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# BMJ Open

## Perceived burdens and benefits of self-management interventions: A qualitative process study of an online intervention for self-managing high blood pressure.

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6 **1 Title page**  
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10 **2 Perceived burdens and benefits of self-management interventions: A qualitative process**  
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12 **3 study of an online intervention for self-managing high blood pressure.**  
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14

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78 **20 ABSTRACT**

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11 **Objectives:** Digital health interventions can change patients' experiences of managing their health,  
12 either creating additional burden or improving their experience of healthcare. This qualitative study  
13 aims to explore perceived burdens and benefits for patients using an online self-management  
14 intervention for high blood pressure. A secondary aim is to further our understanding of how best to  
15 capture these outcomes when evaluating health interventions.  
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22 **Design:** Inductive qualitative process study nested in a randomised controlled trial.  
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25 **Setting:** Primary Care in the UK  
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28 **Participants:** 35 participants taking antihypertensive medication and with uncontrolled blood  
29 pressure at baseline took part in semi-structured telephone interviews.  
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32 **Intervention:** Online self-management intervention to support blood pressure self-monitoring and  
33 medication change when recommended by the healthcare professional.  
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38 **Analysis:** Data were analysed using inductive thematic analysis with techniques from grounded  
39 theory.  
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43 **Results:** Seven themes were developed which reflected perceived burdens and benefits of using the  
44 intervention, including worry about health, uncertainty about self-monitoring, and reassurance. A  
45 model was developed to show how beliefs about their condition and treatment appeared to  
46 influence participants' appraisal of the value of the intervention, suggesting that considering illness  
47 and treatment perceptions in Burden of Treatment theory could further our understanding of how  
48 individuals appraise the personal costs and benefits of self-managing their health.  
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3 40 **Conclusions:** Patients' appraisal of the burden or benefit of using a complex self-management  
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5 41 intervention seemed to be influenced by both experiences within the intervention (such as  
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7 42 perceived availability of support) and beliefs about their condition and treatment (such as perceived  
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9 43 control and risk of side effects). Developing our ability to adequately capture these salient burdens  
10  
11 44 and benefits for patients could help enhance evaluation of self-management interventions in future.  
12  
13 45 Many participants perceived important benefits from using the intervention, highlighting the need  
14  
15 46 for theory to allow that engaging in self-management can include positive as well as negative  
16  
17 47 aspects.  
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22  
23 49 Trial registration: ISRCTN13790648. Registered 14 May 2015.  
24

25 50 **Keywords:** Self-management; digital intervention; qualitative; treatment burden  
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28 51 **Strengths and limitations of this study:**

- 29 52 ❖ The exploratory, open approach to data collection enabled us to capture whichever benefits or  
30  
31 53 burdens were most salient to the participants.  
32  
33 54 ❖ This inductive approach highlighted some novel reactions to using self-management digital  
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35 55 interventions.  
36  
37 56 ❖ We only interviewed participants at one point in time, so were unable to gain an understanding  
38  
39 57 of dynamic changes in perceived benefits or burdens over time.  
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41 58 ❖ Both well and poorly controlled hypertensive patients took part in the interviews, but it was  
42  
43 59 difficult to recruit low users of the intervention which could limit the generalisability of the  
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45 60 findings.  
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47 61 ❖ Qualitative data is not commonly used in health economics evaluation, so further work would be  
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49 62 needed to understand how relevant outcomes could best be captured quantitatively.  
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## 65 BACKGROUND

66 The work involved in looking after one's health when living with a chronic condition can include  
67 complex tasks such as organising and adhering to treatment regimes, interacting with healthcare  
68 professionals (HCPs), regular monitoring of health indicators, and making health-related decisions,  
69 all of which can accumulate into a considerable burden for people<sup>1</sup>. Digital self-management  
70 interventions are often developed to improve health outcomes, but these interventions could also  
71 either increase or minimise the burden of the process of healthcare for patients. Developing our  
72 understanding of the burdens of self-management can help to better optimise the delivery of  
73 healthcare to improve adherence and well-being<sup>1-3</sup>. Burden of Treatment (BoT) theory provides a  
74 mechanism for understanding these experiences in the context of patients' personal capacity to  
75 cope, with emphasis on the role of wider healthcare systems and social networks available to the  
76 patient<sup>1</sup>.

77 Health economic evaluations also focus on understanding the impact of healthcare on patients,  
78 seeking to weigh up the resources used against the health outcomes in order to better inform  
79 decision-making. Recent guidelines for economic evaluations in health and medicine recommend  
80 adopting a societal perspective such that all relevant outcomes are evaluated, rather than focusing  
81 only on formal healthcare costs<sup>4</sup>. In particular, personal costs such as time spent in self-care should  
82 be included. Consequently, BoT theory and health economic evaluations share an interest in  
83 adequately capturing the wider burdens or personal costs of engaging with healthcare. For  
84 consistency in terminology in this paper, negative outcomes/personal costs of healthcare will be  
85 referred to as 'burdens'.

86 BoT theory considers patients' time spent on healthcare as a resource that is used by the healthcare  
87 system, while health economic evaluation counts time as an 'opportunity cost' whereby the patient  
88 'spends' time that could have been spent on something other than healthcare. However, subjective  
89 experiences of time spent on digital interventions may be varied and complex. Heterogeneity in the

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3 90 relative value placed on the outcomes of the intervention<sup>5</sup> may mean that for some participants the  
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5 91 time spent engaging with elements of an intervention is not perceived as a burden but rather as a  
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7 92 benefit, either because it is interesting, pleasant or meaningful in and of itself or because of the  
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9 93 positive outcomes it can lead to. In other words, some people may actually like engaging with  
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11 94 healthcare. The value of exploring the personal benefits of intervention participation has not  
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13 95 received as much focus as understanding the costs, such as treatment burden. McNamee et al.<sup>6</sup>  
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15 96 propose that the health research guidelines for economic analysis may need to be adjusted for  
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17 97 digital health interventions to ensure we can fully capture the heterogeneous costs and benefits  
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19 98 arising when complex interventions are implemented in complex systems.

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23 99 To further our understanding of how patients perceive benefits and burdens when using digital  
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25 100 health interventions, we carried out a qualitative process study. The online HOME BP intervention  
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27 101 was developed based on best practice recommendations to help improve hypertension in poorly  
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29 102 controlled patients by facilitating self-monitoring of blood pressure (BP) at home and prompting  
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31 103 appropriate intensification of medication by healthcare professionals<sup>7</sup>. This intervention could help  
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33 104 to minimise the treatment burden of hypertension by providing a healthcare system in which HCPs  
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35 105 have sight of patients' home readings, streamlining the process for finding the most effective  
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37 106 medication without the need for attending the GP Practice. However, HOME BP is a complex,  
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39 107 interactive multi-component intervention, which creates potential diversity in the perceived burden  
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41 108 and benefits for participants using it. The contexts in which the intervention is embedded may also  
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43 109 be diverse, and factors such as individual differences in patients' health status, beliefs about  
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45 110 medication and risks of high BP, availability of time and resources, and access to support may  
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47 111 influence how the intervention is perceived and valued. The HOME BP intervention was developed  
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49 112 using the person-based approach<sup>8</sup> which emphasises the importance of understanding participants'  
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51 113 unique perspectives and different situations when developing and implementing digital  
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53 114 interventions. Adopting a more granular approach to the evaluation of benefit and burden is  
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3 115 consistent with the person-based approach, and with the BoT approach of fully understanding the  
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5 116 participants' perspective.  
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8 117 The present study aimed to explore the perceived burden and benefits of using a digital health  
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10 118 intervention for self-managing BP using qualitative process interviews with intervention and usual  
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12 119 care participants taking part in a randomised controlled trial (RCT). This paper seeks to interpret  
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14 120 these findings in terms of the implications for optimising the capture of perceived costs and benefits  
15  
16 121 in health economic evaluations and evaluating the burden of treatment.  
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## 23 123 **METHODS**

### 27 124 **Design**

30 125 A qualitative process study embedded in the Home BP trial<sup>7</sup> was approved by the University of  
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32 126 Southampton and NHS Research Ethics committees. The COREQ checklist (Consolidated criteria for  
33  
34 127 reporting qualitative studies) was used to ensure comprehensive reporting of the study<sup>9</sup>  
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36 128 (supplementary file 1).  
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### 43 130 **Intervention**

46 131 The HOME BP online programme supports participants to self-manage their high BP, primarily via  
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48 132 home self-monitoring of BP and making changes to dose/drug type when recommended by the HCP.  
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50 133 Lifestyle change modules are also available, but optional. Participants using HOME BP were  
51  
52 134 supported by a 'prescriber' (GP or nurse prescriber responsible for changing medication) and a  
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54 135 'supporter' (nurse or healthcare assistant who supported participants in self-monitoring and  
55  
56 136 choosing lifestyle changes). Table 1 describes the HOME BP intervention in more detail.  
57



137 Table 1 HOME BP Intervention Characteristics

Target behaviour	Description
Self-monitoring BP	Participants monitor their BP at home for 7 days every 4 weeks. After 7 days, they enter their BP readings into the HOME BP online programme and receive instant automated feedback using a traffic light system. If BP is very high (red) or very low (blue), they are told to contact their GP Practice. If BP is above target (amber), they are told their prescriber will contact them about a medication change. If BP is on target (green), they are congratulated and asked to monitor their BP again next time.
Medication change	The prescriber plans three potential medication changes with the participant at the start of the study. Prescribers are informed by email when a medication change is recommended and can implement a pre-planned change without needing to see the participant for an appointment.
Optional lifestyle changes	Nine weeks after randomisation, participants have the option of choosing an online session to support lifestyle change to help control their BP, specifically weight management, salt reduction, healthy diet, physical activity, or alcohol reduction. Participants are alerted by email when this becomes available, and see an option to view the healthy lifestyles session each time they log on to HOME BP. The online lifestyle change sessions can be started at any time during the 12-month trial, after nine weeks.

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139

## 140 **Participants**

141 Patients were eligible to take part in the HOME BP trial if they had uncontrolled hypertension (mean  
142 BP reading of 140/90 mm Hg or more at baseline) managed in Primary Care, were prescribed 1-3  
143 antihypertensive medications at baseline, and aged over 18 (see<sup>7</sup> for full inclusion and exclusion  
144 criteria).

145 Both intervention and usual care participants were invited to take part in interviews as we felt that  
146 obtaining an understanding of managing BP in usual care would aid interpretation of the perceived  
147 burden and benefits of the intervention. We aimed to speak to participants at a range of time-points  
148 during the 12-month trial from 10 weeks onwards as this gave participants the opportunity to  
149 become familiar with HOME BP. No new intervention content was introduced after nine weeks.

## 150 **Recruitment and interview procedure**

151 A sub-sample of RCT participants were invited by email to provide feedback on their experiences of  
152 managing their BP (n=78). Informed consent was taken by post or online, depending on participant  
153 preference. Recruitment was initially opportunistic, but subsequently a purposive approach was  
154 adopted to target younger participants, low engagers, and those with recent uncontrolled self-  
155 monitored BP readings, informed by the concurrent analysis. Recruitment was stopped once the  
156 researchers agreed that data saturation had been reached and no new burdens or benefits were  
157 arising.

158 Semi-structured interview schedules were co-developed by experts in health psychology (KM, KB, RB,  
159 LY, LD), health economics (JR) and sociology (CM). Open, inductive questions were carefully selected  
160 to elicit data about the burden and benefits of BP management perceived as most salient by the  
161 participants (see Supplementary File 2 for interview schedules). The interviews were conducted by  
162 telephone to minimise the burden on participants, except in one case where the participant asked to  
163 meet face-to-face due to struggling with hearing on the telephone. The interviews took place

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3 164 between February 2016 and February 2017. Each participant was given a £10 gift voucher to thank  
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5 165 them for their time.  
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8 166 All interviews were conducted by KM (MSc, BSc. Termed “the researcher”), a female PhD candidate  
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10 167 in Health Psychology who was also employed as a research assistant. Each interview was audio-  
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12 168 recorded, and the researcher also took notes and completed a self-reflection log afterwards to  
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14 169 record any emerging thoughts on the data. Audio-recordings were transcribed verbatim and checked  
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16 170 thoroughly by the researcher.  
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## 19 20 171 **Analysis** 21 22

23 172 The analysis was an iterative process led by KM, supported by frequent discussion of emerging  
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25 173 themes with LY and LD (who have extensive experience in qualitative research) along with input  
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27 174 regarding health economic and sociological perspectives (JR and CM). Inductive thematic analysis  
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29 175 methods were used<sup>10 11</sup> with techniques from grounded theory such as memoing, constant  
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31 176 comparison, and diagramming to enhance our understanding and facilitate the development of  
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33 177 higher themes<sup>12 13</sup>. Data collection and analysis ran concurrently to enable purposive sampling based  
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35 178 on analytic insights. Thorough line-by-line coding was undertaken in NVivo 10<sup>14</sup>, and a coding  
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37 179 manual was developed which evolved as more data were collected and coded. The emerging codes  
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39 180 were constantly checked against the raw data to ensure the analysis was driven by the participants’  
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41 181 own language and experiences.  
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45 182 All data relating to burdens and benefits of managing BP were analysed. We also coded factors that  
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47 183 appeared to influence perceptions of burdens and benefits to facilitate an in-depth understanding of  
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49 184 how participants appraised the intervention’s value. A broad and open definition was adopted  
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51 185 whereby benefits and burdens were defined as positive and negative outcomes or experiences of  
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53 186 engaging in the intervention<sup>15</sup>, in order to facilitate a comprehensive representation of all potentially  
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55 187 relevant data.  
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67 189 **RESULTS**  
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910 190 **Participant characteristics**  
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13 191 28 of 54 participants from the intervention group (52%), and 7 of 24 usual care participants (29%)  
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15 192 agreed to be interviewed. Most participants who did not take part chose not to reply, but those who  
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17 193 did said they did not have anything to report on the trial (n = 3 in usual care). The participants were  
18  
19 194 from 19 different GP Practices. Table 2 shows the sociodemographic and intervention details of the  
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21 195 sample.  
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25 196  
2627  
28 197 Table 2. Sociodemographic and intervention participant data (n=35)  
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	Intervention participants	Usual care participants
N	28	7
Average duration of interview (range)	39 (15-67) minutes	28 (22-40) minutes
Average age (range)	65 (41-87) years	67 (52-77) years
Gender	71% female	43% female
Ethnicity		
White	24	6
Black African	1	
Pakistani	1	
Other	2	1
Education levels	9 No formal education	2 No formal education

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	8 GCSE or A-level	3 GCSE or A-level
	10 Higher Education	1 Higher Education
	1 Other	1 Other
Number of weeks into study	23 (10-57) weeks	17 (7 to 24) weeks
Poorly controlled BP at the time of the interview	10/28 (36%)	N/A*
Medication change recommended during the study	15/28 (54%)	N/A
Accessed optional healthy lifestyles session	15/28 (54%)	N/A

198 \*As BP self-monitoring was a key component of the intervention, BP readings were available for the  
 199 intervention group throughout the duration of the study but data about BP from the usual care  
 200 group were only available at RCT baseline and follow-up points.

## 201 Themes

202 Table 3 presents seven themes exploring perceptions of burdens and benefits of the HOME BP  
 203 intervention. One meta-theme also emerged concerning how illness and treatment beliefs about  
 204 high BP appeared to influence participants' perceptions about the intervention's burdens and  
 205 benefits, and this is discussed in relation to each theme it applies to. Figure 1 shows how illness and  
 206 treatment perceptions about BP appeared to relate to the sub-themes identified by the thematic  
 207 analysis.

208 Table 3. Themes and sub-themes relating to perceived burdens and benefits of the intervention

Themes	Sub-themes	Exemplar participant quote
Benefit of reassurance from seeing BP readings	Reassurance when BP readings are well-controlled	"I'm so pleased. And my mind is at rest when we go on holidays and all that...I'm alright. I'm alright sort of thing. Yeah, peace of mind" (Intervention p9, well-controlled)
	Reassurance from keeping an eye on BP	"It made me much more aware of what the problem is with the high blood pressure and by monitoring it so regularly, I know exactly where I stand with it" (Intervention p15, well-controlled)
Benefit of motivation for lifestyle change from seeing BP readings	Seeing BP readings motivated lifestyle change	"It is quite interesting to see the effects of what I'm doing on the blood pressure and everything. So, I think that is – it is quite good" (Intervention p18, well-controlled)
Benefit of better	Perceived health improvements	"It helped me to change my medication and then because of change of medication,

health	from medication changes	my blood pressure went down. So definitely there is a benefit" (Intervention p16, well-controlled)
	Intervention can facilitate management of side effects	"That medication didn't work, in that I was on holiday and my ankles swelled up so much – and my feet and my legs, so much so that I couldn't see my toes. So I stopped taking that medication. Was called back to the GP. And I'm now on a medication that works for me and is managing the blood pressure" (Intervention p7, well-controlled)
Burden of worrying about health	Negative emotional responses to seeing high readings	"I was actually quite shocked because it was a—a lot higher" (Intervention p6, poorly controlled)
	Worrying about medication change affecting health	"I don't want to get more medication 'cause I'm already on a high dose and I don't want to increase it because it worries me about my kidneys" (Intervention p24, poorly controlled)
Burden of uncertainty from self-monitoring	Uncertainty about whether readings are representative	"If someone only ever takes it in the morning, and you tend to get those lower readings, are you really getting a true picture of what they're like in the afternoon or the evening?" (Intervention p10, well-controlled)

	Uncertainty about what to do about high or low readings	"I don't know what's going to happen in respect to that [amber feedback]. Whether I'm going to get a call from my GP, or whether he – so I'm a little bit, like, you know, in the air. I don't really know what's going to happen in that respect" (Intervention p22, poorly controlled)
Burden of thinking about making healthy lifestyle changes	Worry or guilt about not engaging with healthy changes	"I have looked at it [online healthy lifestyles session]. I wouldn't say I've looked at it seriously, and I need to" (Intervention p4, poorly controlled)
Burden of the practicalities of adhering to intervention procedures	Burden of fitting self-monitoring into the day	"I like to get up and have a cup of coffee and I'm thinking 'Well, let's get the blood pressure done first because otherwise I can't do that, you know, for a while afterwards.' So, I've found that quite—quite difficult" (Intervention p5, poorly controlled).

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4 211 Insert Figure 1 here  
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7 212 Benefit of reassurance from seeing BP readings  
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10 213 *Reassurance when BP readings are well-controlled*  
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13 214 Seeing well-controlled readings when self-monitoring BP gave participants peace of mind which was  
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15 215 widely perceived as a benefit of the intervention. People described feeling relieved that their BP  
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17 216 readings were lower than at the GP Practice, and felt this gave them more insight into what their BP  
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19 217 was like most of the time.  
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22 218 “What I do like about it is taking the blood pressure here at home, the readings are lower. And I find  
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24 219 that quite reassuring that my blood pressure is not always high” (Intervention p11, well-controlled)  
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27 220 Several usual care participants had decided to use their own BP monitors independently of the  
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29 221 online intervention, and this group also described feeling reassurance when seeing their BP was  
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31 222 well-controlled.  
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34 223 *Reassurance from keeping an eye on BP*  
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37 224 Most participants liked having an increased focus on their BP through regular monitoring and found  
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39 225 it interesting to compare their readings over time. However one participant perceived that taking BP  
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41 226 regularly could encourage too much attention on your health, which was a potential burden of the  
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43 227 intervention for her (Intervention p28, BP control unknown as did not enter BP readings online). This  
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45 228 participant had low concern about her BP generally, and was not motivated to engage in self-  
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47 229 management.  
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50 230 Even when participants had poorly-controlled readings, many felt a benefit from the intervention as  
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52 231 it enabled them to regularly check their BP and detect any problems instantly rather than carrying  
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54 232 on unaware.  
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3 233 "I think it's helping me to know where my blood pressure stands because it's a regular thing every  
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5 234 month" (Intervention p24, poorly-controlled)

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8 235 The knowledge that home BP readings were shared with the prescriber reassured participants as  
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10 236 they knew that any problems would not only be detected but also dealt with at the time, making  
11  
12 237 them feel well cared for. This contrasted with the perceived burden of managing BP in usual care  
13  
14 238 where some participants felt concerned that their GP did not change their medication when their  
15  
16 239 home readings were too high, or would have liked more regular contact with their Practice to check  
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18 240 their BP and medication.

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21 241 "It would be nice to have it checked, I guess, you know, every three months or whatever. How—  
22  
23 242 however often. I mean, how do they know that everything is working?" (Usual care p4).

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25  
26 243 This shows that although participants in usual care gained reassurance from seeing low readings  
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28 244 when they monitored at home, the lack of interaction with the Practice could cause concern when  
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30 245 readings were high or when patients did not regularly monitor BP at home of their own accord.

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36 247 Benefit of motivation for lifestyle change from seeing BP readings

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39 248 Some participants were motivated to increase their physical activity, engage in stress management  
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41 249 activities or healthy eating because they could see this had a positive impact on their BP readings.

42  
43 250 This helped them feel more in control of their BP.

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45  
46 251 "By taking the readings regularly and frequently, it gave me more of a feedback straightaway if you  
47  
48 252 like about anything, changes that I did make like a bit of exercise or...practicing relaxation and this  
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50 253 sort of thing. So that was quite nice, it was nice to feel that I was more in control of it again"

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52 254 (Intervention p20, well-controlled)

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3 255 Other participants felt frustrated after making lifestyle changes in the past which had no effect on  
4  
5 256 their BP. This made them feel that lifestyle was ineffective for controlling BP.  
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8 257 “I’m a completely different person. My diet’s completely different. And my blood pressure remained  
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10 258 the same. So I’ve done literally everything you physically possibly can to help yourself, and nothing’s  
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12 259 worked” (Intervention p1, well-controlled).  
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18 261 Benefit of better health

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21 262 *Perceived health improvements from medication changes*  
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24 263 Many participants felt it was beneficial to change their medication when their readings were too  
25  
26 264 high, and were very pleased when they perceived that a medication change led to lower BP readings  
27  
28 265 because of the positive effect this would have on their health.  
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31 266 “I’ve found that by having the medication changed up at regular intervals my blood pressure’s  
32  
33 267 improved all the time” (Intervention p15, well-controlled)  
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36 268 A few participants felt that a medication change had not been effective at lowering their BP which  
37  
38 269 could create doubt about their medication’s effectiveness.  
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41 270 “It’s been doubled but it hasn’t seemed to lower my blood pressure at all, in fact, it’s at the same  
42  
43 271 levels as it is sort of now, un-medicated. So I just think – I don’t think it’s the right one. You know, I  
44  
45 272 can take the tablet but, actually, I don’t think it’s doing anything”. (Intervention p26, poorly-  
46  
47 273 controlled)  
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50 274 *Intervention can facilitate management of side effects*  
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53 275 Most participants did not experience any side effects from having their medication changed. Where  
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55 276 side effects did occur, participants tended to perceive this as being a cost of taking medication  
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3 277 (which was balanced against the benefit of controlling BP), rather than a burden of the intervention  
4  
5 278 itself. They felt that the intervention could help them to be more aware of side effects, to identify  
6  
7 279 alternative medications and to monitor how these affect their health.  
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9

10 280 “That [side effect] would have happened, you know, no matter what. That would have been an issue  
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12 281 but this has actually highlighted it, sort of, more clearly” (Intervention p5, poorly-controlled)  
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17  
18 283 Burden of worrying about health  
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21 284 *Negative emotional responses to seeing high readings*  
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23  
24 285 A burden of self-monitoring BP for some people was that seeing high readings could cause worry  
25  
26 286 about health. Participants’ beliefs about their BP control appeared to influence their appraisal of  
27  
28 287 high readings. A few participants believed their BP was well-controlled, a belief which was perhaps  
29  
30 288 reinforced by clinical staff approving their readings previously, and had only joined the study to help  
31  
32 289 with research. These participants tended to feel shocked or annoyed when they received above-  
33  
34 290 target feedback from the intervention as this challenged their beliefs.  
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37  
38 291 “At one time, I was told to go on medication, further medication, which I must admit I was not very  
39  
40 292 happy about... When I used to go for a check with the nurse, if I’d have had those particular readings,  
41  
42 293 they wouldn’t have been high” (Intervention p17, poorly controlled)  
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45 294 Others were confused or frustrated by high BP readings when they could not understand why this  
46  
47 295 might have happened.  
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49  
50 296 “I’m thinking about why my blood pressure has gone up. I can’t think why” (Intervention p25, poorly  
51  
52 297 controlled).  
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3 299 Meanwhile people who expected to see high readings were less concerned because they had  
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5 300 accepted that high readings were likely.  
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7  
8 301 “Just par for the course. It’s what I expect from my blood pressure, really, so, it never worries me”  
9  
10 302 (Intervention p5, poorly controlled)  
11  
12  
13 303 Perceptions about the causes of high BP also influenced how anxious people felt about seeing high  
14  
15 304 readings. Those who felt that high readings held serious implications for their health tended to feel  
16  
17 305 frightened. Some even felt apprehensive *before* self-monitoring in case their readings were out-of-  
18  
19 306 range, as they didn't want to see evidence that their BP was too high or low.  
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21  
22 307 “Before I take my blood pressure, I do get stressed. I wouldn't say I get massively stressed because  
23  
24 308 obviously I'm used to doing it now but ... it's just that apprehension and thinking 'Oh, God, I hope it's  
25  
26 309 not too high today. I wonder really what's going on and how serious this is”. (Intervention p26,  
27  
28 310 poorly controlled).  
29  
30  
31 311 Other people were able to dismiss one-off high readings without feeling anxious as they attributed  
32  
33 312 high readings to less threatening explanations such as feeling stressed, not sitting still for long  
34  
35 313 enough, positioning of the cuff, or held a prior expectation of it being normal for BP to fluctuate. In  
36  
37 314 these cases, the high readings had less negative emotional impact as they were not interpreted as  
38  
39 315 indicating a serious underlying health issue.  
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43 316 *Worrying about medication change affecting health*  
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46 317 Some participants were worried about the effects that changing BP medication could have on their  
47  
48 318 health. Previous experience of side effects, existence of co-morbidities, and concerns about  
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50 319 medication dependency or impact on kidneys tended to make participants feel more worried about  
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52 320 changing medication.  
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3 321 Perceptions about the health risk of high BP in terms of stroke and cardiovascular disease tended to  
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5 322 affect how burdensome participants perceived a medication change to be. Anxiety about future  
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7 323 health could override concerns about medication side effects or dependency as the behaviour was  
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9 324 evaluated as beneficial in order to bring BP down, although sometimes participants still experienced  
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11 325 conflict between the perceived benefit and burden.

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14 326 “The blood pressure has gone down but now my worries have changed from blood pressure to other  
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16 327 things. One is actually depending on medicine whole of my life. And secondly impact of medicine  
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18 328 on my body like kidneys” (Intervention p16, well-controlled).

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24 330 Burden of uncertainty from self-monitoring

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27 331 *Uncertainty about whether readings are representative*

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30 332 Whilst some participants were confident making decisions about when to monitor their BP, others  
31  
32 333 were worried about whether their readings were representative, especially when BP was seen to  
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34 334 vary at different times of day or after physical activity or drinking coffee. This could lead to doubt  
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36 335 about the meaningfulness of self-monitoring and the recommendations of the intervention.

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39 336 “I wonder if maybe the time of day I’m doing it, maybe my blood pressure’s always gonna be roughly  
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41 337 that. And could it be different during the day, is the sort of thing that does play in my mind a bit”  
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43 338 (Intervention p1, well controlled).

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46 339 *Uncertainty about what to do about high or low readings*

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50 340 Uncertainty could also become a burden after seeing an out-of-range BP reading, as the participant  
51  
52 341 had to decide what to do next. This burden was removed when the prescriber provided quick,  
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54 342 personalised feedback to the participant, but when they did not receive any contact from their

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3 343 prescriber after an out-of-range reading or felt the prescriber was not available to provide support,  
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5 344 this could create a feeling of doubt.  
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8 345 "I suppose I knew there was nothing to worry about but it's always a bit of a niggle in the back of  
9  
10 346 your mind... even the days she's [the nurse prescriber] at work I can't ring her at work because she  
11  
12 347 may be, you know, doing something else" (Intervention p21, well-controlled)  
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18 349 Burden of thinking about making healthy lifestyle changes  
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21 350 *Worry or guilt about not engaging with healthy changes*  
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24 351 Several participants felt they would like to lose weight, eat more healthily, or do more physical  
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26 352 activity but lacked the motivation or self-efficacy to make these changes, especially if they had other  
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28 353 co-morbidities. This could create feelings of guilt or worry about their failure to make healthy  
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30 354 changes, which was a burden of the intervention for them.  
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32

33 355 "I understand that, obviously, I need to get my blood pressure down because it is very dangerously  
34  
35 356 high, but I just don't know what to do about it, you know?... where I feel fatigued and worn out, I  
36  
37 357 don't feel well enough at the moment to do any exercise" (Intervention p26, poorly controlled)  
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43 359 Burden of the practicalities of adhering to intervention procedures  
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46 360 *Burden of fitting self-monitoring into the day*  
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49 361 Many participants felt that self-monitoring was easy to fit into their day, and some described this as  
50  
51 362 being easier than going to the GP Surgery to have their BP taken. Those with busy daily lifestyles  
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53 363 tended to find it harder to remember to self-monitor, and a burden for some participants was  
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3 364 deciding how best to fit self-monitoring into their routine given the instructions about not drinking  
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5 365 coffee or exercising beforehand.  
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8 366 The perceived burden of regular self-monitoring seemed to be influenced by the perceived benefit  
9  
10 367 of the behaviour, such that those who felt reassurance from seeing low readings or with high  
11  
12 368 motivation to control BP found it less hassle and easier to remember than those who felt anxious  
13  
14 369 about self-monitoring or had only joined the study to help with research.  
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17 370 "There was no big deal. It doesn't take long and it's—it's quite nice to sit down and have a relax  
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19 371 during the day" (Intervention p8, well-controlled)  
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## 373 DISCUSSION

374 This qualitative study has identified diverse perceived burdens and benefits of using a self-  
375 management digital intervention for high BP. In support of the BoT theory<sup>1</sup>, the HOME BP  
376 intervention appeared to reduce the burden on patients to self-manage their condition by improving  
377 access to regular healthcare professional (HCP) support and facilitating better understanding of their  
378 condition, but in some cases there was a burden of worry about health or changing medication. How  
379 much benefit a patient perceived from the intervention compared to burden seemed to be  
380 influenced by the dynamics of the patient-HCP interaction (described as ‘Improving Cooperation’ in  
381 BoT theory) and the patient’s own resources to manage their condition and cope with medication  
382 (described as “Capacity”).

383 Another important factor relating to the burden experienced was personal beliefs about BP and  
384 treatment. Those who recognised that their BP was too high and did not have concerns about side  
385 effects or taking medication appeared to have more positive experiences of the intervention,  
386 perceiving self-monitoring as more worthwhile, and feeling less anxious about seeing high readings  
387 or changing medication. . This is consistent with the necessity-concerns framework<sup>16</sup>. BoT theory  
388 states that people who are better equipped with resources and are more resilient may cope better  
389 with the burden imposed by healthcare<sup>17</sup>, but the importance of an individual’s personal  
390 conceptualisation of their condition in how burdensome they find self-care is not strongly  
391 represented. This beliefs system may be partly encompassed by the “Relational Integration” aspect  
392 of BoT theory, which refers to the extent to which patients trust the tasks they do for healthcare, e.g.  
393 self-monitoring BP, and feel confident in the outcomes of these tasks, e.g. changing medication.  
394 However illness and treatment perceptions<sup>18</sup> are not explicitly covered by the theory and it may be  
395 helpful to consider them as additional factors which might influence the experience of treatment  
396 burden.

397

**398 Implications for measurement of benefit and burden**

399 The present study demonstrates the value of collecting in-depth qualitative data to develop a  
400 detailed understanding of the burden of treatment, and to discover perceptions specific to the  
401 context in which the intervention was implemented. The important psychosocial outcomes  
402 discovered using qualitative research can inform the selection or development of relevant  
403 quantitative measures to capture these factors in further evaluation.

404 Quantitative measures have been developed to appraise the structural aspects of burden of  
405 treatment<sup>19,20</sup>, but these are not intended to assess psychosocial factors such as reassurance, anxiety  
406 or uncertainty which this study suggests can influence the extent to which this work is experienced  
407 subjectively as a burden.

408 Future research could explore how best to capture this. One approach might be to simply ask  
409 participants to quantify the net subjective burden or benefit of interventions. However, it could be  
410 challenging for participants to weigh complex heterogeneous psychosocial outcomes against one  
411 another and decide overall whether an intervention was more burdensome or beneficial. Capturing  
412 the extent to which patients experience positive or negative psychosocial outcomes might better  
413 assess how beneficial or burdensome the intervention was perceived to be. Although this would not  
414 produce a single outcome measure, cost-consequence analysis can be used to inform decision-  
415 making when an intervention has multiple relevant outcomes which cannot be aggregated into one  
416 value<sup>21</sup>. Coast<sup>22</sup> discusses whether a multidimensional approach is more informative for economic  
417 analysis or if a single aggregated value is more pragmatic.

418 Extending the evaluation of outcomes beyond health is in line with the capability approach<sup>23</sup>, which  
419 focuses on broader aspects of subjective well-being which are not assessed by generic measures  
420 such as the EQ-5D<sup>24</sup>. Tools used to capture perceived capability (such as the ICECAP<sup>25</sup>, and ASCOT<sup>26</sup>)

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3 421 are gaining support as holistic measures of economic evaluation, but do not assess the more specific  
4  
5 422 psychosocial burdens and benefits of healthcare raised by participants in this study. Process utility  
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7 423 emphasises the need to quantitatively measure the value that people attach to healthcare delivery.  
8  
9 424 This approach might be relevant for evaluating how much value people perceive in the process of  
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11 425 using digital health interventions and the capability this achieves<sup>27</sup>. It has been argued that process  
12  
13 426 utility measures should also ask about the reasons behind patients' valuations, to better inform the  
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15 427 decision-maker<sup>28</sup>. This would help to capture the individual differences found in this study in how  
16  
17 428 people appraise the personal value of a digital intervention, informed by their underlying illness and  
18  
19 429 treatment beliefs.

### 20 21 22 23 430 **Strengths and limitations**

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26 431 A strength of the study was that we used relatively open questions formulated by a multi-  
27  
28 432 disciplinary team which enabled us to elicit and explore a wide range of perceived burdens and  
29  
30 433 benefits, some of which were not anticipated at the outset of research. We are aware of the lead  
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32 434 researcher's potential influence on the data analysis, which we strived to minimise by transparent  
33  
34 435 memoing of decisions and regular team meetings to discuss the emerging themes. Participants were  
35  
36 436 sent newsletters to describe the findings of the study, but were not invited to provide feedback on  
37  
38 437 the analysis.

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42 438 We succeeded in speaking to well and poorly controlled hypertensive participants at different points  
43  
44 439 in the intervention, although the uptake rate from those invited to interviews was not high,  
45  
46 440 particularly in the usual care group. Perhaps unsurprisingly, it was difficult to recruit low engagers in  
47  
48 441 the intervention group, which could have helped reach theoretical saturation. Despite this, there  
49  
50 442 was a considerable range in the level of engagement of the intervention group patients in the study,  
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52 443 and a wide range of patient demographics in terms of age, education level and gender.  
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3 444 Repeated interviews with the same participants may have offered more insight into the dynamic  
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5 445 nature of perceived burdens and benefits over time, although more regular conversations about the  
6  
7 446 target behaviour could have influenced participants' BP management behaviour therefore  
8  
9 447 threatening the RCT conclusions. It has been noted that a key issue with process evaluations of  
10  
11 448 interventions is the tendency for intervention content and impact to change over time<sup>29</sup>, such that  
12  
13 449 deciding the optimal point to collect evaluation data is challenging.

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15  
16 450 Some of the burdens and benefits described by patients in this study were also found to a lesser  
17  
18 451 extent in the qualitative research undertaken during the development of the HOME BP intervention,  
19  
20 452 such as reassurance from seeing well-controlled readings and knowing that the HCP was aware of  
21  
22 453 your BP readings, as well as the concerns about side effects from medication changes and some  
23  
24 454 evidence of worry about high readings or readings being unreliable due to variability<sup>30</sup>. Others were  
25  
26 455 novel and only arose when participants experienced the full HOME BP intervention during the RCT as  
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28 456 opposed to a prototype, for example the perceived health improvements from medication changes.  
29  
30 457 This demonstrates the value of conducting inductive qualitative research to explore users'  
31  
32 458 perspectives at each stage of intervention development and evaluation, in line with the person-  
33  
34 459 based approach<sup>8</sup>.

## 35 36 37 38 39 460 **CONCLUSIONS**

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42 461 In the context of this digital intervention, the study shows that participants' appraisal of burdens and  
43  
44 462 benefits appeared to be influenced by both intervention factors, such as BP readings and perceived  
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46 463 availability of the healthcare professional, and patient characteristics, such as perceptions of BP  
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48 464 control, previous experience of side effects, and co-morbidities. This nuanced evaluation would be  
49  
50 465 lost in a population-level analysis, demonstrating the advantage of a more individualised approach  
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52 466 for better understanding participants' perspectives of an intervention and how best to minimise the  
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54 467 burden of treatment.

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3 468 The study develops the recommendations of McNamee et al<sup>6</sup> that complex digital health  
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5 469 interventions warrant a wider perspective for measuring health outcomes, and discusses the  
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7 470 implications of capturing broader psychosocial outcomes for Burden of Treatment theory and health  
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9 471 economic evaluations.  
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11  
12 472 The finding that some participants perceived personal benefits from using the intervention  
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14 473 demonstrates that the process of healthcare can, in itself, be positive for some people, highlighting  
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16 474 the importance of capturing transient short-term benefits to take these into account as well as the  
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18 475 burden of self-management.  
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3 479 **CONTRIBUTORS**  
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5

6 480 KM recruited participants, conducted interviews, analysed data, and wrote manuscript. LD & KB  
7  
8 481 contributed to study design and data analysis. KB and RB developed online intervention. PL & RJM  
9  
10 482 contributed to intervention development and interpretation of themes. CM & JR contributed to  
11  
12 483 theoretical and methodological implications of the study findings. LY contributed to study design,  
13  
14 484 data collection, data analysis, and interpretation.  
15

16  
17 485 All authors contributed to the manuscript preparation and provided final approval of the version to  
18  
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40 494• **COMPETING INTERESTS**  
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43 495 RJM has received BP monitors for research purposes from Omron and Lloyds Pharmacies.  
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46 496• **ETHICS APPROVAL**  
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49 497• This qualitative process study was embedded in the Home BP trial and approved by the University of  
50  
51 498 Southampton and NHS Hampshire A Research Ethics committees (REC Reference 15/SC/0082).  
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54 499 **DATA SHARING STATEMENT**  
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3 500 Requests for data sharing can be sent to the corresponding author. Full transcripts of interviews are  
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5 501 not available to protect participants' anonymity.  
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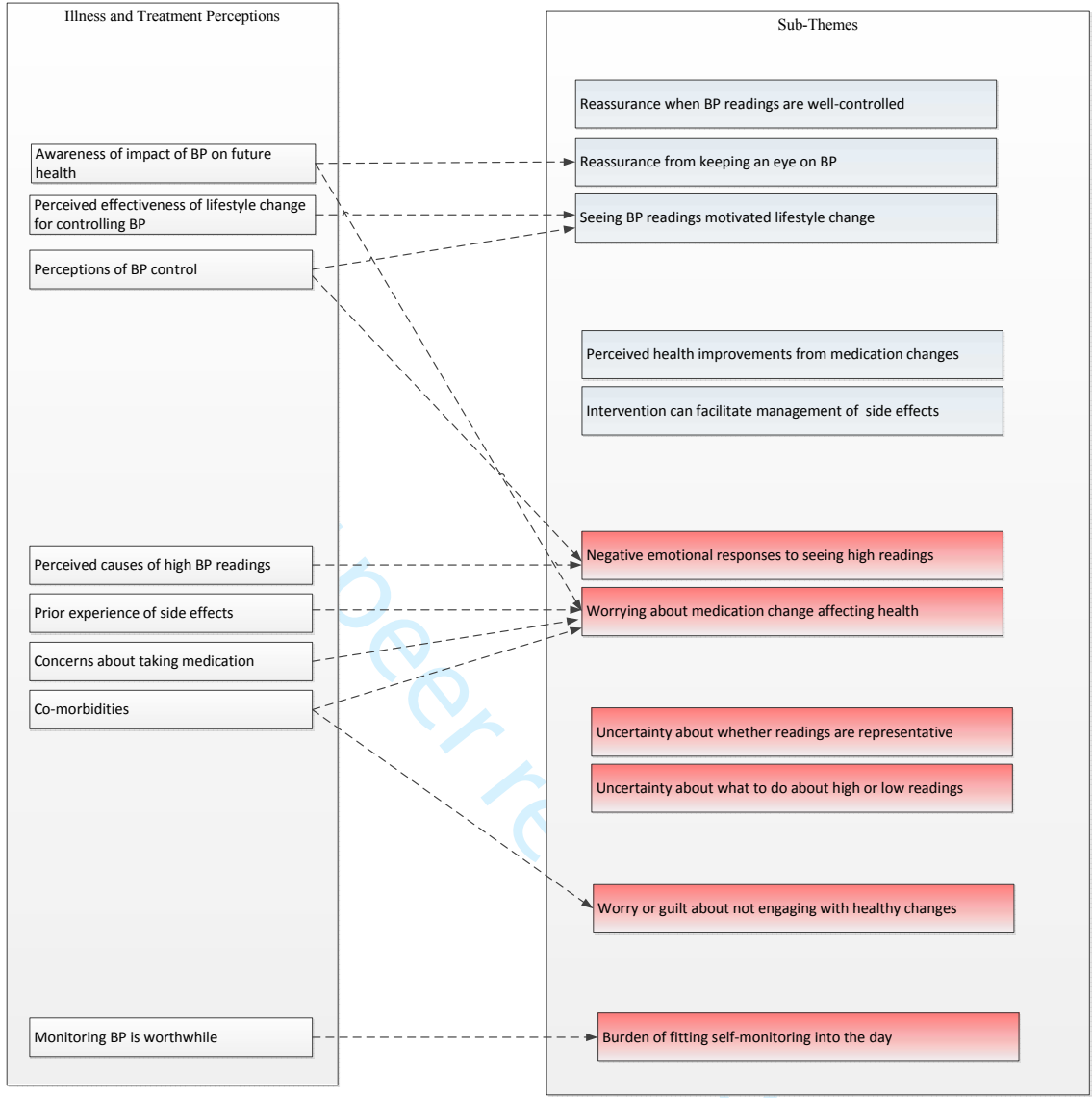


Figure 1 Possible influences of illness and treatment beliefs on perceived burdens and benefits of the intervention

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4 **Additional File 1. Interview schedules for intervention and usual care group**  
5

6 Intervention group interview schedule  
7

8  
9 **Opening questions**  
10

11 Can you tell me about what it is like for you to have high blood pressure?  
12

13  
14  
15 How did you feel when you were first told you had high blood pressure?  
16

17  
18  
19 Can you tell me why you decided to sign up for the Home BP study?  
20

21  
22 I'm really interested in hearing about your experiences of using HOME BP, can you tell me all about  
23 it?  
24  
25

26  
27 Can you tell me about anything that you have liked about the HOME BP study so far?  
28

29  
30 Can you tell me about anything that you have disliked?  
31

32  
33 Can you tell me about any advantages of using HOME BP?  
34

35  
36 And can you tell me about any disadvantages of using HOME BP?  
37

38  
39 How do you feel about your high blood pressure now?  
40

41  
42 Do you think you would choose to keep on using the HOME BP programme if it was still available  
43 after a year?  
44

45 Why/ Why not?  
46  
47

48  
49 Would you recommend the HOME BP programme to other people with high blood pressure?  
50

51  
52  
53  
54 **Self-monitoring**  
55

1  
2  
3 Experiences of monitoring:  
4

5 Can you tell me about what it was like when you were learning how to use your BP monitor at home?  
6  
7

8  
9 Can you tell me about the first time you used your BP monitor at home in the study?  
10  
11

12  
13  
14 Can you tell me about what it has been like to monitor your blood pressure yourself?  
15

16  
17  
18 How did it make you feel?  
19  
20

21  
22 Had you ever monitored your own blood pressure before you took part in the HOME BP study?  
23

24 *If yes:*

25  
26 Can you tell me a bit more about this?  
27

28 Can you tell me whether you've noticed any changes in how you monitor your blood  
29  
30 pressure since you've started the HOME BP programme?  
31  
32

33  
34  
35 *All:* Can you tell me about any concerns that you have about monitoring your blood pressure?  
36  
37

38  
39  
40 Adherence to the monitoring schedule:  
41

42 The HOME BP programme reminds you to monitor your blood pressure for 7 days every 4 weeks.  
43

44 Can you tell me about what it has been like for you to try and monitor your blood pressure for 7 days  
45  
46 every 4 weeks?  
47

48  
49 Can you tell me about the time of day you have been monitoring your blood pressure so far?  
50  
51

52 How do you feel about the instructions HOME BP gives about when to monitor?  
53  
54

55 Was there anything that helped you to monitor your own blood pressure?  
56  
57  
58  
59  
60

1  
2  
3 Was there anything that made it harder to monitor your own blood pressure?  
4

5  
6 Can you tell me about any time when you had to skip your blood pressure monitoring or change  
7  
8 when you did it in the day?  
9

10  
11 Can you tell me how you found it entering your readings on the HOME BP programme?  
12

### 13 Feedback messages

14  
15  
16 Remember after you enter your readings on HOME BP, you see a message which says 'your readings  
17  
18 were amber, or green'? What did you think about these messages?  
19

20  
21 Can you tell me about how you felt when you saw a message about your blood pressure readings on  
22  
23 HOME BP?  
24

25  
26 How did you feel about monitoring your own blood pressure after reading that message?  
27

28  
29 Did you have any very high or very low readings (red/blue) when you were monitoring in the HOME  
30  
31 BP study? How did you feel?  
32

### 33 **2. Medication change**

34  
35 Can you tell me about what it's like for you taking medication for your high blood pressure?  
36  
37

38  
39 Have you been recommended to make a medication change during the HOME BP study?  
40  
41

42  
43 If yes:  
44

45  
46 How did you feel about making a change to your medication when HOME BP recommended  
47  
48 it?  
49

50  
51 Did you make this change to your medication?  
52

53  
54 ***If they chose to make a change:***  
55



1  
2  
3 Can you tell me about what it was like to make a medication change in the HOME BP study?  
4

5  
6 Can you tell me about how the medication change came about?  
7

8  
9 How did you get on with your new medication?  
10

11  
12 How would you feel if HOME BP recommended a medication change for you now?  
13

14 ***If they chose not to make a change –***  
15

16  
17 Can you tell me about why you decided not to change your medication?  
18

19  
20 How would you feel if HOME BP recommended another medication change for you now?  
21

22  
23 *If no:*  
24

25  
26 *If patient has **not** been recommended a med change:* How do you feel about changing your  
27  
28 medication if your blood pressure stayed too high for too long?  
29

30  
31 Can you tell me about any concerns that you have about doing this?  
32

33  
34 *All:*  
35

36  
37 How did you feel about making changes to your medication before you took part in HOME BP?  
38

39 **3. HCP support**  
40

41  
42 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP study?  
43

44  
45 Can you tell me about how you have found the support from your GP or nurse while you were taking  
46  
47 part in the HOME BP study?  
48

49  
50 Can you tell me what you thought about receiving emails from your nurse about HOME BP?  
51

52  
53 If needed, follow-up questions:  
54

55  
56 Have you seen your GP about your blood pressure since the start of the study?  
57

1  
2  
3 And what about appointments with the nurse?  
4

5  
6 Can you tell me about how you have found the emails from HOME BP?  
7

8  
9 **4. Healthy changes**

10  
11 Can you tell me about anything else that you do to try and manage your high blood pressure?  
12

13  
14 There is an option on the HOME BP programme to look at online sessions about making healthy  
15  
16 changes that can help lower your blood pressure, I wonder if you remember if you have seen it?  
17

18  
19 *If no:*

20  
21  
22 Can you tell about how you might feel about making healthy changes to help lower your blood  
23  
24 pressure?  
25

26  
27 *If yes:*

28  
29  
30 Can you tell me about how you found the session on healthy changes?  
31

32  
33 How did you feel about making the healthy changes this session talked about?  
34

35  
36 *If they chose a change:* Can you tell me about what made you choose this/these ones?  
37

38  
39 How did you find the online session about xxxx (cutting down on salt/alcohol/eating a healthier  
40  
41 diet/doing more physical activity/ losing weight)?  
42

43  
44 Can you tell me about what it was like for you trying out this healthy change?  
45

46  
47 How did making a healthy change like this make you feel?  
48

49  
50 *Or if they didn't choose any:* Can you tell me about why you didn't want to choose a healthy change?  
51

52  
53 *All:* Can you tell me about any concerns that you have about making a new healthy change?  
54  
55  
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2  
3 Is there anything else you would like to tell me about the HOME BP study that we haven't already  
4  
5 talked about?  
6  
7  
8  
9

10 Usual care group interview schedule

11  
12  
13 General questions about BP

14  
15  
16 Can you tell me about what it is like for you to have high blood pressure?  
17

18  
19 How did you feel when you were first told you had high blood pressure?  
20

21  
22 Can you talk me through what (if anything) you currently do to manage/control your high blood  
23  
24 pressure?  
25

26  
27 Can you tell me about how your GP and practice nurse are involved in helping you to control  
28  
29 your high blood pressure?  
30

31  
32 How do you feel about monitoring your own blood pressure at home?  
33

34  
35 If they already monitor – can you tell me a bit more about this?  
36

37  
38 Can you tell me about what it's like for you taking medication for your high blood pressure?  
39

40  
41 Can you tell me how you feel about your GP making changes to your blood pressure medication?  
42  
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45

46 HOME BP study experience

47  
48  
49  
50  
51 Can you tell me why you signed up for the Home BP study?  
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2  
3 Can you tell me all about what it has been like for you being in the HOME BP study in the usual  
4  
5 care group?  
6

7  
8 At the start of the HOME BP study, you had a baseline appointment with a nurse at your GP  
9  
10 Practice – can you tell me about that?  
11

12  
13 How did you find it using the HOME BP programme to fill in your questionnaires online at the  
14  
15 start of the study?  
16

17  
18 After you had completed your questionnaires, did you have an appointment with your GP to  
19  
20 check your blood pressure medication? Can you tell me about this?  
21

22  
23  
24  
25  
26 HCP support  
27

28  
29 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP  
30  
31 study?  
32

33  
34 Can you tell me about how you have found the support from your GP or nurse while you were  
35  
36 taking part in the HOME BP study?  
37

## Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

**YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE**

No. Item	Guide questions/description	Reported on Page #
<b>Domain 1: Research team and reflexivity</b>		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 9
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 9
3. Occupation	What was their occupation at the time of the study?	Page 9
4. Gender	Was the researcher male or female?	Page 9
5. Experience and training	What experience or training did the researcher have?	Page 9
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 9
<b>Domain 2: study design</b>		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 9
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 8
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 8

12. Sample size	How many participants were in the study?	Page 10
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 10
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 8
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 10
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 8
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 9
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Page 9
21. Duration	What was the duration of the inter views or focus group?	Page 10
22. Data saturation	Was data saturation discussed?	Page 8
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
<b>Domain 3: analysis and findings</b>		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Page 9
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 12
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 9
27. Software	What software, if applicable, was used to manage the data?	Page 9
28. Participant checking	Did participants provide feedback on the findings?	Page 25
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Throughout results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

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4 **Once you have completed this checklist, please save a copy and upload it as part**  
5 **of your submission. When requested to do so as part of the upload process,**  
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9 **separate file.**  
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# BMJ Open

## A qualitative process study to explore the perceived burdens and benefits of a digital intervention for self-managing high blood pressure in Primary Care.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-020843.R1
Article Type:	Research
Date Submitted by the Author:	01-Feb-2018
Complete List of Authors:	Morton, Katherine; University of Southampton, Psychology Dennison, Laura; University of Southampton, Psychology Bradbury, Katherine; University of Southampton, Psychology Band, Rebecca; University of Southampton, Psychology May, Carl; University of Southampton, Faculty of Health Sciences Raftery, James; Southampton University, School of Medicine Little, Paul; University of Southampton, Primary Care and Population Science McManus, Richard; University of Oxford, Dept of Primary Care Health Sciences Yardley, Lucy ; University of Oxford, Nuffield Department of Primary Health Care Sciences
<b>Primary Subject Heading</b>:	Qualitative research
Secondary Subject Heading:	Cardiovascular medicine, Health services research, Public health
Keywords:	Self-management, digital intervention, qualitative, treatment burden

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6 **1 Title page**  
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10 **2 A qualitative process study to explore the perceived burdens and benefits of a digital**  
11  
12 **3 intervention for self-managing high blood pressure in Primary Care.**  
13  
14

15 4 Kate Morton<sup>a\*</sup>, Laura Dennison<sup>a</sup>, Katherine Bradbury<sup>a</sup>, Rebecca Band<sup>a</sup>, Carl May<sup>b</sup>, James Raftery<sup>c</sup>,  
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67 20 **ABSTRACT**

8  
9  
10  
11 21 **Objectives:** Digital interventions can change patients' experiences of managing their health, either  
12  
13 22 creating additional burden or improving their experience of healthcare. This qualitative study aimed  
14  
15 23 to explore perceived burdens and benefits for patients using a digital self-management intervention  
16  
17 24 for reducing high blood pressure. A secondary aim was to further our understanding of how best to  
18  
19 25 capture burdens and benefits when evaluating health interventions.

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21  
22 26 **Design:** Inductive qualitative process study nested in a randomised controlled trial.

23  
24  
25 27 **Setting:** Primary Care in the UK

26  
27  
28 28 **Participants:** 35 participants taking antihypertensive medication and with uncontrolled blood  
29  
30 29 pressure at baseline participated in semi-structured telephone interviews.

31  
32  
33 30 **Intervention:** Digital self-management intervention to support blood pressure self-monitoring and  
34  
35 31 medication change when recommended by the healthcare professional.

36  
37  
38 32 **Analysis:** Data were analysed using inductive thematic analysis with techniques from grounded  
39  
40 33 theory.

41  
42  
43 34 **Results:** Seven themes were developed which reflected perceived burdens and benefits of using the  
44  
45 35 intervention, including worry about health, uncertainty about self-monitoring, and reassurance. The  
46  
47 36 analysis showed how beliefs about their condition and treatment appeared to influence participants'  
48  
49 37 appraisal of the value of the intervention. This suggested that considering illness and treatment  
50  
51 38 perceptions in Burden of Treatment theory could further our understanding of how individuals  
52  
53 39 appraise the personal costs and benefits of self-managing their health.  
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3 40 **Conclusions:** Patients' appraisal of the burden or benefit of using a complex self-management  
4  
5 41 intervention seemed to be influenced by experiences within the intervention (such as perceived  
6  
7 42 availability of support) and beliefs about their condition and treatment (such as perceived control  
8  
9 43 and risk of side effects). Developing our ability to adequately capture these salient burdens and  
10  
11 44 benefits for patients could help enhance evaluation of self-management interventions in the future.  
12  
13 45 Many participants perceived important benefits from using the intervention, highlighting the need  
14  
15 46 for theory to recognise that engaging in self-management can include positive as well as negative  
16  
17 47 aspects.  
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19  
20 48

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22  
23 49 Trial registration: ISRCTN13790648. Registered 14 May 2015.  
24

25 50 **Keywords:** Self-management; digital intervention; qualitative; treatment burden  
26  
27

28 51 **Strengths and limitations of this study:**

- 29 52 ❖ The exploratory, open approach to data collection enabled us to capture whichever benefits or  
30  
31 53 burdens were most salient to the participants.  
32  
33 54 ❖ We only interviewed participants at one point in time, so were unable to gain an understanding  
34  
35 55 of dynamic changes in perceived benefits or burdens over time.  
36  
37 56 ❖ Both well and poorly controlled hypertensive patients took part in the interviews, but it was  
38  
39 57 difficult to recruit low users of the intervention which could limit the generalisability of the  
40  
41 58 findings.  
42  
43 59 ❖ The asymptomatic nature of hypertension and the unique medication change pathway means  
44  
45 60 that these findings may not be generalisable across conditions.  
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## 63 BACKGROUND

64 The work involved in looking after one's health when living with a chronic condition can include  
65 complex tasks such as organising and adhering to treatment regimes, interacting with healthcare  
66 professionals (HCPs), regular monitoring of health indicators, and making health-related decisions,  
67 all of which can accumulate into a considerable burden<sup>1</sup>. Digital self-management interventions are  
68 often developed to improve health outcomes, but these interventions could also either increase or  
69 minimise the burden of the healthcare process for patients. Developing our understanding of the  
70 burdens of self-management can help to better optimise the delivery of healthcare to improve  
71 adherence and well-being<sup>1-3</sup>. Burden of Treatment (BoT) theory provides a mechanism for  
72 understanding these experiences in the context of patients' personal capacity to cope, with  
73 emphasis on the role of wider healthcare systems and social networks available to the patient<sup>1</sup>.

74 Health economic evaluations also focus on understanding the impact of healthcare on patients,  
75 seeking to weigh up the resources used against the health outcomes in order to better inform  
76 decision-making. Recent guidelines for economic evaluations in health and medicine recommend  
77 adopting a societal perspective such that all relevant outcomes are evaluated, rather than focusing  
78 only on formal healthcare costs<sup>4</sup>. In particular, personal costs such as time spent in self-care should  
79 be included. Consequently, BoT theory and health economic evaluations share an interest in  
80 adequately capturing the wider burdens or personal costs of engaging with healthcare. For  
81 consistency in terminology in this paper, negative outcomes/personal costs of healthcare will be  
82 referred to as 'burdens'.

83 BoT theory considers patients' time as a resource that is used by the healthcare system, while health  
84 economic evaluation counts time as an 'opportunity cost' whereby the patient 'spends' time that  
85 could have been spent on something other than healthcare. However, subjective experiences of  
86 time spent on digital interventions may be varied and complex. Heterogeneity in the relative value  
87 placed on the outcomes of the intervention<sup>5</sup> may mean that for some participants the time spent

1  
2  
3 88 engaging with elements of an intervention is not perceived as a burden but rather as a benefit,  
4  
5 89 either because it is interesting, pleasant or meaningful in and of itself or because of the positive  
6  
7 90 outcomes it can lead to. In other words, some people may actually like engaging with healthcare.  
8  
9 91 The value of exploring the personal benefits of intervention participation has not received as much  
10  
11 92 focus as understanding the costs, such as treatment burden. McNamee et al.<sup>6</sup> proposed that the  
12  
13 93 health research guidelines for economic analysis may need to be adjusted for digital health  
14  
15 94 interventions to ensure we can fully capture the heterogeneous costs and benefits arising when  
16  
17 95 complex interventions are implemented in complex systems.  
18  
19  
20  
21 96 To further our understanding of how patients perceive benefits and burdens when using digital  
22  
23 97 health interventions, we carried out a qualitative process study<sup>7</sup>. The digital HOME BP intervention  
24  
25 98 was developed based on best practice recommendations to help improve hypertension in poorly  
26  
27 99 controlled patients by facilitating self-monitoring of blood pressure (BP) at home and prompting  
28  
29 100 appropriate intensification of medication by HCPs<sup>8</sup>. This intervention could help to minimise the  
30  
31 101 treatment burden of hypertension by providing an online healthcare system in which HCPs have  
32  
33 102 sight of patients' home readings, streamlining the process for finding the most effective medication  
34  
35 103 without the need for attending the GP surgery. However, HOME BP is a complex, interactive multi-  
36  
37 104 component intervention, which creates potential diversity in the perceived burden and benefits for  
38  
39 105 participants using it. The contexts in which the intervention is embedded may also be diverse, and  
40  
41 106 factors such as individual differences in patients' health status, beliefs about medication and risks of  
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43 107 high BP, availability of time and resources, and access to support may influence how the  
44  
45 108 intervention is perceived and valued. The HOME BP intervention was developed using the person-  
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47 109 based approach<sup>9</sup> which emphasises the importance of understanding participants' unique  
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49 110 perspectives and different situations when developing and implementing digital interventions.  
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51 111 Adopting a more granular approach to the evaluation of benefit and burden is consistent with the  
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3 112 person-based approach, and with the BoT approach of fully understanding the participants'  
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5 113 perspective.  
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8 114 The present study aimed to explore the perceived burden and benefits of using a digital health  
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10 115 intervention for self-managing BP using qualitative process interviews with intervention and usual  
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12 116 care participants taking part in a randomised controlled trial (RCT). This paper seeks to interpret the  
13  
14 117 implications for optimising the capture of perceived costs and benefits in health economic  
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16 118 evaluations and evaluating the burden of treatment.  
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## 21 22 23 120 **METHODS**

### 24 25 26 27 121 **Design**

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30 122 A qualitative process study embedded in the HOME BP trial<sup>8</sup> was approved by the University of  
31  
32 123 Southampton and NHS Research Ethics committees. The COREQ checklist (Consolidated criteria for  
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34 124 reporting qualitative studies) was used to ensure comprehensive reporting of the study<sup>10</sup>  
35  
36 125 (supplementary file 1).  
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### 41 42 43 127 **Intervention**

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46 128 The HOME BP programme supports participants to self-manage their high BP, primarily via home  
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48 129 self-monitoring of BP and making changes to dose/drug type when recommended by the HCP.  
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50 130 Lifestyle change modules are also available, but optional as the key target behaviours for the  
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52 131 intervention were self-monitoring and medication change adherence<sup>8,11</sup>. Participants using HOME  
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54 132 BP were supported by a 'prescriber' (GP or nurse prescriber responsible for changing medication)  
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3 133 and a 'supporter' (nurse or healthcare assistant who supported participants in self-monitoring and  
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5 134 choosing lifestyle changes).  
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8 135 Participants were invited to use the online programme by their GP and were randomised to usual  
9  
10 136 care or intervention after completing baseline measures online. Those randomised to the  
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12 137 intervention group completed two online training sessions which sought to overcome concerns  
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14 138 about variability in readings and changing medication. Participants were encouraged to monitor  
15  
16 139 their BP in the mornings, but the programme allowed flexibility as it was most important that people  
17  
18 140 found a time of day that suited them to monitor their BP. Both intervention and usual care  
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20 141 participants were followed-up at 6 and 12 months post-randomisation.  
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22  
23 142 Table 1 describes the HOME BP intervention in more detail.  
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25  
26 143 Table 1 HOME BP Intervention Characteristics

Target behaviour	Description
Self-monitoring BP	Participants monitored their BP at home for 7 days every 4 weeks. After 7 days, they entered their BP readings on the HOME BP website and received instant automated feedback using a traffic light system. If BP was very high (red) or very low (blue), they were told to contact their GP surgery. If BP was above target (amber), they were told their prescriber would contact them about a medication change. If BP was on target (green), they were congratulated and asked to monitor their BP again next time.
Medication change	The prescriber planned three potential medication changes with the participant at the start of the study. HOME BP informed prescribers by email when a patient's home BP readings were above-target and they could implement a pre-

	planned change without needing to see the participant for an appointment.
Optional lifestyle changes	At nine weeks after randomisation, participants had the option of choosing an online session to support lifestyle change to help control their BP, specifically weight management, salt reduction, healthy diet, physical activity, or alcohol reduction. Participants were alerted by email when this became available, and saw an option to view the healthy lifestyles session each time they logged on to HOME BP. The online lifestyle change sessions could be started at any time during the 12-month trial, from nine weeks.

144

145 **Participants**

146 Patients were eligible to take part in the HOME BP trial if they had uncontrolled hypertension (mean  
 147 BP reading of 140/90 mm Hg or more at baseline taken at the GP Surgery using a validated electronic  
 148 automated sphygmomanometer (BP TRU BPM 200)) managed in Primary Care, were prescribed 1-3  
 149 antihypertensive medications at baseline, and aged over 18 (full inclusion and exclusion criteria are  
 150 listed in the protocol<sup>8</sup>).

151 Both intervention and usual care participants were invited to take part in interviews as we felt that  
 152 obtaining an understanding of managing BP in usual care would aid interpretation of the perceived  
 153 burden and benefits of the intervention. We aimed to speak to participants at a range of time-points  
 154 during the 12-month trial from 10 weeks onwards as this gave participants the opportunity to  
 155 become familiar with HOME BP. No new intervention content was introduced after the lifestyles  
 156 sessions became available at nine weeks.



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3 157 **Recruitment and interview procedure**  
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6 158 A sub-sample of RCT participants were invited by email to provide feedback on their experiences of  
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8 159 managing their BP (n=78, of 622 patients in the RCT). Informed consent was taken by post or online,  
9  
10 160 depending on participant preference. Recruitment was initially opportunistic, but subsequently a  
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12 161 purposive approach was adopted to target younger participants, low engagers, and those with  
13  
14 162 recent uncontrolled self-monitored BP readings, informed by the concurrent analysis. Recruitment  
15  
16 163 was stopped once the researchers agreed that data saturation had been reached and no new  
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18 164 burdens or benefits were arising.

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21 165 Semi-structured interview schedules were co-developed by experts in health psychology (KM, KB, RB,  
22  
23 166 LY, LD), health economics (JR) and sociology (CM). Open, inductive questions were carefully selected  
24  
25 167 to elicit data about the burden and benefits of BP management perceived as most salient by the  
26  
27 168 participants (see Supplementary File 2 for interview schedules). The interviews were conducted by  
28  
29 169 telephone to minimise the burden on participants, except in one case where the participant asked to  
30  
31 170 meet face-to-face due to struggling with hearing on the telephone. The interviews took place  
32  
33 171 between February 2016 and February 2017. Each participant was given a £10 gift voucher to thank  
34  
35 172 them for their time.

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39 173 All interviews were conducted by KM (MSc, BSc. termed "the researcher"), a female PhD candidate  
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41 174 in Health Psychology who was also employed as a research assistant. Each interview was audio-  
42  
43 175 recorded, and the researcher also took notes and completed a self-reflection log afterwards to  
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45 176 record any emerging thoughts on the data. Audio-recordings were transcribed verbatim and checked  
46  
47 177 thoroughly by the researcher.

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51 178 **Analysis**  
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54 179 The analysis was an iterative process led by KM, supported by frequent discussion of emerging  
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56 180 themes with LY and LD (who have extensive experience in qualitative research) along with input  
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3 1 81 regarding health economic and sociological perspectives (JR and CM). Inductive thematic analysis  
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5 1 82 methods were used<sup>12 13</sup> with techniques from grounded theory such as memoing, constant  
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7 1 83 comparison, and diagramming to enhance our understanding and facilitate the development of  
8  
9 1 84 higher themes<sup>14 15</sup>. Data collection and analysis ran concurrently to enable purposive sampling based  
10  
11 1 85 on analytic insights. Thorough line-by-line coding was undertaken in NVivo 10<sup>16</sup>, and a coding  
12  
13 1 86 manual was developed which evolved as more data were collected and coded. The emerging codes  
14  
15 1 87 were constantly checked against the raw data to ensure the analysis was driven by the participants'  
16  
17 1 88 own language and experiences.

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20 1 89 All data relating to burdens and benefits of managing BP were analysed. We also coded factors that  
21  
22 1 90 appeared to influence perceptions of burdens and benefits to facilitate an in-depth understanding of  
23  
24 1 91 how participants appraised the intervention's value. A broad and open definition was adopted  
25  
26 1 92 whereby benefits and burdens were defined as positive and negative outcomes or experiences of  
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28 1 93 engaging in the intervention<sup>17</sup>, in order to facilitate a comprehensive representation of all potentially  
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30 1 94 relevant data.

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## 35 36 37 1 96 **RESULTS**

### 38 39 40 41 1 97 **Participant characteristics**

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44 1 98 In the intervention group, 28 of 54 invited participants agreed to be interviewed (52%). In the usual  
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46 1 99 care group, 7 of 24 invited participants agreed (29%). Most participants who did not take part chose  
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48 2 00 not to reply, but those who did said they did not have anything to report on the trial (n = 3 in usual  
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50 2 01 care). The participants were from 19 different GP surgeries. Table 2 shows the sociodemographic  
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52 2 02 and intervention details of the sample.

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204 Table 2. Sociodemographic and intervention participant data (n=35)

	Intervention participants	Usual care participants
N	28	7
Average duration of interview (range)	39 (15-67) minutes	28 (22-40) minutes
Average age (range)	65 (41-87) years	67 (52-77) years
Gender	71% female	43% female
Ethnicity		
White	24	6
Black African	1	
Pakistani	1	
Other	2	1
Education levels	9 No formal education	2 No formal education
	8 GCSE or A-level	3 GCSE or A-level
	10 Higher Education	1 Higher Education
	1 Other	1 Other
Number of weeks since randomisation	23 (10-57) weeks	17 (7 to 24) weeks
Poorly controlled BP at the time of the interview	10/28 (36%)	N/A*
Medication change recommended during the study	15/28 (54%)	N/A
Accessed optional healthy lifestyles session	15/28 (54%)	N/A

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3 205 \*As BP self-monitoring was a key component of the intervention, BP readings were available for the  
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5 206 intervention group throughout the duration of the study but data about BP from the usual care  
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7 207 group were only available at RCT baseline and follow-up points.  
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## 10 208 **Themes**

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14 209 Table 3 presents seven themes exploring perceived burdens and benefits of the HOME BP  
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16 210 intervention. One meta-theme also emerged concerning how illness and treatment beliefs about  
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18 211 high BP appeared to influence participants' perceptions about the intervention's burdens and  
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20 212 benefits, and this is discussed in relation to each theme it applies to. Figure 1 shows how illness and  
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22 213 treatment perceptions about BP appeared to relate to the sub-themes identified by the thematic  
23  
24 214 analysis.  
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30 216 Where quotes are included, participants are referred to as 'p' followed by a number. Study group  
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32 217 (intervention or usual care) is also included to help understand the quotes in context.  
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218 Table 3. Themes and sub-themes relating to perceived burdens and benefits of the intervention

Themes	Sub-themes	Exemplar participant quote
Benefit of reassurance from seeing BP readings	Reassurance when BP readings are well-controlled	"I'm so pleased. And my mind is at rest when we go on holidays and all that...I'm alright. I'm alright sort of thing. Yeah, peace of mind" (Intervention p9, well-controlled)
	Reassurance from keeping an eye on BP	"It made me much more aware of what the problem is with the high blood pressure and by monitoring it so regularly, I know exactly where I stand with it" (Intervention p15, well-controlled)
Benefit of motivation for lifestyle change from seeing BP readings	Seeing BP readings motivated lifestyle change	"It is quite interesting to see the effects of what I'm doing on the blood pressure and everything. So, I think that is – it is quite good" (Intervention p18, well-controlled)
Benefit of better	Perceived health improvements	"It helped me to change my medication and then because of change of medication,

health	from medication changes	my blood pressure went down. So definitely there is a benefit" (Intervention p16, well-controlled)
	Intervention can facilitate management of side effects	"That medication didn't work, in that I was on holiday and my ankles swelled up so much – and my feet and my legs, so much so that I couldn't see my toes. So I stopped taking that medication. Was called back to the GP. And I'm now on a medication that works for me and is managing the blood pressure" (Intervention p7, well-controlled)
Burden of worrying about health	Negative emotional responses to seeing high readings	"I was actually quite shocked because it was a—a lot higher" (Intervention p6, poorly controlled)
	Worrying about medication change affecting health	"I don't want to get more medication 'cause I'm already on a high dose and I don't want to increase it because it worries me about my kidneys" (Intervention p24, poorly controlled)
Burden of uncertainty from self-monitoring	Uncertainty about whether readings are representative	"If someone only ever takes it in the morning, and you tend to get those lower readings, are you really getting a true picture of what they're like in the afternoon or the evening?" (Intervention p10, well-controlled)

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	<p>Uncertainty about what to do about high or low readings</p>	<p>"I don't know what's going to happen in respect to that [amber feedback]. Whether I'm going to get a call from my GP, or whether he – so I'm a little bit, like, you know, in the air. I don't really know what's going to happen in that respect" (Intervention p22, poorly controlled)</p>
<p>Burden of thinking about making healthy lifestyle changes</p>	<p>Worry or guilt about not engaging with healthy changes</p>	<p>"I have looked at it [online healthy lifestyles session]. I wouldn't say I've looked at it seriously, and I need to" (Intervention p4, poorly controlled)</p>
<p>Burden of the practicalities of adhering to intervention procedures</p>	<p>Burden of fitting self-monitoring into the day</p>	<p>"I like to get up and have a cup of coffee and I'm thinking 'Well, let's get the blood pressure done first because otherwise I can't do that, you know, for a while afterwards.' So, I've found that quite—quite difficult" (Intervention p5, poorly controlled).</p>

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For peer review only



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4 221 Insert Figure 1 here  
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7 222 Benefit of reassurance from seeing BP readings  
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10 223 *Reassurance when BP readings are well-controlled*  
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13 224 Seeing well-controlled readings when self-monitoring BP gave participants peace of mind which was  
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15 225 widely perceived as a benefit of the intervention. People described feeling relieved that their BP  
16

17 226 readings were lower than at the GP surgery, and felt this gave them more insight into what their BP  
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19 227 was like most of the time.  
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22 228 “What I do like about it is taking the blood pressure here at home, the readings are lower. And I find  
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24 229 that quite reassuring that my blood pressure is not always high” (Intervention p11, well-controlled)  
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27 230 Several usual care participants had decided to use their own BP monitors, and this group also  
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29 231 described feeling reassurance when seeing their BP was well-controlled.  
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32 232 *Reassurance from keeping an eye on BP*  
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35 233 Most participants liked having an increased focus on their BP through regular monitoring and found  
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37 234 it interesting to compare their readings over time. However one participant perceived that taking BP  
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39 235 regularly could encourage too much attention on your health, which was a potential burden of the  
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41 236 intervention for her (Intervention p28, BP control unknown as did not enter BP readings on HOME  
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43 237 BP). This participant had low concern about her BP generally, and was not motivated to engage in  
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45 238 self-management.  
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48 239 Even when participants had poorly-controlled readings, many felt a benefit from the intervention as  
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50 240 it enabled them to regularly check their BP and detect any problems instantly rather than carrying  
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52 241 on unaware.  
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3 242 “I think it’s helping me to know where my blood pressure stands because it’s a regular thing every  
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5 243 month” (Intervention p24, poorly-controlled)  
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8 244 The knowledge that home readings were shared with the prescriber reassured participants as they  
9  
10 245 knew that any problems would not only be detected but also dealt with at the time, making them  
11  
12 246 feel well cared for. This contrasted with the perceived burden of managing BP in usual care where  
13  
14 247 some participants felt concerned that their GP did not change their medication when their home  
15  
16 248 readings were too high, or would have liked more regular contact with their Practice to check their  
17  
18 249 BP and medication.  
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20

21 250 “It would be nice to have it checked, I guess, you know, every three months or whatever. How—  
22  
23 251 however often. I mean, how do they know that everything is working?” (Usual care p4).  
24  
25

26 252 This shows that although participants in usual care gained reassurance from seeing low readings  
27  
28 253 when they monitored at home, the lack of interaction with the Practice could cause concern when  
29  
30 254 readings were high or when patients did not regularly monitor BP at home of their own accord.  
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34 255  
35

36 256 Benefit of motivation for lifestyle change from seeing BP readings  
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39 257 Some participants were motivated to increase their physical activity, engage in stress management  
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41 258 activities or healthy eating because they could see this had a positive impact on their BP readings.  
42  
43

44 259 This helped them feel more in control of their BP.  
45

46 260 “By taking the readings regularly and frequently, it gave me more of a feedback straightaway if you  
47  
48 261 like about anything, changes that I did make like a bit of exercise or...practicing relaxation and this  
49  
50 262 sort of thing. So that was quite nice, it was nice to feel that I was more in control of it again”  
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53 263 (Intervention p20, well-controlled)  
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3 264 Other participants felt frustrated after making lifestyle changes in the past which had no effect on  
4  
5 265 their BP. This made them feel that lifestyle was ineffective for controlling BP.  
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7  
8 266 “I’m a completely different person. My diet’s completely different. And my blood pressure remained  
9  
10 267 the same. So I’ve done literally everything you physically possibly can to help yourself, and nothing’s  
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12 268 worked” (Intervention p1, well-controlled).  
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18 270 Benefit of better health

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21 271 *Perceived health improvements from medication changes*  
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24 272 Many participants felt it was beneficial to change their medication when their readings were too  
25  
26 273 high, and were very pleased when they perceived that a medication change led to lower BP readings  
27  
28 274 because of the positive effect this would have on their health.  
29

30  
31 275 “I’ve found that by having the medication changed up at regular intervals my blood pressure’s  
32  
33 276 improved all the time” (Intervention p15, well-controlled)  
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35  
36 277 A few participants felt that a medication change had not been effective at lowering their BP which  
37  
38 278 could create doubt about their medication’s effectiveness.  
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40  
41 279 “It’s been doubled but it hasn’t seemed to lower my blood pressure at all, in fact, it’s at the same  
42  
43 280 levels as it is sort of now, un-medicated. So I just think – I don’t think it’s the right one. You know, I  
44  
45 281 can take the tablet but, actually, I don’t think it’s doing anything”. (Intervention p26, poorly-  
46  
47 282 controlled)  
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50 283 *Intervention can facilitate management of side effects*  
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53 284 Most participants did not experience any side effects from having their medication changed. Where  
54  
55 285 side effects did occur, participants tended to perceive this as being a cost of taking medication  
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3 286 (which was balanced against the benefit of controlling BP), rather than a burden of the intervention  
4  
5 287 itself. They felt that the intervention could help them to be more aware of side effects, to identify  
6  
7 288 alternative medications and to monitor how these affect their health.  
8  
9

10 289 “That [side effect] would have happened, you know, no matter what. That would have been an issue  
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12 290 but this has actually highlighted it, sort of, more clearly” (Intervention p5, poorly-controlled)  
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18 292 Burden of worrying about health  
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21 293 *Negative emotional responses to seeing high readings*  
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23  
24 294 A burden of self-monitoring BP for some people was that seeing high readings could cause worry  
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26 295 about health. Participants’ beliefs about their BP control appeared to influence their appraisal of  
27  
28 296 high readings. A few participants believed their BP was well-controlled, a belief which was perhaps  
29  
30 297 reinforced by clinical staff approving their readings previously, and had only joined the study to help  
31  
32 298 with research. These participants tended to feel shocked or annoyed when they received above-  
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34 299 target feedback from the intervention as this challenged their beliefs.  
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37  
38 300 “At one time, I was told to go on medication, further medication, which I must admit I was not very  
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40 301 happy about... When I used to go for a check with the nurse, if I’d have had those particular readings,  
41  
42 302 they wouldn’t have been high” (Intervention p17, poorly controlled)  
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45 303 Others were confused or frustrated by high BP readings when they could not understand why this  
46  
47 304 might have happened.  
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50 305 “I’m thinking about why my blood pressure has gone up. I can’t think why” (Intervention p25, poorly  
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52 306 controlled).  
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3 308 Meanwhile people who expected to see high readings were less concerned because they had  
4  
5 309 accepted that high readings were likely.  
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7  
8 310 “Just par for the course. It’s what I expect from my blood pressure, really, so, it never worries me”  
9  
10 311 (Intervention p5, poorly controlled)  
11  
12  
13 312 Perceptions about the causes of high BP also influenced how anxious people felt about seeing high  
14  
15 313 readings. Those who felt that high readings held serious implications for their health tended to feel  
16  
17 314 frightened. Some even felt apprehensive *before* self-monitoring in case their readings were out-of-  
18  
19 315 range, as they didn't want to see evidence that their BP was too high or low.  
20  
21  
22 316 “Before I take my blood pressure, I do get stressed. I wouldn't say I get massively stressed because  
23  
24 317 obviously I'm used to doing it now but ... it's just that apprehension and thinking 'Oh, God, I hope it's  
25  
26 318 not too high today. I wonder really what's going on and how serious this is”. (Intervention p26,  
27  
28 319 poorly controlled).  
29  
30  
31 320 Other people were able to dismiss one-off high readings without feeling anxious as they attributed  
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33 321 high readings to less threatening explanations such as feeling stressed, not sitting still for long  
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35 322 enough, positioning of the cuff, or held a prior expectation of it being normal for BP to fluctuate. In  
36  
37 323 these cases, the high readings had less negative emotional impact as they were not interpreted as  
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39 324 indicating a serious underlying health issue.  
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43 325 *Worrying about medication change affecting health*  
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46 326 Some participants were worried about the effects that changing BP medication could have on their  
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48 327 health. Previous experience of side effects, existence of co-morbidities, and concerns about  
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50 328 medication dependency or impact on kidneys tended to make participants feel more worried about  
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52 329 changing medication.  
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3 330 Perceptions about the health risk of high BP in terms of stroke and cardiovascular disease tended to  
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5 331 affect how burdensome participants perceived a medication change to be. Anxiety about future  
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7 332 health could override concerns about medication side effects or dependency as the behaviour was  
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9 333 evaluated as beneficial in order to bring BP down, although sometimes participants still experienced  
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11 334 conflict between the perceived benefit and burden.

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13  
14 335 “The blood pressure has gone down but now my worries have changed from blood pressure to other  
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16 336 things. One is actually depending on medicine whole of my life. And secondly impact of medicine  
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18 337 on my body like kidneys” (Intervention p16, well-controlled).

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24 339 Burden of uncertainty from self-monitoring

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27 340 *Uncertainty about whether readings are representative*

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29  
30 341 Whilst some participants were confident making decisions about when to monitor their BP, others  
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32 342 were worried about whether their readings were representative, especially when BP was seen to  
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34 343 vary at different times of day or after physical activity or drinking coffee. This could lead to doubt  
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36 344 about the meaningfulness of self-monitoring and the recommendations of the intervention.

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39 345 “I wonder if maybe the time of day I’m doing it, maybe my blood pressure’s always gonna be roughly  
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41 346 that. And could it be different during the day, is the sort of thing that does play in my mind a bit”  
42  
43 347 (Intervention p1, well controlled).

44  
45  
46 348 *Uncertainty about what to do about high or low readings*

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48  
49 349 Uncertainty could also become a burden after seeing an out-of-range BP reading, as the participant  
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51 350 had to decide what to do next. This burden was removed when the prescriber provided quick,  
52  
53 351 personalised feedback to the participant, but when they did not receive any contact from their

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3 352 prescriber or felt the prescriber was not available to provide support, this could create a feeling of  
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5 353 doubt.

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7  
8 354 "I suppose I knew there was nothing to worry about but it's always a bit of a niggle in the back of  
9  
10 355 your mind... even the days she's [the nurse prescriber] at work I can't ring her at work because she  
11  
12 356 may be, you know, doing something else" (Intervention p21, well-controlled)

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18 358 Burden of thinking about making healthy lifestyle changes

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21 359 *Worry or guilt about not engaging with healthy changes*

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24 360 Several participants felt they would like to lose weight, eat more healthily, or do more physical  
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26 361 activity but lacked the motivation or self-efficacy to make these changes, especially if they had other  
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28 362 co-morbidities. This could create feelings of guilt or worry about their failure to make healthy  
29  
30 363 changes, which was a burden of the intervention for them.

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32  
33 364 "I understand that, obviously, I need to get my blood pressure down because it is very dangerously  
34  
35 365 high, but I just don't know what to do about it, you know?... where I feel fatigued and worn out, I  
36  
37 366 don't feel well enough at the moment to do any exercise" (Intervention p26, poorly controlled)

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43 368 Burden of the practicalities of adhering to intervention procedures

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46 369 *Burden of fitting self-monitoring into the day*

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49 370 Many participants felt that self-monitoring was easy to fit into their day, and some described this as  
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51 371 being easier than going to the GP Surgery to have their BP taken. Those with busy daily lifestyles  
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53 372 tended to find it harder to remember to self-monitor, and a burden for some participants was

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3 373 deciding how best to fit self-monitoring into their routine given the instructions about not drinking  
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5 374 coffee or exercising beforehand.  
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8 375 The perceived burden of regular self-monitoring seemed to be mitigated by the perceived benefit of  
9  
10 376 the behaviour, such that those who felt reassurance from seeing low readings or with high  
11  
12 377 motivation to control BP found it less hassle and easier to remember than those who felt anxious  
13  
14 378 about self-monitoring or had only joined the study to help with research.  
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16  
17 379 "There was no big deal. It doesn't take long and it's—it's quite nice to sit down and have a relax  
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19 380 during the day" (Intervention p8, well-controlled)  
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## 382 DISCUSSION

383 This qualitative study has identified diverse perceived burdens and benefits of using a self-  
384 management digital intervention for high BP. In support of the BoT theory<sup>1</sup>, the HOME BP  
385 intervention appeared to reduce the burden on patients to self-manage their condition by improving  
386 access to regular HCP support and facilitating better understanding of their condition, but in some  
387 cases there was a burden of worry about health or changing medication. How much benefit a  
388 patient perceived from the intervention compared to burden seemed to be influenced by the  
389 dynamics of the patient-HCP interaction (described as ‘Improving Cooperation’ in BoT theory) and  
390 the patient’s own resources to manage their condition and cope with medication (described as  
391 “Capacity”).

392 Another important factor relating to the burden experienced was personal beliefs about BP and  
393 treatment. Those who recognised that their BP was too high and did not have concerns about side  
394 effects or taking medication appeared to have more positive experiences of the intervention,  
395 perceiving self-monitoring as more worthwhile, and feeling less anxious about seeing high readings  
396 or changing medication. This is consistent with the necessity-concerns framework<sup>18</sup>. BoT theory  
397 states that people who are better equipped with resources and are more resilient may cope better  
398 with the burden imposed by healthcare<sup>19</sup>, but the importance of an individual’s personal  
399 conceptualisation of their condition in how burdensome they find self-care is not strongly  
400 represented. This beliefs system may be partly encompassed by the “Relational Integration” aspect  
401 of BoT theory, which refers to the extent to which patients trust the tasks they do for healthcare, e.g.  
402 self-monitoring BP, and feel confident in the outcomes of these tasks, e.g. changing medication.  
403 However illness and treatment perceptions<sup>20</sup> are not explicitly covered by the theory and it may be  
404 helpful to consider them as additional factors which might influence the experience of treatment  
405 burden.

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6 407 **Implications for measurement of benefit and burden**  
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8  
9 408 The present study demonstrates the value of collecting in-depth qualitative data to develop a  
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11 409 detailed understanding of the burden of treatment, and to discover perceptions specific to the  
12  
13 410 context in which the intervention was implemented. The important psychosocial outcomes  
14  
15 411 discovered using qualitative research can inform the selection or development of relevant  
16  
17 412 quantitative measures to capture these factors in further evaluation.  
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19  
20 413 Quantitative measures have been developed to appraise the structural aspects of burden of  
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22 414 treatment<sup>21,22</sup>, but these are not intended to assess psychosocial factors such as reassurance, anxiety  
23  
24 415 or uncertainty which this study suggests can influence the extent to which using an intervention is  
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26 416 experienced subjectively as a burden.  
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28  
29 417 Future research could explore how best to capture the perceived burden or benefit of an  
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31 418 intervention. One approach might be to simply ask participants to quantify the net subjective burden  
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33 419 or benefit of interventions. However, it could be challenging for participants to weigh complex  
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35 420 heterogeneous psychosocial outcomes against one another and decide overall whether an  
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37 421 intervention was more burdensome or beneficial. Capturing the extent to which patients experience  
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39 422 positive or negative psychosocial outcomes might better assess how beneficial or burdensome the  
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41 423 intervention was perceived to be. Although this would not produce a single outcome measure, cost-  
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43 424 consequence analysis can be used to inform decision-making when an intervention has multiple  
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45 425 relevant outcomes which cannot be aggregated into one value<sup>23</sup>. Coast<sup>24</sup> discusses whether a  
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47 426 multidimensional approach is more informative for economic analysis or if a single aggregated value  
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49 427 is more pragmatic.  
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53 428 Extending the evaluation of outcomes beyond health is in line with the capability approach<sup>25</sup>, which  
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55 429 focuses on broader aspects of subjective well-being which are not assessed by generic measures  
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3 430 such as the EQ-5D<sup>26</sup>. Tools used to capture perceived capability (such as the ICECAP<sup>27</sup>, and ASCOT<sup>28</sup>)  
4  
5 431 are gaining support as holistic measures of economic evaluation, but do not assess the more specific  
6  
7 432 psychosocial burdens and benefits of healthcare raised by participants in this study. Process utility  
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9 433 emphasises the need to quantitatively measure the value that people attach to healthcare delivery.  
10  
11 434 This approach might be relevant for evaluating how much value people perceive in the process of  
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13 435 using digital health interventions and the capability this achieves<sup>29</sup>. It has been argued that process  
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15 436 utility measures should also ask about the reasons behind patients' valuations, to better inform the  
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17 437 decision-maker<sup>30</sup>. This would help to capture the individual differences found in this study in how  
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19 438 people appraise the personal value of a digital intervention, informed by their underlying illness and  
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21 439 treatment beliefs.  
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#### 25 440 **Strengths and limitations**

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28 441 A strength of the study was that we used relatively open questions formulated by a multi-  
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30 442 disciplinary team which enabled us to elicit and explore a wide range of perceived burdens and  
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32 443 benefits, some of which were not anticipated at the outset of research. We are aware of the lead  
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34 444 researcher's potential influence on the data analysis, which we strived to minimise by transparent  
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36 445 memoing of decisions and regular team meetings to discuss the emerging themes. Participants were  
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38 446 sent newsletters to describe the findings of the study, but were not invited to provide feedback on  
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40 447 the analysis.  
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44 448 We succeeded in speaking to well and poorly controlled hypertensive participants at different points  
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46 449 in the intervention, and there was a wide range of demographics in terms of age, education level  
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48 450 and gender in the sample. However, the uptake rate from those invited to interviews was not high,  
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50 451 particularly in the usual care group. Perhaps unsurprisingly, it was difficult to recruit low engagers in  
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52 452 the intervention group, which could have helped reach theoretical saturation. In terms of wider  
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54 453 applicability, we are aware that these findings may not be generalizable across other health  
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56 454 conditions, as the lack of symptoms in hypertension and the stepped pathway for changing  
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58 455 medication are quite unique features of this condition.  
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5 457 Repeated interviews with the same participants may have offered more insight into the dynamic  
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7 458 nature of perceived burdens and benefits over time, although more regular conversations about the  
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9 459 target behaviour could have influenced participants' BP management behaviour therefore  
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11 460 threatening the RCT conclusions. It has been noted that a key issue with process evaluations of  
12  
13 461 interventions is the tendency for intervention content and impact to change over time<sup>7</sup>, such that  
14  
15 462 deciding the optimal point to collect evaluation data is challenging.  
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19 463 Some of the burdens and benefits described by patients in this study were also found to a lesser  
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21 464 extent in the qualitative development of the HOME BP intervention, such as reassurance from seeing  
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23 465 well-controlled readings, and some concerns about side effects and high or variable readings<sup>31</sup>.  
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25 466 Others were novel and only arose when participants experienced the full HOME BP intervention  
26  
27 467 during the RCT as opposed to a prototype, for example the perceived health improvements from  
28  
29 468 medication changes. This demonstrates the value of conducting inductive qualitative research to  
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31 469 explore users' perspectives at each stage of intervention development and evaluation, in line with  
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33 470 the person-based approach<sup>9</sup>.  
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## 36 37 471 **CONCLUSIONS**

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41 472 In the context of this digital intervention, the study shows that participants' appraisal of burdens and  
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43 473 benefits appeared to be influenced by both intervention factors, such as BP readings and perceived  
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45 474 availability of the healthcare professional, and patient characteristics, such as perceptions of BP  
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47 475 control, previous experience of side effects, and co-morbidities. This nuanced evaluation would be  
48  
49 476 lost in a population-level analysis, demonstrating the advantage of a more individualised approach  
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51 477 for better understanding participants' perspectives of an intervention and how best to minimise the  
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53 478 burden of treatment.  
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3 479 The study develops the recommendations of McNamee et al<sup>6</sup> that complex digital health  
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5 480 interventions warrant a wider perspective for measuring health outcomes, and discusses the  
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7 481 implications of capturing broader psychosocial outcomes for Burden of Treatment theory and health  
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9 482 economic evaluations.

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12 483 The finding that some participants perceived personal benefits from using the intervention  
13  
14 484 demonstrates that the process of healthcare can, in itself, be positive for some people, highlighting  
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16 485 the importance of capturing transient short-term benefits to take these into account as well as the  
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18 486 burden of self-management.

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3 490 **CONTRIBUTORS**  
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6 491 KM recruited participants, conducted interviews, analysed data, and wrote manuscript. LD & KB  
7  
8 492 contributed to study design and data analysis. KB and RB developed the digital intervention. PL &  
9  
10 493 RJM contributed to intervention development and interpretation of themes. CM & JR contributed to  
11  
12 494 theoretical and methodological implications of the study findings. LY contributed to study design,  
13  
14 495 data collection, data analysis, and interpretation.  
15

16  
17 496 All authors contributed to the manuscript preparation and provided final approval of the version to  
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19 497 be published.  
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29  
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31  
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36 504 NIHR Oxford CLAHRC.  
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40 505• **COMPETING INTERESTS**  
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42  
43 506 RJM has received BP monitors for research purposes from Omron and Lloyds Pharmacies.  
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46 507• **ETHICS APPROVAL**  
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48  
49 508• This qualitative process study was embedded in the HOME BP trial and approved by the University of  
50  
51 509 Southampton and NHS Hampshire A Research Ethics committees (REC Reference 15/SC/0082).  
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54 510 **DATA SHARING STATEMENT**  
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3 511 Requests for data sharing can be sent to the corresponding author. Full transcripts of interviews are  
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5 512 not available to protect participants' anonymity.  
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9 514 **Figure legend:**

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11 515 Figure 1 Possible influences of illness and treatment beliefs on perceived burdens and benefits of the  
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13 516 intervention  
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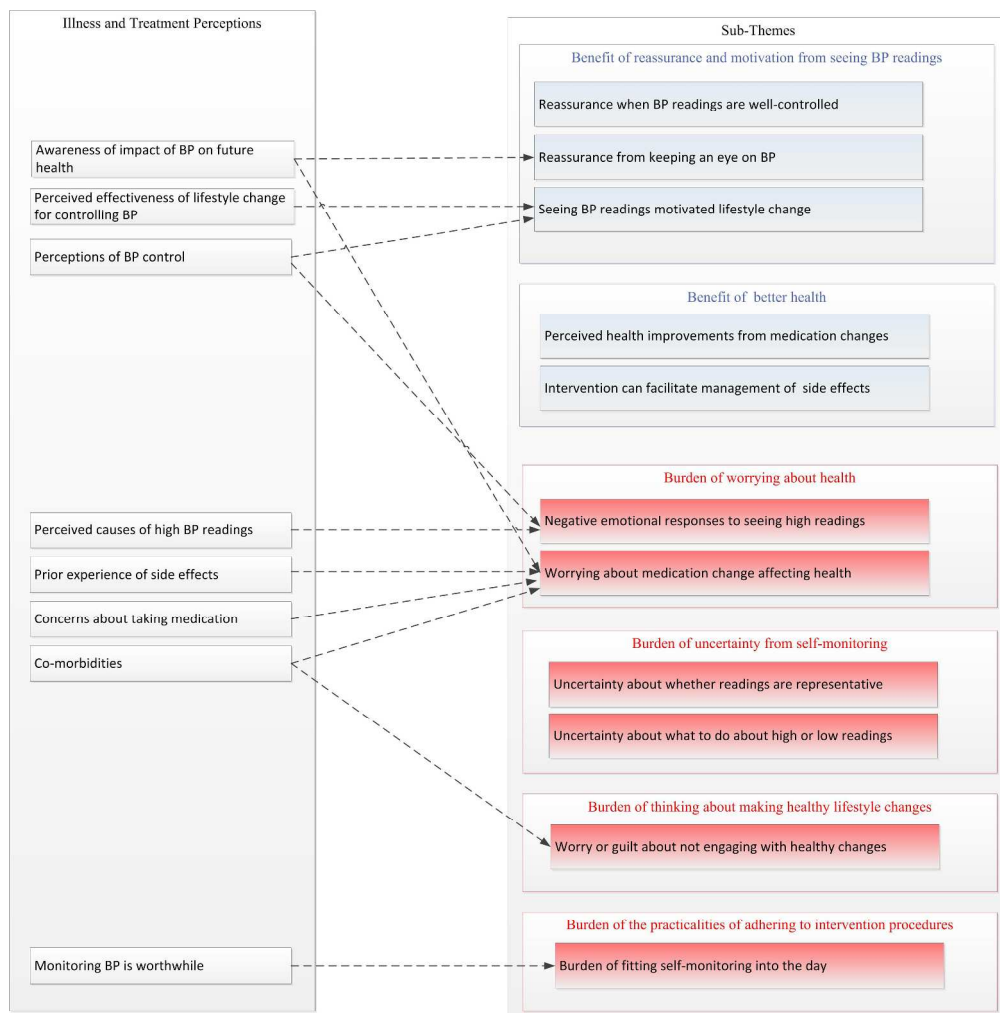


Figure 1. Possible influences of illness and treatment beliefs on perceived burdens and benefits of the intervention

337x340mm (300 x 300 DPI)

## Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

**YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE**

No. Item	Guide questions/description	Reported on Page #
<b>Domain 1: Research team and reflexivity</b>		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 9
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 9
3. Occupation	What was their occupation at the time of the study?	Page 9
4. Gender	Was the researcher male or female?	Page 9
5. Experience and training	What experience or training did the researcher have?	Page 9
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 9
<b>Domain 2: study design</b>		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 9
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 8
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 8

12. Sample size	How many participants were in the study?	Page 10
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 10
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 8
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 11
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 9
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 9
20. Field notes	Were field notes made during and/or after the interview or focus group?	Page 9
21. Duration	What was the duration of the inter views or focus group?	Page 11
22. Data saturation	Was data saturation discussed?	Page 9
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
<b>Domain 3: analysis and findings</b>		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Page 9
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 13
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 9-10
27. Software	What software, if applicable, was used to manage the data?	Page 10
28. Participant checking	Did participants provide feedback on the findings?	Page 26
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Throughout results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

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4 **Once you have completed this checklist, please save a copy and upload it as part**  
5 **of your submission. When requested to do so as part of the upload process,**  
6 **please select the file type: *Checklist*. You will NOT be able to proceed with**  
7 **submission unless the checklist has been uploaded. Please DO NOT include this**  
8 **checklist as part of the main manuscript document. It must be uploaded as a**  
9 **separate file.**  
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4 **Supplementary File 2. Interview schedules for intervention and usual care group**  
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7 Intervention group interview schedule  
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10 **Opening questions**  
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12 Can you tell me about what it is like for you to have high blood pressure?  
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14 How did you feel when you were first told you had high blood pressure?  
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16 Can you tell me why you decided to sign up for the Home BP study?  
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18 I'm really interested in hearing about your experiences of using HOME BP, can you tell me all about  
19 it?  
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21  
22

23 Can you tell me about anything that you have liked about the HOME BP study so far?  
24

25 Can you tell me about anything that you have disliked?  
26  
27

28 Can you tell me about any advantages of using HOME BP?  
29  
30

31 And can you tell me about any disadvantages of using HOME BP?  
32  
33

34 How do you feel about your high blood pressure now?  
35  
36

37 Do you think you would choose to keep on using the HOME BP programme if it was still available  
38 after a year?  
39  
40

41 Why/ Why not?  
42  
43

44 Would you recommend the HOME BP programme to other people with high blood pressure?  
45  
46

47 **Self-monitoring**  
48

49 **Experiences of monitoring:**  
50

51 Can you tell me about what it was like when you were learning how to use your BP monitor at home?  
52  
53

54 Can you tell me about the first time you used your BP monitor at home in the study?  
55  
56  
57  
58  
59  
60



1  
2  
3 Can you tell me about what it has been like to monitor your blood pressure yourself?  
4

5 How did it make you feel?  
6

7 Had you ever monitored your own blood pressure before you took part in the HOME BP study?  
8

9  
10 *If yes:*

11 Can you tell me a bit more about this?  
12

13 Can you tell me whether you've noticed any changes in how you monitor your blood  
14  
15  
16  
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pressure since you've started the HOME BP programme?

All: Can you tell me about any concerns that you have about monitoring your blood pressure?

Adherence to the monitoring schedule:

The HOME BP programme reminds you to monitor your blood pressure for 7 days every 4 weeks.

Can you tell me about what it has been like for you to try and monitor your blood pressure for 7 days every 4 weeks?

Can you tell me about the time of day you have been monitoring your blood pressure so far?

How do you feel about the instructions HOME BP gives about when to monitor?

Was there anything that helped you to monitor your own blood pressure?

Was there anything that made it harder to monitor your own blood pressure?

Can you tell me about any time when you had to skip your blood pressure monitoring or change when you did it in the day?

Can you tell me how you found it entering your readings on the HOME BP programme?

1  
2  
3 Feedback messages  
4  
5

6 Remember after you enter your readings on HOME BP, you see a message which says 'your readings  
7 were amber, or green'? What did you think about these messages?  
8  
9

10  
11 Can you tell me about how you felt when you saw a message about your blood pressure readings on  
12 HOME BP?  
13  
14

15  
16 How did you feel about monitoring your own blood pressure after reading that message?  
17  
18

19  
20 Did you have any very high or very low readings (red/blue) when you were monitoring in the HOME  
21 BP study? How did you feel?  
22  
23  
24

25 **2. Medication change**  
26  
27

28 Can you tell me about what it's like for you taking medication for your high blood pressure?  
29  
30

31 Have you been recommended to make a medication change during the HOME BP study?  
32  
33

34 *If yes:*  
35  
36

37 How did you feel about making a change to your medication when HOME BP recommended  
38 it?  
39  
40

41  
42 Did you make this change to your medication?  
43  
44  
45

46 ***If they chose to make a change:***  
47  
48

49 Can you tell me about what it was like to make a medication change in the HOME BP study?  
50  
51

52 Can you tell me about how the medication change came about?  
53  
54

55 How did you get on with your new medication?  
56  
57

58 How would you feel if HOME BP recommended a medication change for you now?  
59  
60

1  
2  
3 ***If they chose not to make a change –***  
4

5  
6 Can you tell me about why you decided not to change your medication?  
7

8  
9 How would you feel if HOME BP recommended another medication change for you now?  
10

11  
12 ***If no:***  
13

14  
15 ***If patient has not been recommended a med change:*** How do you feel about changing your  
16 medication if your blood pressure stayed too high for too long?  
17

18  
19 Can you tell me about any concerns that you have about doing this?  
20

21  
22 ***All:***  
23

24  
25 How did you feel about making changes to your medication before you took part in HOME BP?  
26  
27

28  
29 **3. HCP support**  
30

31  
32 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP study?  
33

34  
35 Can you tell me about how you have found the support from your GP or nurse while you were taking  
36 part in the HOME BP study?  
37

38  
39 Can you tell me what you thought about receiving emails from your nurse about HOME BP?  
40

41  
42 If needed, follow-up questions:  
43

44  
45 Have you seen your GP about your blood pressure since the start of the study?  
46

47  
48 And what about appointments with the nurse?  
49

50  
51 Can you tell me about how you have found the emails from HOME BP?  
52

53  
54 **4. Healthy changes**  
55

56  
57 Can you tell me about anything else that you do to try and manage your high blood pressure?  
58  
59  
60

1  
2  
3 There is an option on the HOME BP programme to look at online sessions about making healthy  
4 changes that can help lower your blood pressure, I wonder if you remember if you have seen it?  
5  
6  
7

8 *If no:*  
9

10  
11 Can you tell about how you might feel about making healthy changes to help lower your blood  
12 pressure?  
13  
14  
15

16 *If yes:*  
17

18  
19 Can you tell me about how you found the session on healthy changes?  
20  
21

22  
23 How did you feel about making the healthy changes this session talked about?  
24  
25

26 *If they chose a change:* Can you tell me about what made you choose this/these ones?  
27  
28

29 How did you find the online session about xxxx (cutting down on salt/alcohol/eating a healthier  
30 diet/doing more physical activity/ losing weight)?  
31  
32  
33

34 Can you tell me about what it was like for you trying out this healthy change?  
35  
36

37 How did making a healthy change like this make you feel?  
38  
39

40 *Or if they didn't choose any:* Can you tell me about why you didn't want to choose a healthy change?  
41  
42

43 *All:* Can you tell me about any concerns that you have about making a new healthy change?  
44  
45

46 Is there anything else you would like to tell me about the HOME BP study that we haven't already  
47 talked about?  
48  
49  
50

1  
2  
3 Usual care group interview schedule  
4  
5

6 General questions about BP  
7

8  
9 Can you tell me about what it is like for you to have high blood pressure?  
10

11  
12 How did you feel when you were first told you had high blood pressure?  
13

14  
15 Can you talk me through what (if anything) you currently do to manage/control your high blood  
16  
17 pressure?  
18

19  
20 Can you tell me about how your GP and practice nurse are involved in helping you to control  
21  
22 your high blood pressure?  
23

24  
25 How do you feel about monitoring your own blood pressure at home?  
26

27  
28 If they already monitor – can you tell me a bit more about this?  
29

30  
31 Can you tell me about what it's like for you taking medication for your high blood pressure?  
32

33  
34 Can you tell me how you feel about your GP making changes to your blood pressure medication?  
35  
36

37  
38 HOME BP study experience  
39

40  
41 Can you tell me why you signed up for the Home BP study?  
42

43  
44 Can you tell me all about what it has been like for you being in the HOME BP study in the usual  
45  
46 care group?  
47

48  
49 At the start of the HOME BP study, you had a baseline appointment with a nurse at your GP  
50  
51 Practice – can you tell me about that?  
52

53  
54 How did you find it using the HOME BP programme to fill in your questionnaires online at the  
55  
56 start of the study?  
57  
58  
59  
60

1  
2  
3 After you had completed your questionnaires, did you have an appointment with your GP to  
4  
5 check your blood pressure medication? Can you tell me about this?  
6  
7

8 HCP support  
9

10  
11 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP  
12  
13 study?  
14  
15

16  
17 Can you tell me about how you have found the support from your GP or nurse while you were  
18  
19 taking part in the HOME BP study?  
20  
21

# BMJ Open

## A 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.

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6 **1 Title page**  
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9

10 **2 A qualitative process study to explore the perceived burdens and benefits of a digital**  
11  
12 **3 intervention for self-managing high blood pressure in Primary Care in the UK.**  
13  
14

15 4 Kate Morton<sup>a\*</sup>, Laura Dennison<sup>a</sup>, Katherine Bradbury<sup>a</sup>, Rebecca Band<sup>a</sup>, Carl May<sup>b</sup>, James Raftery<sup>c</sup>,  
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78 **20 ABSTRACT**

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11 **21 Objectives:** Digital interventions can change patients' experiences of managing their health, either  
12  
13 **22** creating additional burden or improving their experience of healthcare. This qualitative study aimed  
14  
15 **23** to explore perceived burdens and benefits for patients using a digital self-management intervention  
16  
17 **24** for reducing high blood pressure. A secondary aim was to further our understanding of how best to  
18  
19 **25** capture burdens and benefits when evaluating health interventions.

20  
21  
22 **26 Design:** Inductive qualitative process study nested in a randomised controlled trial.

23  
24  
25 **27 Setting:** Primary Care in the UK

26  
27  
28 **28 Participants:** 35 participants taking antihypertensive medication and with uncontrolled blood  
29  
30 **29** pressure at baseline participated in semi-structured telephone interviews.

31  
32  
33 **30 Intervention:** Digital self-management intervention to support blood pressure self-monitoring and  
34  
35 **31** medication change when recommended by the healthcare professional.

36  
37  
38 **32 Analysis:** Data were analysed using inductive thematic analysis with techniques from grounded  
39  
40 **33** theory.

41  
42  
43 **34 Results:** Seven themes were developed which reflected perceived burdens and benefits of using the  
44  
45 **35** intervention, including worry about health, uncertainty about self-monitoring, and reassurance. The  
46  
47 **36** analysis showed how beliefs about their condition and treatment appeared to influence participants'  
48  
49 **37** appraisal of the value of the intervention. This suggested that considering illness and treatment  
50  
51 **38** perceptions in Burden of Treatment theory could further our understanding of how individuals  
52  
53 **39** appraise the personal costs and benefits of self-managing their health.  
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2  
3 40 **Conclusions:** Patients' appraisal of the burden or benefit of using a complex self-management  
4  
5 41 intervention seemed to be influenced by experiences within the intervention (such as perceived  
6  
7 42 availability of support) and beliefs about their condition and treatment (such as perceived control  
8  
9 43 and risk of side effects). Developing our ability to adequately capture these salient burdens and  
10  
11 44 benefits for patients could help enhance evaluation of self-management interventions in the future.  
12  
13 45 Many participants perceived important benefits from using the intervention, highlighting the need  
14  
15 46 for theory to recognise that engaging in self-management can include positive as well as negative  
16  
17 47 aspects.  
18  
19  
20 48

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22  
23 49 Trial registration: ISRCTN13790648. Registered 14 May 2015.  
24

25 50 **Keywords:** Self-management; digital intervention; qualitative; treatment burden  
26  
27

28 51 **Strengths and limitations of this study:**

- 29 52 ❖ The exploratory, open approach to data collection enabled us to capture whichever benefits or  
30  
31 53 burdens were most salient to the participants.  
32  
33 54 ❖ We only interviewed participants at one point in time, so were unable to gain an understanding  
34  
35 55 of dynamic changes in perceived benefits or burdens over time.  
36  
37 56 ❖ Both well and poorly controlled hypertensive patients took part in the interviews, but it was  
38  
39 57 difficult to recruit low users of the intervention which could limit the generalisability of the  
40  
41 58 findings.  
42  
43 59 ❖ The asymptomatic nature of hypertension and the unique medication change pathway means  
44  
45 60 that these findings may not be generalisable across conditions.  
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## 63 BACKGROUND

64 The work involved in looking after one's health when living with a chronic condition can include  
65 complex tasks such as organising and adhering to treatment regimens, interacting with healthcare  
66 professionals (HCPs), regular monitoring of health indicators, and making health-related decisions,  
67 all of which can accumulate into a considerable burden<sup>1</sup>. Digital self-management interventions are  
68 often developed to improve health outcomes, but these interventions could also either increase or  
69 minimise the burden of the healthcare process for patients. Developing our understanding of the  
70 burdens of self-management can help to better optimise the delivery of healthcare to improve  
71 adherence and well-being<sup>1-3</sup>. Burden of Treatment (BoT) theory provides a mechanism for  
72 understanding these experiences in the context of patients' personal capacity to cope, with  
73 emphasis on the role of wider healthcare systems and social networks available to the patient<sup>1</sup>.

74 Health economic evaluations also focus on understanding the impact of healthcare on patients,  
75 seeking to weigh up the resources used against the health outcomes in order to better inform  
76 decision-making. Recent guidelines for economic evaluations in health and medicine recommend  
77 adopting a societal perspective such that all relevant outcomes are evaluated, rather than focusing  
78 only on formal healthcare costs<sup>4</sup>. In particular, personal costs such as time spent in self-care should  
79 be included. Consequently, BoT theory and health economic evaluations share an interest in  
80 adequately capturing the wider burdens or personal costs of engaging with healthcare. For  
81 consistency in terminology in this paper, negative outcomes/personal costs of healthcare will be  
82 referred to as 'burdens'.

83 BoT theory considers patients' time as a resource that is used by the healthcare system, while health  
84 economic evaluation counts time as an 'opportunity cost' whereby the patient 'spends' time that  
85 could have been spent on something other than healthcare. However, subjective experiences of  
86 time spent on digital interventions may be varied and complex. Heterogeneity in the relative value  
87 placed on the outcomes of the intervention<sup>5</sup> may mean that for some participants the time spent

1  
2  
3 88 engaging with elements of an intervention is not perceived as a burden but rather as a benefit,  
4  
5 89 either because it is interesting, pleasant or meaningful in and of itself or because of the positive  
6  
7 90 outcomes it can lead to. In other words, some people may actually like engaging with healthcare.  
8  
9 91 The value of exploring the personal benefits of intervention participation has not received as much  
10  
11 92 focus as understanding the costs, such as treatment burden. McNamee et al.<sup>6</sup> proposed that the  
12  
13 93 health research guidelines for economic analysis may need to be adjusted for digital health  
14  
15 94 interventions to ensure we can fully capture the heterogeneous costs and benefits arising when  
16  
17 95 complex interventions are implemented in complex systems.  
18  
19  
20  
21 96 To further our understanding of how patients perceive benefits and burdens when using digital  
22  
23 97 health interventions, we carried out a qualitative process study<sup>7</sup>. The digital HOME BP intervention  
24  
25 98 was developed based on best practice recommendations to help improve hypertension in poorly  
26  
27 99 controlled patients by facilitating self-monitoring of blood pressure (BP) at home and prompting  
28  
29 100 appropriate intensification of medication by HCPs<sup>8</sup>. This intervention could help to minimise the  
30  
31 101 treatment burden of hypertension by providing an online healthcare system in which HCPs have  
32  
33 102 sight of patients' home readings, streamlining the process for finding the most effective medication  
34  
35 103 without the need for attending the GP surgery. However, HOME BP is a complex, interactive multi-  
36  
37 104 component intervention, which creates potential diversity in the perceived burden and benefits for  
38  
39 105 participants using it. The contexts in which the intervention is embedded may also be diverse, and  
40  
41 106 factors such as individual differences in patients' health status, beliefs about medication and risks of  
42  
43 107 high BP, availability of time and resources, and access to support may influence how the  
44  
45 108 intervention is perceived and valued. The HOME BP intervention was developed using the person-  
46  
47 109 based approach<sup>9</sup> which emphasises the importance of understanding participants' unique  
48  
49 110 perspectives and different situations when developing and implementing digital interventions.  
50  
51 111 Adopting a more granular approach to the evaluation of benefit and burden is consistent with the  
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3 112 person-based approach, and with the BoT approach of fully understanding the participants'  
4  
5 113 perspective.  
6  
7  
8 114 The present study aimed to explore the perceived burden and benefits of using a digital health  
9  
10 115 intervention for self-managing BP using qualitative process interviews with intervention and usual  
11  
12 116 care participants taking part in a randomised controlled trial (RCT). This paper seeks to interpret the  
13  
14 117 implications for optimising the capture of perceived costs and benefits in health economic  
15  
16 118 evaluations and evaluating the burden of treatment.  
17  
18  
19  
20 119

## 120 **METHODS**

### 121 **Design**

122 A qualitative process study embedded in the HOME BP trial<sup>8</sup> was approved by the University of  
123 Southampton and NHS Research Ethics committees. The COREQ checklist (Consolidated criteria for  
124 reporting qualitative studies) was used to ensure comprehensive reporting of the study<sup>10</sup>  
125 (supplementary file 1).  
126

### 127 **Intervention**

128 The HOME BP programme supported participants to self-manage their high BP, primarily via home  
129 self-monitoring of BP and making changes to dose/drug type when recommended by the HCP.  
130 Lifestyle change modules were also available, but optional as the key target behaviours for the  
131 intervention were self-monitoring and medication change adherence<sup>8,11</sup>. Participants using HOME  
132 BP were supported by a 'prescriber' (GP or nurse prescriber responsible for changing medication)

1  
2  
3 133 and a 'supporter' (nurse or healthcare assistant who supported participants in self-monitoring and  
4  
5 134 choosing lifestyle changes).  
6  
7  
8 135 Participants were invited to use the online programme by their GP and were randomised to usual  
9  
10 136 care or intervention after completing baseline measures online. Those randomised to the  
11  
12 137 intervention group completed two online training sessions which sought to overcome concerns  
13  
14 138 about variability in readings and changing medication. Participants were encouraged to monitor  
15  
16 139 their BP in the mornings, but the programme allowed flexibility as it was most important that people  
17  
18 140 found a time of day that suited them to monitor their BP. Both intervention and usual care  
19  
20 141 participants were followed up at 6 and 12 months post-randomisation.  
21  
22  
23 142 Table 1 describes the HOME BP intervention in more detail.  
24  
25  
26 143 Table 1 HOME BP Intervention Characteristics  
27

Target behaviour	Description
Self-monitoring BP	Participants monitored their BP at home for 7 days every 4 weeks. After 7 days, they entered their BP readings on the HOME BP website and received instant automated feedback using a traffic light system. If BP was very high (red) or very low (blue), they were told to contact their GP surgery. If BP was above target (amber), they were told their prescriber would contact them about a medication change. If BP was on target (green), they were congratulated and asked to monitor their BP again next time.
Medication change	The prescriber planned three potential medication changes with the participant at the start of the study. HOME BP informed prescribers by email when a patient's home BP readings were above-target and they could implement a pre-

	planned change without needing to see the participant for an appointment.
Optional lifestyle changes	At nine weeks after randomisation, participants had the option of choosing an online session to support lifestyle change to help control their BP, specifically weight management, salt reduction, healthy diet, physical activity, or alcohol reduction. Participants were alerted by email when this became available, and saw an option to view the healthy lifestyles session each time they logged on to HOME BP. The online lifestyle change sessions could be started at any time during the 12-month trial, from nine weeks.

144

145 **Participants**

146 Patients were eligible to take part in the HOME BP trial if they had uncontrolled hypertension  
 147 managed in Primary Care (mean BP reading of 140/90 mm Hg or more at baseline taken at the GP  
 148 surgery using a validated electronic automated sphygmomanometer (BP TRU BPM 200)). In addition,  
 149 they needed to be prescribed 1-3 antihypertensive medications at baseline, and aged over 18 (full  
 150 inclusion and exclusion criteria are listed in the protocol<sup>8</sup>).

151 Both intervention and usual care participants were invited to take part in interviews as we felt that  
 152 obtaining an understanding of managing BP in usual care would aid interpretation of the perceived  
 153 burden and benefits of the intervention. We aimed to speak to participants at a range of time-points  
 154 during the 12-month trial from 10 weeks onwards as this gave participants the opportunity to  
 155 become familiar with HOME BP. No new intervention content was introduced after the lifestyles  
 156 sessions became available at nine weeks.

### 157 **Recruitment and interview procedure**

158 A sub-sample of RCT participants were invited by email to provide feedback on their experiences of  
159 managing their BP (n=78, of 622 patients in the RCT). Informed consent was taken by post or online,  
160 depending on participant preference. Recruitment was initially opportunistic, but subsequently a  
161 purposive approach was adopted to target younger participants, low engagers, and those with  
162 recent uncontrolled self-monitored BP readings, informed by the concurrent analysis. Recruitment  
163 was stopped once the researchers agreed that data saturation had been reached and no new  
164 burdens or benefits were arising.

165 Semi-structured interview schedules were co-developed by experts in health psychology (KM, KB, RB,  
166 LY, LD), health economics (JR) and sociology (CM). Open, inductive questions were carefully selected  
167 to elicit data about the burden and benefits of BP management perceived as most salient by the  
168 participants (see Supplementary File 2 for interview schedules). The interviews were conducted by  
169 telephone to minimise the burden on participants, except in one case where the participant asked to  
170 meet face-to-face due to struggling with hearing on the telephone. The interviews took place  
171 between February 2016 and February 2017. Each participant was given a £10 gift voucher to thank  
172 them for their time.

173 All interviews were conducted by KM (MSc, BSc. termed “the researcher”), a female PhD candidate  
174 in Health Psychology who was also employed as a research assistant. Each interview was audio-  
175 recorded, and the researcher also took notes and completed a self-reflection log afterwards to  
176 record any emerging thoughts on the data. Audio-recordings were transcribed verbatim and checked  
177 thoroughly by the researcher.

### 178 **Patient and Public Involvement**

179 Patient and public involvement (PPI) representatives have been involved in the design and conduct  
180 of the randomised controlled trial, including decisions about recruitment processes, outcome



1  
2  
3 181 measures and trial procedures. We also discussed the findings of this qualitative process study with  
4  
5 182 our PPI to facilitate our interpretations of the data. The participants in the study were patients,  
6  
7 183 ensuring we were collecting experiences of burden from the target population, and the results were  
8  
9 184 fed back to the study participants as a newsletter.  
10

## 11 12 13 185 **Analysis**

14  
15  
16 186 The analysis was an iterative process led by KM, supported by frequent discussion of emerging  
17  
18 187 themes with LY and LD (who have extensive experience in qualitative research) along with input  
19  
20 188 regarding health economic and sociological perspectives (JR and CM). Inductive thematic analysis  
21  
22 189 methods were used<sup>12 13</sup> with techniques from grounded theory such as memoing, constant  
23  
24 190 comparison, and diagramming to enhance our understanding and facilitate the development of  
25  
26 191 higher themes<sup>14 15</sup>. Data collection and analysis ran concurrently to enable purposive sampling based  
27  
28 192 on analytic insights. Thorough line-by-line coding was undertaken in NVivo 10<sup>16</sup>, and a coding  
29  
30 193 manual was developed which evolved as more data were collected and coded. The emerging codes  
31  
32 194 were constantly checked against the raw data to ensure the analysis was driven by the participants'  
33  
34 195 own language and experiences.  
35  
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37

38 196 All data relating to burdens and benefits of managing BP were analysed. We also coded factors that  
39  
40 197 appeared to influence perceptions of burdens and benefits to facilitate an in-depth understanding of  
41  
42 198 how participants appraised the intervention's value. A broad and open definition was adopted  
43  
44 199 whereby benefits and burdens were defined as positive and negative outcomes or experiences of  
45  
46 200 engaging in the intervention<sup>17</sup>, in order to facilitate a comprehensive representation of all potentially  
47  
48 201 relevant data.  
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3 **203 RESULTS**  
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7 **204 Participant characteristics**  
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10 **205** In the intervention group, 28 of 54 invited participants agreed to be interviewed (52%). In the usual  
11  
12 **206** care group, 7 of 24 invited participants agreed (29%). Most participants who did not take part chose  
13  
14 **207** not to reply, but those who did said they did not have anything to report on the trial (n = 3 in usual  
15  
16 **208** care). The participants were from 19 different GP surgeries. Table 2 shows the sociodemographic  
17  
18 **209** and intervention details of the sample.  
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22 **210**  
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24 **211** Table 2. Sociodemographic and intervention participant data (n=35)  
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26

	Intervention participants	Usual care participants
N	28	7
Median duration of interview (range)	38 (15-67) minutes	28 (22-40) minutes
Median age (range)	70 (41-87) years	67 (52-77) years
Gender	71% female	43% female
Ethnicity		
White	24	6
Black African	1	
Pakistani	1	
Other	2	1
Education levels	9 No formal education	2 No formal education
	8 GCSE or A-level	3 GCSE or A-level

	10 Higher Education	1 Higher Education
	1 Other	1 Other
Median number of weeks into the study at which the interview took place (range)	20 (10-57) weeks	17 (7 to 24) weeks
Poorly controlled BP at the time of the interview	10/28 (36%)	N/A*
Medication change recommended during the study	15/28 (54%)	N/A
Accessed optional healthy lifestyles session	15/28 (54%)	N/A

212 \*As BP self-monitoring was a key component of the intervention, BP readings were available for the  
 213 intervention group throughout the duration of the study but data about BP from the usual care  
 214 group were only available at RCT baseline and follow-up points.

## 215 Themes

216 Table 3 presents seven themes exploring perceived burdens and benefits of the HOME BP  
 217 intervention. One meta-theme also emerged concerning how illness and treatment beliefs about  
 218 high BP appeared to influence participants' perceptions about the intervention's burdens and  
 219 benefits, and this is discussed in relation to each theme it applies to. Figure 1 shows how illness and  
 220 treatment perceptions about BP appeared to relate to the sub-themes identified by the thematic  
 221 analysis.

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223 Where quotes are included, participants are referred to as 'p' followed by a number. Study group  
224 (intervention or usual care) is also included to help understand the quotes in context.

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225 Table 3. Themes and sub-themes relating to perceived burdens and benefits of the intervention

Themes	Sub-themes	Exemplar participant quote
Benefit of reassurance from seeing BP readings	Reassurance when BP readings are well-controlled	"I'm so pleased. And my mind is at rest when we go on holidays and all that...I'm alright. I'm alright sort of thing. Yeah, peace of mind" (Intervention p9, well-controlled)
	Reassurance from keeping an eye on BP	"It made me much more aware of what the problem is with the high blood pressure and by monitoring it so regularly, I know exactly where I stand with it" (Intervention p15, well-controlled)
Benefit of motivation for lifestyle change from seeing BP readings	Seeing BP readings motivated lifestyle change	"It is quite interesting to see the effects of what I'm doing on the blood pressure and everything. So, I think that is – it is quite good" (Intervention p18, well-controlled)
Benefit of better	Perceived health improvements	"It helped me to change my medication and then because of change of medication,

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health	from medication changes	my blood pressure went down. So definitely there is a benefit" (Intervention p16, well-controlled)
	Intervention can facilitate management of side effects	"That medication didn't work, in that I was on holiday and my ankles swelled up so much – and my feet and my legs, so much so that I couldn't see my toes. So I stopped taking that medication. Was called back to the GP. And I'm now on a medication that works for me and is managing the blood pressure" (Intervention p7, well-controlled)
Burden of worrying about health	Negative emotional responses to seeing high readings	"I was actually quite shocked because it was a—a lot higher" (Intervention p6, poorly controlled)
	Worrying about medication change affecting health	"I don't want to get more medication 'cause I'm already on a high dose and I don't want to increase it because it worries me about my kidneys" (Intervention p24, poorly controlled)
Burden of uncertainty from self-monitoring	Uncertainty about whether readings are representative	"If someone only ever takes it in the morning, and you tend to get those lower readings, are you really getting a true picture of what they're like in the afternoon or the evening?" (Intervention p10, well-controlled)

	Uncertainty about what to do about high or low readings	"I don't know what's going to happen in respect to that [amber feedback]. Whether I'm going to get a call from my GP, or whether he – so I'm a little bit, like, you know, in the air. I don't really know what's going to happen in that respect" (Intervention p22, poorly controlled)
Burden of thinking about making healthy lifestyle changes	Worry or guilt about not engaging with healthy changes	"I have looked at it [online healthy lifestyles session]. I wouldn't say I've looked at it seriously, and I need to" (Intervention p4, poorly controlled)
Burden of the practicalities of adhering to intervention procedures	Burden of fitting self-monitoring into the day	"I like to get up and have a cup of coffee and I'm thinking 'Well, let's get the blood pressure done first because otherwise I can't do that, you know, for a while afterwards.' So, I've found that quite—quite difficult" (Intervention p5, poorly controlled).

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4 228 Insert Figure 1 here  
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7 229 Benefit of reassurance from seeing BP readings  
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10 230 *Reassurance when BP readings are well-controlled*  
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13 231 Seeing well-controlled readings when self-monitoring BP gave participants peace of mind which was  
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15 232 widely perceived as a benefit of the intervention. People described feeling relieved that their BP  
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17 233 readings were lower than at the GP surgery, and felt this gave them more insight into what their BP  
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19 234 was like most of the time.  
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21  
22 235 “What I do like about it is taking the blood pressure here at home, the readings are lower. And I find  
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24 236 that quite reassuring that my blood pressure is not always high” (Intervention p11, well-controlled)  
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27 237 Several usual care participants had decided to use their own BP monitors, and this group also  
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29 238 described feeling reassurance when seeing their BP was well-controlled.  
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32 239 *Reassurance from keeping an eye on BP*  
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35 240 Most participants liked having an increased focus on their BP through regular monitoring and found  
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37 241 it interesting to compare their readings over time. However one participant perceived that taking BP  
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39 242 regularly could encourage too much attention on your health, which was a potential burden of the  
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41 243 intervention for her (Intervention p28, BP control unknown as did not enter BP readings on HOME  
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43 244 BP). This participant had low concern about her BP generally, and was not motivated to engage in  
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45 245 self-management.  
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48 246 Even when participants had poorly-controlled readings, many felt a benefit from the intervention as  
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50 247 it enabled them to regularly check their BP and detect any problems instantly rather than carrying  
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52 248 on unaware.  
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3 249 "I think it's helping me to know where my blood pressure stands because it's a regular thing every  
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5 250 month" (Intervention p24, poorly-controlled)  
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8 251 The knowledge that home readings were shared with the prescriber reassured participants as they  
9  
10 252 knew that any problems would not only be detected but also dealt with at the time, making them  
11  
12 253 feel well cared for. This contrasted with the perceived burden of managing BP in usual care where  
13  
14 254 some participants felt concerned that their GP did not change their medication when their home  
15  
16 255 readings were too high, or would have liked more regular contact with their GP surgery to check  
17  
18 256 their BP and medication.  
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20  
21 257 "It would be nice to have it checked, I guess, you know, every three months or whatever. How—  
22  
23 258 however often. I mean, how do they know that everything is working?" (Usual care p4).  
24  
25  
26 259 This shows that although participants in usual care gained reassurance from seeing low readings  
27  
28 260 when they monitored at home, the lack of interaction with the GP surgery could cause concern  
29  
30 261 when readings were high or when patients did not regularly monitor BP at home of their own accord.  
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33 262  
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36 263 Benefit of motivation for lifestyle change from seeing BP readings  
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39 264 Some participants were motivated to increase their physical activity, engage in stress management  
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41 265 activities or healthy eating because they could see this had a positive impact on their BP readings.  
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43 266 This helped them feel more in control of their BP.  
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45  
46 267 "By taking the readings regularly and frequently, it gave me more of a feedback straightaway if you  
47  
48 268 like about anything, changes that I did make like a bit of exercise or...practicing relaxation and this  
49  
50 269 sort of thing. So that was quite nice, it was nice to feel that I was more in control of it again"  
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52 270 (Intervention p20, well-controlled)  
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3 271 Other participants felt frustrated after making lifestyle changes in the past which had no effect on  
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5 272 their BP. This made them feel that lifestyle was ineffective for controlling BP.  
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8 273 “I’m a completely different person. My diet’s completely different. And my blood pressure remained  
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10 274 the same. So I’ve done literally everything you physically possibly can to help yourself, and nothing’s  
11  
12 275 worked” (Intervention p1, well-controlled).

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18 277 Benefit of better health

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21 278 *Perceived health improvements from medication changes*

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24 279 Many participants felt it was beneficial to change their medication when their readings were too  
25  
26 280 high, and were very pleased when they perceived that a medication change led to lower BP readings  
27  
28 281 because of the positive effect this would have on their health.

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31 282 “I’ve found that by having the medication changed up at regular intervals my blood pressure’s  
32  
33 283 improved all the time” (Intervention p15, well-controlled)

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36 284 A few participants felt that a medication change had not been effective at lowering their BP which  
37  
38 285 could create doubt about their medication’s effectiveness.

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41 286 “It’s been doubled but it hasn’t seemed to lower my blood pressure at all, in fact, it’s at the same  
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43 287 levels as it is sort of now, un-medicated. So I just think – I don’t think it’s the right one. You know, I  
44  
45 288 can take the tablet but, actually, I don’t think it’s doing anything”. (Intervention p26, poorly-  
46  
47 289 controlled)

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50 290 *Intervention can facilitate management of side effects*

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52  
53 291 Most participants did not experience any side effects from having their medication changed. Where  
54  
55 292 side effects did occur, participants tended to perceive this as being a cost of taking medication

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3 293 (which was balanced against the benefit of controlling BP), rather than a burden of the intervention  
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5 294 itself. They felt that the intervention could help them to be more aware of side effects, to identify  
6  
7 295 alternative medications and to monitor how these affect their health.  
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9

10 296 “That [side effect] would have happened, you know, no matter what. That would have been an issue  
11  
12 297 but this has actually highlighted it, sort of, more clearly” (Intervention p5, poorly-controlled)  
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18 299 Burden of worrying about health  
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21 300 *Negative emotional responses to seeing high readings*  
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24 301 A burden of self-monitoring BP for some people was that seeing high readings could cause worry  
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26 302 about health. Participants’ beliefs about their BP control appeared to influence their appraisal of  
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28 303 high readings. A few participants believed their BP was well-controlled, a belief which was perhaps  
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30 304 reinforced by clinical staff approving their readings previously, and had only joined the study to help  
31  
32 305 with research. These participants tended to feel shocked or annoyed when they received above-  
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34 306 target feedback from the intervention as this challenged their beliefs.  
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37 307 “At one time, I was told to go on medication, further medication, which I must admit I was not very  
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39 308 happy about... When I used to go for a check with the nurse, if I’d have had those particular readings,  
40  
41 309 they wouldn’t have been high” (Intervention p17, poorly controlled)  
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45 310 Others were confused or frustrated by high BP readings when they could not understand why this  
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47 311 might have happened.  
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50 312 “I’m thinking about why my blood pressure has gone up. I can’t think why” (Intervention p25, poorly  
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52 313 controlled).  
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3 315 Meanwhile people who expected to see high readings were less concerned because they had  
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5 316 accepted that high readings were likely.  
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8 317 “Just par for the course. It’s what I expect from my blood pressure, really, so, it never worries me”  
9  
10 318 (Intervention p5, poorly controlled)  
11  
12  
13 319 Perceptions about the causes of high BP also influenced how anxious people felt about seeing high  
14  
15 320 readings. Those who felt that high readings held serious implications for their health tended to feel  
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17 321 frightened. Some even felt apprehensive *before* self-monitoring in case their readings were out-of-  
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19 322 range, as they didn't want to see evidence that their BP was too high or low.  
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21  
22 323 “Before I take my blood pressure, I do get stressed. I wouldn't say I get massively stressed because  
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24 324 obviously I'm used to doing it now but ... it's just that apprehension and thinking 'Oh, God, I hope it's  
25  
26 325 not too high today. I wonder really what's going on and how serious this is”. (Intervention p26,  
27  
28 326 poorly controlled).  
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31 327 Other people were able to dismiss one-off high readings without feeling anxious as they attributed  
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33 328 high readings to less threatening explanations such as feeling stressed, not sitting still for long  
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35 329 enough, positioning of the cuff, or held a prior expectation of it being normal for BP to fluctuate. In  
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37 330 these cases, the high readings had less negative emotional impact as they were not interpreted as  
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39 331 indicating a serious underlying health issue.  
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43 332 *Worrying about medication change affecting health*  
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46 333 Some participants were worried about the effects that changing BP medication could have on their  
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48 334 health. Previous experience of side effects, existence of co-morbidities, and concerns about  
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50 335 medication dependency or impact on kidneys tended to make participants feel more worried about  
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52 336 changing medication.  
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3 337 Perceptions about the health risk of high BP in terms of stroke and cardiovascular disease tended to  
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5 338 affect how burdensome participants perceived a medication change to be. Anxiety about future  
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7 339 health could override concerns about medication side effects or dependency as the behaviour was  
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9 340 evaluated as beneficial in order to bring BP down, although sometimes participants still experienced  
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11 341 conflict between the perceived benefit and burden.

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14 342 “The blood pressure has gone down but now my worries have changed from blood pressure to other  
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16 343 things. One is actually depending on medicine whole of my life. And secondly impact of medicine  
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18 344 on my body like kidneys” (Intervention p16, well-controlled).

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24 346 Burden of uncertainty from self-monitoring

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27 347 *Uncertainty about whether readings are representative*

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30 348 Whilst some participants were confident making decisions about when to monitor their BP, others  
31  
32 349 were worried about whether their readings were representative, especially when BP was seen to  
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34 350 vary at different times of day or after physical activity or drinking coffee. This could lead to doubt  
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36 351 about the meaningfulness of self-monitoring and the recommendations of the intervention.

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39 352 “I wonder if maybe the time of day I’m doing it, maybe my blood pressure’s always gonna be roughly  
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41 353 that. And could it be different during the day, is the sort of thing that does play in my mind a bit”  
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43 354 (Intervention p1, well controlled).

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46 355 *Uncertainty about what to do about high or low readings*

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50 356 Uncertainty could also become a burden after seeing an out-of-range BP reading, as the participant  
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52 357 had to decide what to do next. This burden was removed when the prescriber provided quick,  
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54 358 personalised feedback to the participant, but when they did not receive any contact from their

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3 359 prescriber or felt the prescriber was not available to provide support, this could create a feeling of  
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5 360 doubt.

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8 361 "I suppose I knew there was nothing to worry about but it's always a bit of a niggle in the back of  
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10 362 your mind... even the days she's [the nurse prescriber] at work I can't ring her at work because she  
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12 363 may be, you know, doing something else" (Intervention p21, well-controlled)

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18 365 Burden of thinking about making healthy lifestyle changes

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21 366 *Worry or guilt about not engaging with healthy changes*

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24 367 Several participants felt they would like to lose weight, eat more healthily, or do more physical  
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26 368 activity but lacked the motivation or self-efficacy to make these changes, especially if they had other  
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28 369 co-morbidities. This could create feelings of guilt or worry about their failure to make healthy  
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30 370 changes, which was a burden of the intervention for them.

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33 371 "I understand that, obviously, I need to get my blood pressure down because it is very dangerously  
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35 372 high, but I just don't know what to do about it, you know?... where I feel fatigued and worn out, I  
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37 373 don't feel well enough at the moment to do any exercise" (Intervention p26, poorly controlled)

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44 375 Burden of the practicalities of adhering to intervention procedures

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47 376 *Burden of fitting self-monitoring into the day*

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50 377 Many participants felt that self-monitoring was easy to fit into their day, and some described this as  
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52 378 being easier than going to the GP surgery to have their BP taken. Those with busy daily lifestyles  
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54 379 tended to find it harder to remember to self-monitor, and a burden for some participants was

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3 380 deciding how best to fit self-monitoring into their routine given the instructions about not drinking

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5 381 coffee or exercising beforehand.  
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8 382 The perceived burden of regular self-monitoring seemed to be mitigated by the perceived benefit of

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10 383 the behaviour, such that those who felt reassurance from seeing low readings or with high

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12 384 motivation to control BP found it less hassle and easier to remember than those who felt anxious

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14 385 about self-monitoring or had only joined the study to help with research.  
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17 386 "There was no big deal. It doesn't take long and it's—it's quite nice to sit down and have a relax

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19 387 during the day" (Intervention p8, well-controlled)  
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## 389 DISCUSSION

390 This qualitative study has identified diverse perceived burdens and benefits of using a self-  
391 management digital intervention for high BP. In support of the BoT theory<sup>1</sup>, the HOME BP  
392 intervention appeared to reduce the burden on patients to self-manage their condition by improving  
393 access to regular HCP support and facilitating better understanding of their condition, but in some  
394 cases there was a burden of worry about health or changing medication. How much benefit a  
395 patient perceived from the intervention compared to burden seemed to be influenced by the  
396 dynamics of the patient-HCP interaction (described as ‘Improving Cooperation’ in BoT theory) and  
397 the patient’s own resources to manage their condition and cope with medication (described as  
398 “Capacity”).

399 Another important factor relating to the burden experienced was personal beliefs about BP and  
400 treatment. Those who recognised that their BP was too high and did not have concerns about side  
401 effects or taking medication appeared to have more positive experiences of the intervention,  
402 perceiving self-monitoring as more worthwhile, and feeling less anxious about seeing high readings  
403 or changing medication. This is consistent with the necessity-concerns framework<sup>18</sup>. BoT theory  
404 states that people who are better equipped with resources and are more resilient may cope better  
405 with the burden imposed by healthcare<sup>19</sup>, but the importance of an individual’s personal  
406 conceptualisation of their condition in how burdensome they find self-care is not strongly  
407 represented. This beliefs system may be partly encompassed by the “Relational Integration” aspect  
408 of BoT theory, which refers to the extent to which patients trust the tasks they do for healthcare, e.g.  
409 self-monitoring BP, and feel confident in the outcomes of these tasks, e.g. changing medication.

410 However illness and treatment perceptions<sup>20</sup> are not explicitly covered by the theory and it may be  
411 helpful to consider them as additional factors which might influence the experience of treatment  
412 burden.

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56 414 **Implications for measurement of benefit and burden**  
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9 415 The present study demonstrates the value of collecting in-depth qualitative data to develop a  
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11 416 detailed understanding of the burden of treatment, and to discover perceptions specific to the  
12  
13 417 context in which the intervention was implemented. The important psychosocial outcomes  
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15 418 discovered using qualitative research can inform the selection or development of relevant  
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17 419 quantitative measures to capture these factors in further evaluation.  
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20 420 Quantitative measures have been developed to appraise the structural aspects of burden of  
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22 421 treatment<sup>21,22</sup>, but these are not intended to assess psychosocial factors such as reassurance, anxiety  
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24 422 or uncertainty which this study suggests can influence the extent to which using an intervention is  
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26 423 experienced subjectively as a burden.  
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29 424 Future research could explore how best to capture the perceived burden or benefit of an  
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31 425 intervention. One approach might be to simply ask participants to quantify the net subjective burden  
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33 426 or benefit of interventions. However, it could be challenging for participants to weigh complex  
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35 427 heterogeneous psychosocial outcomes against one another and decide overall whether an  
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37 428 intervention was more burdensome or beneficial. Capturing the extent to which patients experience  
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39 429 positive or negative psychosocial outcomes might better assess how beneficial or burdensome the  
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41 430 intervention was perceived to be. Although this would not produce a single outcome measure, cost-  
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43 431 consequence analysis can be used to inform decision-making when an intervention has multiple  
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45 432 relevant outcomes which cannot be aggregated into one value<sup>23</sup>. Coast<sup>24</sup> discusses whether a  
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47 433 multidimensional approach is more informative for economic analysis or if a single aggregated value  
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49 434 is more pragmatic.  
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53 435 Extending the evaluation of outcomes beyond health is in line with the capability approach<sup>25</sup>, which  
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55 436 focuses on broader aspects of subjective well-being which are not assessed by generic measures  
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3 437 such as the EQ-5D<sup>26</sup>. Tools used to capture perceived capability (such as the ICECAP<sup>27</sup>, and ASCOT<sup>28</sup>)  
4  
5 438 are gaining support as holistic measures of economic evaluation, but do not assess the more specific  
6  
7 439 psychosocial burdens and benefits of healthcare raised by participants in this study. Process utility  
8  
9 440 emphasises the need to quantitatively measure the value that people attach to healthcare delivery.  
10  
11 441 This approach might be relevant for evaluating how much value people perceive in the process of  
12  
13 442 using digital health interventions and the capability this achieves<sup>29</sup>. It has been argued that process  
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15 443 utility measures should also ask about the reasons behind patients' valuations, to better inform the  
16  
17 444 decision-maker<sup>30</sup>. This would help to capture the individual differences found in this study in how  
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19 445 people appraise the personal value of a digital intervention, informed by their underlying illness and  
20  
21 446 treatment beliefs.  
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#### 25 447 **Strengths and limitations**

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28 448 A strength of the study was that we used relatively open questions formulated by a multi-  
29  
30 449 disciplinary team which enabled us to elicit and explore a wide range of perceived burdens and  
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32 450 benefits, some of which were not anticipated at the outset of research. We are aware of the lead  
33  
34 451 researcher's potential influence on the data analysis, which we strived to minimise by transparent  
35  
36 452 memoing of decisions and regular team meetings to discuss the emerging themes. Participants were  
37  
38 453 sent newsletters to describe the findings of the study, but were not invited to provide feedback on  
39  
40 454 the analysis.  
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44 455 We succeeded in speaking to well and poorly controlled hypertensive participants at different points  
45  
46 456 in the intervention, and there was a wide range of demographics in terms of age, education level  
47  
48 457 and gender in the sample. However, the uptake rate from those invited to interviews was not high,  
49  
50 458 particularly in the usual care group. Perhaps unsurprisingly, it was difficult to recruit low engagers in  
51  
52 459 the intervention group, which could have helped reach theoretical saturation. In terms of wider  
53  
54 460 applicability, we are aware that these findings may not be generalisable across other health  
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3 461 conditions, as the lack of symptoms in hypertension and the stepped pathway for changing  
4  
5 462 medication are quite unique features of this condition.  
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8 463  
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10 464 Repeated interviews with the same participants may have offered more insight into the dynamic  
11  
12 465 nature of perceived burdens and benefits over time, although more regular conversations about the  
13  
14 466 target behaviour could have influenced participants' BP management behaviour therefore  
15  
16 467 threatening the RCT conclusions. It has been noted that a key issue with process evaluations of  
17  
18 468 interventions is the tendency for intervention content and impact to change over time<sup>7</sup>, such that  
19  
20 469 deciding the optimal point to collect evaluation data is challenging.  
21  
22  
23  
24 470 Some of the burdens and benefits described by patients in this study were also found to a lesser  
25  
26 471 extent in the qualitative development of the HOME BP intervention, such as reassurance from seeing  
27  
28 472 well-controlled readings, and some concerns about side effects and high or variable readings<sup>31</sup>.  
29  
30 473 Others were novel and only arose when participants experienced the full HOME BP intervention  
31  
32 474 during the RCT as opposed to a prototype, for example the perceived health improvements from  
33  
34 475 medication changes. This demonstrates the value of conducting inductive qualitative research to  
35  
36 476 explore users' perspectives at each stage of intervention development and evaluation, in line with  
37  
38 477 the person-based approach<sup>9</sup>.  
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## 42 478 **CONCLUSIONS**

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46 479 In the context of this digital intervention, the study shows that participants' appraisal of burdens and  
47  
48 480 benefits appeared to be influenced by both intervention factors, such as BP readings and perceived  
49  
50 481 availability of the healthcare professional, and patient characteristics, such as perceptions of BP  
51  
52 482 control, previous experience of side effects, and co-morbidities. This nuanced evaluation would be  
53  
54 483 lost in a population-level analysis, demonstrating the advantage of a more individualised approach  
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3 484 for better understanding participants' perspectives of an intervention and how best to minimise the  
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5 485 burden of treatment.  
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8 486 The study develops the recommendations of McNamee et al<sup>6</sup> that complex digital health  
9  
10 487 interventions warrant a wider perspective for measuring health outcomes, and discusses the  
11  
12 488 implications of capturing broader psychosocial outcomes for Burden of Treatment theory and health  
13  
14 489 economic evaluations.  
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16

17 490 The finding that some participants perceived personal benefits from using the intervention  
18  
19 491 demonstrates that the process of healthcare can, in itself, be positive for some people, highlighting  
20  
21 492 the importance of capturing transient short-term benefits to take these into account as well as the  
22  
23 493 burden of self-management.  
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3 497 **CONTRIBUTORS**  
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6 498 KM recruited participants, conducted interviews, analysed data, and wrote manuscript. LD & KB  
7  
8 499 contributed to study design and data analysis. KB and RB developed the digital intervention. PL &  
9  
10 500 RJM contributed to intervention development and interpretation of themes. CM & JR contributed to  
11  
12 501 theoretical and methodological implications of the study findings. LY contributed to study design,  
13  
14 502 data collection, data analysis, and interpretation.  
15  
16  
17 503 All authors contributed to the manuscript preparation and provided final approval of the version to  
18  
19 504 be published.  
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22  
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24

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26  
27 507 the design and conduct of the research.  
28

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31

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34  
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36  
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41 513 NIHR Oxford CLAHRC.  
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45 514• **COMPETING INTERESTS**  
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47  
48 515 RJM has received BP monitors for research purposes from Omron and Lloyds Pharmacies.  
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51 516• **ETHICS APPROVAL**  
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53 517• This qualitative process study was embedded in the HOME BP trial and approved by the University of  
54  
55 518 Southampton and NHS Hampshire A Research Ethics committees (REC Reference 15/SC/0082).  
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3 519 **DATA SHARING STATEMENT**  
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6 520 Requests for data sharing can be sent to the corresponding author. Full transcripts of interviews are  
7  
8 521 not available to protect participants' anonymity.  
9

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13 523 **Figure legend:**

14 524 Figure 1 Possible influences of illness and treatment beliefs on perceived burdens and benefits of the  
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16 525 intervention  
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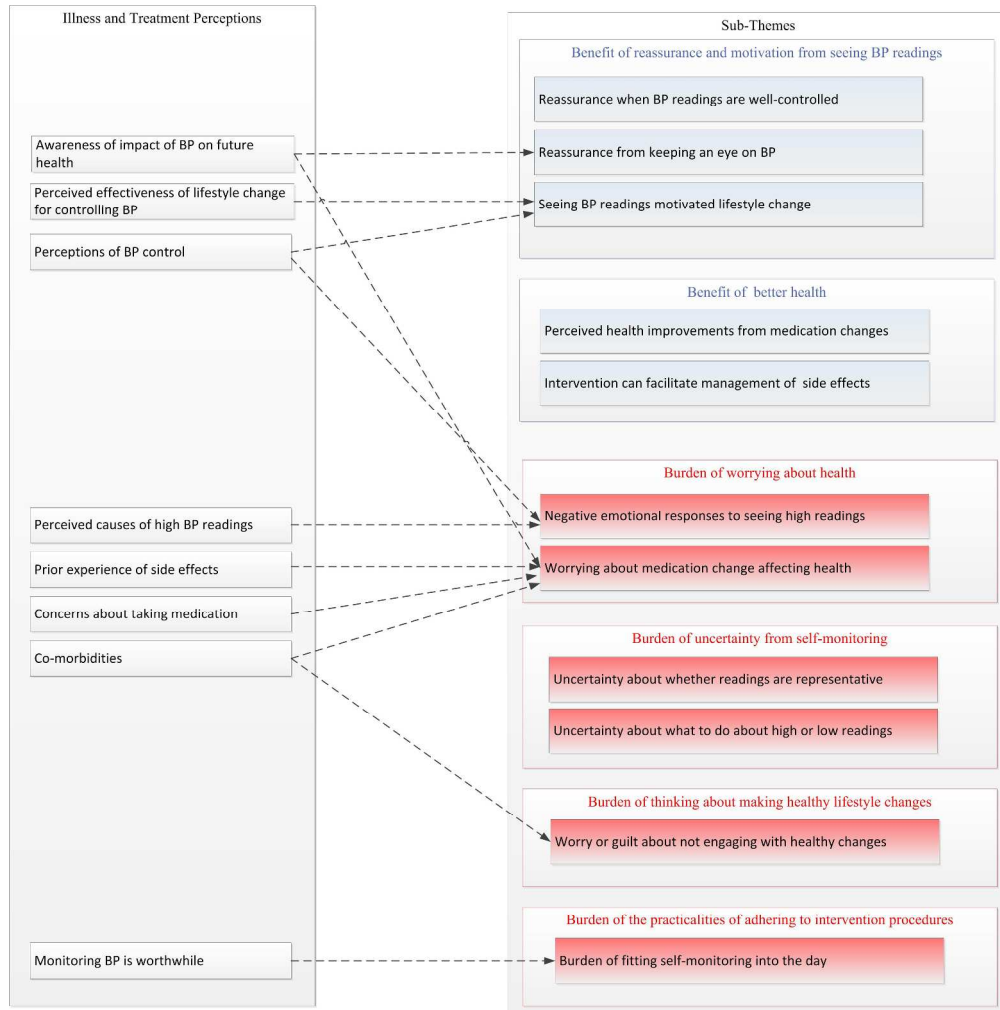


Figure 1. Possible influences of illness and treatment beliefs on perceived burdens and benefits of the intervention

337x340mm (300 x 300 DPI)

## Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

**YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE**

No. Item	Guide questions/description	Reported on Page #
<b>Domain 1: Research team and reflexivity</b>		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 9
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 9
3. Occupation	What was their occupation at the time of the study?	Page 9
4. Gender	Was the researcher male or female?	Page 9
5. Experience and training	What experience or training did the researcher have?	Page 9
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 9
<b>Domain 2: study design</b>		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 9
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 8
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 8

12. Sample size	How many participants were in the study?	Page 10
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Page 10
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 8
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 11
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 9
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 9
20. Field notes	Were field notes made during and/or after the interview or focus group?	Page 9
21. Duration	What was the duration of the inter views or focus group?	Page 11
22. Data saturation	Was data saturation discussed?	Page 9
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
<b>Domain 3: analysis and findings</b>		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Page 9
25. Description of the coding tree	Did authors provide a description of the coding tree?	Page 13
26. Derivation of themes	Were themes identified in advance or derived from the data?	Page 9-10
27. Software	What software, if applicable, was used to manage the data?	Page 10
28. Participant checking	Did participants provide feedback on the findings?	Page 26
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Throughout results
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

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4 **Once you have completed this checklist, please save a copy and upload it as part**  
5 **of your submission. When requested to do so as part of the upload process,**  
6 **please select the file type: *Checklist*. You will NOT be able to proceed with**  
7 **submission unless the checklist has been uploaded. Please DO NOT include this**  
8 **checklist as part of the main manuscript document. It must be uploaded as a**  
9 **separate file.**  
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For peer review only

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4 **Supplementary File 2. Interview schedules for intervention and usual care group**  
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6

7 Intervention group interview schedule  
8  
9

10 **Opening questions**  
11

12 Can you tell me about what it is like for you to have high blood pressure?  
13

14 How did you feel when you were first told you had high blood pressure?  
15

16 Can you tell me why you decided to sign up for the Home BP study?  
17

18 I'm really interested in hearing about your experiences of using HOME BP, can you tell me all about  
19 it?  
20  
21  
22

23 Can you tell me about anything that you have liked about the HOME BP study so far?  
24  
25

26 Can you tell me about anything that you have disliked?  
27  
28

29 Can you tell me about any advantages of using HOME BP?  
30  
31

32 And can you tell me about any disadvantages of using HOME BP?  
33  
34

35 How do you feel about your high blood pressure now?  
36  
37

38 Do you think you would choose to keep on using the HOME BP programme if it was still available  
39 after a year?  
40  
41  
42

43 Why/ Why not?  
44  
45  
46

47 Would you recommend the HOME BP programme to other people with high blood pressure?  
48  
49

50 **Self-monitoring**  
51

52 **Experiences of monitoring:**  
53

54 Can you tell me about what it was like when you were learning how to use your BP monitor at home?  
55  
56

57 Can you tell me about the first time you used your BP monitor at home in the study?  
58  
59  
60



1  
2  
3 Can you tell me about what it has been like to monitor your blood pressure yourself?  
4

5 How did it make you feel?  
6

7 Had you ever monitored your own blood pressure before you took part in the HOME BP study?  
8

9  
10 *If yes:*

11 Can you tell me a bit more about this?  
12

13 Can you tell me whether you've noticed any changes in how you monitor your blood  
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pressure since you've started the HOME BP programme?

All: Can you tell me about any concerns that you have about monitoring your blood pressure?

Adherence to the monitoring schedule:

The HOME BP programme reminds you to monitor your blood pressure for 7 days every 4 weeks.

Can you tell me about what it has been like for you to try and monitor your blood pressure for 7 days every 4 weeks?

Can you tell me about the time of day you have been monitoring your blood pressure so far?

How do you feel about the instructions HOME BP gives about when to monitor?

Was there anything that helped you to monitor your own blood pressure?

Was there anything that made it harder to monitor your own blood pressure?

Can you tell me about any time when you had to skip your blood pressure monitoring or change when you did it in the day?

Can you tell me how you found it entering your readings on the HOME BP programme?

1  
2  
3 Feedback messages  
4  
5

6 Remember after you enter your readings on HOME BP, you see a message which says 'your readings  
7 were amber, or green'? What did you think about these messages?  
8  
9

10  
11 Can you tell me about how you felt when you saw a message about your blood pressure readings on  
12 HOME BP?  
13  
14

15  
16 How did you feel about monitoring your own blood pressure after reading that message?  
17  
18

19  
20 Did you have any very high or very low readings (red/blue) when you were monitoring in the HOME  
21 BP study? How did you feel?  
22  
23  
24

25 **2. Medication change**  
26  
27

28 Can you tell me about what it's like for you taking medication for your high blood pressure?  
29  
30

31 Have you been recommended to make a medication change during the HOME BP study?  
32  
33

34 *If yes:*  
35  
36

37 How did you feel about making a change to your medication when HOME BP recommended  
38 it?  
39  
40

41  
42 Did you make this change to your medication?  
43  
44  
45

46 ***If they chose to make a change:***  
47  
48

49 Can you tell me about what it was like to make a medication change in the HOME BP study?  
50  
51

52 Can you tell me about how the medication change came about?  
53  
54

55 How did you get on with your new medication?  
56  
57

58 How would you feel if HOME BP recommended a medication change for you now?  
59  
60

1  
2  
3 ***If they chose not to make a change –***  
4

5  
6 Can you tell me about why you decided not to change your medication?  
7

8  
9 How would you feel if HOME BP recommended another medication change for you now?  
10

11  
12 ***If no:***  
13

14  
15 *If patient has **not** been recommended a med change:* How do you feel about changing your  
16 medication if your blood pressure stayed too high for too long?  
17

18  
19 Can you tell me about any concerns that you have about doing this?  
20

21  
22 ***All:***  
23

24  
25 How did you feel about making changes to your medication before you took part in HOME BP?  
26  
27

28  
29 **3. HCP support**  
30

31  
32 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP study?  
33

34  
35 Can you tell me about how you have found the support from your GP or nurse while you were taking  
36 part in the HOME BP study?  
37

38  
39 Can you tell me what you thought about receiving emails from your nurse about HOME BP?  
40

41  
42 If needed, follow-up questions:  
43

44  
45 Have you seen your GP about your blood pressure since the start of the study?  
46

47  
48 And what about appointments with the nurse?  
49

50  
51 Can you tell me about how you have found the emails from HOME BP?  
52

53  
54 **4. Healthy changes**  
55

56  
57 Can you tell me about anything else that you do to try and manage your high blood pressure?  
58  
59  
60

1  
2  
3 There is an option on the HOME BP programme to look at online sessions about making healthy  
4 changes that can help lower your blood pressure, I wonder if you remember if you have seen it?  
5  
6  
7

8 *If no:*  
9

10  
11 Can you tell about how you might feel about making healthy changes to help lower your blood  
12 pressure?  
13  
14

15  
16  
17 *If yes:*  
18

19  
20 Can you tell me about how you found the session on healthy changes?  
21

22  
23 How did you feel about making the healthy changes this session talked about?  
24

25  
26 *If they chose a change:* Can you tell me about what made you choose this/these ones?  
27

28  
29 How did you find the online session about xxxx (cutting down on salt/alcohol/eating a healthier  
30 diet/doing more physical activity/ losing weight)?  
31  
32

33  
34 Can you tell me about what it was like for you trying out this healthy change?  
35

36  
37 How did making a healthy change like this make you feel?  
38

39  
40 *Or if they didn't choose any:* Can you tell me about why you didn't want to choose a healthy change?  
41

42  
43 *All:* Can you tell me about any concerns that you have about making a new healthy change?  
44

45  
46 Is there anything else you would like to tell me about the HOME BP study that we haven't already  
47 talked about?  
48  
49  
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3 Usual care group interview schedule  
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6 General questions about BP  
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8  
9 Can you tell me about what it is like for you to have high blood pressure?  
10

11  
12 How did you feel when you were first told you had high blood pressure?  
13

14  
15 Can you talk me through what (if anything) you currently do to manage/control your high blood  
16  
17 pressure?  
18

19  
20 Can you tell me about how your GP and practice nurse are involved in helping you to control  
21  
22 your high blood pressure?  
23

24  
25 How do you feel about monitoring your own blood pressure at home?  
26

27  
28 If they already monitor – can you tell me a bit more about this?  
29

30  
31 Can you tell me about what it's like for you taking medication for your high blood pressure?  
32

33  
34 Can you tell me how you feel about your GP making changes to your blood pressure medication?  
35  
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37

38 HOME BP study experience  
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40  
41 Can you tell me why you signed up for the Home BP study?  
42

43  
44 Can you tell me all about what it has been like for you being in the HOME BP study in the usual  
45  
46 care group?  
47

48  
49 At the start of the HOME BP study, you had a baseline appointment with a nurse at your GP  
50  
51 Practice – can you tell me about that?  
52

53  
54 How did you find it using the HOME BP programme to fill in your questionnaires online at the  
55  
56 start of the study?  
57  
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3 After you had completed your questionnaires, did you have an appointment with your GP to  
4  
5 check your blood pressure medication? Can you tell me about this?  
6  
7

8 HCP support  
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10  
11 Can you tell me about the contact you have had with your GP or nurse so far in the HOME BP  
12  
13 study?  
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16  
17 Can you tell me about how you have found the support from your GP or nurse while you were  
18  
19 taking part in the HOME BP study?  
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