**Title: Development and evaluation of digital interventions for hypertension and asthma in primary care: The DIPSS research programme including 2 RCTs**

**Keywords:** digital intervention; asthma; respiratory; hypertension; blood pressure; primary health care; mixed-methods; person-based approach; self-management; adult; quality of life.

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**Abstract:**

**Background:** Digital interventions (DIs) offer a potentially cost-effective means to support patient self-management in primary care, but evidence for the feasibility, acceptability, and cost-effectiveness of DIs remains mixed. This programme focused on the potential for self-management DIs to improve outcomes in two common, contrasting conditions (hypertension and asthma) where care is currently sub-optimal, leading to excess deaths, illness, disability, and costs for the NHS.

**Objective(s)**: The overall purpose was to address the question of how DIs can best provide cost-effective support for patient self-management in primary care. Our aims were to develop and trial DIs to support patient self-management of hypertension and asthma. Through the process of planning, developing, and evaluating these interventions we also aimed to generate a better understanding of what features and methods for implementing DIs could make them acceptable, feasible, effective, and cost-effective to integrate into primary care.

**Design:** Hypertension strand: Systematic reviews of quantitative and qualitative evidence, intervention planning, development, and optimisation, unmasked randomised controlled trial (RCT) comparing DI with usual care, with a health economic analysis, and nested process evaluation.

Asthma strand: Systematic review of quantitative evidence, intervention planning, development, and optimisation, and feasibility RCT comparing DI with usual care, with nested process evaluation.

**Setting**: General practices (76 hypertension; 7 asthma) across Wessex and Thames Valley regions in Southern England.

**Participants:** People with uncontrolled hypertension taking 1-3 antihypertensive medications; adults with asthma and impaired asthma-related quality of life.

**Interventions:**

HOME BP: A DI including motivational training for patients to self-monitor blood pressure (BP) and healthcare professionals to support self-management; a digital interface to send monthly readings to the healthcare professional and to prompt planned medication changes when patients’ readings exceeded recommended targets for two consecutive months; and support for optional patient healthy behaviour change (healthy diet/weight loss, increased physical activity, reduced alcohol and salt consumption). The control group were provided with the Blood Pressure UK leaflet for hypertension and received routine hypertension care.

My Breathing Matters: A DI to improve the functional quality of life of primary care patients with asthma by supporting illness self-management. Motivational content intended to facilitate use of pharmacological (medication adherence, appropriate health care service use) and non-pharmacological (breathing retraining, stress reduction, healthy behaviour change) self-management strategies. The control group were given the Asthma UK information booklet on asthma self-management and received routine asthma care.

**Main outcome measures:** The primary outcome for the hypertension RCT was difference between intervention and usual care groups in mean systolic BP (mmHg) at 12-months, adjusted for baseline BP, BP target (standard, diabetic or aged over 80), age, and General Practitioner (GP) practice. The primary outcome for the asthma feasibility study was the feasibility of the trial design, including recruitment, adherence, intervention engagement, and retention at follow-up. Healthcare utilisation data were collected via notes review. **Review methods**: The quantitative reviews included a meta-analysis. The qualitative review comprised a meta-ethnography.

**Results:** 622 hypertensive patients were recruited to the RCT, and 552 (89 per cent) were followed-up at 12-months. Systolic BP was significantly lower in the intervention group at 12-months with a difference of -3.53 mmHg (-6.19, -0.86). This gave an incremental cost per unit of systolic BP reduction of £11 (95% CI £5 to £29). Long-term modelling puts the incremental cost per QALY at just over £9k. due to a cost difference of £402, and a QALY difference of 0.044. The probability of being cost effective was 66% at willingness to pay of £20k per QALY and higher at higher thresholds. 88 patients were recruited to the asthma feasibility trial (target 80; 44 in each arm). At 3-month follow-up, two patients withdrew and six did not complete outcome measures. At 12 months, two withdrew and four did not complete outcome measures. 36/44 patients in the intervention group engaged with My Breathing Matters (median of four logins, range 0-25).

**Limitations:** Although the interventions were designed to be as accessible as was feasible, most trial participants were white and those of lower socioeconomic status were less likely to take part and complete follow-up measures. Challenges remain in terms of integrating digital interventions with clinical records.

**Conclusions**: A DI using self-monitored BP to inform medication titration led to significantly lower BP than usual care. The observed reduction in BP would be expected to lead to a reduction of 10-15 per cent in patients suffering a stroke. The feasibility trial of My Breathing Matters suggests that a fully powered RCT study of the intervention is warranted. The theory-, evidence- and person-based approach to intervention development refined through this programme enabled us to identify and address important contextual barriers to and facilitators of engagement with the interventions.

**Future work:** This research justifies consideration of further implementation of the hypertension intervention, a fully powered RCT of the asthma intervention, and wide dissemination of our methods for intervention development. Our interventions can also be adapted for a range of other health conditions.

**Study registration**: ISRCTN13790648 (hypertension); ISRCTN15698435 (asthma); PROSPERO CRD42013004773 (hypertension review) CRD42014013455 (asthma review).

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Table of Contents

[List of tables 10](#_Toc98942017)

[List of figures 12](#_Toc98942018)

[List of supplementary material 12](#_Toc98942019)

[List of boxes 12](#_Toc98942020)

[List of abbreviations 13](#_Toc98942021)

[Plain English summary 14](#_Toc98942022)

[Scientific summary 15](#_Toc98942023)

[Aims, overview and context of research programme 23](#_Toc98942024)

[Summary of aims and rationale 23](#_Toc98942025)

[Summary of research 24](#_Toc98942026)

[Changes to the digital, clinical and research context since the research programme commenced 26](#_Toc98942027)

[Changes to the digital context 26](#_Toc98942028)

[Changes to the clinical context 28](#_Toc98942029)

[Changes to the research context 29](#_Toc98942030)

[Development of HOME BP 30](#_Toc98942031)

[Introduction 31](#_Toc98942032)

[Intervention development team and patient and public involvement (PPI) 31](#_Toc98942033)

[Objectives 32](#_Toc98942034)

[Phase 1: Collating evidence from primary mixed methods research, and evidence from quantitative and qualitative reviews of the literature 33](#_Toc98942035)

[Collating evidence from a previous primary mixed methods research study (described in28) 33](#_Toc98942036)

[A systematic review and meta-analysis of the quantitative evidence for digital interventions for hypertension (described in26) 34](#_Toc98942037)

[Identification of barriers and facilitators from the qualitative literature (described in27) 36](#_Toc98942038)

[Phase 2: Behavioural analysis: identifying facilitators and barriers, and how to address them (described in28). 38](#_Toc98942039)

[Phase 3: Intervention development and optimisation alongside developing guiding principles 39](#_Toc98942040)

[Qualitative research: think-aloud interviews and retrospective interviews with patients (described in 29) 39](#_Toc98942041)

[Qualitative research: focus groups with healthcare professionals (described in 30) 42](#_Toc98942042)

[Guiding principles (described in 28) 44](#_Toc98942043)

[Phase 4: Mapping facilitators and barriers on to theory (described in 28) 45](#_Toc98942044)

[2.8 Mapping the HOME BP planning and development process to the INDEX actions 47](#_Toc98942045)

[Evaluation of HOME BP 57](#_Toc98942046)

[Objectives 57](#_Toc98942047)

[Randomised controlled trial to assess clinical and cost effectiveness 58](#_Toc98942048)

[Process evaluation exploring how patients and healthcare professionals experienced and implemented the intervention in practice 66](#_Toc98942049)

[Patient qualitative process study: perceived benefits and burdens of using the intervention for patients 66](#_Toc98942050)

[Patient quantitative process study: engagement and usage of the HOME BP intervention by patients 68](#_Toc98942051)

[Healthcare professionals mixed methods process study: exploration of healthcare professionals’ experiences of and adherence to using the intervention 71](#_Toc98942052)

[Conclusions 74](#_Toc98942053)

[Development of My Breathing Matters 76](#_Toc98942054)

[Objectives 76](#_Toc98942055)

[Intervention development team and PPI 77](#_Toc98942056)

[Phase 1: collate and synthesise evidence 77](#_Toc98942057)

[Systematic review and meta-analysis of interactive digital interventions to promote self-management in adults with asthma (described in 58) 77](#_Toc98942058)

[Meta-ethnography review of published qualitative studies on digital interventions for self-management of chronic physical conditions (described in27) 79](#_Toc98942059)

[Primary mixed-methods research 80](#_Toc98942060)

[Phase 2: creation of an intervention plan. 83](#_Toc98942061)

[Guiding principles 83](#_Toc98942062)

[Behavioural analysis 84](#_Toc98942063)

[Phase 3: creating and optimising the intervention. 85](#_Toc98942064)

[Phase 4: mapping the evidence onto behavioural barriers and intervention components onto theory 87](#_Toc98942065)

[Mapping the My Breathing Matters intervention development process to the INDEX actions 90](#_Toc98942066)

[Conclusion 98](#_Toc98942067)

[Evaluation of My Breathing Matters 99](#_Toc98942068)

[Aims and objectives 99](#_Toc98942069)

[Feasibility randomised controlled trial to assess feasibility of trial procedures and data analysis. 99](#_Toc98942070)

[Mixed methods process evaluation exploring the acceptability of My Breathing Matters 104](#_Toc98942071)

[Conclusion 106](#_Toc98942072)

[Conclusions 107](#_Toc98942073)

[Objectives 107](#_Toc98942074)

[Implications of our findings for future digital health intervention research 108](#_Toc98942075)

[Reflections on what was learned from the intervention development process 108](#_Toc98942076)

[Implications of our findings for integrating digital interventions for hypertension and asthma into primary care 111](#_Toc98942077)

[Implications of our findings for future research and practice in hypertension 111](#_Toc98942078)

[Implications of our findings for future research and practice in asthma 113](#_Toc98942079)

[The contribution of patient and public involvement 114](#_Toc98942080)

[Strengths and limitations 118](#_Toc98942081)

[Strengths 118](#_Toc98942082)

[Limitations 118](#_Toc98942083)

[Summary and recommendations for future research 119](#_Toc98942084)

[Recommendations for future research 120](#_Toc98942085)

[Implications for healthcare 121](#_Toc98942086)

[Acknowledgements 121](#_Toc98942087)

[Contributions of authors 121](#_Toc98942088)

[Funding 123](#_Toc98942089)

[Publications 123](#_Toc98942090)

[Data sharing statement 125](#_Toc98942091)

[Patient data 125](#_Toc98942092)

[References 126](#_Toc98942093)

[Appendices 133](#_Toc98942094)

[Appendix 1: TIDieR report of the HOME BP intervention 133](#_Toc98942095)

[Appendix 2. Health economic evaluation 142](#_Toc98942096)

[Appendix 3. Predictors of systolic blood pressure at 12 months, and engagement with self-reporting blood pressure readings 167](#_Toc98942097)

[Predictors of systolic BP at 12 months 167](#_Toc98942098)

[Predictors of number of BP entries 168](#_Toc98942099)

[Appendix 4: Behaviour change constructs and techniques in My Breathing Matters 169](#_Toc98942100)

[Appendix 5. TIDieR report of the My Breathing Matters intervention 180](#_Toc98942101)

# List of tables

[Table 1 List of barriers to implementation at the practice or health care professional, and patient level arising from the feasibility study and optimisation solutions actioned in HOME BP to overcome these 34](#_Toc98942102)

[Table 2 HOME BP intervention planning and development actions mapped to INDEX guidance actions 48](#_Toc98942103)

[Table 3 Baseline characteristics of HOME BP participants. 62](#_Toc98942104)

[Table 4 Mean blood pressure at baseline, 6 months and 12 months 63](#_Toc98942105)

[Table 5 NHS cost, Primary Outcome, QALY and Incremental cost effectiveness, mean per patient based on differences observed between the Usual Care and the Intervention arms 64](#_Toc98942106)

[Table 6 Mean cost per patient in primary care by arm in primary care, disaggregated by consultations and prescription costs 65](#_Toc98942107)

[Table 7 Base case results for Home BP versus Usual Care, base case, over patients’ lifetime 66](#_Toc98942108)

[Table 8 Demographic characteristics of participants in the qualitative process study. 68](#_Toc98942109)

[Table 9 Key issue identified in the primary mixed-methods research and intervention features included in My Breathing Matters to address these. 82](#_Toc98942110)

[Table 10 My Breathing Matters intervention development actions mapped to INDEX guidance actions 91](#_Toc98942111)

[Table 11 Baseline demographic characteristics of My Breathing Matters study population per group 102](#_Toc98942112)

[Table 12 Mean Mini AQLQ and ACQ scores, and percentage of patients achieving a Minimal Clinically Important Difference at baseline, 3 months, and 12 months 104](#_Toc98942113)

[Table 13 Resource use headings, data and costing approach 144](#_Toc98942114)

[Table 14 Unit costs for primary care contacts, by GP, Practice Nurse (PN) and Health Care Assistant (HCA), by F2F and Telephone 147](#_Toc98942115)

[Table 15 Inpatient admissions related to BP 148](#_Toc98942116)

[Table 16 A&E attendances related to BP, by type 150](#_Toc98942117)

[Table 17 Unit costs for inpatient, outpatient and A&E, 2017/18. NHS National Tariff 150](#_Toc98942118)

[Table 18 Cost of intervention in Home BP, different methods 153](#_Toc98942119)

[Table 19 Mean EQ5D scores over 12 months in each group based on complete data 154](#_Toc98942120)

[Table 20 NHS cost, Primary Outcome, QALY and Incremental cost effectiveness, mean per patient based on differences observed between the Usual Care and the Intervention arms 155](#_Toc98942121)

[Table 21 Mean primary care cost per patient by arm in primary care, disaggregated by , consultations and prescription costs 156](#_Toc98942122)

[Table 22 Base case results for Home BP versus Usual Care, base case, over patients’ lifetime 159](#_Toc98942123)

[Table 23 Effect of different initial cost differences on the incremental cost effectiveness ratio (ICER) 162](#_Toc98942124)

[Table 24 Base-case – events by arm as predicted in the long-term model. Based on model run of 50,000 individuals 163](#_Toc98942125)

[Table 25 Differences in Blood Pressure and cost inputs and outputs in Tasminh4 and HomeBP from long-term model 164](#_Toc98942126)

[Table 26 Model using number of BP entries to predict systolic BP at 12 months 168](#_Toc98942127)

[Table 27 Model using number of recommended changes to predict systolic BP at 12 months 168](#_Toc98942128)

[Table 28 Model using baseline medication necessity beliefs to predict systolic BP at 12 months 168](#_Toc98942129)

[Table 29 Model using baseline medication adherence (MARS) to predict number of BP entries 169](#_Toc98942130)

[Table 30 Model using baseline medication concerns to predict number of BP entries 169](#_Toc98942131)

[Table 31 Model using baseline medication perceived necessity to predict number of BP entries 169](#_Toc98942132)

[Table 32 Behaviour change constructs and techniques in My Breathing Matters 170](#_Toc98942133)

[Table 33 TIDieR report of the My Breathing Matters intervention 181](#_Toc98942134)

# List of figures

[Figure 1 Research pathway diagram for DIPSS 26](#_Toc98942135)

[Figure 2 Flow of participants through HOME BP trial 62](#_Toc98942136)

[Figure 3 Distribution of average systolic BP readings in cases where the recommendation for a medication change was not adhered to 74](#_Toc98942137)

[Figure 4 Logic Model of My Breathing Matters intervention to improve quality of life in patients with asthma. 90](file:///\\soton.ac.uk\resource\Psychology%20Research\Public\DIPSS\DIPSS%20docs\End%20of%20project%20report\Final%20report\FINAL\RP-PG-1211-20001%20Final%20report%20revised%20v6.docx#_Toc98942138)

[Figure 5 CONSORT flow diagram for My Breathing Matters feasibility trial 103](file:///\\soton.ac.uk\resource\Psychology%20Research\Public\DIPSS\DIPSS%20docs\End%20of%20project%20report\Final%20report\FINAL\RP-PG-1211-20001%20Final%20report%20revised%20v6.docx#_Toc98942139)

[Figure 6 HOME BP intervention procedures 138](file:///\\soton.ac.uk\resource\Psychology%20Research\Public\DIPSS\DIPSS%20docs\End%20of%20project%20report\Final%20report\FINAL\RP-PG-1211-20001%20Final%20report%20revised%20v6.docx#_Toc98942140)

[Figure 7 Scatterplot of joint distribution of incremental mean cost from NHS perspective and mean blood pressure reduction from baseline (mmg) over 12 months 157](#_Toc98942141)

[Figure 8 Cost effectiveness acceptability curve of the intervention and usual care groups based on blood pressure from baseline over 12 months. 158](#_Toc98942142)

[Figure 9 Scattergram of repeated runs of long term model 160](#_Toc98942143)

[Figure 10 Cost effectiveness acceptability curve of long term cost per QALY 161](#_Toc98942144)

# List of supplementary material

Report supplementary material 1: CHEERS checklist

Report supplementary material 2: List of dissemination events

Report supplementary material 3: Withdrawal letter before and after patient and public involvement input

# List of boxes

[Box 1 Specific examples of PPI contributions to HOME BP from Cathy Rice 117](#_Toc98942145)

[Box 2 Reflections from Cathy Rice on her public contributor role in HOME BP 118](#_Toc98942146)

# List of abbreviations

|  |  |
| --- | --- |
| ACQ | Asthma Control Questionnaire |
| BCT | Behaviour Change Technique |
| BCW | Behaviour Change Wheel |
| BMQ | Beliefs about Medication Questionnaire |
| BREATHE | Breathing Retraining for Asthma – a Trial of Home Exercises |
| CARE | Congratulate, Ask, Reassure, Encourage |
| DI | Digital Intervention |
| DIPSS | Integrating Digital Interventions into Patient Self-Management Support |
| GP | General Practitioner |
| HCP | Healthcare Professional |
| INDEX | IdentifyiNg and assessing different approaches to DEveloping compleX interventions |
| MARS | Medication Adherence Scale |
| Mini AQLQ | Mini Asthma Quality of Life Questionnaire |
| NICE | National Institute for Health and Care Excellence |
| NPT | Normalization Process Theory |
| PBA | Person-Based Approach |
| PETS | Problematic Experience of Therapies Scale |
| PPI | Patient and Public Involvement |
| RAISIN | The Randomised trial of an Asthma Internet Self-management InterventioN |
| RCT | Randomised Controlled Trial |
| TASMINH2 | Telemonitoring and Self-Management in the Control of Hypertension |
| TASMIN-SR | Targets and Self-Management for the Control of Blood Pressure in Stroke and at Risk Groups |
| TASMIN5S | Towards An Integrated Self-Monitoring SolutIoN for Stroke/TIA |
| TIDieR | Template for Intervention Description and Replication |
| WS | Workstream |

# Plain English summary

Long-term conditions can be difficult and costly to manage. Online interventions (e.g. websites) can support people to look after their health at home, but we need to understand how to make these interventions acceptable and effective.

We carried out a review of existing research, which showed that digital interventions could lower blood pressure and improve asthma symptoms, but the evidence was varied in terms of how well the interventions worked. We also developed and evaluated two online interventions; one for high blood pressure and one for asthma. Detailed feedback from patients and General Practitioners (GPs) helped us to improve the interventions to ensure they were persuasive and easy to understand.

Our hypertension intervention (HOME BP) helped patients to monitor their own blood pressure at home and prompted GPs to change their medication when blood pressure was raised over time. A trial with 622 patients found that patients using HOME BP had lower blood pressure after one year than those patients receiving their usual care. The intervention had a high probability of being cost effective in relation to the criteria used by the NHS.

Our asthma intervention (My Breathing Matters) provided information and support to help patients engage in activities that would help them to better control their asthma. For example, using their medication as prescribed or learning breathing exercises. We carried out a small trial to check whether our research procedures were feasible. We recruited 88 asthma patients (our target was 80) and only a small number of people did not complete questionnaires at all time points. This suggested it would be worthwhile testing the asthma intervention with a larger amount of people.

Interviews with patients and GPs suggested the online interventions were acceptable and useful for helping to manage the condition. This research suggested modifications for improving users’ experiences.

**Word count:** 300/300

# Scientific summary

**Background**

Digital interventions (DIs) can promote patient self-management of long-term conditions, but evidence for how best to optimise their effectiveness and cost effectiveness remains inconclusive.

**Objectives**

This research programme sought to determine the most feasible, acceptable, effective, and cost-effective methods of integrating DIs into primary care to support patient self-management of long-term conditions. Two long-term conditions with different self-management approaches were selected as the focus of this research: hypertension and asthma. The specific research objectives outlined in the original proposal were to:

1. Identify key features associated with maximising feasibility, acceptability (to patients and health professionals), effectiveness, and cost-effectiveness of DIs;
2. Examine the range of delivery and support modes that can be used for DIs and assess their relative feasibility, acceptability (to health professionals and patients), effectiveness, and cost-effectiveness;
3. Optimise interventions for hypertension and asthma and carry out feasibility studies in preparation for full randomised controlled trials (RCT);
4. Undertake a RCT of a DI for hypertension to determine the effectiveness and cost-effectiveness of integrating it into routine care.

**Hypertension: Intervention planning and development**

Objectives:

1. To review qualitative and quantitative evidence relating to self-management DIs in the context of hypertension.
2. To identify behavioural barriers and facilitators from the evidence.
3. To optimise a prototype DI using in-depth qualitative research with patients and healthcare professionals (HCPs).
4. To map intervention components to behaviour change theory.

Methods:

The intervention development team included patient and public involvement (PPI) contributors, clinicians, behaviour change experts, and representatives of the charity Blood Pressure UK.

The hypertension intervention planning and development provided one of the first examples of the widely used person-based approach, which emphasises understanding and addressing the population’s needs and beliefs about the target behaviours, as well as drawing on evidence and theory.

A systematic review and meta-analysis of quantitative research on the effectiveness of digital interventions for hypertension was conducted to evaluate mean change in systolic and diastolic blood pressure (BP). A meta-ethnography of qualitative studies explored patients’ and HCPs’ experiences of using DIs for self-management of long-term conditions. Facilitators and barriers to each target behaviour were extracted from the evidence and tabulated. Intervention components were identified to promote facilitators and overcome barriers. This intervention planning informed the development of a web-based intervention incorporating patient training, an entry system for home BP readings, and an HCP training module.

Think-aloud interviews with 12 hypertensive patients and focus groups with 55 HCPs explored perceptions of the prototype intervention. 11 patients were interviewed after using the intervention to explore barriers in a real-life setting. Iterative analysis of the transcripts identified beliefs which could interfere with the target behaviours. Guiding principles were developed which described the key behavioural challenges for this population and outlined key design features of the intervention to address these.

The intervention components were mapped on to the behaviour change wheel, and implementation mechanisms from Normalization Process Theory (NPT). A logic model was developed to propose how the intervention was theorised to change behaviour.

Results

The meta-analysis of 8 studies found a weighted mean difference of -3.74 mmHg in systolic BP for patients using interactive DIs for hypertension. There were too few studies to understand why some interventions were more effective than others. The meta-ethnography synthesised 30 qualitative studies and suggested that self-monitoring was a powerful mechanism for changing behaviour but that feedback messages needed to emphasise patients’ responsibility to act rather than increasing HCP burden. Behavioural analysis identified four target patient behaviours (engaging with the online intervention, self-monitoring BP, adhering to medication changes, and healthy behaviour change), and three target HCP behaviours (engaging with the online intervention, changing medication when recommended, and providing behavioural support to patients).

Qualitative research identified modifications to the intervention to address barriers, such as a practice week to increase patients’ and HCPs’ confidence in home BP readings. Mapping the intervention components to theoretical constructs provided a description of the intervention. The logic model showed the intervention components were theorised to increase self-efficacy and outcome expectancies, in line with Social Cognitive Theory.

**Hypertension intervention: Intervention evaluation**

Objectives:

1. To conduct a RCT to assess clinical and cost effectiveness of the hypertension DI.
2. To conduct process evaluation studies to explore patients’ and HCPs’ adherence to target behaviours and experiences of the hypertension DI.

Methods:

RCT:

An internal pilot trial was conducted, which ran directly into the main RCT as no changes were required. Patients with uncontrolled hypertension (>140/90 mmHg) taking 1-3 antihypertensive medications were randomised (*n =* 622) from 76 GP Practices across Wessex and Thames Valley regions in Southern England. Patients in the intervention group completed two online motivational training sessions, took 7 days of BP readings once a month, and entered these online. HCPs received email prompts when planned medication changes were needed according to an algorithm based on national BP targets. Optional healthy behaviour change support was available via the DI. The primary outcome was difference in systolic BP at 12 months between the groups, controlling for baseline factors and using multiple imputation for missing values. The control group were provided with the Blood Pressure UK leaflet for hypertension and received routine hypertension care. Patients’ medical records were reviewed to record changes in antihypertensive drug prescriptions and healthcare appointments during the trial, for the economic analysis.

General linear modelling compared systolic BP between groups at 12-months, adjusting for baseline blood pressure, practice, blood pressure targets, and sex.

Process analysis:

Usage data were recorded automatically by the DI, and self-report questionnaires were completed by patients and HCPs. Semi-structured telephone interviews were conducted with 28 intervention group patients, 7 usual care patients, and 27 HCPs. Thematic analysis explored how patients appraised the benefits or burdens of the DI, and regression analyses identified factors predicting patient engagement. A mixed-methods approach triangulated the HCP qualitative and quantitative findings.

Results:

Systolic BP was significantly lower at 12 months in the intervention group (-3.53 (-6.19, -0.86) / -0.55 (-1.89, 0.80) mmHg). There were significantly more increases to antihypertensive medication in the intervention group, both in terms of dose increases (relative risk 2.03 (1.54, 2.69)) and new drugs added (1.46 (1.12, 1.91)). Cost-effectiveness analysis showed that the incremental cost per unit of systolic BP reduction was £11 (95% CI 5-29). Long-term modelling puts the incremental cost per QALY at just over £9k due to a cost difference of £402, and a QALY difference of 0.044. The probability of being cost effective was 66 per cent at willingness to pay of £20k per QALY and higher at higher thresholds.

The findings of the process evaluation included:

* Patients appraised the value of the DI in terms of perceived benefits (such as reassurance and improved health) and burdens (such as worry about health). Illness and treatment perceptions about hypertension appeared to influence perception of benefit or burden.
* Patient engagement was high with 70 per cent of the sample continuing to enter BP readings in the final quarter of the 12-month trial. However only 29 per cent of patients registered online for healthy behaviour change support. Engagement with entering BP readings was predicted by self-reported medication adherence and perceived necessity and concerns at baseline.
* HCPs implemented 53 per cent of recommended medication changes. HCPs were less likely to implement medication changes when systolic BP was closer to the threshold, and when the patient had already been recommended a medication change. The qualitative analysis indicated a more general reluctance amongst some HCPs to change medication, with concerns about a lack of context and a preference for recommending healthy behaviour change.

**Asthma intervention: Intervention planning and development**

Objectives:

1. To collate and synthesise quantitative and qualitative evidence relating to DIs for asthma self-management.
2. To create an intervention plan, which involved developing guiding principles and carrying out behavioural analysis to identify barriers to key behaviours and specify how these will be addressed.
3. To create an intervention prototype and use iterative qualitative interviews to optimise the intervention.
4. To map the evidence onto behavioural barriers and intervention components onto theory.

Methods:

The development process was guided throughout by a multidisciplinary intervention development team that included patient and public involvement (PPI) contributors and representatives of Asthma UK, a key stakeholder organisation. A systematic review of quantitative studies assessing the effects of interactive DIs (compared to usual care) to support self-management of asthma in adults was carried out. Two published primary mixed methods studies of DIs for asthma helped identify effective intervention components to be included in My Breathing Matters. 34 think-aloud interviews with 14 adults with asthma and 12 semi-structured telephone interviews with adults with asthma who used the intervention for 2 weeks were carried out. The other methods are the same as those described for the development of HOME BP.

Results:

The systematic review provided some support for the potential efficacy of a DI for adults with asthma for improving asthma-related quality of life and asthma control. A DI was developed (My Breathing Matters) to improve functional quality of life in primary care patients with asthma by supporting illness self-management. Motivational content intended to facilitate use of pharmacological (medication adherence, appropriate health care service use) and non-pharmacological (breathing retraining, stress reduction, healthy behaviour change) self-management strategies.Guiding principles identified important considerations for the intervention design, including the need to engage people who do not view themselves as having active asthma (e.g. by demonstrating that impaired quality of life can be improved) and encouraging users to employ non-pharmacological methods of improving quality of life (e.g. by educating users on the benefits of breathing retraining). The behavioural analysis identified five target behaviours relating to the intervention’s pharmacological (e.g. preventer medication adherence, engagement with a personal asthma action plan) and non-pharmacological (e.g. engagement with breathing retraining and cognitive behavioural stress management practice) components. Qualitative interviews showed that participants found the website acceptable and easy to navigate and understand. Several issues affecting acceptability of the intervention were identified, and the findings were used to optimise the intervention.

**Asthma intervention: Intervention evaluation**

Objectives:

1. To assess the feasibility of trial procedures and data analysis to inform a phase three RCT.
2. To explore the acceptability of My Breathing Matters, including how patients experienced and used the intervention.

Methods:

Using a feasibility RCT design, adults in primary care with impaired asthma-specific quality of life were randomised to usual care or the intervention group who accessed My Breathing Matters. The usual care group received routine asthma care the Asthma UK information booklet on asthma self-management. Participants completed outcome measures, including asthma-specific quality of life (Mini Asthma Quality of Life Questionnaire; Mini AQLQ) and asthma control (Asthma Control Questionnaire; ACQ), at baseline, 3 months, and 12 months. Healthcare utilisation data (e.g. medication use) were collected via retrospective notes review. Intervention usage data were collected for intervention participants over the 12-month study period. A Satisfaction Questionnaire was administered to those who used the intervention (*n =* 36) at 12-month follow-up. Retrospective telephone interviews were carried out with 18 intervention participants at 3 month follow-up to explore intervention participants’ views and experiences of using the intervention. Qualitative data were analysed using inductive thematic analysis.

Results:

88 participants were recruited (target 80) from seven GP practices from Wessex. Follow-up data were gathered from 91 per cent of patients at 3 and 12-months. 4 patients formally withdrew from the study and four did not complete 12-month follow up questionnaires. Notes reviews completed by the practice varied substantially in quality and data quality were insufficient for a health economic analysis.

82 per cent (*n =* 36) of intervention participants logged in at least once (Median logins = 4; Interquartile Range = 8). 86 per cent (*n =* 31) indicated that they gained benefit from using the intervention and 78 per cent (*n =* 28) reported there were no, or very little, disadvantages to using it. 78 per cent (*n =* 28) rated that they would recommend My Breathing Matters to friends and family.

Overall, interview participants expressed positive views of the intervention and found the content easy to understand and the website easy to use. Users reported several benefits from taking part in the intervention including improvements in their asthma symptoms (e.g. reduced coughing and breathlessness); medication use (improved medication adherence, correct use of their inhalers, reduction in reliever inhaler use); and breathing awareness, technique, and posture. Interviews highlighted minor improvements to the intervention design and factors that influenced users’ engagement with the intervention (e.g. participants’ perceptions of their asthma control and current self-management practices).

**Conclusions**

Implications for healthcare: The HOME BP trial findings suggest that the use of digital support to help patients self-manage their hypertension is not only effective but also cost-effective by NHS standards, and both feasible and acceptable for clinicians and patients. The hypertension DI could offer a feasible system for further implementation in primary care and could potentially make a worthwhile impact on the reduction of cardiovascular risk. My Breathing Matters appeared feasible, and the feasibility trial findings suggest that there is potential for a benefit in asthma patient reported outcomes of an order of magnitude within the range of that seen from commonly used pharmacological treatments.

Recommendations for research: A fully powered RCT should be carried out to assess clinical and cost effectiveness of My Breathing Matters. For HOME BP, more comprehensive modelling of the long-term effects of blood pressure reduction is recommended.

Limitations: Compared with the wider patient population, recruited participants were generally white (both conditions), older (asthma), highly educated (asthma) and there was a bias towards higher socio-economic status amongst participants (hypertension). Issues with integrating digital interventions with existing clinical records systems could restrict the potential for wider implementation. Although our researchers and statisticians were blind to group allocation, participants in both RCTs were not blinded. The digital aspects of the HOME BP intervention were challenging to cost accurately.

This research programme has begun to influence future clinical research and practice through further implementation. The intervention development approach used in this programme of research involved combining theory-, evidence- and person-based approaches, and was found to be successful in facilitating the identification of important contextual barriers and optimisation of the intervention. Dissemination of this process is underway.

**Study registration**

ISRCTN13790648 (hypertension; Registered 14 May 2015); ISRCTN15698435 (asthma; Registered 11 March 2019).

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**Word count:** 2400/2400

# Aims, overview and context of research programme

## Summary of aims and rationale

The overall purpose of the DIPSS (Integrating Digital Interventions into Patient Self-Management Support) programme was to address the question of how digital interventions (DIs) can be used to provide cost-effective support for patient self-management of long-term conditions in primary care. To address this question we chose to focus specifically on improving management and consequently outcomes for two common, contrasting long-term conditions (hypertension and asthma). We chose contrasting clinical conditions to allow comparison of patients from different age groups, with very different patterns of symptoms and different self-management regimes. This would enable us to consider which findings were specific to one condition and which might be more common across different conditions or management regimes. The proposed project team brought together: a) researchers with leading international expertise in e-health, hypertension, asthma, behaviour change, health economics, and developing, trialling and implementing complex healthcare interventions; and b) patient and public involvement (PPI) representatives, including people with experience of hypertension and asthma and representatives of two relevant patient organisations (Blood Pressure UK and Asthma UK).

Our programme of research was intended to undertake the rigorous development and evaluation necessary to maximise the likelihood of effective integration of DIs within NHS primary care, while identifying and using best practice methods of designing and delivering DIs to ensure that they were considered accessible and useful by patients and clinicians. Our specific objectives were therefore to:

1. Identify key features associated with maximising feasibility, acceptability (to patients and health professionals), effectiveness, and cost-effectiveness of DIs;
2. Examine the range of delivery and support modes that can be used for DIs and assess their relative feasibility, acceptability (to health professionals and patients), effectiveness, and cost-effectiveness;
3. Optimise interventions for hypertension and asthma and carry out feasibility studies in preparation for full randomised controlled trials (RCT);
4. Undertake a RCT of a DI for hypertension to determine the effectiveness and cost-effectiveness of integrating it into routine care.

## Summary of research

We proposed three closely linked parallel workstreams (see *Figure 1*). A behavioural and economic workstream (WS1) focused on identifying condition-specific and common factors influencing cost-effective integration of DIs into primary care. This research was embedded in two clinical workstreams that developed and trialled DIs for self-management of hypertension (WS2) and asthma (WS3).

**Workstream 2 (WS2): Develop and trial digital self-management of hypertension with primary care support**

Development of a digital intervention for the self-management of hypertension

Randomised controlled trial of the intervention

**Workstream 3 (WS3): Develop and trial digital self-management of asthma**

Development of a digital intervention (DI) for the self-management of asthma

Feasibility trial of the intervention

**Workstream 1 (WS1): Identify factors influencing cost-effective integration of digital interventions**

Systematic reviews of the relevant qualitative and quantitative literature

Intervention planning to inform intervention content and design features

Qualitative studies of user views

Quantitative and qualitative process analyses with patients and healthcare professionals

Cost-effectiveness analysis

Figure 1 Research pathway diagram for DIPSS

WS1 undertook detailed intervention planning to identify factors influencing acceptable and cost-effective integration of DIs into primary care, and hence the required elements and characteristics of the interventions and support to be offered for hypertension and asthma self-management in WS2 and WS3. To inform our planning we completed systematic reviews of the relevant quantitative and qualitative literature and also drew on our primary qualitative studies of patient and health professional views and experiences.

WS2 and WS3 developed DIs for self-management of hypertension and asthma (respectively), using iterative qualitative research to ensure that they were viewed as acceptable and useful by patients and primary care staff. We proposed that both workstreams would complete feasibility trials of the DIs, using quantitative and qualitative methods to evaluate patient and primary care experiences of different delivery formats. WS2 also carried out a full RCT of the cost-effectiveness for reducing blood pressure (BP) over one year of the optimum method(s) of delivering the DI compared with usual care, with an embedded qualitative process analysis.

There were two changes from the original proposal that affected the direction of the research programme. First, the feasibility trial in WS2 for the hypertension intervention was integrated into the main trial as an internal pilot study, since no changes to the intervention or trial procedures were required. Second, we originally proposed to test two intervention arms, alongside a usual care arm: 1) the most intensive support for the DI considered likely to be feasible and cost-effective in routine care (at least face-to-face consultations and telephone and/or email support, with the option of further support if required); and 2) the least intensive support for the DI considered likely to be effective in routine care (one face-to-face consultation at baseline, with further support up to the level of condition, provided only as required). Instead, we trialled only one intervention arm (versus usual care arm), which included a minimal level of nurse support (a compulsory face-to-face or telephone conversation), with the option of more face-to-face, telephone and email nurse support if required. This was deemed the acceptable and efficient compromise between the two originally proposed.

## Changes to the digital, clinical and research context since the research programme commenced

### Changes to the digital context

When the DIPSS research proposal was written in 2013, online self-management of health was sufficiently novel that its functionality and its potential value to the NHS had to be explained in the proposal, while its feasibility as a method of delivering interventions had to be justified to the funding panel as follows: ‘The problem of internet access is rapidly diminishing, even for older people and socially disadvantaged sectors of the population; in early 2011 77 per cent of households had internet access (with the proportion still growing fast), including 55 per cent of those aged 65-75’. During the lifetime of this project the use and potential of the internet has continued to increase in all age groups: in 2018 95 per cent of adults aged 16 to 74 years in the UK were recent internet users and 47 per cent of those aged over 75.1 There has also been a huge proliferation in DIs, mainly provided by the private sector, with little or no evaluation of their effectiveness. Consequently, the question of whether DIs have a role to play supporting patient self-management has become less relevant. However, the question of how best to implement DIs and integrate them into primary care has become even more pressing. It is also important to think about how to provide this support most effectively and most cost-effectively – particularly in view of the ageing population, the inexorable rise in the prevalence of chronic and multimorbid conditions, higher expectations for medical care, and the limited health care staff resource available to manage those conditions.

During this period there has also been a major shift from delivering and accessing DIs via computers to delivering and accessing them via mobile phones (although this shift has been more rapid among younger than older people). When designing DIs delivered by computer it was customary to assume that the user would devote some dedicated periods of time to accessing interactive ‘sessions’ of advice, similar to what might be delivered by a health professional in a face-to-face meeting. As users became accustomed to accessing digital content on-the-go via smartphones the assumptions about usage and design changed; it became necessary to deliver advice in smaller chunks that could be accessed on a phone screen during shorter periods of time. This change in technology usage was reflected in the design of the DIPSS interventions. The HOME BP intervention was aimed at older people mainly using computers at home, whereas the My Breathing Matters intervention was developed later and had to be designed to be accessible by younger people using their phones.

Another major change in the digital context is that the digital environment is becoming better regulated. Increased data regulation relevant to all digital technology has now been introduced, such as the 2018 EU General Data Protection Regulation. There is also increased regulation internationally of apps considered to be medical devices, and criteria for evaluating digital health interventions are being developed by the Department of Health, working with the National Institute for Health and Care Excellence (NICE) and other partners.2

### Changes to the clinical context

*Hypertension*

BP is a key risk factor for cardiovascular disease, the largest cause of morbidity and mortality worldwide.3 Over 13 per cent of NHS patients are currently recorded on hypertension registers (almost 7 million in England alone), but the Health Survey for England (2017) found that around 40% were inadequately controlled. A 10 mmHg reduction in BP is estimated to lead to a 41 per cent reduction in stroke and a 22 per cent reduction in coronary heart disease.4 Every day 670 people go to hospital because of a suspected stroke, more than 100,000 strokes per year of whom around 38,000 will die in the UK each year. Overall there are 1.2 million stroke survivors. This leads to NHS and social care costs of around £1.7bn per year. Hypertension is the most important risk factor.

Factors responsible for suboptimal BP control include those due to patients, physicians, and the health system.5 The key patient factors are adherence to medication and other health behaviours. Clinical inertia is another key issue, whereby clinicians fail to intensify treatment, despite evidence of inadequate control. A Scottish study found that treatment was not intensified in nearly half (45 per cent) of consultations in which patients had a single BP reading above target, and around a third (36 per cent) with two successive readings above target.6 There is evidence that self-monitoring BP is useful in improving medication adherence, reducing therapeutic inertia and controlling BP.7-10 Finally, a recent Cochrane review concluded that “an organised system of registration, recall and regular review allied to a vigorous stepped care approach to antihypertensive drug treatment appears the most likely way to improve the control of high BP”.11 Research by our team and others has shown that sustained reductions in BP can indeed be achieved by linking self-monitoring to pre-planned medication titration when hypertension is uncontrolled.8, 12-14 The latest NICE guidance 15 recommends self-monitoring as a possible intervention for the management of hypertension but stops short of an outright clear recommendation, perhaps due to concerns regarding the evidence base.

*Asthma:*

The UK has one of the highest prevalences of asthma in the world; nearly 6 per cent of the UK population have asthma, comprising 5.4 million people, most of whom are managed in primary care.16 Hospital admission and mortality rates for asthma showed improvements in the last decades of the last century, but these improvements have stalled since the millennium. Retrospective audits of asthma deaths have consistently suggested that poor self-management and other potentially preventable factors occur commonly in association with asthma fatalities. The largest such audit, which occurred in the UK was funded by the Department of Health, found that potentially avoidable factors played a significant role in over 60% of the 195 asthma deaths audited, and that 77% lacked an agreed self-management plan, and 50% lacked awareness of asthma triggers. 17

Although the UK leads the world in providing guidelines for asthma management, these have been poorly implemented and people with asthma do not receive evidence-based interventions, particularly individual action plans, which are known to impact positively on outcomes.18 Patient education and proactive self-management have been convincingly shown to improve clinical outcomes in asthma and have been advocated in guidelines for 20 years.17,19 People with asthma without a management plan are four times more likely to have an asthma attack needing emergency care in hospital20 and a national review of UK asthma deaths suggested that only a quarter of people who died had been given a self-management plan.21 Self-management in asthma can also encompass non-pharmacological interventions to improve control and empower the patient, such as breathing exercises or healthy behaviour changes such as smoking cessation and weight reduction (since smoking and obesity are associated with worse prognosis in asthma.22

### Changes to the research context

In addition to these changes in the digital and clinical context of the research, during the period that this project was carried out there has been considerable development in thinking and guidance relating to intervention development and evaluation, culminating in new recommendations and guidance, for example in relation to intervention development,23 process evaluation,24 and mixed methods implementation research.25 This project has responded to these changes as far as possible (given that it commenced prior to them) and has also actively contributed to them, as described in the following three sections.

# Development of HOME BP

Parts of this section are reported in more detail in the following publications:

1. McLean G, Band R, Saunderson K, Hanlon P, Murray E, Little P, McManus RJ, Yardley L, Mair FS; DIPSS co-investigators. Digital interventions to promote self-management in adults with hypertension systematic review and meta-analysis. *J Hypertens.* 2016 Apr;34(4):600-12. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4947544/> (last accessed: 18 July 2019)26 (follows the PRISMA reporting guidelines for systematic reviews)
2. Morton K, Dennison L, May C, Murray E, Little P, McManus RJ, Yardley L. Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. *Patient Educ Couns.* 2017 Apr;100(4):616-635. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5380218/> (last accessed: 18 July 2019)27
3. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, Murray E, McManus RJ, Little P, Yardley L. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person-based approach*. Implement Sci.* 2017 Feb 23;12(1):25. <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0553-4> (last accessed: 18 July 2019)28
4. Bradbury K, Morton K, Band R, van Woezik A, Grist R, McManus RJ, Little P, Yardley L. Using the Person-Based Approach to optimise a digital intervention for the management of hypertension. *PLoS One.* 2018 May 3;13(5):e0196868. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933761/> (last accessed: 18 July 2019)29
5. Bradbury K, Morton K, Band R, May C, McManus R, Little P, Yardley L. Understanding how primary care practitioners perceive an online intervention for the management of hypertension. *BMC Med Inform Decis Mak.* 2017 Jan 9;17(1):5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5223423/>(last accessed: 18 July 2019)30

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## Introduction

Some key elements of the HOME BP intervention were informed by a previous programme of work developing and trialling non-DIs for managing high BP.13, 31 These elements included the frequency of self-monitoring, the algorithm for interpreting BP readings and recommending appropriate action, and the procedure for the healthcare professional (HCP) to plan three potential medication changes in advance for each patient. This workstream (WS2) sought to explore how to adapt these procedures to be implemented successfully via an online intervention. This adaptation process is not simply a matter of transferring written materials into a digital delivery format. It is well established that it is vital to ensure that patients and clinicians find the intervention easy to use and are motivated and confident to implement the procedures correctly with only digital support.32-34 In addition, a secondary aim of WS2 was to examine whether digital support for healthy behaviour change could contribute to better self-management of hypertension. Therefore WS1 also involved developing and adapting our existing digital healthy behaviour change resources for use by people with hypertension in WS2.

## Intervention development team and patient and public involvement (PPI)

The intervention development team included clinicians with expertise in hypertension management, e-health and lifestyle change, health psychologists, web developers, representatives of the charity Blood Pressure UK, and PPI contributors. Our PPI contributors included three patients with hypertension and/or stroke (Shelley Mason, Keith Manship, Cathy Rice) and one public contributor with a general interest in DIs (Samantha Richards Hall) joined the project team and provided essential advice on the grant proposal. All PPI contributors were subsequently invited to each management committee meeting to discuss important issues arising in the planning and development of HOME BP. This included decisions about support for healthy behaviour change, insights into patient burden of self-monitoring, and discussions around approaches to participant recruitment and how to promote accessibility of the patient materials.

Early prototypes of the intervention were shared with the PPI contributors for feedback from a patient perspective. This led to important changes to optimise the intervention, such as the introduction of additional optional information for patients who might like to know more about clinical risks of hypertension. PPI contributors also provided an important patient perspective during debates amongst the research team, for example, some researchers were concerned that the motivational quiz might be irritating or hard to relate to, but PPI contributors felt the quiz was useful and engaging. PPI contributors promoted a focus on patient priorities throughout this phase of intervention planning and development, and provided the opportunity for rapid feedback on the early development of the intervention to maximise potential to meet patients’ needs.

## Objectives

This section will describe the sub-studies used to inform the planning and development of the HOME BP DI, based on evidence, theory and qualitative research. For each sub-study or discrete research activity, we report aims, methods, results, and practical implications for how it informed the intervention development. These are described in chronological order, as follows:

* **Phase 1: Collate and synthesise evidence:** 
  + Primary mixed methods research
  + Evidence from quantitative review of the literature
  + Evidence from qualitative review of the literature
* **Phase 2: Behavioural analysis**: Identifying facilitators and barriers, and how to address them
* **Phase 3: Intervention development and optimisation**, alongside developing guiding principles
* **Phase 4: Mapping facilitators and barriers on to theory**

The section ends by considering how the INDEX (IdentifyiNg and assessing different approaches to DEveloping compleX interventions) actions for developing complex interventions were met in this planning and development process.23 The INDEX actions were published in 2019 and are comprised of 18 recommended actions for intervention developers to consider, collated through a systematic synthesis of intervention development approaches.

## Phase 1: Collating evidence from primary mixed methods research, and evidence from quantitative and qualitative reviews of the literature

### **Collating evidence from a previous primary mixed methods research study** **(described in**28**)**

Aims:

To collate the feedback from a small feasibility study which explored patients’ and healthcare professionals’ experiences of managing high BP using an online intervention prototype.

Methods:

The feasibility study was completed before the start of this programme grant. The online prototype of the intervention was based closely on the written materials used for BP self-management in the Telemonitoring and Self-Management in the Control of Hypertension (TASMINH2) trial.13 Eight General Practitioner (GP) practices participated, recruiting 50 patients with hypertension. Semi-structured qualitative interviews were conducted with a sub-sample of 16 patients and 3 healthcare professionals, and a debriefing focus group was held with 8 healthcare professionals. In order to inform the development of the HOME BP intervention for the current programme grant, a rapid analysis was adopted in which the transcripts from the feasibility study were read and barriers to implementation were extracted from the data and tabulated to help consider how best to overcome them.

Results and practical implications for intervention development:

See *Table 1* for a list of the barriers to implementation at the practice or health care professional level, and patient level and optimisation solutions actioned in the HOME BP intervention to overcome these.

Table 1 List of barriers to implementation at the practice or health care professional, and patient level arising from the feasibility study and optimisation solutions actioned in HOME BP to overcome these

|  |  |
| --- | --- |
| **Barriers to implementation** | **Optimisation solutions actioned in HOME BP** |
| **Practice or health care professional level** | |
| * GPs forgetting the procedures from their training for initiating planned medication changes. | * The process for initiating recommended medication changes needed to be better integrated into practice. * Making the online training for health care professionals compulsory to complete, and enabling the research team to track when it has been done would also help ensure that practice staff are aware of study procedures. |
| * GPs not checking the prompts to change patients’ medication. | * Email prompts should be sent directly to the GP, rather than use a study account which GPs may not remember to check. |
| * Reception staff booking appointments for patients when they contacted the practice with raised readings due to a lack of awareness about the automated procedures for medication change. | * A summary information sheet about the study should be provided to reception staff to ensure they also understand the intervention procedures. |
| **Patient level** | |
| * Low motivation for healthy behaviour changes as patients felt they were already living healthily. | * Healthy behaviour change and the nurse appointment to support healthy behaviour change needed to be optional. |
| * Some patients did not consider hypertension to be a serious health issue that needed active management. | * The patient training needed to persuade patients of the importance of controlling high BP to raise motivation. |

### **A systematic review and meta-analysis of the quantitative evidence for digital interventions for hypertension** (described in26)

Aims:

To conduct a systematic review of quantitative evidence relating to interactive DIs for hypertension.

Methods:

An exhaustive search was conducted using MEDLINE, EMBASE, CINAHL, PsycINFO, ERIC, Cochrane Library, DoPHER, TROPHI, Social Science Citation Index and Science Citation Index., identifying 5606 papers for abstract screening, after which 164 papers were reviewed in full. Two independent researchers screened the search results and extracted data relating to the eligibility criteria into a standard template for comparison. Eight papers were eligible for inclusion, and for each of these detailed data extraction was performed using pre-specified fields, including study details, intervention components, participant details, and outcomes. A meta-analysis was conducted using a random-effects model to explore the difference in mean change in systolic and diastolic BP.

Results:

Patients using interactive DIs for BP were found to have significantly lower systolic BP than those receiving usual care in four of the seven studies. Overall there was a weighted mean difference of -3.74 mmHg systolic BP after using interactive DIs compared with usual care. No differences were found in systolic BP reductions between interventions with or without a theoretical basis, with or without additional healthcare professional (HCP) support (such as sending patients personalised recommendations based on their readings, or monthly counselling calls), or with more or less intensive self-monitoring regimens.

Practical Implications for intervention development:

This meta-analysis provided evidence that DIs can reduce BP across a range of participants. The reduction in systolic blood pressure found in this review would be of clinical significance at a population level, with a drop of 3mmHg reducing the chance of stroke mortality by 8 per cent35.

However, it was noted that only a small number of studies were included and only one study lasted longer than 12 months meaning that sustainability of the effect was uncertain. There was also insufficient evidence to aid understanding of how different components of the interventions might work to reduce BP.

In terms of HOME BP, the meta-analysis provided support for the concept of a DI and some reassurance that this could be effective with minimal healthcare professional support but could not offer more specific suggestions for how to promote effectiveness.

### **Identification of barriers and facilitators from the qualitative literature** (described in27)

Aims:

To undertake a systematic review of qualitative evidence to explore how patients and healthcare professionals (HCPs) perceived self-management DIs across a range of long-term physical health conditions, including hypertension and asthma.

Methods:

A combination of search terms were developed relating to e-health, qualitative research, intervention, and chronic illness. Searches were conducted using CINAHL, Embase, PsycINFO, MEDLINE, Web of Science, and The Cochrane Library. Inclusion criteria specified that the population were adults with a chronic health condition or HCPs, the main component of the intervention was delivered digitally and promoted self-management, and that the research adopted qualitative research methods.

Data were extracted for each paper on the study, intervention details, participants, target self-management behaviours, HCP involvement, methods, and main findings. A meta-ethnography approach was used to synthesise the primary studies and generate a higher conceptual level understanding.36 This involved comparing key concepts between each paper and every other paper to develop a line of argument identifying similarities and differences between the studies. The meta-ethnography synthesised research from across a range of interventions (from complex behaviour change programmes to more simplistic tele-monitoring interventions) and conditions (including hypertension, chronic heart failure, diabetes, asthma, chronic obstructive pulmonary disease, and back pain).

Results:

The search identified 1256 papers for abstract screening, of which 120 went to full text screening and 30 were eligible for inclusion. Three third-order constructs were developed to explain how patients and HCPs perceive DIs: ‘perceived purpose of the DI: Who is responsible’, ‘perceiving meaning in self-monitored data’ and ‘patients carefully consider recommended medication changes’. These are summarised below.

Perceived purpose of the DI: Who is responsible: It appeared that patients and HCPs focus on different purposes of the intervention, with patients valuing increased self-management skills and understanding of their condition, while HCPs value improved clinical control. A risk in some intervention studies was that patients relied on their HCP to continually check on their health data, creating an unfeasible level of HCP burden, therefore the feedback messages for patients needed to clearly define who was responsible for taking action in the case of out-of-range readings. Clear feedback also helps avoid uncertainty for the patient and HCP, which can otherwise be a negative outcome of self-monitoring.

Perceiving meaning in self-monitored data: The action of self-monitoring data appeared to be powerful for patients, and simple tele-monitoring interventions alone could change how the patient perceived their condition and their role as self-managers. However it appeared that where self-monitored data were stable over time or appeared meaningless in relation to patients’ efforts to control their condition, this could result in frustration.

Patients carefully consider recommended medication changes: Some interventions prompted medication changes in response to self-monitored data, and it appeared that concerns and belief in the necessity of the change may influence to what extent patients adhere to these changes, and that there are possible differences in these perceptions between health conditions.

Practical Implications for intervention development:

The meta-ethnography highlighted several practical implications for the development of the HOME BP intervention. These included the importance of providing clear actions for the patient and HCP in response to home readings, ensuring patients are responsible for responding to out-of-range readings rather than expecting the practitioner to constantly monitor their readings, building patients’ confidence to engage with planned medication changes, and increasing positive outcome expectancies for the patient and HCP for the effects of changing medication at the target threshold.

## **Phase 2: Behavioural analysis: identifying facilitators and barriers, and how to address them** (described in28).

Aims:

To map the evidence identified from the primary mixed methods research and quantitative and qualitative literature reviews regarding influences on patient and HCP target behaviours on to intervention elements that could address these influences.

Methods:

Likely facilitators and barriers to each target behaviour for patients and HCPs were extracted from the evidence and recorded in a behavioural analysis table. Expert and stakeholder input regarding facilitators and barriers were also recorded in the table. Intervention components were then identified to optimise the facilitators and minimise the barriers, based on stakeholder expertise and knowledge of behaviour change theory and frameworks (particularly Social Cognitive Theory,37 Normalization Process Theory (NPT),33 and the Behaviour Change Wheel (BCW)32).

Results:

Four target patient behaviours were identified: engaging with the online intervention, self-monitoring BP, adhering to medication changes, and healthy behaviour change, and three behaviours were identified for HCPs: engaging with the online intervention, changing medication when recommended, and providing behavioural support to patients. A range of facilitators and barriers were collated from the evidence for each behaviour, along with suggestions for how this could inform the intervention. For example, the evidence showed that challenges for patients in engaging with regular self-monitoring included forgetting and limited time/competing priorities, and possible solutions identified included sending automated email prompts via the intervention as reminders, and enabling a flexible monitoring routine which patients could choose to delay by one week when necessary.

Practical Implications for intervention development

This process helped to ensure that the intervention being developed was addressing the key concerns of patients and HCPs, as informed by the literature and expert knowledge of stakeholders in the research team. This collation of facilitators and barriers also helped inform complex decisions, such as the extent and format of HCP support during the intervention, by interpreting the available evidence through an applied lens with a focus on how to promote the behaviour.

## Phase 3: Intervention development and optimisation alongside developing guiding principles

The HOME BP DI included both patient and HCP components. The patients completed two online training sessions designed to raise motivation and teach patients how to self-monitor their BP. After the first online session, patients attended a baseline medication review with their prescriber, in which a three-step medication plan was created. The patient then completed one week of practice BP readings to increase confidence, after which they were reminded by email to self-monitor their BP for seven days every month. Patients entered their readings online, and if the average reading was above-target for two consecutive months, the prescriber received an email alert recommending the next medication change in the plan was made. A third optional online session became available after nine weeks to increase motivation and self-efficacy to engage in healthy lifestyle changes for managing high blood pressure. From this optional session, patients could choose to complete one-off online educational modules on reducing salt, eating a healthy diet, or reducing alcohol, or could sign-up to a multi-session digital intervention to support physical activity, or weight loss 38 (the latter only available to those with a Body Mass Index (BMI) over 25). Supporters (nurses or healthcare assistants who had completed online training for this role) were asked to send monthly support emails to patients throughout the trial, and to provide optional face-to-face support as needed. See *Appendix 1* for full details of the intervention.

### **Qualitative research: think-aloud interviews and retrospective interviews with patients** (described in 29)

Aims:

To gain an in-depth understanding of hypertensive patients’ beliefs about the target behaviours and their psychosocial contexts, in order to identify possible barriers to engagement and how best to optimise the intervention.

Methods:

Twelve participants each completed three separate think-aloud interviews to explore perceptions of the three online sessions of the HOME BP intervention. Refinements were made to the intervention iteratively such that concerns raised by the first batch of participants were addressed before conducting further think-aloud interviews with a new batch of participants. Recruitment ceased when data saturation was reached and no further issues were arising with the intervention.

At this point, 11 participants were recruited to use the intervention in a real-world setting. After using the intervention independently, including completing all three online sessions and submitting seven days of home readings to receive online feedback, participants took part in a retrospective semi-structured telephone interview to identify further ways to optimise the intervention. In addition, seven participants who did not want to use a DI to manage their BP were purposively recruited, to explore their concerns in semi-structured interviews and gain insight into potential barriers to uptake.

In order to use the qualitative data systematically and efficiently to inform intervention modification we developed a rapid analysis approach, which was used for the data. This analysis involved tabulating all data from the transcripts relating to the intervention and systematically deciding which changes to make to optimise behaviour change using a set of criteria for modifications. The criteria included how important each modification was for promoting behaviour change, how easy it was to implement, and whether it was in line with theory and evidence.

Results:

The think-aloud interviews showed that many patients liked the idea of self-monitoring their BP at home and felt motivated by the training sessions to become more involved in their care. However, some barriers were also discovered and the intervention was iteratively modified to address these, as described below.

In order to help patients understand the rationale for the intervention, the first online training session explained that HCPs often do not change patients’ medication despite clinic readings being raised, but the intervention would address this by encouraging HCPs to plan medication changes in advance and prompt change based on accurate home readings. However, some patients did not accept this rationale as they had high trust in their GP and believed they were already receiving the best care. These beliefs undermined the rationale for the intervention, therefore the training session was changed to be more compatible with patients’ high regard for GP care, emphasising instead how home readings would help the GP and make it easier for them to provide the best care. Another barrier was that some patients felt very anxious about the risk of negative health outcomes from raised BP which were highlighted by a quiz in the first training session. This was addressed by reassuring patients at the end of the quiz that these risks could be managed effectively by taking the right medication to control BP.

The retrospective interviews conducted with patients after using the intervention independently suggested that the intervention was feasible to implement in a real-life setting, and many patients described positive responses, such as reassurance when seeing readings were well-controlled. Low confidence in the accuracy of readings could arise when patients felt uncertain about how to use the monitor, therefore a week of practice home readings was introduced with the option to discuss monitoring technique with the nurse in order to increase self-efficacy. Another barrier was reluctance to fully fasten the cuff due to discomfort, which was addressed by adding the rationale for securely fastening the cuff to the training, explaining this was necessary in order to obtain accurate readings. There was also evidence of possible reluctance to receive medication changes remotely, with some patients explaining that they would want to see their GP at this point. The intervention aimed to avoid increasing face-to-face consultations, in order to maximise cost-effectiveness. Consequently, rather than prompting patients to have an appointment at this point, further reassurance was added to patients’ feedback by reminding them that they had agreed on this medication change at the start with their GP, and patients were given the option to send any concerns they had at the time of a medication change via an email for their GP to consider.

Participants who did not want to use a DI to manage their BP discussed their concerns about the behavioural changes involved, including misconceptions that the intervention would change their medication without their GP’s involvement, and concerns about internet security for health data. These perceptions informed modifications to the patient recruitment materials to ensure these possible barriers were addressed using accessible, clear explanations in order to maximise uptake to the trial.

Practical implications for intervention development:

This qualitative research was essential for ensuring that the HOME BP intervention was motivating, persuasive, feasible, and enjoyable for people to use, and that concerns which could interfere with engagement with the target behaviours were addressed. Additional specific barriers were discovered through this research which had not been predicted by other elements of the planning process (including stakeholder involvement), demonstrating the value of conducting this development work. The intervention was optimised to ensure that the rationale was consistent with patients’ perceptions of their care, that fears about future health were mitigated by increased self-efficacy to control BP via medication, and that patients’ confidence to use the BP monitor and change medication without an appointment with their GP was maximised.

### **Qualitative research: focus groups with healthcare professionals** (described in 30)

Aims:

To explore HCPs’ beliefs and concerns about implementing the HOME BP intervention in practice in order to optimise the intervention.

Methods:

Seven focus groups were conducted with 55 HCPs after they had completed the mandatory online training session relating to the intervention (GPs, nurses and healthcare assistants) or read summary information about implementing the trial (reception staff and practice managers). The rapid analysis approach our team developed was used to identify important changes to the intervention to promote feasibility and optimise engagement, after which further data were collected from new participants. Recruitment ceased once no concerns were emerging during the focus groups. After the intervention had been optimised, thematic analysis was conducted to gain an in-depth understanding of HCPs’ perceptions of this DI.39

Results:

The rapid analysis revealed important changes to the online intervention training in order to address HCPs’ concerns about implementing these procedures in practice. This included adding evidence that the intervention was unlikely to result in more consultations, due to fears about increased workload, and reassuring HCPs in the training session about the accuracy of home readings by explaining that patients would complete a practice week of readings. There was also some concern about how to plan three medication changes in advance for more complex patients, which was addressed by adding scenarios to the training to demonstrate how to successfully implement this behaviour. From the nurses’ perspective, some were anxious about not being able to give advice when using the Congratulate, Ask, Reassure, Encourage approach (CARE) to support patients.40 Therefore the training was adapted to incorporate further rationale for using this approach, supported by quotes from our previous research showing it had been well-received by nurses and patients,40 to increase confidence in the value of this approach.

Three themes were developed in the thematic analysis: Managing BP at home; Agreeing medication changes in advance; and Supporting patients with HOME BP. It appeared that some HCPs felt that self-monitoring BP and planning medication change could help patients become more involved in their care, and improve their own management of BP, although there were some concerns about patients becoming anxious about their readings and needing more support. Some HCPs were also unsure about the benefits of planning medication changes in advance in case the changes were no longer appropriate at the time.

Practical implications for intervention development:

These focus groups suggested that the HOME BP intervention was acceptable and persuasive to HCPs, but also highlighted some important modifications needed to optimise the intervention, including adding elements designed to increase confidence to plan medication changes in advance, demonstrate the accuracy of home readings, and persuade HCPs that the CARE approach is effective for supporting patients.

### **Guiding principles** (described in 28)

Aims:

To develop guiding principles which identify how the intervention design will address specific challenges to engaging with the target behaviours in this particular context and population.

Methods:

Guiding principles consist of two elements. *Intervention* *design objectives* were based on the key context-specific behavioural needs, issues or challenges identified by the review of qualitative evidence, the mixed-methods primary research, and the qualitative development interviews. We also consulted the intervention development team who have extensive stakeholder expertise in hypertension and developing DIs and knowledge of the relevant evidence-base. The *key features* of the intervention consist of intervention characteristics that address these objectives. The guiding principles were progressively refined as intervention planning proceeded, in line with ongoing accumulation of relevant quantitative and qualitative evidence.

Results:

Changing medication (‘titration’) was identified as a challenging behaviour for both patients and HCPs, due to concerns about side effects and doubts about necessity to increase medication when readings are borderline. Therefore motivating users to engage in medication change was a key objective for the intervention, and several features were included to achieve this, such as educating patients and staff about the benefits of medication change and providing reassurance about safety and side effects. Furthermore, the process for medication change needed to be easy for HCPs and patients to implement in practice, and this became another design objective which could be achieved by ensuring the procedures were as automated and compatible as possible. Cost-effectiveness and feasibility were identified as a third design objective as the intervention needed to be appropriate to implement in primary care, with features such as online training included to help achieve this objective. The full guiding principles have been published.28

Practical implications for intervention development:

The guiding principles provided a coherent and succinct summary of the key aims of the intervention and how these would be achieved, to promote its acceptability and, ultimately, its effectiveness. The guiding principles were useful to refer back to during any decisions about the intervention, and they helped ensure these central priorities were kept in mind by the research team during the day-to-day running of the project.

## **Phase 4: Mapping facilitators and barriers on to theory** (described in 28)

Aims:

To comprehensively describe the intervention in terms of existing theory and programme level theory.

Methods:

Once the intervention was complete, the intervention components identified in the behavioural analysis were mapped on to theory, represented as a large table.28 The BCW and Behaviour Change Techniques (BCT) Taxonomy provide a standardised system of well-defined theoretical concepts for describing complex interventions and identifying the techniques they use to change behaviour.32,41 Therefore each intervention component was mapped on to an intervention function from the BCW, and the relevant BCT was also identified to demonstrate how the intervention was theorised to be working. In addition, the intervention components were mapped on to NPT,33 which helped to describe the mechanisms likely to be involved in implementing the target behaviours for the patient and HCP. After mapping the intervention to theory, the BCW and NPT were checked for any additional theoretical constructs which had not emerged from the evidence but which may be important for promoting behaviour change in this intervention.

Subsequently, a logic model was developed in line with the Medical Research Council guidance for process evaluation.24 The target behaviours were theorised to influence the primary outcome of reducing BP, and the intervention components identified in the behavioural analysis were represented as intervention processes which would change the target behaviours. In addition to the evidence from the qualitative and quantitative reviews, further non-systematic scoping literature searches were conducted to enhance understanding of the causal mechanisms shown to influence the target behaviours.42 Potential determinants of behaviour were extracted from papers and mapped on to existing theories of behaviour change.

Results:

The behavioural analysis helped to clearly characterise the intervention. When mapped on to the BCW, the HOME BP intervention components were shown to target physical and social opportunity, reflective motivation, and psychological capability, using the intervention functions of environmental restructuring, education, persuasion, training, and enablement. The HOME BP intervention components also mapped on to ten different BCTs, including prompts/cues, biofeedback, and behavioural practice/rehearsal. Mapping to NPT showed that the intervention was targeting several mechanisms to promote successful implementation, such as training patients to use BP monitors to increase *skillset workability*, and providing patients with written confirmation of medication change from their HCP to promote *initiation* of a medication change (from the *Cognitive Participation* construct of NPT). In addition, each construct from the BCW and NPT was evaluated in terms of how it might contribute to the HOME BP intervention. This did not identify any additional intervention content required to change behaviour.

In terms of the logic model, outcome expectancies appeared to be important in patients’ and HCPs’ willingness to change medication, as described by Social Cognitive Theory.37 More specifically, beliefs about hypertension and antihypertensive treatment seemed to inform these outcome expectancies, as described by the Extended Common Sense Model.43 Both theories were incorporated into the logic model. Also in line with Social Cognitive Theory, self-efficacy was theorised to influence engagement with self-monitoring BP. Each intervention process in the logic model was defined using NPT mechanisms, to show how it sought to promote implementation. See Band et al. for the full logic model.28

Practical implications for intervention development:

The behavioural mapping was useful for ensuring the intervention content could be described using standard terminology, and for checking that no theoretical concepts had been missed when planning the intervention from the evidence. The logic model also explicitly described the underlying mechanisms theorised to change behaviour.

2.8 Mapping the HOME BP planning and development process to the INDEX actions(IdentifyiNg and assessing different approaches to DEveloping compleX interventions)23

New guidance for complex intervention development has recently emerged,23 based on a taxonomy of approaches to intervention development, interviews, Delphi consultation and workshops with developers and stakeholders. The authors completed a comprehensive review of approaches and produced 18 actions which are recommended for consideration during intervention planning and development. For completeness, *Table 2* shows a retrospective mapping of the HOME BP planning and development process to the 18 actions from this guidance. See *Appendix 1* for a full description of the HOME BP intervention using the Template for Intervention Description and Replication (TIDieR) checklist.44 A demo of HOME BP can be found here: <https://www.lifeguideonline.org/player/play/homebpdemo>.

Completing *Table 2* provided a useful prompt and a template for describing aspects of the intervention development process that are important but are seldom currently described, such as details of the decision-making process and planning for efficient future implementation.

Table 2 HOME BP intervention planning and development actions mapped to INDEX guidance actions

|  |  |
| --- | --- |
| **Action from INDEX guidance** | **How this action was addressed in HOME BP intervention** |
| 1. Identify that there is a problem in need of a new intervention | The rationale for HOME BP was identified in the funding application, based on existing evidence (see *Section 1*) that:  a) Over 13 per cent of NHS patients are currently recorded on hypertension registers and around half are inadequately controlled. Clinically significant reductions in BP will reduce disability and mortality due to stroke and heart disease.  b) Self-monitoring interventions with pre-planned medication changes can successfully reduce uncontrolled BP.  c) A DI might enable these procedures to be implemented more feasibly and cost-effectively in primary care.  d) No cost-effective DI supporting management of uncontrolled BP had yet been developed and trialled in the UK.  e) PPI input indicated that patients felt that digital support could be helpful, providing convenient personalised support for self-management of their health, linked to appropriate healthcare professional monitoring of patient status. |
| 2. Establish a group or set of groups to guide the development process, thinking about engagement of relevant stakeholders such as the public, patients, practitioners and policy makers | The management group (which met three monthly to oversee all important decisions) was set up at the proposal stage and included hypertensive patients, behaviour change specialists, health economists, policy makers, statisticians, trial managers and clinicians.  All members of the management group were invited (if interested) to join the intervention development team which met monthly (or as necessary) to oversee and guide intervention development; this team included patients, clinicians and health psychologists.  A core intervention development team met weekly, comprising the health psychologists developing the intervention, in close consultation with key clinical academics when necessary. |
| 3. Understand the problems or issues to be addressed | Facilitators and barriers to key behaviours were identified from a) reviews of the existing quantitative and qualitative evidence;  b) in-depth primary qualitative and mixed methods research.  These evidence sources (detailed above) enabled us to understand the specific beliefs and contextual factors that appeared to influence target behaviours. |
| 4. Make a decision about the specific problem or problems that an intervention will address, and the aims or goals for the intervention. This may involve defining the behaviours to target | A logic model was created to map the hypothesised mechanisms (including target behaviours) through which the intervention was theorised to change behaviour and outcomes.  Our behavioural analysis table documented the target behaviours for patients and health professionals, the barriers and facilitators for implementing them, and intervention ingredients intended to support target behaviours.  Guiding principles were developed to specify how the intervention would meet design objectives to promote engagement with the target behaviours in this specific population and context. |
| 5. Identify possible ways of making changes to address the problems. This involves identifying what needs to change, how to bring about this change and what might need to change at individual, interpersonal, organisational, community or societal levels | The primary and secondary research and analyses described above helped identify what needed to change at the individual patient and healthcare professional level, and at a more organisational level in the healthcare systems, and provided insights into how this might best be achieved.  The development and management teams reviewed and agreed the design of the intervention, informed by the evidence reviews, behavioural analysis table and the guiding principles, together with stakeholder expertise (clinical and experiential) and knowledge of existing relevant theory and theoretical frameworks (in particular Social Cognitive Theory,37 NPT,33 and the BCW).32 |
| 6. Specify who will change, how and when. Selections may depend on consideration of the likely impact of the change, how easy it is to change, how influential it is for the problem being addressed, and how easy it is to measure | Decisions about the appropriate target group for behaviour change, core behaviours to target and intervention outcome measurement (e.g. required sample size, trial design and duration and the primary and secondary outcomes) were informed by the funding application, previous evidence relating to BP management (especially13) and the wider review of evidence undertaken as part of the intervention planning described above.  There was good evidence that a face-to-face version of the intervention procedures for self-management of BP was acceptable and effective, and so steps were taken to ensure that the key procedures were preserved for the online delivery, e.g. GP creating a 3-step medication plan; patient self-monitoring at home; prompting GP when medication change was required.  The evidence was less strong that healthy behaviour change would be acceptable to patients and would have clinically useful effects on BP, and so this aspect of the intervention was encouraged but was not made a core part of the intervention. |
| 7. Consider real-world issues about cost and delivery of any intervention at this early stage to reduce the risk of implementation failure at a later stage | Since the rationale for the intervention was to provide a more feasible and cost-effective method of controlling BP, a key focus was to design the intervention to be as pragmatic, efficient and easy to implement as possible. This included: creating standardised, easily disseminated online training for patients and HCPs; minimising requirements for healthcare professional input; using automated prompts to action; and providing online templates for health professional communications with patients.  Regular management meetings were held amongst stakeholders, including patient contributors and clinicians, at which optimising the feasibility of the intervention in primary care was thoroughly discussed. |
| 8. Consider whether it is worthwhile continuing with the process of developing an intervention | Early review of the evidence suggested that DIs were effective for controlling BP, suggesting that it was worthwhile continuing with the development process.  PPI, stakeholder and qualitative feedback on prototype versions of the intervention also provided encouraging evidence that the intervention was accessible and well-liked by patients and acceptable and feasible for health professionals. |
| 9. Generate ideas about solutions, and components and features of an intervention | Qualitative research was undertaken with a range of patients and HCPs from the target population. This included:   1. Think-aloud interviews, in which the patient used the intervention with a researcher present and described their thoughts aloud 2. Retrospective interviews, in which the patient used the intervention independently for three weeks at home and then took part in a retrospective interview about their experiences 3. Focus groups with HCPs who had completed the online training.   All interviews and focus groups were transcribed verbatim.  Decisions about how to optimise the intervention based on feedback were made at weekly core development meetings, and straightforward changes to overcome users’ concerns about the intervention were made directly. Any decisions which were more complex or needed clinical input were raised with the wider development team at monthly meetings, with PPI contibutors, or with the full management group.  Further user feedback was sought on the revised intervention from new participants. |
| 10. Re-visit decisions about where to intervene This can involve consideration of the different levels at which to intervene, and the wider system in which the intervention will operate | The in-depth qualitative development research enabled the development team to review decisions about how the intervention would work, and key points for support. For example, feedback from some patients during retrospective interviews after using the intervention independently indicated that they did not feel confident using the BP monitor, which led to the addition of an optional support appointment with the nurse after a week of practice readings. |
| 11. Make decisions about the content, format and delivery of the intervention | As described above, decisions about the content, format and delivery of the intervention were informed by in-depth qualitative and mixed methods research with the target user population, reviews of the evidence, behavioural analysis, and input from the development team and wider management team. |
| 12. Design an implementation plan, thinking about who will adopt the intervention and maintain it | The grant proposal for the intervention included an implementation plan should the intervention prove effective.  This involved disseminating the findings through multiple pathways, including: open-access, peer-reviewed publications; presentation at conferences; workshops for patients, HCPs, and policy makers to discuss the next steps; and speaking to NHS Clinical Commissioning Groups, NHS Choices and NHS Digital. The plan also specified that the intervention software would facilitate adaptation of the DI materials for future roll-out in different contexts, e.g. adapting for certain patient sub-groups, or adding new components. It was planned that the intervention could be used by the NHS, as well as in the private sector, third sector, and by other health researchers.  Blood Pressure UK were involved in the project from the outset, with their Chief Executive Officer, Katharine Jenner, being invited to all management meetings. Omron healthcare were also informed of this research project, and provided the patient BP monitors for the trial. |
| 13. Make prototypes or mock-ups of the intervention, where relevant | The intervention was developed using LifeGuide software which enabled creation of a prototype intervention that could be easily modified throughout the development process, based on user feedback (especially from think-aloud interviews). This was an essential, iterative phase of intervention development which helped to ensure that the intervention was accessible, appropriate, feasible, motivating, convincing and persuasive for users. |
| 14. Test on small samples for feasibility and acceptability and make changes to the intervention if possible | At early stages of development, feedback on the intervention was sought from the development team and management group. Subsequently, detailed think-aloud interviews (*n =* 36), retrospective interviews with patients who had used the intervention independently (*n =* 11), and focus groups with healthcare professionals (*n =* 7) informed decisions about changes to the intervention. |
| 15. Test on a more diverse population, moving away from the single setting where early development of the intervention took place and seeking a more diverse sample. This can involve asking questions such as ‘is it working as intended?’, ‘is it achieving short term goals?’, ‘is it having serious adverse effects’? | Due to the extensive prior development work (including a previous feasibility study that informed intervention planning) and time constraints, this project included an internal pilot study rather than a feasibility study to enable any final minor but essential modifications to the intervention to be made. The pilot study was carried out in 15 practices that had not been involved in the intervention development work. While outcomes could not be assessed, the feasibility of the intervention procedures was confirmed via usage data and process interviews with patients and HCPs. |
| 16. Optimise the intervention for efficiency prior to full RCT | The intervention was optimised to promote feasibility based on the findings during the internal pilot trial. Decisions were made by the core intervention developers when changes were very minor, but more significant changes were discussed with the development team. Examples of optimisations included additional reminder emails about healthy behaviour changes, and revising the content of GPs' emails about medication change to further encourage the use of remote rather than face-to-face procedures for changing patients' medication. |
| 17. Document the intervention, describing the intervention so others can use it and offer instructions on how to train practitioners delivering the intervention and on how to implement the intervention | The intervention was described in detail using the TIDieR checklist (see *Appendix 1*).44  [Note intervention content will be made widely available in full as a demo; online training can be directly disseminated; the intervention has also been described in numerous papers and shared via workshop dissemination] |
| 18. Develop the objectives of the outcome and process evaluations. This includes determining how outcomes and mediators of change can be measured, developing measures, specifying evaluation design, planning recruitment and considering feasibility of a full RCT | The process evaluation was planned in consultation with the management group, and appropriate measures were selected to capture beliefs theorised to influence adherence to the target behaviours, informed by the logic model.  This involved:   1. Semi-structured qualitative process interviews with a sub-sample of patients and HCPs during the RCT about their perceptions and experiences of using the intervention. 2. Quantitative data captured via questionnaires measuring beliefs theorised to be important influences on intervention outcomes in the logic model, such as medication adherence, and self-efficacy 3. Usage data captured automatically via the online intervention to indicate patient and HCP engagement 4. HCP adherence to medication change captured via review of patients’ medical notes   The data were planned to be analysed independently, and a mixed-methods approach adopted for triangulating the individual findings. This would facilitate an enhanced understanding of patients’ and HCPs’ experiences and perceptions of engaging with an online intervention for managing hypertension. |

# Evaluation of HOME BP

Parts of this section are reported in more detail in the following publication:

1. McManus, R., Little, P., Stuart, B., et al. (2021). Home and Online Management and Evaluation of Blood Pressure (HOME BP) using a digital intervention in poorly controlled hypertension: a randomised controlled trial. *BMJ,* 10.1136/bmj.m4858 45 <https://www.bmj.com/content/372/bmj.m4858>
2. Morton K, Dennison L, Bradbury K, et al. (2018). Qualitative process study to explore the perceived burdens and benefits of a digital intervention for self-managing high blood pressure in Primary Care in the UK. *BMJ Open*;8:e020843. doi: 10.1136/bmjopen-2017-02084346 <https://bmjopen.bmj.com/content/8/5/e020843> (follows the COREQ checklist for reporting qualitative research)
3. Morton, K., Dennison, L., Band, R. et al. Implementing a digital intervention for managing uncontrolled hypertension in Primary Care: a mixed methods process evaluation. *Implementation Sci.*2021 May 26; 16, 57 47<https://implementationscience.biomedcentral.com/articles/10.1186/s13012-021-01123-1>

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Additional findings are also being written up as a paper reporting on the HCP process analysis.

## Objectives

This section will describe the evaluation of the HOME BP intervention during a 12-month RCT. Aims, methods, results and implications are described for each discrete piece of research as follows:

* RCT to assess clinical and cost effectiveness
* Process evaluation exploring how patients and healthcare professionals (HCPs) experienced and implemented the intervention in practice:
  + Patient qualitative process study: Perceived benefits and burdens of using the intervention for patients
  + Patient quantitative process study: Engagement and usage of the HOME BP intervention by patients
  + HCP mixed methods process study: Exploration of HCPs’ experiences of and adherence to using the intervention

The section finishes with a conclusions section which draws the findings together.

## Randomised controlled trial to assess clinical and cost effectiveness

Aims:

To establish whether a DI for guided self-management of uncontrolled BP in primary care is effective compared with usual care.

Methods:

Patients from 76 GP practices across Wessex and Thames Valley regions in southern England were randomised to the trial (*n =* 622). In order to be eligible, patients had to be prescribed 1-3 antihypertensive medications and have a BP reading exceeding 140/90 mmHg at baseline. An online system randomised participants to the intervention (n=305) or usual care (n=317) in a 1:1 ratio (<https://www.lifeguideonline.org>). Minimisation took account of patients’ baseline systolic blood pressure reading, age, whether or not they had diabetes and GP practice. Randomisation was concealed from participants until after completion of the baseline questionnaires. Healthcare professionals were notified of participants’ randomisation group by email. The intervention group completed online training to self-monitor BP, and had planned changes to medication initiated by the GP in response to raised home readings. The intervention group were prompted to self-monitor at home for 7 days, every 4 weeks. The intervention group also had the option to make a healthy behaviour change, with online support.

Both groups had a baseline medication review with their GP, as their BP was above-target at baseline. The target thresholds for home readings in the intervention group were in line with UK National Guidelines (135/85 mmHg) and were adjusted for patients with diabetes or those aged over 80 years. The difference in systolic BP at 12 months was the primary outcome, adjusting for BP at baseline, BP target, patient age and GP practice. Multiple imputation was used for missing values. Cost-effectiveness analysis took an NHS perspective in which the costs comprised that of intervention and use of NHS blood pressure related services. Two economic analyses are reported: cost per unit of blood pressure reduction in a within trial analysis, and a long-term cost per QALY gained.

During the trial, the target sample size was increased from 574 to 610, as initial withdrawal rates suggested that it would be prudent to allow for a 20 percent drop out rather than 10 per cent, although this later proved not to be necessary.

Results:

*Figure 2* shows the flow of participants through the trial.

Assessed for eligibility (n=1389)

Randomised (n= 622)

Partial withdrawals\* (n=3)

Disliked intervention (n=1)

Ill health (n=1)

Admin error in Practice (n=1)

Complete withdrawals (n=10)

Disliked intervention (n=3)

Ill health (n=2)

Admin error in Practice (n=3)

Moved away (n=1)

Unknown (n=1)

Did not attend follow-up (n=24)

12-month follow-up (n=271)

Excluded (n= 767)

Not eligible (n=734)

Eligible but did not complete baseline measures and randomisation (n= 33)

Allocated to HOME BP intervention (n= 305)

Allocated to control (n=317)

Partial withdrawals\* (n=4)

Disliked intervention (n=1)

Ill health/spouse ill health (n=2)

Moved away (n=1)

Complete withdrawals (n=5)

Disliked intervention (n=2)

Ill health (n=2)

Admin error in Practice (n=1)

Lost to follow-up (n=17)

Partial withdrawals\*\* (n=1)

Did not want follow-up (n=1)

Complete withdrawals (n= 6)

Did not want follow-up (n=2)

Randomisation issue (n=2)

Ill health (n=1)

Admin error in Practice (n=1)

Did not attend follow-up (n=33)

Complete withdrawals (n= 7)

Did not want follow-up (n=2)

Died (n=3)

Ill health (n=1)

Unknown (n=1)

Lost to follow-up (n= 22)

12-month follow-up (n=282)

6-month follow-up (n=269)

6-month follow-up (n=278)

Analysed (n=305 with imputation)

Analysed (n=305 with imputation)

Key: \* Partial withdrawals withdrew from the intervention but consented to be followed-up

\*\* Partial withdrawals in usual care consented to follow-up

Figure 2 Flow of participants through HOME BP trial

(Note: Reproduced from 45 according to the Open Access licence cc-by-4.0)

See *Table 3* for the baseline characteristics of the sample.

Table 3 Baseline characteristics of HOME BP participants.

|  |  |  |
| --- | --- | --- |
|  | **Intervention\***  **N = 305**  Number (%) or mean (SD) | **Usual Care\***  **N=317**  Number (%) or mean (SD) |
| Age | 65.2 (10.3) | 66.7 (10.2) |
| Female | 145/305 (47.5%) | 143/318 (45.0%) |
| Ethnicity |  |  |
| White | 285/304 (93.8%) | 299/317 (94.3%) |
| Black African | 5/304 (1.6%) | 3/317 (1.0%) |
| Black Carribbean | 0/304 (0.0%) | 1/317 (0.3%) |
| Indian | 3/304 (1.0%) | 0/317 (0.0%) |
| Pakistani | 1/304 (0.3%) | 3/317 (1.0%) |
| Other | 10/304 (3.3%) | 11/317 (3.5%) |
| Index of Multiple Deprivation |  |  |
| 1-3 (most deprived) | 36/304 (11.8%) | 27/318 (8.5%) |
| 4-7 | 108/304 (35.5%) | 125/318 (39.3%) |
| 8-10 (least deprived) | 160/304 (52.6%) | 166/318 (52.2%) |
| Diabetes  Of which: Type I | 24/278 (8.6%)  1/278 (0.4%) | 32/291 (11.0%)  1/291 (0.3%) |
| Systolic blood pressure | 151.7 (11.8) | 151.6 (11.1) |
| Diastolic blood pressure | 86.4 (9.6) | 85.3 (9.9) |

The 12-month follow-up rate was 89 per cent in both groups. Systolic BP at 12-months was significantly lower in the intervention group at 138.4/80.2mmHg compared with 141.8/79.8mmHg in the control group; a difference of -3.53 (-6.19, -0.86) / -0.55 (-1.89, 0.80) mmHg (see *Table 4*). Exploratory sub-group analyses suggested that the intervention had a larger effect in younger participants. Self-reported adverse effects showed no differences between the two groups. According to a self-reported symptoms scale used as an indication of side effects, a significantly higher proportion of the intervention group reported weight loss at 12 months but this was not born out on objective measurement of weight. While engagement with self-monitoring was relatively high across the sample (with 80 per cent completing both training sessions and at least three complete sets of BP entries), less than one third of the sample chose to register on an optional programme for healthy behaviour change.

Table 4 Mean blood pressure at baseline, 6 months and 12 months

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Systolic blood pressure** | **n** | **Baseline** | **6 months** | **12 months** |
| Usual Care | 282 | 151.65 (11.10) | 140.87 (15.98) | 141.83 (16.76) |
| Intervention | 271 | 151.74 (11.82) | 138.69 (17.04) | 138.43 (15.99) |
| **Diastolic blood pressure** |  | **Baseline** | **6 months** | **12 months** |
| Usual Care | 282 | 85.27 (9.88) | 80.18 (10.32) | 79.77 (10.10) |
| Intervention | 271 | 86.44 (9.65) | 79.88 (9.68) | 80.22 (10.07) |

A within-trial cost effectiveness analysis was conducted from an NHS perspective using data collected on use of services and on the intervention. This reduction in blood pressure of 3.45 mmHg, combined with increased cost in the intervention arm of £38, led to incremental cost per unit blood pressure reduction in the base case (See *Table 5*) of £11 (95% CI £5 to £29). The increased cost per patient of £38 in the intervention arm was due almost entirely to that of the intervention (£39.73).

The base case relies on the imputed values but the complete case results were the same for cost and only slightly different for the clinical outcome (Table 5).

Table 5 also shows a small QALY loss of 0.01 in the intervention arm. Given that the combination of higher cost and very slightly reduced QALYs, this means the intervention arm was dominated by the usual care arm. However since QALY differences to do with improved blood pressure control at 12 months are of less interest that those in the longer term, the results of the life long modelling reported below are of more interest.

Table 5 NHS cost, Primary Outcome, QALY and Incremental cost effectiveness, mean per patient based on differences observed between the Usual Care and the Intervention arms

|  |  |  |
| --- | --- | --- |
|  | Base case | Alternative |
| NHS cost | |  |  | | --- | --- | | Imputed | Complete cases | | |  |  | | --- | --- | | Complete cases | Complete cases | |
| Usual Care (£) | 100 | 100 |
| Intervention (£) | 138 | 138 |
| Difference (£) | 38 | 38 |
|  | Imputed | Complete cases |
| Difference in primary outcome at 12 months (mmHg) | 3.45 | 3.54 |
| Cost/BP (£) | 11 | 11 |
|  |  |  |
| QALY difference | -0.01 | -0.01 |
| Cost/QALY (£) | -3,800 | -3,800 |

The base case included use of NHS services related to BP. This included the full range of NHS services including hospital admissions. Although few such admissions were recorded, some were elective procedures that had to have been planned before entry to the trial. Consequently, only those hospital admissions which occurred after a change of medication were included in the base case costing. To test the sensitivity of results to this assumption, a scenario was costed which included all hospital, BP related, service use regardless of timing. This made little difference overall but reduced both the cost difference and the incremental cost effectiveness.

The mean cost per patient in primary care was similar to those in the base case, indicating that primary care accounted for almost all the costs (See *Table 6*). Within primary care, costs were split roughly 60/40 between those attributable to consultation and those due to prescriptions. Patients in the intervention arm had slightly higher prescription costs associated with changes in medication and/or dose. These did not increase the cost of primary care consultations however due to the role of the digital intervention. These trends as might be expected. Further analysis of these changes is planned for a separate publication which will include changes in the time spent by patients in managing their hypertension.

Table Mean cost per patient in primary care by arm in primary care, disaggregated by consultations and prescription costs

|  |  |  |  |
| --- | --- | --- | --- |
|  | Of which: | Of which: |  |
|  | Primary care | Consultations | Prescriptions |
| Usual Care | 97.3 | 62.5 | 34.8 |
| Intervention | 96.5 | 55.8 | 40.7 |

Since the benefits of reduced blood pressure take the form of lowered risk of cardiovascular disease, long term modelling was required to capture these effects. The most comprehensive approach involves estimation of life time benefits measured in terms of quality adjusted life years. Life years reflect reduced mortality and quality adjustment allows for the effects of non fatal cardiovascular events.

Rather than develop a new long term model, we fed the results of the randomised trial into a pre-existing model developed by one of the lead clinicians in the present study for previous trials of blood pressure interventions. This model, TASMINH448 is a markov patient-level simulation undertaken in TreeAge2018 (TreeAge Software, Inc, Williamstown, MA). This tracks the costs and consequences of individual patients passing through the model, with characteristics (taken from the trial) free to vary between patients. The model was run over the maximum lifetime of the patients (maximum of 65 years; minimum trial inclusion criteria was age 35), a time horizon sufficient to capture all relevant long-term costs and consequences.

All patients started in the well/no event health state. Within a 6-month time cycle, a patient had a risk of suffering a fatal or non-fatal cardiovascular event or dying from other causes. The possible cardiovascular events in the model were stable angina, unstable angina, stroke, myocardial infarction, and transient ischemic attack. Ten-year cardiovascular risk was calculated for each individual patient, with the distribution of coronary heart disease and stroke events dependent on age and sex. Patients who suffered a nonfatal cardiovascular event transitioned to a post-event cardiovascular health state and additional clinical events were not modelled. Once a cardiovascular event had occurred, mortality risk was adjusted accordingly. The impact of each intervention in terms of event reduction was applied as a relative risk, taking into account the mean differences in systolic BP observed in the Home BP trial.

The results from inputting the Home BP trial results into the long-term TASMIN4 cost effectiveness model put the incremental cost effectiveness ratio (ICER) at just over £9k (See *Table 7*). This was due to a cost difference of £402, and a QALY difference of 0.044. The probability of being cost effective at different levels of willingness to pay was explored using a cost effectivness acceptability curve. This put the probability of the intervention being cost effective at 66% at a willingness to pay of £20km rising to 80% as willingness to pay increased to £50k. Such results compare well with those assessed for use in the NHS by NICE, albeit with a sizeable degree of uncertainty.

See *Appendix 2* for the full cost-effectiveness analyses and See *supplementary material 1* for a CHEERS checklist.

Table 7 Base case results for Home BP versus Usual Care, base case, over patients’ lifetime

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 2,685 |  | 11.562 |  |  |
| Self-Monitoring | 3,087 | 402 | 11.606 | 0.044 | 9,107 |

**Note** Incr = Incremental

The intervention group had significantly more changes to their antihypertensive medication than the usual care group during the trial, both in terms of dose increases (relative risk 2.03 (1.54, 2.69)) and new drugs added (1.46 (1.12, 1.91)). This, however, had minimal impact on costs.

Further details of the secondary outcomes are reported in the main trial publication45.

Implications:

The HOME BP intervention led to significantly lower BP at 12 months amongst a sample of participants with raised BP at baseline. The reduction in blood pressure in Home BP was similar to that in other comparable trials. The cost of the intervention was modest at just under £40 per patient. While this is probably an overestimate given it was based on providing a novel service for relatively few people, it nonetheless delivered benefits which would be considered cost effective in terms of NICE and the NHS. Long-term modelling puts the incremental cost per QALY at just over £9k. If included in a suite of digital interventions which seems increasingly possible, the cost per patient would probably reduce. More generally post-COVID and in line with demographic trends, self-management seems likely to become more widely used in modernised health services. The work reported here provides evidence of both its clinical and cost effectiveness.

It was encouraging that this DI had a similar, albeit slightly smaller effect size to previous paper-based interventions for BP management, as HOME BP offers a more feasible system for wider implementation. Further, the cost of the intervention was less than those previous interventions.48, 49 It would be interesting to further explore the interaction whereby the intervention appeared to be more effective for younger participants, in order to better understand how to optimise effectiveness for all participants in wider implementation.

## Process evaluation exploring how patients and healthcare professionals experienced and implemented the intervention in practice

### Patient qualitative process study: perceived benefits and burdens of using the intervention for patients

Aims:

To explore the benefits and burdens perceived by patients using the HOME BP self-management intervention.

Methods:

Semi-structured telephone interviews were conducted with 28 patients using the HOME BP intervention, and 7 patients in the usual care group. The uptake rate to interviews of those invited was 52 per cent in the intervention group, and 29 per cent in the usual care group. Interviews were transcribed verbatim and the data were analysed using thematic analysis with some techniques from grounded theory.39,50

Results:

See *Table 8* for the characteristics of participants in the qualitative process study.

Table 8 Demographic characteristics of participants in the qualitative process study.

|  |  |  |
| --- | --- | --- |
|  | Intervention participants | Usual care participants |
| N | 28 | 7 |
| Median age (range) years | 70 (41-87) | 67 (52-77) |
| Female % | 71% | 43% |
| Ethnicity |  |  |
| White | 24 | 6 |
| Black African | 1 |  |
| Pakistani | 1 |  |
| Other | 2 | 1 |

The thematic analysis generated three perceived benefits resulting from the use of HOME BP: reassurance, improved health, and motivation to engage in healthy behaviour change. Four perceived burdens were also developed from the data: worrying about health, uncertainty about self-monitoring, guilt about not engaging with healthy behaviour change, and fitting self-monitoring into the day. It appeared that the beliefs patients held about their illness and treatment could influence the extent to which they experienced these benefits or burdens. For example, those with high confidence that their BP could be controlled by medication and with low concerns around side effects or co-morbidities tended to be more focused on the benefits of improved health and reassurance that the intervention could bring.

Implications:

This study suggested that the benefit of reassurance from seeing well-controlled readings could encourage ongoing engagement with the intervention, even when readings were stable. However, those with poorly controlled readings might need more support to maintain engagement over time. Intervention optimisation to minimise burdens for these users might include a guided conversation at baseline with the GP to address expectancies for medication change and manage concerns about side effects.

More generally, these findings suggested that it is important to capture the benefits of using a self-management DI, as well as the burdens. Benefits such as reassurance appeared to be strong sources of motivation to keep people engaging with the intervention over time, but currently measures such as the Patient Experience with Treatment and Self-management questionnaire focus only on the structural burden for patients, such as attending appointments, or engaging in self-monitoring.51 In addition, intervention evaluations could seek to explore the more subjective, psychosocial outcomes of using an intervention, as well as objective factors such as time and number of appointments, as these psychosocial perceptions are critical for understanding people’s experiences and therefore building knowledge about how best to optimise digital self-management interventions.

The participant demographics show that a higher proportion of the process study participants were female (71 per cent) compared with the sample in the overall RCT (48 percent), and the average age was a little higher (70 compared with 65 years).

### Patient quantitative process study: engagement and usage of the HOME BP intervention by patients

Aims:

To describe patient uptake and engagement with the HOME BP intervention and determine which factors were associated with adherence to target behaviours.

Methods:

GP practices were asked to report the gender, age and postcode of all patients invited to the study, to establish whether there was evidence of a response bias within the RCT. The online intervention automatically recorded usage data, including number of logins to the intervention and BP readings entered by participants. A sub-sample of 20 BP monitors was audited to compare the readings saved on the monitor with those entered by patients on the online intervention.

Participants in the RCT completed self-report questionnaires at baseline and 12 months, including:

* Medication Adherence scale (MARS)52
* Beliefs about Medication Questionnaire (BMQ)53
* Self-efficacy to engage in self-monitoring and manage BP, developed using Social Cognitive Theory54
* Patient Enablement Questionnaire55
* Change in healthy lifestyle behaviours (12 months only)

Data analysis to explore differences between participants and non-participants in the trial included Mann Whitney U tests for continuous data, and chi square tests for categorical data. Multiple regression analyses were used to explore predictors of the main outcome; systolic BP at 12 months controlling for systolic BP and age at baseline.

Results:

Data were available from 54 of the 76 GP practices in the trial, and showed no evidence of a response bias in terms of the age (U = 1539847.5, n1 = 6616, n2 = 469, *p=.786*) or gender (2 (1, *n =* 8429) = 1.16, *p=.333*) of participants randomised to the trial compared with those who were not. However there was a very small but significant difference in Index of Multiple Deprivation (IMD) as indicated by home postcode, with those who took part being from less deprived areas than those who did not take part in the study (U = 1539193.0, 1 = 7106, n2 = 468, *p=.007*).

Engagement with the DI was high, with most patients completing both core training sessions (92 per cent), and entering a week of practice readings (88 per cent). Seventy percent of the intervention group continued to enter at least one BP entry into the final quarter of the study (months 10, 11 and 12). The number of BP entries patients made during the study was predicted by baseline self-reported medication adherence (MARS) and perceived concerns and necessity of BP medication (BMQ), controlling for age and baseline BP (see *Appendix 3*). Systolic BP at 12 months was predicted by the number of BP entries a patient made, the number of medication changes recommended, and their medication necessity beliefs at baseline, controlling for baseline BP and age (see *Appendix 3*). An audit of BP monitors showed that readings were entered on HOME BP with 95 per cent accuracy (557/589 readings entered accurately).  Where discrepancies occurred, some appeared to be genuine errors whereas others indicated a potentially deliberate attempt to lower the average.

In terms of engagement with the healthy behaviour change session, 95 participants (31 per cent) completed the optional session, which described the health benefits of making healthy behaviour changes. The difference in systolic BP at 12 months between those who did and did not complete the optional session on healthy behaviours was not significant, but there was a trend towards participants who completed the optional session having a higher systolic BP at 12 months by 2.78 mmHg (95% CI -1.16, 6.73), after controlling for baseline systolic BP, age, sex, target category and the random effect for practice.

Of the 243 intervention group participants with a BMI above 25, 46 (19 per cent) signed up to the weight loss intervention. Of the remaining healthy lifestyle sessions: 25 participants registered for the physical activity intervention, 24 for healthy eating, 16 for reducing salt, and 6 for reducing alcohol. A significantly higher proportion of the intervention group reported increasing the amount of fruit and vegetables in their diet during the last 12 months compared with usual care (37 per cent compared with 25 per cent, 2 (2, *n =* 486) = 10.70, *p=*.005).

Practical Implications

These findings suggested that engagement with self-monitoring BP throughout the intervention was high, and it was encouraging that the audit indicated that patients entered their readings on the intervention with high levels of accuracy. Entering more BP readings was predictive of lower systolic BP at 12 months, demonstrating the importance of maintaining engagement, especially when readings are poorly controlled. Although uptake to optional healthy behaviour change sessions was relatively low, the findings suggested that the intervention group may have engaged in more offline healthy behaviour change than usual care with a significantly higher proportion reporting an increase in healthy diet at 12 months.

### Healthcare professionals mixed methods process study: exploration of healthcare professionals’ experiences of and adherence to using the intervention

Aims:

To develop a detailed understanding of adherence levels, factors influencing adherence, and the barriers and facilitators to implementing the intervention in primary care.

Methods:

A mixed-methods approach was adopted for the HCP process evaluation. The HOME BP intervention was used by 125 HCPs across 70 GP practices, and adherence data were collected either automatically by the online programme or from the patients’ medical notes. The following measures of adherence were used:

* Percentage of automated recommendations to increase patients’ medication in response to home readings which were actioned.
* Percentage of patients for whom a three-step medication plan was created
* Percentage of medication changes which were issued remotely (by letter or email)

HCPs also completed self-report questionnaires before and after completing compulsory online training at the start of the trial, capturing perceived self-efficacy, outcome expectancies and perceived intervention acceptability for patients. The data were analysed using a combination of correlations, Mann Whitney U tests and chi square tests.

Qualitative semi-structured process interviews were conducted with 27 HCPs during the trial, including GPs, nurse prescribers, nurses, and healthcare assistants. To begin with, all prescribers and supporters were invited to an interview (17/25 accepted) and subsequently purposive sampling was used to target HCPs with more patients in the study and HCPs who were acting as both prescriber and supporter. The interviews were transcribed and analysed using thematic analysis.39

The quantitative and qualitative data were analysed separately to maximise the strengths of each research method, and subsequently integrated using triangulation in which key findings from each analysis were compared to establish whether they were in agreement, partial agreement (complemented one another), disagreement, or silence.56

Findings:

The sample for the quantitative analyses included 62 prescribers (GPs or nurse prescribers; 35% female), 58 supporters (nurses or healthcare assistants; 95% female) and 5 prescriber-supporters who performed both roles (60% female). The sub-sample of HCPs who took part in qualitative interviews included 13 prescribers (38% female), 11 supporters (91% female) and 3 prescriber-supporters (100% female).

In terms of adherence to the target behaviour of escalating patients’ antihypertensive medication in response to average home readings being above target for two consecutive months, 405 email recommendations were sent to HCPs of which 215 (53 per cent) were actioned. Comparisons of recommendations actioned against those which weren’t showed that cases where systolic BP was closer to the threshold of 135/85 mmHg, and cases in which the patient had already been recommended a medication change previously, were less likely to be actioned. Meanwhile patient age did not appear to make a difference.

*Figure 3* shows the distribution of average systolic BP readings in cases where the recommendation for a medication change was not adhered to. This shows that in 181/190 of cases not adhered to, the patient had a mean BP reading below 150 mmHg (150 mmHg the target for the national Quality and Outcomes Framework in UK General Practice 57), although there were a few higher means which did not result in a change.

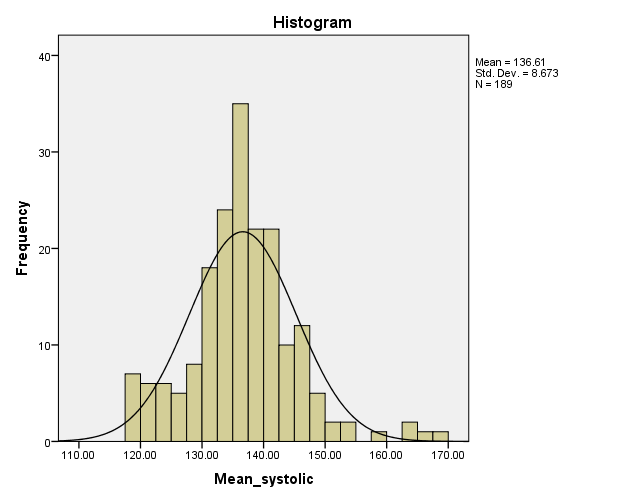


Figure 3 Distribution of average systolic BP readings in cases where the recommendation for a medication change was not adhered to

Note: The cases in which systolic BP was below 135 mmHg triggered a medication change recommendation due to the diastolic mean exceeding the target, rather than the systolic.

The qualitative data also indicated that borderline readings were a reason for not changing patients’ medication when recommended, and other reasons included concerns about the lack of context in which the readings had occurred (e.g. whether the patient had recently experienced a stressful event or illness), and preferring to recommend healthy behaviour change instead.

Adherence to planning three medication changes in advance for each patient was 82 per cent, but the qualitative interviews highlighted several issues with implementing this procedure in practice. Some HCPs found it challenging to plan three medication changes for more complex patients, and there were also concerns about planning in advance when side effects or changes in health might mean the medication change is no longer appropriate. A few HCPs described negative experiences of having to update the 3-step plan, which could create additional work for them and cause anxiety for the patient.

Notifying patients of medication change remotely (by email or letter) occurred in 38 per cent of cases, while the rest of the time the HCP spoke to the patient by phone or face-to-face. Adherence to sending a monthly support email to patients in the trial was 56 per cent. Qualitative data indicated that HCPs had some concerns about contacting patients remotely, especially that patients might not receive or value the information.

Practice Implications:

This mixed-methods evaluation suggested that there were practical issues with creating a 3-step medication plan for some hypertensive patients and that this process might need more flexibility to improve implementation in practice. The processes of changing patients’ medication when their BP was above-target and supporting patients’ BP management via email appeared straightforward to enact but some HCPs were doubtful about the benefit of changing their working processes in this way. It may be that changes at the organisational level to BP targets and normalising email support for patients might facilitate implementation of these processes.

## Conclusions

Overall the HOME BP intervention appeared to be both clinically effective and cost-effective, with significant reductions in BP compared with usual care for a low cost per unit of BP. The reduction in BP found in this trial is important in terms of long-term health outcomes, with an anticipated reduction of 10-15 per cent of patients suffering a stroke, and 5-10 per cent of patients experiencing coronary-related events.

The detailed process evaluation of patients’ and HCPs’ experiences of implementing the intervention suggested some ideas for optimising the intervention, including:

* A guided discussion at baseline to increase patients’ and HCPs’ motivation to change medication when average BP exceeds the threshold, and to address some of the common concerns for patients about taking more medication
* Additional support for patients with continuously raised BP readings to encourage them to maintain engagement with self-monitoring
* Acknowledgements for HCPs when patients have received information sent remotely, to reassure them that it has been received and increase the feasibility of remote support

# Development of My Breathing Matters

Parts of this section are reported in more detail in the following publications:

1. McLean G, Murray E, Band R, Moffat KR, Hanlon P, Bruton A, Thomas M, Yardley L, Mair FS. Interactive digital interventions to promote self-management in adults with asthma: systematic review and meta-analysis. *BMC Pulm Med.* 2016 May 23;16(1):8358 <https://pubmed.ncbi.nlm.nih.gov/26845284/> (follows the PRISMA reporting guidelines for systematic reviews)
2. Morton K, Dennison L, May C, Murray E, Little P, McManus RJ, Yardley L. Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies. *Patient Educ Couns.* 2017 Apr;100(4):616-635. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5380218/> (last accessed: 18 July 2019)27

## Objectives

In this section, we describe the intervention planning (WS1), development, and testing (WS3) of My Breathing Matters, a digital self-management intervention for adults with asthma. The intervention objective was to improve functional quality of life of primary care patients with asthma, by supporting illness self-management by pharmacological (medication adherence, appropriate health care service use) and non-pharmacological (breathing retraining, cognitive behaviour therapy/stress reduction, healthy behaviour change) means. Development was carried out in four phases. These have not been reported elsewhere (apart from the development of the ‘guiding principles’59) and are therefore fully described in this section. These phases are described in chronological order and for each phase we report on the aims, methods, results, and practical implications for how the findings informed intervention development.

* Phase 1: Collate and synthesise evidence to inform intervention planning, including a systematic review of quantitative evidence, a qualitative meta-ethnography, and primary mixed methods research.
* Phase 2: Create an intervention plan, which involved developing guiding principles and carrying out behavioural analysis to identify barriers to key behaviours and specify how these will be addressed.
* Phase 3: Create an intervention prototype and use iterative qualitative interviews (think-aloud and retrospective interviews) to optimise the intervention.
* Phase 4: Mapping the evidence onto behavioural barriers and intervention components onto theory.

At the end of this section we demonstrate how the INDEX actions for developing complex interventions were met in this development process.23

## Intervention development team and PPI

The intervention development process was guided throughout by an intervention development team that involved asthma-focused clinicians, psychologists, web developers, PPI contributors, and representatives of Asthma UK, a key stakeholder organisation. Asthma UK were invited on our steering committee and intervention development team to provide their extensive knowledge of asthma and available self-management resources, and help recruit PPI contributors. They would also provide a suitable channel for national intervention dissemination once its acceptability and effectiveness is established.

Our PPI contributors included two people with asthma (David Russell, Mark Stafford-Watson) and one public contributor with a general interest in DIs (Samantha Richards Hall). They provided feedback on study materials (e.g. interview topic guides, participant information sheets) and detailed feedback on the intervention prototype, and changes were made following their feedback. Two PPI contributors (David Russell, Samantha Richards Hall) provided their feedback on the key findings and final interpretations of the mixed methods process evaluation and one (David Russell) was a co-author on the associated manuscript for this work, which is currently in revision with npj Primary Care Respiratory Medicine.

## Phase 1: collate and synthesise evidence

### Systematic review and meta-analysis of interactive digital interventions to promote self-management in adults with asthma (described in 58)

Aim:

To carry out a systematic review with meta-analysis of quantitative evidence assessing the effects of interactive DIs to support patient self-management of asthma.

Methods:

Ten electronic databases were searched to identify RCT studies of interactive DIs for adults (16 years and over) with asthma, which used usual care as a comparator. 58 Outcomes were change in clinical outcomes, patient-reported outcomes of wellbeing or quality of life, and cost-effectiveness. Studies were eligible if published in peer-reviewed journals and in English. Two independent researchers screened potential studies, extracted data from the eligible studies, and assessed risk of bias using the Cochrane collaboration tool. Where possible, meta-analysis using a random effects model was performed.

Results:

Eight publications of five trials with 593 participants were included. All 5 interventions provided health education and facilitated self-monitoring (e.g. monitoring symptoms, medication usage, or quality of life). Three of the trials were eligible for inclusion in a meta-analysis, which showed no significant changes in asthma quality of life and asthma control (when compared to usual care) and extremely high heterogeneity. To reduce heterogeneity, one study was removed as its’ aim was to reduce the total dose of oral prednisolone, compared to the other two studies, which was improving asthma control. The remaining two studies demonstrated significant improvement for Asthma Quality of Life (Standardised Mean Difference (SMD) = 0.45) and asthma control (SMD = 0.54). No evidence of harm was identified. Most studies were likely to be underpowered for most outcomes as they were small, of moderate quality, and short in duration.

Practical implications:

Although the findings show potential for benefit, with evidence of improvements in some outcomes, the evidence-base is weak due to a lack of large, robust trials. In terms of My Breathing Matters, the meta-analysis provided some, albeit weak, support for the potential efficacy of a DI for asthma. However, it could not offer more specific implications for how to promote effectiveness.

### **Meta-ethnography review of published qualitative studies on digital interventions for self-management of chronic physical conditions** (described in27)

Aim:

To synthesise the qualitative evidence on DIs for self-management of chronic physical health conditions to identify key barriers and facilitators to the target behaviours in My Breathing Matters.

Methods and Results:

The methods and key findings of this study were reported previously (see *Section 2*).

Practical implications:

The meta-ethnography suggested that tailoring of self-monitoring feedback could be important to promote perceived necessity of medication change for patients. It was also theorised that meaningful feedback could help patients understand how their self-monitored data are influenced by lifestyle activities. To facilitate meaningful self-monitoring while minimising burden, My Breathing Matters included simple self-monitoring of domains of asthma-related quality of life. Users were asked to rate how much their asthma has affected their quality of life over the last week by reporting how often (from ‘Almost all the time’ to ‘Not at all’) single-item statements applied to them. For example, one statement read ‘My breathing has made some activities a bit more difficult (e.g. exercising, sleeping, working, housework, or seeing friends)’. Tailored feedback on how users rated these items was then used to try to motivate users to make appropriate changes in their management of symptoms. For example, users could be recommended to do the 4-week challenge, which encouraged them to engage in habitual optimal preventer inhaler use and report the results.

Within the meta-ethnography, several asthma studies noted that health professionals were concerned about the additional time required to process or review DI data.60 To ensure My Breathing Matters minimised the demands on health professionals’ time and was easily scalable, the intervention advertised existing telephone support offered by trained nurses from Asthma UK. The telephone helpline could provide people with additional information and support to follow the behavioural advice provided in the intervention, but did not provide patients with medical advice. Patients were recommended to contact their health professional if they had any concerns about their symptoms or medications. This type of support would also be sustainable if Asthma UK were to disseminate the final intervention.

### Primary mixed-methods research

Aim:

To use published and directly relevant primary mixed methods research to inform the design of My Breathing Matters.

Methods:

There were two primary research projects previously conducted by members of the project research team that directly informed the design and development of My Breathing Matters.

1. The *Randomised trial of an Asthma Internet Self-management InterventioN* (RAISIN) involved a non-blinded pilot RCT to evaluate the feasibility of a theory-informed, evidence based online resource (‘Living Well with Asthma’) to support self-management in people with asthma.61, 62 Those in the intervention group (*n =* 25) completed the ﻿Problematic Experience of Therapies Scale (PETS) ﻿to identify barriers to using the website and following its advice. Quantitative usage data were also explored.
2. The BREATHE Study (*Breathing Retraining for Asthma – a Trial of Home Exercises)* was a large randomised-controlled trial that investigated the use of breathing retraining, a non-pharmacological treatment involving exercises to retrain dysfunctional breathing. The intervention was delivered by DVD and booklet, or by DVD and booklet plus three face-to-face sessions with a physiotherapist.63

Members of the RAISIN and BREATHE study teams provided stakeholder input when developing My Breathing Matters, sharing their expertise and the lessons they learned from their research.

Results:

Recruitment and retention in the RAISIN study confirmed feasibility and trends towards improved asthma-related quality of life and asthma control, which suggested that use of Living Well with Asthma may improve self-management in adults with asthma, compared to usual care. To be included in the trial, participants needed to have poorly controlled asthma (as defined by Asthma Control Questionnaire (ACQ) score ≥1) and introduction questions at the start of the website revealed that 95 per cent of users reported that asthma was negatively impacting on their lives. Despite this, 42 per cent of users reported doubting the personal relevance of the website (as measured by the PETS), stating that the intervention would be more useful to those with more severe asthma. Exploration of usage patterns revealed that although engagement was comparable to other behaviour change websites (﻿76 per cent of individuals logging in), some users missed core intervention sections that they may have benefitted from (e.g. sections promoting use of personal asthma action plans and attendance at annual asthma reviews). At stakeholder meetings, the RAISIN research team explained how some users found the Living Well with Asthma website large and difficult to navigate, and that it was not always clear what content they had already accessed.

In the BREATHE study, both breathing retraining groups demonstrated improved asthma-related quality of life compared to usual care. There was no inferiority of the DVD-only group versus patients supported by a physiotherapist indicating the effectiveness of self-guided breathing retraining.

Practical implications:

See *Table 9* for a summary of the intervention features that were included in My Breathing Matters to address each key issue identified in the primary mixed-methods research.

Table 9 Key issue identified in the primary mixed-methods research and intervention features included in My Breathing Matters to address these.

|  |  |
| --- | --- |
| **Key issue identified** | **Intervention features included in My Breathing Matters** |
| ***RAISIN study*** | |
| * The RAISIN study confirmed feasibility and trends towards improved asthma-related quality of life and asthma control. | * Key intervention components from Living Well with Asthma included in My Breathing Matters (e.g. sessions using BCTs to support best practice asthma management by using an personal asthma action plan and attending an annual asthma review). |
| * Many users of Living Well with Asthma reported doubting its personal relevance. | * Included specific content aimed at engaging those who do not view themselves as having active asthma to address the identified mismatch between users’ perceptions of the intervention’s personal relevance and their subjectively reported poor asthma control. |
| * Some users missed core intervention sections that they may have benefitted from. | * Include ‘unlockable content’, whereby new intervention content became available after a certain time period to maximise engagement. |
| * Living Well with Asthma website was large and difficult to navigate. | * Users were notified by email when content was unlocked and content that users had seen was marked with a ‘tick’ to help navigate users to unseen intervention content. |
| ***BREATHE study*** | |
| * Both breathing retraining groups demonstrated improved asthma-related quality of life compared to usual care. | * Included a video-based breathing retraining exercise component. |
| * No inferiority of the DVD-only group versus patients supported by a physiotherapist. | * Provide optional, rather than mandatory, nurse support through the existing Asthma UK helpline. |

## Phase 2: creation of an intervention plan.

### Guiding principles

Aim:

To develop brief guiding principles to inform intervention development.

Methods:

Guiding principles are a key part of the ‘Person-Based Approach’ (PBA), which was developed and refined in the process of completing the DIPSS research programme. It is discussed fully later in this report (see *Section 6*) and published in Yardley et al.34 The methods for developing the guiding principles were the same as those used in the HOME BP intervention (see *Section 2*). The development of the My Breathing Matters guiding principles is published in more detail in Yardley et al.59

Results:

The evidence collated in Phase 1 suggested that most people with non-optimal asthma control nevertheless do not consider themselves as patients with active asthma. Therefore, one intervention design objective was to engage these people and we aimed to do this using three key features: (1) maintaining positive illness context throughout (i.e. promote health rather than illness); (2) simple unobtrusive interface to provide optional (and flexible) support only when needed; and (3) demonstrating that impaired quality of life is not ‘just my breathing’ but can be improved.

The Phase 1 evidence also highlighted that users are not likely to adhere to medication, nor to use an asthma management plan, and may be sceptical of necessity and efficacy of both. Therefore, a second intervention design objective was to persuade and educate users to implement appropriate pharmacological management. Key features included persuading and educating users regarding the necessity, efficacy and safety of preventative asthma medication; and tailoring appropriate information regarding medical management according to users’ current medication behaviour.

Phase 1 findings also highlighted that there were other factors contributing to increased asthma symptoms and reduced quality of life, but these are often not known or acknowledged, particularly anxiety and stress and lifestyle (e.g. smoking, obesity, physical activity). Therefore, a third intervention objective was to encourage users to employ non-pharmacological methods of improving quality of life. The intervention aimed to address this by educating users on the benefits of these methods and offer psychological methods to improve quality of life (e.g. cognitive behavioural techniques for symptom management). The intervention also provided tailored access, and addressed patient concerns about, relevant positive healthy behaviour changes. This was done by giving users access to several previously evaluated interventions promoting healthy behaviours (smoking cessation64, physical activity65, weight management38, handwashing to prevent infections66).

Practical implications:

Similar to HOME BP, the guiding principles succinctly summarised the distinctive design objectives and features of My Breathing Matters to ensure that the psychosocial context and perspectives of target users was considered and accommodated throughout development.

### Behavioural analysis

Aims:

To systematically identify the influences on patient target behaviours and the intervention components that could address these.

Methods:

The methods for the behaviour analysis were the same as those used in the HOME BP intervention (see *Section 2*). Key target behaviours were identified from the primary mixed methods research and key barriers for each behaviour were identified across all of the evidence collated and synthesised in Phase 1.

Results:

See *Appendix 4* for the behavioural analysis table (Columns 1 and 2). Five target behaviours were identified: preventer medication adherence, engagement with a personal asthma action plan, attendance at annual asthma reviews, engagement with breathing retraining, and engagement with cognitive behavioural stress management practice. We also identified one subsidiary behaviour (effective engagement with DI) that is necessary to enact these target behaviours. The healthy behaviour changes were not included in the behavioural analysis as the interventions targeting these behaviours were not developed as part of this research. A range of barriers were identified for each behaviour, along with suggestions for how these could be addressed in the intervention. For example, to address patients’ belief that breathing retraining is not as effective as medicine, we provided information regarding the rationale behind breathing retraining and stories from other asthma patients emphasising its potential benefits.

Practical implications:

The behavioural analysis helped ensure that the intervention addressed key barriers identified in the literature and expert knowledge of stakeholders in the development team. This aimed to maximise user engagement with the intervention’s key target behaviours. Specifying the key target behaviours ensured intervention development focused on the self-management components most likely to have an impact on the intervention outcomes.

## Phase 3: creating and optimising the intervention.

Aim:

To create an intervention prototype and use in-depth iterative qualitative research to optimise the intervention.

Methods:

An intervention prototype was developed with input from all members of the intervention development team.

To explore target users’ perception of My Breathing Matters, 34 think-aloud interviews were carried out with 14 adults with asthma. Refinements were iterative in that changes were made in between each interview based on the feedback from the previous interview. Semi-structured telephone interviews were then carried out with 12 additional adults with asthma who were asked to use the intervention for 2 weeks. These interviews allowed us to further explore intervention aspects that were not appropriate for single-session think-aloud testing. For example, the optimal timing for sending emails and releasing the different intervention content. Each negative comment from participants in both studies was recorded in a table and possible changes were discussed by the research team. Recruitment ceased for each study when no further issues were arising with the intervention that seemed important and that could be addressed.

Results:

Overall, both sets of qualitative interviews showed that participants found the website acceptable and easy to navigate, and the content was easy to understand. They particularly liked that the website included both pharmacological and non-pharmacological content. However, several issues affecting the acceptability of the intervention were identified and the findings were used to optimise the intervention. When taking part in the think-aloud interviews, participants found the intervention tailoring process to be too demanding and onerous. On each unique log-in, users completed a brief assessment of quality of life in five areas: activities, sleep, stress, illness and reliever medication use (this tool was named ‘My Breath Check’). They were then signposted to relevant content based on their scores. After discussion within the development team, it was decided to modify the tailoring to focus on three areas only: activities, stress and reliever inhaler use.

Several participants in the retrospective interview study appreciated the value of My Breathing Matters for people with asthma generally, but did not consider the intervention relevant to them. This is because they believed their asthma was not particularly severe or problematic for them (despite reporting impaired quality of life in ‘My Breath Check’). Indeed, participants noted that they would be unlikely to use certain intervention components that they did not consider relevant. For example, they would not engage with the 4-week medication challenge if they believed they were already adhering to their medication, and the support for making a personal asthma action plan was not relevant to them if they already had created one with their GP. Findings from both studies indicated that many users did not consider the possible benefits of improved symptom control to be personally relevant. This was considered a major issue by the development team as users who did not consider the intervention relevant were less likely to engage with the intervention and be motivated to change behaviours. However, to address this by introducing additional content was considered by the development team to be in conflict with guiding principles (simple, clear, unobtrusive). Consequently, the issue was addressed by increasing the prominence of the content that highlights the personal relevance of impaired quality of life and challenges participants’ perceptions about what it means to have active asthma by making this the first section users viewed after the sign-up process. This was then tested with new users, who felt that the intervention was personally relevant.

Practical implications:

This iterative qualitative research suggested that My Breathing Matters was acceptable and persuasive to adults with asthma. It also highlighted some important modifications to optimise the intervention, including increasing its ease of use and perceived relevance.

## Phase 4: mapping the evidence onto behavioural barriers and **intervention components onto theory**

Aims:

1. To comprehensively describe the intervention in terms of existing theory and programme level theory.
2. To create a logic model to illustrate the hypothesised mechanisms of action that explain how My Breathing Matters is expected to lead to improvements in asthma-related quality of life.

Methods:

The methods for the behaviour analysis and logic modelling were the same as those used in the HOME BP intervention (see *Section 2*). For the logic model, relevant hypothesised mechanisms were identified from a literature review of existing evidence and the considerable behavioural science expertise in the study team.

Results:

See *Appendix 4* for this mapping in the behavioural analysis table (See Columns 3-6). When mapped onto the BCW, the My Breathing Matters intervention components were shown to target all six target constructs: psychological and physical capability, reflective and automatic motivation, and physical and social opportunity. The intervention components mapped onto six intervention functions (education, persuasion, training, modelling, enablement, and environmental restructuring) and 22 different BCTs. The intervention mapped onto all four core constructs of NPT (coherence, cognitive participation, collective action, reflexive monitoring).

For the logic model (*Figure 4*), three types of variables proposed to mediate the impact of My Breathing Matters on asthma-related quality of life were identified: (1) behavioural adherence, including effective engagement with DIs and improved pharmacological and non-pharmacological management (preventer medication adherence, engagement with a personal asthma action plan, attendance at annual asthma reviews, engagement with breathing retraining, engagement with cognitive behavioural stress management practice, and engagement with healthy behaviour change); (2) physiological mediators (improved asthma control, improved lung function and fewer exacerbations); (3) and psychological mediators (reduced stress, improved mood, and improved enablement).

Practical implications:

Similar to the development of HOME BP, the behavioural analysis was useful for ensuring the intervention content could be described using standard terminology. The logic model explicitly illustrated the mechanisms theorised to change asthma-related quality of life.

Figure 4 Logic Model of My Breathing Matters intervention to improve quality of life in patients with asthma.

*Key: aUptake and engagement facilitation; bPharmacological support; cNon-pharmacological support.*

**Intervention Target**

**Theory and evidence-based intervention ingredients**

**Primary Outcome**

**Proposed mediating variables**

**Improved asthma-related quality of life**

* Reduced stress
* Improved mood
* Improved enablement

**Psychological mediators**

* Improved asthma control
* Improved lung function
* Fewer exacerbations

**Physiological mediators**

**Behavioural adherence**

**To improve functional quality of life in primary care patients with asthma**

By supporting pharmacological and non-pharmacological self-management.

**Medication adherenceb:**

Persuasive/credible information & user stories on the health & emotional consequences of appropriate medication use; Instructions on correct inhaler technique; Information to address medication concerns and overcoming barriers to adherence; Goal-setting, action planning, and email reminders for using preventer medication.

**Appropriate healthcare service useb:**

Persuasive/credible information & user/GP stories on the health & emotional consequences of personal asthma action plans (PAAPs) & asthma reviews; PAAP for patients to complete; Reminders to book a GP appointment to create a PAAP & for an asthma review.

**Breathing Retraining (BR)c:**

Persuasive/credible information on health & emotional consequences of BR; Instructions and video demonstration of BR technique and feedback on technique; Information on overcoming barriers to practice & habit formation; Goal setting, action planning and self-monitoring of BR practice; Email reminders for practicing BR.

**Cognitive Behavioural Stress Managementc:**

Persuasive/credible information and user stories on health & emotional consequences of stress reduction; Instructions on how to perform stress reduction techniques; Action planning and email reminders for practicing stress reduction.

**Healthy behaviour changec:**

Persuasive/credible information about the health consequences of healthy behaviour change; Provide access to healthy behaviour change interventions.

**Patient engagement with interventiona:**

Persuasive/credible information & user stories on the health & emotional consequences of intervention; Information on the development team’s expertise; Self-monitoring of asthma quality of life & tailored feedback; Email reminders to use intervention.

**Social supporta:**

Persuasive/credible information & user stories on the health & emotional consequences of social support; Link to information about asthma management for family & friends; Information about support provided by Asthma UK & relevant contact details.

Effective engagement with digital intervention

Improved pharmacological and non-pharmacological management

## Mapping the My Breathing Matters intervention development process to the INDEX actions

As in the HOME BP development (see *Section 2*), we retrospectively mapped the My Breathing Matters intervention development process to the 18 recommended actions for consideration during intervention development provided by O’Cathain et al. (see *Table 10*).23

Table 10 My Breathing Matters intervention development actions mapped to INDEX guidance actions

|  |  |
| --- | --- |
| **Action from INDEX guidance** | **How this action was addressed in the My Breathing Matters intervention** |
| 1. Identify that there is a problem in need of a new intervention | The rationale for My Breathing Matters was identified in the funding application, based on existing evidence (see *Section 1*) suggesting that:   1. Asthma control and primary care support for asthma self-management remains sub-optimal in the UK. 2. Patient education and proactive self-management have been convincingly shown to improve clinical outcomes in asthma. 3. A DI might be a cost-effective means of supporting improved self-management in asthma patients. 4. There are no UK-based DIs similar to those we proposed. 5. PPI input indicated that patients felt that digital support could be helpful. |
| 2. Establish a group or set of groups to guide the development process, thinking about engagement of relevant stakeholders such as the public, patients, practitioners and policy makers | The management group (which met three monthly to oversee all important decisions) was set-up at the proposal stage and included people with asthma, behaviour change specialists, Asthma UK, clinicians, health economists, policy makers, statisticians, and trial managers.  All members of the management group were invited (if interested) to join the intervention development team which met monthly (or as necessary) to oversee and guide intervention development; this team included patients, clinicians and health psychologists.  A core intervention development team met weekly, comprising the health psychologists developing the intervention, in close consultation with key clinical academics when necessary. |
| 3. Understand the problems or issues to be addressed | Barriers to key behaviours were identified from a) reviews of the existing quantitative and qualitative evidence;  b) in-depth primary mixed methods research.  These evidence sources (detailed above) enabled us to understand the specific beliefs and contextual factors that appeared to influence target behaviours. |
| 4. Make a decision about the specific problem or problems that an intervention will address, and the aims or goals for the intervention. This may involve defining the behaviours to target. | A logic model was created to map the hypothesised mechanisms (including target behaviours) through which the intervention was theorised to change behaviour and outcomes.  Our behavioural analysis table documented the target behaviours for patients, the barriers for implementing them, and intervention ingredients intended to support target behaviours.  Guiding principles were developed to specify how the intervention would meet design objectives to promote engagement with the target behaviours in this specific population and context. |
| 5. Identify possible ways of making changes to address the problems. This involves identifying what needs to change, how to bring about this change and what might need to change at individual, interpersonal, organisational, community or societal levels | The primary and secondary research and analyses described above helped identify what needed to change at the individual patient level, and at a more organisational level in the healthcare systems, and provided insights into how this might best be achieved.  The development and management teams reviewed and agreed the design of the intervention, informed by the evidence reviews, behavioural analysis table and the guiding principles, together with stakeholder expertise (clinical and experiential) and knowledge of existing relevant theory and theoretical frameworks (in particular NPT and the BCW).32,32 |
| 6. Specify who will change, how and when. Selections may depend on consideration of the likely impact of the change, how easy it is to change, how influential it is for the problem being addressed, and how easy it is to measure | Decisions about the appropriate target group for behaviour change, core behaviours to target and intervention outcome measurement (e.g. required sample size, trial design and duration and the primary and secondary outcomes) were informed by the funding application, previous evidence relating to asthma management (especially61-63) and the wider review of evidence undertaken as part of the intervention planning described above.  There was good evidence that a digital self-management intervention and breathing retraining delivered using digital technology (i.e. DVDs) was acceptable and effective for asthma. So steps were taken to ensure that the key behaviours were incorporated into My Breathing Matters, e.g. breathing retraining delivered using videos; 4-week challenge to facilitate medication adherence; promoting better utilisation of healthcare resources (action plans, annual asthma reviews); providing stress management strategies. |
| 7. Consider real-world issues about cost and delivery of any intervention at this early stage to reduce the risk of implementation failure at a later stage | Since the rationale for the intervention was to provide a more feasible and cost-effective method of managing asthma, a key focus was to design the intervention to be as pragmatic, efficient and easy to implement as possible. For example, it was self-guided and advertised existing telephone support offered by trained nurses from Asthma UK.  Regular management meetings were held amongst stakeholders, including patient contributors and clinicians, at which optimising the feasibility of the intervention in primary care was thoroughly discussed. |
| 8. Consider whether it is worthwhile continuing with the process of developing an intervention | Early review of the evidence provided some, albeit weak, support for the potential efficacy of DIs for asthma, suggesting that it was worthwhile continuing with the development process.  PPI, stakeholder and qualitative feedback on prototype versions of the intervention also provided encouraging evidence that the intervention was accessible and well-liked by patients. |
| 9. Generate ideas about solutions, and components and features of an intervention | Qualitative research was undertaken with a range of patients from the target population. This included:   1. Think-aloud interviews, in which the patient used the intervention with a researcher present and described their thoughts aloud 2. Retrospective interviews, in which the patient used the intervention independently for two weeks at home and then took part in a retrospective interview about their experiences   All interviews were transcribed verbatim. Modifications were made to the intervention based on this feedback. |
| 10. Re-visit decisions about where to intervene This can involve consideration of the different levels at which to intervene, and the wider system in which the intervention will operate | The in-depth qualitative development research enabled the development team to review decisions about how the intervention would work, and the appropriateness of providing additional support using the Asthma UK helpline. For example, patients during retrospective and think-aloud interviews liked the links with Asthma UK as it added credibility to the intervention. |
| 11. Make decisions about the content, format and delivery of the intervention | As described above, decisions about the content, format and delivery of the intervention were informed by in-depth qualitative and mixed methods research with the target user population, reviews of the evidence, behavioural analysis, and input from the development team and wider management team. |
| 12. Design an implementation plan, thinking about who will adopt the intervention and maintain it | The grant proposal for the intervention included an implementation plan should the intervention prove effective.  This involved disseminating the findings through multiple pathways, including: open-access, peer-reviewed publications; presentation at conferences; and speaking to NHS Clinical Commissioning Groups, NHS Choices and NHS Digital. The plan also specified that the intervention software would facilitate adaptation of the DI materials for future roll-out in different contexts, e.g. adapting for certain patient sub-groups, or adding new components. It was planned that the intervention could be used by the NHS, as well as in the private sector, third sector, and by other health researchers.  Asthma UK were involved in the project from the outset, with their Head of Health Advice, Colette Harris, attending management and development meetings, and helping to recruit PPI team members. |
| 13. Make prototypes or mock-ups of the intervention, where relevant | The intervention was developed using Lifeguide software which enabled creation of a prototype intervention that could be easily modified throughout the development process, based on user feedback (especially from think-aloud interviews). This was an essential, iterative phase of intervention development which helped to ensure that the intervention was accessible, appropriate, feasible, motivating, convincing and persuasive for users. |
| 14. Test on small samples for feasibility and acceptability and make changes to the intervention if possible | At early stages of development, feedback on the intervention was sought from the development team and management group. Subsequently, detailed think-aloud interviews (*n =* 34), retrospective interviews with patients who had used the intervention independently (*n =* 12) informed decisions about changes to the intervention. |
| 15. Test on a more diverse population, moving away from the single setting where early development of the intervention took place and seeking a more diverse sample. This can involve asking questions such as ‘is it working as intended?’, ‘is it achieving short term goals?’, ‘is it having serious adverse effects’? | This project included to a feasibility RCT, which recruited 88 adults with asthma from a diverse mix of GP practices (rural/urban, different SES and practice sizes). We built in a mixed methods process evaluation (usage data and process interviews with patients) so that we could identify any acceptability, feasibility, or engagement issues with the final intervention. |
| 16. Optimise the intervention for efficiency prior to full RCT | The iterative qualitative findings were used to optimise the intervention to maximise user acceptability and engagement. The acceptability issues identified by the process evaluation will be addressed before a full RCT. |
| 17. Document the intervention, describing the intervention so others can use it and offer instructions on how to train practitioners delivering the intervention and on how to implement the intervention | The intervention was described in detail using the TIDieR checklist (see *Appendix 5*). |
| 18. Develop the objectives of the outcome and process evaluations. This includes determining how outcomes and mediators of change can be measured, developing measures, specifying evaluation design, planning recruitment and considering feasibility of a full RCT | The feasibility process evaluation was planned in consultation with the management group.  This involved:   1. Semi-structured qualitative process interviews with a sub-sample of patients allocated to the intervention arm of the feasibility RCT about their perceptions and experiences of using the intervention. 2. Usage data captured automatically via the online intervention to indicate user engagement   The data were planned to be analysed independently, and a mixed-methods approach adopted for triangulating the individual findings. This would facilitate an enhanced understanding of patients’ experiences of, and interactions with, a DI for asthma self-management.  The feasibility of trial procedures for a future definitive RCT and full quantitative process analysis was assessed. This included questionnaires measuring purported mediators (informed by the logic model) and medication and health resource use captured via review of patients’ medical notes. This identified potential improvements to the trial procedures (see *Section 5*). |

## Conclusion

Similar to HOME BP, the combination of these approaches to intervention development helped ensure that the intervention was optimally persuasive, motivating, and feasible to implement in practice for adults with asthma. See *Appendix 5* for a full description of the My Breathing Matters Programme using the TIDieR checklist.44 A demo of My Breathing Matters intervention can be accessed here: <http://www.mybreathingmatters.co.uk>.

# Evaluation of My Breathing Matters

Parts of this section are reported in more detail in the following publication:

1. Ainsworth, B. *et al.* Feasibility trial of a digital self-management intervention ’ My Breathing Matters’ to improve asthma-related quality of life for UK primary care patients with asthma. *BMJ Open* **9**, e032465 (2019)67 . <https://bmjopen.bmj.com/content/9/11/e032465>
2. Greenwell *et al.* Mixed methods process evaluation of My Breathing Matters, a digital intervention to support self-management of asthma. npj Primary Care Respiratory Medicine, 31, 3568 <https://www.nature.com/articles/s41533-021-00248-6> (follows the COREQ checklist for reporting qualitative research)

## Aims and objectives

In this section, we describe the evaluation of My Breathing Matters during a 12-month feasibility RCT. Aims, methods, results and implications are described for each discrete piece of research as follows:

* Feasibility RCT to assess feasibility of trial procedures and data analysis.
* Mixed methods process evaluation exploring the acceptability of My Breathing Matters, including how patients experienced and used the intervention.

The section finishes with a conclusions section which draws together all the findings.

## Feasibility randomised controlled trial to assess feasibility of trial procedures and data analysis.

Aims:

* To assess feasibility of trial procedures including: recruitment strategy, eligibility criteria, consent/withdrawal, randomisation and blinding.
* To assess feasibility of data analysis, including data collection, data quality and management of trial data across trial endpoint measures to inform sample size calculations for a fully powered RCT.

Methods:

88 primary care patients with asthma from seven GP practices in Wessex, aged 18+ years with impaired asthma-specific quality of life, were randomised to usual care (*n =* 44) or the intervention group (*n =* 44) in which they accessed My Breathing Matters. Block randomisation stratified by an average score of 4.3 on the Mini Asthma Quality of Life Questionnaire (Mini AQLQ69; taken from a previous trial using the same inclusion criteria) was used 63. Practices were purposively sampled to be both rural (*n =* 4) and urban (*n =* 3), with a spread across socio-economic deprivation (mean practice deprivation index 20.60 per cent (SD 10.5); practice socio-economic deprivation deciles = 2, 4, 4, 5, 8, 10, 10, in which lower deciles indicate more deprivation).70  
Participants completed postal screening questionnaires (Mini AQLQ) to identify impaired asthma-specific quality of life, and attended a baseline appointment at their local GP practice with a trained research nurse. Randomisation was carried out by a computer programme and allocation concealed from both the participant and research nurse. Participants completed postal follow-up measures after three months and attended a follow-up appointment after 12 months. The primary outcome was the feasibility of the trial design, including recruitment, adherence, intervention engagement and retention at follow-up. Secondary outcomes were the feasibility and effect sizes of specific trial measures including asthma-specific quality of life (Mini AQLQ) and asthma control (measured with the ACQ).71 Healthcare utilisation data (medication use, frequency of GP consultations, A&E admissions, and hospitalisations) were collected via retrospective notes review conducted by practice staff. Exploratory analysis compared group differences in continuous primary endpoint measures (AQLQ, ACQ) using linear regression models, adjusted for baseline scores of each measure. The trial registration number is [ISRCTN15698435](https://doi.org/10.1186/ISRCTN15698435).

Results:

See *Table 11* for the baseline demographic characteristics of the study population by group and *Figure 5* shows participants’ flow through the trial. Follow-up data at three months was gathered from 91 per cent of patients (80/88; intervention: 36/44, control 44/44), and at 12-months was gathered from 90 per cent of participants (79/88; intervention: 36/44, control 43/44). At 12 months, four patients formally withdrew from the study, 1 patient was withdrawn as they were no longer eligible (i.e. they were referred to secondary care), and 4 patients did not complete their 12 month follow up questionnaires. There were 9 adverse events and three serious adverse events that were unrelated to the study.

Table 11 Baseline demographic characteristics of My Breathing Matters study population per group

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Overall sample**  **(N = 88)** | **Intervention group  (N = 44)** | **Control Group  (N = 44)** |
| **Age** *Mean (SD)* |  | 56.6 (15.2) | 57.0 (14.2) | 56.3 (16.2) |
| **Female** *N (%)* |  | 53.0 (60.2) | 27.0 (61.4) | 26.0 (59.1) |
| **BMI** *Mean (SD)* |  | 29.5 (6.1) | 28.9 (5.9) | 30.1 (6.3) |
| **Length of diagnosis (years)** *Mean (SD)* |  | 24.0 (17.5) | 25.2 (17.2) | 22.8 (17.8) |
| **Ethnicity** | White *N (%)* | 84 (95.5) | 42 (95.5) | 42 (95.5) |
|  | Other *N (%)* | 4 (4.5) | 2 (4.5) | 2 (4.5) |
| **Smoking Status** | Current *N (%)* | 9 (10.2) | 7 (15.9) | 2 (4.5) |
|  | Former *N (%)* | 29 (33.0) | 13 (29.5) | 16 (36.3) |
|  | Never *N (%)* | 50 (56.8) | 24 (54.5) | 26 (59.1) |
| **Age left education** |  | 18.5 (5.3) | 19.4 (7.0)**\*** | 17.7 (2.7) |
|  | 16 or under *N (%)* | 40 (46.5) | 18 (42.9) | 22 (50.0) |
|  | 17-18 *N (%)* | 22 (25.6) | 9 (21.4) | 13 (29.5) |
|  | Above 18 *N (%)* | 24 (27.9) | 15 (35.7) | 9 (20.5) |
| **Index of Multiple Deprivation  Mean Rank (Median Decile)** |  | 17192 (5.5) | 17231 (6.5) | 17212  (5) |

**Note:** \* Percentages are reported from 42 participants as 2 intervention participants did not provide this data.

Figure 5 CONSORT flow diagram for My Breathing Matters feasibility trial

**3m Follow-Up**

Lost to follow-up (n=0)

**Enrolment**

**Allocation**

Allocated to usual care (n=44)

Randomised (n=88)

Excluded (n=68,390)

  Not meeting inclusion criteria (n=65,390)

  Declined to participate (n= 2932)

  Responded to invitation after study closed (n=30)

  Could not be contacted to arrange baseline appointment (n=35)

  Incomplete screening questionnaire (n=3)

Assessed for eligibility (n=68,478)

Lost to follow-up (n=8)

 Withdrawal (n=2)

 Did not return 3m questionnaire (n=6)

Discontinued intervention (n=1)

Analysed (n=44)

**Analysis**

Analysed (n=44)

Lost to follow-up (n=1)

 Did not attend 12m appointment or return questionnaire (n=1)

**12m Follow-Up**

Lost to follow-up (n=6)

 Withdrawal (n=2)

 Withdrawn as referred to secondary care (n=1)

 Did not attend 12m appointment or return questionnaire (n=3)

Allocated to intervention (n=44)

 Received allocated intervention (n=36)

 Did not receive allocated intervention:

* Did not register (n=8)

The mean Mini AQLQ and ACQ scores (and standard deviations) and the percentage of patients achieving a Minimal Clinically Important Difference (MCID) improvement in Mini AQLQ scores of 0.5 or greater at each time point are presented in *Table 12*. Patients in the intervention group who completed 12 month follow-up measures (*n =* 36) had mean improvement in asthma-related quality of life (Mini AQLQ score) of 0.35 (95% CI: 0.10, 0.60) and in the control group of 0.21 (95% CI: -0.09, 0.51). The between-group difference (controlling for baseline differences) was 0.18 higher (95% CI: -0.21, 0.56) in the intervention group, indicating better quality of life. In the ACQ 12-month analysis, the between-groups ACQ score was 0.14 lower (95% CI -0.40, 0.11) in the intervention group, indicating better control. These findings are not significant but indicate consistent trends to improvement in both asthma quality of life and asthma control in the intervention group compared to the control. There was no statistically significant difference in the number of patients who showed MCID improvement at 3 or 12 months across groups. There was no suggestion of an effect on physiological measures of lung function. The data quality check, and subsequent examination by research team clinicians, found that reviews completed by the practice nurses lacked the detail to quantify the amount of medication prescribed. Specifically, the reviews did not provide information on the number of inhalers issued on each prescription, or specify the device prescribed in enough detail (e.g. metered dose inhaler or dry powder inhaler). In any future trial, data collection plans would need to ensure that these data were collected.

Table 12 Mean Mini AQLQ and ACQ scores, and percentage of patients achieving a Minimal Clinically Important Difference at baseline, 3 months, and 12 months

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Intervention** | | | **Control** | | |
|  | **Baseline (n=44)** | **3 months (n=36)** | **12 months (n=37)** | **Baseline (n=44)** | **3 months (n=44)** | **12 months (n=43)** |
| Mini AQLQ Mean (SD) | 4.85 (0.94) | 5.51 (0.85) | 5.29 (0.98) | 4.78 (1.09) | 5.30 (1.07) | 5.00 (1.25) |
| Mini AQLQ %>Minimal Clinically Important Difference improvement | - | 47.2 | 38.9 | - | 47.7 | 39.5 |
| ACQ Mean (SD) | 1.35 (0.66) | 0.98 (0.65) | 1.00 (0.59) | 1.56 (0.91) | 1.28 (0.87) | 1.26 (0.69) |

Implications:

Our findings are that a fully-powered confirmatory RCT to demonstrate the effectiveness of My Breathing Matters is feasible, requiring only minor modifications to trial procedures. In addition to this, the observed trends towards improved asthma control and quality of life in patients who were randomised to the My Breathing Matters intervention, support the need for a confirmatory RCT.

## Mixed methods process evaluation exploring the acceptability of My Breathing Matters

Aims:

* To assess feasibility and acceptability of My Breathing Matters and highlight any future modifications to optimise for phase 3 RCT.

Methods:

Intervention usage data were collected to describe patters of intervention usage for all intervention participants (*n =* 44) over the 12-month study period. A My Breathing Matters Satisfaction Questionnaire was administered to those who used the intervention (*n =* 36) at 12-month follow-up to assess their satisfaction with the intervention. The questionnaire included two items to assess benefits gained from using the intervention and disadvantages of the intervention and open questions allowed participants to report any benefits and disadvantages. The one-item NHS Friends and Family Test assessed how likely participants are to recommend the intervention to friends and family if they needed similar care and treatment using a 5-point Likert scale ranging from ‘extremely likely’ to ‘extremely unlikely’, with a ‘don’t know’ option72.

Retrospective semi-structured telephone interviews were carried out with 18 intervention participants at 3 month follow-up to explore intervention participants’ views on the intervention content and design, reasons for any non-usage, and any changes users experienced. Qualitative interview data were analysed using inductive thematic analysis.39

Results:

Of the participants in the intervention group, 81.8 per cent (*n =* 36) logged in at least once and between 1 and 25 times (Median = 4; Interquartile Range = 8). When given the choice, most users (71 per cent) choose to look at the non-pharmacological content first (instead of the pharmacological content) and the breathing retraining module was the most viewed component, with over half of participants signing up to the breathing retraining challenge. 86 per cent (*n =* 31) indicated that they gained benefit from using My Breathing Matters and 78 per cent (*n =* 28) reported that there were no, or very little, disadvantages to using the intervention. Seventy eight percent (*n =* 28) rated that they would recommend My Breathing Matters to friends and family if they needed similar care and treatment.

Overall, interview participants expressed positive views of the intervention and found the content easy to understand and the website easy to use. Users reported gaining several benefits from taking part in the intervention including improvements in their asthma symptoms (e.g. reduced coughing, chest tightness, and breathlessness); medication use (improved medication adherence, correct use of their inhalers, reduction in reliever inhaler use); breathing awareness, technique and posture; and identification, and ability to deal with, asthma triggers (e.g. air pollution). Participants particularly liked that My Breathing Matters provided alternative non-pharmacological strategies for managing their asthma and, consistent with the findings of the usage analysis, the breathing retraining was particularly popular.

In My Breathing Matters, content was not available all at once, rather different content was ‘unlocked’ at various time points after the user’s first visit to the website to encourage long-term engagement with the intervention. Participants’ views on this design feature were mixed. On the one hand, some participants liked this feature as it meant that the intervention content was more digestible when made available in stages and it encouraged them to practice each individual exercise fully before moving onto the next. On the other hand, some found it frustrating and annoying when they were unable to access content they wanted to view or were unclear why this feature was important.

The qualitative interviews also highlighted several factors than influenced users’ engagement with the intervention. Participants’ engagement with My Breathing Matters was influenced by their perceptions of their asthma control, their current self-management practices, the season, the time since diagnosis, their confidence with, and dislike of, computers, and their other health priorities.

Implications:

The findings demonstrated that My Breathing Matters was feasible and acceptable to adults with asthma. It also highlighted one important future modification. Future versions of the intervention will keep the current information structure, but will provide users with an explanation for why the unlocking feature is important (e.g. it is helpful to practice easier breathing exercises before progressing onto harder ones). Those who are still keen to progress will have the option to unlock additional content themselves so that no content is restricted. The findings also identified the type of people who would benefit more from the intervention, such as those who perceive their asthma control to be problematic and those who are motivated to improve their self-management practices.

## Conclusion

Overall, the findings demonstrated that a fully-powered confirmatory RCT to assess the effectiveness of My Breathing Matters is feasible and the outcomes evaluation supported the need for a confirmatory RCT, with some optimisation of specific trial procedures for recording health utilisation data in order to improve the quality of the data collected for a health economics analysis. My Breathing Matters appeared to be acceptable to adults with asthma and there was good user engagement with the intervention. Future iterations of the intervention should include modifications to its information structure to facilitate easy, but structured, access to content important to users.

# Conclusions

## Objectives

Our objectives (see *Section 1*) were to develop and trial DIs to support patient self-management of two common, contrasting health conditions, i.e. hypertension and asthma (objectives 3 and 4, workstreams 2 and 3). Through the process of planning, developing and evaluating these interventions we also aimed to generate a better understanding of what features and methods for implementing DIs could make them acceptable, feasible, effective and cost-effective to integrate into primary care (objectives 1 and 2, workstream 1).

Workstreams 2 and 3 fully achieved the aims of developing and trialling interventions that proved acceptable, feasible and (in the fully trialled intervention) also cost-effective. An in-depth theory-, evidence- and person-based planning and development process was undertaken for both interventions, drawing on extensive qualitative research, PPI input, review of the evidence and behavioural analysis to ensure that key behavioural barriers to engaging with the target behaviours were addressed. Feasibility studies were successfully carried out for both DIs; as an internal pilot trial for the hypertension DI and as a standalone feasibility study for the asthma DI. Both studies suggested that fully RCTs were feasible with only minor modifications to the intervention and the asthma health utilisation data collection methods.

A RCT recruited 622 patients in primary care to explore the effectiveness and cost-effectiveness of the DI for hypertension. 89 per cent of patients completed 12-month follow-up, and the DI was found to be effective with the intervention group having significantly lower BP at 12 months than the usual care group. The intervention cost was £11 per unit reduction in systolic BP, less than in previous similar studies.48, 49

Section 6.2 reflects on the generalisable insights that we obtained through this programme of research into how to develop engaging and useful DIs using the person-based approach, theory and evidence. Section 6.3 then considers the clinical implications of our research in terms of hypertension and asthma, and Section 6.4 provides a reflection on the important contributions PPI made to this programme. Finally, Section 6.5 describes some strengths and limitations of the research programme, and Section 6.6 summarises the recommendations for future research.

## Implications of our findings for future digital health intervention research

### Reflections on what was learned from the intervention development process

A specific aim of the DIPSS research programme was to identify key features associated with maximising feasibility, acceptability (to patients and health professionals), effectiveness, and cost-effectiveness of DIs. In this respect the research programme was extremely fruitful, as it provided valuable opportunities for our research team to explicitly articulate and refine the Person-Based Approach (PBA) that we were using to develop the interventions.

Prior to the DIPSS programme of research we had employed core elements of the PBA to develop several interventions but had not systematically described these methods. These methods included using a combination of primary qualitative research and behavioural theory to inform initial intervention development,73 developing ‘guiding principles’ that captured the key design aims and strategies for enhancing engagement with the intervention,74 and using ‘think-aloud’ interviews to enhance the accessibility, acceptability, and persuasiveness of the intervention.75-77 As the DIs developed using these methods completed trialling and process analysis we accumulated evidence that our interventions had a remarkably good rate of success in terms of both effectiveness38, 66, 78 and accessibility and acceptability.79, 80 This gave us confidence that our methods might be useful to other intervention developers and we published an initial paper setting out the rationale and core methods of the PBA.34 We then used the opportunities provided by the DIPSS programme to refine and illustrate our PBA methods whenever possible.

The most substantial novel work undertaken to illustrate and document the application of the PBA was the intervention planning for the HOME BP intervention for management of hypertension (see *Section 2*). This intervention planning process integrated the PBA with theory and evidence-based approaches to intervention planning,28 and clearly delineated how these approaches made important complementary contributions to intervention planning. To identify probable barriers and facilitators to uptake, engagement and implementation evidence was collated from a mixed methods feasibility study, a systematic review of quantitative evidence and a synthesis of qualitative research. This evidence was then used to inform the guiding principles for intervention design, and input to our behavioural analysis and logic model. As the DIPSS team included leading theory-based researchers in the fields of health psychology and sociology this paper was able to convincingly demonstrate how the PBA could be combined with mapping intervention elements onto the theoretical constructs from both disciplines.

As well as refining these intervention planning techniques, HOME BP also provided the opportunity to enhance early techniques for developing interventions. Conducting detailed qualitative research during intervention development had already been identified as essential by the research team to inform how best to optimise interventions to overcome specific barriers arising for a population within a certain context.81 However, a clear system for making decisions about which changes to make and recording these decisions had not yet been developed. In HOME BP, our method for recording and documenting decisions about how to optimise the intervention was systematised using an early version of the Table of Changes, which is now a core component of the PBA. The Table of Changes is a tool which offers researchers a method for categorising the reason for a change as important, easy, responding to repeated feedback, or in line with stakeholder experience or the literature.29 It also has the option to record if a change was not made, and why. Criteria are used for prioritising changes, identifying which are essential to promote behaviour change and which are just desirable but unlikely to impact on intervention outcomes.82

During the period of this programme grant we started to actively disseminate the PBA to the wider research and intervention development community by a variety of methods. As planned in the DIPSS proposal, we held three workshops funded by the DIPSS grant and used these to illustrate the methods and the value of the PBA for developing the DIPSS interventions. We also presented the use of the PBA at conferences through symposia, workshops and individual papers and we now have a dedicated website ([www.personbasedapproach.org](http://www.personbasedapproach.org)) and newsletter to update the research community on the latest developments in the approach (see *Supplementary material 2* for a full list of dissemination events). We have found the research community very receptive to and appreciative of the PBA methods, while discussions of our methods at these workshops and presentations have stimulated and helped us to develop our methods further. As the PBA has become more widely known it has in turn directly informed development of more generic national guidance, such as the Medical Research Council-funded INDEX guidance (see *Sections 2 and 4*) and the Public Health England guidance.23,83

The PBA evolved considerably during the course of the DIPSS research programme and continues to evolve; in particular, we have recently been focusing our attention on how best to combine stakeholder and PPI input with our PBA qualitative research methods. A useful comment from one of our PPI contributors when writing this report was that they had not felt aware of the PBA process or how they did and could contribute to it. In future, we need to introduce the aims and methods of the PBA process explicitly to PPI contributors and explain to them how their comments on the design and qualitative findings are integrated into the PBA development process. Integrating PPI more explicitly with the PBA will be facilitated, structured and documented in future by expanding the behavioural analysis table which informs intervention development into a template similar to the ‘Table of Changes’ that can be used at the design stage to integrate all sources of evidence informing design, including stakeholder views.

In addition to our methods for developing DIs, some of the intervention elements have proven useful across both interventions in DIPSS, and for developing other interventions. In this respect, it has proved useful to not only deploy common BCTs across different interventions, but to also preserve as far as possible the insights we gained from our PBA work into how these techniques can be made most accessible and engaging. For example, we have learned how to simplify the format for goal setting, self-monitoring and tailored feedback so that it is quick and easy for users to set realistic but useful goals and receive feedback that matches their self-perceived progress. We have also developed a brief quiz format that provides an engaging method of communicating positive messages about consequences of health-related behaviour. Both these behavioural modules needed only minor modification in order to form a well-received part of both our DIPSS interventions, and are now also being used in numerous other DIs developed by our team and collaborators. Larger modules developed by our team are also being adapted and used in a large number of further interventions, including the modules to support physical activity and healthy eating for a range of health conditions (e.g. to promote quality of life in cancer survivors and reduce cognitive decline in older people). We are currently building collaborations to disseminate these modules widely for clinical use, for example through the new applied research collaborations and through partnerships with the private sector.

Preserving the positive holistic qualities of our interventions and their components is consistent with realist approaches to health interventions, which predict that effects of interventions may result from emergent properties of the whole intervention package and could therefore be altered if behaviour change elements are isolated and delivered in isolation or in a different format. However, changes in delivery format for DIs are inevitable as the technology for delivering them changes. A challenge for the future is to determine how to identify and preserve the important characteristics of DIs across digital delivery formats.84

## **Implications of our findings for integrating digital interventions for hypertension and asthma into primary care**

### Implications of our findings for future research and practice in hypertension

The main results suggest that HOME BP, by using very efficient digital support and minimal staff resource, is not only effective but cost-effective, and both feasible and acceptable for both clinicians and patients. The reduction in BP found in this trial is important in terms of long-term health outcomes, with an anticipated reduction of 10-15 per cent of patients suffering a stroke, and 5-10 per cent of patients experiencing coronary-related events. The effect size was similar to a paper based BP management intervention 13, and the 12-month follow-up showed a greater difference between groups than six months, suggesting the intervention may have a longer-term impact. Therefore, it is potentially scalable for use in the NHS, although further economic evaluations of the long-term cost-effectiveness will better inform the potential for widespread adoption.

Current plans for wider implementation of the HOME BP algorithm for managing BP include a collaboration via the Oxford/Thames Valley Applied Research Centre for an implementation trial sharing the results from HOME BP with those from the previous TASMINH2 and Targets and Self-Management for the Control of Blood Pressure in Stroke and at Risk Groups (TASMIN-SR) trials of self-management and the recently published trial of titration using self or telemonitored monitoring of BP. 13, 31,85 This will in turn link to the planned national strategy for cardiovascular prevention.

At the end of the HOME BP project, we wanted to hold a public engagement event to share the findings and involve a range of stakeholders in BP management in discussions about possible next steps. A half-day dissemination workshop was organised which was advertised via local GP practice patient groups, Clinical Research Networks, the Blood Pressure UK charity, as well as being open to anyone to register via Eventbrite. Targeted invites were also sent to all GPs and nurses who took part in the trial, and people working in digital health or BP management within the NHS, Public Health England, Blood Pressure UK, the British and Irish Hypertension Society, and NICE. Eleven attendees were present, including a PPI contributor, three nurse practitioners with a special interest in hypertension, two GPs, a digital health tools designer, and a policy maker from Public Health England.

There was excellent participation in interactive activities throughout the event, with rich discussions between the various stakeholders. It was perceived that the HOME BP intervention was highly relevant for primary care given the current focus on self-management and improving cardiovascular outcomes, and that it could contribute to a cultural shift where regular BP checks and ‘knowing your numbers’ is perceived to be as routine as regularly attending the dentist for check-ups.

There was enthusiasm for implementing the HOME BP intervention more widely, including suggestions for potential application in care homes, secondary care, and for patients with carers, as well as in a primary care population. It was suggested that self-monitoring could be prompted monthly until the patient is well-controlled, and then less frequently or when triggered by a change in circumstances, such as developing another health condition. Suggestions for ways to increase intervention feasibility included involving pharmacies in the medication change process, and managing patients’ expectations about side effects and BP variability at the outset. Practical barriers to wider implementation identified by stakeholders included the restriction on prescribing BP monitors for patients, the nurse time involved in sending monthly support emails to patients (which it was suggested could be overcome by automating this process), and the issue of the intervention being unable to interact with existing medical records systems. Feedback at the end of the event suggested that people had enjoyed the workshop and found it interesting to hear the perspectives of other stakeholders.

The findings from the HOME BP process evaluation suggest the intervention was both acceptable and feasible but also highlighted simple ways to make the intervention even more effective in wider implementation. The process evaluation has also already been used to inform the development of a DI for stroke patients and their carers to self-manage BP in primary care. 86 This intervention was based on the same procedures and algorithms which informed HOME BP,13, 31 but changes were made to optimise engagement and adherence following insights gained from the HOME BP process evaluation. For example, the baseline medication review has been adapted to include a guided discussion between the GP and patient to manage expectations about the likelihood of medication change and increase confidence in medication change for both parties. The GP alerts regarding medication change have also been tailored to include additional evidence and rationale designed to overcome common barriers to changing medication, such as the BP readings being borderline. In addition, patients have the choice of sending their readings via SMS, an app, or a website, instead of only via website, which is intended to make the intervention available to a wider group of people and up-to-date with changing technology. The process evaluation of this intervention for stroke patients will enable us to continue learning about how best to optimise DIs for managing high BP.

### Implications of our findings for future research and practice in asthma

Since the inception of the DIPSS study, asthma outcomes have remained suboptimal and effective self-management is frequently poorly achieved. Although there are a number of commercial and pharmaceutical industry sponsored digital asthma programmes available, they have failed to have widespread use or impact. The need for an effective digital self-management support intervention for people with asthma remains pressing, and is supported by our findings from the My Breathing Matters evaluation which suggest that a fully powered RCT study of the intervention is feasible and justified. In such a trial, the health utilisation data collection methods should be improved to ensure data quality is sufficient for a health economic analysis, by collecting data from patients’ medical record by a trained member of the study team (such as a dedicated research nurse) as has been successfully used in previous studies.63

In terms of the magnitude of benefits seen in asthma outcomes, as a pilot feasibility study we were not powered to show a significant between-groups difference, and the confidence intervals on our likely primary outcomes (AQLQ and ACQ) are accordingly wide. However, there are non-significant trends to improvement in both these outcomes, and the mean between-groups improvement we observed in AQLQ of 0.18 (95% CI -0.21, 0.56) can be compared to between-group difference in AQLQ from placebo controlled pharmacological interventions reported in meta-analysis of 0.06 for short acting B agonists, 0.20 for leukotriene receptor antagonists, 0.30 for anti-IgE monoclonal antibody treatment and 0.35 for long acting beta agonists treatment for add-on pharmacological treatments in asthma patients receiving inhaled corticosteroids.87 We would therefore conclude that there is potential for a benefit in patient reported outcomes of an order of magnitude within the range of that seen from commonly used pharmacological treatments, thus warranting a definite fully powered trial.

Our findings highlighted potential future improvements to the intervention design and trial methodology. On the basis of these findings, we are currently developing a proposal for a fully-powered RCT study of My Breathing Matters, to be submitted to the NIHR Health Technology Assessment programme.

The detailed development and process analysis also has implications for other digital behaviour-change interventions in primary care populations with asthma. For example, we were able to develop and disseminate a digital version of ‘Breathe Freely’, an NIHR HTA-funded breathing retraining intervention that drew directly on the breathing retraining resources provided in My Breathing Matters (available here: <http://www.breathestudy.co.uk/>). Findings from the feasibility study are also directly informing related NIHR-funded work such as ‘BREATHE-4T’, the NIHR Research for Patient Benefit-funded optimisation and feasibility trial of Breathe Freely for adolescents.

## The contribution of patient and public involvement

The aim of PPI involvement in the programme was to ensure that patients’ needs were taken into account throughout the research, that the interventions were reassuring, motivating, and enjoyable to use, that the research studies were accessible and feasible for participants to take part in, and that the research was more likely to lead to sustainable change. Our PPI contributors were an integral part of all stages of the research cycle, including designing and undertaking the research, and interpreting and disseminating the findings. We worked closely with PPI contributors one-to-one and during group meetings throughout the programme, as well as seeking written input on research documents and interventions.

Our work with PPI contributors made a significant and valuable input throughout the DIPSS research programme and we gained important generalisable learning about how to combine PPI with our theory, evidence- and person-based approach. This section therefore seeks to share insights into this process, which we obtained from reflecting on the PPI contribution. These reflections are presented in Boxes 1-2. Box 1 gives specific examples of how our HOME BP PPI contributor, Cathy Rice, improved the research. Box 2 presents her own reflections on the process of contributing to HOME BP.

Box 1 Specific examples of PPI contributions to HOME BP from Cathy Rice

1. Improving patient study documents to promote study engagement and patient experience

* Improving clarity of statements in the Participant Information Sheet for the main trial, to avoid ambiguity for the patient
* Optimising the email to notify usual care patients which group they are in, to ensure they felt valued and understood the next steps.
* Optimising the email used to invite trial participants to take part in a qualitative process interview, to increase uptake and ensure all the relevant information was provided to help patients make a decision about whether they want to be interviewed
* Informing decisions about a new process to share a study flowchart with patients in the trial, in response to patient feedback indicating confusion about the order of trial procedures
* Improving the communication of key findings from the patient qualitative process interviews in a newsletter designed for study participants
* Revising the letter sent to participants when they withdraw from the study, to improve clarity and reassurance for the patient (see *Supplementary material 3* for before and after examples).

1. Intervention optimisation

* Modifying the content of intervention training sessions, e.g. how to explain about taking readings in the morning
* Testing the Getting Active intervention for physical activity and providing feedback on how it could be improved to optimise patient experience

1. Providing a PPI perspective on findings

* Working closely with the research team to interpret the qualitative process interviews with patients about their experiences of using the HOME BP intervention, and reading the draft manuscript prior to submission

1. Dissemination

* Inputting to discussions about dissemination of the intervention at an interactive stakeholder workshop

Box 2 Reflections from Cathy Rice on her public contributor role in HOME BP

My involvement started in April 2016 when I phoned Kate Morton in response to an ad on the INVOLVE Research website for a member of the public to join the team.

**It made a big difference having an informal pre-meeting with Kate each time I attended a management meeting in person.** The first time, we spoke for perhaps an hour and a half, discussing my comments on the Patient Information leaflet, filling me in on the context of the study and what had happened so far, as well as more social getting to know each other. I remember being particularly impressed that Kate had offered to meet me at the train station, at the end of her working day. I felt this was a clear statement that the research team wanted to make the trip as easy as possible for me, and that members of the public are appreciated.

September 2016 Management meeting. This time I suggested we meet at the B&B as I was happy to get the taxi alone, and we went to the same pub for a chat, again perhaps one and a half hours. **To me this socialising was important, as it developed our relationship to the extent that we were then easily able to discuss lots of aspects of the study over the phone.** (Academics have ‘corridor conversations’ all the time. Even if they’re not based at the same institution, they meet up at conferences, etc, and develop relationships that make it more feasible to collaborate. It’s much harder for public contributors to build up working relationships when we’re on the fringes.)

February 2017 Management Meeting was the final one I attended in person. Since then, most of the meetings have been by teleconference only, and that has worked well for me. But **I wouldn’t have had the confidence to chip in during these meetings if I hadn’t already met Lucy Yardley at the previous meetings, and built a rapport with her and Kate**.

My involvement throughout has centred around giving email feedback to documents Kate emailed me, and phone conversations with Kate. Because Kate sometimes showed me several iterations of a document**, I could quickly see that my comments were taken seriously, and documents changed as a result. This is tremendously good feedback to be receiving, and it makes it feel worthwhile to put the effort in.**

Phone conversations have often been useful to tease out different options— **I always feel, at the end of a conversation with Kate, that we have ended up at a place that neither of us would have reached alone.** It’s so rewarding. She has always been extremely accommodating in arranging for calls to be at a time to suit me, and has always left me to make the choice whether I wanted the conversation, as opposed to email. Last, but certainly not least, Lucy Yardley has made clear by her own behaviour that she believes public contributors should be treated with respect, consideration and appreciation.

## Strengths and limitations

### Strengths

This programme of work benefitted from the inclusion of two diverse patient populations (asthma and hypertension), which helped to compare findings between these different contexts and further developed our understanding of how self-management DIs can facilitate long-term condition management. In-depth PPI was a strength of the programme, with both projects working closely with dedicated PPI contributors throughout all phases of research, enhancing the relevance and value of the research. Furthermore, rigorous methods included RCTs with nested process evaluation studies using mixed-methods analysis to develop a more holistic understanding of how patients and HCPs experienced the interventions and which factors influenced adherence, to better inform the potential for further implementation.

This programme used the PBA to develop the two interventions. A strength of this approach is its use of in-depth qualitative research to provide a detailed understanding of the target population’s beliefs about their health condition and the target behaviours. This helped inform a rigorous intervention optimisation process to ensure that the interventions were as feasible, persuasive and enjoyable for participants to use as possible. Another strength of the PBA is that it is a highly flexible approach that can be used alongside other intervention development approaches to complement the use of theory and evidence, which are important for identifying effective intervention content and features.

### Limitations

Although we endeavoured to recruit participants across varied demographics, participants were generally white (Asthma 96 per cent; Hypertension 94 per cent; compared to 86 per cent of the population of England and Wales as a whole).88 Participants in the asthma feasibility study were generally older (median age 61 years; compared to 39 years of the population of England and Wales as a whole)88 and those in the process evaluation interview studyhad high levels of educational attainment (55 per cent had an undergraduate qualification or higher). Furthermore, people invited to the HOME BP study who declined to take part and those lost to follow-up in the My Breathing Matters study were more likely to be from deprived areas, suggesting a bias towards higher socio-economic status. This suggests that while we sought to make the interventions accessible to as much of the population as possible, we were only partially successful. One of the most common reasons for declining to take part in the HOME BP study was lack of internet access, which suggests technological barriers remain an issue despite steady increases in online access. While the reach of DIs improves as digital literacy increases nationally, care must be taken to ensure that these interventions do not further facilitate healthcare inequalities. Further research is required to investigate whether and how it may be possible to overcome barriers to engagement with digital support among people with higher socioeconomic deprivation, and ensure that digital interventions can improve healthcare outcomes across the population.

Another limitation of this research in terms of wider implementation is the challenge of integrating digital interventions with existing clinical systems in Primary Care. Using a separate digital system increases the burden on healthcare professionals, and reduces the feasibility of long-term maintenance of the intervention. It is recommended that wider dissemination of evidence-based, effective digital interventions be supported in Primary Care.

As is commonly the case in trials of complex behavioural interventions, patients in both RCTs were not blinded and would have known that they were allocated to the intervention rather than the usual care control. However, our researchers and statisticians were blind to group allocation.

The digital aspects of the HOME BP intervention were challenging to cost accurately. The cost of the digital intervention may be overstated in the trial since its potential for scale means it could be used many more patients at very low marginal cost. While this is to some extent inevitable, the results indicated that such interventions can be provided at a modest cost per patient, which would be very likely to show economies of scale and reduced cost per patient if made widely available.

## Summary and recommendations for future research

In summary, the DIPSS research programme achieved the objectives of developing highly acceptable and feasible DIs for the contrasting conditions of asthma and hypertension. As intended, we showed that the intervention for hypertension was both effective and cost-effective, and the intervention for asthma had good potential for a full effectiveness trial. Our research is already beginning to influence future clinical research and practice through further implementation. In addition, the theory-, evidence- and person-based approach to intervention development that we refined through this research programme was shown to be successful in enabling us to identify and address important contextual barriers to and facilitators of engagement with the intervention by healthcare professionals and patients. We have therefore documented, reported and are very actively disseminating these methods to the wider community of intervention developers in the public and private sector.

### Recommendations for future research

1. A fully-powered RCT study of My Breathing Matters should be carried out to assess clinical and cost effectiveness. To ensure adequate data quality, the health care utilisation data should be collected from the patients’ medical record by a trained member of the study team (such as a trained research nurse), as has been successfully used in previous studies.63
2. For HOME BP, more comprehensive modelling of the long-term effects of blood pressure reduction would appear to be useful, perhaps supported by a meta-analysis of the relevant trials.
3. Further research is required to investigate whether and how it may be possible to overcome barriers to engagement with digital support among people with higher socioeconomic deprivation.
4. For My Breathing Matters, a process evaluation nested in the RCT fully-powered RCT study should assess whether quantitative process measures, such as perceptions of asthma, pre-intervention levels of medication adherence, and time since diagnosis, is associated with user engagement and asthma outcomes.
5. Intervention evaluations should explore perceived benefits as well as burdens for patients using DIs to better understand how to optimise the experience. Developing suitable measures to capture the emotional benefits and burdens of using DIs could complement the existing measures of structural burden, and further enhance our understanding of patients’ experiences.
6. Self-monitoring interventions can be empowering and reassuring, but more research is needed to consider how to sustain engagement when patients are not well-controlled and may find self-monitoring a stressful experience.

### Implications for healthcare

1. Our HOME BP findings suggest that the use of digital support to help patients self-manage their hypertension is not only effective but also cost-effective, and both feasible and acceptable for clinicians and patients. The HOME BP intervention is potentially scalable for use in the NHS.
2. Our asthma feasibility trial findings suggest that there is potential for a benefit in asthma patient reported outcomes of an order of magnitude within the range of that seen from commonly used pharmacological treatments. However, a definite fully powered trial is required to confirm this.
3. Careful consideration about how to optimally feedback self-monitored data from DIs to HCPs is needed, to promote more feasible integrated digital systems and reduce the workload in Primary Care.
4. Using the PBA to complement evidence and theory in developing behaviour change interventions can help ensure the intervention is feasible, persuasive and enjoyable for the target population, and that key behavioural barriers are addressed.
5. Providing training for patients online rather than face-to-face minimised the burden on HCPs, and could be a cost-effective option for DIs provided the training is developed with thorough patient input to ensure it meets people’s needs.

# Acknowledgements

## Contributions of authors

All authors made substantial contributions to design, or acquisition of data, analysis and interpretation of data, all were involved in the drafting of the manuscript or revising it critically for important intellectual content, and all authors approved the final version to be published.

**Professor Lucy Yardley** (Professor, Health Psychology) was the Chief Investigator and initiated, led and had overall responsibility for the programme.

**Dr Kate Morton** (Senior Research Assistant, Health Psychology) was lead researcher on the qualitative meta-ethnography, qualitative and mixed-methods hypertension process analyses and PPI engagement for HOME BP.

**Dr Kate Greenwell** (Senior Research Fellow, Health Psychology) was lead researcher on the asthma mixed methods process evaluation.

**Dr Beth Stuart** (Associate Professor, Medical Statistics) led on the quantitative statistical analysis for both trials and was a member of the programme management group.

**Cathy Rice** (PPI contributor) provided PPI input throughout the research programme and drafted and revised the relevant PPI sections of this report (Plain English Summary; see *Section 6*).

**Dr Katherine Bradbury**(Senior Research Fellow, Health Psychology) co-led the hypertension intervention development and supervised the qualitative HOME BP process analyses.

**Dr Ben Ainsworth**(Lecturer, Health Psychology) was lead researcher on the development of the My Breathing Matters intervention and the asthma feasibility trial.

**Dr Rebecca Band**(Senior Research Fellow, Health Psychology) co-led the development of the HOME BP intervention and the HOME BP quantitative process evaluation.

**Professor Elizabeth Murray** (Professor, e-Health and Primary Care) led the hypertension systematic review and was a member of overall the programme management group contributing expertise in implementing digital interventions in primary care.

**Professor Frances Mair** (Professor, General Practice and Primary Care) led the asthma systematic review and was a member of overall the programme management group contributing expertise in implementing digital interventions in primary care.

**Professor Carl May**(Professor, Medical Sociology) was a member of the programme management group contributing expertise in Normalisation Process Theory and implementation of digital interventions.

**Professor Susan Michie** (Professor, Health Psychology) was a member of the programme management group contributing expertise in behaviour change techniques.

**Samantha Richards-Hall** (PPI contributor) was a member of the programme management group providing public contributor perspectives throughout the research programme.

**Professor Peter Smith** (Professor, Social Statistics) was a member of the programme management group providing senior expertise in statistical methods.

**Professor Anne Bruton** (Professor, Respiratory Rehabilitation) was a member of the programme management group and co-led the asthma workstream, including the intervention development.

**Professor James Raftery**(Professor, Health Technology Assessment) was a member of the programme management group and led the health economics analysis.

**Dr Shihua Zhu** (Senior Research Fellow, Health Economics) assisted with the health economics analysis.

**Professor Mike Thomas**(Professor, Primary Care Research) was a member of the programme management group and led the asthma workstream.

**Professor Richard J. McManus**(Professor, Primary Care) was a member of the programme management group and led the hypertension workstream.

**Professor Paul Little**(Professor, Primary Care Research) was a member of the programme management group, helped initiate and oversee programme, and co-led the hypertension workstream.

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## Publications

McLean G, Murray E, Band R, Saunderson K, Hanlon P, Little P, McManus RJ, Yardley L, Mair FS. Digital Interventions to Promote Self-Management in Adults With Hypertension: Protocol for Systematic Review and Meta-Analysis. *JMIR Res Protoc.* 2015 Nov 20;4(4):e133. <https://www.researchprotocols.org/2015/4/e133/>

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McLean G, Murray E, Band R, Moffat KR, Hanlon P, Bruton A, Thomas M, Yardley L, Mair FS. Interactive digital interventions to promote self-management in adults with asthma: systematic review and meta-analysis. *BMC Pulm Med.* 2016 May 23;16(1):83. <https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-016-0248-7>

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Ainsworth, Greenwell, K, Stuart, B., Raftery, J., Mair, F., Bruton, A., Yardley, L, Thomas, M. Feasibility trial of a digital self-management intervention ‘My Breathing Matters’ to improve asthma-related quality of life for UK primary care patients with asthma. *BMJ Open.* 2019 Nov 12,9: e032465. <https://bmjopen.bmj.com/content/9/11/e032465>

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## Data sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review.

## Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people’s patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone’s privacy, and it’s important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data is used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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# Appendices

## Appendix 1: TIDieR report of the HOME BP intervention

This section describes the HOME BP intervention using the TIDieR checklist.44

**1. Brief name:** HOME BP

**2. Why:**

High blood pressure (BP) or hypertension is a common condition in the UK affecting approximately 1 in 4 adults and many patients taking medication for high BP remain above national targets.89,90 Raised BP is a key risk factor for cardiovascular events, including heart attack and stroke.91 Clinical inertia is a recognised contributor to uncontrolled BP.6 This occurs when a healthcare professional chooses not to increase antihypertensive medication during an appointment, despite the patient’s BP reading being above target. Reasons for this can include uncertainty about the accuracy of readings taken in clinic, and concerns about side effects or patient reluctance to take more medication. Previous evidence has shown that non-digital interventions (DIs) can reduce BP by encouraging patients and GPs to make medication changes in accordance with a pre-agreed plan, based on an algorithm for home BP readings.13, 31 The HOME BP intervention aimed to provide a cost-effective, feasible digital solution for managing uncontrolled BP by translating these effective procedures into an online intervention.

The target behaviours to reduce BP included self-monitoring BP at home, changing medication when BP was above-target, and optional healthy behaviour changes. Social Cognitive Theory37 and Normalization Process Theory (NPT)33 were used to explain how the intervention would change the target behaviours.

**3. What: Materials**

The HOME BP intervention was comprised of three online training sessions for patients, monthly online BP entry and feedback pages, two online training sessions for healthcare professionals, and automated emails which acted as reminders and prompts for action for patients and healthcare professionals.

The intervention materials can be viewed here: <https://www.lifeguideonline.org/player/play/homebpdemo>

Each participant received an Omron M3 BP monitor to use for self-monitoring.

The online materials are described here:

* HOME BP patient session 1. This session took approximately 20 minutes to complete and provided information about the health consequences of raised BP in the form of a motivational quiz, with click through pages for those who wanted to read more. It explained the rationale for home monitoring in terms of increased accuracy, and sought to promote engagement by letting patients know how self-monitoring would help their GP find the right medicine for them. At the end of the session, a question and answer section was provided to address common concerns and increase self-efficacy, for example, explaining what support would be available from the GP and nurse during the intervention, and reassuring people about side effects.
* HOME BP patient session 2. This session took approximately 30 minutes to complete and sought to build patient ‘s skills to self-monitor BP and their self-efficacy to do this accurately. It included a video , step-by-step written instructions with diagrams showing how to use the monitor, and clear explanations of when to self-monitor and how to enter the readings online. Session 2 also covered what to do in the event of a very high or very low reading, and explained the targets for BP. At the end of the session, there was the option to read short stories from people who have used the intervention, which aimed to increase self-efficacy by showing that the intervention had worked for people.

Sessions 1 and 2 were compulsory to complete before the patient could enter any readings online. They were tunnelled so that session 2 was only available after session 1 had been completed.

* HOME BP patient session 3. This session was optional and only became available 9 weeks after randomisation. It explained the benefits of engaging in healthy behaviours for health in general, and specifically for managing BP. The patient could choose to view more information about each health behaviour: reducing salt; reducing alcohol; healthy diet; increasing physical activity; and, for those with a Body Mass Index over 25, losing weight. If they chose to try one of the healthy behaviour changes, patients received an email with a link to register on a standalone online intervention to support the behaviour change of their choice.
* BP entry and feedback pages: When patients logged in having completed the compulsory training, they were prompted to enter 7 home BP readings to receive instant feedback. This option was only available once every four weeks, and patients received emails to notify them when it was time to start monitoring, and time to enter their readings on the HOME BP intervention. Tailored feedback was shown immediately after they submitted their readings, based on the average of their readings. Patients could choose to receive their feedback as an email, and in some cases (when a medication change was recommended, or had been recommended last month), they could send an email to their GP via the intervention.
* Tools, Ask the Nurse and FAQs: The home page which patients saw every time they logged in after completing the compulsory training showed a menu with options including ‘Tools’, which provided links to various key sections of the intervention, ‘Ask the Nurse’ which enabled the patient to send an email to the nurse at their GP practice about the intervention, and ‘FAQs’ which provided answers to frequently asked questions about the intervention.
* Prescriber training: Prescribers in the intervention could be GPs or nurse prescribers. The online training session was compulsory for each prescriber prior to recruiting patients to the intervention. It took approximately 20 minutes to complete, and included a rationale for the intervention and supporting evidence which sought to change prescribers’ perceptions of the likely outcomes of changing patients’ medication. The online training also explained how to plan 3 medication changes for each patient, with examples given to increase self-efficacy, and how to implement medication changes when needed. Common concerns were addressed using evidence to show that, e.g. patients using this kind of intervention did not need more consultations and only rarely had very high or low readings. The team who created HOME BP were also introduced at the start of the training, to increase perceived credibility of the intervention.
* Supporter training: Supporters in the intervention could be practice nurses or healthcare assistants. The online training was compulsory for each supporter prior to recruiting patients to the intervention. It took approximately 20 minutes to complete, and the first few pages were the same as the prescriber training, including a rationale for the intervention, supporting evidence and the opportunity to see who had created the intervention. Subsequently the supporter training explained how to deliver face-to-face support for patients in the intervention using the CARE approach (Congratulate, Ask, Reassure, Encourage),30 including a rationale for why this approach was effective, quotes from patients and healthcare professionals to increase confidence in the approach, and examples of how to implement CARE for both types of patient appointment that could occur within the intervention. The supporter training also explained how to email patients via the intervention to provide remote support for self-monitoring and medication change.
* Emails: The HOME BP intervention included a large number of tailored emails for patients and healthcare professionals. These included prompts for when to start monitoring, prompts to enter readings online, and tailored feedback for the patient and healthcare professionals on the patient’s BP readings and recommended actions.

**4. What: Procedures**

The intervention procedures are shown in *Figure 6*.

Figure 6 HOME BP intervention procedures

Patient

Session 1

Why is controlling blood pressure important?

Overcome concerns

Session 2

How and when do I monitor?

How do I send my readings?

Self-monitor

Practice week of readings

Continue self-monitoring for 12 months

Enter readings for feedback each month

Session 3

Optional

Which lifestyle change will work best for me?

Online training

GP receives email to change medication if blood pressure is raised

GP appointment

Choose 3 possible medication changes

Support

Nurse appointment regarding practice readings or lifestyle change.

Nurse sends support email every month

HCP

GP appt

Choose 3 possible medication changes

HCP

Support

Nurse appt re practice readings or lifestyle change.

Nurse sends support email every month

*Figure 6* shows that patients completed the first training session online, then had an appointment with their prescriber to agree 3 potential medication changes. The prescriber recorded the 3 planned medication changes in a template, which was saved to the patient’s notes. At this time the patient also collected their BP monitor at the GP practice. At home, the patient could then login to HOME BP and complete session 2, which trained patients to take two morning readings for seven days, record these on paper, and then to enter the second reading from each day on to the HOME BP intervention.

Following completion of session 2, patients were prompted to take 1 week of practice home readings and enter these on HOME BP. The intervention offered the opportunity for patients to send their nurse a message via HOME BP about their practice readings if they wanted to. Patients also received an email which reminded them that they could make an appointment to see their nurse if they wanted to talk about how to use the BP monitor. This was to help promote patients’ self-efficacy in home readings and ensure they felt confident to take their own BP going forwards.

After entering their week of practice readings, patients received reminders to monitor their BP every four weeks during the 12 months, except after three consecutive months of well-controlled readings at which point the reminders dropped to once every eight weeks. They received automated feedback on their readings as soon as they were entered, and the readings were also shared with the prescriber and supporter. The algorithm calculated an average, and if the average was above-target for two consecutive months, a medication change was recommended. Prescribers were trained in the procedure for changing medication during their online training, and the steps were reinforced in the email they received at the time a change was needed. This involved checking the planned change was still appropriate for the patient, and issuing the new prescription along with a template letter which included instructions for the patient on how to make the change and any blood tests which might be needed.

Throughout the 12-month intervention, supporters were asked to send monthly emails to patients using predesigned templates, which could be edited to personalise the email. This monthly remote support was designed to help patients feel supported when self-monitoring their BP at home, and reinforce the benefits of adhering to self-monitoring and medication change.

Nine weeks from when the patient was randomised, an automated email was sent to alert patients that the optional healthy behaviour change session was now available, and there was also an option to view session 3 from their home page when they logged into HOME BP. If they wanted, the patient could book an appointment with the supporter at this point to discuss their choice of healthy behaviour change.

**5. Who provided?**

The intervention was delivered by a prescriber (a GP or nurse prescriber) and a supporter (practice nurse or healthcare assistant) at each GP practice. Each prescriber and supporter was required to complete an online training session prior to recruiting any patients to the intervention, the content of which is described in section 3. GP practices were reimbursed for taking part in the research study.

**6. How?**

The majority of the intervention was delivered online individually. Some components of the intervention involved face-to-face or telephone appointments with a healthcare professional, which could be initiated by the patient or healthcare professional.

**7. Where?**

The intervention was implemented in a primary care context in Southern England from 2015-2018. Online components were completed by patients at home, or by healthcare professionals at their GP practice. Patients needed to have internet access in order to be able to take part. Any GP practice was eligible to sign up to the study.

**8. When and how much?**

The intervention was designed to last 12 months. Patients were asked to take their BP readings for seven days, twice every morning. They would then have three weeks off before starting again. Patients record their seven days of readings online at the end of the week. If their BP average was well-controlled for three consecutive months, their self-monitoring frequency dropped to once every eight weeks.

It was anticipated that each online training session for patients would take approximately 30 minutes to complete.

**9. Tailoring**

BP targets were tailored to take account of age and diabetes, as follows:

1. Patients under 80 years without diabetes: 135/85 mmHg
2. Patients with diabetes: 135/75 mmHg
3. Patients 80 years or older without diabetes 145/85 mmHg

The optional healthy behaviour session (session 3) was tailored to only offer the fifth option of weight loss if the patient’s Body Mass Index was above 25.

**10. Modifications**

The intervention procedures and materials were only minimally modified during the course of the study. Small changes were made in line with feedback from process interviews during the internal pilot trial, such as the addition of a quiz question in session 1 about stress due to the prevalent perception amongst participants that stress was the main cause of their high BP, additional emails about the benefits of healthy behaviour changes to increase uptake, and the option to launch a healthy behavoiur change module from the intervention home page rather than needing to complete the optional healthy behaviour change session.

**11. How well: Planned**

Online usage data were captured automatically by the intervention software, Lifeguide. This enabled patient and HCP engagement to be assessed in the following ways:

1. Number of patients completing the core training (sessions 1 and 2)
2. Number of patients completing optional session 3
3. Number of patients completing 7 days of practice readings
4. Number of BP entries made by patients
5. Number of prescribers completing the core training
6. Number of supporters completing the core training
7. Number of recommendations made to change patients’ medication

In addition, reviews were conducted of the patients’ medical notes at the end of the study in order to explore prescribers’ adherence to planning 3 medication changes in advance, and implementing recommended medication changes.

Qualitative process evaluations were undertaken to explore patients’ and healthcare professionals’ experiences of implementing the intervention.

**12. How well: Actual**

Two detailed mixed methods process evaluation studies were undertaken to explore patients’ and healthcare professionals’ adherence and experiences of implementing the HOME BP intervention. The findings are described in detail in this report (see *Section 3*).

## Appendix 2. Health economic evaluation

This report was authored by James Raftery, Sue Jowett, Shihua Zhu and Richard McManus.

**Introduction**

The Home BP trial aimed to assess the cost effectiveness of the HOME BP digital intervention relative to usual care. Within trial results are reported in a cost effectiveness analysis in terms of cost per unit of blood pressure reduction. Since the intended effects are reduced risk of stroke, heart failure and unstable angina, these longer term effects were estimated in a model previously developed for that purpose1. That analysis is expressed in terms of incremental cost per QALY gained. The perspective in both short and long term analyses is that of the NHS but the role of non NHS costs on patients was explored in the within trial analysis. Costing was based on unit costs in 2018/19. Bootstrapping was used to estimate mean values for costs and QALYs.

The main results of the trial are reported fully elsewhere45 as are details of the longer term model48. Although key elements are summarised here, please see these publications for fuller details.

The next section reports on the within trial analysis of the Home BP trial. A later section reports on the long-term economic modelling, along with exploration of various scenarios before making comparisons with other similar analyses and drawing some general conclusions.

**Costing**

Costing was based on the resource use headings (See *Table 13*) under which data on which were collected in the trial. These data were collected from a review of case notes at the end of the trial. Cost estimates derived were for each patient and included as a cost variable in the statistical analysis. Only service use related to blood pressure (BP) were included. These covered cardiovascular disease and possible side effects of anti-hypertensive medications, including dizziness and falls. Clinical advice was used to adjudicate on the inclusion/exclusion decisions. The number of patients using each service is shown along with costs of BP related services.

Table 13 Resource use headings, data and costing approach

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Heading | Data | Costing | No. patients | Comments |
| 1.Drugs at baseline | Drug by name, dose and duration | NHS Drugs Tariff June 2018, with BNF for drugs not on Tariff | All (n=575) | Assumptions needed for a few drugs with doses not listed in Tariff/BNF (check) |
| 2. Drugs changed during the trial | Ditto | Ditto | 304 | Ditto |
| 3. Costs related to changes in drugs | Type of communication (letter, phone, F2F etc) | Unit cost for Face to Face (F2F) consultations with estimates for other types of consultation. | Ditto | Lacking staff linked to F2F, Assumed captured in 4 to avoid double counting. Scope for detailed cross referencing in future. |
| 4. Other BP related primary care contacts | Contacts by staff (GP, Practice Nurse, HC Assistant) by type (F2F, Telephone) | 6 unit costs were estimated and applied | 544 | Based on PSSRU unit costs for GP, applied to PN and to Band 4 (=HCA), with pro rata for GP telephone cost |
| 5. A&E visits related to BP | Data by reason for visit | £160/visit from NHS Improvement | 9 (92 all) | Included only if visit was after a medication change |
| 6.Outpatient attendances related to BP | Data by specialty and reason for attendance | £125 per attendance from NHS Improvement | 13 (673 all) | Ditto |
| 7.Inpatient admissions | Reason for admission | By HRG, National Tariff | 5 (108) all) | Ditto |
| Total |  |  |  |  |
| Intervention cost  (not included above) | Ongoing cost of running website. Any instruction time to practice or patients. | Based on trial | £39.72 | See relevant section below |

As the trial ran between 2015 and 2018 the year for costing was taken as 2018. Discounting of costs was not considered necessary as the follow up period was limited to 12 months.

Few patients recorded use of A&E, Outpatient (OP) or inpatients that were related to BP. Inpatient admissions received particular attention due to their relatively high cost. Five inpatient admissions, potentially related to BP, were recorded. A review, carried out blind to which arm patients were in, showed that the dates on which all these admissions occurred were all before any changes in medication by patients in the trial. These admissions were thus taken to reflect decisions made or conditions in place before the start of the trial. For that reason, they were excluded from the base case but were included in a sensitivity analysis.

The same logic of excluding service use that occurred before any medication changes in the trial was applied to outpatient and A&E visits. Thus the base or preferred case costing included only inpatient, outpatient and A&E use that occurred after any medication changes in the trial. Again, this decision was made and applied before the data were unblinded. The sensitivity analysis included all BP related use of these services regardless of their timing in relation to medication changes.

**Costing drugs**

Data were collected on all BP related drugs patients were on at baseline, including name, dose and duration along with subsequent consultations and changes in medication. BP related drugs were defined as anti hypertensives, broadly defined (see list available on request). Clinical advice was sought in unclear instances. For patients that did not have a change of medication during the trial, we assumed they have continued their baseline medication unchanged for the duration of the trial. Where data were missing on the duration of those who had changes, they were assumed to continue unchanged to the next change or to the end of the trial, whichever was reached first. . These assumptions involved a minority, around 100-150 patients, most of which had no change in their drugs.

The NHS Drugs Tariff June 2018 was copied for each BP drug mentioned in the trial. Each patient’s use of drugs was costed, from baseline and through changes during the trial, at the dose specific prices listed in the Drugs Tariff. Where the branded rather than generic drugs were recorded, the generic rather than the brand price was used. This reflected common NHS prescribing practice but also avoided bias due to the occasional prescription of brand rather than generic drugs. As very few brand names were listed, this assumption made little difference. The few drugs that did not have a generic version were costed using the stated price for the brand by dose.

If a drug was not included in the Drugs Tariff, the BNF was used. This applied in only a small number of cases.

When the dose recorded in the trial was not listed in the Drugs Tariff or the BNF, it was assumed that the dose could be made up by several dosages. This meant patients might have to use two pills rather than one, but in a few cases it involved up to four drugs (e.g. 4\*25mg atenolol for 100 mg atenolol).

**Costing primary care contacts**

The data recorded were in response to the questions “Who did patient speak to” followed by 3 options: General Practitioner (GP), Practice Nurse (PN) or Health Care Assistant (HCA)” and “How” followed by the options: Face to Face (F2F) Telephone, Letter, or email. These led to 12 options listed as GP-F2F, GP-Tel, PN-F2F, PN-Tel, HCA-F2F, HCA-Tel. The A unit cost (See *Table 14*) was estimated for each and applied to all BP related contacts.

Table 14 Unit costs for primary care contacts, by GP, Practice Nurse (PN) and Health Care Assistant (HCA), by F2F and Telephone

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Unit costs (£) | 1 F2F | 2 Tel | 3 Letter | 4 email |
| 1 General Practitioner | 34.30 | 8.10 | 1.67 | 1 |
| 2 Practice Nurse | 6.45 | 1.52 | 1.67 | 1 |
| 3 Health Care Assistant | 4.00 | 0.94 | 1.67 | 1 |

Notes: F2F = Face to Face, Tel. = Telephone

PSSRU unit costs for 2017/8 put the cost per hour of GP time from £181 to £243 (depending on in/exclusion of direct care costs and with/out qualification costs (PSSRU, page 127 92). A cost per consultation is provided only for GPs and not for other staff. This varied from £28.30 to £37.40 for a 9.22 minute average consultation.

The costing in Table 14 used the cost per GP consultation of £34.3, that is including qualification but not direct costs. The higher figure which included direct costs was not considered appropriate as it appeared to include the overhead costs which are also included in the estimate of the cost of the practice nurse.

The cost per hour of a Practice Nurse in the PRSSU data was from £36 to £42/hour depending on qualifications. We used the higher nurse cost per hour including qualification as with the GP estimate. Assuming the same duration of consultation as for a GP, this put the cost per F2F nurse consultation at £6.50.

As the term Health Care Assistant (HCA) is not listed by PSSRU, this was costed as a band 4 nurse, the lowest grade for which PSSRU provided a unit cost.

PSSRU provide an estimate for a GP phone call of £8.10, based on a small study to do with triage in general practice. This seems a reasonable proportion as £8.1/£34.3 is approximately 25%. The same proportion was applied to the cost per F2F consultations for Practice Nurses and HCAs.

A small number of letter and email contacts were recorded. These were costed at £1.67 and £1.00 each respectively, as a fixed cost, regardless of who they were from. A small number of non-BP related primary care contacts were recorded. These were reviewed and included/excluded prior to unblinding by two clinicians (RMcM, PL).

All patients in the trial had an initial GP consultation to do with entering the trial. This was not included in the costing as it was considered a research cost and applied equally to both arms of the trial. If the intervention were to become routine practice, the assumption implied here is that discussion of patients’ use of the intervention would occur in a routine consultation.

**Costing inpatient episodes**

The data collected showed all BP related inpatient admissions by specialty and reason (See *Table 15*). Checking the dates of these admissions showed all occurred before any changes of medication that occurred once in the trial. A decision was made pre unblinding that these should be omitted from the base case cost, included as part of a sensitivity analysis (discussed below).

Table 15 Inpatient admissions related to BP

|  |  |  |
| --- | --- | --- |
| **Secondary care stay**  **Reason for stay** | **BP-Related or not: Comments** | **Classified as** |
| NSTEM1 Coronary angioplasty | Had chest pain OP attendance and was admitted same day | Angiplasty, most common HRG |
| Angioplasty and stent insertion | Had OP for chest pain 1 after operation | Angioplasty, most common HRG |
| Pacemaker insertion | No other consultation | Pacemaker insertion, most common HRG |
| Falls due to postural hypotension | Preceded by same day OP for fall, admitted for 9 days, had subsequent admission for UTI 2 months later | Fall related HRG, most common |
| Falls team review | Followed same day OP for contusion. Discharged same day. | As above but short stay |

The two angioplasty admissions were allocated to an angioplasty Healthcare Resource Group (HRG) using the national tariff which puts the cost in 2017/18 at £2404 for the most common HRG, EY41D Standard Percutaneous Transluminal Coronary Angioplasty with CC score 0-3).

Similarly with pacemaker insertion, the cost of the most common HRG was put at £2,814 (EY06E, Dual Chamber pacemaker insertion CC score 0-2).93

The two admissions linked to falls were classified under HRG WHO9G “Tendency to Fall, Senility or Other Conditions Affecting Cognitive Functions, without Interventions, with CC Score 0-1”. One was classed as routine with a cost of £1844, the as short stay with a cost of £533

**A&E**

Data were collected on all attendances at A&E by reason. Those deemed most likely to be BP related are listed in *Table 16*. The most common reason was chest pain. As discussed above, A&E attendances occurring before any change in medication were excluded from the base case costing following the logic outlined above for inpatients. The cost per A&E attendance was put at £160 in 2017/8 by NHS Improvement.93

Table 16 A&E attendances related to BP, by type

|  |  |  |
| --- | --- | --- |
| **Patient ID number** | **Reasons** | **Reasons (2)** |
| 27526 | fall – hypotension | UTI |
| 25925 | to exclude DVT | swollen legs secondary to Amlodipine |
| 22225 | Chest pain |  |
| 28005 | Chest pain |  |
| 24952 | Chest pain diagnosis unstable angina |  |
| 27861 | Chest pain, gastritis |  |
| 23994 | Chest pain |  |
| 25673 | Chest pain |  |
| 27295 | A.F. |  |

Note: reasons in Table 16 refer to those recorded in the case note search.

**Costing Outpatient (OP) attendances**

Data were collected on all outpatient attendances. Those most likely related to BP are shown in *Table 17*.

Outpatient visits occurring before any change in medication in trial patients were excluded following the logic outlined above for inpatients. This led to only a small number of outpatient visits being included. The cost per outpatient attendance was put at £125 in 2017/8 by NHS Improvement. More detailed unit costs are available for A&E, Ops and inpatients. The higher level averages have been used as a first cut but see more detailed unit costs below for inpatients. Data are not available to disaggregate A&E but may be applicable to OP attendances depending on in/exclusion criteria.

Table 17 Unit costs for inpatient, outpatient and A&E, 2017/18. NHS National Tariff

|  |  |  |  |
| --- | --- | --- | --- |
| **NHS Service** | **HRG code** | **HRG** | **Cost** |
| Angoplasty | EY41D | Standard Percutaneous Transluminal Coronary Angioplasty with CC Score 0-3 | 1707 |
| Pacemaker | EY06d | Implantation of Dual-Chamber Pacemaker with CC Score 3-5 | 2909 |
| Falls | WHO9G | Tendency to Fall, Senility or Other Conditions Affecting Cognitive Functions, without Interventions, with CC Score 0-1 | 1844 |
| Falls (short stay) | WHO9G short stay | Tendency to Fall, Senility or Other Conditions Affecting Cognitive Functions, without Interventions, with CC Score 0-1 | 533 |
| Outpatient | Cardiology |  | 125 |
| A&E | VB08Z | Emergency Medicine, Category 2 Investigation with Category 1 Treatment | 160 |

**Sensitivity analysis**

As discussed above, the base case scenario was costed on the basis of BP related service use in primary care, including for outpatients and A&E those attendances that occurred after a medication change in the trial. This latter criterion excluded the five inpatient admissions that might have been BP-related.

An alternative scenario was costed, based on including those inpatient, outpatient and A&E visits plausibly related to BP.

A third scenario explored costing only primary care costs, that is excluding the relatively small numbers of outpatient and A&E attendances that occurred after a medication change in the trial. This gave results almost identical to the base case scenario, reflecting the paucity of use of these services.

Non NHS costs

Although data were collected on the amount of time patients spent using the website, we decided not to cost it. This was due the finding from the process evaluation which showed that patients valued the digital intervention both in terms of perceived benefits (such as reassurance, and improved health) and but also experienced burdens (such as worry about health). Time did not appear to be an important feature. Further, their perceptions of illness and treatment perceptions about hypertension appeared to influence perception of benefit or burden. Valuation of such issues would require going well beyond estimates of time spent online.

We offer suggestions under recommendations for research on how these matters might be developed.

On diet and lifestyle, very few patients recorded any changes, a finding consistent with the overall finding that the key changes arising from the intervention were to do with changes in prescribed drugs. No further costing was deemed necessary.

The result was that we are able to present only cost effectiveness estimates from an NHS perspective. We note that this is the perspective required by NICE.

**Costing the Home BP intervention**

The BP monitors were provided by Omron at a lower cost than those sold commercially. The cost to the trial was £23 while the commercially available units cost around £65 (Boots current price). Since these monitors last for several years, usually taken as four or five years, an estimate of the cost for one year, the same as for other cost headings is required. This can be done in two ways: straightline depreciation (offset the same amount each year e.g. 25% for each year if over four years). The £23 cost incurred in the study is shown in annual terms using both methods and in time frames of 4 and 5 years in Table 13. The methods make fairly little difference, ranging from £4.60 to £6.26.

The other element of the intervention had to do with the website. Following advice from the Principal Investigator this was based on the cost of the employee who programmed and maintained LifeGuide. This cost was estimated based on the programmer’s salary and proportion of time spent on maintaining server, spread over then current 10 projects:

* 5% of £48,677 (Level 5/spine point 43) for 3 years (HOME BP was live from 2015-2018) = £7300.
* Divided by number of participants in the intervention arm (n=305) = £23.9

This gives the figure of £23.9 used in *Table 18*. Since this does not appear to include overhead costs (rent, utilities etc) a 40% overhead has been added on in the lower part of the table.

Depending on the overhead issue and writing off the monitor over four years puts the cost of the intervention at £30.16 or £39.72 (first column). Slightly different results due to different assumptions are shown in other columns in *Table 18*.

The higher cost figure of £39.72 was chosen for the base case on the grounds that using the higher cost meant that estimates of cost effectiveness would err on the high rather than the low side.

Table 18 Cost of intervention in Home BP, different methods

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Annuity method** |  | **Straightline** |  |
|  | 4 year | 5 year | 4 year | 5 year |
| Monitor | 6.26 | 5.09 | 5.75 | 4.6 |
| Programmer | 23.9 | 23 | 23.9 | 23.9 |
| Total | 30.16 | 28.09 | 29.65 | 28.5 |
| Programmer with 40% overhead costs |  |  |  |  |
|  | Annuity method |  | Straightline |  |
|  | 4 year | 5 year | 4 year | 5 year |
| Monitor | 6.26 | 5.09 | 5.75 | 4.6 |
| Programmer | 33.46 | 33.46 | 33.46 | 33.46 |
| Total | 39.72 | 38.55 | 39.21 | 38.06 |

**QALYS**

The data from EQ5D, which was collected at baseline and at 6 and 12 months, was used to estimate QALYs. Although the health gain from reduced blood pressure has to do with long term effects of reduced risk of cardiovascular events and death, these data help indicate whether any short-term changes might result from the intervention. The more relevant long-term cost effectiveness of the intervention was estimated in long-term modelling which is reported below. For completeness the within trial results for incremental cost per QALY are reported here.

Data collected using EQ5D were used to estimate QALYs via preferences based on a survey of the public. The results indicated a very small QALY, statistically non-significant, loss in the intervention group relative to the control (See *Table 19*).

Some EQ5D scores were missing. Full values were available for 89% of patients with no difference by arm45. The principal analysis of the primary outcome used raw and adjusted data, and was agreed in a statistical analysis plan before final data lock (BMJ report). The primary analysis used general linear modelling to compare systolic blood pressure in the intervention and usual care groups at follow-up, adjusting for baseline blood pressure, practice (as a random effect to take into account clustering), blood pressure target levels, and sex. Analyses were on an intention-to-treat basis and used 100 multiple imputations by chained equations for missing data. The imputation model included all outcome and stratification variables.

The QALY values were in then imputed based on blood pressure. These values were used in both the within trial analysis and in the longer term modelling.

Table 19 Mean EQ5D scores over 12 months in each group based on complete data

|  |  |  |
| --- | --- | --- |
| **Groups** | **Time** | **Mean score in EQ5D (SD), n** |
| Usual care N=277 | Baseline | 0.84 (0.16) n=277 |
| 6 months | 0.88 (0.14) n=190 |
| 12 months | 0.85 (0.14) n=183 |
| Intervention  N=266 | Baseline | 0.85 (0.17) n=266 |
| 6 months | 0.85 (0.17) n=243 |
| 12 months | 0.85 (0.17) n=209 |

**Results**

A within-trial cost effectiveness analysis was conducted from an NHS perspective using data collected on use of services and on the intervention. This reduction in blood pressure of 3.45 mmHg, combined with increased cost in the intervention arm of £38, led to incremental cost per unit blood pressure reduction in the base case (See *Table 20*) of £11 (95% CI £5 to £29). The increased cost per patient of £38 in the intervention arm was due almost entirely to that of the intervention (£39.73).

Complete case and imputed analyses (also shown in *Table 20*) gave almost identical results with only very small differences. The uncertainty around this estimate was simulated probabilistically using 10,000 runs giving the scattergram Figure 7.

The base case included use of NHS services related to BP. This included the full range of NHS services including hospital admissions. Although few such admissions were recorded, some were elective procedures that had to have been planned before entry to the trial. Consequently, only those hospital admissions which occurred after a change of medication were included in the base case costing. To test the sensitivity of results to this assumption, a scenario was costed which included all hospital, BP related, service use regardless of timing. This made little difference overall but reduced both the cost difference and the incremental cost effectiveness.

Table 20 NHS cost, Primary Outcome, QALY and Incremental cost effectiveness, mean per patient based on differences observed between the Usual Care and the Intervention arms

|  |  |  |
| --- | --- | --- |
|  |  |  |
| NHS cost | Base case | Base case |
| Usual Care (£) | 100 | 100 |
| Intervention (£) | 138 | 138 |
| Difference (£) | 38 | 38 |
|  | Imputed | Complete cases |
| Difference in primary outcome at 12 months (mmHg) | 3.45 | 3.54 |
| Cost/BP (£) | 11 | 11 |
|  |  |  |
| QALY difference | -0.01 | -0.01 |
| Cost/QALY (£) | -3,800 | -3,800 |

A small, non statistically significant decrement in QALYs was observed in the intervention arm (Table 20) which combined with its higher cost meant that he intervention arm was dominated by the usual care arm. However since QALY differences to do with improved blood pressure control at 12 months are of little interest compared to those in the longer term, the results of the life long modelling reported below provide a more robust and plausible estimate of cost effectivness.The mean cost per patient in primary care was similar to those in the base case, indicating that primary care accounted for almost all the costs (See *Table 21*). Within primary care, costs were split roughly 60/40 between those attributable to consultation and those due to prescriptions. Patients in the intervention arm had slightly higher prescription costs associated with changes in medication and/or dose. These did not increase the cost of primary care consultations however due to the role of the digital intervention. These trends as might be expected. Further analysis of these changes is planned for a separate publication which will include changes in the time spent by patients in managing their hypertension.

Table 21 Mean primary care cost per patient by arm in primary care, disaggregated by , consultations and prescription costs

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Of which: |  |
|  | Primary care | Consultations | Prescriptions |
| Usual Care | 97.3 | 62.5 | 34.8 |
| Intervention | 96.5 | 55.8 | 40.7 |

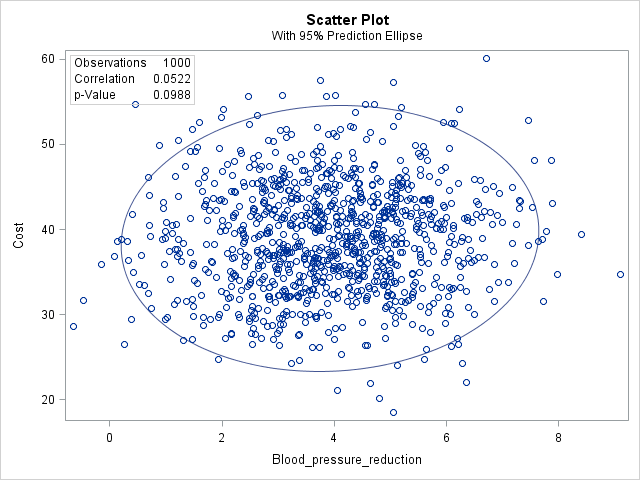


Figure 7 Scatterplot of joint distribution of incremental mean cost from NHS perspective and mean blood pressure reduction from baseline (mmg) over 12 months

The resulting Cost Effectivness Acceptability Curve (See *Figure 8*) indicatated that the probabilities of being cost-effective for the intervention against the usual care are 51% , 90%, and 98% at thresholds of £10, £20, and £50 per unit of blood pressure respectively.

Figure 8 Cost effectiveness acceptability curve of the intervention and usual care groups based on blood pressure from baseline over 12 months.

**Long term cost effectiveness**

A published long-term cost effectiveness study1 of self-management of BP with and without telephone support, broadly similar to the intervention in Home BP, published in 2019, provided a relevant long-term model. Use of this model was facilitated by the overlap of investigators (RJ McManus) in these two trials.

The model, hereafter the TasminH4 model, was Markov patient-level simulation undertaken in TreeAge2018 (TreeAge Software, Inc, Williamstown, MA) to model the different strategies. This type of Markov model tracks the costs and consequences of individual patients passing through the model, with characteristics (taken from the trial) free to vary between patients. The model was run over the maximum lifetime of the patients (maximum of 65 years; minimum trial inclusion criteria was age 35), a time horizon sufficient to capture all relevant long-term costs and consequences.

Each patient had characteristics created by randomly sampling the trial patient-level data by means of a uniform distribution. These characteristics affected their probability of subsequent model events. For instance, males had a higher cardiovascular disease risk relative to females. The model was run with a large number of simulated patients (50, 000) to account for interpatient variability and to adequately model a representative clinical population.

Model Structure

All patients started in the well/no event health state. Within a 6-month time cycle, a patient had a risk of suffering a fatal or non-fatal cardiovascular event or dying from other causes. The possible cardiovascular events in the model were stable angina, unstable angina, stroke, myocardial infarction, and transient ischemic attack. Ten-year cardiovascular risk was calculated for each individual patient, with the distribution of coronary heart disease and stroke events dependent on age and sex. Patients who suffered a nonfatal cardiovascular event transitioned to a post-event cardiovascular health state and additional clinical events were not modelled. Once a cardiovascular event had occurred, mortality risk was adjusted accordingly. The impact of each intervention in terms of event reduction was applied as a relative risk, taking into account the mean differences in systolic BP observed in the Home BP trial.

**Results (Long-term)**

The results from inputting the Home BP trial results into the long-term TasminH4 cost effectiveness model put the incremental cost effectiveness ratio (ICER) at just over £9k (Table 22). This was due to a cost difference of £402, and a QALY difference of 0.044. The key inputs from the Home BP trial were 3.45 mm Hg difference in BP and a cost difference of £38. The small QALY decrement in the intervention arm in the trial was offset in the longer term modelling by reductions in cardiovascular events and deaths (See *Table 2*2).

Table 22 Base case results for Home BP versus Usual Care, base case, over patients’ lifetime

(90% Credibility interval values in brackets)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 2,685 |  | 11.562 |  |  |
| Self-Monitoring | 3,087 | 402  (-2,379 to +3,936 | 11.606 | 0.044  (0.01 to 0.09) | 9,107 |

**Note** Incr = Incremental

The range of the increments in the different runs of the model as shown in scattergram form (See *Figure 9*). The cost effectiveness acceptability curves (See *Figure 10*) show a 66 per cent probability of the intervention being cost-effective at £20k/QALY, rising to 72 per cent at £30k (these relatively low probabilities imply considerable noisiness or wide confidence intervals).

Figure 9 Scattergram of repeated runs of long term model

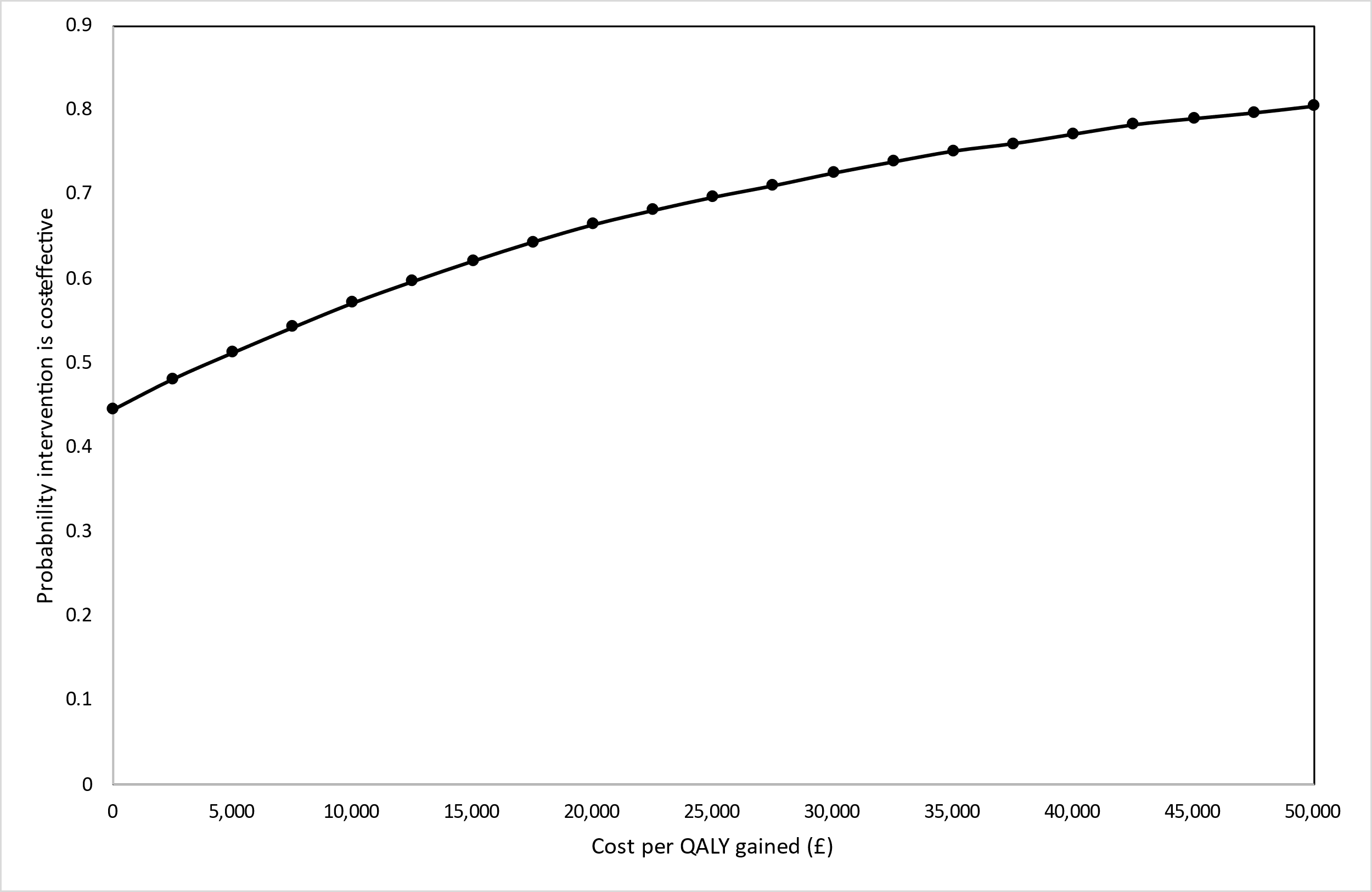


Figure 10 Cost effectiveness acceptability curve of long term cost per QALY

**Scenario analyses**

Different scenarios explored the implications of varying the inputs to the model including the cost difference and the time scale (See *Table 23*) as well as the number of events averted (See *Table 24*).

As expected, when the cost difference in the Base case (£38 a year), was increased so too did the QALY ICER. When the difference was increased to £100, the ICER rose to £26,432. A cost difference of £77 led to an ICER of just under £20,000, taken by some as a willingness to pay threshold.

As also expected, when the time frame was reduced from lifetime in the base case, the ICER increased (See *Table 25*) from just over £9k to just under £67k. This implies that the health gains occur mainly after 5 years.

Table 23 Effect of different initial cost differences on the incremental cost effectiveness ratio (ICER)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **£50 difference (£92 vs £142)** |  |  |  |  |  |
| Strategy | **Total Cost** | **Incr Cost** | **QALYs** | **Incr Eff** | **Incr C/QALY** |
| Usual Care | 2685 |  | 11.562 |  |  |
| Self-Monitoring | 3235 | 550 | 11.606 | 0.044 | 12,460 |
| **£75 difference (£92 vs £167)** |  |  |  |  |  |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 2685 |  | 11.562 |  |  |
| Self-Monitoring | 3543 | 858 | 11.606 | 0.044 | 19,446 |
| **£100 difference (£92 vs £192)** |  |  |  |  |  |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 2685 |  | 11.562 |  |  |
| Self-Monitoring | 3851 | 1166 | 11.606 | 0.044 | 26,432 |
| **Cost difference for £20,000/QALY** |  |  |  |  |  |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 2685 |  | 11.562 |  |  |
| Self-Monitoring | 3568 | 882 | 11.606 | 0.044 | 20,005 |
| **Model time horizon 5 years** |  |  |  |  |  |
| Strategy | Total Cost | Incr Cost | QALYs | Incr Eff | Incr C/E |
| Usual Care | 694 |  | 3.872 |  |  |
| Self-Monitoring | 844 | 150 | 3.874 | 0.002 | 66,768 |

The long-term cost effectiveness of the intervention depends on the number of cardiovascular events averted. *Table 24* shows the number of events predicted in the model for each arm along with the proportions.

7.4% of individuals in the usual care strategy had a non-fatal stroke, compared with 6.9% in the Home BP arm. The majority of people did not have an event and died from other causes (about 71-72%). Differences in outcomes were from the 28% who had an event.

The cost per major event avoided was about £36,000 (£402/0.0112).

Discounting made a difference as might be expected. When only costs were discounted 3.5%, then the base case QALY ICER was £4,508/QALY, and the difference in QALYs is 0.0891. When neither costs nor QALYS were discounted, the ICER of £6,573/QALY

Table 24 Base-case – events by arm as predicted in the long-term model. Based on model run of 50,000 individuals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Usual care**  **(n=)** | **HomeBP**  **(n=)** | **Usual care**  **(proportion)** | **HomeBP**  **(proportion)** | **Difference** |
| **CHD death** | 1,149 | 1,138 | 0.0230 | 0.0228 | 0.0002 |
| **CVD death (stroke)** | 888 | 801 | 0.0178 | 0.0160 | 0.0017 |
| **Non-fatal MI** | 2,814 | 2,760 | 0.0563 | 0.0552 | 0.0011 |
| **Non-fatal stroke** | 3,711 | 3,461 | 0.0742 | 0.0692 | 0.0050 |
| **TIA** | 761 | 714 | 0.0152 | 0.0143 | 0.0009 |
| **Stable angina** | 3,806 | 3,706 | 0.0761 | 0.0741 | 0.0020 |
| **Unstable angina** | 1,312 | 1,303 | 0.0262 | 0.0261 | 0.0002 |
| **Any event** | **14,441** | **13,883** | **0.2888** | **0.2777** | **0.0112** |

**Comparisons with other similar studies**

The relevant studies are TASMINH4 and HITS, a Scottish 2013 randomised trial of telemonitoring (HITS) to control BP94, 95. These are briefly summarized *in Table 25*.

The reported comparisons from Tasminh 4 were Self Management v Usual Care and Telemonitoring v Self Management. These are summarized along with Home BP and HITS in *Table 25*. Several points are noted.

First, the reductions in BP are broadly similar across the three trials ranging from 3.5 to 4.7. The differences are more apparent in terms of their costs, which varied by a factor of 3 between TasminH4 and Home BP, with HITS having a much higher cost.

Second, the relevant comparison between TasminH4 and Home BP would be that between Telephone (Tel) and Usual Care. This was not presented in the published analysis which followed the standard practice of reporting interventions in terms of next best. However, the relevant ICER for that comparison was just over £3k, well below that for Home BP. Which prompts the question of how the relative cost compared.

Table 25 Differences in Blood Pressure and cost inputs and outputs in Tasminh4 and HomeBP from long-term model

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Input | Input | Output | Output | Output |
|  | BP Diff @6m/12m | £NHS Diff @12m | £ Difference | Q Diff Life | £/Q ICER |
| T4:SM v UC | 3.5 | 8 | 124 | 0.0407 | 3,035 |
| T4: Tel v SM | 4.7 | 14 | 302 | 0.0137 | 17,424 |
|  |  |  |  |  |  |
| Home BP | 3.45 | 38 | 402 | 0.044 | 9,107 |
| Not included in modelling |  |  |  |  |  |
| HITS | 4.5 | 109 |

**Notes**: TasminH4 data from Monahan et al. with cost difference for SM v UC at 12 months from S Jowett

SM = Self-management

UC = Usual Care

Tel = telephone support which was provided as an add on to self-management

HTS refers to the Scottish trial94, 95

The costs in *Table 25* refer to the differences between Tasminh4 and Home BP in total cost after 12 months, including both the cost of the intervention and of services used. Neither Tasminh4 nor Home BP provide precise estimates of the intervention for several reasons. Costs of interventions in trials reflect those incurred during the trial which might well be different if those interventions were used in routine practice. The emphasis in trials is on delivering a new untried intervention which may incur costs that would not otherwise be incurred. Further if used in routine practice most interventions, and particularly those that are digital, would benefit from economies of scale. With the interventions under discussion, separation of the intervention and service use cost was difficult, with some elements of the intervention such as follow up reminders or telephone calls being recorded as service use rather than part of the intervention. For these reasons we do not consider that the cost differences between the various interventions shown in Table 25 for Tasminh4 and Home BP should be treated as precise. Rather they provide an indication of the likely low cost of the interventions.

Turning to the HITS trial, two points are worth making. It showed a similar reduction in blood pressure as TasminH4 and Home BP but a higher per patient cost put at £109 compared to £38 for Home BP (See *Table 25*). This higher cost may reflect that trial’s reliance on telemonitoring which may have been more expensive at that time. Although we have not analysed that cost difference in detail, the long-term scenario analyses reported above included one with a cost difference of £100, close to that in HITS. That resulted in an incremental cost per QALY of £26,432. Although well above the incremental cost per QALY in the two other trials, this might still be considered as worthwhile value for money, particularly if the cost of providing the intervention might have declined since then.

**Limitations**

The usual limitations to do with randomised trials apply in that every trial is a specific one-off experiment. Against that, two other trials discussed above have come to similar conclusions. All three trials were fairly big and recruited from general practice in different locations. The overall conclusion must be that self-monitoring, supported to some extent by telemonitoring or a website, can lead to improvements in blood pressure. Although the improvements are modest, as might be expected given the populations (mostly already on medication for blood pressure) they seem to be clinically worthwhile and reasonably cost-effective.

All three trials shared a limitation to do with the costing of the intervention and its knock-on cost impact in the short run. While this is to some extent inevitable, the results indicated that such interventions can be provided at a modest cost per patient, which would be very likely to show economies of scale and reduced cost per patient if made widely available.

**Recommendations for research**

First, more comprehensive modelling of the long-term effects of blood pressure reduction would appear to be useful, perhaps supported by an individual level meta-analysis of the relevant trials. The informal review of the most relevant trials above showed that the interventions trialled resulted in QALY gains which seemed to be mainly in the longer term, a finding consistent with cost effectiveness modelling carried out for NICE. Modelling might also be improved by more detailed comparisons between the relevant models and by monitoring the extent to which the projected reductions in cardiovascular events are confirmed in practice.

Second, more attention to the costing of the range of relevant interventions would be helpful. As discussed above randomised trials providing a novel intervention designed only for that trial are not an ideal way to study what such interventions might cost in routine care, particularly if provided to large numbers of people.

Third, as noted above, while we aimed to include costs incurred beyond the NHS, we were unable to do so. Very few patients reported cost effects due to changes in lifestyle, which is consistent with the overall finding that the main impact of the intervention was on use of the appropriate medications. Although we collected data on the amount of time patients “spent” using the web support, the process evaluation found that patients using he website experienced benefits as well as costs. Research might usefully explore improved ways of measuring these contrasting elements.

Finally, research is needed on how digital aids for treating hypertension can best be located within the range of other self-management in other diseases and conditions. Post-COVID, a shift to remote consultation seems likely to continue as does increased provision of digital supports.

**Conclusions**

The reduction in blood pressure in Home BP was similar to that in other comparable trials. The cost of the intervention was modest at just under £40 per patient. While this is probably an overestimate given it was based on providing a novel service for relatively few people, it nonetheless delivered benefits which would be considered cost-effective in terms of NICE and the NHS. Long-term modelling puts the incremental cost per QALY at just over £9k. If included in a suite of digital interventions which seems increasingly possible the cost per patient would probably reduce.

More generally post-COVID and in line with demographic trends, self-management seems likely to become more widely used in modernised health services. The work reported here provides evidence of both its clinical and cost-effectiveness.

**Contributions**

JR designed, costed, and wrote this report, with input from RMcM, and SZ provided input on the within trial analysis and SJ and RMcM on the long-term modelling.

## Appendix 3. Predictors of systolic blood pressure at 12 months, and engagement with self-reporting blood pressure readings

### Predictors of systolic BP at 12 months

The number of BP entries a patient made, the number of medication changes recommended, and medication necessity beliefs at baseline predicted systolic BP at 12 months are provided in *Tables 26, 27, and 28*

Table 26 Model using number of BP entries to predict systolic BP at 12 months

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| No of BP entries | **-0.908** | **0.26** | **0.001** |
| Baseline systolic BP | **0.323** | **0.077** | **<.001** |
| Age | 0.151 | 0.105 | 0.344 |

Table 27 Model using number of recommended changes to predict systolic BP at 12 months

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| No of recommended changes | -1.527 | 0.463 | 0.001 |
| Baseline systolic BP | 0.347 | 0.078 | <.001 |
| Age | 0.061 | 0.106 | 0.566 |

Table 28 Model using baseline medication necessity beliefs to predict systolic BP at 12 months

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| Baseline medication necessity | **-4.104** | **1.74** | **.018** |
| Baseline systolic BP | **0.347** | **0.078** | **< .001** |
| Age | 0.124 | 0.107 | 0.246 |

### Predictors of number of BP entries

Patients’ self-reported medication adherence (MARS) and their perceived concerns and necessity of BP medication (BMQ) predicted the number of BP entries they made during the study, controlling for age and baseline BP are provided in *Tables 29, 30, and 31*.

Table 29 Model using baseline medication adherence (MARS) to predict number of BP entries

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| BL MARS | **3.874** | **0.416** | **<.001** |
| Baseline systolic BP | -0.007 | 0.016 | 0.654 |
| Age | 0.047 | 0.022 | 0.032 |

Table 30 Model using baseline medication concerns to predict number of BP entries

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| BL medication concerns | **2.851** | **0.345** | **<.001** |
| Baseline systolic BP | 0.0006 | 0.017 | 0.968 |
| Age | 0.037 | 0.023 | 0.098 |

Table 31 Model using baseline medication perceived necessity to predict number of BP entries

|  |  |  |  |
| --- | --- | --- | --- |
| Predictor variables | β | SE | *p* |
| BL medication necessity | **2.604** | **0.331** | **<.001** |
| Baseline systolic BP | -0.013 | 0.016 | 0.442 |
| Age | 0.041 | 0.022 | 0.068 |

## Appendix 4: Behaviour change constructs and techniques in My Breathing Matters

Table 32 Behaviour change constructs and techniques in My Breathing Matters

| **Key barriers identified** | **Intervention component** | **Target construct (BCW)** | **Intervention function (BCW)** | **Behaviour change technique (BCTv1)** | **Target construct (NPT)** |
| --- | --- | --- | --- | --- | --- |
| ***Key Behaviour:******Improved preventer medication adherence*** | | | | | |
| Participants do not know the difference between preventers/relievers and do not associate symptom improvement with use of preventer. | Simple information about different types of medication (including preventer vs. reliever) – including noted normalisation of incorrect technique & videos of correct technique. | Physical capability | Education;  Training | 4.1. Instructions on how to perform the behaviour  5.1. Information about health consequences  6.1. Demonstration of behaviour | Collective action  (Skill set workability) |
| Information and advice is often too complex and large because of the large range of reasons for non-adherence. | Tailored information about how to improve adherence based on current inhaler use. | Psychological capability | Enablement;  Education | 5.1. Information about health consequences  2.2. Feedback on behaviour | Coherence  (individual specification) |
| User stories demonstrating how others benefited from more appropriate medication use. | Reflective motivation | Persuasion | 5.1. Information about health consequences  6.2 Social comparison | Cognitive participation  (legitimation)  Coherence (communal specification) |
| Information about identification of asthma triggers and appropriate management. | Psychological capability; Physical capability | Education; Training | 4.1. Instructions on how to perform the behaviour | Collective action  (Skill set workability) |
| Information about asthma symptoms and appropriate management of them. | Psychological capability; Physical capability | Education; Training | 4.1. Instructions on how to perform the behaviour |
| Education and information about asthma medication and answers to common concerns. | Psychological capability | Education | 5.1. Information about health consequences  9.1. Credible source  9.2. Pros & Cons |
| Irregular schedule / too busy/ run out of medicine / forget. | Information on initial barriers to beginning challenge, and how to overcome them. | Psychological capability; Physical capability | Education;  Enablement | 1.2. Problem solving  8.6. Generalisation of a target behaviour  12.1. Restructuring the physical environment | Cognitive participation  (enrolment)  Collective action (contextual integration) |
| Patients lack motivation to use inhaler regularly. | Set goal dates of 1 month medication adherence. | Physical opportunity | Enablement;  Environmental restructuring | 1.1 Goal setting (behaviour)  1.4 Action planning | Cognitive participation  (enrolment / activation / initiation) |
| Emails throughout challenge to remind user of commitment. | Physical opportunity | Environmental restructuring | 7.1. Prompts/cues  8.1. Behavioural practice/ rehearsal  8.3. Habit formation  12.5. Adding objects to the environment | Collective action (contextual integration) |
| User stories of benefits of 4-week adherence to medication. | Automatic motivation | Persuasion;  Modelling | 5.1. Information about health consequences  5.6. Information about emotional consequences  6.2. Social comparison | Reflexive monitoring  (communal appraisal) |
| Patients do not associate slow improvement of symptoms with increased adherence. | Self-reporting of subjective symptoms to establish benefit. | Reflective motivation | Enablement;  Persuasion | 2.2. Feedback on behaviour  2.4. Self-monitoring of outcome of behaviour | Reflexive monitoring (systematization, individual appraisal, reconfiguration) |
| ***Key Behaviour:******Engagement with a Personal Asthma Action Plan (PAAP)*** | | | | | |
| Patients have not heard of action plan. | Information about benefits of action plan to provide motivation to create PAAP with health care professional (HCP). | Psychological capability | Education | 4.1. Instructions on how to perform the behaviour  5.1. Information about health consequences | Coherence  (internalization) |
| Patients want to make their PAAP without input from HCP. | Robust evidence that PAAPs work best when created in conjunction with HCPs. | Reflective motivation | Persuasion | 5.1. Information about health consequences | Coherence  (individual specification)  Collective action  (contextual integration) |
| User stories of benefits of creating PAAP. | Reflective motivation; Automatic motivation | Persuasion;  Modelling | 5.1. Information about health consequences  5.6. Information about emotional consequences | Coherence  (communal specification) |
| Patients do not schedule HCP appointment to make their PAAP. | Blank PAAP to facilitate HCP consultation. | Physical capability; Physical opportunity | Enablement  Environmental restructuring | 1.4. Action planning  12.1. Restructuring the physical environment | Cognitive participation (initiation / enrolment)  Collective action  (contextual integration) |
| Reminder to facilitate booking appointment with HCP. | Physical opportunity | Environmental restructuring | 7.1. Prompts and cues |
| PAAP may not be used once made. | Online storage and access of PAAP. | Physical opportunity | Environmental restructuring | 12.1. Restructuring the physical environment | Cognitive participation  (activation) |
| Option to review PAAP if having noticeable asthma symptoms. | Physical opportunity | Environmental restructuring | 1.4. Action planning  2.7. Feedback on outcomes of behaviour |
| ***Key Behaviour:******Attendance at annual asthma reviews*** | | | | | |
| Patients do not believe their quality of life can be improved. | Information about relevance of asthma review to improve quality of life. | Psychological capability; Reflective motivation | Education;  Persuasion | 5.1. Information about health consequences  5.6. Information about emotional consequences | Coherence  (internalization / communal specification / individual specification)  Cognitive participation (legitimation) |
| User stories from patients and GPs about benefits of asthma review. | Reflective motivation; Automatic motivation | Persuasion;  Modelling | 5.1. Information about health consequences  5.6. Information about emotional consequences  6.2. Social comparison |
| Patients do not schedule HCP appointment for a review. | Facility to schedule reminder before asthma review and encouragement to book. | Physical opportunity | Environmental restructuring | 7.1. Prompts/cues  12.5. Adding objects to the environment | Cognitive participation  (initiation / activation)  Collective action  (contextual integration) |
| ***Key Behaviour:******Engagement with breathing retraining*** | | | | | |
| Patients do not believe breathing retraining is as effective as medicine. | Information regarding rationale behind breathing retraining and potential benefits. | Reflective motivation | Education;  Persuasion | 5.1. Information about health consequences  5.6 Information about emotional consequences | Coherence  (internalization) |
| Assessment of current breathing habits and tailored feedback regarding opportunities to improve. | Psychological capability | Education; Enablement | 1.1. Goal setting (behaviour)  2.2. Feedback on behaviour | Reflexive monitoring  (individual appraisal) |
| User stories emphasising benefits of breathing retraining. | Automatic motivation | Persuasion; Modelling | 5.1. Information about health consequences  5.6. Information about emotional consequences  6.2. Social comparison | Coherence  (communal specification) |
| Patients find breathing retraining time consuming and difficult, lose motivation. | Facility to plan times to practice in order to facilitate regular practice at convenient times. | Physical opportunity; Physical capability | Enablement; Environmental restructuring | 1.1. Goal setting (behaviour)  1.4. Action planning  4.1. Instruction on how to perform a behaviour | Coherence  (individual specification)  Cognitive participation (initiation) |
| Emails to remind user of ongoing practice and facilitate proactive overcoming of barriers. | Physical opportunity | Environmental restructuring; Enablement | 7.1. Prompts/cues | Reflexive monitoring  (individual appraisal) |
| Examples of positive HCP views of breathing retraining. | Psychological capability; Reflective motivation | Education;  Enablement | 6.3. Information about others’ approval  9.1. Credible source | Cognitive participation  (legitimation)  Collective action  (relational integration) |
| Videos to demonstrate breathing retraining techniques (and text descriptions). | Psychological capability | Education;  Training | 4.1 Instructions on how to perform the behaviour  6.1. Demonstration of behaviour  8.1. Behavioural practice/ rehearsal | Collective action  (skill set workability) |
| Examples of effectively integrating techniques into everyday life. | Psychological capability | Education; Enablement | 1.2. Problem solving  1.4. Action planning  4.1. Instructions on how to perform the behaviour  8.3. Habit formation | Collective action (Interactional workability) |
| Patients do not associate slow improvement with breathing retraining practice. | Self-monitoring of progress including ability to track slow breathing and breath holds. | Psychological capability | Training | 2.4. Self-monitoring of outcome of behaviour | Reflexive monitoring  (individual appraisal) |
| Self-report symptom change over last month to establish benefit. | Reflective motivation | Education | 5.2. Salience of consequences | Reflexive monitoring  (systematizing) |
| ***Key Behaviour:******Engagement with cognitive behavioural stress management practice*** | | | | | |
| Patients do not consider asthma to impact quality of life / stress. | Information about how stress impacts on quality of life. | Reflective motivation | Education;  Persuasion | 5.1. Information about health consequences  5.6. Information about emotional consequences  6.3. Information about others’ approval  9.1. Credible source | Coherence  (individual specification / internalization) |
| Information about prevalence in of stress in asthma population. | Psychological capability | Education | 5.1. Information about health consequences | Coherence  (individual specification) |
| User stories on how to select appropriate stress reduction method and impact on asthma quality of life. | Reflective motivation; Automatic motivation | Persuasion;  Modelling | 5.1. Information about health consequences  6.2. Social comparison | Cognitive participation  (legitimation) |
| Information about unhelpful thought patterns that maintain and exacerbate disease. | Psychological capability | Training | 5.6. Information about emotional consequences | Reflexive monitoring  (individual appraisal) |
| Stress occurs for many reasons and can be ‘just my breathing’. | Provide instruction on relaxation methods to reduce stress. | Psychological capability | Training | 4.1. Instructions on how to perform the behaviour  6.1. Demonstration of behaviour | Collective action (skill-set workability)  Reflexive monitoring  (reconfiguration) |
| Stress management through planning, time-management and self-care. | Psychological capability | Training | 4.1. Instructions on how to perform the behaviour  6.1. Demonstration of behaviour |
| Patients have trouble finding time/continuing motivation for destress activities. | Help planning time for practice and advice on when to schedule. | Psychological capability; Physical opportunity | Enablement;  Environmental restructuring | 1.4. Action planning  4.1. Instructions on how to perform the behaviour | Cognitive participation  (enrolment) |
| Reminder emails to facilitate practice. | Physical opportunity | Environmental restructuring | 7.1. Prompts/cues | Collective action (contextual integration) |
| ***Subsidiary Behaviour:******Effective engagement with DI and its target behaviours*** | | | | | |
| Patients do not believe their quality of life can be improved. | Information about awareness of symptom prevalence in population, and impact of symptoms on quality of life. | Psychological capability | Education | 5.1. Information about health consequences  5.6 Information about emotional consequences | Coherence  (internalization) |
| Robust evidence that others have benefited/could benefit (e.g. scientific studies, individual success stories). | Reflective motivation | Education;  Persuasion | 5.1. Information about health consequences  6.3. Information about others’ approval  9.1. Credible source | Coherence  (communal specification) |
| Evidence of development team expertise. | Automatic motivation | Persuasion | 6.3. Information about others’ approval  9.1. Credible source | Collective action  (relational integration) |
| Informing participants of necessary support provided by Asthma UK alongside DI. | Physical opportunity | Enablement | 3.1. Social support (unspecified)  9.1. Credible source | Cognitive participation  (legitimation) |
| Patients do not view asthma as chronic disease (‘no symptoms, no asthma’). | Subjective self-monitoring of quality of life over last 2 weeks. | Reflective motivation; Psychological capability | Enablement | 5.2. Salience of consequences | Reflexive monitoring  (Systematization/ individual appraisal) |
| Tailored feedback to increase intervention relevance. | Psychological capability; Reflective motivation | Education | 5.1. Information about health consequences  2.2. Feedback on behaviour | Coherence  (individual specification) |
| Education and information on asthma management & My Breathing Matters. | Psychological capability; Reflective motivation | Education;  Persuasion; Environmental restructuring; | 7.1. Prompts/cues  12.5. Adding objects to the environment | Cognitive participation  (activation) |
| Patients are not motivated to engage family/friends in asthma management. | Information about how social support can improve asthma quality of life. | Psychological capability; Reflective motivation | Education | 5.1. Information about health consequences  5.6. Information about emotional consequences | Coherence  (individual specification / communal specification) |
| User stories of successfully involving social support in asthma management. | Automatic motivation | Persuasion; Modelling | 5.1. Information about health consequences  5.6. Information about emotional consequences  3.1. Social support (unspecified) | Cognitive participation (activation)  Collective participation  (legitimation) |
| Patients find it difficult to approach family and friends in care management. | Email link to friends and family in order to involve them in asthma management. | Physical opportunity | Enablement | 3.1. Social support (unspecified) | Cognitive participation (enrolment)  Collective action (contextual integration) |
| Family/friends don’t understand maintenance treatment. | Information for friends and family about asthma treatment and impact on quality of life. | Social opportunity | Environmental restructuring | 5.1. Information about health consequences  6.3. Information about others’ approval | Coherence (communal specification) |

**Key:** BCW = Behaviour Change Wheel; BCTv1 = Behaviour Change Techniques Taxonomy V1; NPT = Normalization Process Theory

## Appendix 5. TIDieR report of the My Breathing Matters intervention

Table 33 TIDieR report of the My Breathing Matters intervention

|  |  |
| --- | --- |
| **Intervention** | **Intervention Item** |
| 1. **Name** | My Breathing Matters, a DI to support self-management of asthma for patients in primary care. |
| 1. **Rationale** | The aim of My Breathing Matters was to improve functional quality of life of primary care patients with asthma, by supporting illness self-management by both pharmacological and non-pharmacological means. |
| 1. **Materials** | My Breathing Matters contained several components, each with content designed to address specific behavioural targets. After an introductory session intended to improve motivation and engagement, session content was tailored for users based on their self-reported asthma-related quality of life scores. Users also received motivating emails specific to content they had accessed (or were now able to access), as well as general ‘reminder emails’ intended to facilitate adaptive behaviour change independent of online My Breathing Matters usage. All of the content was released over a period ranging from 4 days to one month, depending on their tailored content and choices during the online programme. |
| **Pharmacological content:**  All pharmacological content was tailored according to 1) frequency of current medication use; and 2) self-reported medication behaviours. Based on these, users were recommended either:   1. *A Personalised Asthma Action Plan* (PAAP)*.* This content provided information about what a PAAP is, as well as demonstrating benefits to encourage and increase motivation to create a PAAP jointly with their healthcare provider and to use it. My Breathing Matters also attempted to facilitate PAAP use by allowing users store their PAAP online for later use. 2. *An Annual Asthma Review.* Users were provided with information about the benefits of having an Asthma Review with a health care professional to try to increase motivation to make one. My Breathing Matters also attempted to facilitate behavioural change by providing reminder emails to attend their review once they had confirmed they had booked an appointment. 3. *The Medication Adherence Challenge.* In the ‘4-week challenge’ users were encouraged to engage in habitual optimal preventer inhaler use and report the results. This content attempted to support users to overcome barriers to behaviour change (e.g. running out of medication, forgetting dose when tired) and reminder emails were provided in an attempt to support behaviour change. After four weeks, users were sent emails encouraging them to reflect on whether they had noticed any improved quality of life and maintain ongoing behaviour. 4. *Information addressing common concerns regarding medication.* Information on common concerns about medication (e.g. incorrect beliefs about inhaled steroids causing a barrier to habitual use) in an attempt to improve medication adherence). Content focused on maintaining quality of life during times of increased asthma symptoms, asthma triggers, and general medication concerns. |
| **Non-pharmacological content:**  Non-pharmacological content was similarly preceded by content to increase motivation and engagement before users were ‘tunnelled’ into the Breathing Retraining content. The non-pharmacological content is as follows:   * *Breathing Retraining.* Users were given personalised motivation content intended to help them engage in Breathing Retraining behaviour, which was based on self-reported breathing behaviours. They were then provided with 7 ‘unlockable’ stages (a new stage unlocked 24 hours after each previous stage) with videos and text intended to support the new behaviour. Content also addressed barriers to Breathing Retraining (e.g. online progress chart to track progress, or ‘Make a plan’ function to overcome barrier of limited time to practice). Regular emails were intended to increase motivation and engagement and provide information about newly unlocked training stages. * *Stress reduction.* This content intended to target asthma-related anxiety and provided ‘success stories’ of other users’ success to try to improve motivation for reducing stress. Stress-management, relaxation and ‘healthy-thinking’ content aimed to reduce non-adaptive cognitions and behaviours that could impact quality of life. * *Friends & Family.* This content intended to facilitate optimal pharmacological and non-pharmacological management by facilitating support from friends and family members. Users were provided with a hyperlink to this content to share with their friends and family. * *Healthy behaviour modification.* Users were also directed towards additional healthy behaviour modification resources that were considered beneficial to patients with asthma, such as increasing physical activity, improving hand hygiene, weight reduction and smoking cessation. |
| 1. **Procedures** | Users needed to sign up to My Breathing Matters online using an access code that allows the study team to monitor their engagement and intervention usage. My Breathing Matters was designed to be unobtrusive to users’ lives. Users were encouraged to use My Breathing Matters as frequently as they saw necessary consistent with their perceived quality of life impairment (although intervention content aimed to increase motivation and engagement with adaptive behaviours). For example, if users were to have no current symptoms, low My Breathing Matters engagement would be expected. Email reminders were sent out biweekly/monthly intended to facilitate engagement should symptom severity increase. |
| 1. **Provision** | The intervention was created by a collaborative, multidisciplinary team of respiratory clinicians, physiotherapists, behaviour change and DI development experts, and two patient representatives (adults with asthma). My Breathing Matters was developed and is hosted using the opensource Lifeguide ([www.lifeguideonline.org](http://www.lifeguideonline.org)) platform at University of Southampton. |
| 1. **Delivery** | My Breathing Matters is designed to be delivered entirely online and by email. Optional external support for the intervention was provided by trained research nurses through the Asthma UK helpline. |
| 1. **Location** | My Breathing Matters was designed to be accessible entirely online. The website could be accessed wherever was convenient for the user. |
| 1. **Timing** | My Breathing Matters is designed to facilitate effective engagement with adaptive behaviours through a time course that suits users, reflecting the varied symptom severity that is characteristic of asthma patients. For example, some patients may immediately engage with support for improved medication adherence or healthy behaviour change, while others may sign up to My Breathing Matters but not engage until their symptoms noticeably affect their quality of life. |
| 1. **Tailoring** | My Breathing Matters was tailored at several points to facilitate tailored information for users. Techniques to do this included:   * Tunnelling users through ‘essential’ content while optional additional content could be accessed through click-through links. * Tailored content based on self-reported quality of life in ‘My Breath Check’ * Tailored content based on self-reported preventer medication adherence * Tailored content based on self-reported current medical management. |
| 1. **Modifications** | My Breathing Matters was not modified during the course of the study. |
| 1. **Planned Fidelity** | Data on intervention engagement of individual users is available to the research team through usage data generated by the Lifeguide platform. This data were collected on 44 participants who were randomised to the intervention arm of the feasibility trial. This report (see *Section 5*) details the methods for the trial and usage analysis in full. |
| 1. **Actual Fidelity** | Of the participants in the intervention group (*n =* 44), 81.8 per cent (*n =* 36) logged into My Breathing Matters at least once. Participants logged in between 1 and 25 times (Median = 4; Interquartile Range = 8) and those using the intervention more than once (*n =* 27) used it between 1.89 to 337.85 days (Median = 120.96; Interquartile Range = 148.23). This report (see *Section 5*) reports the usage analysis in full. |