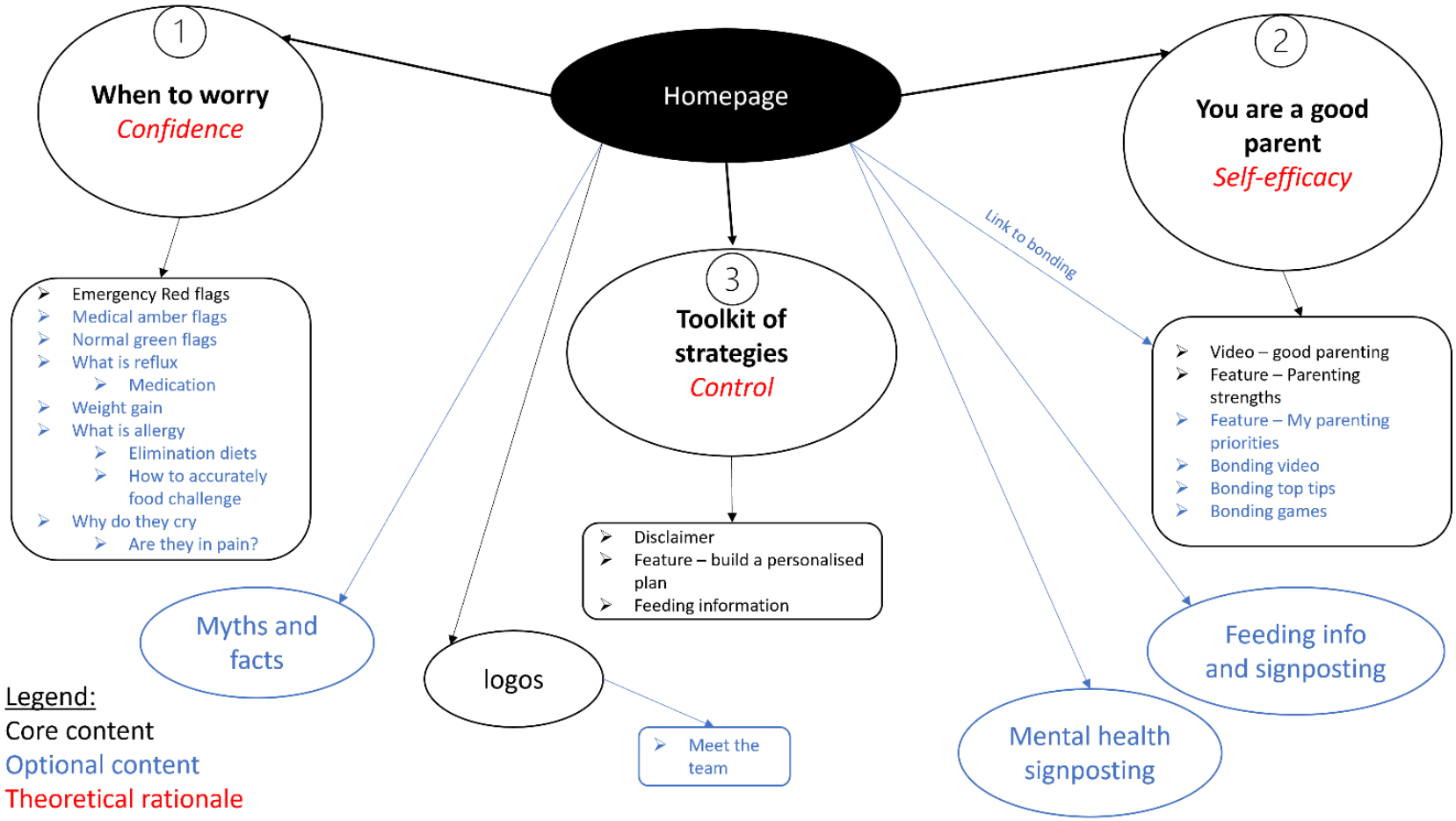


Figure 11: Content map of draft intervention content before think-aloud interviews

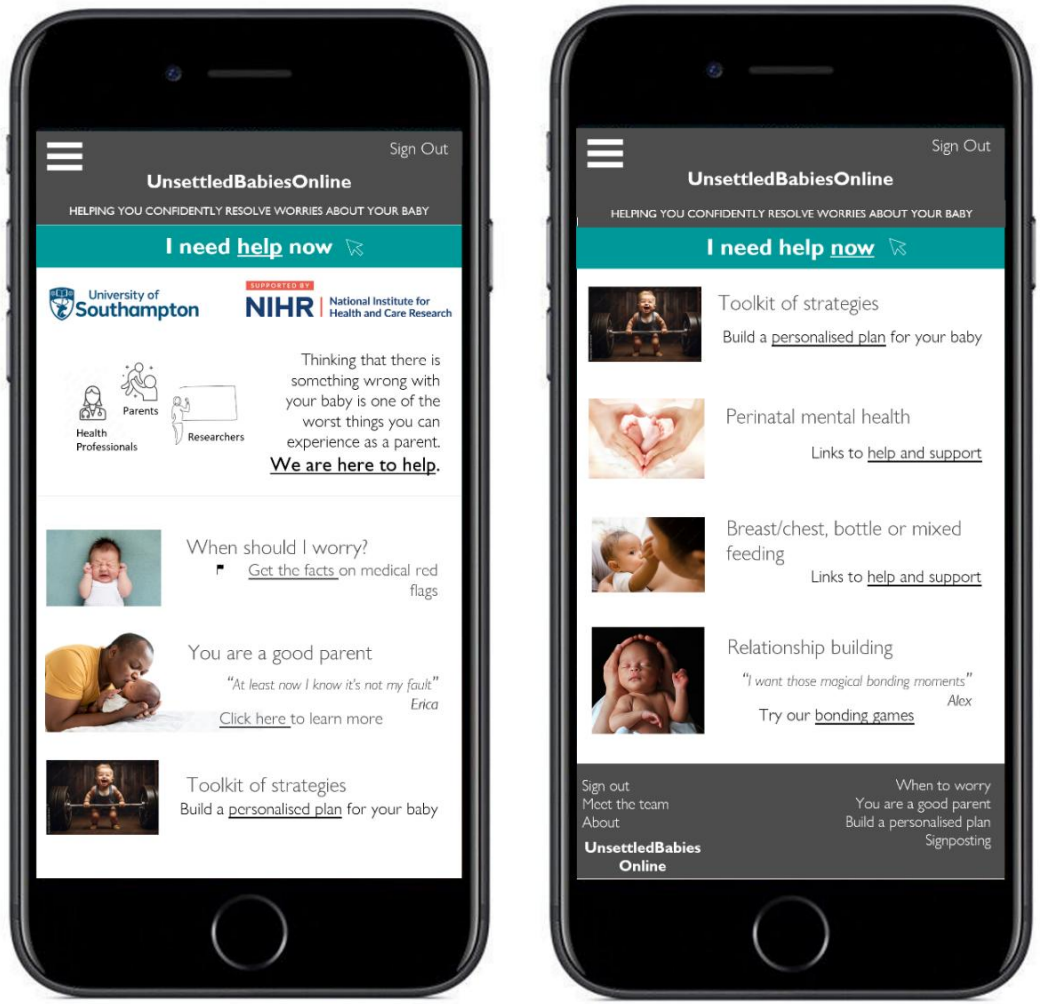


Figure 12: Screenshot of homepage content before think-alouds

7.2.6.2 Intervention features and rationale

Intervention planning was conducted using the Behaviour Change Techniques (BCT) Taxonomy v1 of 93 hierarchically clustered techniques based on health psychology and behavioural science principles [353]. These techniques have been well established and used in a variety of health-related behavioural interventions. The advantages of using a systematic and well recognised taxonomy of behaviour change techniques are articulated in the original article and are fivefold [353]. Firstly, the taxonomy allows for replication of interventions. Secondly, it allows for interventions to be implemented faithfully, as they were intended to be used. It also allows for systematic reviews to accurately assess the effectiveness of various interventions and specific techniques within them. Intervention developers benefit from the taxonomy because they are able to select from a wide range of available techniques and clearly articulate their chosen ones in well-defined and well understood common language. Finally, it allows for better investigation of how the intervention is purported to work, or the mechanisms within it [353]. This is important for impact and implementation [252].

The intervention planning table, Table 13, includes a breakdown of the barriers to behaviour change identified within the context of unsettled babies and the intervention ingredient used to overcome these barriers. It also shows which BCT within the taxonomy these ingredients are associated with.

In conclusion, the intervention content was developed using the person based approach and drawing on the qualitative research, PPIE and the user context and was framed around the logic model and guiding principles. Behaviour change techniques were applied during intervention planning.

Table 13: Intervention planning table

Barrier to target behaviour EC = Expert consensus (PPI/stakeholder input) L = Evidence from literature Q = Qual research w users	**Detail about the evidence for barrier**	**Possible intervention ingredient to overcome barriers**	**Behaviour Change Theory (BCT)** Using 93 BCT taxonomy v1[353]
Target behaviour: Parenting self-efficacy			
Parents often feel dismissed or invalidated (EC, L, Q)	During public engagement listening cafes, the parents told me that they trust and believe the words of other parents with shared experience ('people talking my language') The systematic review (content analysis of forum data) emphasised how important parent's shared experience was to building trust and authenticity In qualitative interviews parents reported that other parents comments were helpful because they knew they truly understood	• Personal stories • Parents own words • Quotes.	3.1 Social support 6.2 Social comparison 9.1 Credible source
Parents believe that there could be a problem with their milk or, if they are breastfeeding, that their diet impacts their baby (L, Q).	Systematic review highlighted parent worries about their milk. Qualitative interviews described parents being worried about their milk and using elimination diets extensively.	• Pages on feeding and elimination diets. • "Breastmilk is made from your blood, not your stomach contents".	4.1 Instruction on how to perform the behaviour 9.1 Credible source

Parents describe feeling helpless when they are at their lowest and most desperate (EC, Q, L).	In the qualitative interviews parents reported the importance of helplessness or control, wanting to try different strategies, feeling listened to or taken seriously if given something to try. The systematic review emphasised the importance of having a plan.	• Interactive tool for making a personalised plan of soothing strategies • Option for email reminders	1.1 Goal setting (behaviour) 1.4 Action planning 4.1 Instruction on how to perform the behaviour 7.1 Prompts / cues
Crying feels like a dire warning sign. Indicative of pain. Worries about pain being reflective of an ominous 'underlying cause' (Q).	In qualitative interviews parents reported worrying about crying being an alarming signal to them. One parent said "if an adult was crying this much we would be at A&E". Parents described their fear of pain and dread of underlying serious medical issue. They reported it just simply 'doesn't feel normal'.	• Red flags for serious illness • Information about crying as communication • Relatable quote from parents to show that worrying about crying is normal.	3.3 Social support (emotional) 4.1 Instruction on how to perform the behaviour 4.4 Behavioural experiments 9.1 Credible source
Parents and infants experience a shared emotional climate – this can become a negative emotional spiral (L, Q, EC).	In qualitative interviews and PPI parents describe being connected emotionally to their baby. This is also consistent with literature on attachment theory.	• Perinatal mental health resources page • Video encouraging self-care • Information about emotion regulation.	3.3 Social support (emotional) 4.2 Information about antecedents 5.1 Information about health consequences 5.6 Information about emotional consequences 9.1 Credible source

Parents find it difficult to enjoy their baby and to interact in a positive way (L, Q).	In qualitative interviews parents describe how everything revolves around the unsettled behaviour, it's all consuming so you don't get the chance to enjoy them. This was also found in the bonding themes within the systematic review.	• Bonding games • Video examples of bonding activities • Optional reminders of games.	6.1 Demonstration of the behaviour 6.2 Social comparison 7.1 Prompts / cues
Parents are scared of judgement and are worried about appearing a good parent to others, especially professionals (EC, Q, L).	Parents in the qualitative interviews and in the listening café's describing fearing judgement. This theme was also reflected in the systematic review.	• Activities to encourage reframing of 'good parent'. • Video advising parents to imagine another good parent in this situation.	3.3 Social support (emotional) 4.1 Instruction on how to perform the behaviour 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source 13.2 Framing / reframing
Huge amounts of confusion and uncertainty about unsettled behaviours (Q, EC, L).	In qualitative interviews and listening cafes parents described feeling like they were constantly asking themselves 'is this normal?' The systematic review identified studies finding confusion between various diagnostic labels and descriptors (eg. allergy, intolerance, reflux).	• Information on the continuum of normal • Medical red flags • Relatable quotes from parents describing feeling worried about normal behaviours.	3.3 Social support (emotional) 4.1 Instruction on how to perform the behaviour 4.4 Behavioural experiments 9.1 Credible source

Absence of unbiased information (EC, L).	Parents in the listening café and qualitative interviews report not knowing what information to trust, with lots of conflicting, opinion-based information and an absence of evidence based 'facts'. Literature suggests there is significant commercial bias in the unsettled baby space, particularly online. See Chapter 2.5.3 for details.	• Logos • About us page • Independent of commercial funding.	9.1 Credible source
Parents are scared of repercussions if they admit how hard they are finding it to cope. This can be a barrier to them seeking help (EC).	Parents in the listening café reported avoiding A&E if they were aware they had attended frequently, because they were fearful of repercussions.	• Activities to encourage reframing of 'good parent' • Video advising parents to imagine another good parent in this situation.	6.2 Social comparison 6.3 Information about others' approval 13.1 Identification of self as a role model 13.2 Framing / reframing
Parents compare themselves to others and worry that they are a 'bad parent' (EC, Q, L).	In PPIE work, contributors report comparing themselves (often unfavourably) with parents they see around them.	• Activities to encourage reframing of 'good parent' • Video advising parents to imagine another good parent in this situation. • Listing own strengths as a parent • Optional email reminder of list	6.2 Social comparison 13.1 Identification of self as a role model 13.2 Framing / reframing 15.3 Focus on past success 15.4 Self talk
Parents worry when parenting doesn't always come naturally (EC, Q, L).	Parents in the qualitative interviews and PPIE work describe their expectations before the	• Reassurance and information on the bonding page	3.3 Social support (emotional)

	baby is born that they will love them instantly, feed with ease and naturally know what to do. This is consistent with results in the theme 'expectations' from the systematic review.	• Bonding video • Relatable quotes from other parents in this position.	6.1 Demonstration of the behaviour 6.2 Social comparison 9.1 Credible source
Parents feel that they have 'failed' if their baby doesn't stop crying (Q, L).	In the qualitative interviews and the systematic review, feelings of guilt and failure were strongly associated with experience of unsettled baby behaviours.	• Information about crying as communication • Activity to list parenting priorities • Listing own strengths as a parent • Optional email reminders of lists.	13.2 Framing / reframing 6.2 Social comparison 15.3 Focus on past success 15.4 Self talk
Parents sometimes are in crisis and may lose control and harm their baby (EC, L).	Parents in PPIE described feeling a loss of control at times. This is consistent with literature about crying as a trigger for non-accidental injury.	• 'I need help now' link from homepage • Crisis signposting • Disclaimer • Advice around taking a break and calling in help when needed.	4.1 Instruction on how to perform the behaviour 9.1 Credible source 3.3 Social support (practical)

Chapter 8 Intervention Optimisation

8.1 Study context

Draft intervention content had been designed using the person-based approach [244] (see Chapter 7) and the results of a systematic review of qualitative studies of parent experiences of unsettled babies [314] (see Chapter 5). Intervention design was also informed by a separate qualitative interview study exploring parent experiences of unsettled babies, the analysis of which is reported in Chapter 6.

In this intervention optimisation study, parents within the target population are asked to view the intervention and give feedback on the content. Content can then be refined and optimised based on this feedback. This technique is particularly suitable for intervention optimisation as it enables an in-depth understanding of people's experiences whilst using the intervention. It has been found to improve usability, accessibility and ensure the intervention is meaningful to target users [244]

8.2 Aim and objectives

8.2.1 Aim

To optimise the acceptability of and engagement with these materials designed to improve the wellbeing, bonding and feeding satisfaction of families with unsettled babies whilst reducing medicalisation.

8.2.2 Objectives

- Develop content for a behavioural intervention for parents of unsettled babies to support self-management of unsettled symptoms, improve wellbeing, bonding and feeding satisfaction and reduce medicalisation, through building parents' self-efficacy.
- Iteratively improve the materials through parent feedback; with a focus on acceptability and engagement.

8.3 Methods

This study is reported using the COREQ [326] checklist for qualitative research.

8.3.1 Design

The study was a series of interviews using a 'think-aloud' technique [354]. This involves asking the parent to look at the resources and use them as they would if the researcher was not present, saying their thoughts out loud as they do. Researchers can direct participant attention to specific areas, offer prompts or ask specific questions to elicit feedback on particular components if needed.

8.3.2 Recruitment

Parents were recruited through social media advertising. An advert (see Appendix K) was designed by a PPI contributor with lived experience of having an unsettled baby. Multiple adverts were created to generate resources which were welcoming of different ethnicities and genders. These adverts were shared with permission on a variety of Facebook community pages; virtual baby groups (including a baby swim school, baby feeding advice and support groups, support groups for unsettled babies including colic, allergy and reflux groups, baby sensory groups, new dad groups, black parents groups and universal new baby parent support groups) and was shared by an infant feeding specialist (IBCLC) on Instagram. The advert included a link to an online expression of interest form [355] which contained a link to the full participant information sheet and gathered basic demographic information and contact details from potential participants. A total of 90 expression of interest forms were received. All parents received a follow up phone call or email with the researcher (AD) to discuss participation.

Participants were sampled purposively to include a range of gender, ethnicity and families living in areas of economic deprivation. Deliberate over-recruitment was used as a strategy to ensure inclusion of parents from ethnic minority backgrounds and under-served communities, as well as fathers and non-female parents, as these groups have been under-represented in previous qualitative research amongst parents of unsettled babies.

Parents were recruited who had fed their babies in a variety of ways (breast/chest feeding; formula feeding; mixed feeding) in order to ensure that the intervention materials are maximally engaging for all families. Parents were selectively sampled with younger babies less than six months of age, as this is the most relevant time period for the intervention materials.

8.3.3 Inclusion and exclusion criteria

Inclusion criteria

- Parent of a baby aged less than 12months
- Baby has symptoms the parent views as 'unsettled' (crying, fussing, vomiting, wind, apparent discomfort, changes in stools)

Exclusion criteria

- Unable to understand and communicate in English
- Unable to read English
- Where children of participants are outside the stated age range
- Parents of babies with ongoing, relevant/confounding complex health needs
- Living outside the UK

8.3.4 Sample size

Three rounds of interviews were planned, with a maximum target of 25 interviews in total. This was anticipated to provide adequate information power for analysis. There were short periods of time between rounds to allow time for the changes to be implemented.

8.3.5 Ethics

Ethics was granted by University of Southampton Ethics Committee registration number 77547. Informed verbal participant consent was gained prior to the start of all interviews. All parents consented to video recording and transcribing. All parents were given a debrief leaflet after the interview with details of where to access additional support should they need it.

8.3.6 Data collection:

Think-aloud interviews took place via Teams videoconferencing. They were conducted by AD, who identified herself as a researcher at the University of Southampton interested in unsettled babies. It was not shared with the participants that AD had written the materials, although she was featured in the video so parents could have assumed this. None of the participants were known to the interviewer in advance. The interviewer shared a 'powerpoint live', which allows the participant to navigate around the website and click on links freely. The interviewer can see the pages they are viewing on the shared screen.

Interviews involved the parent viewing the website and exploring it however they wished to, speaking aloud as they did so. Parents were asked to give their thoughts and reactions to the

content as they read it. Occasionally prompts or follow up questions from a pre-approved interview guide (see Appendix L) were used to clarify a comment, get more detail, or obtain specific opinions on particular aspects of the content.

£15 amazon shopping vouchers were sent to each parent after the interview to thank them for their contribution to the research.

8.3.7 Data analysis

Field notes were completed during and after each interview. Recordings were sent to professional transcribers who removed identifying information (such as first names) and returned a written transcript. These were reviewed and accuracy checked against original recordings where it was unclear. It was not possible due to pragmatic restrictions to return transcripts to participants for review. Transcripts were read and actionable comments (all negative comments or suggestions) were transferred over into a table of changes. This table allows for a thorough and methodical approach to intervention optimisation as per the Person Based Approach [2]. The changes were rated as Must, Ought, Should, Could and Would (MOSCOW) to indicate urgency of the change. Simple changes were rated and actioned by AD alone, more complex changes required discussion to resolve or problem solve, where necessary this took place in supervision meetings or via email. They were further labelled with codes to reflect the type of change needed such as EAS (easy, uncomplicated changes such as aesthetics), REP (repeated comment by multiple participants), IMP (important for behaviour change), NCON (non-controversial, in line with the logic model and guiding principles), SAF (safeguarding, for suggestions or comments that reflect possible harm or emotional distress which could be associated with the materials), EXP (in line with experience, detailed whether this is from stakeholders, public contributors or has been found in previous literature), NC (not changed – rationale for this was noted). The changes were then made in order of priority.

Interviews were completed in ‘rounds’ with a small group of interviews (6-8) conducted, transcribed and analysed using the table of changes; followed by implementation of major changes and a second round of interviews testing out the updated materials. The cycle was then repeated until the planned number of participants had been reached and there was sufficient information power for analysis. By the end of round three, no new major changes were being suggested, so this was deemed to be sufficient number of interviews.

After completion of all the interviews, the transcripts were also coded with conceptual labels in NVivo and codes grouped into conceptual themes, which offered additional insight on the parents’ opinions of the resources [340]. Analysis was mostly descriptive rather than interpretive, with a goal

of grouping together similar feedback simply and clearly. The coding tree was initially divided into positive and negative comments, with codes describing elements of the intervention such as 'aesthetics', 'navigation', 'relatable', 'control', 'confidence' etc. Resulting themes were then developed inductively from the data to best summarise the key messages from the interviews. Analysis was discussed and developed with supervisors to increase trustworthiness of the resulting themes.

8.3.8 Harms analysis: 'Dark' logic model

Following data analysis, the thematic analysis and table of changes both suggested that there was a number of possible unintended consequences which needed to be considered. I have therefore completed a potential harms analysis including a dark logic model [356].

Bonell and colleagues advocate that a 'Dark Logic' model should be developed in advance of an intervention, to enable a thorough assessment of plausible harms and mechanisms underpinning these [356]. In my case, I had no apriori theories of possible unintended consequences from my intervention, so have been unable to predict these ahead of time and thereby measure them in this systematic approach. This may mean that there are harmful externalities which occurred that I have not been able to assess [356]. However, my think-aloud qualitative data may provide insight into possible consequences from the intervention which were not anticipated or desired. Indeed, Bonell and colleagues recognise that unanticipated harms will happen regardless and an a-priori approach to harm assessment can be used together with a post-hoc analysis [356]. Consideration about harms after the intervention development could also be used as a dark logic model to inform future research trialling this intervention if required.

Bonell and colleagues propose three potential methods for identifying harms and mechanisms [356], which were later applied by Cavanagh and Brehony in reference to environmental conservation research [357]. Although a different context, the methods remain broadly transferrable to a range of research areas. The first is to interrogate the intended logic model, the second to use previous similar research describing harms as a source for triangulation and the third by consulting with individuals with lived experience or special expertise to imagine how the intervention may work in practice [356, 357]. In conducting the think-aloud interviews with parents of unsettled babies, it could be suggested that my research shares some commonality with this third approach. This approach is more participatory in nature and ensures that the research is grounded in parent experiences [357], making it complementary to my PPIE work and to the person-based approach.

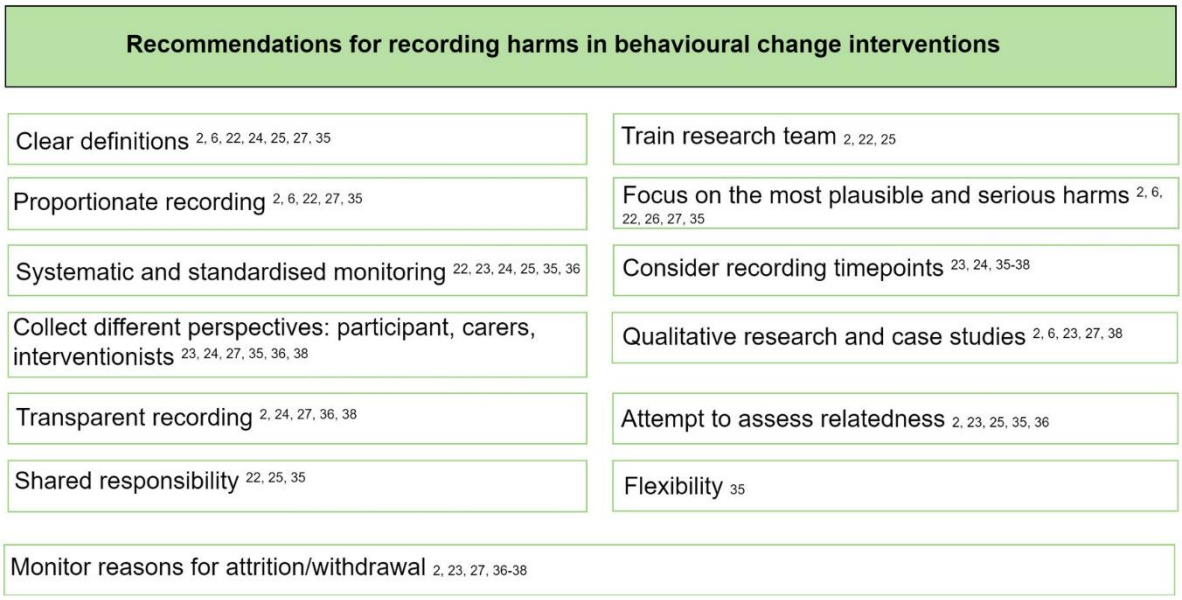


Figure 13: 13 Recommendations for recording harms in behaviour change interventions. Partial reproduction of a larger figure in [1]

Reporting of dark logic models appears to vary, with some researchers writing a short narrative paragraph under the heading 'dark logic model' [358], some using a process figure alongside a series of themes [359] or some giving various taxonomies of harms listed in tabulated formats [1]. In their scoping review and mapping exercise, Papaioannou propose thirteen recommendations for harm recording and reporting, which are reproduced here in Figure 2 [1]. The most relevant of these for my project are the importance of having clear definition of harms, a focus on most serious or most plausible harms, use of qualitative research and incorporating different perspectives [1]. In presenting the possible unintended consequences, therefore, in Chapter 8.4.4 I have attempted to use a combination of these formats in a pragmatic way to enable a systematic assessment of possible harm.

8.4 Findings

8.4.1 Participant characteristics

A total of 90 expression of interest forms were received. All parents were contacted if they had left a correct phone number or email address. Of these, 49 parents did not reply to the initial contact or were ineligible. The main reason for ineligibility was living outside the UK. The remaining parents

were selectively sampled to allow for maximal sample diversity. A final number of 22 interviews was conducted. Sample demographics are presented in Table 14. The age of baby at time of interview ranges between six weeks and nine months. Parent gender was majority female, with three participants identifying as male. Nine of the 22 parents interviewed live in the lowest five postcode deciles on the UK index of multiple deprivation (IMD), there were some postcodes for which I could not find IMD data. The majority of parents interviewed were white, with one Asian mother, three black parents and one parent of mixed heritage.

Parents reported a range of feeding experiences and methods. 12 were exclusively breastfeeding at the time of interview, eight were formula feeding (of whom three were breastfeeding initially and had subsequently switched to a hypoallergenic formula). Two parents were mixed feeding. Not all parents who were formula feeding volunteered the name of the formula, so it is unknown how many were using hypoallergenic milk. However all the parents interviewed discussed having changed, or thought about changing their milk or diet in some way as a result of the symptoms.

Table 14: Participant characteristics

Demographics			**N**	**Range (mean)**
Baby	Age	0-3 months	5	
		4-6 months	8	
		7-9 months	7	
		10-12 months	2	
	Feeding method (at time of interview)	Breastfeeding	12	
		Formula feeding	8	
		Mix feeding	2	
	Issues (as described by the parent)	Crying	15	
		Vomiting	8	

		Stool issues (smell, colour)	1	
		'Clingyness'	4	
		Sleep problems	5	
		Rash	1	
Parent	Age			22 – 42 years (31.86 years)
	Gender	Male	3	
		Female	19	
	IMD Decile	0-5	9	1-5 (4.1)
		5-10	9	7-10 (8.5)
		unavailable	4	
	Ethnicity	White	17	
		Black / African / Caribbean	3	
		Asian	1	
		Mixed heritage	1	

8.4.2 Table of changes

Table 15 below lists some of the key actionable comments across all three rounds of think aloud interviews. Where the same comment was made by more than one parent that has been indicated. The action taken as a result of the comment is detailed, where a change was not made this is justified. Positive comments about the intervention have not been included, so Table 15 reports only comments which might suggest changes.

Changes are made according to the table of changes systematic approach recommended in the PBA [360]. According to this method, the final column in Table 15 reflects the MOSCOW (Must, Ought, Should, Could, Would) change status which was allocated to each change to indicate priority and urgency of change. 'Must' was allocated to changes that were important for behaviour change, in

line with the logic model and / or repeated by multiple people. Ought and Should were allocated to changes which would improve the resource and need to be made as a priority. Could and Would were allocated to changes which are outside the capacity of this PhD, but are considerations for future iterations of the website or future research. Could and Would were also used for changes which are less fundamental to behaviour change (than O or S), but are advisable given capacity. For reasons of space and accessibility in this thesis, I have condensed multiple similar comments in Table 15. The table included here is therefore a summary of the most common changes and should be seen as exemplifying the change process rather than as an exhaustive list of changes. For the full Table of Actionable Changes please see Appendix M.

8.4.2.1 Narrative summary:

Everyone interviewed who saw the resources reported that they found elements of the website interesting or useful in some way. Support for the research was unanimous and in general, parents found the tone of the website supportive, validating and helpful. Some parents expressed that they would like to have access to the intervention after the end of the project, or that they would like to share it with friends or family who were pregnant. The majority of parents interviewed related strongly to the quotes and content on the website.

The most common suggestions resulted in minor changes to the resource, either in the navigation, aesthetics, adding links, rewording or altering the information to make it clearer and more accessible. Within Table 15 these suggestions have been grouped together for presentation purposes under group 1 and include ‘aesthetics’, ‘accessibility’, ‘navigation’ and ‘unclear’. Parents often suggested additions which could be made to the website, these are listed together under group 2 ‘content request’. Most of these were actioned by adding the requested resource or information, those which could not be are addressed individually are in the ‘action taken’ column.

Additionally, there were several comments which emphasized the importance of implementation of this resource within a robust network or system of support for parents. These have been labelled as ‘contextual factors’, grouped in group 3 and will be discussed further in Chapter 9, as well as in the harms analysis Chapter 8.4.4.

Credibility was an additional large area which necessitated change, and led to the introduction of ‘landing pages’ to establish credentials and orient the parent to the site. This appeared to make a big improvement in later iterations, although there remain some details which could be developed further in future research. These changes are grouped together in group 4.

There were several comments which could have a significant impact on the effectiveness of the resource and required large scale change. In both the 'when to worry' and the 'personal plan' sections, a significant reorganization of both modules was required to make them clearer, easier to use and more effective. These changes are in group 5.

Several comments (grouped in group 6) suggested that the materials may require more adaptation to make them optimally effective and engaging to parents who are not female. Future research could explore this in more depth.

Several parents felt that the information was not new to them in different areas of the site. These items relating to novelty are in group 7.

Throughout the development of this intervention careful attention was needed to ensure that the resource got the 'tone' and language use right. This was challenging because of the emotive nature of the topic, parents natural propensity to blame themselves and my previous research suggesting that often parents were coming to the resource expecting to feel dismissed, judged or guilty (see Chapter 5, 6 and 7). In some cases this was relatively easily resolved once identified, by a simple change in the wording of the text. These cases are grouped in group 8.

In other cases, some comments (collected together in group 9) reflected possible unintended consequences which may have a negative impact. These were considered carefully and led to the development of a 'dark logic model' (see Chapter 8.4.4) to explore possible harm which could be caused by this intervention. In the main, these concerns were associated with a challenge or a change to a previously strongly held belief, in the context of this highly emotive area. For example, when communicating to a parent who believes their baby has a dairy allergy and has been using a strict exclusion diet that these interventions may not be accurate or evidence based. Clearly in a complex and emotive behavioural intervention some level of difficulty in these conversations is to be anticipated. Therefore particular attention has been paid to these comments and careful action has been taken to try and achieve a balanced and empathic intervention which is kind and supportive; while continuing to be accurate and trustworthy.

Overall, the majority of parents interviewed went away with a very positive view of the intervention, however the possible unintended consequences of the intervention may be an important factor which is explored further in Chapter 8.4.4. There are additional areas such as gender and contextual factors which also require attention in future research and implementation.

Table 15: Table of actionable changes, organised by group then summary of issue within that group

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
1*	Accessibility – subtitles on video - **x 2 parents**	“The option for subtitles on the video. Often don't watch things with sound on when I'm around my baby”	This would be added in a future iteration of the website.	W
1*	Navigation	“That is probably too hidden. I want to click the quote…”	Added a link.	O
1*	Unclear wording	“So lethargic, what does that mean?”	Added ‘hard to wake’.	O
1*	Unclear wording	“The way it's worded, I just know if I was really tired I might misread that.”	Clarified.	O
2*	Content request	Parent wanted information on oral thrush to be added.	Added to amber flags.	O
2*	Content request	“you could then print it out so that you could… stick it on your fridge or wherever…it's just there visually, because sometimes people don't always look back on their phones…an option to print it out as a PDF would be good”.	Added print option.	C
2*	Content request	Parent requested content around unrelated topics such as car seats and buggies.	Outside the scope of this PhD.	Not changed

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
2*	Content request on sleep **x2 parents**	“I think, you know sleep was a thing for me, so I think if I was going to give some other feedback I'd say if there's a page that takes people to sleep. I think as a new mum the biggest shock to the system is the sleep deprivation.” “I think if there's a section on sleep, I would be interested.”	Added a section on sleep.	M
2*	Content requested on commercial resources **x2 parents**	“I don't know if you're able to, but other resources that I actually ended up finding really useful were Instagram accounts.” “Maybe where you're talking about formula, to kind of have a little table, with pictures of the different formulas that are available.”	Unable to include these resources because they violated the principles of the resource to remain evidence based and free of commercial influence. No action taken.	Not Changed
2*	Content requested on feeding aversion – **x2 parents**	“We've struggled to actually feed him at all. I'm not offended but it feels I'm outside of this comment; it doesn't fit me.”	Changed wording of the section to be more inclusive and added information about babies refusing to feed.	M
3*	Contextual factor Parent wanted a local and national service signposting section accessible through the intervention **x5 parents**	“I like that you've got links to going back to getting feeding support and finding a specialist service as well. I think if you had a link there for different things, and then obviously you can put in where you're from, that would be useful. Because I'd read that and I'd be like, yes, I'll do that, and then not do it.”	This was not feasible in the current prototype; however it will be an important comment to take into consideration for implementation at a later stage.	W

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
3*	Contextual factor Wanted it antenatally **x2 parents**	"It would be quite nice, actually, if…this was available to you as soon as you find out that you're pregnant"	Could consider antenatal version for implementation.	W
4*	Credibility **x6 parents**	"I obviously don't know how medically backed this is. I'm guessing it's all completely factual, based on medical guidance, best practice. So it would make me question that kind of - what someone had said to me about cutting stuff out. So I just want to know where this came from, yes."	Added additional credibility information on 'landing pages' to establish site credentials. Added section explaining the science around exclusion diets with links to the research and a prompt before the information which explains that it may be different from information they have heard elsewhere.	M
5*	Parent found the 'when to worry' page hard to navigate **x4 parents total,** (Requesting a search function x2 parents)	"Is there going to be a search thing on there or anything for specific topics? Just because, how many different categories are there? Are there six different ones you can go into? Just you don't always know which one you want to be going into…" "I'm a little bit unclear on what this means. This box…Yes. I think maybe the wording needs to change…I don't know if what's coming is like a full article, and not skipping to sections of it. Or if these are different pages that I'm going to be taken to."	Section was significantly restructured and simplified, traffic lights system was added. This improved functionality and future iterations were reportedly very clear and easy to use. Search function could be added in future iterations and when the website was live.	M
5*	Unclear how to use the personal plan section - **x8 parents**	"Again, I don't know the plan is for but saying, 'It's useful to have a plan for whatever'… It just says, 'Build a personal plan,' I don't know what for…"	Changed the navigation and organization of the page significantly to make it easier and clearer to use.	M

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
6*	Content requested Not enough signposting for dads, in particular dads' mental health **x2 parents**	"I think, sometimes, again, it doesn't mention… Well, it's 'mums and families' is the name of the link. It's always… I get it. They have obviously gone through a massive physical change. I think dads are forgotten about quite a lot."	Added additional links for dads' and LGBTQ+ parents' mental health support.	M
6*	Not relatable	"I wouldn't be as bothered about the, 'You are a good parent'… I didn't suffer too much from…from dad guilt. I know that …you can only do your best."	Did not feel the good parent resources were relevant or useful to him. Attempted to recruit more dads to see whether the site could be more appealing to parents of different genders. Added a sentence 'all parents worry they're not good enough' to make it more universally relatable.	
7*	Nothing novel **x3 parents**	One parent felt she already knew most of the information so couldn't imagine herself using the website. Another felt she knew most of the red flags for medical worries. A final one felt she knew most of the strategies on the 'make a plan section.	In other parts of the interviews all three of these parents reported they thought the website was useful. Although there was nothing novel in the section they were talking about at this point, later in the interviews other sections had novel content for all of them. No action taken.	Not changed

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
8*	Needed validation for formula feeding families **x2 parents**	“I just think, from the get-go, maybe even in that fact is something like 'as long as a baby is fed with milk, it doesn't matter what it is, and love, that's what a baby needs'. The pressure on breastfeeding, I just feel like it's so intense that it can be really…” “Maybe if you can reiterate the fact that there's no such thing as breast is best. It really frustrates me that people believe that women believe they have to breastfeed for their baby to be in the best care.”	Added more validation and supportive messages for formula feeding parents	M
8*	Needs more validation of closeness being hard and holding baby constantly being impossible **x4 parents**	“So yes, I just think there's something in that underlying - just the tone of it that you have choices, because I think that's always what I was trying to find. I was just trying to find some resources that gave me some options… there were times when… I was like, I love my baby, but I don't want him to sleep on me again.”	Added messaging about self-care and myth emphasising that you don’t have to hold baby 100% of the time to be a good parent.	M
8*	Reflux fact felt dismissive **x2 parents**	“I feel like, when I was in the thick of it, I didn't want someone to tell me it was normal because I just don't think it's normal.”	Considered how the website language across the site can be altered to feel less threatening or dismissive to parents who are convinced of a medical diagnosis. Added link to when is reflux a medical problem, changed language to make it more empathic.	M
8*	Wording suggestion Needs more positivity on first landing page	“something around, like, you're here to help”	Added positive message at the end of the first landing page	O

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
9*	Possible unintentional consequence Information could be frustrating for parents.	“All that cheese my wife has been missing out on, she wouldn't be very happy reading this.”	Challenging existing beliefs may be evidence of a positive attitude change according to the goals of the intervention. However, we need to maintain positivity and ensure that parents leave feeling empowered and better than they did before they arrived. Changes made to ensure positivity messages are prominent as well as ‘what to do instead’ options and links.	O
9*	Parent appeared upset with healthcare professionals who had given her inaccurate advice. Conflicting information could cause harm by damaging the relationship between parent and professional **x2 parents**	“It's different from what they tell you as well. I'm like, because you trust when you go to the doctors with your baby or something, that what they're saying is right…because if it doesn't actually make a difference, why are they making us do all this and feel really bad? It will make you feel like it's your fault…because you're the one that's feeding them. …Why don't they know any of this? Why aren't they told about this…actually it's very contradicting information. The science is obviously out there, it's proven, so why aren't they using it too?”	In this case, this was resolved in the post interview debrief with an explanation of research dissemination and changes to practice. For future parents, it will be important to ensure the intervention is not used in isolation but rather as part of an embedded systems approach including a healthcare professional intervention as well. Consideration for the dark logic model.	M

Group*	Summary of issue	Example quote / explanation	Action taken	MOSCOW
9*	Possible unintentional consequence Emotive topic	“because some of this, it's like - it just hits home a bit, doesn't it? So sorry if I'm crying!”	Considered whether this was a reflection of harm. Discussed with supervisors and agreed this is an emotive topic. With any successful intervention Parents may find thinking and talking about it distressing. Considered possible contribution of a dark logic model. Many of PPI contributors, other stakeholders and professionals who have seen the videos have had similar reactions. Agreed it is a reflection of the effectiveness and relatable nature of the resources.	Not changed
9*	Possible unintentional consequence Parent went away feeling confused rather than empowered	“I have had some feeding support, but she's not always settled…It makes me question, oh, maybe I should get another opinion, I don't know.”	Added empowering messaging, positivity and clearer messaging about the 3 key elements of the site – when to worry, you are a good parent and make a plan. Landing pages added to orient the information in context of making a plan of something to help.	M

*Group: 1 aesthetics, accessibility, navigation, unclear. 2 content request. 3 contextual factors. 4 credibility. 5 reorganization. 6 gender 7 novelty. 8 wording. 9 unintended consequences

8.4.3 Thematic Analysis

Overall six themes were developed, with four subthemes, presented in Figure 13. Each theme is discussed in more detail below, with supporting quotes. Parent ID numbers indicate the source of each quote.

Figure 14: Map of themes developed from thematic analysis of 22 'think-aloud' interviews with parents of unsettled babies

8.4.3.1 Easy and enjoyable to access

Most parents reported that the colours chosen were calming and pleasing and that the site appeared professional, clearly laid out and easy to navigate without too much text. In earlier iterations, some parents made suggestions which would improve the navigation around the site,

accessibility and the length of some sections. All these suggestions were implemented (see Table 15 in Chapter 8.4.2) and the changes were received positively by subsequent interviewees.

The way the resource was presented, using a mixture of videos, activities, interactive features and text was commented on by several parents. In this example, the parent liked the personal link to myself through the video and the novel ways of presenting information.

> *"Yes, I like that video. It just gives a bit more of a personal touch to it….There's activities. Yes, I like that…I think it's just different. It's not something that I've seen…on a website like this… I've not ever seen then things that make you emotionally feel better…having these things dotted through the website, I think it's a nice touch… it shows that some thought has been put into it… there is clearly someone that cares about the emotional side of it."* ***P308***

Other parents appreciated the wording and involvement with parents, as well as the different information formats, such as video elements, images and email reminders.

> *"Good that you can tell parents have written it. Like, it's not just a doctor shouting at you. It's worded in a nice way".* ***P302***

> *"I like the fact that you've got a video…I like that it's more interactive, instead of just reading…it feels like there's someone talking to you and going, it's not that bad, don't worry."* ***P102***

> *"That's a really calming video, as well. You have a really soothing voice, which I think would really like bring someone who's down who's getting a bit stressed. That would make them think, okay, yes, I'm all right. … just made me feel really calm and I liked the breather where you're saying, 'Forgive yourself.' I was like… I don't even feel stressed out now but that's really nice to have that. It makes you take a moment for yourself."* ***P201***

Parents reported either finding the activity email reminders practical and easy to use or else did not mention it:

> *"I like the idea of getting it emailed or text to you, because if you are in the middle of the night with a fussy baby, no one's got the time to go on the website in the moment. Whereas if you've got it accessible on you - everyone's scrolling on a shopping app or something."* ***P208***

The video messaging was received very well by all the parents who viewed it, but two parents reported being put off clicking on the video because they would want subtitles. These could be added in future iterations of the intervention.

> *"If I'm on my phone to begin with, it's normally because the baby's sleeping so I wouldn't be looking at videos anyway… You're just terrified to wake them up…she would be sleeping on me"* ***P301***

In particular, the photographs of babies throughout were very popular, with parents reporting they made the site enjoyable and accessible to view.

> *"It's cute. Gives a little bit of comedic relief as well when you're probably stressed out."* ***P301***

Two parents also reported noticing that the pictures reinforced the validating and normalising messaging of the site.

> *"It's good to have that picture with the 'Normal' because babies are sick. It's just a thing that they do."* ***P201***

Five parents commented on the inclusivity of the photos and appreciated this.

> *"Yes. It's good to have a picture of a dad and a baby, as well, because sometimes it's always just the mum"* ***P303***

> *"I obviously saw a white baby, and I can see a black baby. I think that's really, really important to the world we're living in."* ***P309***

8.4.3.2 Building Credibility: 'you can trust it as fact'

Whether the information on the site could be trusted or not was of great importance to the parents interviewed. Overall 19 of the 22 parents interviewed explicitly mentioned the credibility of the resource as something they would consider.

In early iterations of the website, many parents reported being unsure of the accuracy of the 'facts' presented, particularly when it contradicted advice they had seen elsewhere (such as in advising against exclusion diets).

> *"I'm not sure. I'd want to know…this is what this is saying, but how do I know this is correct compared to what the GPs are saying?"* ***P110***

Following this feedback I designed a new 'landing page' to the site. This included a statement explaining that the resource was designed by professionals and researchers along with parents, the advice was evidence based and included the logos of the NIHR and the University of Southampton. This seemed to improve the credibility of the site, with parents citing both the qualifications of the team behind it and because of the trust placed on the experiences of other parents.

> *"As a parent, I'd be like, okay, literally every single one of them is qualified to know…They've actually got experience in the field… I would be like, right, they know what they're on about."* ***P208***

> *"So what I like about that is I quite like the fact…that it's been done in partnership with parents. So my instant reaction to that is that this is going to be real-life advice rather than just maybe the kind of advice that sometimes feels a bit generic"* ***P203***

Parents stated that they valued having credible information easily available in one place, to prevent them having to do their own research and feeling unsure about the quality of the advice they were reading.

> *"Yes, I like that. I like a bit of myth-busting. I think that's really useful because when you do google bits and bobs to do with babies there's so much conflicting evidence and advice out there. I think having that is really helpful. Especially because on that previous bit, you then know that it's from a credible source…I like that it's drawing together bits from different sources. You haven't got to go and seek out the credible stuff elsewhere. It's all brought it all here which is helpful.* ***P202***

Some parents expressed that they found there was often an 'agenda' in the information they received elsewhere online and that they were conscious of trying to find unbiased information.

> *"It feels credible. It feels honest and it feels supportive without having an agenda."* ***P201***

Several parents talked about the logos and how important they were to their perception of the trustworthiness of the website.

> *"I always like credentials and assurance, because there's so much out there, and a lot of it is contradictory. So seeing familiar and reassuring stamps on information would always make me feel a little bit more like, 'Yes, this is something that I should be doing, something I should be reading.' I can see you've got your university logo there. NIHR…"* ***P306***

However, this same parent also noted the absence of the NHS logo and expressed that this would detract from the credibility of the resource if it was not there. The missing NHS logo was also noted by one other parent, who also referenced the importance of advice being consistent with other NHS resources and regularly updated.

> *"I always look for the NHS one, which isn't on this particular prototype…I would probably notice that that's not there. It wouldn't necessarily make me not read it, but it's something I'd have in the back of my mind."* ***P306***

> *"[reading]' 'I think at this point I'd be wondering if it… Had anything to do with the NHS as well. It would be good to know that all the information that's on here is regularly updated with the NHS guidelines…so that they match each other… I wouldn't want to end up looking at the app and going, 'Hang on, but the NHS says something different, so what do I trust?' Naturally, I think I would go, 'Well, I trust the NHS website,' because the NHS is our national health service. It would have to match up for me."* ***P309***

One parent described how the information was presented in a way which helped them understand the facts, which for them was an important aspect of believing and trusting the information they were given.

> *"I'm a big person who likes to understand why things happen, because then it helps me understand why it's... If someone just says, 'Oh, that's not a problem', then I want to know why it's not a problem, for me to believe that it's not a problem, so it's good to have the actual explanations."* ***P302***

8.4.3.3 "Golden nuggets" of information

Many parents talked about the information given on the website in a positive way, that they found it helpful and that it built their confidence. Some asked for specific additional content to be added.

8.4.3.3.1 Useful, novel and important

All 22 participants reported that the information on the site was useful and important for new parents. A few parents reported they knew most of the information in some sections of the site, but all of them found useful and novel information elsewhere.

> *"I think it'd be useful for more inexperienced parents, say first-time parents, or have never really had children before, never really been around young children, to give them strategies to cope when - or to know what to do when their baby is unsettled…**Interviewer:** It's perhaps not something you would use because you feel like you already have most of the strategies? **Parent:** Yes. I've quite a lot of experience with working with children as well."* ***P106***

However, the majority found novel things that they thought were useful and those who knew some of the information already reported they could see the value in it for other parents, or as a reminder for themselves.

> *"'Fact…[reading]…I didn't know that. That's actually good to know. Yes, it's really good to know. It's good that that's one of the first things you see*

> *because I don't think many people will know that. 'Read more common myths and facts.' That would make me click…. I'm learning. This is teaching me a lot… I love this section. This section is really - I'm speaking for lots of other people here, but I'm going to guess that not many people know that"* ***P208***

> *"I guess a lot of this…A lot of this I do obviously know because I've had two babies. I think again for first-time parents this would be amazing…[later]…No, I really I really like this. I think this is really, really good. If I knew that someone was about to become a first-time parent, I think I would 100 per cent refer them to this app…Even as a mum of two, I'd still be interested to have an app like this, so I can always refer back to it."* ***P309***

Two parents stated they would have valued having access to this site when they were pregnant, to prepare themselves with the information in advance.

> *"To be fair, even if I'd have had a website like this whilst I was pregnant, even before I technically had an unsettled baby, I would've read this website in full, just to get as much information as possible… Yes, it's obviously a website about unsettled babies, but it's got so much information."* ***P308***

8.4.3.3.2 Building confidence

Many parents described liking the 'you are a good parent' materials. In particular, one parent noted that they had not expected the material encouraging the development of a positive parenting identity; but that this was a good addition, making the resource exceed their expectations.

> *"Well, it is actually a little bit different to what I expected. I didn't really know exactly what to expect but my first instinct was it might be just sections of advice around things like colic, reflux, that kind of thing. So actually, now that there's a slant more on actually you're a good parent, that's quite nice because I didn't expect that…Yes. I feel like it's going to be more supportive than I thought it might be, now that I'm seeing the pages."* ***P203***

In particular, almost all the parents valued the information on medical red flags which helped them determine what was a health concern and what was within the spectrum of normal baby behaviour. Those who did not state this did not view this area of the site, instead choosing to access the 'good parent' or 'make a plan' sections.

> *"[reads] So that's a big thing for me… it's actually knowing when you should actually worry, so that's a massive thing for me, knowing if I'm*

> *being too blasé…I think my main things is not knowing if what she's doing is normal, basically."* ***P302***

In early iterations of the website, several parents reported finding the 'when to worry' section difficult to navigate and understand.

> *"I'm a little bit unclear on what this means… I don't know if what's coming is like a full article, and not skipping to sections of it. Or if these are different pages that I'm going to be taken to"* ***P101***

As a result of this feedback, a traffic light system was introduced after the first round of interviews. After this change, all parents who saw this section reported valuing the clear and simple way that the information in this section was presented; often commenting positively on the traffic lights system and feeling that it would help them reduce the confusion they experienced regarding their baby's unsettled behaviours.

> *"I like the traffic light system. I would imagine a lot of people would be familiar with that kind of traffic light system. Or if they're not, I think they'd understand it."* ***P203***

8.4.3.3.3 "Could you include…"

Nineteen of the parents suggested adding specific content. In many cases, these changes were made, expanding the information available. Specifically, sections were added on sleep, extra links and resources on the feeding pages and two extra 'myths' to the myths and facts. The first myth that was added (alongside lots of supportive messaging about breastfeeding) emphasised that you don't have to breastfeed in order to be a 'good parent'. The second went alongside another myth and fact giving information about a babies' inability to self soothe and gave permission for parents to practice self-care when needed.

> *"I think if I was going to give some other feedback I'd say if there's a page that takes people to sleep. I think as a new mum the biggest shock to the system is the sleep deprivation."* ***P110***

> *"I just think, from the get-go, maybe even in that fact is something like 'as long as a baby is fed with milk, it doesn't matter what it is, and love, that's what a baby needs'. The pressure on breastfeeding, I just feel like it's so intense"* ***P205***

However, some of the suggestions for sections to add in were not included, mostly because they recommended commercial or other branded products, or because the advice was not evidence based.

> *"Yes. Maybe where you're talking about formula, to kind of have a little table, with pictures of the different formulas that are available."* ***P309***

> *"Yes. Again, I wonder, with that closeness - like, you do not need to teach your baby to self-soothe… you never have to, but if you want to, maybe here's a link to how to get your baby to self-soothe."* ***P205***

8.4.3.4 Dealing with challenging or emotive content

Parents were often finding that the website was challenging their previous perceptions and ideas. In some cases this led to them experiencing and expressing a change of attitude. For most, this experience was reported to be a positive or useful one.

> *"So, I was wondering whether it was a milk allergy. Reading this, I'm like, oh. Then, since we've started him on prescription formula, we've then had doubts whether it was a milk allergy or not. We're still investigating that. He's nearly nine months old. We stopped breastfeeding at four and a half months. I really convinced myself it was a milk allergy. That was what was causing the problem. So, yes, that's really interesting to read."* ***P101***

> *"We're meant to be going out for afternoon tea tomorrow, a group of my friends…they won't cater for allergies, so I have to take my own food there. So this kind of thing, if I know that this was completely medically backed by lots of different sources, then I'd be like, well, I'll just eat dairy, then"* ***P109***

> *"Oh, okay. I'm actually getting some new things here. That's actually really nice [reads] I do think my [dietary] intake actually affects my baby…so I do not really need to worry about what I take in, since it does not affect my baby. The breastmilk actually does not depend on my food content."* ***P210***

Four parents reported finding the resources supportive of breastfeeding, which is in line with the goals of the intervention.

> *"I was convinced it was something [I was eating]… It was like she was having all these problems after I'd feed her… should I just do formula?...it's nice that there is a validation about breastfeeding, and it's not you poisoning your baby."* ***P301***

Several parents also reported valuing the self-care messaging, others did not mention it.

> *Yes, I think it's important that you do get that, almost permission, that you can put them down and just have them cry for a little bit whilst you just... Whether you need to just have five minutes to yourself, or go to the toilet, make yourself something to eat, yes, I think it's important, so yes, that's good that it's at the top as well.* ***P308***

Two parents reported saying they would like to share the information with other people in their lives, to help support them in their parenting decisions, as in this example:

> *"[reads] That's really interesting; I'd really like to show my mother-in-law that. She is like, 'You need to stop breastfeeding that baby; formula is better. They're hungry.' I just tune it out now. From my experience, breastfeeding works great for me and my babies. I have wondered, should I be trying to get a bottle in them before night? That is interesting that there's been a study of 700 babies."* ***P306***

However, there were also less positive experiences reported. For example, two parents' comments suggested that it introduced some doubt or lack of trust in the healthcare professionals who had given them the previous advice. This was explored further in the dark logic model in Chapter 8.4.4.

> *"It's different from what they tell you as well. I'm like, because you trust when you go to the doctors with your baby or something, that what they're saying is right…That's completely taken me by surprise…because if it doesn't actually make a difference, why are they making us do all this and feel really bad? It will make you feel like it's your fault that this has happened as well, because you're the one that's feeding them. That's really surprised me."* ***P102***

Another parent reported that reading information so contradictory to their own experience was difficult, because they had already experienced personal hardship as a result, and because the information did not match their own experience.

> *"All that cheese my wife has been missing out on, she wouldn't be very happy reading this.* ***Interviewer:*** *No. I think that's a really good point, actually. I could imagine it might be quite upsetting if that's something you've already done and experienced for quite a long time.* ***Parent:*** *Yes, more so for my wife, I can imagine. Even from - not just from what we've been told but from our actual experience with him, reintroducing dairy to my wife…he has reacted to it, so there must be something to it"* ***P107***

Many of the parents using the resource reported it also had a positive impact on their emotional wellbeing and their perception of their own parenting competence:

> *"It's actually made me think I am good at all these things that I just do, that I don't think about on a day-to-day basis."* ***P102***

> *"I absolutely love that. It really made me think about it a little bit differently. Some of the images are really relatable. When I'm holding my baby and he just will not stop crying, and I've tried everything. You do feel*

> *like crap:…next time baby won't settle and I'm a bit embarrassed in public, I'll be like, 'Nobody is…[judging me]'"* ***P306***

> *"It's a really nice, simple way of going, 'Yes, I'm doing enough. Things are safe. Baby feels loved.' Yes, the needs are getting met in the middle of everything. It filters out all those little, niggly standards we have in life, and just looks at the main stuff. I think that's a really good activity. I'm definitely going to do some of these afterwards."* ***P306***

One parent found the materials difficult to read, stating that this was because they were so relatable. This parent became visibly upset during the interview, but wanted to continue. She reported finding the messages on the website reassuring and validating, although emotionally challenging.

> *"sorry if I'm crying!... [after watching the video]… You do just feel like you're doing a crappy job all the time…it is relatable. Again, it's probably helpful thinking that…other people are probably feeling like that, and you're not so alone in things."* ***P109***

8.4.3.4.1 Conflict expectant

For three of the parents we interviewed, the materials were raising issues that they had experienced conflict with healthcare professionals over in the past and had formed strongly held opinions as a result. In these cases, they found the resources more difficult to engage with. These interviews were valuable in helping me to identify which sections of the website and which words specifically were triggering these reactions. I then made changes to the wording aiming to help reduce and/or mitigate the feelings of defensiveness or readiness to conflict, whilst maintaining the evidence based and accurate nature of the information.

For the first of these examples, the parent had felt dismissed by healthcare professionals in the past and expressed that she felt she had to 'fight' for her baby. From this perspective, she found the focus of the site on normalising baby behaviours as challenging to read and she related this back to her experiences in the past.

> *"I just feel like often, your maternal instinct…With [second baby], I felt a little bit more armed because I'd done so much research, but with [first baby], it was sort of - lots of health visitors just told me it was fine he was crying, like it's normal. Also, I took him to A&E quite a few times, and it was like, 'Is this your first baby?' It doesn't matter if it's my first baby or not. I know that he's just vomited up every single feed he's had today, and something is not right. Like, I don't care if it's my 75th or my first."* ***P205***

This parent also struggled with the information in the website about cows' milk allergy; because it went against her own experience and the experiences of other parents she had spoken to. This raised my awareness of the importance of including evidence based information about 'intolerance' and the evolution of milk tolerance through human life course, alongside information about allergy, which is something that could be added in future iterations of the website.

> *"I imagine it's a bit of a controversial viewpoint, but I just think - and I've seen so many mums that have gone dairy-free and it does settle for their children, so I do think there's something about it that - I definitely agree that it's not an allergy…but I feel like, when they're so teeny-tiny and their guts are so immature… just there's so much less for them to break down, and so their guts don't feel as - aren't so overwhelmed. So I do agree with the fact, but I definitely think that it can help, and it's definitely something to potentially explore for some parents"* ***P205***

In the second case, she reported often being worried about being a 'good parent' and therefore found this section of the resource emotionally challenging for her.

> *"'Know that you are a good parent.' Again, I don't know what's a good parent. Maybe something more like, 'Know that you're good enough.' Something less labelling. Like, there are good parents and there are bad parents... Parents spend a lot of time feeling not good."* ***P306***

For this parent, her readiness to blame herself seemed to have led to her feeling defensive automatically. This exemplified the level of sensitivity required to develop a resource like this effectively and the extreme nature of the emotions involved.

> *"I'd probably click on that first, and just see: What does that say? How do I know if I'm good? I've just read it. It says, 'Remember, you are a good parent,' not, 'Are you a good parent?' I changed the word in my head, there!"* ***P306***

For a third parent, the parts of the resource they found challenging were related to what is normal baby behaviour and when to worry.

> *"My first instinct to that, 'Will help you know when to worry.' I'm trying to think how - yes, can a website tell me when to worry about my own baby? Maybe not. I know what it's saying, but maybe it needs rephrasing… I'm not keen on the word normal… I guess it's just that different people can interpret the word normal in different ways… there is no such thing as normal."* ***P309***

Finally, one parent expressed that although it was useful to have the knowledge about when a medical concern should be suspected, this was only helpful if the healthcare professionals also had access to this same information and if the required support services were readily available.

> *"'Get feeding support', whatever, that's fine. It is easier said than done. For myself, I've been trying for ten months to get that kind of support, and it's just not happening. I do think if I was seeing that in the midst of arguing with the doctors and trying to get help, it would just be frustrating, if that makes sense, just because a lot of parents naturally are… trying to get help. I think the main problem is that there isn't any help."* ***P301***

8.4.3.5 Validating, relatable and reassuring

All the parents in the study reported finding the resources validating, relatable or reassuring at some point in their interview. In particular parents reported that the quotations from other parents resonated with them and made them feel 'heard'.

> *"Past me would have loved reading that, thinking, right, I'm not doing anything wrong; I am feeding him enough, that kind of thing."* ***P208***

> *"Oh, yes, that's true. [reads] Yes, everything there is actually true. Yes, I can relate to that."* ***P210***

> *"Oh, [reading]. Yes, that is exactly what we call [A*]. Exactly what we call her. I call my little koala. She's just always stuck on me…Yes, I'm literally in the exact same situation so that's very validating, the whole older child. That's very, very validating. I love that."* ***P301***

8.4.3.6 Giving back control

Many of the parents related to the experience of helplessness when they had a crying baby, and four parents explicitly reported finding the resources on the site useful as a way to regain a sense of control.

> *"That personal plan thing, that would be quite good…Sometimes, it's even just helpful thinking that you're trying to do anything to try and ease the screaming. Having a plan, it would help, even mentally, thinking, well, I'm trying to do something. Actually, a toolkit where there are different things to know what might be a good thing to try…having something to try makes you feel better, because you're trying. You're not just accepting, oh, they'll grow out of it"* ***P109***

"Yes, I think that's a good idea because then you'd be like, right, here's my four things. Let's try that… It is really useful because you just feel helpless, really" ***P208***

8.4.4 Possible Unintended Consequences

In the following section, possible unintended consequences of my intervention, which could be considered as part of a dark logic model, have been outlined. This harms analysis includes the development of a Dark Logic Model (Figure 14) as well as a Table (Table 16) summarising and elaborating on the included harms and mitigations, the source, estimated plausibility and seriousness. The methods for harms analysis and Dark Logic Modelling are discussed in more detail in Chapter 8.3.8. I have also presented these in a visual format in Figure 14, which attempts to illustrate how they might interact with each other in a dynamic, live context. Figure 14 also includes harms from inaction – postulated harm from not implementing an intervention like this. These are marked in yellow in Figure 14 but are not included in Table 16. For discussion of these harms see the background of this thesis Chapter 2.1.

Harms are divided into two categories, paradoxical harms (consequences which are directly opposite to the planned and stated aims of the intervention) and harmful externalities (other harms which are contextual or tangential to the aims of the intervention).

8.4.4.1 Narrative summary:

In particular, harms which have been presented fall into two main conceptual groups, with some additional outliers. Firstly, there is an important issue about the way information is communicated with families sensitively and empathically to reduce risk of triggering negative emotions, making parents feel dismissed, judged or guilty. Secondly, there is a wider systems issue, which suggests this intervention will need to be nested within a wider network of support which must be independent of commercial influence and include a healthcare professional intervention and sufficient feeding support to enable parents to reach their personal feeding goals. This is needed to prevent the intervention, if used in isolation, causing potential harm to relationships between parents and healthcare professionals and contributing to the conflict expectancy in this space.

The main goal of this harms assessment exercise is that future research using this intervention can be conducted to best mitigate and reduce the risk of any unintended negative consequences. It also allows for and proposes hypothesised mechanisms by which harm may be done which are then

measurable and testable in future development and refinement of the intervention. Finally, it acts as a starting point to be built on for future apriori dark logic model development in this research area.

It should be stressed that the harms proposed here are a list of all possible harms I can currently anticipate through use of the intervention, some of which build on the evidence from think-aloud interviews; however we do not currently have evidence that they would occur in a real world scenario. The likelihood of their occurrence cannot be accurately estimated at this time, however I have indicated in Table 16 those which I believe are plausible and / or serious to allow for a pragmatic prioritisation in future research. Potential mitigations which I have implemented in the intervention to date are detailed in Table 16, alongside potential mitigations or preventative strategies which could be considered for future research.

8.4.4.2 Dark logic model:

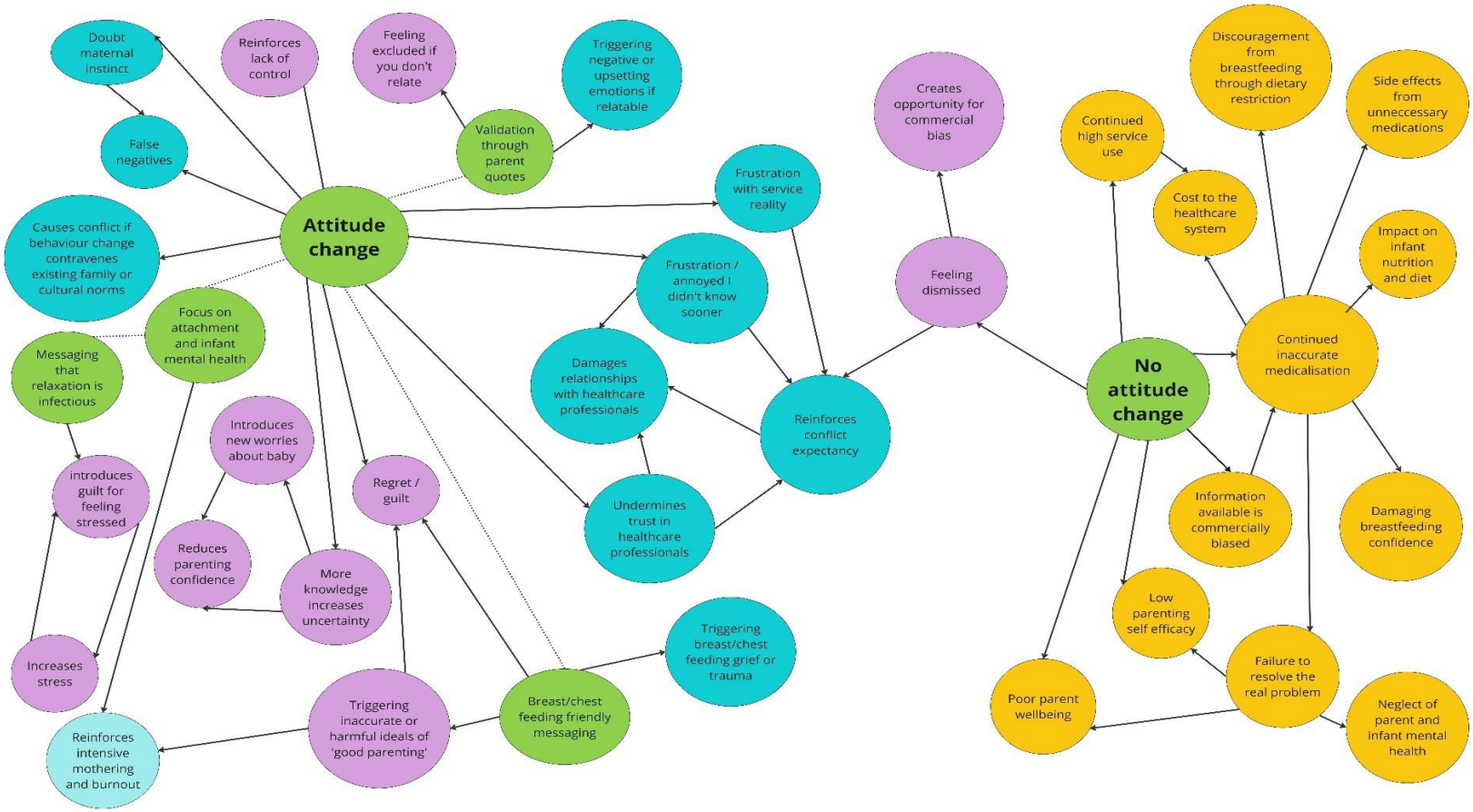


Figure 15: Dark logic model - mapping of possible theoretical harms and their potential interactions. from inaction (yellow), intervention goals (green), harmful externalities (blue) and paradoxical harm (purple). Suggested interaction directionality is indicated by arrowhead. Dotted lines indicate connected intervention elements.

8.4.4.3 Table of possible harms:

Table 16: Possible harms from the intervention and mitigations which could be taken in future research and implementation. harmful externalities (blue) and paradoxical harms (purple)

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Reinforces intensive mothering and burnout	Parents could internalise messaging about infant brain development, inability to self-soothe and importance of physical closeness as a directive; leading them to have impossibly high aspirations to never put their baby down.	"Although you validated and saying, 'Don't feel guilty about spoiling the baby and picking them up,' I would also put in something…'It's okay to put them down for a few minutes if you need to.'"	Harmful externality	Discussion in supervisory team; think-aloud interviews; listening cafe	Plausible	Included self-care messaging as well as an additional / myth & fact	
Introduces guilt for feeling stressed	Messaging around dyadic emotional regulation could make parents feel worried, guilty or anxious about feeling stressed. This could then lead to them feeling more stressed and a subsequent vicious circle.	"my brain was like, oh my gosh, does that mean I'm stressing my baby out"	Paradoxical harm	Think-aloud interviews	Plausible	Wording changed to emphasise the positive and reduce responsibility / blame on parents.	

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
More knowledge increases uncertainty	Additional information, especially on a complex or nuanced topic such as this can increase the 'known unknowns'. Discomfort with uncertainty may reduce parenting confidence through fear of an unknown 'underlying problem' [314]. Additionally, increased knowledge of issues the parent had not previously come across may introduce new worries about their baby.	"I'm reading is it reflux, maybe it could be reflux… I don't know"	Paradoxical harm	Think-aloud interviews	Implausible – single example, the parent did not appear unduly worried. Uncertainty was reduced in later think-alouds.	Format of information refined to maximise clarity and confidence.	
Regret / Guilt	New information they did not previously know may make parents regret and / or feel guilty about decisions they have made in the past.	"you might feel guilty that you are giving them the reflux medication"	Paradoxical harm	Think-aloud interviews, clinical experience.	Plausible	Wording edited to minimise blame and soften language use.	Could add a trigger warning system for facts that have the potential to be upsetting for parents.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Triggering inaccurate or harmful ideals of good parenting	Breast/chest feeding messaging may trigger difficult feelings that parents are being judged if they do not breastfeed.	"It really frustrates me that people believe that women believe they have to breastfeed for their baby to be in the best care"	Paradoxical harm	Think-aloud interviews	Plausible	Added information and myth/fact about validity of formula feeding and freedom of choice within good parenting.	None
Triggering breast/chest feeding grief or trauma	Reading parent stories about infant feeding or seeing images of breast/chest feeding may trigger existing trauma	N/A	Harmful externality	Theory and evidence around infant feeding grief and trauma [55].	Plausible	Added supportive messaging about formula feeding and individual informed choice.	Could add a trigger warning system for facts that have the potential to be upsetting for parents.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Causes conflict if behaviour change contravenes existing family or cultural norms.	Parents could use the intervention to provide support their case in arguments with family members	“That's really interesting; I'd really like to show my mother-in-law that.”	Harmful externality	Think aloud interviews	Implausible. Unlikely that the resource itself would create conflict. Instead, it is more likely to be used to support parenting confidence in their parenting decisions.	None	None

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
False negatives	Parents could be falsely reassured by the website into thinking their baby does not have a medical condition when they in fact do. This could also lead them to doubt their maternal instinct.	"I just feel like often, your maternal instinct… I took him to A&E quite a few times, and it was like, 'Is this your first baby?' It doesn't matter if it's my first baby or not. I know that he's just vomited up every single feed he's had today, and something is not right."	Harmful externality	Engagement work with a clinician who raised this worry. Emphasis on the importance of mothers instinct in one of the think-aloud interviews.	Implausible. Given that the existing pattern is to overdiagnosis, this seems unlikely. Infants requiring medical intervention would be likely to present with more extreme symptoms than those covered on this website.	High quality red flag advice.	None

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Reinforces lack of control	If effective, by reducing the likelihood of an allergy or reflux diagnosis the intervention is removing a sense of control or the idea that parents have something they can 'do' to help their baby, which may increase their sense of helplessness and so cause distress.	"You're at the point of if you've tried lots of other things and you're telling me… I don't… then what can I change."	Paradoxical harm	Think-Aloud interviews	Plausible, serious. Feelings of helplessness have been associated with the strongest emotions expressed by parents in my research.	Emphasis on positivity, access to help and signposting. 'Make a plan' section Crisis disclaimer	Implementing the website within a broader system or network of more intensive support for those who need it.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Triggering negative or upsetting emotions if relatable	When parents relate to the materials they often find this brings out strong emotions.	“Because some of this, it's like - it just hits home a bit, doesn't it? So sorry if I'm crying!”	Harmful externality	PPIE, listening cafes, think-alouds	Plausible, not serious. I often find my materials trigger strong emotions. Everyone who has responded in this way so far has expressed their support for the research and for the materials and has been keen to continue participating.	None	None

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Feeling excluded if you don't relate	If parents don't recognise themselves in the quotes they may feel excluded	"I'm not offended but it feels I'm outside of this comment; it doesn't fit me."	Paradoxical harm	Think-alouds	Plausible	Diversity of participants targeted in think-alouds and across my PhD. Changing content when it is not relatable to make it more inclusive.	Continued diversity in recruitment.
Frustration with service reality	Parents using the website are better informed about which symptoms are worrying and which are normal; as well as when they need to seek help. However, if when they reach out the service provision is not receptive or accessible then this is frustrating for them.	"'Get feeding support', whatever, that's fine. It is easier said than done. For myself, I've been trying for ten months to get that kind of support, and it's just not happening"	Harmful externality	Think-alouds	Plausible, Serious.	None	Ensure that this intervention is rolled out as one part of a nested system of high quality support which must include an intervention targeting healthcare professionals and sufficient feeding support.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Frustration/annoyed I didn't know sooner	Parents who are now better informed may feel frustrated that they were not given this information in time to help them with their previous baby or earlier in their journey. This is particularly relevant where parents have experienced significant hardship, such as in the case of exclusion diets.	"All that cheese my wife has been missing out on, she wouldn't be very happy reading this."	Harmful externality	Think-Alouds	Plausible	Positivity messages emphasised and 'what to do instead' options more clearly signposted; aiming to leave parents feeling empowered.	
Undermines trust in healthcare professionals	If parents feel they have been misinformed by the healthcare provider they had consulted in the past this may lead to them distrusting this healthcare provider again in the future.	"It's different from what they tell you as well. I'm like, because you trust when you go to the doctors with your baby or something, that what they're saying is right…"	Harmful externality	Think-Alouds	Plausible, Serious. This could have implications for the relationships between parents and healthcare professionals, which might be important in them accessing support in the future.	In the think-alouds, this was resolved with the parents in the post-interview debrief.	Ensure that this intervention is rolled out as one part of a nested system of high quality support which must include an intervention targeting healthcare professionals.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Reinforces conflict expectancy	Throughout this research it has been consistently found that parents often approach interactions with healthcare professionals with a degree of conflict expectancy [314]. Through feeling frustrated with service inadequacies, frustrated that they didn't know the information sooner, or mistrustful of the professional they are seeing leading to a more difficult, conflict driven interaction.	"It's different from what they tell you as well. I'm like, because you trust when you go to the doctors with your baby or something, that what they're saying is right."	Harmful externality	Think-Alouds Literature suggesting conflict between parents and healthcare professionals [314].	Plausible, Serious.		Ensure that this intervention is rolled out as one part of a nested system of high quality support which must include an intervention targeting healthcare professionals. This intervention should include conflict management and prioritise therapeutic communication skills.

Possible harm	Explanation	Example quote (if available)	Type of harm	Source / rationale	Plausible / serious	Mitigation to date	Proposed mitigation
Feeling dismissed	If the intervention is ineffective and the parent does not find it relatable, validating or supportive enough, this may lead to them feeling dismissed and therefore more defensive in their next interactions, which may in turn damage their relationship with the healthcare professional	"I'm trying to think how - yes, can a website tell me when to worry about my own baby? Maybe not."	Paradoxical harm	Think-alouds	Plausible, serious	Wording changed to be less emotive. Tone of the site improved and made more neutral.	Ensure that this intervention is rolled out as one part of a nested system of high quality support which must include an intervention targeting healthcare professionals.
Creates opportunity for commercial bias	If parents feel dismissed and mistrustful of healthcare professionals, they may seek information elsewhere, which leaves an opportunity for companies with commercial interest to capitalise on this and provide inaccurate information	NA	Paradoxical harm	Current theory suggests that industry are benefiting from the way in which allergy and reflux are currently diagnosed and managed.	Plausible, Serious.	Wording changed to be less emotive. Credibility of the site improved.	Ensure that this intervention is rolled out as one part of a nested system of high quality support. This should include consideration of industry influence and be independent of bias.

8.5 Conclusions

In conclusion, draft intervention content has been presented to parents of unsettled babies through 22 think-aloud interviews. Changes were made to the intervention to maximise accessibility, engagement and relevance for parents with unsettled babies; and to mitigate against possible unintended consequences which emerged. Overall goals of the content being validating, relatable, useful and empowering were supported by the parent comments. The resulting intervention requires further research and development, but provides a promising starting point to support parents with unsettled babies.

This research was limited by pragmatic considerations such as budget and time. These made some elements of the research more challenging, particularly in reaching a diverse sample. Although effort was made with some success throughout intervention development to include diverse perspectives, this will need to be sustained and increased in further research moving forwards. Efforts could be made to make the materials accessible to parents who do not have English as a first language; and to test the acceptability and feasibility of the materials in this group.

Stakeholder and expert review is yet to take place and will be an important part of further development of these materials. In particular, clinical psychology, lactation consultant (IBCLC), allergist and paediatric specialist input would be valuable.

Future research is required to further refine this intervention and check it's acceptability in different groups, specifically for parents of other genders. Particular attention in future research could be paid to the possible harms. Mitigation of these will involve consideration of a nested system of interventions which work together, with this digital intervention for parents as one element of it. Another key element would be a health professional intervention, which has yet to be developed.

The controversy regarding digestion and tolerance of allergens in infancy was clearly highlighted throughout this research. Additional research is needed to provide the high quality knowledge base needed to advise parents who are worried about these issues. Research looking into conflict expectancy or problem readiness could also be of value in supporting positive parent-professional relationships. The research is required to be free of commercial influence through formula industry bias or funding.

Chapter 9 Discussion

9.1 Key findings summary

The research reported in this thesis has involved a detailed and in-depth exploration of the experiences of parents worried about their unsettled babies. A systematic review was conducted and a conceptual model developed to facilitate understanding of the process parents may go through when faced with unsettled baby behaviours (such as crying and vomiting); exploring why parents may look for medical explanations (such as allergy or reflux) for these behaviours. These findings informed development of a person-, theory- and evidence-based behavioural intervention to support parents of unsettled babies, in partnership with families. The intervention content was then further refined for acceptability and engagement through think-aloud interviews reported in Chapter 8.

This research has added to the existing literature in several important ways. Firstly, it forms part of a small but growing body of literature recognising the considerable risks to the parent, baby and to healthcare systems of inaccurately medicalising unsettled baby behaviours; to the benefit of commercial industry [30, 39, 41]. New data supporting this perspective has been presented throughout Chapters 5 and 6 of this thesis. It also fits within a broader body of literature introduced in Chapter 2.1.2 which argues that modern, WEIRD societal expectations of infants and of parents are unrealistic and do not fit with normal, evolved healthy behaviours for newborn humans. The impact of this is that parents are managing the transition to parenthood in the context mismatched expectations and are arguable being 'set up to fail' [45-49]. Furthermore, commercial industries are capitalising on these unrealistic expectations for financial gain [141].

Parents in my research have described how a sense of dissonance or disappointment when their experiences of early days with their baby failed to meet their own expectations (see Chapter 5 and 6). This provides support to literature suggesting that wider societal ideals provide the framework for expectations in the pre-conception and antenatal period. It seems plausible, considering this thesis in the context of this wider literature, to imagine that these social norms and expectations might be a factor in parents' developing a personal sense of guilt and failure. Moving forwards, it may be important to consider pre-conception, antenatal or broader public health strategies to support informed expectations for new parents in order to provide a holistic solution to the harms experienced by families with unsettled babies. See Chapter 9.2 for further discussion of this.

Furthermore, this thesis considers the experience of the emotional transition to parenthood for families with unsettled babies and articulates the unmet needs of parents who present multiple times to healthcare practitioners worried about their unsettled baby. It suggests that these parents may be struggling with feelings of guilt, failure and helplessness and may feel their concerns have been ignored, dismissed or minimised. The psychosocial aspects of these concerns, such as parenting self-efficacy and bonding, may be sometimes be overlooked in favour of a focus on finding a medical cause for the unsettled behaviours. This may be important to understand for clinicians supporting families in practice and complements the existing literature, which demonstrates the benefits of moving towards a person-centred approach to care, valuing the role of psychological factors in health and closing the gap between caring for physical and mental health care [361]. It further supports literature advocating for a relational approach to unsettled baby behaviours [72].

Understanding the guilt, helplessness and feelings of dismissal experienced by parents with unsettled babies fits with previous research in this area, where individual qualitative studies have found suggestions of these feelings [32, 51, 71, 118, 126]. However, my work is the first in the field to systematically synthesise this and examine these feelings in depth. It is also the first to relate these feelings to an underlying need driving the search for a medical explanation for unsettled baby behaviours and to produce a coherent conceptual model capturing this (Chapter 5 and Chapter 6.4.4). In this way it builds on the existing literature to allow for practical, clinical recommendations and provides theoretical rationale for intervention design.

It appears also that a medical diagnosis, particularly when combined with an investigation or treatment in the form of medication or specialist formula, may reduce sensations of helplessness and provide a feeling of control (see Chapters 5 and 6). These findings suggest that the experience of unsettled baby behaviours for parents may share some similarities with disorders with medically unexplained symptoms introduced in the background Chapter 2.2; such as chronic fatigue syndrome, chronic pain, dizziness and fibromyalgia [116, 117, 119, 120]. There are complex moral and practical implications of diagnosing and prescribing for these conditions, such as balancing biological and psychosocial aspects of presenting complaints; whilst also minimising the risks of self-fulfilling prophecy and unnecessary harm [124, 125]. These were discussed in Chapter 2.2 and my PhD research suggests that the same considerations may need to be applied to the field of unsettled babies. This is the first time that unsettled baby behaviours have been discussed alongside these other disorders with medically unexplained symptoms and the ethical implications applied to both.

This thesis presents a balanced consideration of the risks and ethics involved in working to increase parenting self-efficacy as management strategy for unsettled babies. There is an important moral

consideration to avoid minimising or dismissing parent experience [233]. Data presented in Chapters 5, 6 and 8 provides evidence suggesting that there may be conflict expectancy in the clinician – parent interaction, demonstrating the need to be mindful and respectful of parenting intuition and also the need for empathy and active listening skills in the consultation. These insights will be a key part of handling the ethical dilemma of diagnostic uncertainty for unsettled babies in practice.

Further to this, feminist literature suggesting that there is a gendered experience for parents socialised as women [111] may also be relevant context to consider in relation to this thesis. It is possible that mothers may be more likely to experience and to be sensitive to dismissal by healthcare professionals due to the sociopolitical history of misogyny which has been pervasive in healthcare [362], and which was discussed in Chapter 2.1.3. This has implications for the interpretation of my findings in a number of ways. Firstly, it emphasises the need to exercise caution in language use in consultations with parents of unsettled babies, in order to prevent minimisation of concerns or dismissal and contribute to the conflict in primary care consultations. Parents in my research reported that healthcare practitioners saw them as an overly anxious parent, specifically a mother. Literature highlighting the dismissal of women's experiences as 'hysterical' or 'unreliable' therefore provides important context for the interpretation of these findings [362, 363].

In my research, experiences of parents of other genders was difficult to access, with a number of challenges to recruitment discussed in Chapter 8. I did manage to recruit some fathers to my think-aloud study reported in Chapter 8, and their feedback was mixed. Some of the comments they gave on the intervention suggested that some elements of the content may have been less relevant for them – specifically the content around reframing being a 'good parent'. This was presented in Chapter 8.4, Table 15. It is possible that socialisation as a woman may put mothers at higher risk of feelings of guilt and failure in relation to parenting of unsettled babies; explaining differences between mothers and fathers in how relatable they found my intervention content. Further research will be needed to explore this.

My research suggests that parenting-self efficacy theory [170, 171] and attachment theory [239, 240] may both be effectively applied to the area of unsettled baby support to underpin the development of a digital intervention. In particular, the use of attachment theory throughout intervention development has been helpful in ensuring that the intervention may be supportive of infant mental health, infant neurological development and early bonding relationships; however there is a risk that it further exposes parents to unattainable ideals such as those contained within the 'motherhood myth' discussed in Chapter 2.3. In intervention development, it has therefore been

important to be mindful of this risk and to balance and mitigate it wherever possible. This has been further discussed and reflected on in the dark logic model in Chapter 8.4.4.

Parenting self-efficacy (PSE) theory has also supported the development of underpinning concepts and ideas throughout this thesis, and provided a framework for intervention development. Past research discussed in Chapter 2.6 has found some success in interventions which aim to increase parenting self-efficacy for parents of unsettled babies, in turn improving wellbeing-related outcomes and reducing medication requirements [37, 227, 228]. However, my research is the first to present a systematic consideration of the PSE mechanisms at play within these interventions (through the conceptual model and through the intervention planning and logic modelling, and the first to attempt to apply these mechanisms to a digital intervention.

One key finding of my research has been that medications and diagnoses may be serving an emotional or psychological purpose for families with unsettled babies, particularly in supporting parents to cope with feelings of helplessness, guilt and dismissal. PSE theory offers insight into the importance of a sense of control in parenting and the application of this theory to the field of unsettled babies suggests that future interventions for unsettled babies need to include practical aspects to increase parents' sense of control. Particularly, PSE theory suggests that lower confidence in their ability to soothe their baby (competence) and lack of a concrete toolkit of strategies to manage unsettled behaviour (planning) might lead parents to a vicious cycle, where their own confidence in their parenting is negatively impacted; their perception of their success as a parent is lower; thereby reinforcing their low confidence [255]. The work presented in Chapters 5 and 6 illustrate how this vicious cycle might be playing out in families with unsettled babies, potentially leading to the acquisition of medical labels when parents lack self-efficacy.

. This suggests that future interventions need to build in aspects of self-efficacy theory such as planning to support parents sense of autonomy and control and combat feelings of helplessness.

Finally, the findings of this research suggest that a digital behavioural intervention such as a website is both acceptable and desirable to parents as a part of a whole system solution to the distress caused by unsettled baby behaviour. It presents the first draft of these materials for further refinement and testing to determine effectiveness.

9.2 Other interventions

There are a number of other interventions which have been discussed in this thesis and which this proposed digital behavioural intervention could complement and sit alongside.

Firstly, a number of face-to-face solutions have been proposed and have been found to be successful in helping improve outcomes for parents of unsettled babies. In one study, a residential educational intervention with reassurance and teaching settling techniques was implemented for babies receiving medication as treatment for colic or reflux in the USA. At the start of this study medication was ceased with parental consent and following medical assessment. By the end of the study maternal mood had improved as measured by EPDS and the authors concluded that there was no organic cause for unsettled behaviour requiring medication in the majority of the infants [227]. Similarly, a quasi-experimental study design was used in Queensland Australia to demonstrate that colic symptoms (measured by pre and post intervention crying diaries) and parent infant interactions (measured by pre and post intervention completion of the Nursing Child Assessment Feeding Scale) can be improved through an educational intervention based around reading and responding to infant behavioural cues [228]. These are both potentially examples of useful solutions which offer the opportunity to consider unsettled baby behaviours in the wider family context, taking account of parent mental health and parent-infant relationships. Finally, the 'Possums' programme, trialled with great success in Australia [225], offers an example of a holistic approach to unsettled baby behaviours and includes high quality feeding support as well as sleep coaching, all within an attachment-based philosophy. As yet there is no similar holistic solution (including support for infant sleep, infant feeding, parent mental health and parent-infant relationships) in place in the UK; although the recent developments from the sleep lab in Durham University offer possible interpretations of the sleep aspects of the Possums approach adapted for the UK in the form of the 'Sleep, Baby and You' intervention [364].

In addition, the 'Surviving Crying' research programme in the UK [229] [230] [231] offers promising support for families worried about infant crying behaviour through CBT delivered by trained healthcare professionals, combined with leaflets and a website. The findings of research reported in Chapters 5 and 6 suggest that parents may experience feelings of guilt, helplessness and are seeking to develop a positive parenting identity and may be supported by therapeutic communication, active listening, strengths-based techniques and reframing the parent's concept of a 'good parent'. Given the conceptual similarity with CBT type approaches and health visiting practice; it may be beneficial to consider the 'Surviving Crying' intervention in the context of medical labels for unsettled baby behaviours and to investigate whether this approach may also be helpful for parents who are considering a medical explanation for their infant's unsettled behaviour.

It is likely that the resources drafted as part of this PhD are complementary to those discussed above. Primarily, the main difference between this intervention and other resources is that this is a

digital behavioural intervention, with no face-to-face element. This has both advantages in terms of cost efficiency, accessibility and ability to scale up quickly and easily; as well as disadvantages as it will not be sufficient to meet the needs of all parents and therefore requires embedding within a well funded NHS system of face-to-face support. Future research could consider how a digital intervention such as the one developed in this thesis might be helpfully combined with a face-to-face resource to meet the needs of families who are worried about their unsettled baby, reducing the need for medical labels.

9.3 Strengths and limitations of the PhD

Key strengths of this body of work lie in the depth and insight gained through the qualitative approach and in the partnership working, particularly with underserved communities such as families living in low income areas and ethnically and culturally diverse voices. Throughout this PhD I have made attempts to discuss my research with parents with lived experience through a range of patient and public involvement and engagement activities (Chapter 4). These insights into parent context provided important background understanding the parent experience which was helpful when developing my intervention materials. This knowledge contributed to language use and tone. In addition to the impact on the research directly, this engagement was important for my personal development as a researcher as it helped build my confidence in approaching and talking to members of the public about my work.

Many of the limitations of the individual studies are summarised at the end of each research chapter. For the systematic review, methodological choices in coding as well as the lack of ethnic and gender diversity and paucity of detail in some of the included studies were challenging. In the hybrid inductive & deductive analysis, the complexity, depth and thoroughness of this method made it resource heavy in terms of time, although strengthened the overall insight from the findings. In the intervention development and optimisation, additional time and resources could have allowed for the content to be developed into a 'live prototype' which might have improved the think-aloud delivery. It is plausible that some of the mechanisms at work in this intervention may be specifically more helpful for parents who are affected by the 'intensive mothering' or 'motherhood myth' societal norms, discussed in Chapter 2.3. Therefore, more parents/carers of other genders would have strengthened the findings by testing the acceptability and engagement of the materials in parents who have not been socialised as women or who do not identify as mothers. Additionally, while I was satisfied that I was able to include a diverse range of parents in terms of area of deprivation (by IMD postcode) and ethnicity across the think-aloud interviews (Chapter 8) and the

qualitative interviews (Chapter 6); I did not reach all of the underserved communities I aimed to across the thesis as a whole. Further research could extend the accessibility of the resources, for example to families with limited English and / or limited literacy.

Taken together, the combination of limitations across the thesis as a whole reflects the ongoing need for more engagement with underserved communities, in particular parents of other genders and non-english speaking parents. Furthermore, additional engagement activities with different groups could have assessed the extent to which this digital intervention may be accessible or desirable to parents from underserved communities, or whether there may be additional challenges facing these communities which suggest they may benefit from face-to-face support. As yet, this is unclear from my research and insight into this could have strengthened the body of work as a whole.

I have learnt over the course of the doctorate (as a training programme) about how to navigate and access existing networks to facilitate positive relationships with underserved communities. In some cases I learnt about groups with existing relationships which could have been helpful; such as the RViR network (raising voices in research https://rvir.co.uk/); however often too late to be able to make full use of them in this PhD. This learning will be very beneficial as I move forwards to other research projects.

As discussed in Chapter 1.1.2 – research aims and scope; it was decided at the outset of this PhD to limit my work to the postnatal period, therefore antenatal research and pregnant women were excluded from the systematic review (Chapter 5), interviews (Chapter 6) and subsequent intervention development (Chapters 7 and 8). Whilst this decision was necessary to limit my work to within realistic capacity boundaries; it became clear through the course of the research that antenatal expectations could be very important for the perception and interpretation of unsettled baby behaviours. Parents in the think-aloud phase of the intervention development expressed that they would have found the resource helpful while they were pregnant. This suggests that care provision throughout the full perinatal period, including the preconception period, should be considered in research moving forwards.

9.4 Reflexivity: Going from clinician to researcher

In addition to my lived experience as a parent discussed in Chapter 2.5.2, throughout my PhD I have been learning to navigate research as a clinician. This has presented opportunities, strengths and challenges. Firstly, my knowledge of clinical practice has helped me to interpret parent narratives and to understand their journey; as well as guiding recruitment strategies. Given that I am used to

supporting families who are struggling with unsettled babies in my clinical role, this helped me to deeply familiarise myself with the parent experience, which I feel strengthened my intervention design process. Because of my familiarity, both the user characteristics and underpinning guiding principles of the intervention were informed by a strong knowledge of the parent 'persona' I was hoping to help. Additionally, I believe that my experience talking to many parents about their babies made my content feel 'authentic' and relatable which made it appealing for parents in the think-aloud phase.

From an impact perspective, efforts have long been advocated to close the gap between research and practice [365]; and clinically active researchers are of potential value in ensuring findings are pragmatic, research questions are clinically useful and their dissemination translates to real-world changes [366].

However, these advantages are not without difficulty. Assimilating 'researcher' into my own personal identity alongside and; during the course of this PhD at least; instead of 'clinician' has been challenging.

In reading a recent systematic review-compiled typology of experiences from clinician-researchers [367]; I recognise ethical or practical considerations I faced through the course of my PhD. Firstly; I struggled with disclosure of my role and when this was appropriate. As an example; during my PPI work I often chose not to disclose my professional qualification as a health visitor; to allow contributors to speak freely about their own experiences. However; over the course of the listening cafes I found that at times my role as health visitor was useful for the parents and I was able to balance the two identities within the research. A second ethical consideration was when in the think-aloud interviews parents reported having received incorrect or clinically unsafe advice. In these cases I continued the interview as normal, but then had a short conversation in the debriefing session at the end which allowed me to signpost the parent to the correct information and advise them to seek further healthcare support where this was indicated.

Throughout the course of the research, parent voices, parent contributors and data from my reviews of the literature has led to a subtle shift in the emphasis of my research. My goals have moved away from reducing medicalisation; instead focusing on reducing feelings of parenting guilt and failure. My hope is that by supporting parent wellbeing and reducing these negative emotions; medicalisation of unsettled behaviours will be less prevalent. However the primary focus of my future research and any further testing and implementation of my intervention will be to reduce parent suffering and improve wellbeing.

Moving forwards, my identity as a clinical academic is continually developing and continues to influence my positionality in research [367].

9.5 Directions for research

Before this intervention is used in practice, further testing is required including with fathers and non-female parents. Stakeholder involvement is also needed to refine the intervention and check for gaps in information provision; and this should include policy makers, third sector organisations, healthcare professionals (including paediatricians, general practitioners, breastfeeding specialists / IBCLCs, perinatal mental health specialists, health visitors and midwives). The involvement of wider stakeholders is also important in the implementation and impact for this intervention moving forwards.

Feedback throughout my PhD from parents and healthcare practitioners (HCPs) strongly suggests a HCP intervention to support accurate diagnosis and prescription is also needed – this was outside the scope of this PhD, however the logic modelling and research within this thesis may contribute to its later development. Some promising work has already begun which might help to underpin the development of a resource for healthcare professionals in the form of a recent Delphi study which was conducted free from commercial influence and aiming to produce new guidance for the diagnosis of milk allergy [368].

Aside from interventions for healthcare professionals and parents, this research highlighted the role of expectation formation in self-management and coping for families with unsettled babies (see Chapters 5 and 6). There are currently a great number of antenatal educational interventions available for use in pregnancy [369, 370], future research could consider which of the existing options might best support expectation formation for healthy newborn behaviours. In addition, and more broadly than this, it could be argued that a wider public health approach is needed to address inaccuracies and myths in the existing societal norms and expectations within WEIRD, individualist cultures about newborn human behaviour, to make these more realistic and more in line with real life experiences of parents [45, 47]. These approaches, if taken together, could provide a holistic method for resolving the distress caused for families with unsettled babies.

9.6 Directions for clinical practice

Practitioners working with families in the transition to parenthood who are worried about unsettled baby behaviours may find the results of this research helpful in understanding the possible

experiences, thoughts and feelings of parents during this vulnerable time. This research suggests that parents may be feeling guilty, helpless and / or dismissed. It might therefore be helpful for practitioners to demonstrate empathy and active listening and to take a strengths-based approach [371, 372] when interacting with families with unsettled babies to build parenting self-efficacy. It may also be helpful to support families in building a plan including non-medical strategies to support their baby when they are unsettled, reducing feelings of helplessness. If successful, active listening, self-efficacy and strengths-based interventions combined with having a plan might help to meet the needs of parents presenting with an unsettled baby.

The resulting intervention from this PhD is intended, with some additional development, to function alongside existing NHS primary care services. There is good evidence that provision of healthcare support within a digital format is effective for parents with healthcare concerns [235], including for parents experiencing healthcare disadvantage [236]. In practice, consideration of how this intervention might be implemented will require stakeholder and parent consultation and additional research moving forwards. It is likely that the service delivery will require an additional escalation pathway with more intensive intervention, as a website alone will not be enough to meet the need for everyone. However, a digital behavioural intervention may be enough to support parents to self-manage where there are mild to moderate concerns and alongside existing provision. In these cases it is likely to be a fast, efficient and cost-effective part of the solution [88].

9.7 Conclusions

This thesis presents work understanding the needs of parents worried about their unsettled baby and developing a co-designed digital behavioural intervention to support families to self-manage unsettled baby behaviours. Some additional refinement and testing of the intervention is required before it is implemented. Implementation of this intervention should not take place alone, but rather within a wider system of support for families of unsettled babies.

Appendix A Identified interventions and resources for unsettled babies

Name/Organisation	Year
Possums	2021
NSPCC Baby Steps	2015
ICON campaign	2016
Solihull Approach	2019
Brazelton Centre	
Association for Infant Mental Health UK	
Institute of Health Visiting Parent Factsheets	2020
Cry-Sis	
National Childbirth Trust	
Centre for the Developing Child	
Unicef Responsive Feeding Resources	
Understanding Childhood (previously Child Psychotherapy Trust)	2014
PsychAlive Dr Allan Schore on Rupture and Repair	2014
PsychAlive Dr Allan Schore on emotional regulation	2014
Circle of Security	
Sleep Baby and You	
Lullaby Trust	
Channel Mum	
Period of Purple Crying	
Zero to three	
Family Lives	
Incredible Years	
Promotional Guide	2014
Minding the Baby	2013

Name/Organisation	Year
Triple P	
Tuning Into Kids	
Five to thrive	
Breastfeeding and Normal Baby Behaviours in an Abnormal Society	
Professor Amy Brown's Articles	
Baby Buddy App by Best Beginnings	
Tiny Happy People	
Blackpool Better Start - Big Little Moments	
Alberta Brain Story	
NHS Choices	
Parent Infant Foundation	
The Science of Human Connection	
The Therapeutic Parenting Podcast	
Social Workers Toolbox - Parenting Guides	
Mellow Parenting	
Watch, Wait and Wonder	
Thrive Parent Toolkit	
Dyadic Developmental Parenting with PACE	
Child Mind Institute	
Raised Good: The attached child	
Hand in Hand Parenting	
Understanding your baby (Starting Well NHS Leeds)	
UNICEF Building a Happy Baby	
WAVE trust	
SO-S Parenting	
NSPCC Look, Say, Sing, Play	
BrightPIP	
Beacon House	

Name/Organisation	**Year**
Evolutionary Parenting Podcast	
Fed up &/ FAILSAFE (Sue Dengate)	
Shel Banks IBCLC Unsettled Babies	
Joy Anderson Dietetics and Lactation - 'Food Sensitive Babies'	
La Leche League GB	
The Breastfeeding Network	
Butterfly Baby Clinic (University of Edinburgh)	2014-current
Milk Matters (Maureen Minchin)	

Appendix B PPIE plan V06

1. "Unsettled Infants" Research: Embedded in Parent Experiences

1. V.06. Updated 24.06.2022

Throughout the process, opportunities for feedback, evaluation and learning will be built in to allow for reflection on how well I have succeeded in placing parent experiences at the heart of the intervention.

2. Equality, Diversity and Inclusion

Despite the breadth of literature across fields as diverse as psychology, interpersonal neurobiology, primary care, medicine, attachment and parenting, nursing and public health; much of the research has been with white, middle class, affluent women; with ethnic minorities, other genders and low income families conspicuously missing from research, even when authors have made specific effort to include these groups [1].

1. Family Income

A recent review study attempted to pinpoint parental factors related to differences in incidence rates of colic [2]. This review found that high socio-economic status is related to higher incidence of colic, however this finding was based on just one research paper of two hundred and nineteen infants and is now outdated [3]. Data from Chile has suggested a similar result, however this may not be transferrable to our UK population and had methodological flaws in the blinding of the allergy diagnosis process [4]. Given the recent surge in UK prescriptions and overmedicalisation of CMA and reflux in this population, it is plausible that this is no longer a problem experienced only by more affluent families; but rather has spread to vulnerable groups as the medicalisation narrative has become prevalent [5].

In addition, there are good reasons for including families of low socio-economic status in unsettled infants research. There is a compelling argument that infants born to families struggling with many complex social issues are by definition more vulnerable, even more in need of responsive parenting interventions to buffer the neurological effects of toxic stress [6]. Families on a low income may also be disproportionately affected by the impacts of misdiagnosis, such as premature cessation of breastfeeding and the need to purchase formula milk [7]; and this has the potential to widen the already worrying health inequality gap [8].

2. Culture

Few studies have looked at differences in prevalence of unsettled infant symptoms across cultures. Research in a Malaysian population suggested dramatically lower rates of functional gastro intestinal disorder than have been seen in Caucasian populations [9]. One study compared three cultures across the UK and South Africa and found differences in child emotion regulation and aggression, relating this to differences in parenting [10]. Another found that parents in the US, Sweden and China had different opinions on the temperament characteristics that were interpreted as positive and negative [11]. Some limited additional data from PhD thesis work is available suggesting Hispanic mothers may differ from Caucasian mothers in their interpretation of the causal factors for their infant's colic, with

Hispanic mothers being more likely to believe that colic was related to the way they cared for their infant [12].
It is widely accepted that different cultures have very different beliefs, perspectives and practices in relation to infant feeding, sleep and behaviour. Researchers have explored temperamental differences across cultures and postulated that these could be due to differences in customs and parent belief systems which create the infant's daily environment [13]. It is also possible that the cultural milieu surrounding a parent may impact not only the infant's behaviour but also the parent's framing or interpretation of that behaviour [13]. The parent's perception of their infant's symptoms is thought to be of foremost importance in providing meaningful and effective support to families [14]; highlighting the importance of capturing and including cultural differences in unsettled infants research.

3. Fathers & Co-parents

Despite mounting evidence of the importance of fathers and other co-parents in the perinatal period [15-17]; they remain largely underserved in intervention studies about unsettled infants. Research which has included them has focussed largely on the prevention of abusive head trauma [18-20].
Research into infant temperament suggests that this may be perceived differently by fathers than mothers [21], and therefore it will be important to consider this perspective.

3. Public Engagement

Prior to and alongside formal PPI, some informal public engagement work will take place talking to members of the public; especially parents; about my research plans. Since the topic can be considered emotive or sensitive, this engagement work serves an important purpose in learning how best to navigate these issues.

At the early stages engagement will give me a sense of how the focus and goals of my research are received, opinions of the planned term 'unsettled infant' and thoughts on the language to use and how best to approach sensitive topics such as interrupted feeding journeys and parenting style. It will also give a sense for the right tone and approach to take to the work in order to avoid dismissing parents, ignoring their role as the expert in their child or minimising the stress and misery these symptoms can cause.

In later stages it may help me to imagine how the website fits with the wider community and societal context.

In the course of this engagement work it is possible that I may identify one or two individuals with particular expertise who might want to contribute to the PPI panel as a public contributor.

1. Listening Café

As part of this early public engagement work, I aim to include parents who would not typically get involved with research. As such I plan to work with the University of Southampton project 'Finding Out Together'. This is an innovative new scheme partnering with a Southampton children's centre to run food, craft and research sessions focusing around face to face interactive engagement with parents to discuss research which is important to them.

The listening café is scheduled to run weekly in September 2022 for 4 initial 2hr sessions, with a 5th follow up session several weeks later. Up to 10 parents will take part in all 5 sessions. These sessions will aim to inform my PhD and also a programme grant application in the same research area. The goal will be to discuss with parents the problem we believe we have identified, the possible goals or planned outcomes for our intervention and to present them with a draft of the intervention content. We would hope to learn from them by getting their opinions and feedback on the ideas we are suggesting and gain a richer and deeper understanding of the issue, perhaps from a new perspective.

In particular I am interested to learn the perspectives of parents with unsettled infants from different cultural groups and from low income families. These groups have been largely missing from published research to date and as such their voices are not likely to be captured elsewhere in the research project; however there is good reason to believe these perspectives may be relevant. Specifically, families from different cultures are likely to perceive infant sleep, feeding and crying issues differently and therefore may have a markedly different perspective to add to the research. Furthermore, families living on low income may be at higher risk of poor outcomes as a result of unwanted cessation of breastfeeding, dietary restrictions, purchasing of formula and other products unnecessarily; with the potential to widen the health inequality gap.

2. Pint of Science &/ The Bright Club

An additional group who have not yet been represented adequately by published research or by our own qualitative work are fathers. There is a growing body of evidence that fathers are a vital part of the family dynamics, providing crucial support for both the birth parent and the child. It is likely that they offer an additional, unique perspective on unsettled infants and currently their voices are missing from the picture.

Part of my work will be to attempt to target fathers and co-parents, perhaps through traditionally male dominated outreach engagement programmes such as a ‘Pint of Science’ or ‘The Bright Club’. Additionally, I could reach out to father and infant stay-and-play groups or social media networks.

4. Stakeholder Engagement

This research spans diverse topics and is very multi-disciplinary. As such it is important to recognise the limits of my own clinical expertise. I hope to draw on specialist input to review and comment on my intervention content to ensure it is accurate and comprehensive.

This will also include building links with organisations and groups who may be linked on the website as additional resources for parents to access, in order to build a picture of how this intervention fits within the wider context of support for new parents.

Further, towards the end of the research period, this could involve engagement with policy makers and service leaders to get feedback on how the intervention could fit within the broader context of the NHS service.

One possibility for this stakeholder engagement could be to model the activity on a previous, highly successful project run by a University of Southampton researcher in a related area – 'the Breastfeeding Dilemma' (https://www.southampton.ac.uk/per/cases/breastfeeding-dilemma.page)

5. PPI Panel

A PPIE panel will be established comprising a small group with direct personal experience of being a primary caregiver for an unsettled infant. The panel should also include a mixture of feeding journeys, perhaps including a parent who feels unhappy with their breast/chestfeeding experience and a parent who is happy to be using formula.

Ideally this panel will include someone with an infant currently below 6months and experiencing unsettled symptoms as well as parents of older children, reflecting on their past lived experiences. Recruiting to this PPI panel would therefore need to be on a rolling basis, to attempt to include parents of very young children who are growing throughout the course of the PhD.

Additionally the panel will aim to include both an experienced public contributor and someone who is completely new to research. Public contributors from under-served groups would be helpful, particularly parents with educational disadvantage or low income families. This is particularly important with this research topic as they are largely absent from the literature on unsettled infants so far, meaning we have a very poor understanding of what the prevalence and experience of unsettled infants may be in this group. It is plausible that there may be important differences in how these groups perceive and experience unsettled infants and how they might respond to and engage with a digital healthcare intervention. Having this perspective in the steering and research design might be important to help us reach participants from these under-served groups and design study materials in an accessible and relevant way.

In summary, the characteristics of the ideal PPI panel will be as follows:

- Parents/Carers of unsettled infants (currently less than 6months)
- Parents/Carers who have had an unsettled infant in the last 5years
- Parents who are breast/chestfeeding and happy with their feeding journey
- Parents who are formula feeding and happy with their feeding journey
- Parents feeding by any method who are unhappy with their feeding journey or who have experienced guilt or grief about feeding
- Experienced and new public contributors
- Parents living with low income
- Parents with educational disadvantage

1. Table 1. Plans and Costings for PPI input

6. When	7. Why/Goals	8. Costs
June 2022	• Feedback on the key research concepts • Feedback on materials for Study 2 (think aloud interviews)	60mins for discussion 60mins to read materials Total 2hrs Up to 3 public contributors = £150
April 2023	• Recruitment for Study 3 • Feedback on materials for Study 3 (feasibility study)	60mins to read materials, 60mins to give feedback. Total 2hrs Up to 3 contributors £150
May 2024	• Overall results feedback • Thanks to contributors and plans for development moving forwards • Learning for me to improve my PPI work in the future.	1hr discussion session Up to 6 contributors (to account for possibly different individuals at the previous 2 occasions) = £150
At all stages	• Cost per meeting of consumables (internet, printing etc)	Remote working costs for all contributors (£5 per contributor per meeting) = £60
		TOTAL: £510

9. Co-Production Method of Research

The intervention will be designed using the person based approach [22]. This is approach is designed to be similar in essence and style to co-production and is complementary to other forms of engagement [23]. My goal will be to recognise that the research participants are actively contributing to and steering the content, design, layout and functionality of the website itself. I understand the importance of sharing the decision making power with parents who have experience with unsettled infants, to allow for a more acceptable and effective intervention.

As such, a diverse sample of research participants will be recruited and qualitative think-aloud interviews will take place in accordance with the study protocol and subject to ethical approval. These interviews will give real-time information on how parents perceive and navigate the content and their initial reactions to it; which will help me understand where

changes are needed. Iterative progress will be made in intervention design and then additional think-aloud interviews will continue to refine the website further.

1. Table 2. Summary of anticipated outcomes and corresponding type of engagement planned

10. Type of Engagement	11. Aim/Purpose/Goal
Parent groups, children's centre, public, community engagement	How is the language we are using perceived?
Parent groups, children's centre, public, community engagement	What is the most acceptable term? "unsettled infant" / "common infant symptoms" / "unhappy baby"?
Parent groups, children's centre, public, community engagement	Gain a breadth of understanding of the Phenomenon of Interest (PoI)
Parent groups, children's centre, public, community engagement	Get a sense of how to pitch the emotive or potentially contentious issues.
Parent groups, children's centre, public, community engagement	Understand where the intervention fits within the wider community from a patient perspective
Stakeholder engagement, IBCLCs, HVs, GPs	Expert review of content
Stakeholder engagement, IBCLCs, HVs, GPs	Spot inaccuracies
Stakeholder engagement, IBCLCs, HVs, GPs	Identify any missing information
Stakeholder engagement, IBCLCs, HVs, GPs, service leaders, policy makers.	Consider impact and where the intervention could practically fit into and complement existing services.
PPI forum	Diverse recruitment strategies
PPI forum	Study materials review
PPI forum	First review of the logic model
Research Participants – in co-production	Website content feedback – shaping and tweaking
Research Participants – in co-production	Website navigation and layout feedback
Research Participants – in co-production	Website design feedback

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Appendix C Photo prompts for Listening Cafe

Appendix D Discussion starter quotes for Listening Café

Appendix E Slides from Listening Café feedback session

"Thinking that there is something wrong with your baby; seeing them unsettled, unhappy or in pain is one of the worst things you can experience as a parent.

If that's you, we are here to help."

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University of Southampton

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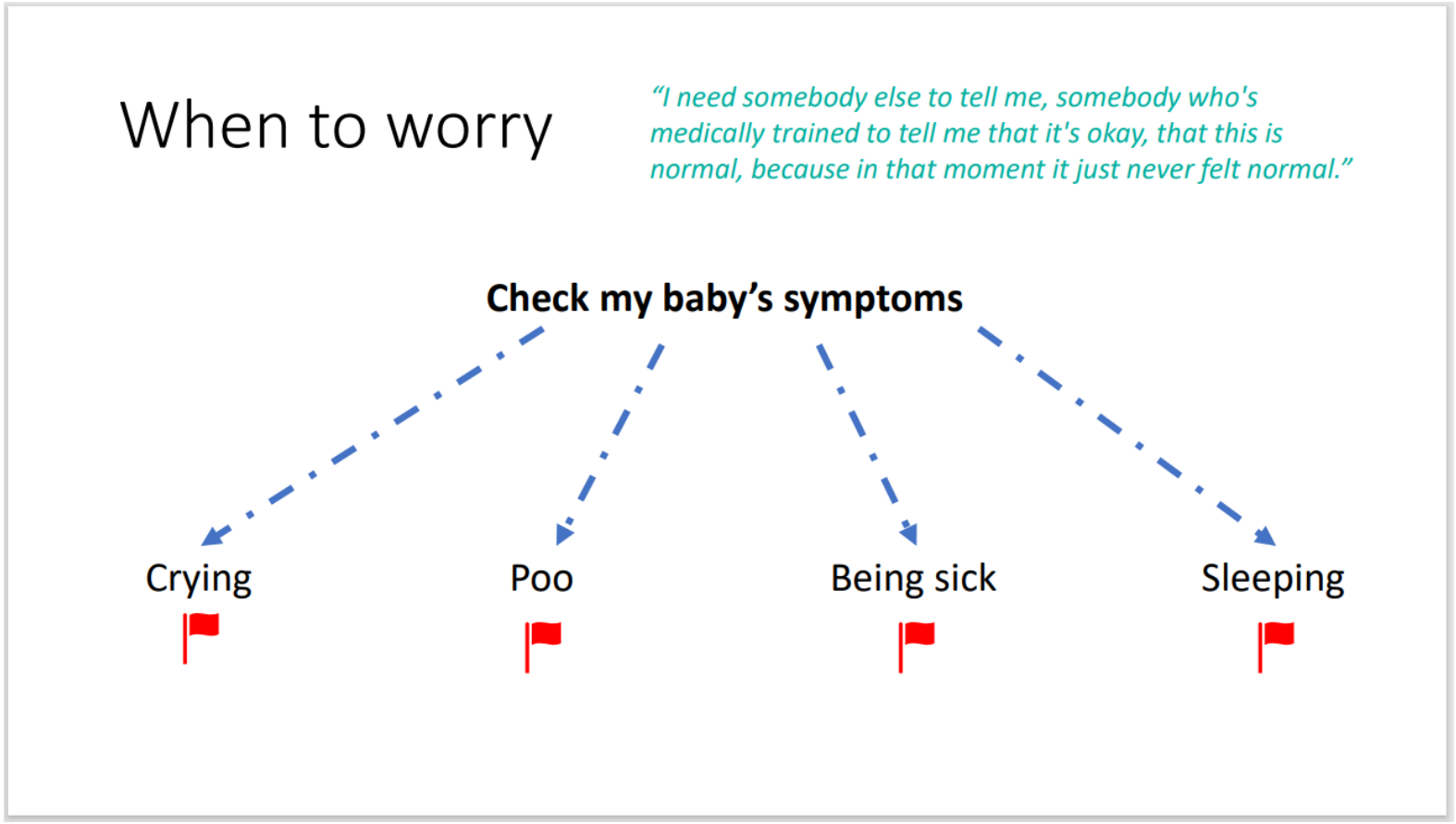
The information is evidence-based without commercial funding or bias.

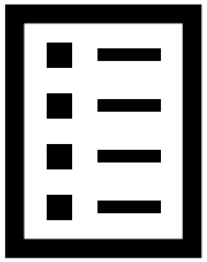

When to worry
"I need somebody else to tell me, somebody who's medically trained to tell me that it's okay, that this is normal, because in that moment it just never felt normal."
Check my baby's symptoms
Crying
Poo
Being sick
Sleeping

I am a good parent

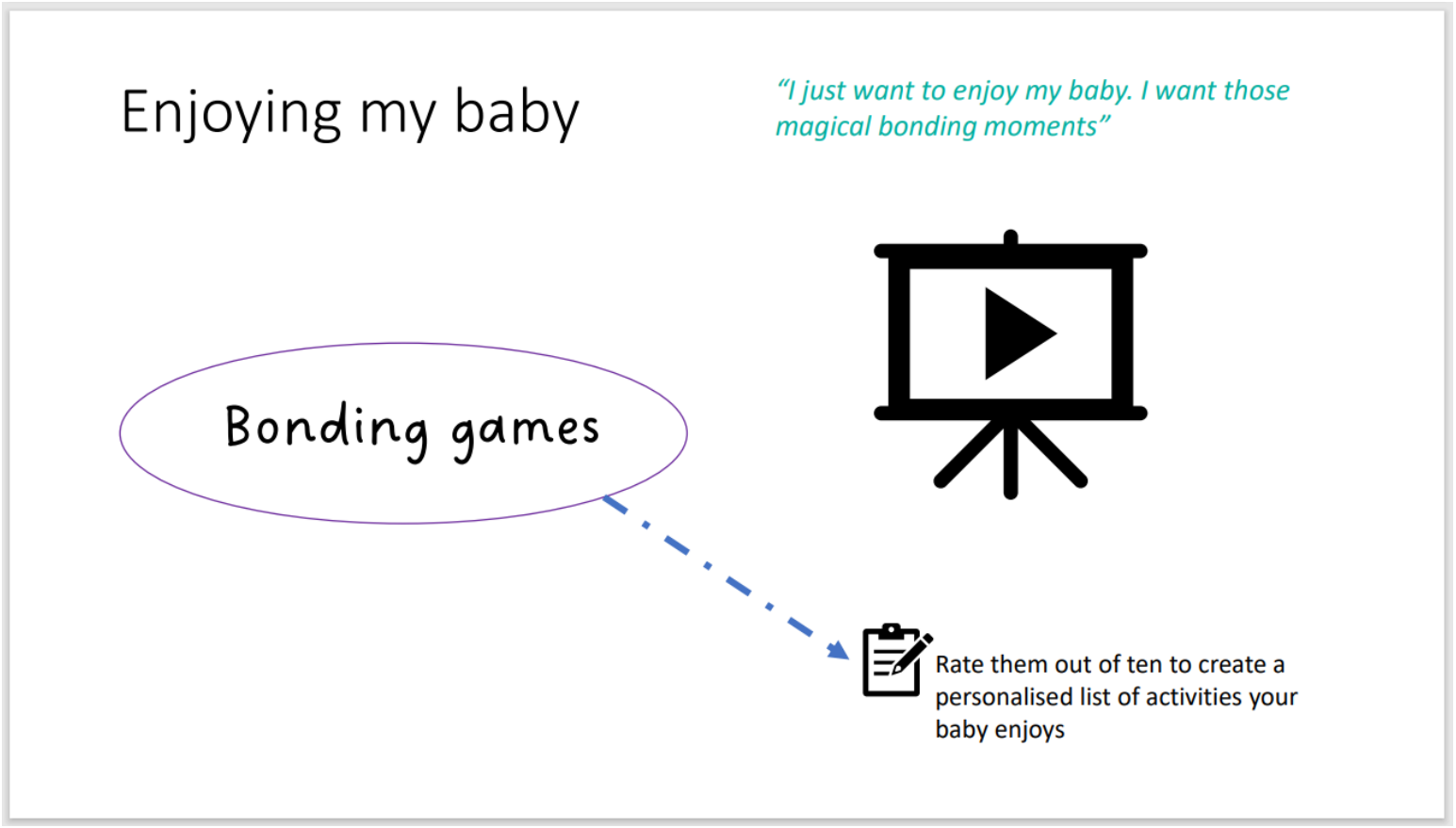
"You know, it'll pass, you just have to persevere, look after yourself emotionally, um, question those thoughts that pop up to, in your head in the middle of the night, 3:00 am in the morning, that tell you you're doing a horrible job"

What are you doing right?

Imagine yourself as a friend or loved one might see you. What are you are doing right? What are you good at as a parent? How do you look after your baby?



Click here to get a monthly email reminder of your list.


Enjoying my baby
"I just want to enjoy my baby. I want those magical bonding moments"
Bonding games
Rate them out of ten to create a personalised list of activities your baby enjoys

Tips from other parents

"I think because I was trying something that I had heard, it made me feel more in control, because I was like, right, I'll try this, rather than feeling helpless"

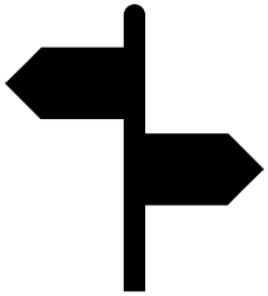
"I found it was like a relief to have something to guide me, to have something to just try made me feel better about things. And I felt like it did work to an extent. Obviously, it kept happening, but it was better than if I didn't do those things."

Build a personalised toolbox

Our plan

More help

Feeding



Mental health

Appendix F Leaflet for parents after listening café ended

Sure Start
Family Hub Southampton

University of Southampton

The Listening Café

Thankyou for sharing your experiences of unsettled babies:

- Feeling judged, guilty and helpless
- Feeling like a 'bad mum'
- Feeling worried and uncertain about medical labels like allergy and reflux
- Needing to be listened to and cared about
- Needing to talk to other parents who have had similar experiences
- Needing to have clear health information

So far…

We have written up your thoughts and combined them with other parents opinions in an article. This will be published in a journal for health professionals

We have produced a draft website for parents including a symptom checker, supportive videos and some 'parent tips'.

We have got funding and have started interviews with health visitors too.

Next steps:

We are planning more listening cafes with parents from different cultures

We are applying for funding of £2 million to improve wellbeing for parents of unsettled babies around the country. This will include both training for professionals and parent support.

Thank-you

Together we are making a difference!

Appendix G Full list of search terms

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	Search ID	Search Term	Search Term	Search Term	Search Term:	Search Term
	1	Parent*	Parent*	Parent*	Parent*	Parent*
	2	Caregiver	Caregiver	Caregiver	Caregiver	Caregiver
	3	Mother*	Mother*	Mother*	Mother*	Mother*
	4	Father*	Father*	Father*	Father*	Father*
	5	Maternal	Maternal	Maternal	Maternal	Maternal
	6	Paternal	Paternal	Paternal	Paternal	Paternal
	7	MH "Parents"	exp Parents/	Parent/	[MH Parenting]	DE "Parents"
	8	MH "Parenting"	Parenting/	father/	[MH Parents]	DE "Fathers" +
	9	1 OR 2 or 3 or 4 or 5 or 6 or 7 or 8	Child rearing/	mother/	[MH ^"Child Rearing"]	DE "Mothers"
	10	Infant*	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	DE "Adolescent mothers"
	11	Baby	Infant*	Infant*	Infant*	DE "Single mothers"
	12	Babies	Baby	Baby	Baby	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
	13	Newborn	Babies	Babies	Babies	Infant*
	14	MH "Infant"	Newborn	Newborn	Newborn	Baby
	15	MH "Infant, Newborn"	exp Infant/	infant/	[MH ^Infant]	Babies
	16	10 or 11 or 12 or 13 or 14 or 15	11 or 12 or 13 or 14 or 15	baby/	[MH ^"Infant, Newborn"]	Newborn
	17	9 AND 16	10 AND 16	newborn/	11 or 12 or 13 or 14 or 15 or 16	DE "Neonatal period"
	18	cry*	cry*	11 or 12 or 13 or 14 or 15 or 16 or 17	10 AND 17	DE "Infant development"

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	19	colic*	colic*	10 AND 18	cry*	DE "Postnatal period"
	20	(unsettl* N3 (infant OR Infants OR infancy OR baby OR babies OR newborn))	(unsettl* adj3 (infant* OR infancy OR baby OR babies OR newborn))	cry*	colic*	13 or 14 or 15 or 16 or 17 or 18 or 19
	21	(fuss* N3 (infant OR Infants OR infancy OR baby OR babies or newborn))	(fuss* adj3 (infant* OR infancy OR baby OR babies or newborn))	colic*	(unsettl* NEAR/3 (infant OR Infants OR infancy OR baby OR babies))	12 and 20
	22	(dysregulat* N3 (infant OR infants OR infancy OR baby OR babies or newborn))	(dysregulat* adj3 (infant* OR infancy OR baby OR babies or newborn))	(unsettl* adj3 (infant* OR infancy OR baby OR babies or newborn))	(fuss* NEAR/3 (infant OR Infants OR infancy OR baby OR babies or newborn))	cry*
	23	"regulatory problems"	"regulatory problems"	(fuss* adj3 (infant* OR infancy OR baby OR babies or newborn))	(dysregulat* NEAR/3 (infant OR infants OR infancy OR baby OR babies or newborn))	colic*
	24	distress* N3 (infancy OR infant or Infants or baby or babies or newborn)	upset* adj3 (infancy OR infant* or baby or babies or newborn)	(dysregulat* adj3 (infant* OR infancy OR baby OR babies or newborn))	"regulatory problems"	unsettl* N3 (infant* OR infancy OR baby OR babies OR newborn)
	25	upset* N3 (infancy OR infant or Infants or baby or babies or newborn)	distress* adj3 (infancy OR infant* or baby or babies or newborn)	"regulatory problems"	upset* NEAR/3 (infancy OR infant or Infants or baby or babies or newborn)	fuss* N3 (infant* OR infancy OR baby OR babies OR newborn)
	26	discomfort	discomfort	upset* adj3 (infancy OR infant* or baby or babies or newborn)	distress* NEAR/3 (infancy OR infant or Infants or baby or babies or newborn)	dysregulat* N3 (infant* OR infancy OR baby OR babies or newborn)

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	27	irritab*	irritab*	distress* adj3 (infancy OR infant* or baby or babies or newborn)	discomfort	"regulatory problems"
	28	temperament*	temperament*	discomfort	irritab*	upset* N3 (infant* OR infancy OR baby OR babies OR newborn)
	29	orchid* N3 dandelion*	orchid* adj3 dandelion*	irritab*	temperament*	distress* N3 (infant* OR infancy OR baby OR babies OR newborn)
	30	orchid* N3 dais*	orchid* adj3 dais*	temperament*	orchid* NEAR/3 dandelion*	discomfort
	31	"infant mental health"	(difficult adj3 (infant* OR infancy OR baby OR babies or newborn))	orchid* adj3 dandelion*	orchid* NEAR/3 dais*	irritab*
	32	soothability	(intolerance adj3 (food OR milk))	orchid* adj3 dais*	(difficult NEAR/3 (infant OR infants or infancy OR baby OR babies or newborn))	temperament*
	33	("negative affect*" N3 (infant* OR infancy OR baby OR babies or newborn))	hypersensitiv* adj3 (infant* or infancy or baby or babies or newborn or milk or food)	(difficult adj3 (infant* OR infancy OR baby OR babies or newborn))	(intolerance NEAR/3 (food OR milk))	orchid* N3 dandelion*
	34	("negative emotionality" N3 (infant* OR infancy OR baby OR babies or newborn))	(sensiti* adj3 (food OR milk))	(intolerance adj3 (food OR milk))	hypersensitiv* NEAR/3 (infant* or infancy or baby or babies or newborn or milk or food)	orchid* N3 dais*
	35	("regulatory disorder" N3 (infant* OR infancy OR baby OR babies or newborn))	"lacto* intolerance"	hypersensitiv* adj3 (infant* or infancy or baby or babies or newborn or milk or food)	(sensiti* NEAR/3 (food OR milk))	difficult N3 (infant* OR infancy OR baby OR babies OR newborn)

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	36	("emotional reactivity" N3 (infant* OR infancy OR baby OR babies or newborn))	milk adj3 allerg*	(sensiti* adj3 (food OR milk))	lacto* NEXT intolerance	intolerance N3 (food OR milk)
	37	difficult N3 (infant* OR infancy OR baby OR babies or newborn)	"food allergy"	"lacto* intolerance"	milk NEAR/3 allerg*	hypersensitiv* N3 (infant* or infancy or baby or babies or newborn or milk or food)
	38	intolerance N3 (food OR milk)	"functional gastro* disorder"	milk adj3 allerg*	"food allergy"	sensiti* N3 (food OR milk)
	39	hypersensitiv* N3 (infant* or infancy or baby or babies or newborn or milk or food)	"digestive problems"	"food allergy"	functional NEXT gastro* NEXT disorder	"lacto* intolerance"
	40	sensiti* N3 (food OR milk)	reflux	"functional gastro* disorder"	"digestive problems"	milk N3 allerg*
	41	"lacto* intolerance"	vomit*	"digestive problems"	reflux	"food allergy"
	42	milk N3 allerg*	regurgitation	reflux	vomit*	"functional gastro* disorder"
	43	"food allergy"	constipation	vomit*	regurgitation	"digestive problems"
	44	"functional gastro* disorder"	"hard stool"	regurgitation	constipation	reflux
	45	"digestive problems"	diarrhea	constipation	"hard stool"	vomit*
	46	"intestinal dis*"	diarrhoea	"hard stool"	diarrhea	regurgitation
	47	reflux	"loose stool"	diarrhea	diarrhoea	constipation
	48	vomit*	mucous adj3 stool	diarrhoea	"loose stool"	"hard stool"
	49	regurgitation	mucus adj3 stool	"loose stool"	mucous NEAR/3 stool	diarrhea

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	50	constipation	rash*	mucous adj3 stool	mucus NEAR/3 stool	diarrhoea
	51	"hard stool"	eczema	mucus adj3 stool	rash*	"loose stool"
	52	diarrhea	"dry skin"	rash*	eczema	mucous N3 stool
	53	diarrhoea	"infant mental health"	eczema	"dry skin"	mucus N3 stool
	54	"loose stool"	soothability	"dry skin"	"infant mental health"	rash*
	55	mucous N3 stool	("negative affect*" adj3 (infant* OR infancy OR baby OR babies or newborn))	"infant mental health"	soothability	eczema
	56	mucus N3 stool	("negative emotionality" adj3 (infant* OR infancy OR baby OR babies or newborn))	soothability	("negative affect" OR "negative affective" NEAR/3 (infant* OR infancy OR baby OR babies or newborn))	"dry skin"
	57	rash*	("regulatory disorder" adj3 (infant* OR infancy OR baby OR babies or newborn))	("negative affect*" adj3 (infant* OR infancy OR baby OR babies or newborn))	("negative emotionality" NEAR/3 (infant* OR infancy OR baby OR babies or newborn))	"infant mental health"
	58	eczema	("emotional reactivity" adj3 (infant* OR infancy OR baby OR babies or newborn))	("negative emotionality" adj3 (infant* OR infancy OR baby OR babies or newborn))	("regulatory disorder" NEAR/3 (infant* OR infancy OR baby OR babies or newborn))	soothability
	59	"dry skin"	feed* adj3 (problem* or refus* or difficult*)	("regulatory disorder" adj3 (infant* OR infancy OR baby OR babies or newborn))	("emotional reactivity" NEAR/3 (infant* OR infancy OR baby OR babies or newborn))	"negative affect*" N3 (infant* OR infancy OR baby OR babies or newborn)
	60	feed* N3 (problem* or refus* or difficult*)	"breast*refusal"	("emotional reactivity" adj3 (infant* OR infancy OR baby OR babies or newborn))	feed* NEAR/3 (problem* or refus* or difficult*)	"negative emotionality" N3 (infant* OR infancy OR baby OR babies or newborn)

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	61	"breast* refusal"	Infant behavior/	feed* adj3 (problem* or refus* or difficult*)	"breast?refusal"	"regulatory disorder" N3 (infant* OR infancy OR baby OR babies or newborn)
	62	MH "Infant Behavior"	Crying/	"breast*refusal"	[MH Infant Behavior]	"emotional reactivity" N3 (infant* OR infancy OR baby OR babies or newborn)
	63	MH "Temperament"	Colic/	crying/	[MH Infant Welfare]	feed* N3 (problem* or refus* or difficult*)
	64	MH "Colic+"	Temperament/	infantile colic/	[MH Infant Health]	"breast*refusal"
	65	MH "Crying"	Milk Hypersensitivity/	colic/	[MH Colic]	DE "Crying"
	66	MH "Food Hypersensitivity"	Food Hypersensitivity/	temperament/	[MH Crying]	DE "Infant Vocalization"
	67	MH "Milk Hypersensitivity"	Exp Hypersensitivity, Delayed/	allergy/	[MH Temperament]	DE "Infant Temperament"
	68	MH "Hypersensitivity, Delayed"	Gastrointestinal Diseases/	hypersensitivity/	[MH ^"Psychological Distress"]	DE "Distress"
	69	MH "Signs and Symptoms, Digestive+"	Gastroesophageal Reflux/	milk allergy/	[MH ^Hypersensitivity]	DE "Agitation"
	70	MH "Gastroesophageal Reflux"	Vomiting/	food allergy/	[MH "Hypersensitivity, Delayed"]	DE "Restlessness"
	71	MH "Eczema"	Food intolerance/	atopic dermatitis/	[MH ^"Food Hypersensitivity"]	DE "Negative emotions"
	72	MH "Dermatitis, Atopic"	Abdominal Pain/	digestive system function disorder/	[MH Milk Hypersensitivity]	DE "Food Allergies"
	73	MH "Diet Adverse Effects"	Constipation/	gastroesophageal reflux/	[MH ^"Signs and Symptoms, Digestive"]	DE "Vomiting"

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	74	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 71 or 71 or 72 or 73	Exp Diarrhea/	Vomiting/	[MH ^"Abdominal Pain"]	DE "Gastrointestinal disorders"
	75	qualitative	Flatulence/	Newborn vomiting/	[MH ^Constipation]	DE "constipation"
	76	interview*	Gagging/	constipation/	[MH Diarrhea]	DE "Diarrhea"
	77	"focus group*"	Heartburn/	diarrhea/	[MH Flatulence]	DE "Dermatitis"
	78	observation*	Exp Exanthema/	Infantile diarrhea/	[MH ^Vomiting]	DE "Eczema"

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	79	ethnomethod*	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78	rash/	[MH ^"Gastroesophageal Reflux"]	DE "Allergic skin disorders"
	80	"ethnological research"	"experience*".m_titl.	allergic rash/	[MH Exanthema]	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79
	81	ethnograph*	belie*.m_titl.	feeding difficulty/	[MH ^Eczema]	TI experience*

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	82	"grounded theor*"	attitude*.m_titl.	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81	[MH Atopic Dermatitis]	TI belie*
	83	Phenomenol*	qualitative	experience* (title only)	[MH ^"Gastrointestinal Diseases"]	TI attitude*
	84	ethnonurs*	interview*	belie* (title only)	19 OR 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83	qualitative
	85	"content analysis"	"focus group*"	attitude* (title only)	(experience*):ti	interview*

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	86	heuristic*	"observational method"	qualitative	(belie*):ti	"focus group*"
	87	hermeneutic*	ethnomethod*	interview*	(attitude*):ti	"observational method"
	88	"observational method"	"ethnological research"	"focus group*"	qualitative	ethnomethod*
	89	"discourse analysis"	"case study"	"observational method"	interview*	"ethnological research"
	90	"theoretical sample"	ethnograph*	ethnomethod*	focus NEXT group*	"case study"
	91	"field stud*"	"grounded theor*"	"ethnological research"	"observational method"	ethnograph*
	92	"case study"	Phenomenol*	"case study"	ethnomethod*	"grounded theor*"
	93	"constant comparative method"	ethnonurs*	ethnograph*	"ethnological research"	Phenomenol*
	94	"purposive sampl*"	"content analysis"	"grounded theor*"	"case study"	ethnonurs*
	95	"thematic analysis"	hermeneutic*	Phenomenol*	ethnograph*	"content analysis"
	96	mixed N3 method*	"discourse analysis"	ethnonurs*	grounded NEXT theor*	hermeneutic*
	97	multiple N3 method*	"theoretical sampl*"	"content analysis"	Phenomenol*	"discourse analysis"
	98	multi method*	"field stud*"	hermeneutic*	ethnonurs*	"theoretical sampl*"
	99	multimethod*	"constant comparative method"	"discourse analysis"	"content analysis"	"field stud*"
	100	MH "Qualitative Studies+"	"purposive sampl*"	"theoretical sampl*"	hermeneutic*	"constant comparative method"
	101	MH "Interviews+"	"thematic analysis"	"field stud*"	"discourse analysis"	"purposive sampl*"
	102	MH "Focus Group"	mixed adj3 method*	"constant comparative method"	theoretical NEXT sampl*	"thematic analysis"
	103	TI Experience*	multiple adj3 method*	"purposive sampl*"	field NEXT stud*	mixed N3 method*
	104	TI belie*	"multi method*"	"thematic analysis"	"constant comparative method"	multiple N3 method*

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	105	TI perce*	multimethod*	mixed adj3 method*	purposive NEXT sampl*	"multi method*"
	106	narrative*	"perce* adj3 (infant* OR babies OR baby OR newborn)"	multiple adj3 method*	"thematic analysis"	multimethod*
	107	attach* N3 relationship	attach* adj3 relationship	"multi method*"	mixed NEAR/3 method*	perce* N3 (infant* OR infancy OR babies OR baby OR newborn)
	108	Attachment	attribution*	multimethod*	multiple NEAR/3 method*	attach* N3 relationship
	109	bond* N3 (infant* OR infancy OR babies OR baby OR newborn) AND (parent OR mother OR father OR caregiver)	infant adj3 attach*	"perce* adj3 (infant* OR infancy OR babies OR baby OR newborn)"	"multi method*"	attribution*
	110	attribution*	"parent infant relationship"	attach* adj3 relationship	multimethod*	infant N3 attach*
	111	infant N3 attach*	"bond* adj3 (infant* OR infancy OR babies OR baby OR newborn) AND (parent OR mother OR father OR caregiver)"	attribution*	perce* NEAR/3 (infant* OR infancy OR babies OR baby OR newborn)	"parent infant relationship"
	112	"parent infant relationship"	Exp Qualitative research/	"bond* adj3 (infant* OR infancy OR babies OR baby OR newborn) AND (parent OR mother OR father OR caregiver)"	attach* NEAR/3 relationship	bond* N3 (infant* OR infancy OR babies OR baby OR newborn) AND (parent OR mother OR father OR caregiver)
	113	MH "Parent-Infant Relations+"	Grounded theory/	infant adj3 attach*	attribution*	DE "Parent Child Relations" +

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	114	75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113	Interviews as topic/	"parent infant relationship"	bond* NEAR/3 (infant* OR infancy OR babies OR baby OR newborn)	DE "Parental attitudes" +
	115	17 AND 76 AND 116	Focus Groups/	exp child parent relation/	infant NEAR/3 attach*	DE "Attachment behavior"
	116		Narration/	Qualitative analysis/	"parent infant relationship"	DE "Attachment theory"
	117		Exp Parent-Child Relations/	exp qualitative research/	[MH "Parent-Child Relations"]	DE "Qualitative Methods" +
	118		Attitude to health/	exp interview/	[MH "Object Attachment"]	DE "Interviews"
	119		Health Knowledge, attitudes, practice/	exp observational method/	[MH "Qualitative Research"]	DE "Mixed Methods Research"

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	120		80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119	behavioural observation/	[MH "Grounded Theory"]	DE "Observation methods"+
	121		17 AND 79 AND 120	exploratory research/	[MH "Interviews as topic"]	DE "Phenomenology"
	122			grounded theory/	[MH "Focus Groups"]	DE "Constructivism"
	123			multimethod study/	[MH "Narration"]	DE "Hermeneutics"
	124			naturalistic inquiry/	[MH "Community Based Participatory Research"]	DE "Content analysis"+
	125			exp participatory research/	[MH "Observational Studies as Topic"]	DE "Health attitudes"
	126			exp action research/	[MH "Transactional Analysis"]	DE "attribution"
	127			field study/	[MH ^"Attitude"]	DE "Case report"
	128			phenomenology/	[MH ^"Attitude to Health"]	81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	129			ethnonursing research/	[MH "Health Knowledge, attitudes, practice"]	21 AND 80 AND 128
	130			content analysis/	[MH "Case Reports"]	
	131			thematic analysis/	85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130	
	132			emotional attachment/	18 and 84 and 131	
	133			personal experience/		
	134			attitude to breast feeding/		
	135			attutude to health/		
	136			attuitude to illness/		
	137			exp family attitude/		
	138			exp parental behaviour/		
	139			narrative/		
	140			case study/		
	141			emotion/		

Database:		CINAHL (Ebsco)	MEDLINE (Ovid/Ebsco)	EMBASE (Ovid)	Cochrane Library	PsychInfo (Ebsco)
	142			83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140 or 141		
	143			19 AND 82 AND 141		

Appendix H CASP Checklists for each included study

H.1 CASP Harskamp van Ginkle et al 2023

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Harskamp van Ginkel, M., W. Klazema, M. Hoogsteder, M.

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments:	

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments:	

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments:

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments:

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes ✔
Can't Tell
No

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments:

9. Is there a clear statement of findings?

Yes ✔
Can't Tell
No

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments:

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Valuable

H.2 CASP Cox & Roos 2008

Paper for appraisal and reference: Cox & Roos 2008

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?	Yes	✔	HINT: Consider • If the researcher has explained how the participants were selected • If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study • If there are any discussions around recruitment (e.g. why some people chose not to take part)
	Can't Tell		
	No		

Comments: Great study recruitment idea. Well justified for research question.

5. Was the data collected in a way that addressed the research issue?	Yes	✔	HINT: Consider • If the setting for the data collection was justified • If it is clear how data were collected (e.g. focus group, semi-structured interview etc.) • If the researcher has justified the methods chosen • If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide) • If methods were modified during the study. If so, has the researcher explained how and why • If the form of data is clear (e.g. tape recordings, video material, notes etc.) • If the researcher has discussed saturation of data
	Can't Tell		
	No		

Comments: Explicit and detailed description of the interview process and questions. Clear description of data form. Discusses data saturation.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: Discussed using a process of peer debriefing to probe researcher biases.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: Thorough ethics section. Clear description of consent confidentiality and follow up debriefs.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Good support for the findings from the data. Descriptive analysis explicitly stated as methodology. Literature control was used. Detailed description of researcher's own role and 'distortions'.

9. Is there a clear statement of findings?

Yes	✔
Can't Tell	
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Literature control, peer debriefing, trustworthiness section.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Very valuable and unique, makes novel contribution. Clearly articulated so can easily judge transferability.

H.3 CASP Ghio et al 2022

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Ghio et al 2022

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: Data collected from online forums. Detailed description of how forums were identified - transparency.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Detailed description of process of data aggregation and collection. Justification for excluded threads.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments:	Detail is given around which researcher was responsible for which aspects of the study, however no documentation of researcher personal stance/perspectives on the data. Some consideration of researcher stance in the results section - discusses how codes were agreed within the wider team to establish quality control. Good information given about participant recruitment and selection - enough to be confident there is no personal relationship between the study participants and the researcher.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments:	through ethics section

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes ✔
Can't Tell
No

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Clear description of the 2 analytical approaches used. Detail was given around how codes were identified. Examples given. Sufficiency of data to support findings. Discussion of how agreement with coding was reached within study team.

9. Is there a clear statement of findings?

Yes ✔
Can't Tell
No

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Good evidence of credibility for findings through mutiple analysts, team discussions. Explicit and clear findings with a themes summary map given. Research questions answered systematically.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Very important and valuable research. Novel contribution. Identifies gaps or areas for future research. Identifies other populations which need further study.

H.4 CASP Gunnarsson

Paper for appraisal and reference: Gunnarsson & Hyden 2009

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes ✔ | Can't Tell | No

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes ✔ | Can't Tell | No

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes ✔ | Can't Tell | No

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Interviews are known to be appropriate for this type of question. There is discussion about why they are using a narrative approach to elicit patient stories.

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments:	Good description of how and why participants were selected. Detailed description of how the participant characteristics was given.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments:	Detailed description of the process and interview. Clear data form.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?	Yes ✔ Can't Tell No	HINT: Consider • If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location • How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: No evidence of reflection on researcher position, bias or stance. However, sufficient detail was given in terms of participant recruitment and sample choice to be confident the researcher is not personally connected to the participants.

Section B: What are the results?

7. Have ethical issues been taken into consideration?	Yes ✔ Can't Tell No	HINT: Consider • If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained • If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study) • If approval has been sought from the ethics committee

Comments: Informed consent to contact parents discussed as being obtained from an earlier study. No explicit ethics statement or approval statement. However, sufficient detail was provided about the process and methods to allow for the reader to make an assessment of the ethics.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Lots of data are presented to support the findings, and it appears clearly rooted in the data. There is no explicit statement of how this was done or what named methodology was used, but there is sufficient detail to allow the reader to recreate it.

9. Is there a clear statement of findings?

Yes	
Can't Tell	✔
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Findings are plentiful and related to the research question, however there is no discussion of credibility (triangulation, multiple coding etc) or researcher stance.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Valuable insight into parent perspectives and construction of illness narratives. Unique and makes a contribution. Very detailed description of participants enables reader to apply the research.

H.5 CASP Jurich 2021

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Jurich 2021

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Good justification for the use of Netnography as a way of accessing candid, anonymous data.

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: Clear description of how the groups were identified and how relevant threads were gathered within those groups.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Detailed description of data form and process for gathering it.

CASP Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: Discussion of researcher relationship with participants explicitly as an 'outsider' - not interacting with group members.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: No explicit statement about ethics. No ethics approval reported. Discussion of attempts made to inform the group administrators of the research question and responses to interested community members, which is probably sufficient for an online group analysis without direct contact with members.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Sufficient detail was given to explain where categories and themes had arisen from in the data and sufficient data was presented to support the findings.

9. Is there a clear statement of findings?

Yes	
Can't Tell	✔
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Findings are presented and are relevant to the research question, but there is no evidence for credibility or discussion for and against the researcher's arguments.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Interesting, relevant and important. New contribution to the field. Relevant for the understanding of how parents may think about allergy.

H.6 CASP Kidd et al 2019

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Kidd et al 2019

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Interviews listed, well established as appropriate for this type of research. Not explicitly stated. Discussion of desire for focus groups also and how this would enrich the research but how this was deemed impossible for every participant given time restraints.

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: detailed discussion of inclusion and exclusion and recruitment. No explanation of why these participants were chosen, but appears clear from context.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Methods and topic guide discussed. Form of data clear. Discussion of how interview guide evolved in response to focus groups.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: Discussion of change of plan from focus groups to interviews and consideration of the implications of this.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: Informed consent discussed. Anonymity discussed.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Very detailed description given of process of coding including multiple analysts, discussion and exploration of challenging or contradictory data.

9. Is there a clear statement of findings?

Yes	✔
Can't Tell	
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Excellent description of credibility. Findings are clear and presented in relation to the research question.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?	
10. How valuable is the research?	HINT: Consider • If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature • If they identify new areas where research is necessary • If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used
Comments:	Very relevant and valuable. Insightful. Novel contribution to the literature with relevant applications for policy and practice. Highlights areas for future research. Sufficient detail on participants for transferability.

H.7 CASP Lauritzen 2004

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Lauritzen 2004

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes ✔ / Can't Tell / No

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes ✔ / Can't Tell / No

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes ✔ / Can't Tell / No

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Gives detail of how the interviews took place in terms of illiciting a narrative and justifies this as a way to elicit more data and deeper understanding.

2

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments:	Participants recruited from parents attending an initial appointment at an allergy clinic. Wanting to focus on the pre-assessment and pre-diagnosis phase of illness, so this is an appropriate recruitment strategy. It could be argued that once parents have obtained a referral to a specialist clinic the parent is likely to be convinced of a diagnosis; however this may be setting specific. NHS specialist referrals for allergy are unlikely unless the infant has severe symptoms or evidence of anaphylaxis; this may not be the same in Sweden.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments:	Good clear description of data collection method. Explicit description of the interview questions.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: No discussion of researcher role or bias. However sufficient detail given about participant recruitment that reader can be confident there is no personal relationship to the participants.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: Statement of ethics approval. Consent discussed. Detailed description given of methods.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	
Can't Tell	✔
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: States they are using a narrative style of analysis, doesn't explicitly reference a specific technique. Examples used to justify findings, but no discussion of how these examples were selected. No discussion or critical consideration of researcher bias in analysis.

9. Is there a clear statement of findings?

Yes	✔
Can't Tell	
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: There is an explicit and clear statement of the findings in the abstract. Findings are clearly presented under a heading related to research aims; but there is no evidence of credibility or trustworthiness. There is no discussion of evidence for and against the arguments.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?	
10. How valuable is the research?	HINT: Consider • If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature • If they identify new areas where research is necessary • If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used
Comments:	Moderate. The research is reasonably relevant to the current setting/context as it represents the early 'pre diagnostic' thought processes of parents with allergic children. There is some discussion of the findings within the wider literature context. However there is very little detail about the symptoms of the children involved or the healthcare system and setting; which makes transferring the findings to our local setting more difficult.

H.8 CASP Long & Johnson 2001

Paper for appraisal and reference: Long & Johnson 2001

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes ✔ | Can't Tell | No

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes ✔ | Can't Tell | No

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes ✔ | Can't Tell | No

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments:

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: Recruitment initially through health visitors, however effort was made to broaden the sample when the HV featured in study sample. This is discussed explicitly and efforts were made to correct potential bias.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Clear description of the data collection process. Justification given for the use of observations.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: No discussion of researcher personal stance or biases. However, sufficient detail given in participant recruitment and sample choice to be confident the researcher is not personally connected to the participants.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: ethics section. risks considered. written consent. approval by research ethics committee.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments:	Detailed description of data analysis process. Adequate data to support findings. clear description of how contructs were established.

9. Is there a clear statement of findings?

Yes	
Can't Tell	✔
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments:	Findings are clearly presented and related to research question. However there is no discussion or researcher position or bias, evidence for and against researcher arguments and no discussion of the credibility of their findings (eg. evidence for multiple analysts).

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?

HINT: Consider
- If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature
- If they identify new areas where research is necessary
- If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Interesting, useful and very applicable to practice. Researcher discusses areas for more research and illustrates direct implications for practice and policy.

H.9 CASP Megel et al 2011

Paper for appraisal and reference: Megel et al 2011

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Researcher justifies the choice of grounded theory as most appropriate methodology to uncover complex transactional processes such as parenting an infant who cries excessively.

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: Description of opportunistic sampling given. No in depth justification of why or how these parents were selected as most appropriate to provide in depth knowledge, how they were similar or different to one another and why that was important. Opportunity sampling likely to mean 'whoever we could get', but no reason to think that inappropriate. Clear explanation of the type of sampling and how - newsletters, posters, snowball sampling. Considered sufficient to determine that it is appropriate to the aims of the research.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Interview guide described, good description of types of questions and how the guide evolved during the analysis and data collection. Form of data clear.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	
Can't Tell	✔
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: No explicit discussion of researcher stance or possible bias. Some detail given around study recruitment but included advertising by 'word of mouth'. Unclear how exactly participants were recruited.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: review board and informed consent stated. Description of methods in detail.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: Good description of how categories and themes derived from data. Sufficient data presented to support conclusions. Clear description of analysis process including level one and two codes.

9. Is there a clear statement of findings?

Yes	
Can't Tell	✔
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Findings are presented clearly and related to the research question, but there is no explicit discussion of researcher credibility or methods/tools taken to reduce bias.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?	
10. How valuable is the research?	HINT: Consider • If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature • If they identify new areas where research is necessary • If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used
Comments:	Interesting, relevant and important. Discusses in the context of existing theory. Recommendations for practice and research are given.

H.10 CASP Nuyts et al 2021

CASP
Critical Appraisal Skills Programme

Paper for appraisal and reference: Nuyts et al 2021

Section A: Are the results valid?

1. Was there a clear statement of the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- what was the goal of the research
- why it was thought important
- its relevance

Comments:

2. Is a qualitative methodology appropriate?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
- Is qualitative research the right methodology for addressing the research goal

Comments:

Is it worth continuing?

3. Was the research design appropriate to address the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- if the researcher has justified the research design (e.g. have they discussed how they decided which method to use)

Comments: Good justification given for the approach taken.

CASP
Critical Appraisal Skills Programme

4. Was the recruitment strategy appropriate to the aims of the research?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher has explained how the participants were selected
- If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study
- If there are any discussions around recruitment (e.g. why some people chose not to take part)

Comments: Very specific experiences and recruited participants who met that exact critera.

5. Was the data collected in a way that addressed the research issue?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the setting for the data collection was justified
- If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)
- If the researcher has justified the methods chosen
- If the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews are conducted, or did they use a topic guide)
- If methods were modified during the study. If so, has the researcher explained how and why
- If the form of data is clear (e.g. tape recordings, video material, notes etc.)
- If the researcher has discussed saturation of data

Comments: Details given of interview guide and icebreaker questions, justification for the choice of interview to obtain detailed parent perspectives. Clear data form. Data saturation discussed.

CASP
Critical Appraisal Skills Programme

6. Has the relationship between researcher and participants been adequately considered?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location
- How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Comments: Describes open discussion in the team of researcher bias.

Section B: What are the results?

7. Have ethical issues been taken into consideration?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained
- If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)
- If approval has been sought from the ethics committee

Comments: Ethics statement included. Approval from ethics committee, informed consent, distress consideration.

CASP
Critical Appraisal Skills Programme

8. Was the data analysis sufficiently rigorous?

Yes	✔
Can't Tell	
No	

HINT: Consider
- If there is an in-depth description of the analysis process
- If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
- Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
- If sufficient data are presented to support the findings
- To what extent contradictory data are taken into account
- Whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation

Comments: In depth discussion of the analysis method. consideration of researcher role and biases.

9. Is there a clear statement of findings?

Yes	✔
Can't Tell	
No	

HINT: Consider whether
- If the findings are explicit
- If there is adequate discussion of the evidence both for and against the researcher's arguments
- If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
- If the findings are discussed in relation to the original research question

Comments: Details given of triangulation processes. Explicit findings given and connected to research questions.

CASP
Critical Appraisal Skills Programme

Section C: Will the results help locally?

10. How valuable is the research?	HINT: Consider • If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature • If they identify new areas where research is necessary • If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Comments:	Very important and relevant data. Novel and unique contribution to the literature. Sufficient detail given to allow some transferring of data to other populations. Research recommendations made.

Appendix I Topic guide for qualitative interview study

Parents' experiences of common baby symptoms: qualitative interview study – semi-structured interview topic guide

Introduction

1. **Researcher introduces herself and the study.**
2. **Researcher discusses PIS -** will give the opportunity for the participant to read through the PIS again and ask any questions
3. **Researcher discusses the consent form –** The researcher will give the opportunity for the participant to read through again or ask any questions. The researcher will confirm that the participant has signed the consent beforehand and is still happy to continue.
4. **Discuss the process of a qualitative interview:** open-ended questions, expected to take 30 mins to an hour but the participant can discuss as much or as little as they like.
5. **Discuss and agree recording of the interview –**If not recording, written notes will be taken.
6. **Reiterate that the participant can stop at any time.**

[Start recording, if applicable]

Questions

1. Firstly, please could you tell me about your baby's symptoms?
   a. What did you think about the [insert which symptom(s) they introduce]?
   b. What if anything, did you think caused or made the symptoms worse?
   c. What, if anything did you feel helped or improved their symptom

2. How did you feel when your baby was experiencing those symptoms?
   a. What thoughts occurred to you at the time
   b. What feelings or emotions did you experience
   c. Did any of these thoughts or feelings worry you?

3. At what point did your baby's crying/vomiting start [insert emotion they mention] you?
   a. What happened?

4. Have you looked for help or advice from anywhere for your baby's symptoms? If so, can you please tell me about this?
   a. *Family, friends, organisations like NCT, social support?*
   b. *What advice have you looked for online?*
      i. *How easy / difficult was it to find information online?*
      ii. *How helpful did you find it?*
      iii. *Do you remember where / who provided this information online?*
   c. *At what point did you decide to seek this help?*

5. If applicable, what advice were you given from elsewhere (for example, family, friends, social support, organisations or online) [If more than one, ask about one at a time]
    a. *How did the advice make you feel?*
    b. *Was the advice helpful to you? Did you follow it?*

6. [If participant has not already mentioned seeking advice from a health professional. Or use these question probes to gather further comments about health professionals] Have you looked for help or advice from a healthcare professional like a doctor, nurse or Health Visitor for your baby's crying/vomiting? If so, please can you tell more about this?
    a. *What made you decide to seek help from a healthcare professional?*
    b. *Who did you speak to? What did you ask them about?*
    c. *Did you have an idea about what help / support you were looking for before you spoke to them?*

7. If applicable, what advice were you given by the healthcare professional. [if more than 1 HCP encounter, ask about one at a time]
    a. How did the advice make you feel?
    b. *Was the advice helpful to you? Did you follow it?*

8. Some people have talked to us about these symptoms affecting their feeding. In what way, if any, has your baby's crying / vomiting affected the way you feed them?
    a. Has it affected your decision about whether or not to breastfeed, or led you to stop breastfeeding earlier than planned?
    b. Has it led you to change your own diet if you are breastfeeding? What impact does this have on you?
    c. Has it affected what type of formula milk or bottle you use?
    d. Has it impacted your feeding schedule/routine if you have one?
    e. How do your baby's symptoms make you feel about feeding?
    f. Please describe whether finance has impacted your feeding decisions, and if so, how?

9. To what extent, if any, has your baby's symptoms made you think there might be a medical cause?
    a. Did you suspect any specific diagnosis?
        i. What made you think that?
        ii. Where have you previously come across this?
        iii. Where did you seek information about this?
    b. Has a health professional been able to confirm this medical diagnosis?
        i. How did they confirm this?
        ii. Has this diagnosis been useful for you?
        iii. If having a label has helped, why has it? If not, why not?

c. How did you feel about this diagnosis (or potential diagnosis) at the time?

10. What treatments, if any, have you tried to help your baby's symptoms such as crying / vomiting?
    a. Do you think it helped?
    b. Did your baby have any side effects from it?
    c. Have you ever bought any over the counter medication for your baby's symptoms?

11. [If participant describes anything from question 8] Has the diagnosis / have your thoughts about this impacted on you and your family?

12. What was your experience of becoming a parent?
    a. Do you think this was different from parents whose babies did not have these symptoms
    b. Was it different from what you expected? If so how?

13. Do you think having a baby with these unsettled symptoms impacted your developing relationship with them at the time?
    a. If so how?
    b. How did this make you feel?
    c. How is your relationship now?

14. Are there any aspects of your life (financial problems, relationship issues, discrimination) which have impacted your experience?
    a. If so what and how?

15. What advice would you give other families of babies with these symptoms?

16. Is there anything else that you would like to add?

General probes

- How does/did that make you feel?
- Can you tell me a little bit more about that?
- That's really interesting – please can you explain a bit more?
- That sounds really upsetting for you.
- That sounds really difficult – do you feel able to tell me a bit more about that?

[Stop recording. If applicable]

Demographics questions

1. How old is your baby?
2. Do you have any other children?
3. What is your age?
4. What is your gender?
5. What is your ethnicity?

Ending the interview

1. Thank the participant
2. Read them the debrief sheet (and/or agree to post/email it to them, if they prefer)
3. Ask participant which GP practice they are from (or where they found out about the study) for the purpose of tracking recruitment for the CRN
4. Discuss participation voucher

Appendix J Study materials for qualitative interview study (Advert and Participant Information Sheet)

Seeking parents/carers for a chat about experiences of common baby symptoms

We are researchers exploring parents/carers experiences of common baby symptoms (such as crying for hours without being settled, fussing unless being held, vomiting, rash, changes in their nappies, gas/wind or congestion) and how having an unsettled baby might affect feeding decisions.

What's involved?

- *A chat with us that will take from 30 minutes to an hour by telephone or videocall, at a time/date suitable for you.*
- ***£15 gift voucher for each participant***

You can take part if:

- *You have a baby who is 12 months old or younger*
- *Your baby experienced common baby symptoms (such as those listed above) in the first 4 months of life, or you considered allergy, reflux or colic.*

To get further information / find out how to be involved:

Follow this link and complete the reply form
[insert link]

or** email Sam Hornsey: **s.j.hornsey@soton.ac.uk

NIHR | School for Primary Care Research

This study/project is funded by the National Institute for Health Research (NIHR) School for Primary Care Research (project reference 536). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Participant Information Sheet

Exploring parents' experiences of common baby symptoms

Researchers: Ms Sam Hornsey, Dr Ingrid Muller

You are invited to take part in a research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to take part you will be asked to sign a consent form.

What is the study about?

Some babies cry or vomit or seem more unsettled than others, with common symptoms such as:

- excessive crying (not stopping crying for hours without being settled),
- fussing unless being held
- vomiting,
- Rash
- changes in their nappies
- Excessive gas/wind or congestion.

This study is to better understand parents and carers' experiences of these baby symptoms, when and where they seek help, support or information, and how having an unsettled baby might affect feeding decisions. This study will help with knowing when and how to provide support in dealing with these symptoms.

We want to chat to parents of babies who have had any or multiple common symptoms (such as the symptoms listed above) when they were less than 4 months old, even if they have never consulted a GP or a nurse about this. We would also like to speak to parents who have considered **Cow's Milk Allergy, Reflux or Colic** (whether or not they have received a diagnosis of this).

This study is funded by the NIHR School of Primary Care Research and is being run (and sponsored) by the University of Southampton.

Why have I been invited?

You have been asked to take part in this study as you may have a baby (less than 1 year old).

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will sign a consent form to show you have agreed to take part.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form. The researcher will contact you to arrange a time that suits to have a chat about your experiences of having an unsettled baby. This may be by phone or videoconference (e.g. TEAMS or Zoom) depending on what suits you best. The interview will take 30 mins to an hour. With your permission, this conversation will be recorded and transcribed (to written text). All personal details will be removed and fully anonymised.

Are there any benefits in my taking part?

You will be given a **£15 gift voucher** for taking part in the study. The findings of this study will help researchers understand how to better support parents with unsettled babies.

Are there any risks involved?

There are minimal risks to taking part in this study. You may find it upsetting to talk about your experiences. If this happens, we will stop the interview and give you details where you can get advice and support.

What data will be collected?

The interviewer will ask questions about your baby's symptoms and how you made sense of the symptoms. They will also ask about what support and advice you have received from friends/family, online, or from health professionals such as health visitors or GPs, as well as possible causes you may have considered and how this affected your baby and your family. Data such as gender and ethnicity will also be collected, optionally.

What happens to the data being collected?

After the interview, the recording will be put on a university password-protected computer and deleted from the recording device. The recording will be typed up by a professional transcriber or a member of the research team. They will keep everything they hear private and will type code names instead of your name and any other names or places, so no-one can find out who you are. We will delete all audio recordings on completion of the study. Only anonymised information will be analysed.

We will review what you have told us and put that together with what other parents tell us. This will help us understand parents' views and experiences of an unsettled baby. Your personal details and code name will be stored separately from the typed-up interviews and audio-recordings; all of this information will be stored securely on computers at the University of Southampton and will only be accessible by the research team. We will delete the personal details that match your code name at the end of the study.

Will my participation be confidential?

Your participation and the information we collect about you will be kept strictly confidential. We will not share your interview with anyone who is not a member of the research team. We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require access to the information we collect about you to

check that we are carrying out the research correctly. Only individuals from regulatory authorities will be able to see your information. These people have a duty to keep your information strictly confidential.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason. If you decide to withdraw, any data you have provided will be kept up to the point of withdrawal but will be deleted if you request this.

What will happen to the results of the research?

Your personal details will remain strictly confidential. The results of the study will be written up as a report for NIHR School of Primary Care Research and will be published in scientific journals and presented at research conferences. We may use quotes from the interview but none of your personal details that could identify you will be used (like your name).

Where can I get more information?

If you have any questions about this study, please contact:

Sam Hornsey
Primary Care Research Centre
Faculty of Medicine
University of Southampton
Aldermoor Close
Southampton
SO16 5ST

Email: s.j.hornsey@soton.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher (s.j.hornsey@soton.ac.uk) who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Thank you

Thank you for taking the time to read the information sheet and considering taking part in the study.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Appendix K Study adverts for think-aloud interviews


ARE YOU THE PARENT OF AN 'UNSETTLED' BABY UNDER 1 YR?
We want to chat to you!
What's in it for me?
We'll give parents selected to take part a £15 Amazon (or alternative) voucher to thank you. You will be helping to support other parents with unsettled babies
What do I need to do?
Chat to our researcher about a website we have designed to help parents. This can be face-to-face or by video call. That's it!
Crying
Poo problems
Vomiting
Rashes
Wind
Something else
How do I sign up?
Scan the QR code below to find out more and sign up
a.e.dobson@soton.ac.uk
University of Southampton
Visit https://qualtricsxmr8pj8ttq8.qualtrics.com/jfe/form/SV_0cBPSLcqpJcKMQe to find out more and to sign up
Ethics registration number 77547


ARE YOU THE PARENT OF AN 'UNSETTLED' BABY UNDER 1 YR?
We want to chat to you!
Crying
Poo problems
Vomiting
Something else
University of Southampton
Visit https://qualtricsxmr8pj8ttq8.qualtrics.com/jfe/form/SV_0cBPSLcqpJcKMQe to find out more and to sign up
Ethics registration number 77547
What's in it for me?
We'll give parents selected to take part a £15 Amazon (or alternative) voucher to thank you. You will be helping to support other parents with unsettled babies
What do I need to do?
Chat to our researcher about a website we have designed to help parents. This can be face-to-face or by video call. That's it!
How do I sign up?
Scan the QR code below to find out more and sign up
a.e.dobson@soton.ac.uk

Appendix L Interview guide for think-aloud interviews

UNIVERSITY OF Southampton

Supporting families of unsettled infants: Development of digital intervention materials

Think aloud Interview guide

Introduction

Take consent before interview commences

*Before I start there's just one thing I forgot to ask you one the phone. Would you mind giving me your age? Thanks!

We're interested in your views of our new website for parents of unsettled babies. All you have to do is use the website as you would normally if I were not here and say your thoughts out loud.

After you have finished looking at the website, I would like to have a chat with you about your experiences and your overall views of the materials.

I'm going to turn on the recording in a moment and then I'll just read out a series of consent statements, there are 9 sentences in total, I will just ask you to say yes if you are happy with each one. Does that sound ok?

Do you have any questions before we start?

Start recording

CONSENT STATEMENTS:

I have been sent the information sheet and have had the opportunity to ask questions about the study.	
I agree to take part in this research study and agree for my data to be used for the purpose of the study.	
I understand my participation is voluntary and I may withdraw for any reason without my rights being affected.	
I understand that if I withdraw from the study then the information collected about me up to this point may still be used for the purposes of achieving the objectives of the study only.	
I understand that personal information collected about me such as my name will not be shared beyond the study team.	

The following are optional - please only click the box(es) you wish to agree to:

I understand that taking part in the study involves audio/video recording which will be transcribed and then destroyed for the purposes set out in the participation information sheet.	
I understand that I may be quoted directly in reports of the research but that I will not be directly identified (e.g. that my name will not be used).	
I understand that my anonymised data may be shared outside the study team for research purposes.	
I am happy for the study to contact me in a few months about taking part in another related research project.	

OK thankyou, so we will get started.

To help you think aloud you may find it useful to read aloud or tell me what you are clicking on and why. You may find at times I will say aloud what you have clicked on or what page you are looking at – this is just so when I listen to your views again, I know what part of the website you are talking about.

This is not a test. There are no right or wrong answers, so please say any thoughts which spring to mind, even if you think they might not be important. I just want you to say out loud any thoughts which are running through your mind.

Please do feel free to say any negative thoughts you may have about the advice as these will be really useful in helping us improve it. Your views are really important, the more you can tell us, the better.

Think aloud interview

So, first of all I'm going to ask you to take control of the Power-point so that you can flick through the content and click on the links yourself. Can you see somewhere in the top left it says 'take control'?

OK great, and now there should be three little dots with more options, somewhere around your bottom left, if you click on more actions and then 'hide presenter view'.

That should make the phone picture a little bit bigger. Has that worked ok?

Excellent. OK so this is the homepage, what are your first impressions?

- Remember to state page titles for the recording

- Use the following prompts
  - ***What are you first impressions?***
  - ***What are you thinking now?***
  - ***Why did you click on that?***
  - ***Why did you choose that option?***
  - ***How did you feel about that [information / video / page / section]?***
  - ***What do you think about following this advice?***

Neutral prompts

- ***That's interesting, could you say a bit more about that?***
- ***What makes you say that?***
- ***Could you tell me more about that?***
- ***Why do you think that?***
- ***What do you think about that?***
- Avoid offering help using the website. If asked a direct question about navigation (such as – "do I just click here now?"), you could try saying, "just use it as you would if I wasn't here", or maybe ask the user if they think the instructions are unclear on that page.

Post Think-aloud questions

- Can you tell me about your first thoughts when you saw the website?
- How did you find the website overall?
- How do you feel about the advice in the website?
- What did you like/dislike about the advice in the website?
- Have you come across websites like this before? If so, how does this one compare?
- Which bits of the website were particularly helpful/ not helpful?
- Were any parts of the website too complicated? If so, can you tell me about these?

- Is there any advice in the website you didn't understand? If so can you tell me about it?
- What did you think of the video?
- Is there anything you would like to have seen that wasn't in the website?
- What did you think about (insert specific part for feedback)?

Questions relating to study materials

We are planning future research to test the website

- Do you have any feedback for us on the study advert or poster you saw?
- Where did you hear about this study? Are there any other places you might see an advert or letter?

End of interview

That is all really useful, thank you. Is there anything that we haven't discussed that you would like to add? Thank you so much.

Would you like us to send you a copy of the results by email? This will be available in a few months' time.

Appendix M Table of Actionable Changes

Group (1 aesthetics, accessibility, navigation, unclear. 2 content request. 3 contextual factors. 4 credibility. 5 reorganization. 6 gender 7 novelty. 8 wording. 9 unintended consequences.)	Summary of issue	Example quote / explanation	Action taken
1	Accessibility	“For me, I’m scrolling past this quote, I’m not even reading it, it’s too long for me.”	Mixed comments – other parents have requested some longer quotes. Left in, most of the quotes are much shorter and the message in this longer quote is not essential and is repeated elsewhere.
1	Accessibility	“I’d click through this quite quickly, although probably not reading much of it.”	Changed structure of the page, layout, added myth/fact to break up the text and emphasise key point
1	Accessibility	“So I think I can see why the fonts in the keywords are bigger, but I actually think that feels harder to read.”	Changed to bold text instead of larger.
1	Accessibility	“Again I'm thinking, because obviously I'm juggling a crying baby at the moment, the writing feels quite small in terms of taking it in and reading it.”	Made text clearer.
1	Accessibility	“Sorry. My eyesight's terrible.”	Increased size of text.

1	Accessibility	“I actually think it's more confusing that it's on different slides rather than just all in one. I think it would make sense if all of the information was in one. I think I get that you guys probably don't want to make it too wordy and too much to read, but yes. I do like the certain keywords in bold, the little labels of the accreditations and things.”	Only parent to say this, all other responses to the clickable landing pages have been positive and parents have preferred the information being broken down into chunks. Change not made.
1	Accessibility – subtitles on video - **x 2 parents**	“The option for subtitles on the video. Often don't watch things with sound on when I'm around my baby”	This should be added in a future iteration of the website.
1	Accessibility – text was hard to read – **x2 parents**	“As someone that is colour dyslexic, black on white tends to be quite hard. So, the bit that's got the blue background behind it, that's really easy to read, but some things do get harder to read.” P102 “I'm dyslexic, and I'm finding it a little bit hard to read…it's just a bit of a difficult font for dyslexics. We all tend to go towards the same kind of fonts and prefer bolder text.” P101	To add a tinted background and accessible font when the website is developed.
1	Accessibility - text was too small to read **x2 parents**	“That is very tiny print… my face is right up against the screen to read it.”	Multiple parents across different areas of the site. Either made the text bigger, clearer, shorter or changed into an optional click out box to allow for bigger text.
1	Accessibility - too long	“If I was looking to see why my baby was unsettled, I wouldn't stop and read it, to be honest.”	Made information shorter and more accessible.
1	Aesthetics	“It's quite unusual to start with text, like a… Usually things like people having feedback and stuff usually, that's not the first thing you see. I mean, not necessarily a bad thing.”	Altered location of the quote to put further down the page.

1	Aesthetics	“It'd be nice if that, maybe, I don't know had a cycle of things that changed.”	In future iterations could present the myths and facts as a ‘gallery’.
1	Aesthetics	“I think with this bit here that would be … to see something more related to mental health. It just seems a little bit off-topic.”	Changed photo to be more topic-linked.
1	Aesthetics	“I'd probably say the colours, I'd probably say looking at maybe having a bit more brighter, more vibrant colours”	Likely to change in future iterations.
1	Inclusive language was off-putting	“Yes. I do find the term chest feeding quite interesting, because it’s more – I get it, you have to be more…accommodating to different people’s views. INT: Does it put you off, that term? P: It does a little bit, but then I’ve got to be open to people’s different – their views and there’s lots of different…”	Decision made to keep inclusivity despite this comment. Other parents have discussed valuing the inclusivity on the site.
1	Navigation	“How do I go…?”	Included an additional link.
1	Navigation	“P: What shall I do next? INT: Just as if I wasn’t here. What would you do, do you think? P: I don’t know, there’s no links on here. I could go back and look through the links again.”	Added better navigation with options from here.
1	Navigation	“If there are myths, like with the allergies and stuff, debunking them, but with enough other things to try… So you still feel like you're trying or doing something for your baby.”	Added clearer links to the ‘make a plan’ section from this area of the website.
1	Navigation	“Would I not click on this and then home? Oh no!”	Clearer links to homepage sent.
1	Navigation	“Which arrow? Oh, I'd make that arrow clearer, because you wouldn't even know that you could click on that, it's a bit too faint.”	In a live version of the site this would be clearer. No action taken.

1	Navigation	“Is there anything on feeding, or would there be anything on feeding?”	Added links to feeding section and burger symbol with working links.
1	Navigation	“That is probably too hidden. I want to click the quote…”	Added a link.
1	Navigation	“I’d go back to the home button. Then, probably click the three lines at the top to see what else at this point”	Added working burger symbol.
1	Navigation	“I've disappeared. It's taken me to a link.” Parent had accidentally navigated off the resource to an external website.	In future iterations could add a pop up prompt asking if they want to leave the site.
1	Navigation	“It would be good to see…this is an exercise to focus on why you're a good parent”	Clarified how to use this section of the site. Visual prompts added to show it is an exercise.
1	Navigation	“Oh, did I click through two there? Yes, I did … Is that the same thing?”	Visual prompts added to clarify what is an exercise.
1	Navigation	“It'd be nice to be able to click on this and go to that…”	Link added.
1	Navigation	“Although it's validating, it is repetitive. I think it takes a while to get to the actual information…I think my main focus is solutions, so I'd want the solutions to be very kind of - at the forefront of your mind.”	Parent wanted a clearer link to the plan and when to worry sections. This is likely to be clearer where to get to this info on a live website. No change made in this setting.
1	Navigation	“even if you just had a blue link at that bit”	Link added.
1	Navigation	Parent was unsure what to click on	Clarified links and added a ‘skip to’ button.
1	Navigation	Parent wanted the picture to be a link	Added picture link.
1	Ordering change suggested	“Yes, that first one I’d move down the list or get rid of.”	Moved down the list.
1	Ordering change suggested	“That's nice. I think I'd like to see that a bit nearer the top.”	Different requests for different orders on this page – reflects parents different priorities. Creating a gallery which automatically cycles through myths and facts could improve this.

1	Parent preferred gender neutral pronouns in the information text	“I do think that maybe needs gender-neutral terms, rather than, 'Himself.' Not everybody has a boy”	Unable to change this example since it was an existing tool. However checked the rest of the site to ensure gender neutral pronouns on all our intervention content.
1	Typo	“I was like, oh, hang on a minute because it's not necessarily to do with vomiting. Did you spot that as well?”	Typo corrected.
1	Unclear	“That checklist, is it meant to be a link or is that list the checklist?”	Clearer label added.
1	Unclear label	“The table itself is really clear. I know what is what, I just don't know what the table is.”	Added clearer label to nappy table.
1	Unclear wording Key message was missed by this parent.	Parent had not understood that the food needs to be reintroduced in a food challenge.	Made the key message clearer and more noticeable.
1	Unclear wording	“[reads]’ I feel like it should be, ‘Reach out for help urgently.’ Or something else. Does that make sense?”	Changed wording to be clearer.
1	Unclear wording	“it probably just needs a little title that’s, ‘If you want further help with feeding, here are some resources.’”	Added signposting sentence.
1	Unclear wording	“I just don't feel like it's completely clear the way it's written”	Reworded.
1	Unclear wording	“So lethargic, what does that mean?”	Added ‘hard to wake’.
1	Unclear wording	“I'm wondering if that might just need some quantification around what repeatedly might mean.”	Added clarification.
1	Unclear wording	“Yes. I don't know if I know what it means. As in does it mean they're not getting enough food in, or…”	Clarified.
1	Unclear wording	“I thought, oh, I wonder what medication it means.”	Clarified.

1	Unclear wording	“both my babies have been lethargic, tired, sleepy babies, but they are fine. Touch wood. As a mum, I know that he's okay, but I think I would maybe worry a little bit reading the 'very lethargic' one”	Clarified wording.
1	Unclear wording	“'Rate the games below for yourself and your baby, and marks out of ten.' I don't understand what that means.”	Added a clarifying sentence for parents who have not watched the video.
1	Unclear wording	“I would say maybe to just specify what kind of medical help you're talking about”	Clarification added.
1	Unclear wording	“The way it's worded, I just know if I was really tired I might misread that.”	Clarified.
1	Unclear wording	“either link it or say what expert help”	Clarified.
1	Unclear wording	“'safe co-sleeping can help everyone get some rest' because if you need to then follow a link or follow something, people are less likely to do that, so if you just 'safe co-sleeping”	Wording changed as requested.
1	Unclear wording	“credentials, it's not very - what do you mean, sorry?”	Clarified.
1	Unclear wording	“I thought that was for the bit of material that you end up putting together yourself. Fair enough. That's really interesting.”	Added sentence to clarify applies to all babywearing carriers.
2	Content request	“One of the other things that we found hard with the restrictive diet; they were saying is nutritional things. My wife has to take supplements.”	Included a sentence for what to do if the elimination diet and food challenge is positive.
2	Content request	“Pictures of poo are particularly important I think.”	Added a click out for photos to relevant sections.
2	Content request	“I think it's good it's in there. I just wonder if there's a link that could be put with that maybe, in terms of where someone could just maybe find out a bit more about perinatal mental health or something”	Added a link.

2	Content request	Crying info felt underwhelming. Parent was expecting more detail eg. the crying curve	Added small amount of engaging info and changed title to why do babies cry to make it more succinct and prime what to expect.
2	Content request	“Maybe just a little nod to sometimes or often babies, we need to rule out any difficulties with feeding.”	Added link to feeding pages from here.
2	Content request	“You might need a link to that leopard in the tree pose thing. I know that I didn't know what that was until someone showed me.”	Added a photo.
2	Content request	Parent requested inclusion of information on tongue tie.	This is difficult to assess and provide information for remotely, however the WHO checklist on the feeding resources page would catch it and signpost to services. Therefore not changed.
2	Content request	“I don't know if you've got anything about sterilisation but that was really…”	Added info and a link.
2	Content request	“I think if you added some bits in there of if people want to express, like putting in some recommendations for breast pumps…if they are pumping, a bit of how [to pump]… How long you can store it in the fridge?...can you add the freshly expressed milk to cold milk?”	Added in additional information and extra links to resources about expressing breastmilk.
2	Content request	“It would be good to know what age this is aimed at.”	Added age guidance to the feeding page.

2	Content request	“I don’t know how much information and research is out there for premmie babies. I really struggled to find that information…that applied to him. So, that might be something to have as a section…A lot of places, especially with sleep advice, we found everything said, ‘Only do this if your baby was full term and was of a normal weight.’ That never applied to us. Then, it didn’t tell us what to do if your baby was early or underweight.”	In future iterations of the intervention we could develop something specifically for premature babies. They are likely to have different needs and require different things from this resource; so this was not feasible within the scope of this PhD.
2	Content request	“I feel like maybe some more things about breastfeeding and better positions maybe for breastfeeding if the baby has got reflux.”	Added links to the resources section.
2	Content request	“What ages is it going up to? It only goes up to 28 days, maybe it should be a thereafter, this is what's considered normal for a baby.”	Inserted sentence to say there is a huge degree of variability in normal beyond the first month.
2	Content request	Parent would like more information on normal poo in relation to blood.	Inserted information requested.
2	Content request	“Is there anything about, I don't know if this is relevant, but winding afterwards? Just making sure you wind them.”	Inserted information requested.
2	Content request	Parent wanted information on oral thrush to be added.	Added to amber flags.
2	Content request	“On that…I would want to know then what 'responsive feeding techniques' were.”	Added link to info on responsive feeding techniques.
2	Content request	“to have something that says something about how other people … aren't bothered about babies crying when you go out the house… babies are expected to cry. No one looks at you as a bad parent or anything because your baby's crying. I think that's the fear.”	Added info about other people’s perceptions when leaving the house.

2	Content request	“If you didn't know why a thickened formula would work, you'd maybe just want a little - I know now, but I don't think I would have done as a first-time mum. I'd have been like, well, how does that help?”	Added information.
2	Content request	“I feel like I know because it needs to be concise, but it may be nice to have a little thing in there just being like, 'You're not spoiling your baby' or whatever.”	Link added to this content elsewhere on the site.
2	Content request	“you could then print it out so that you could… stick it on your fridge or wherever…it's just there visually, because sometimes people don't always look back on their phones…an option to print it out as a PDF would be good”.	Added print option.
2	Content request	Parent requested content around unrelated topics such as car seats and buggies.	Outside the scope of this PhD.
2	Content request	“Maybe somewhere actually to add on the front home page that parenting doesn't come with a book. It doesn't come with any guidelines. So, as long as you're trying, that's all that matters.”	Not added as covered by other messaging throughout the site, but could be considered for future iterations.
2	Content request	“Is there anywhere that tells parents that they can donate their expressed milk?”	Added link to information about milk banks.
2	Content request on sleep **x2 parents**	“I think, you know sleep was a thing for me, so I think if I was going to give some other feedback I'd say if there's a page that takes people to sleep. I think as a new mum the biggest shock to the system is the sleep deprivation.” “I think if there's a section on sleep, I would be interested.”	Added a section on sleep.
2	Content requested on ‘good enough’ **x2 parents**	“Wanted more information about not needing to be perfect”	Added in section about ‘good enough’ parenting.

2	Content requested on commercial resources **x2 parents**	“I don't know if you're able to, but other resources that I actually ended up finding really useful were Instagram accounts.” “Maybe where you're talking about formula, to kind of have a little table, with pictures of the different formulas that are available.”	Unable to include these resources because they violated the principles of the resource to remain evidence based and free of commercial influence. No action taken.
2	Content requested on feeding aversion – **x2 parents**	“We've struggled to actually feed him at all. I'm not offended but it feels I'm outside of this comment; it doesn't fit me.”	Changed wording of the section to be more inclusive and added information about babies refusing to feed.
2	Content requested on normal poo **x2 parents**	“I would say [add] what is normal poo and then what is not normal”	Added more details and click out to photos in some places.
3	Contextual factor Content request	“It would be quite nice, as well, I suppose to see this maybe updated; if there was a worries page someone could put things into. Then, a frequently-asked-questions page.”	In future iterations could consider how FAQs could be more interactive. Outside the scope of this PhD.
3	Contextual factor Content request	“you know on the NHS website, there's a whole page of vomiting blood, right? If you had just a link to that website where it's just like you could immediately get more information about the medical condition.”	Unable to add this level of detail within the scope of this PhD, however in implementation this could be considered.
3	Contextual factor Content request	I think something like this could be really, really useful….'Let's be friends, we've both got Velcro babies, let's support each other,' maybe to turn it to even a form of social media where you can send messages to each other and become friendly, that would be really, really nice. Really lovely.!	Outside the scope of this PhD but may be interesting for future research or implementation.

3	Contextual factor Parent wanted a local and national service signposting section accessible through the intervention **x5 parents**	"I like that you've got links to going back to getting feeding support and finding a specialist service as well. I think if you had a link there for different things, and then obviously you can put in where you're from, that would be useful. Because I'd read that and I'd be like, yes, I'll do that, and then not do it."	This was not feasible in the current prototype; however it will be an important comment to take into consideration for implementation at a later stage.
3	Contextual factor Wanted it antenatally **x2 parents**	"It would be quite nice, actually, if…this was available to you as soon as you find out that you're pregnant"	Could consider antenatal version for implementation.
3	Contextual factor Wants an app	Parent would prefer an app format	Not feasible within the PhD but something to consider for future development
3	Contextual Factors Possible unintentional consequence Felt judgemental	"I don't like it personally, because I think it implies that... I think for the vast majority of people that probably is possible. I think we were in a position where we saw all the lactation consultants and did everything right, and I still couldn't get my supply to a high enough level to support her. I think had I read that at that point, I think I would have felt a bit frustrated because you're like, well, I am, but it's still not working. LATER: Not a massive fan because I think you can have all of the help. Again, for the vast majority of people that would be the case. I think if you're one of the few that it isn't you're like, oh there's another kick in the..."	Quote changed to reflect how hard it can be to get the right kind of help. Emphasises the importance of contextual factors and the implementation of the intervention within a nested system of robust support.

3	Contextual factors Wanted integration with NHS website	"It would be good to know that all the information that's on here is regularly updated with the NHS guidelines, let's say, so that they match each other…I wouldn't want to end up looking at the app and going, 'Hang on, but the NHS says something different, so what do I trust?' Naturally, I think I would go, 'Well, I trust the NHS website,' because the NHS is our national health service. It would have to match up for me."	Underlines the importance of a network of interventions and for regular updates. Important for implementation planning.
3	Contextual factors	"'Get feeding support', whatever, that's fine. It is easier said than done….parents are trying to get help…and it's just not happening…I think the main problem is that there isn't any help."	Outside the scope of this intervention, but emphasises the importance of implementation into a nested system of other interventions and support provision. No action taken here, but used to inform future research.
4	Credibility of quotes	I'm just thinking, again, similar to the facts and myths and stuff, how do I know that this person… is a real person…not just like, 'I was paid to review this,' kind of thing."	Added more information about sources of quotes to the 'meet the team' page.
4	Credibility needed the NHS logo to trust it **x2 parents**	"I think at this point I'd be wondering if it was also… Had anything to do with the NHS as well." "I always look for the NHS one, which isn't on this particular prototype. I don't know whether or not it will be, but I would probably notice that that's not there. It wouldn't necessarily make me not read it, but it's something I'd have in the back of my mind."	In implementation will need NHS logo as well.

4	Credibility **x6 parents**	“Well, it's not just that. It seems like we were told - our experience is that this isn't correct. We had to change our diet, so this doesn't feel correct. Maybe it was a coincidence with us, then, I don't know because this seems to suggest otherwise.” “I obviously don't know how medically backed this is. I'm guessing it's all completely factual, based on medical guidance, best practice. So it would make me question that kind of - what someone had said to me about cutting stuff out. So I just want to know where this came from, yes.” “Yes, so I sort of half agree with that fact, half don't. I agree that I don't think either of my boys have an allergy, but I think the milk is way nicer on their gut because it's just so gentle.”	Added additional credibility information on ‘landing pages’ to establish site credentials in advance. Also added an additional section explaining the science around exclusion diets with links to the research and a prompt before the information which explains that it may be different from information they have heard elsewhere.

5	Parent found the 'when to worry' page hard to navigate **x4 parents total (Requesting a search function x2 parents)**	"Is there going to be a search thing on there or anything for specific topics? Just because, how many different categories are there? Are there six different ones you can go into? Just you don't always know which one you want to be going into…" "I'm a little bit unclear on what this means. This box…Yes. I think maybe the wording needs to change…I don't know if what's coming is like a full article, and not skipping to sections of it. Or if these are different pages that I'm going to be taken to."	Section was significantly restructured and simplified, traffic lights system was added. This improved functionality and future iterations were reportedly very clear and easy to use. Search function could be added in future iterations and when the website was live.
5	Personal plan section not good enough	"I think I would feel a bit like... Almost underwhelmed by the solution of it."	Plan section has been completely reorganised, later iterations had very positive feedback on this.
5	Unclear how to use the personal plan section - **x8 parents**	"Again, I don't know the plan is for but saying, 'It's useful to have a plan for whatever'… It just says, 'Build a personal plan,' I don't know what for. Then, it tells me about something. I would have thought it's maybe relevant to plan-making. Then, it goes into steps for the plan, but I don't know what I'm planning for."	Changed the navigation and organization of the page significantly to make it easier and clearer to use.
6	Content request	"The relationship-building one, that's between parent and baby, I guess, the bonding moments. One thing that I don't know whether we'll get on to it scrolling through, one thing that, I guess, as a parent, as a dad that I think I found…the bond between you and your partner does take a hit."	Parent wants addition of info on relationship dynamics outside the parent-child dyad. This could be added but is outside the feasibility and scope of the current PhD. Something to consider for future development.

6	Content requested Not enough signposting for dad's, in particular dad's mental health **x2 parents**	"I think, sometimes, again, it doesn't mention… Well, it's 'mums and families' is the name of the link. It's always… I get it. They have obviously gone through a massive physical change. I think dads are forgotten about quite a lot."	Added additional links for dads and LGBTQ+ parents mental health support.
6	Not relatable	"I wouldn't be as bothered about the, 'You are a good parent'… I didn't suffer too much from…from dad guilt. I know that …you can only do your best."	Did not feel the good parent resources were relevant or useful to him. Attempted to recruit more dads to see whether the site could be more appealing to parents of different genders. Added a sentence 'all parents worry they're not good enough' to make it more universally relatable.
6	Not relatable	"So, the bottom bit of this page I would say appeals more to mums. The mental health side of things"	Added more quotes from names with male connotations, added more resources explicitly for fathers mental health. Attempted to increase the number of fathers in the think aloud interviews.
6	Quotes were too short **x2 parents**	"It'd be quite interesting, as well, on these pages to have longer testimonials or a section where people have talked a bit more in detail so you can say, 'Oh, that's more like my story. I relate to that.'"	Different from most parents' responses, but important if these two parents didn't feel it related to them. Added in two longer 'stories'. Interesting both male parents who said this, so I have made the longer stories stereotypically male names.

7	Nothing novel **x 3parents**	One parent felt she already knew most of the information so couldn't imagine herself using the website. Another felt she knew most of the red flags for medical worries. A final one felt she knew most of the strategies on the 'make a plan section.	In other parts of the interviews all the parents reported they thought the website was useful. Other sections had novel content for all of them. No action taken.
8	Wording change needed Content request Possible unintentional consequence Needed validation for formula feeding families **x2 parents**	"I just think, from the get-go, maybe even in that fact is something like 'as long as a baby is fed with milk, it doesn't matter what it is, and love, that's what a baby needs'. The pressure on breastfeeding, I just feel like it's so intense that it can be really…" "Maybe if you can reiterate the fact that there's no such thing as breast is best. It really frustrates me that people believe that women believe they have to breastfeed for their baby to be in the best care."	Added more validation and supportive messages for formula feeding parents

8	Wording change needed Content request Possible unintentional consequence Needs more validation of closeness being hard and holding baby constantly being impossible **x4 parents**	“So yes, I just think there's something in that underlying - just the tone of it that you have choices, because I think that's always what I was trying to find. I was just trying to find some resources that gave me some options… there were times when… I was like, I love my baby, but I don't want him to sleep on me again.” “although you validated and saying, 'Don't feel guilty about spoiling the baby and picking them up,' I would also put in something maybe a bit more validating about, 'But it's going to get overwhelming for anyone. It will get overwhelming. It's okay to put them down for a few minutes if you need to. It's normal to get frustrated” “Maybe, with that one, what might be quite helpful is if it was followed by, 'It's okay to take a break. Leave them somewhere safe and come back.' That way, if somebody had done that, they would instantly be like, 'Okay, it's okay to do it. Just don't think that I'm doing it because they're going to soothe themselves to sleep. What I could do instead is just have a few minutes.'”	Added messaging about self-care and myth emphasising that you don’t have to hold baby 100% of the time to be a good parent.

8	Wording change needed Possible unintentional consequence Could make parents feel guilty.	“my brain was like, oh my gosh, does that mean I'm stressing my baby out?…Then your next thought is, okay, well, maybe I do need to do that….I know that realistically, it's not just me stressing my baby and that's why he's a fussy baby, but it does cross your mind, but then you come back to reality and you're like, you're not the only reason that your baby's crying.”	Discussed how vulnerable parents are to feeling guilty and responsible. Section reworded to ensure it can’t make parents feel more guilty, but while retaining the message.
8	Wording change needed Possible unintentional consequence Could make parents feel guilty for feeding choices.	“it makes me a bit sad because I chose not to breastfeed for my mental health and then he's got reflux because he's - well, not because, but he's formula feeding and he's got really bad reflux. So personally I'm like, aw, bless him. Would it be as bad if he was breastfed? Should I have given it up? Equally, it's good to know that because I didn't know that, but yes, personally it does make me feel like a little bit urgh.”	Wording changed to reduce the risk of parents feeling guilty.
8	Wording change needed Possible unintentional consequence Could make parents feel guilty	“you might feel guilty that you are giving them the reflux medication”	Wording changed to reduce the risk of parents feeling guilty.
8	Wording change needed Possible unintentional consequence Reflux fact felt dismissive **x2 parents**	“that is a fact, but that doesn't mean that your baby might not still be…” “I feel like, when I was in the thick of it, I didn't want someone to tell me it was normal because I just don't think it's normal.”	Considered how the website language across the site can be altered to feel less threatening or dismissive to parents who are convinced of a medical diagnosis. Added link to when is reflux a medical problem, changed language to make it more empathic.

8	Wording change suggested Not relatable	Parent didn't relate to one of the quotes.	Reworded to make more inclusive
8	Wording suggestion Needs more positivity	Parent felt the information on elimination diets was unhelpful because they wanted to change something but it didn't leave them with anything to do or change.	Added statements about us being here to help and links to the make a plan section
8	Wording suggestion Needs more positivity / control	"I wonder if it's 'this toolkit will hopefully' - 'we're here to help' or 'this toolkit will hopefully help you find some answers' type thing."	Added a positive message upfront.
8	Wording suggestion Needs more positivity on first landing page	"something around, like, you're here to help"	Added positive message at the end of the first landing page
8	Wording suggestion Needs more validation	"I'm thinking as well, maybe that it would be nice to have something in there. Just a reference to just what I was saying before that it is normal, but it doesn't mean it's not easy to deal with."	Added some solution focussed info and positivity.
8	Wording suggestion Disliked wording 'normal' **- x2 parents**	I'm not keen on the word normal…I guess it's just that different people can interpret the word normal in different ways, and maybe I guess there is no such thing as normal, like there's no such thing as perfect."	Changed the wording
8	Wording suggestion Disliked wording 'when to worry'	"My first instinct to that, 'Will help you know when to worry.' I'm trying to think how - yes, can a website tell me when to worry about my own baby? Maybe not. I know what it's saying, but maybe it needs rephrasing."	Wording adjusted to be more empathic.

8	Wording suggestion Needed validation and emphasis on control and choice	“So again, I feel like, what would be a really great message through all of this is, like, you have options, and ultimately, you should do what you're comfortable with.”	Added a sentence prefacing the personal plan to the effect 'the ideas suggested here are all safe and will cause no harm. You have options and can pick the ones that appeal to you’.
8	Wording suggestion	“Rather than 'believe' just maybe 'know that you're a good parent'”	Changed the wording to reflect this
8	Wording suggestion - ‘bonding’ may be off-putting	“That's just for me personally because I feel like I've got a great relationship, so I don't think I'd… Maybe when I first started, I found it hard to bond in the first couple of weeks.”	Wording changed to be less sensitive.
8	Wording suggestion - Language use	“I suppose I'm even reading it from a mental health point of view or something. Just when I read the whole thing, I felt that I was like, oh right, it's maybe around the crying mostly and that's why I was just wondering if that bit needed to go first.”	Softened the tone and wording.
9	Possible unintentional consequence Disliked wording ‘good parent’ -**x2 parents**	I'm not so keen on when it says, 'You're a good parent,' for the same kind of reasons…Because what justifies, or what makes you a good or a not-good parent? We've all got different ways of doing things… I think the only time I would call someone a bad parent is if they're abusing their child. Like if they're hitting, or if they're doing terrible things like that.” “Parents spend a lot of time feeling not good. I don't really want to take a test to tell me I'm good or I'm not good”	Wording changed

9	Possible unintentional consequence Information could be frustrating for parents.	“All that cheese my wife has been missing out on, she wouldn't be very happy reading this.”	Discussed with supervisors and observed that this is an uncomfortable topic and so if discussing hard things or challenging beliefs is difficult for parents then that is ok; it may be evidence of a positive attitude change according to the goals of the intervention. However, we need to maintain positivity and ensure that parents leave feeling empowered and better than they did before they arrived. Changes made to ensure positivity messages are prominent as well as ‘what to do instead’ options and links.

9	Possible unintentional consequence Parent appeared upset with healthcare professionals who had given her inaccurate advice. Introduced the concern that with conflicting information this could cause harm by damaging the relationship between parent and professional **x2 parents**	"It's different from what they tell you as well. I'm like, because you trust when you go to the doctors with your baby or something, that what they're saying is right…because if it doesn't actually make a difference, why are they making us do all this and feel really bad? It will make you feel like it's your fault…because you're the one that's feeding them. …Why don't they know any of this? Why aren't they told about this…instead of going, oh, that baby's got an allergy, here you go, have some formula that's £38 a tin to have instead? That's costing more money than actually reading up about stuff. So, I could eat chocolate. They'd be like, 'You can't eat chocolate.' Well, I want to eat chocolate. That's what I want to do. You can't take that away from me. I feel like they're just pushing stuff aside and going, oh, it's this, here, do this instead. It's not working because if someone had have read that, they'd have gone, actually it's very contradicting information. The science is obviously out there, it's proven, so why aren't they using it too?" "I've had lots of very questionable advice from my particular doctor's surgery…It was all old wives' tales and rubbish, so the fact that that's [elimination diets information] actually backed up by science, that's news to me."	In this case, this was resolved in the post interview debrief with an explanation of research dissemination and changes to practice. For future parents, it will be important to ensure the intervention is not used in isolation but rather as part of an embedded systems approach including a healthcare professional intervention as well. Consideration for the dark logic model.

9	Possible unintentional consequence Parent seems to be considering reflux for her baby when reading the website.	“My daughter is quite sicky even quite long after feeds. I’m reading is it reflux, maybe it could be reflux. It doesn’t seem to bother her that much, but then at the same time, she doesn’t like to be laid down, she likes to be sat up. She prefers to be sat up. I don’t know whether it’s more comfortable for her or whether she just likes to see what’s going on, I don’t know.”	Parent doesn’t appear worried about the reflux or keen to change anything. Did not then try to read about medication. No change therefore necessary. Considered for inclusion in dark logic model.
9	Possible unintentional consequence Emotive topic	“because some of this, it's like - it just hits home a bit, doesn't it? So sorry if I'm crying!”	Considered whether this was a reflection of harm. Discussed with supervisors and agreed this is an emotive topic. With any successful intervention Parents may find thinking and talking about it distressing. Considered possible contribution of a dark logic model. Many of PPI contributors, other stakeholders and professionals who have seen the videos have had similar reactions. Agreed it is a reflection of the effectiveness and relatable nature of the resources.
9	Possible unintentional consequence Parent went away feeling confused rather than empowered	“I have had some feeding support, but she's not always settled…It makes me question, oh, maybe I should get another opinion, I don't know.”	Added empowering messaging, positivity and clearer messaging about the 3 key elements of the site – when to worry, you are a good parent and make a plan. Landing pages added to orient the information in context of making a plan of something to help.

Appendix N Published paper

Journal of Advanced Nursing

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REVIEW

Open Access

- **'Either something's wrong, or I'm a terrible parent': A systematic review of parent experiences of illness-related interpretations for unsettled babies**

Amy Dobson, Samantha Hornsey, Daniela Ghio, Susan Latter, Miriam Santer, Ingrid Muller

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Sections

PDF PDF

Tools

Share

- **Abstract**
- Aims

To explore parents' experiences of unsettled babies and medical labels.

- Design

Qualitative systematic review, thematic synthesis and development of a conceptual model.

- Review Methods

Systematic review and thematic synthesis of primary, qualitative research into parents' experiences of unsettled babies <12 months of age. 'Unsettled' was defined as perception of excessive crying with additional feature(s) such as vomiting, skin or stool problems. The Critical Appraisal Skills Programme (CASP) checklist was used to assess trustworthiness.

- Data Sources

Structured searches completed in CINAHL, Medline, Embase, PsychINFO and CochraneCT on 23 March 2022 and rerun on 14 April 2023.

- Results

Ten eligible studies were included across eight countries contributing data from 103 mothers and 24 fathers. Two analytical themes and eight descriptive themes were developed.

Firstly, parents expressed fearing judgement, feeling guilty and out of control as a result of babies' unsettled symptoms and seeking strategies to construct an *'Identity as a "Good Parent"'*.

This desire for positive parenting identity underpinned the second analytical theme *'Searching for an explanation'* which included seeking external (medical) causes for babies' unsettled behaviours.

- Conclusion

Parents can become trapped in a cycle of 'searching for an explanation' for their baby's unsettled behaviours, experiencing considerable distress which is exacerbated by feelings of guilt and failure.

- Impact and Implications for Patient Care

Insight gained from this review could inform interventions to support parents, reducing inaccurate medicalization.

Health visiting teams supporting parents with unsettled baby behaviour could focus on supporting a positive parenting identity by managing expectations, normalizing the continuum of infant behaviours, reducing feelings of guilt or uncertainty and helping parents regain a feeling of control.

- Reporting Method

ENTREQ guidelines were adhered to in the reporting of this review.

- Patient or Public Contribution

Parent input was crucial in the design phase; shaping the language used (e.g., ‘unsettled babies’) and in the analysis sense-checking findings.

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