

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Mhealth – Using a Mindfulness App for women with chronic pelvic pain: Qualitative data analysis of user experience and lessons learnt

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030711
Article Type:	Research
Date Submitted by the Author:	15-Apr-2019
Complete List of Authors:	Ball, Elizabeth; Queen Mary University of London - Whitechapel Campus, Yvonne Carter Building Newton, Sian Rohricht, Frank ; East London NHS Foundation Trust Steed, Liz; Barts and The London School of Medicine and Dentistry, Centre for Primary Care and Public Health Birch, Judy; Pelvic Pain Support Network Dodds, Julie; Barts and The London School of Medicine and Dentistry, Women's Health Research Unit Cantalapiedra Calvete, Clara; Barts Health NHS Trust, United Kingdom, Department of Obstetrics and Gynaecology Taylor, Stephanie; Queen Mary University of London, Centre for Primary Care and Public Health Rivas, Carol; University College London
Keywords:	Chronic pelvic pain, mHealth, mindfulness, patient engagement, health app, feasibility study

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 **Mhealth – Using a Mindfulness App for women with chronic pelvic pain:**  
4 **Qualitative data analysis of user experience and lessons learnt**  
5

6 **Ball, Elizabeth**

7 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom,*  
8 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
9 *Queen Mary University of London, United Kingdom, Centre for Maternal and child Health*  
10 *Research, City University London*  
11

12 **Newton, Sian**

13 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
14 *Kingdom*  
15

16 **Rohricht, Frank**

17 *East London NHS Foundation Trust, United Kingdom*  
18

19 **Steed, Liz**

20 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
21 *Kingdom*  
22

23 **Birch, Judy**

24 *Pelvic Pain Support Network, UK*  
25

26 **Dodds, Julie**

27 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
28 *Queen Mary University of London, United Kingdom*  
29

30 **Cantalapiedra, Clara**

31 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom*  
32

33 **Taylor, Stephanie JC**

34 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
35 *Kingdom*  
36

37 **Rivas, Carol**

38 *Department of Social Science, University College London, United Kingdom*  
39

40 Corresponding author

41 Carol Rivas, Department of Social Science, University College London, United Kingdom

42 E-mail: c.rivas@ucl.ac.uk  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Abstract

### Objective

To determine whether a pre-existing smartphone App to teach Mindfulness Meditation is acceptable to women with chronic pelvic pain (CPP) and can be integrated into clinical practice within NHS CPP pathways. To inform the design of a potential randomised clinical trial.

### Design

A pre-study patient and public involvement (PPI) group to collect feedback on the acceptability of the existing app and study design was followed by a three-arm randomised feasibility trial. In addition, we undertook interviews and focus groups with patients and staff to explore app usability and acceptability.

### Setting

Two gynaecology clinics within Barts Health NHS, London, UK.

### Participants

Patients with CPP lasting  $\geq 6$  months with access to smartphone or PC and understanding of basic English.

### Intervention

The intervention was mindfulness meditation content plus additional pain module delivered by smartphone app, active controls received muscle relaxation content by the same app. Passive (waiting list) controls received usual care.

### Main outcome measures

Themes on user feedback, app usability and integration and reasons for using/not using the app.

### Results

App use was low in both active groups.

Patients in the pre-study PPI group, all volunteers, were enthusiastic about the app (convenience, content, portability, flexibility, ease of use). Women contributing to the interview or focus group data (n=14), from a 'real world' clinic, (some not regular app users) were less positive, citing as barriers lack of opportunities/motivation to use the app, and lack of familiarity

1  
2  
3 and capabilities with technology. Staff (n=7) were concerned about the potential need for extra  
4 support for patients and staff and considered the app needed organisational backing and peer  
5 acceptance.  
6  
7  
8  
9

## 10 **Conclusion**

11  
12 The opinions of pre-study PPI volunteers meeting in their private time may not represent that  
13 of patients recruited at a routine clinic appointment.  
14

15  
16 It may be more successful to co-design/co-develop an app with typical users than to adapt  
17 existing apps for use in real-world clinical populations.  
18  
19  
20  
21  
22

## 23 **Trial registration and funding**

24  
25 The trial (ISRCTN 10925965) was funded by the UK National Institute of Health Research,  
26 Research for Patient Benefit programme (RfPB PB-PG-1013-32025).  
27  
28  
29  
30

## 31 **Keywords**

32  
33 Chronic pelvic pain, mHealth, mindfulness, Headspace, PPI, patient engagement, feasibility  
34 study, health app  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### Article Summary; 'Strengths and limitations of this study' (relating to methods)

- The study was designed with the help of a study design group of CPP patients
- Recruitment to the study was good
- The qualitative analysis suggests low acceptability which has implications for evaluations of efficacy
- In depth interviews with participants give learning points for future apps, indicating apps co-designed with patients may be preferable for use within health care than modified commercial apps
- Participant feedback and recruitment showed that the research process per se was successful and can be used in the future.

The original protocol for the study has been published separately (1). The UK National Institute of Health Research supported this work (RfPB PB-PG-1013-32025). There are no competing interests.

### Introduction

Smartphone health apps, as one form of mhealth (2), are popular in the UK, our study setting, with more than two-thirds of the UK population using smartphones (3,4,5). Health apps are one of the fastest growing app categories, thus numbers of users are still increasing (6). Currently these apps are usually developed either by researchers or (in the majority) by commercial companies, without collaboration between these groups (7,8). The lack of interaction between researchers and commercial developers in the field of pain-related apps has led to a situation where commercially available apps have not been scientifically validated and apps that have been developed from research projects are not commercially available (9).

We were interested in using an app to support women with chronic pelvic pain (CPP) in a

1  
2  
3 clinical setting, where validation of an intervention is important to ensure best care. CPP is  
4 defined as a subjective physical and emotional experience of pain in the pelvic area that has  
5 been present for at least six months that may or may not have an identifiable pathology. CPP  
6 affects up to 24% of women worldwide (10) and accounts for 20% of gynaecological clinic  
7 referrals. (11,12) It has considerable impact on patients' quality of life and their income (13),  
8 and annual costs to the NHS have been estimated at approximately £326 million.(14) CPP is  
9 especially common in younger women, who may be categorised as digital natives, making an  
10 app-based intervention particularly appropriate. Despite costly interventions, CPP is often  
11 resistant to surgical and medical treatment and appears to respond better to a multimodal,  
12 holistic approach, (15) with a focus on coping strategies. Apps with such a focus have been  
13 shown to be beneficial in various conditions (16). As one example, evidence from uncontrolled  
14 trials (17,18) suggests positive effects of mindfulness meditation (MM) as a coping strategy in  
15 CPP. We therefore chose to evaluate MM delivered via an app to women with CPP as our  
16 intervention.

17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

Mindfulness meditation (MM) depends on activating the psychological state of mindfulness. This refers to an awareness that emerges by way of paying attention intentionally and non-judgementally, in the present moment, to the unfolding of the moment-by-moment experience. Generally two main complementary approaches have been used for mindfulness meditation 1) exercises focusing attention and 2) monitoring of experiences in the present moment. While systematic reviews show that mindfulness meditation may have positive effects on depression, quality of life and pain symptoms in patients with chronic pain (16,19,20) none of the reviewed papers included meditation delivered via mobile phone apps or women with CPP. Evaluation of an existing app is often appropriate (21) and is both quicker and more cost-effective than designing an app from scratch. We chose to evaluate an existing commercial app platform that teaches mindfulness by guided meditation (Headspace ®), with a ten day basic meditation module followed by a pain module specifically designed for MEMPHIS, the name we gave to the study. The Headspace app was publicly nominated favourite health app



1  
2  
3 of 2013,(22) has a 5 star user rating in the Apple™ app shop and has scored top in a  
4 systematic review (23) of 23 mindfulness apps using the Mobile Application Rating Scale  
5 (visual aesthetics, engagement, functionality or information quality). Headspace has  
6 reportedly seen over 15 million downloads up to mid-2018.(24)  
7  
8  
9  
10

11  
12 We undertook a feasibility study to assess whether or not to proceed with a full randomised  
13 controlled trial of a modified Headspace meditation app for women with CPP. In this paper we  
14 report on the qualitative interview and focus group data from this study; the protocol and  
15 quantitative results have been published/ submitted (1,25).  
16  
17  
18  
19  
20  
21  
22

### 23 **Methods**

24  
25 The MEMPHIS trial was a three-arm parallel randomised feasibility trial approved by Camden  
26 and Kings Cross Research Ethics Committee in 2016 (15/LO/1967). Objectives for the  
27 qualitative part of this study were to consider:  
28  
29  
30

- 31 1) The acceptability, use and usability of the app in the intended service user population and  
32 for health care professionals (doctors, health care assistants, clinical and research nurses)  
33  
34 2) The feasibility of integrating such an app into existing healthcare pathways.  
35  
36  
37  
38

### 39 **Patient and Public Involvement**

40  
41  
42 We held a Patient and Public Involvement (PPI) group workshop before the study to discuss  
43 acceptability of the Headspace app and help us design our study. Women attending the Royal  
44 London Hospital CPP clinic were invited to volunteer to use the unmodified Headspace app  
45 for a week and then feed back in an evening discussion group. Women were not involved in  
46 the design of the modified app. Two patient representatives provided support from the study  
47 design stage through recruitment to the interpretation of the results and regularly attended  
48 Trial Management Group meetings.  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58

### 59 **Study recruitment**

60

1  
2  
3 The trial recruited at two outpatient gynaecology clinics within Barts Health NHS trust in two  
4 separate deprived areas of inner East London. Female patients with new or follow-up  
5 gynaecology appointments were assessed for eligibility by a researcher in clinic, having been  
6 posted a Patient Information Sheet. Women were eligible if they had been suffering with CPP  
7 for 6 months or more and had at least a basic understanding of the English language. Women  
8 were excluded if they did not meet these criteria or they did not have access to a smartphone  
9 or personal computer or were currently using the Headspace app (there were very few of the  
10 latter). All patients gave full and informed consent to be randomised and data was collected  
11 through all stages of the study.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

23 For the study of quantitative data, 90 patients were allocated randomly in a 1:1:1 ratio to the  
24 mindfulness meditation app, a muscle relaxation app active control or the usual care arm.  
25 Patients in the two active arms were asked to download the modified app in the clinic with  
26 support from a research staff member and were sent a questionnaire about app usability, an  
27 analysis of which is reported in a companion paper. (25) We used these data to inform topic  
28 guides for the qualitative part of the study, i.e. our outlines of key issues and areas of  
29 questioning that were used to guide our semi-structured interviews and focus groups with  
30 patients and staff.  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42

### 43 **Interviews and focus groups**

44 All patients in the two active arms were invited to one of two focus groups at their own study  
45 site after the 6-month follow up. We offered telephone interviews as an alternative. All staff  
46 participating in the study were invited to attend a staff focus group overseen by the patient  
47 representative and facilitated by a researcher. Qualitative outcomes included feedback on  
48 app usability and acceptability. In addition, members of the staff focus group (doctors, health  
49 care assistants, clinical and research nurses) were asked about the ease of integration into  
50 existing NHS pathways. Part of the staff discussion was free flowing with open-ended  
51 questions, and part was structured using questions modified from the Normalisation Process  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 Theory (NPT) toolkit; NPT is a theory of implementation practices (26). Patients were also  
4 asked to 'walk through' the app with researchers and comment on its different specific  
5 features, (27) as well as feeding back on our study process. Walkthroughs are often used in  
6  
7 developing technologies such as mhealth; patients 'walked through' use of the app, articulating  
8 their thought processes while they did so (27). This helped to identify issues or barriers to use  
9  
10 of the app from the users' points of view without the need for technical discussions. Results  
11  
12 for the walkthrough, showing comments on different features specific to the usability of the  
13  
14 intervention app used in our study are shown in Appendix 1; walkthroughs were undertaken  
15  
16 by two patients. All data were audio-recorded at point of collection and transcribed, with  
17  
18 personal identifying data removed from transcripts. Raw data were stored in a Primary Care  
19  
20 Clinical Trial Unit database to clinical trial standards.  
21  
22  
23  
24  
25  
26  
27  
28

### 29 **Analysis**

30  
31 Analysis was carried out blinded as to which study app was used, and deployed the  
32  
33 immersion-crystallisation method (28). Thus, the lead qualitative researcher immersed herself  
34  
35 in the data, reading transcripts carefully, then writing down articulated or crystallised patterns  
36  
37 or themes that related to the aims and research questions of the study. These were discussed  
38  
39 with another researcher from the team, and themes modified as appropriate. This process  
40  
41 was repeated until all the data had been examined and all patterns that had been noticed were  
42  
43 articulated, discussed and substantiated with exemplar extracts. This approach was  
44  
45 considered appropriate since we had a small dataset and we were not aiming to develop  
46  
47 conceptual themes but rather to inform the design and development of a randomised  
48  
49 controlled trial for the modified app.  
50

51 We used the SRQR checklist when writing our report (29).  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Results

We screened 488 women between May and September 2016 for their eligibility to participate in the study. After exclusions, 90 women gave full consent to participate and were randomised to the intervention arm (31 women), the active control arm (30 women) or the usual care arm (29 women).

### Demographics

Women were aged a mean of 35 years, 66% were employed and overall approximately 50% had stayed in full time education until at least the age of 20 though the proportion was least, at 36.7% in the intervention arm. Overall 44% were of white ethnicity though the proportion was lowest in the intervention arm (35.7%) and highest in the usual care arm (53.6%). The second most common self-reported ethnic groups were 'Southern Asian' and 'Black'. Women in the intervention arm were most likely to have experienced CPP for 3-5 years (40.3% of this group), women in the usual care group for over 10 years (42.9% of this group). More women had pain for longer than two years in the intervention arm than in either of the other two arms. All women reported a high pain intensity, with means of 6.8 to 6.9 in the previous week (on a scale from 1-10). Other demographic data are reported in Forbes *et al.* (25) Our qualitative sample was taken from the two active arms but we did not record separate demographic data for the women in this smaller sample.

### ***Pre-study PPI group***

The ten women in the pre-study PPI group were self-selected local women who were familiar with using apps. They anticipated no technical issues even in women who were not used to apps. They considered that the Headspace app would be successfully adopted by patients taking part in the study, given that a smartphone, like CPP, is 'always with you'. They praised the flexibility of the app, welcomed its portability and were unanimous in saying it was easy to slip off for 10 minutes when at work to use it. As a result, they found they could use it at times when they most needed pain relief as well as to prevent pain and found the app helpful in relieving pain and stress. The group reported being able to meditate without the app, once they had tried it with the app; however, they still preferred to use the app because they found the voice soothing.

### ***App usage in the study***

Patient adherence to the app was less than expected from our pre-study PPI group discussions. (25) Only 36% of meditation app patients and 46% of the active control patients used the app at least once. (25)

### ***Thematic analysis***

Qualitative data were obtained from 14 patients; 12 preferred a telephone interview, two attended face-to-face interviews, one participant at the University attached to one of the recruiting clinics and one participant at the other recruiting hospital. Patients chose not to attend focus groups. Seven people attended the staff focus group: two recruiting nurses, three clinic nurses one consultant and a representative from the pelvic pain support network.

The qualitative analysis revealed three main themes from all participants combined (the analyst remained blind to app group) regarding usability, and four subthemes:

1. Familiarity and capabilities with app technology
2. Motivations to use the app
  - Perceived benefits

- Relation to other therapies
3. Opportunities to use the app:
- Technology issues getting in the way
  - Life getting in the way

These are explored below.

#### *Familiarity and capabilities with app technology*

Around half of the patients were sufficiently familiar with technology and apps to be comfortable using the study apps. However, six participants reported difficulty with them because they were “*not very good at technology*”, or were unsure how to get started or use the app effectively without help.

*I am not good with technical some things that is why the problems I had arisen, right okay. So I consulted with my daughter and she helped me work it out... so I don't try everything. (patient 1002)*

One patient (1001) was not used to technical app language; ‘help’ suggested emotional support to her, for example. Two more changed handsets and therefore did not continue with the app. In all cases these technical difficulties appeared to lead to abandoning of the app or restricted use of its functionality.

Five patients having technical problems suggested possible solutions such as a ‘class’ or group for first time users, a YouTube orientation video, or a pictorial leaflet. This might include an introduction to meditation and mindfulness as well as the app itself. One woman commented: “*If your market is targeting people who are not using apps then you are going to have to get together and find ways to do this*”, (patient 1041); she also suggested we could get ideas from other apps on the market in this regard.

1  
2  
3 Given their experiences in the study, staff were concerned about additional staff time needed  
4 to support women in using the app. This would sit in tension with one of the original rationales  
5 to support women in using the app. This would sit in tension with one of the original rationales  
6 behind choosing an app as the mode of delivery, which was to increase the effective use of  
7 staff contact time with patients. Language barriers might compound problems.  
8  
9  
10

### 11 12 13 14 15 *Motivations to use the app*

16 Staff, though unaware of the low sustained app use in the study, felt it would be common  
17 sense to hold occasional motivating meetings with patients if the intention was for them to use  
18 the app long term. The patient data suggested the main motivators or lack of motivation for  
19 using the app in our sample, which could be drawn on in such meetings, and which we now  
20 consider.  
21  
22  
23  
24  
25  
26  
27  
28  
29

### 30 31 Perceived benefits

32  
33 Three patients said they only entered the trial to help others through research but were already  
34 using alternative forms of pain control. They explained that this meant they were not motivated  
35 to actually use the app, perceiving the relative benefit to be small. The failure of such altruism  
36 to actually use the app, perceiving the relative benefit to be small. The failure of such altruism  
37 to extend to using the app is a recognised phenomenon in clinical trials that has been called  
38 'weak altruism'. (30) Thus, only one of these three patients persevered. Even though she was  
39 one of the women who experienced difficulties with the technology, she explained, "*with*  
40 *something that is as soul destroying as the pain, it is important to help others off the back of*  
41 *other people's misfortune as it were*" (1036). However, she wondered how relevant her data  
42 were:  
43  
44  
45  
46  
47  
48  
49  
50  
51

52  
53 *I took steps to improve my situation from a weight loss perspective as well and I've lost a lot*  
54 *of weight which has significantly helped not 100% but it is has significantly helped so I felt a*  
55 *bit fraudulent the last time filling in the forms because , so everything had improved so much*  
56  
57  
58  
59  
60

1  
2  
3 *so from the medical study perspective it was more about the weight loss than the app. So I*  
4 *felt a bit bad that I was still taking part. (patient 1036)*  
5  
6  
7

8 There was no clear pattern regarding the impact of current pain on app use by patients. Six  
9 said they used it regardless of pain intensity – sometimes developing a daily routine - while  
10 four only used it when in severe pain or expecting to be (e.g. during menstruation). This cyclical  
11 or intermittent use in some patients should be considered when looking at our study  
12 outcomes.(25) The Headspace app requires regular use to learn and benefit from  
13 psychological techniques. To address this, healthcare professional alerts have been effective  
14 in other studies, (31) whilst Headspace only has a reminder function that the user can set.  
15 This was often not sufficient, as one patient said even with this feature, *“To be quite honest I*  
16 *used it a couple of times and then forgot. And then I [remembered it and] used it more*  
17 *frequently.” (patient 1036)*  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

29 One patient said medication was not working but the app did, though she was not sure whether  
30 this was ‘mind over matter’ (1065), which was her term for a placebo effect. Three others said  
31 it did not reduce their pain. Other benefits were considered good reason for using the app  
32 even when participants did not feel that it reduced pain intensity. Alternative or unanticipated  
33 benefits were not formally measured or taken into account in the study’s effectiveness  
34 outcomes (25). For example, ten patients valued the way the app helped them to relax or de-  
35 stress or focus and re-assess their life; three of these specifically said they used it to induce a  
36 relaxed state to get to sleep. Notably the active control was a relaxation app, so it may be that  
37 most of the patients interviewed were in this study arm; we were blind to this. One participant  
38 said she did not like the focus on pain per se as her condition impacted on various areas of  
39 her life. Even when the app was positively received, women might stop using it because it was  
40 too powerful, and they had gained the change they wanted:  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54

55 *I think it was day 3, I could see the change that was happening, I was able to speak up for*  
56 *myself .....I can't explain it, even now I am getting emotional... it's just a lack of focus, I just*  
57 *needed direction. To try and put it into words. To me it meant so much that I have gone back*  
58  
59  
60



1  
2  
3 *to church... I use it outside of the app now I have got from it what was missing, so it's done*  
4 *something to me and for me which is very positive, and I may try it to lose weight but those*  
5 *positive vibes are still there. I can't go back to it because I did not want to go any further*  
6 *because what I got at the time helped me to focus, to change my way of thinking. I used it for*  
7 *about two or three weeks. (patient 1001)*  
8  
9  
10  
11  
12

13  
14 Three patients found the app put them more in tune with their bodies and their breathing, (two  
15 of these were among those who also found the app de-stressing) while another found yoga  
16 better for that. Six patients, like pre-study PPI group members, also learned to use techniques  
17 from the app to alter their stress patterns without the app, having tried it, for example in traffic  
18 or by sitting down and taking time out or for general relaxation. Four of these came from the  
19 group of ten patients that reported de-stressing as the app's main benefit, and it is not clear  
20 whether they had the intervention app or the active control.  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31

### 32 Relation to other therapies

33  
34 Two patients preferred 'pure' meditation. Another considered the app to be "*very much about*  
35 *meditation*". It may be that the former two were in the active control and the latter in the  
36 intervention arm. An alternative therapy practitioner and two further patients reported that they  
37 preferred yoga; one said this was because it focussed on each part of the body in turn.  
38  
39  
40  
41  
42

43 Three patients thought the app was useful as an adjunct to other methods rather than a  
44 replacement for them, for example physical interventions such as Pilates, or listening to  
45 classical music.  
46  
47  
48  
49

### 50 *Opportunities to use the app*

#### 51 Technology issues getting in the way

52  
53 Staff pointed out that not all patients had smartphones (not appreciating that PCs/tablets were  
54 alternatives allowed in this study). Some patients lacked the storage space to load the app on  
55 their phones. There were also issues with Wi-Fi connectivity when staff tried to help the  
56 patients load the app within the hospital sites. Possible solutions that staff suggested were to  
57  
58  
59  
60

1  
2  
3 lend patients phones and to have group upload sessions in a location with good Wi-Fi signal  
4  
5 – though they acknowledged the resource implications.  
6  
7  
8  
9

### 10 Life getting in the way

11  
12  
13 Seven patients revealed they preferred to use the app in the evenings because of other life  
14  
15 commitments. This meant they did not always use it as a direct response to pain, reducing its  
16  
17 potential for contemporaneous effect. One patient who used it in response to pain but only  
18  
19 used it once or twice blamed this on having no spare time because of juggling work and  
20  
21 children; however, another patient managed despite such commitments.  
22  
23

### 24 **Barriers to integration for staff**

25  
26  
27 Staff believed that the biggest barrier to clinical adoption of the app was a possible lack of  
28  
29 support from the host organisation. It might also be hard to integrate the app within existing  
30  
31 professional work practices if the staff in the position of offering the app to patients failed to  
32  
33 see its relative advantage over other interventions. Collection of feedback on the app's  
34  
35 effectiveness would be necessary for staff to support sustained use. It was felt that staff would  
36  
37 need training on how to introduce the app to women in practice, and that complexity and high  
38  
39 staff turnover could impede sustained use. An app was also seen as impersonal compared  
40  
41 with face-to-face contact, which was more favoured by staff.  
42  
43  
44  
45  
46

### 47 **Participant comments on the research process**

48  
49 The study questionnaires that were used for the main quantitative outcome measures (25)  
50  
51 were acceptable to patients except for some discomfort with a question about sex, which  
52  
53 patients considered a delicate question that was missing a 'no sex' option. Most preferred a  
54  
55 paper form reflecting their lack of affinity with technology. There were no indications that the  
56  
57 study design or study processes had contributed to the participants' lack of engagement with  
58  
59  
60

1  
2  
3 the apps. A full summary of patient comments on the study design and procedures is given  
4  
5 in Appendix 1.  
6  
7  
8  
9

## 10 **Discussion**

11 Our study adds to the limited evidence on mHealth app user behaviour and experience  
12 (32,33). We were able to explore reasons for low app usage in our feasibility study.(25) The  
13  
14 thematic analysis of qualitative data from this study suggests that the low app use in the trial  
15  
16 occurred because many patients were not familiar with apps in general or lacked capabilities  
17  
18 with technology. Women also stated limited motivation to use the app because of a lack of  
19  
20 perceived benefit, or a lack of opportunity to use the app due to Wi-Fi issues or due to other  
21  
22 commitments.  
23  
24  
25  
26  
27

28 Similar findings were reported by Laurie *et al.*(33) who interviewed 16 healthy city-dwelling  
29  
30 participants (25-38 years) about their user behaviour before and after 30-40 days of  
31  
32 Headspace app exposure. Like us, they reported barriers of busy lives, failure to establish a  
33  
34 routine and a lack of perceived benefit; all users in their study tried the app at least once  
35  
36 hoping it could deliver a quick fix but were disappointed if this did not happen. In our study  
37  
38 many patients failed to perceive a benefit from using the app. Hence excuses stating other  
39  
40 commitments may mask a deeper lack of motivation linked to perceptions of benefits.(34)  
41  
42  
43  
44

45 The advantages and disadvantages of using the app stand-alone were also illustrated by our  
46  
47 data. Some suggestions made by participants to improve usage, such as more guidance at  
48  
49 the start, seem obvious in hindsight. But they had not been considered because of the  
50  
51 feedback from the pre-study PPI group and the commercial success of Headspace. The use  
52  
53 of community contacts may be a helpful alternative.(35) Social support can create a  
54  
55 community of practice, help to clarify expectations,(36) and improve health outcomes (as  
56  
57 shown for example in internet based psychological treatment for depression (37).  
58  
59  
60

1  
2  
3 The data suggest that for successful app use we need to understand what motivates  
4 individuals with clinical need to use the app and target this, for example by setting appropriate  
5 expectations. Incentivisation might also improve motivation. This could be achieved through  
6 app gamification (8), or encouragement through integration with patient-clinician face-to-face  
7 encounters, which was lacking in our study since the app was used stand-alone. The present  
8 study provided extensive technical support but no coaching and incentivising, in keeping with  
9 the protocol. Future app studies should take this into account. Participants in our study may  
10 have also have benefitted from training and support to improve their app use capabilities and  
11 guidance on how to create more opportunities for app use – such as through sharing  
12 experiences in clinic support groups. This is in keeping with the COM-B model of behaviour  
13 change (38) which our themes matched, though this was only realised after analysis. The  
14 COM-B model says that Capability, Opportunity and Motivation are key drivers of behaviour  
15 and has been used to develop a number of complex interventions including smartphone apps  
16 (e.g. 4).

17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35 Lack of engagement after recruitment, or good initial engagement but minimal or inconsistent  
36 use, have been reported in other studies (39,40), including in Headspace trials other than our  
37 own (41, 42). Settings were a university and a psychiatric inpatients clinic, both in the USA.  
38 Inconsistent app use was noted by Wen (43) in junior doctors who used self-guided  
39 Headspace. Morrison Wylde (44) compared face-to-face MM with headspace use in novice  
40 paediatric nurses. Although, unlike our study there were no dropouts/non-users and also no  
41 record of whether or how long the app was used for which is an important omission.

42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52 None of these studies included a qualitative component. Yet, each of the Headspace study  
53 groups were very different, and so will likely have differed in motivations, contexts for  
54 opportunity to use the app, and incentivisations (45). While these aspects were not considered  
55 in the other studies, we have been able to do so. Our findings suggest these are important  
56 considerations in any study of app use and therefore this study makes a contribution to the  
57  
58  
59  
60

1  
2  
3 field. For example, some of the groups in other studies may have differed from ours in  
4 likelihood of using mhealth apps in the first place, and familiarity with technology. In-patients  
5 may have more time to use the app and more support – and may also have had specific  
6 barriers to app use, such as related to setting and to illness.  
7  
8  
9  
10

11  
12  
13 Patients in the qualitative part of our study tended not to use apps on a regular basis (or at  
14 least apps other than simple games), and in terms of our themes, also represented in the  
15 COM-B model, may be said to have few capabilities in technology use. They therefore do not  
16 represent the typical users of the Headspace app in a commercial setting. Accessing the app  
17 regularly requires energy, time and effort, but patients with CPP often suffer from fatigue and  
18 anxiety as co-morbidities, perhaps whilst having to juggle family life and work. Therefore, this  
19 may be seen as a challenging clinical population in which to trial an app. Further Headspace  
20 trials with diabetic (NCT03274362) and pain (NCT03495726) outpatients are underway.  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

31  
32 Our study has also shown that clear consideration of unexpected benefits should be included  
33 in future studies and these can be informed by our finding that benefits for patients may be  
34 more diffuse than anticipated (e.g. app relieving stress rather than pain). Though we were  
35 blind as to whether the patients we interviewed were in the active arm or the intervention arm  
36 of the study, there is indication from responses (especially in the patients who did a  
37 walkthrough) that many with these extra benefits were in the intervention arm. Our data also  
38 suggest that staff benefits may be less than anticipated, as participants sometimes needed a  
39 lot of support and scaffolding in technology use at least initially.  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50

51 Young age, co-morbid anxiety and low educational attainment are predictors for dropping out  
52 of web-based interventions according to studies in the field of depression. (46,47) This may  
53 be true despite regular phone support (47) though our participants all considered active  
54 motivational support from staff or app support groups would have improved app use. Our  
55  
56  
57  
58  
59  
60

1  
2  
3 intervention arm participants were particularly likely to be young and with low educational  
4 attainment.  
5  
6  
7  
8

9 Our data suggest that it is important to involve real world end users in the agile design or  
10 development or modification of apps in close collaboration with researchers and commercial  
11 app developers.(8) Although the evaluation of existing apps has been recommended as a  
12 cost-effective and rapid process, (21) our findings suggest that in actual clinical practice these  
13 may be problematic.  
14  
15  
16  
17  
18  
19  
20  
21

### 22 *Strengths and weaknesses of the study and in relation to other studies*

23 One strength of this study is that it creates much-needed evidence in the field of evaluating  
24 existing health apps in a clinic population (7,9,21) and recording user experience. This  
25 provides us with lessons to be learned.  
26  
27  
28  
29

30 Researchers conducting interviews and focus groups were: a senior mixed methods medical  
31 sociology researcher, a recruiting nurse, a representative from the pelvic pain support network  
32 and an experienced health psychologist. Findings were similar across the data and the  
33 different backgrounds of the researchers therefore does not appear to have influenced  
34 findings. The main analysis was undertaken by the medical sociologist and so the  
35 concordance with the COM-B model is not due to background discipline bias.  
36  
37  
38  
39  
40  
41  
42

43 We were able to recruit successfully, and we obtained valuable information from patients with  
44 CPP, who were recruited from a deprived urban area of the UK as typical local clinical patients.  
45 However we report a marked discrepancy between the attitudes of the pre-study PPI group of  
46 volunteer patients from the local area, who actively put themselves forward for a 7-day trial of  
47 the app, and the participants asked to take part when they attended clinics. The opinions of  
48 pre-study PPI volunteers meeting in their private time may not be representative of the  
49 opinions of patients recruited at a routine clinic appointment. Women in the PPI group were  
50 used to using apps, which had led them to be interested in the study in the first place. Whereas  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 women in the PPI group had all trialled the app at home and work without support from us,  
4 many patients from clinic were unable to use their phone beyond calls, texts and photos.  
5  
6  
7  
8

9 To our knowledge the present observation on failure of PPI work to translate into practice in a  
10 trial has not been formally reported before, and is lacking from a recent comprehensive  
11 systematic review.<sup>(48)</sup> PPI involvement is a stipulated requirement when applying for some  
12 funding, and the present research findings should be taken into account when drafting  
13 guidelines for future PPI involvement in study planning. PPI groups are able to provide  
14 significant help and advice in any study but our findings shows the value of adding agile co-  
15 development as a requirement for app intervention development as likely to provide a more  
16 effective intervention than one informed by PPI alone.  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

### 28 *Implications for clinicians and policymakers*

29 Given the patchy use of the app and the way that some participants did not manage to unlock  
30 its full functionality, and an indication of diffusion of benefit, more work is needed to see  
31 whether the app reduces pain per se. This study is a good example of the need to move away  
32 from 'one size fits all' behavioural interventions. Future studies should do more work on  
33 implementation before doing an effectiveness trial. This will enable researchers to be more  
34 nuanced about saying who the app is effective for, if at all.  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

46 Strategies to involve busy, less motivated, and less technologically experienced individuals in  
47 PPI and lay app design groups need to be further developed. These groups should include  
48 considerable scaffolding, which we have shown extends to study involvement by patients.  
49 More care is also needed to obtain PPI input that is representative of the study group with  
50 typical users of the target group, taking into account their capabilities, opportunities and  
51 motivational aspects. Moreover, we can confirm a recent review suggesting that health apps  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 should be co- designed with users (8), rather than presenting them with a pre-existing app.  
4  
5 These implications for our study are also generalisable to other technology studies.  
6  
7  
8

9  
10 Our study did not show the app was ineffective but rather that we could not show any possible  
11 effectiveness. Thus, further work is needed on MM app effectiveness in clinical subgroups  
12 such as our local users, bearing in mind also that diffuse benefits were found.  
13  
14  
15

## 16 17 18 **Research in context**

### 19 20 **What is known**

- 21  
22 1. Chronic pelvic pain has a large impact on patients and the NHS and is difficult  
23 to treat.
- 24  
25 2. Health outcomes are improved by psychological and lifestyle interventions but  
26 are often not addressed due to difficult access or service shortages.
- 27  
28 3. Mindfulness meditation has not been investigated in chronic pelvic pain  
29 patients but randomised controlled trials show improved health outcomes in  
30 other chronic pain conditions.
- 31  
32 4. Mhealth apps are increasingly popular.  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42

### 43 44 **What the study adds**

- 45  
46 1. A mindfulness meditation app may not necessarily be taken up by patients  
47 with CPP even when it is a commercial success in the general population.  
48 Considerable supportive scaffolding may be needed.
- 49  
50 2. Use of existing commercial apps in actual clinical practice may be problematic  
51 compared with the agile development of apps with collaboration between  
52 researchers, clinicians, developers and end users/  
53  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 3. Chronic Pain patients are interested in alternatives to drug or surgical  
4  
5 treatments and further research is required in this area, including with MM, the  
6  
7 benefits of which may extend beyond pain relief itself.  
8  
9  
10 4. PPI groups may be more motivated to use an intervention than a real world clinical  
11  
12 group as they are volunteers who are interested in the research topic. This may be  
13  
14 particularly problematic for interventions that require considerable capability or  
15  
16 motivation in use.  
17  
18  
19  
20

### 21 **Author contributions**

22 EB, CR, JB, JD, BK, ST, ES, FR, BK, SN and KK contributed to the study design and initial  
23  
24 protocol.

25 CC was a researcher and contributed to the study design

26 BK and GF provided statistical support and ran the statistical analysis.

27  
28 CR and LS led the interview and focus group field work and analysis. All authors provided  
29  
30 support throughout the trial and contributed towards the final paper.  
31  
32

### 33 **Role of the funding source**

34  
35 The UK National Institute of Health Research, Research for Patient Benefit (RfPB No. PB-  
36  
37 PG1013-32025) funded the MEMPHIS study. The funder had no role in the study design, in  
38  
39 the collection, analysis, and interpretation of the data, in the writing of this report, or in the  
40  
41 decision to submit the paper for publication. The first and last authors vouch for the integrity,  
42  
43 completeness and accuracy of the data and analyses, and for the fidelity of this report to the  
44  
45 protocol and statistical analysis plan. The views and opinions expressed herein are those of  
46  
47 the authors and do not necessarily reflect those of the RfPB, NIHR, NHS or the Department  
48  
49 of Health.

### 50 **Competing interests**

51 We have read and understood BMJ policy on declaration of interests.  
52  
53

### 54 **Data sharing**

55 No additional data available.  
56  
57

### 58 **Transparency**

59  
60

1  
2  
3 The lead author confirms that the manuscript is an honest, accurate and transparent account  
4 of the study being reported; that no important aspects of the study have been omitted; and  
5 that any discrepancies from the study as planned and registered have been explained.  
6  
7  
8

### 9 **Acknowledgements**

10  
11 We would like to thank all the researchers, consultant obstetricians and gynaecologists and  
12 data assistants at each of the recruiting clinics for their hard work in promoting the study,  
13 recruiting participants and for data entry. Our thanks go to the Trial Steering Committee;  
14 Andrew Horne, Sohinee Bhattacharya, Christina Lioffi, and Hulya Guzel for their constant  
15 support throughout the trial.  
16  
17  
18

19  
20 We thank the Pelvic Pain Support Network and Endometriosis UK for their promotion and  
21 guidance in developing the study design. We would also like to acknowledge the NIHR RfPB  
22 programme for their on-going support.  
23  
24

25 Lastly, thank you to Headspace Ltd for providing our participants with access to the  
26 Headspace platform, designing novel content for the study, and for their continuous support  
27 and advice throughout the study.  
28  
29  
30

### 31 **References**

- 32  
33  
34  
35  
36  
37 1. Ball E, Newton S, Kahan BC, Forbes G, Wright N, Cantalapiedra Calvete C, et al.  
38 Smartphone App Using Mindfulness Meditation for Women With Chronic Pelvic Pain  
39 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*. 2018;7(1):e8.  
40 2. Ali EE, Chew L, Yap KY. Evolution and current status of mhealth research: a systematic  
41 review. *BMJ Innovations* 2016;2:33-40  
42 3. Ofcom. The Communications Market Report. Ofcom: United Kingdom 2015.  
43 <https://www.ofcom.org.uk/research-and-data/multi-sector-research/cmr/cmr15/uk> [accessed  
44 21 March 2019]  
45 4. Kayyali R, Peletidi A, Ismail M, Hashim Z, Bandeira P, Bonnah J. Awareness and Use of  
46 mHealth Apps: A Study from England. *Pharmacy* 2017, 5, 33.  
47 5. Sezgin E, Yildirim S, Özkan-Yildirim S, Sumuer E. Current and Emerging mHealth  
48 Technologies: Adoption, Implementation, and Use: Springer International Publishing; 2018  
49 2018.  
50 6. Lunden I. 6.1B Smartphone Users Globally By 2020, Overtaking Basic Phone  
51 Subscriptions [https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-](https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015)  
52 [overtaking-basic-fixed-phone-subscriptions/?guccounter=12015](https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015) [cited 2018 28 August  
53 2018].  
54 7. Subhi Y, Bube SH, Rolskov Bojsen S, Skou Thomsen AS, Konge L. Expert Involvement  
55 and Adherence to Medical Evidence in Medical Mobile Phone Apps: A Systematic Review.  
56 *JMIR Mhealth Uhealth*. 2015;3(3):e79.  
57 8. Edwards EA, Lumsden J, Rivas C, et al. Gamification for health promotion: systematic  
58 review of behaviour change techniques in smartphone apps. *BMJ Open*.  
59 2016;6(10):e012447. doi:10.1136/bmjopen-2016-012447.  
60

- 1
- 2
- 3
- 4 9. de la Vega R, Miro J. mHealth: a strategic field without a solid scientific soul. a systematic
- 5 review of pain-related apps. *PLoS One*. 2014;9(7):e101312.
- 6 10. Latthe, P., Latthe, M., Say, L., Gülmezoglu, M., & Khan, K. S. (2006). WHO systematic
- 7 review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity. *BMC*
- 8 *public health*, 6, 177. doi:10.1186/1471-2458-6-177
- 9 11. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in
- 10 women: an epidemiological perspective. *Womens Health (Lond)*. 2015;11(6):851-64.
- 11 12. Howard F. The Role of Laparoscopy in Chronic Pelvic Pain: Promise and Pitfalls.
- 12 *Obstetrical & Gynecological Survey*. 1993;48(6):357-87.
- 13 13. Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al.
- 14 Chronic pelvic pain in the community--symptoms, investigations, and diagnoses. *Am J*
- 15 *Obstet Gynecol*. 2001;184(6):1149-55.
- 16 14. Curtis L. Unit Costs of Health and Social Care 2014 Personal Social Services Research
- 17 Unit, University of Kent, Canterbury.: University of Kent, Canterbury; 2014 [Available from:
- 18 <https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2014/>.
- 19 15. Peters AA, van Dorst E, Jellis B, van Zuuren E, Hermans J, Trimbos JB. A randomized
- 20 clinical trial to compare two different approaches in women with chronic pelvic pain. *Obstet*
- 21 *Gynecol*. 1991;77(5):740-4.
- 22 16. Ball EF, Nur Shafina Muhammad Sharizan E, Franklin G, Rogozinska E. Does
- 23 mindfulness meditation improve chronic pain? A systematic review. *Curr Opin Obstet*
- 24 *Gynecol*. 2017;29(6):359-66.
- 25 17. Kold M, Hansen T, Vedsted-Hansen H, Forman A. Mindfulness-based psychological
- 26 intervention for coping with pain in endometriosis. *Nordic Psychology*. 2012;64(1):2-16.
- 27 18. Fox SD FE, Allen RH. Mindfulness meditation for women with chronic pelvic pain: a pilot
- 28 study. *J Reprod Med* 2011;56(3-4):158-62.
- 29 19. Plaza I, Demarzo MM, Herrera-Mercadal P, Garcia-Campayo J. Mindfulness-based
- 30 mobile applications: literature review and analysis of current features. *JMIR Mhealth*
- 31 *Uhealth*. 2013;1(2):e24.
- 32 20. Hilton L, Hempel S, Ewing BA, Apaydin E, Xenakis L, Newberry S, et al. Mindfulness
- 33 Meditation for Chronic Pain: Systematic Review and Meta-analysis. *Ann Behav Med*.
- 34 2017;51(2):199-213.
- 35 21. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S. Evaluating
- 36 and selecting mobile health apps: strategies for healthcare providers and healthcare
- 37 organizations. *Transl Behav Med*. 2014;4(4):363-71.
- 38 22. My Health Apps [Available from: [http://myhealthapps.net/app/details/127/Headspace-on-](http://myhealthapps.net/app/details/127/Headspace-on-the-go)
- 39 [the-go](http://myhealthapps.net/app/details/127/Headspace-on-the-go)] (Accessed 28 August 2018).
- 40 23. Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and Evaluation of Mindfulness-
- 41 Based iPhone Apps. *JMIR Mhealth Uhealth*. 2015;3(3):e82.
- 42 24. App Annie 2018 [Available from: <https://www.appannie.com/en/>] (Accessed 28 August
- 43 2018).
- 44 25. Forbes G, Newton S, Cantalapiedra C, Birch J, Dodds J, Steed E, Rivas C, Khan KS,
- 45 Rohricht F, Taylor SJC, Kahan B, Ball E. A smartphone app using psychological
- 46 approaches for women with chronic pelvic pain (MEMPHIS): a randomised feasibility trial.
- 47 submitted
- 48 26. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation
- 49 process theory: a framework for developing, evaluating and implementing complex
- 50 interventions. *BMC Med*. 2010;8:63.
- 51 27. Gerhardt?Powals J. Cognitive engineering principles for enhancing human?computer
- 52 performance. *International Journal of Human-Computer Interaction*. 1996;8(2):189-211.
- 53 28. Borkan J. Immersion/Crystallization. In BF Crabtree and WL Miller (Eds) *Doing*
- 54 *Qualitative Research* (2nd edition). Thousand Oaks, CA: Sage Publication; 1999. p. pp. 179-
- 55 94.
- 56 29. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting
- 57 qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245-1251.
- 58
- 59
- 60

- 1  
2  
3 30. McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating in  
4 randomised controlled trials: conditional altruism and considerations for self. *Trials*, 11, 31.  
5 doi:10.1186/1745-6215-11-31
- 6 31. Palmer, M., Sutherland, J., Barnard, S., Wynne, A., Rezel, E., Doel, A., Grigsby-Duffy,  
7 L., Edwards, S., Russell, S., Hotopf, E., Perel, P., ... Free, C. (2018). The effectiveness of  
8 smoking cessation, physical activity/diet and alcohol reduction interventions delivered by  
9 mobile phones for the prevention of non-communicable diseases: A systematic review of  
10 randomised controlled trials. *PloS one*, 13(1), e0189801. doi:10.1371/journal.pone.0189801
- 11 32. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D.  
12 The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. *JMIR*  
13 *Mhealth Uhealth*. 2018;6(1):e23.
- 14 33. Laurie J, Blandford A. Making time for mindfulness. *Int J Med Inform*. 2016;96:38-50.
- 15 34. Collins M, Shattell M, Thomas SP. Problematic Interviewee Behaviors in Qualitative  
16 Research. *Western Journal of Nursing Research*. 2016;27(2):188-99.
- 17 35. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The  
18 behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building  
19 an international consensus for the reporting of behavior change interventions. *Ann Behav*  
20 *Med*. 2013;46(1):81-95.
- 21 36. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing human  
22 support to enhance adherence to eHealth interventions. *J Med Internet Res*. 2011;13(1):e30.
- 23 37. Andersson G. Using the Internet to provide cognitive behaviour therapy. *Behav Res*  
24 *Ther*. 2009;47(3):175-80.
- 25 38. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for  
26 characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42.
- 27 39. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth Intervention Using  
28 a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot Study. *JMIR*  
29 *Mhealth Uhealth*. 2016;4(3):e109. Published 2016 Sep 22. doi:10.2196/mhealth.5227
- 30 40. Geraghty AW, Torres LD, Leykin Y, Perez-Stable EJ, Munoz RF. Understanding attrition  
31 from international Internet health interventions: a step towards global eHealth. *Health Promot*  
32 *Int*. 2013;28(3):442-52.
- 33 41. Mistler LA, Ben-Zeev D, Carpenter-Song E, Brunette MF, Friedman MJ. Mobile  
34 Mindfulness Intervention on an Acute Psychiatric Unit: Feasibility and Acceptability Study.  
35 *JMIR Ment Health*. 2017;4(3):e34.
- 36 42. Noone C, Hogan MJ. A randomised active-controlled trial to examine the effects of an  
37 online mindfulness intervention on executive control, critical thinking and key thinking  
38 dispositions in a university student sample. *BMC Psychol*. 2018;6(1):13.
- 39 43. Wen L, Sweeney TE, Welton L, Trockel M, Katznelson L. Encouraging Mindfulness in  
40 Medical House Staff via Smartphone App: A Pilot Study. *Acad Psychiatry*. 2017;41(5):646-  
41 50.
- 42 44. Morrison Wylde C, Mahrer NE, Meyer RML, Gold JI. Mindfulness for Novice Pediatric  
43 Nurses: Smartphone Application Versus Traditional Intervention. *J Pediatr Nurs*.  
44 2017;36:205-12.
- 45 45. Lim D, Condon P, DeSteno D. Mindfulness and compassion: an examination of  
46 mechanism and scalability. *PLoS One*. 2015;10(2):e0118221.
- 47 46. Arean PA, Hallgren KA, Jordan JT, Gazzaley A, Atkins DC, Heagerty PJ, et al. The Use  
48 and Effectiveness of Mobile Apps for Depression: Results From a Fully Remote Clinical  
49 Trial. *J Med Internet Res*. 2016;18(12):e330.
- 50 47. Gilbody S, Lewis H, Adamson J, Atherton K, Bailey D, Birtwistle J, et al. Effect of  
51 Collaborative Care vs Usual Care on Depressive Symptoms in Older Adults With  
52 Subthreshold Depression: The CASPER Randomized Clinical Trial. *JAMA*. 2017;317(7):728-  
53 37.
- 54 48. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A  
55 systematic review of the impact of patient and public involvement on service users,  
56 researchers and communities. *Patient*. 2014;7(4):387-95.
- 57  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

## APPENDIX 1

Feature	Positive aspects	Negative aspects	Solutions
<b>Voice</b>	Liked by some participants, considered soothing and even spiritual	<p>The voice was not relaxing. One had to listen carefully which meant you could not switch off; otherwise you could not hear instruction clearly during meditation.</p> <p>It was also too repetitive, after 10 times it felt like a chore and not something to look forward to.</p>	<p>Choice of different voices</p> <p>participants should be told it takes time to get into the rhythm of the instructions, but you can get used to it</p>
<b>General interface aesthetics</b>	colours really fresh, interface not too busy, with pleasing layout and aesthetics	one participant would prefer different, bright, colours such as purple	None needed
<b>Graphics</b>		<p>The pictures were often not appropriate as they focused on the problem (e.g. tooth pain logo) rather than something positive or soothing. Unanticipated problems could arise according to one participant; she found it hard to lose weight and felt the food icons a) did not represent success and b) reminded her of eating.</p> <p>One participant found the pictures hard to see.</p>	Psychological theory supports the view that positive images would be advisable



<b>Animations</b>	liked	poorly chosen	None needed
<b>Progress</b>	<p>One participant liked the way the app helped progress through the stages.</p> <p>Another participant, with cyclical pain and hence cyclical use, did not aim to progress but simply chose to use the baseline video each time.</p>	<p>Three participants were frustrated and even 'angry' and 'patronised' at having to do the same (basic) meditation several times before moving up a stage.</p> <p>There was no indication of goals, duration of each level or gamification rewards.</p>	<p>Goal setting is recommended by psychological theory and could be as simple as using "day 1 of 30" rather than simply Day 1.</p> <p>Changing emojis could show progress, for example from a sad face to a smiley face to a heart; the inbuilt progress function was not felt sufficiently motivating.</p>
<b>Introduction</b>		Experienced app users suggested the introduction could be improved for initiates	<p>overview of the entire app and its levels suggested for the start.</p> <p>One participant had done mindfulness before but thought an introduction to mindfulness might be helpful for others.</p>
<b>Enjoyment</b>	considered fun by some participants.	One said it was not very 'interesting'.	<p>Include examples of a patient's day with the app to cater for a greater variety of participants</p> <p>It would be good to have other features as drop down options that were fun and</p>

			did not involve meditation.
<b>Session intensity</b>		Would be good to choose the duration of the meditation.	15 or 20 mins would be better than 10, which is not enough time shut off and meditate deeply.  The option to control this was important as even 10 minutes was a difficult commitment for some busy participants (1074, 1075, 1078) or those battling with chronic fatigue (1074)
<b>Pain modules</b>		it can be hard to focus on something like using the app when you are in pain.	None needed

**Comments on app acceptability and usability made by n=13 patients. Two patients walked through the app with the researcher**



# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	6
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4 and 5
Purpose or research question	#4 Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The	7

rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

1			
2			
3			
4			
5			
6			
7			
8			
9			
10	Researcher characteristics	#6	19
11	and reflexivity		
12			
13			
14			
15			
16			
17			
18			
19			
20	Context	#7	7
21			
22	Sampling strategy	#8	7
23			
24			
25			
26			
27	Ethical issues pertaining	#9	6
28	to human subjects		
29			
30			
31			
32			
33	Data collection methods	#10	7
34			
35			
36			
37			
38			
39			
40			
41	Data collection	#11	8
42	instruments and		
43	technologies		
44			
45			
46	Units of study	#12	See note
47			1
48			
49			
50			
51	Data processing	#13	8
52			
53			
54			
55			
56			
57			
58	Data analysis	#14	8
59			
60			

		developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	
1			
2			
3			
4	Techniques to enhance trustworthiness	#15 Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
5			
6			
7			
8			
9	Syntheses and interpretation	#16 Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-16
10			
11			
12			
13			
14	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	See note 2
15			
16			
17			
18	Intergration with prior work, implications, transferability and contribution(s) to the field	#18 Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	16
19			
20			
21			
22			
23			
24			
25			
26	Limitations	#19 Trustworthiness and limitations of findings	19
27			
28			
29	Conflicts of interest	#20 Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	4
30			
31			
32			
33	Funding	#21 Sources of funding and other support; role of funders in data collection, interpretation and reporting	3
34			
35			
36			

## Author notes

1. 7,8,9 and especially 10
2. 8-16 and appendix

The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist was completed on 26. March 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in gynaecology outpatient clinics: Qualitative data analysis of user experience and lessons learnt

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030711.R1
Article Type:	Original research
Date Submitted by the Author:	26-Sep-2019
Complete List of Authors:	Ball, Elizabeth; Queen Mary University of London - Whitechapel Campus, Yvonne Carter Building Newton, Sian; QMUL Rohricht, Frank ; East London NHS Foundation Trust Steed, Liz; QMUL Birch, Judy Dodds, Julie; QMUL, Women'shealth Research Unit Cantalapiedra Calvete, Clara; QMUL, Women's Health Research Unit Taylor, Stephanie; QMUL, Center for Primary Care and Population Health Rivas, Carol; University College London
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Health informatics
Keywords:	Chronic pelvic pain, mHealth, mindfulness, patient engagement, health app, feasibility study

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 **Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in**  
4 **gynaecology outpatient clinics: Qualitative data analysis of user experience and**  
5 **lessons learnt**  
6

7 **Ball, Elizabeth**

8 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom,*  
9 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
10 *Queen Mary University of London, United Kingdom, Centre for Maternal and child Health*  
11 *Research, City University London*  
12

13 **Newton, Sian**

14 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
15 *Kingdom*  
16

17 **Rohricht, Frank**

18 *East London NHS Foundation Trust, United Kingdom*  
19

20 **Steed, Liz**

21 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
22 *Kingdom*  
23

24 **Birch, Judy**

25 *Pelvic Pain Support Network, UK*  
26

27 **Dodds, Julie**

28 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
29 *Queen Mary University of London, United Kingdom*  
30

31 **Cantalapiedra Calvete, Clara**

32 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom*  
33

34 **Taylor, Stephanie JC**

35 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
36 *Kingdom*  
37

38 **Rivas, Carol**

39 *Department of Social Science, University College London, United Kingdom*  
40

41 Corresponding author

42 Carol Rivas, Department of Social Science, University College London, United Kingdom  
43 E-mail: c.rivas@ucl.ac.uk  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Abstract

### Objective

To determine whether a pre-existing smartphone App to teach Mindfulness Meditation is acceptable to women with chronic pelvic pain (CPP) and can be integrated into clinical practice within NHS CPP pathways. To inform the design of a potential randomised clinical trial.

### Design

A pre-study patient and public involvement (PPI) group to collect feedback on the acceptability of the existing app and study design was followed by a three-arm randomised feasibility trial. In addition, we undertook interviews and focus groups with patients and staff to explore app usability and acceptability. We also obtained participant comments on the research process, such as acceptability of the study questionnaires.

### Setting

Two gynaecology clinics within Barts Health NHS, London, UK.

### Participants

Patients with CPP lasting  $\geq 6$  months with access to smartphone or PC and understanding of basic English.

### Intervention

The intervention was mindfulness meditation content plus additional pain module delivered by smartphone app, active controls received muscle relaxation content by the same app. Passive (waiting list) controls received usual care.

### Main outcome measures

Themes on user feedback, app usability and integration and reasons for using/not using the app.

### Results

App use was low in both active groups.

Patients in the pre-study PPI group, all volunteers, were enthusiastic about the app (convenience, content, portability, flexibility, ease of use). Women contributing to the

1  
2  
3 interview or focus group data (n=14), from a 'real world' clinic, (some not regular app users)  
4  
5 were less positive, citing as barriers lack of opportunities/motivation to use the app, and lack  
6  
7 of familiarity and capabilities with technology. Staff (n=7) were concerned about the potential  
8  
9 need for extra support for patients and staff and considered the app needed organisational  
10  
11 backing and peer acceptance.  
12  
13

### 14 **Conclusion**

15  
16 The opinions of pre-study PPI volunteers meeting in their private time may not represent  
17  
18 those of patients recruited at a routine clinic appointment.  
19

20  
21 It may be more successful to co-design/co-develop an app with typical users than to adapt  
22  
23 existing apps for use in real-world clinical populations.  
24  
25

### 26 **Trial registration and funding**

27  
28 The trial (ISRCTN 10925965) was funded by the UK National Institute of Health Research,  
29  
30 Research for Patient Benefit programme (RfPB PB-PG-1013-32025).  
31  
32

### 33 **Keywords**

34  
35  
36  
37 Chronic pelvic pain, mHealth, mindfulness, Headspace, PPI, patient engagement, feasibility  
38  
39 study, health app  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60



### Article Summary; 'Strengths and limitations of this study' (relating to methods)

- The study was designed with the help of a study design group of CPP patients
- Recruitment to the study was good
- The qualitative analysis suggests low acceptability which has implications for evaluations of efficacy
- In depth interviews with participants give learning points for future apps, indicating apps co-designed with patients may be preferable for use within health care than modified commercial apps
- Participant feedback and recruitment showed that the research process per se was successful and can be used in the future.

The original protocol for the study has been published separately. The UK National Institute of Health Research supported this work (RfPB PB-PG-1013-32025). There are no competing interests.

### Introduction

Smartphone health apps, as one form of mhealth (1), are popular in the UK, our study setting. With more than two-thirds of the UK population using smartphones (2,3,4), health apps are one of the fastest growing app categories, thus numbers of users are still increasing (5). Currently these apps are usually developed either by researchers or (in the majority) by commercial companies, without collaboration between these groups (6,7). The lack of interaction between researchers and commercial developers in the field of pain-related apps has led to a situation where commercially available apps have not been scientifically validated and apps that have been developed from research projects are not commercially available (8).

1  
2  
3 We were interested in using an app to support women with chronic pelvic pain (CPP) in a  
4 clinical setting, where validation of an intervention is important to ensure best care. CPP is  
5 defined as a subjective physical and emotional experience of pain in the pelvic area that has  
6 been present for at least six months that may or may not have an identifiable pathology (9).  
7  
8 CPP affects up to 24% of women worldwide (10) and accounts for 20% of gynaecological  
9 clinic referrals. (11,12) It has considerable impact on patients' quality of life, including their  
10 mental health and their income (13) due to loss of working days and diminished work  
11 capacity. Annual costs to the NHS have been estimated at approximately £326 million (14).  
12  
13 For endometriosis alone, which is just one cause of CPP, a European study of over 900  
14 women showed average annual total costs per woman of €9579. Costs of productivity loss of  
15 €6298 were double the health care costs of €3113 per woman. The latter were due to  
16 surgery (29%), monitoring tests (19%) and hospitalization (18%) and physician visits (16%)  
17 (15).  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30  
31 Despite costly interventions, CPP is often resistant to surgical and medical treatment and  
32 appears to respond better to a multimodal, holistic approach, (16) with a focus on coping  
33 strategies. A systematic review of randomised controlled trials (RCTs) by authors has  
34 identified mindfulness meditation (MM) as an effective coping strategy in other chronic pain  
35 conditions (17). In addition, evidence from uncontrolled trials suggests positive effects of MM  
36 for CPP, such as an increased ability to control pain, improvements in mental health,  
37 emotional well-being, work and family life and social functioning (18,19), but these have  
38 never been examined in an RCT.  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 We therefore chose to evaluate MM delivered via an app to women with CPP as our  
50 intervention. CPP is especially common in younger women, who may be categorised as  
51 digital natives, making an app-based intervention particularly appropriate in this group.  
52  
53  
54  
55

56 In MM the aim is to keep focussed on one's own breathing. Whenever attention wanders to  
57 intrusive thoughts and feelings these are simply taken notice of in a neutral way, that is,  
58  
59  
60

1  
2  
3 without elaboration or judgements or consideration of action. They are then let go as  
4  
5 attention is returned to the breath. The idea is to bring awareness back to the here and now  
6  
7 whenever worries and troubles intrude into thoughts.(20)  
8  
9

10 Generally two main complementary approaches have been used for MM: 1) exercises  
11  
12 focusing one's attention to the present moment, and 2) monitoring of experiences in the  
13  
14 present moment. While systematic reviews show that MM may have positive effects on  
15  
16 depression, quality of life and pain symptoms in patients with chronic pain (17,21,22) and  
17  
18 apps with such a focus on chronic disease have been shown to be beneficial in various  
19  
20 conditions (23) none of the reviewed papers included meditation delivered via mobile phone  
21  
22 apps or in women with CPP.  
23  
24  
25  
26  
27  
28

29 Evaluation of an existing app is often appropriate (24) and is both quicker and more cost-  
30  
31 effective than designing an app from scratch. We chose to evaluate an existing commercial  
32  
33 app platform that teaches mindfulness by guided meditation (Headspace ®), with a ten day  
34  
35 basic meditation module followed by a pain module specifically designed for the MEMPHIS  
36  
37 (Mindfulness meditation using a smart-phone application for women with chronic pelvic pain)  
38  
39 study. The Headspace app was publicly nominated favourite health app of 2013,(25) has a 5  
40  
41 star user rating in the Apple™ app shop and has scored top in a systematic review of 23  
42  
43 mindfulness apps using the Mobile Application Rating Scale (visual aesthetics, engagement,  
44  
45 functionality or information quality) (26). Headspace had reportedly seen over 15 million  
46  
47 downloads up to mid-2018 when our study began.(27) To our knowledge the Headspace  
48  
49 app in its original or modified form has not been assessed in any other pain conditions.  
50  
51

52 We undertook a feasibility study (28) to assess whether or not to proceed with a full  
53  
54 randomised controlled trial of the modified Headspace meditation app for women with CPP.  
55  
56 In the current paper we report on the qualitative interview and focus group data from this  
57  
58 study; the protocol and quantitative results have been published/ submitted (29,30). Our aim  
59  
60

1  
2  
3 in this analysis was to determine whether a pre-existing smartphone app to teach MM is  
4 acceptable to women with CPP and can be integrated into clinical practice within NHS CPP  
5 pathways.  
6  
7  
8  
9

## 10 11 **Methods**

12 The MEMPHIS trial was a three-arm parallel randomised feasibility trial approved by  
13 Camden and Kings Cross Research Ethics Committee in 2016 (15/LO/1967). The  
14 quantitative analysis is published in a companion paper (29); the present paper reports the  
15 qualitative analysis.  
16  
17  
18  
19  
20  
21

22 Objectives for the qualitative part of this study, using interviews and focus groups were to  
23 consider:  
24

- 25 1) The acceptability, use and usability of the app in the intended service user population  
26 and for health care professionals (doctors, health care assistants, clinical and research  
27 nurses).  
28  
29  
30  
31
- 32 2) The feasibility of integrating such an app into existing healthcare pathways.  
33
- 34 3) Feedback on the research process.  
35  
36

37 We follow the ISO 9241-11 (<https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-2:v1:en>)  
38 concept of technology usability (user friendliness) as the extent to which the app could be  
39 satisfactorily used by participants to meditate. By acceptability we mean whether  
40 participants could see a reason for using the app when given in clinic, and would be happy  
41 to use it for meditation.  
42  
43  
44  
45  
46  
47

## 48 **Outcomes**

49  
50  
51 The outcomes of this analysis were inductively derived descriptive themes on acceptability,  
52 use and usability of the app and feasibility of integrating it into existing pathways.  
53  
54  
55  
56

## 57 **Intervention Procedures**

58  
59  
60

1  
2  
3 Women in the mindfulness meditation group received access to a 60-day progressive  
4 mindfulness meditation course delivered via the Headspace app. The first 10 days of the  
5 course taught basics of mindfulness meditation. Following this, participants were able to  
6 access the module on meditation which was targeted at for chronic pain. This module had  
7 been specifically made for this study. Session length was 10 minutes for the first 10 days, 15  
8 min up to day 20 and 20 min up to day 60. The active control group received access to a  
9 series of muscle relaxation sessions. These sessions were identical every day, except that  
10 their duration increased to mirror the increasing duration of the meditation content being  
11 listened to by the intervention group. Usage data are reported elsewhere (30).  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

### 23 **Patient and Public Involvement**

24  
25  
26 We held a Patient and Public Involvement (PPI) group workshop before the study to discuss  
27 acceptability of the Headspace app and help us design our study. Women attending the  
28 Royal London Hospital CPP clinic were invited to volunteer for a week of using the  
29 unmodified (normal commercially available) Headspace app (which did not have the pain  
30 module at the time we undertook our pre study workshop) and then feed back on their  
31 experiences with the app in an evening discussion group. Women were not involved in the  
32 design of the modified app. The focus for the PPI group was on the use of the generic MM  
33 app.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43

44 Two patient representatives provided support from the study design stage through  
45 recruitment to the interpretation of the results and regularly attended Trial Management  
46 Group meetings.  
47  
48  
49  
50  
51  
52  
53

### 54 **Study recruitment and eligibility**

55  
56 The trial recruited at two outpatient gynaecology clinics within Barts Health NHS trust in two  
57 separate deprived areas of inner East London. Female patients with new or follow-up  
58  
59  
60

1  
2  
3 gynaecology appointments were assessed for eligibility by a researcher in clinic, having  
4 been posted a Patient Information Sheet. Women were eligible if they had been suffering  
5 with CPP for 6 months or more and had at least a basic understanding of the English  
6 language, sufficient to follow instructions, as assessed during discussion about the study for  
7 informed consent; no women were excluded on this basis. Women were excluded if they did  
8 not meet these criteria or they did not have access to a smartphone or personal computer or  
9 were currently using the Headspace app (there were very few of the latter, according to the  
10 impression of the recruiting nurses). All patients gave full and informed consent to be  
11 randomised and data were collected through all stages of the study. All healthcare  
12 professionals and research nurses involved in the two clinics were also invited to take part in  
13 the feasibility study as the only eligibility criterion for staff. Full enrolment data are provided  
14 in Forbes et al (30). A key difference of these patients from those in the PPI group was that  
15 their focus was on managing their pain, with the app given explicitly as part of their clinic  
16 management support.

17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35 For the study of quantitative data, 90 patients were allocated randomly in a 1:1:1 ratio to the  
36 mindfulness meditation app, a muscle relaxation app active control or the usual care arm (for  
37 full details see (29)). Patients in the two active arms were asked to download the modified  
38 app in the clinic with support from a research staff member and were sent a questionnaire  
39 about app usability, an analysis of which is reported in a companion paper.(30) We used  
40 data from the app usability questionnaire to inform topic guides for the qualitative part of the  
41 study. This outlined key usability issues that had been uncovered, to guide our semi-  
42 structured interviews and focus groups with patients and staff.

43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54 All women in the intervention and active control arms were eligible for the qualitative  
55 component of the study, and all staff participating in the study.

### 56 57 58 59 60 **Within-study interviews and focus groups**

1  
2  
3 All patients in the intervention and active control arms were invited to one of two focus  
4 groups at their own study site after the 6-month follow up. We offered telephone interviews  
5 as an alternative. Patients were asked to 'walk through' the app with researchers, articulating  
6 their thought processes while they did so and commenting on its different specific features,  
7  
8 (31). Walkthroughs are often used in developing technologies such as mhealth. This helped  
9 to identify app usability issues or barriers to use of the app from the users' points of view  
10 without the need for technical discussions. Results for the walkthrough, showing comments  
11 on different features specific to the usability of the intervention app used in our study are  
12 shown in Appendix 1; walkthroughs were undertaken by two patients. Patients also  
13 discussed with us their experiences around app usability and acceptability.  
14  
15

16  
17  
18 Staff were invited to attend a staff focus group overseen by the patient representative and  
19 facilitated by a researcher. In addition to considering app usability and acceptability,  
20 members of the staff focus group (consultants, health care assistants, clinical and research  
21 nurses and a representative from the pelvic pain support network were eligible) were asked  
22 about the ease of integration into existing NHS pathways. Part of the staff discussion was  
23 free flowing with open-ended questions, which gave us patient-focussed information on app  
24 acceptability, and part was structured using questions developed from the Normalisation  
25 Process Theory (NPT) toolkit in the way recommended by the NPT developers (32). For  
26 example, we asked whether staff could see a purpose to the app in clinical practice, as  
27 adding something different, which corresponds to the NPT toolkit question 'Participants  
28 distinguish the intervention from current ways of working'. Since this was a semi-structured  
29 approach questions were not rigidly worded. This helped us to consider the feasibility of  
30 integration of the app into practice. NPT is a theory of implementation practices that was  
31 initially developed for consideration of technology implementation and is in common use  
32  
33 (32).  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 All data were audio-recorded at point of collection and transcribed, with personal identifying  
4 data removed from transcripts. Raw data were stored in a Primary Care Clinical Trial Unit  
5 database to clinical trial standards.  
6  
7  
8  
9

## 10 11 **Analysis**

12  
13 Analysis of within-study focus groups and interviews was carried out blinded as to which  
14 study app was used, and deployed the immersion-crystallisation method (33). Thus, the lead  
15 qualitative researcher immersed herself in the data, reading transcripts carefully, then writing  
16 down articulated or crystallised patterns or themes that related to the aims and research  
17 questions of the study. These were discussed with another researcher from the team, and  
18 themes modified as appropriate. This process was repeated until all the data had been  
19 examined and all patterns that had been noticed were articulated, discussed and  
20 substantiated with exemplar extracts. This approach was considered appropriate since we  
21 had a small dataset and we were not aiming to develop conceptual themes but rather to  
22 inform the design and development of a randomised controlled trial for the modified app.  
23 We used the SRQR checklist when writing our report (34).  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38

## 39 **Results**

40  
41 We screened 488 women between May and September 2016 for their eligibility to participate  
42 in the study. After exclusions, 90 women gave full consent to participate and were  
43 randomised to the intervention arm (31 women), the active control arm (30 women) or the  
44 usual care arm (29 women).  
45  
46  
47  
48  
49  
50

## 51 **Demographics**

52  
53 Women in the main feasibility trial (30) were aged a mean of 35 years, 66% were employed  
54 and overall approximately 50% had stayed in full time education until at least the age of 20  
55 though the proportion was least, at 36.7% in the intervention arm. Overall 44% were of white  
56  
57  
58  
59  
60



1  
2  
3 ethnicity though the proportion was lowest in the intervention arm (35.7%) and highest in the  
4 usual care arm (53.6%). The second most common self-reported ethnic groups were  
5 'Southern Asian' and 'Black'. Women in the intervention arm were most likely to have  
6 experienced CPP for 3-5 years (40.3% of this group), women in the usual care group for  
7 over 10 years (42.9% of this group). More women had pain for longer than two years in the  
8 intervention arm than in either of the other two arms. All women reported a high pain  
9 intensity, with means of 6.8 to 6.9 in the previous week (on a scale from 1-10) (30). These  
10 and other demographic data are reported in more detail in Forbes *et al.* (30) Our qualitative  
11 sample was taken from the two active arms and was comprised of 16% of trial participants  
12 and 23% of those eligible for the qualitative study. We did not record separate demographic  
13 data for the women in this smaller sample.  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### ***Pre-study PPI group***

The ten women in the pre-study PPI group were self-selected local women who were familiar with using apps and focused on app use per se. They anticipated no technical issues even in women who were not used to apps. They considered that the Headspace app would be successfully adopted by patients taking part in the study, given that a smartphone, like CPP, is 'always with you'. They praised the flexibility of the app, welcomed its portability and were unanimous in saying it was easy to slip off for 10 minutes when at work to use it. As a result, they found they could use it at times when they most needed pain relief as well as to prevent pain and found the app helpful in relieving pain and stress. The group reported being able to meditate without the app, once they had tried it with the app; however, they still preferred to use the app because they found the voice soothing.

### ***App usage in the study***

Patient usage of the app was less than expected from our pre-study PPI group discussions. Only 36% of meditation app patients and 46% of the active control patients used the app at least once. (30)

### ***Thematic analysis of within-study data***

Qualitative data were obtained from 14 study patients; 12 preferred a telephone interview, two attended face-to-face interviews, one participant at the University attached to one of the recruiting clinics and one participant at the other recruiting hospital. Patients chose not to attend focus groups. Four of the patients were from the active control arm and 10 from the intervention arm. The two women we met face to face had both used the intervention and neither had progressed beyond the training stage, something that we cannot discount for other participants and which may help to explain reports of lack of effect on pain. Seven people attended the staff focus group: two recruiting nurses, three clinic nurses one consultant and a representative from the pelvic pain support network.

1  
2  
3 The qualitative analysis revealed three main themes from all within-study interviews and  
4 focus groups combined regarding usability, and four subthemes:  
5  
6  
7

- 8 1. Familiarity and capabilities with app technology
- 9 2. Motivations to use the app
- 10     ○ Perceived benefits
- 11     ○ Relation to other therapies
- 12 3. Opportunities to use the app:
- 13     ○ Technology issues getting in the way
- 14     ○ Life getting in the way
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22

23 These are explored below. As the PPI group data were not research data we did not  
24 analyse them for themes.  
25

26 While we initially combined active control and intervention groups in our analysis, we then  
27 looked for instances where there was a difference between these two groups. Only where  
28 we found this difference in any theme or statement have we specified which group women  
29 belonged to.  
30

### 31 *Familiarity and capabilities with app technology*

32 Around half of the patients were sufficiently familiar with technology and apps to be  
33 comfortable using the study apps. However, six participants (all using the intervention, which  
34 was more complex than the active control) reported difficulty because they were “*not very*  
35 *good at technology*” (patient 1002, intervention), or were unsure how to get started or use  
36 the app effectively without help.  
37

38 *I am not good with technical some things that is why the problems I had arisen, right*  
39 *okay. So I consulted with my daughter and she helped me work it out... so I don't try*  
40 *everything. (patient 1002, intervention)*  
41

42 One further patient (1001, intervention) was not used to technical app language; ‘help’  
43 suggested emotional support to her, for example. Two more (one intervention, one active  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 control) changed handsets and therefore did not continue with the app. In all cases these  
4 technical difficulties appeared to lead to abandoning of the app or restricted use of its  
5 functionality.  
6  
7  
8  
9

10 Five patients having technical problems suggested possible solutions such as a 'class' or  
11 group for first time users, a YouTube orientation video, or a pictorial leaflet. This might  
12 include an introduction to meditation and mindfulness as well as the app itself. One woman  
13 commented: *"If your market is targeting people who are not using apps then you are going to*  
14 *have to get together and find ways to do this"*, (patient 1041, intervention); she also  
15 suggested we could get ideas from other apps on the market in this regard.  
16  
17  
18  
19  
20  
21  
22

23 Given their experiences in the study, staff were concerned about additional staff time needed  
24 to support women in using the app. This would sit in tension with one of the original  
25 rationales behind choosing an app as the mode of delivery, which was to increase the  
26 effective use of staff contact time with patients. Language barriers might compound  
27 problems.  
28  
29  
30  
31  
32  
33  
34  
35  
36

### 37 *Motivations to use the app*

38 Staff, though unaware of the low sustained app use in the study, felt it would be common  
39 sense to hold occasional motivating meetings with patients if the intention was for them to  
40 use the app long term. The patient data suggested the main motivators or lack of motivation  
41 for using the app in our sample, which could be drawn on in such meetings, and which we  
42 now consider.  
43  
44  
45  
46  
47  
48  
49  
50  
51

### 52 Perceived benefits

53 Three intervention arm patients said they only entered the trial to help others through  
54 research but were already using alternative forms of pain control. They explained that this  
55 meant they were not motivated to actually use the app, perceiving the relative benefit to be  
56  
57  
58  
59  
60

1  
2  
3 small. The failure of such altruism to extend to using the app is a recognised phenomenon in  
4 clinical trials and has been called ‘weak altruism’. (35) Thus, only one of these three patients  
5 persevered. Even though she was one of the women who experienced difficulties with the  
6 technology, she explained, “*with something that is as soul destroying as the pain, it is*  
7 *important to help others off the back of other people's misfortune as it were*” (1036,  
8 intervention). However, she wondered how relevant her data were:  
9  
10  
11  
12  
13  
14

15  
16 *I took steps to improve my situation from a weight loss perspective as well and I've lost a lot*  
17 *of weight which has significantly helped not 100% but it is has significantly helped so I felt a*  
18 *bit fraudulent the last time filling in the forms because , so everything had improved so much*  
19 *so from the medical study perspective it was more about the weight loss than the app. So I*  
20 *felt a bit bad that I was still taking part. (patient 1036)*  
21  
22  
23  
24  
25  
26  
27

28 There was no clear pattern regarding the impact of current pain on app use by patients. Six  
29 said they used it regardless of pain intensity – sometimes developing a daily routine – while  
30 four only used it when in severe pain or expecting to be (e.g. during menstruation). This  
31 cyclical or intermittent use in some patients – which was irrespective of study arm - should  
32 be considered when looking at our main study outcomes.(30) The Headspace app requires  
33 regular use to learn and benefit from psychological techniques. To address this, healthcare  
34 professional alerts have been effective in other studies, (36) whilst Headspace only has a  
35 reminder function that the user can set. This was often not sufficient, as one patient said  
36 even with this feature, “*To be quite honest I used it a couple of times and then forgot. And*  
37 *then I [remembered it and] used it more frequently.*” (patient 1036, intervention)  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 One patient said medication was not working but the app did, though she was not sure  
50 whether this was ‘*mind over matter*’ (1065, intervention), which was her term for a placebo  
51 effect. Three others said it did not reduce their pain; all three were using the intervention  
52 app. The remaining patients considered other benefits were good reason for using the app  
53 even when they did not feel that it reduced pain intensity. Alternative or unanticipated  
54 benefits were not formally measured or taken into account in the study’s effectiveness  
55  
56  
57  
58  
59  
60

1  
2  
3 outcomes (30). For example, ten patients valued the way the app helped them to relax or de-  
4 stress or focus and re-assess their life; three of these specifically said they used it to induce  
5 a relaxed state to get to sleep. Notably the active control was a relaxation app; however this  
6 benefit was also reported by many women in the intervention arm. One participant (active  
7 control) said she did not like the focus on pain per se as her condition impacted on various  
8 areas of her life. Even when the intervention app was positively received, women might stop  
9 using it because it was too powerful, and they had gained the change they wanted:  
10  
11  
12  
13  
14  
15  
16  
17

18 *I think it was day 3, I could see the change that was happening, I was able to speak up for*  
19 *myself .....I can't explain it, even now I am getting emotional... it's just a lack of focus, I just*  
20 *needed direction. To try and put it into words. To me it meant so much that I have gone back*  
21 *to church... I use it outside of the app now I have got from it what was missing, so it's done*  
22 *something to me and for me which is very positive, and I may try it to lose weight but those*  
23 *positive vibes are still there. I can't go back to it because I did not want to go any further*  
24 *because what I got at the time helped me to focus, to change my way of thinking. I used it for*  
25 *about two or three weeks. (patient 1001, intervention)*  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35

36 Three intervention app patients found the app put them more in tune with their bodies and  
37 their breathing, (two of these were among those who also found the app de-stressing) while  
38 another found yoga better for that. Six patients, like pre-study PPI group members, also  
39 learned to use techniques from the app to alter their stress patterns without the app, having  
40 tried it, for example in traffic or by sitting down and taking time out or for general relaxation.  
41  
42  
43  
44  
45  
46  
47  
48  
49

#### 50 Relation to other therapies

51 Two patients (both active control) preferred 'pure' meditation, another considered the app to  
52 be "very much about meditation" (1041, intervention), which is in keeping with the arms they  
53 were in. An alternative therapy practitioner and two further patients reported that they  
54 preferred yoga. One (active control) said this was because it focussed on each part of the  
55 body in turn.  
56  
57  
58  
59  
60

1  
2  
3 Three intervention app patients thought the app was useful as an adjunct to other methods  
4 rather than a replacement for them, for example physical interventions such as Pilates, or  
5 listening to classical music.  
6  
7  
8

9  
10 *Opportunities to use the app*

11  
12 Technology issues getting in the way

13 Staff pointed out that not all patients had smartphones (not appreciating that PCs/tablets  
14 were alternatives allowed in this study). Some patients lacked the storage space to load the  
15 app on their phones. There were also issues with Wi-Fi connectivity when staff tried to help  
16 the patients load the app within the hospital sites. Possible solutions that staff suggested  
17 were to lend patients phones and to have group upload sessions in a location with good Wi-  
18 Fi signal – though they acknowledged the resource implications.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30 Life getting in the way

31  
32 Seven patients revealed they preferred to use the app in the evenings because of other life  
33 commitments. This meant they did not always use it as a direct response to pain, reducing  
34 its potential for contemporaneous effect. One patient who used it in response to pain but  
35 only used it once or twice blamed this on having no spare time because of juggling work and  
36 children (active control); however, another patient (intervention) managed despite such  
37 commitments the fact that she was in the intervention arm may have played a role.  
38  
39  
40  
41  
42  
43  
44  
45

46 **Barriers to integration for staff**

47  
48 Staff believed that the biggest barrier to clinical adoption of the app was a possible lack of  
49 support from the host organisation. It might also be hard to integrate the app within existing  
50 professional work practices if the staff in the position of offering the app to patients failed to  
51 see its relative advantage over other interventions. Collection of feedback on the app's  
52 effectiveness would be necessary for staff to support sustained use. It was felt that staff  
53 would need training on how to introduce the app to women in practice, and that complexity  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 and high staff turnover could impede sustained use. An app was also seen as impersonal  
4 compared with face-to-face contact, which was more favoured by staff.  
5  
6  
7  
8  
9

### 10 **Participant comments on the research process**

11  
12 The study questionnaires that were used for the main quantitative outcome measures (30)  
13 were acceptable to patients except for some discomfort with a question about sex, which  
14 patients considered a delicate question that was missing a 'no sex' option. Most preferred a  
15 paper form reflecting their lack of affinity with technology. There were no indications that the  
16 study design or study processes had contributed to the participants' lack of engagement with  
17 the apps – with a caveat around support with the technology as mentioned above - though  
18 we did not systematically consider this. A full summary of patient comments on the study  
19 design and procedures is given in Appendix 1.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

### 31 **Discussion**

32  
33 Our study adds to the limited evidence on mHealth app user behaviour and experience  
34 (36,37). The pre-study PPI group (young women, of a generation who were familiar with  
35 using apps and who were asked to focus on the study design use of the app) liked the idea  
36 of delivering the intervention via an app, praising the contemporary design and flexibility.  
37 Hence we expected a similar positive attitude from trial participants, who were of a  
38 comparable age, and we assumed would be keen on using apps. Participant feedback  
39 revealed that this assumption was too simplistic.  
40  
41  
42  
43  
44  
45  
46  
47

48 Using our qualitative data, we were able to explore reasons for low app usage that had been  
49 recorded in our feasibility study.(30) Our thematic analysis suggests that the low app use in  
50 the trial occurred because many patients were not familiar with apps in general or lacked  
51 capabilities with technology. This was particularly true for the more complex intervention  
52 app. The other themes we report did not differ between groups (although the three cases of  
53 weak altruism' all occurred in the intervention arm) which suggests more generic issues that  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 can be transferable to other app use situations. For example, women stated limited  
4 motivation to use the app because of a lack of perceived benefit, or a lack of opportunity to  
5 use the app due to Wi-Fi issues or due to other commitments.  
6  
7  
8  
9

10  
11 Similar findings were reported by Laurie *et al.*(38) who interviewed 16 healthy city-dwelling  
12 participants (25-38 years) about their user behaviour before and after 30-40 days of  
13 Headspace app exposure. Like us, they reported barriers of busy lives, failure to establish a  
14 routine and a lack of perceived benefit; all users in their study tried the app at least once  
15 hoping it could deliver a quick fix but were disappointed if this did not happen. In our study  
16 many patients failed to perceive a benefit from using the app. Hence excuses stating other  
17 commitments may mask a deeper lack of motivation linked to perceptions of benefits.(39)  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

28 The advantages and disadvantages of using the app stand-alone were also illustrated by our  
29 data. Some suggestions made by participants to improve usage, such as more guidance at  
30 the start, seem obvious in hindsight. But they had not been considered because of the  
31 feedback from the pre-study PPI group and the commercial success of Headspace. The use  
32 of community contacts may be a helpful alternative.(40) Social support can create a  
33 community of practice, help to clarify expectations,(41) and improve health outcomes (as  
34 shown for example in internet based psychological treatment for depression (42).  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

45 The data suggest that for successful app use we need to understand what motivates  
46 individuals with clinical need to use the app for clinical reasons (which our PPI group did not  
47 focus on) and target this, for example by setting appropriate expectations. Incentivisation  
48 might also improve motivation. This could be achieved through app gamification (7), or  
49 encouragement through integration with patient-clinician face-to-face encounters, which was  
50 lacking in our study since the app was used stand-alone. The present study provided  
51 extensive initial technical support but no coaching and incentivising, in keeping with the  
52 protocol. Future app studies should take this into account. Participants in our study may  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 have also have benefitted from training and support to improve their app use capabilities and  
4 guidance on how to create more opportunities for app use – such as through sharing  
5 experiences in clinic support groups. This is in keeping with the COM-B model of behaviour  
6 change (43) which our themes matched, though this was only realised after analysis. The  
7 COM-B model says that Capability, Opportunity and Motivation are key drivers of behaviour  
8 and has been used to develop a number of complex interventions including smartphone  
9 apps (e.g. 3).

10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20 Lack of engagement after recruitment, or good initial engagement but minimal or  
21 inconsistent use, have been reported in other studies (44,45), including in Headspace trials  
22 other than our own (46, 47). Settings were a university and a psychiatric inpatients clinic,  
23 both in the USA. Inconsistent app use was noted by Wen (48) in junior doctors who used  
24 self-guided Headspace. Morrison Wylde (49) compared face-to-face MM with headspace  
25 use in novice paediatric nurses. However, unlike our study there were no recorded  
26 dropouts/non-users and also no record of whether or how long the app was used for which is  
27 an important omission.

28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39 None of these studies included a qualitative component. Yet, each of the Headspace study  
40 groups were very different, and so will likely have differed in motivations, contexts for  
41 opportunity to use the app, and incentivisations (50). While these aspects were not  
42 considered in the other studies, our use of qualitative research has enabled us to explore  
43 these in more depth. Our findings suggest these are important considerations in any study  
44 of app use and therefore this study makes a contribution to the field. For example, some of  
45 the groups in other studies may have differed from ours in likelihood of using mhealth apps  
46 in the first place, and familiarity with technology. In-patients may have more time to use the  
47 app and more support – and may also have had specific barriers to app use, such as related  
48 to setting and to illness.

1  
2  
3 Patients in the qualitative part of our study tended not to use apps on a regular basis (or at  
4 least apps other than simple games), and in terms of our themes, also represented in the  
5 COM-B model, may be said to have few capabilities in technology use. They therefore do  
6 not represent the typical users of the Headspace app in a commercial setting. Accessing the  
7 app regularly requires energy, time and effort, but patients with CPP often suffer from fatigue  
8 and anxiety as co-morbidities, perhaps whilst having to juggle family life and work.

9  
10 Therefore, this may be seen as a challenging clinical population in which to trial an app.  
11  
12 Further Headspace trials with diabetic (NCT03274362) and pain (NCT03495726) outpatients  
13 are underway.  
14  
15

16  
17 Our study has also shown that clear consideration of unexpected benefits should be  
18 included in future studies and these can be informed by our finding that benefits for patients  
19 may be more diffuse than anticipated (e.g. app relieving stress rather than pain). Such  
20 benefits were found in the active control as well as the intervention arm and so it may be that  
21 they represent a placebo effect though the effect could equally be real. Our data also  
22 suggest that staff benefits may be less than anticipated, as participants sometimes needed a  
23 lot of support and scaffolding in technology use at least initially.  
24  
25

26  
27 Young age, co-morbid anxiety and low educational attainment are predictors for dropping out  
28 of web-based interventions according to studies in the field of depression. (51, 52) This may  
29 be true despite regular phone support (52) though our participants all considered active  
30 motivational support from staff or app support groups would have improved app use. Our  
31 intervention arm participants were particularly likely to be young and with low educational  
32 attainment.  
33  
34

35  
36 Our data suggest that it is important to involve real world end users in the agile design or  
37 development or modification of apps in close collaboration with researchers and commercial  
38 app developers.(7) Although the evaluation of existing apps has been recommended as a  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 cost-effective and rapid process, (24) our findings suggest that in actual clinical practice  
4 these may be problematic.  
5  
6  
7  
8

9 *Strengths and weaknesses of the study and in relation to other studies*

10  
11 One strength of this study is that it creates much-needed evidence in the field of evaluating  
12 existing health apps in a clinic population (6,8,24) and recording user experience. This  
13 provides us with lessons to be learned.  
14  
15  
16

17  
18 Researchers conducting interviews and focus groups were: a senior mixed methods medical  
19 sociology researcher, a recruiting nurse, a representative from the pelvic pain support  
20 network and an experienced health psychologist. Findings were similar across the data and  
21 the different backgrounds of the researchers therefore does not appear to have influenced  
22 findings. The main analysis was undertaken by the medical sociologist and so the  
23 concordance with the COM-B model is not due to background discipline bias.  
24  
25  
26  
27  
28  
29

30 We were able to recruit successfully, and we obtained valuable information from patients  
31 with CPP, who were recruited from a deprived urban area of the UK as typical local clinical  
32 patients.  
33  
34  
35

36  
37 However, we report a marked discrepancy between the attitudes of the pre-study PPI group  
38 of volunteer patients from the local area, who actively put themselves forward for a 7-day  
39 trial of the app, and the participants asked to take part when they attended clinics. The  
40 opinions of pre-study PPI volunteers meeting in their private time may not be representative  
41 of the opinions of patients recruited at a routine clinic appointment. Women in the PPI group  
42 were used to using apps, which had led them to be interested in the study in the first place.  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
Whereas women in the PPI group had all trialled the app at home and work without support  
from us, many patients from clinic were unable to use their phone beyond calls, texts and  
photos. Moreover, most of the women we interviewed used the intervention app. We can  
only speculate as to why this is so but it does mean that concordances and divergences  
across the intervention and active control arm do need to be treated with circumspection.

1  
2  
3 To our knowledge the present observation on failure of PPI work to translate into practice in  
4 a trial has not been formally reported before, and is lacking from a recent comprehensive  
5 systematic review.(53) PPI involvement is a stipulated requirement when applying for some  
6 funding, and the present research findings should be taken into account when drafting  
7 guidelines for future PPI involvement in study planning. PPI groups are able to provide  
8 significant help and advice in any study but our findings shows the value of adding agile co-  
9 development as a requirement for app intervention development as likely to provide a more  
10 effective intervention than one informed by PPI alone. Moreover, there is a difference  
11 between app use for active clinical management (as with our study participants), and  
12 consideration of the potential for app use for this (as with our PPI group).  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

### 26 *Implications for clinicians and policymakers*

27  
28 Given the patchy use of the app and the way that some participants did not manage to  
29 unlock its full functionality, and an indication of diffusion of benefit, more work is needed to  
30 see whether the app reduces pain per se. This study is a good example of the need to move  
31 away from 'one size fits all' behavioural interventions. Future studies should do more work  
32 on implementation before doing an effectiveness trial. This will enable researchers to be  
33 more nuanced about saying who the app is effective for, if at all.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43

44 Strategies to involve busy, less motivated, and less technologically experienced individuals  
45 in PPI and lay app design groups need to be further developed. These groups should  
46 include considerable scaffolding, which we have shown extends to study involvement by  
47 patients. More care is also needed to obtain PPI input that is representative of the target  
48 group, taking into account their capabilities, opportunities and motivational aspects. It may  
49 be useful to give the PPI group a small condition management task that emulates what trial  
50 participants will be required to do. Moreover, we can confirm a recent review suggesting  
51 that health apps should be co- designed with users (7), rather than presenting them with a  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 pre-existing app. These implications for our study are also generalisable to other  
4  
5 technology studies.  
6  
7  
8  
9  
10

## 11 **Research in context**

### 12 **What is known**

- 13  
14  
15  
16 1. Chronic pelvic pain has a large impact on patients and the NHS and is difficult  
17  
18 to treat.
- 19  
20  
21 2. Health outcomes are improved by psychological and lifestyle interventions but  
22  
23 are often not addressed due to difficult access or service shortages.
- 24  
25  
26 3. Mindfulness meditation has not been investigated in chronic pelvic pain  
27  
28 patients but randomised controlled trials show improved health outcomes in  
29  
30 other chronic pain conditions.
- 31  
32  
33 4. Mhealth apps are increasingly popular.  
34  
35  
36

### 37 **What the study adds**

- 38  
39  
40 1. A mindfulness meditation app may not necessarily be taken up by patients with CPP  
41  
42 even when it is a commercial success in the general population. Considerable  
43  
44 supportive scaffolding may be needed.
- 45  
46  
47 2. Use of existing commercial apps in actual clinical practice may be problematic  
48  
49 compared with the agile development of apps with collaboration between  
50  
51 researchers, clinicians, developers and end users.
- 52  
53  
54 3. Chronic Pain patients are interested in alternatives to drug or surgical treatments and  
55  
56 further research is required in this area, including with MM, the benefits of which may  
57  
58 extend beyond pain relief itself.  
59  
60

- 1  
2  
3 4. PPI groups may be more motivated to use an intervention than a real world clinical  
4 group as they are volunteers who are interested in the research topic. This may be  
5 particularly problematic for interventions that require considerable capability or  
6 motivation in use.  
7  
8  
9  
10

### 11 12 13 **Author contributions**

14 EB led the study as the CI. EB and CR were the main authors of the grant application for  
15 this study, and co-lead authors of the current paper. All other authors contributed to the  
16 study design and initial protocol, provided support throughout the trial and contributed  
17 towards the final paper. CR led on the PPI and CR and LS led the interview and focus group  
18 field work and analysis reported here. CR, LS, SN, CC, JD and JB were all involved in the  
19 field work.  
20  
21  
22  
23  
24

### 25 **Role of the funding source**

26 The UK National Institute of Health Research, Research for Patient Benefit (RfPB No. PB-  
27 PG1013-32025) funded the MEMPHIS study. The funder had no role in the study design, in  
28 the collection, analysis, and interpretation of the data, in the writing of this report, or in the  
29 decision to submit the paper for publication. The first and last authors vouch for the integrity,  
30 completeness and accuracy of the data and analyses, and for the fidelity of this report to the  
31 protocol and statistical analysis plan. The views and opinions expressed herein are those of  
32 the authors and do not necessarily reflect those of the RfPB, NIHR, NHS or the Department  
33 of Health.  
34  
35  
36  
37  
38  
39  
40  
41

### 42 **Competing interests**

43 We have read and understood BMJ policy on declaration of interests.  
44  
45  
46

### 47 **Data sharing**

48 The data are collected from a small number of people which could compromise their identity  
49 if shared with others. Therefore we are not making them available except under exceptional  
50 circumstances which will be determined by the custodian of the data (Elizabeth Ball) on an  
51 individual basis.  
52  
53  
54  
55  
56  
57

### 58 **Transparency**

59  
60

1  
2  
3 The lead author confirms that the manuscript is an honest, accurate and transparent account  
4 of the study being reported; that no important aspects of the study have been omitted; and  
5 that any discrepancies from the study as planned and registered have been explained.  
6  
7  
8

### 9 **Acknowledgements**

10 We would like to thank all the researchers, consultant obstetricians and gynaecologists and  
11 data assistants at each of the recruiting clinics for their hard work in promoting the study,  
12 recruiting participants and for data entry. Our thanks go to the Trial Steering Committee;  
13 Andrew Horne, Sohinee Bhattacharya, Christina Lioffi, and Hulya Guzel for their constant  
14 support throughout the trial.  
15  
16  
17  
18

19 We thank the Pelvic Pain Support Network and Endometriosis UK for their promotion and  
20 guidance in developing the study design. We would also like to acknowledge the NIHR RfPB  
21 programme for their on-going support.  
22  
23  
24

25 Lastly, thank you to Headspace Ltd for providing our participants with access to the  
26 Headspace platform, designing novel content for the study, and for their continuous support  
27 and advice throughout the study.  
28  
29  
30  
31  
32  
33  
34

### 35 **References**

- 36  
37  
38  
39  
40 1. Ali EE, Chew L, Yap KY. Evolution and current status of mhealth research: a  
41 systematic review. *BMJ Innovations* 2016;2:33-40  
42  
43 2. Ofcom. The Communications Market Report. Ofcom: United Kingdom 2015.  
44 <https://www.ofcom.org.uk/research-and-data/multi-sector-research/cmr/cmr15/uk>  
45 [accessed 21 March 2019]  
46  
47  
48 3. Kayyali R, Peletidi A, Ismail M, Hashim Z, Bandeira P, Bonnah J. Awareness and  
49 Use of mHealth Apps: A Study from England. *Pharmacy* 2017, 5, 33.  
50  
51 4. Sezgin E, Yildirim S, Özkan-Yildirim S, Sumuer E. Current and Emerging mHealth  
52 Technologies: Adoption, Implementation, and Use: Springer International Publishing;  
53 2018 2018.  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 5. Lunden I. 6.1B Smartphone Users Globally By 2020, Overtaking Basic Phone  
4 Subscriptions [https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-](https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015)  
5  
6 2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015 [cited 2018 28  
7  
8 August 2018].  
9
- 10  
11 6. Subhi Y, Bube SH, Rolskov Bojsen S, Skou Thomsen AS, Konge L. Expert  
12  
13 Involvement and Adherence to Medical Evidence in Medical Mobile Phone Apps: A  
14  
15 Systematic Review. *JMIR Mhealth Uhealth*. 2015;3(3):e79.  
16
- 17  
18 7. Edwards EA, Lumsden J, Rivas C, et al. Gamification for health promotion:  
19  
20 systematic review of behaviour change techniques in smartphone apps. *BMJ Open*.  
21  
22 2016;6(10):e012447. doi:10.1136/bmjopen-2016-012447.  
23
- 24  
25 8. de la Vega R, Miro J. mHealth: a strategic field without a solid scientific soul. a  
26  
27 systematic review of pain-related apps. *PLoS One*. 2014;9(7):e101312.  
28
- 29  
30 9. Engeler D, Baranowski AP, Borovicka J, et al. European Association of Urology.  
31  
32 Guidelines on chronic pelvic pain. [http://uroweb.org/wp-content/uploads/EAU-Guidelines-](http://uroweb.org/wp-content/uploads/EAU-Guidelines-Chronic-Pelvic-Pain-2015.pdf)  
33  
34 [Chronic-Pelvic-Pain-2015.pdf](http://uroweb.org/wp-content/uploads/EAU-Guidelines-Chronic-Pelvic-Pain-2015.pdf). Accessed Sept 19, 2019.  
35
- 36  
37 10. Ahangari, A. Prevalence of chronic pelvic pain among women: an updated review.  
38  
39 *Pain Physician*. 2014 Mar-Apr;17(2):E141-7.  
40
- 41  
42 11. Latthe, P., Latthe, M., Say, L., Gülmezoglu, M., & Khan, K. S. (2006). WHO  
43  
44 systematic review of prevalence of chronic pelvic pain: a neglected reproductive  
45  
46 health morbidity. *BMC public health*, 6, 177. doi:10.1186/1471-2458-6-177  
47
- 48  
49 12. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in  
50  
51 women: an epidemiological perspective. *Womens Health (Lond)*. 2015;11(6):851-64.  
52
- 53  
54 13. Howard F. The Role of Laparoscopy in Chronic Pelvic Pain: Promise and Pitfalls.  
55  
56 *Obstetrical & Gynecological Survey*. 1993;48(6):357-87.  
57
- 58  
59 14. Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al.  
60  
Chronic pelvic pain in the community--symptoms, investigations, and diagnoses. *Am J Obstet Gynecol*. 2001;184(6):1149-55.

- 1  
2  
3 15. Curtis L. Unit Costs of Health and Social Care 2014 Personal Social Services  
4 Research Unit, University of Kent, Canterbury.: University of Kent, Canterbury; 2014  
5 [Available from: <https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2014/>.  
6  
7  
8  
9  
10 16. Simoens S, Dunselman G, Dirksen C, The burden of endometriosis: costs and quality  
11 of life of women with endometriosis and treated in referral centres. *Hum Reprod*.  
12 2012 May;27(5):1292-9. doi: 10.1093/humrep/des073. Epub 2012 Mar 14.  
13  
14  
15 17. Peters AA, van Dorst E, Jellis B, van Zuuren E, Hermans J, Trimbos JB. A  
16 randomized clinical trial to compare two different approaches in women with chronic  
17 pelvic pain. *Obstet Gynecol*. 1991;77(5):740-4.  
18  
19  
20 18. Ball EF, Nur Shafina Muhammad Sharizan E, Franklin G, Rogozinska E. Does  
21 mindfulness meditation improve chronic pain? A systematic review. *Curr Opin Obstet*  
22 *Gynecol*. 2017;29(6):359-66.  
23  
24  
25 19. Kold M, Hansen T, Vedsted-Hansen H, Forman A. Mindfulness-based psychological  
26 intervention for coping with pain in endometriosis. *Nordic Psychology*. 2012;64(1):2-  
27 16.  
28  
29  
30 20. Fox SD FE, Allen RH. Mindfulness meditation for women with chronic pelvic pain: a  
31 pilot study. *J Reprod Med* 2011;56(3-4):158-62.  
32  
33  
34 21. Bishop SR. Mindfulness: A proposed operational definition. *Clinical Psychology:*  
35 *Science and Practice*; Autumn 2004; 11, 3; Health Module, pg. 230)  
36  
37  
38 22. Plaza I, Demarzo MM, Herrera-Mercadal P, Garcia-Campayo J. Mindfulness-based  
39 mobile applications: literature review and analysis of current features. *JMIR Mhealth*  
40 *Uhealth*. 2013;1(2):e24.  
41  
42  
43 23. Hilton L, Hempel S, Ewing BA, Apaydin E, Xenakis L, Newberry S, et al. Mindfulness  
44 Meditation for Chronic Pain: Systematic Review and Meta-analysis. *Ann Behav Med*.  
45 2017;51(2):199-213.  
46  
47  
48 24. Wang J,Wang Y, Wei C, Yao NA, Yuan A, Shan Y, Yuan C. Smartphone  
49 interventions for long-term health management of chronic diseases: an integrative  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 review. *Telemed J E Health*. 2014 Jun;20(6):570-83. doi: 10.1089/tmj.2013.0243.  
4  
5 Epub 2014 May 1.

- 6  
7 25. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S.  
8  
9 Evaluating and selecting mobile health apps: strategies for healthcare providers and  
10  
11 healthcare organizations. *Transl Behav Med*. 2014;4(4):363-71.  
12  
13 26. My Health Apps [Available from: [http://myhealthapps.net/app/details/127/Headspace-](http://myhealthapps.net/app/details/127/Headspace-on-the-go)  
14  
15 [on-the-go](http://myhealthapps.net/app/details/127/Headspace-on-the-go)] (Accessed 28 August 2018).  
16  
17 27. Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and Evaluation of  
18  
19 Mindfulness-Based iPhone Apps. *JMIR Mhealth Uhealth*. 2015;3(3):e82.  
20  
21 28. App Annie 2018 [Available from: <https://www.appannie.com/en/>] (Accessed 28  
22  
23 August 2018).  
24  
25 29. Ball E, Newton S, Kahan BC, Forbes G, Wright N, Cantalapiedra Calvete C, et al.  
26  
27 Smartphone App Using Mindfulness Meditation for Women With Chronic Pelvic Pain  
28  
29 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*.  
30  
31 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*.  
32  
33 2018;7(1):e8.  
34  
35 30. Forbes G, Newton S, Cantalapiedra C, Birch J, Dodds J, Steed E, Rivas C, Khan  
36  
37 KS, Rohricht F, Taylor SJC, Kahan B, Ball E. A smartphone app using psychological  
38  
39 approaches for women with chronic pelvic pain (MEMPHIS): a randomised feasibility  
40  
41 trial. submitted  
42  
43 31. Gerhardt-Powals J. Cognitive engineering principles for enhancing human-computer  
44  
45 performance. *International Journal of Human-Computer Interaction*. 1996;8(2):189-  
46  
47 211.  
48  
49 32. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al.  
50  
51 Normalisation process theory: a framework for developing, evaluating and  
52  
53 implementing complex interventions. *BMC Med*. 2010;8:63.  
54  
55 33. Borkan J. Immersion/Crystallization. In BF Crabtree and WL Miller (Eds) *Doing*  
56  
57 *Qualitative Research* (2nd edition). Thousand Oaks, CA: Sage Publication; 1999. p.  
58  
59 pp. 179-94.  
60

- 1  
2  
3 34. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting  
4 qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-  
5 1251.  
6  
7  
8  
9  
10 35. McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating  
11 in randomised controlled trials: conditional altruism and considerations for  
12 self. *Trials*, 11, 31. doi:10.1186/1745-6215-11-31  
13  
14  
15  
16 36. Palmer, M., Sutherland, J., Barnard, S., Wynne, A., Rezel, E., Doel, A., Grigsby-  
17 Duffy, L., Edwards, S., Russell, S., Hotopf, E., Perel, P. Free, C. (2018). The  
18 effectiveness of smoking cessation, physical activity/diet and alcohol reduction  
19 interventions delivered by mobile phones for the prevention of non-communicable  
20 diseases: A systematic review of randomised controlled trials. *PloS one*, 13(1),  
21 e0189801. doi:10.1371/journal.pone.0189801  
22  
23  
24  
25  
26  
27  
28 37. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D.  
29 The Impact of mHealth Interventions: Systematic Review of Systematic Reviews.  
30 *JMIR Mhealth Uhealth.* 2018;6(1):e23.  
31  
32  
33  
34  
35 38. Laurie J, Blandford A. Making time for mindfulness. *Int J Med Inform.* 2016;96:38-50.  
36  
37 39. Collins M, Shattell M, Thomas SP. Problematic Interviewee Behaviors in Qualitative  
38 Research. *Western Journal of Nursing Research.* 2016;27(2):188-99.  
39  
40  
41 40. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The  
42 behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques:  
43 building an international consensus for the reporting of behavior change  
44 interventions. *Ann Behav Med.* 2013;46(1):81-95.  
45  
46  
47  
48  
49 41. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing  
50 human support to enhance adherence to eHealth interventions. *J Med Internet Res.*  
51 2011;13(1):e30.  
52  
53  
54  
55 42. Andersson G. Using the Internet to provide cognitive behaviour therapy. *Behav Res*  
56 *Ther.* 2009;47(3):175-80.  
57  
58  
59  
60

- 1  
2  
3 43. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for  
4 characterising and designing behaviour change interventions. *Implement Sci.*  
5 2011;6:42.  
6  
7  
8  
9 44. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth Intervention  
10 Using a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot  
11 Study. *JMIR Mhealth Uhealth.* 2016;4(3):e109. Published 2016 Sep 22.  
12  
13  
14  
15  
16  
17  
18 45. Geraghty AW, Torres LD, Leykin Y, Perez-Stable EJ, Munoz RF. Understanding  
19 attrition from international Internet health interventions: a step towards global  
20 eHealth. *Health Promot Int.* 2013;28(3):442-52.  
21  
22  
23  
24 46. Mistler LA, Ben-Zeev D, Carpenter-Song E, Brunette MF, Friedman MJ. Mobile  
25 Mindfulness Intervention on an Acute Psychiatric Unit: Feasibility and Acceptability  
26 Study. *JMIR Ment Health.* 2017;4(3):e34.  
27  
28  
29  
30 47. Noone C, Hogan MJ. A randomised active-controlled trial to examine the effects of  
31 an online mindfulness intervention on executive control, critical thinking and key  
32 thinking dispositions in a university student sample. *BMC Psychol.* 2018;6(1):13.  
33  
34  
35  
36 48. Wen L, Sweeney TE, Welton L, Trockel M, Katznelson L. Encouraging Mindfulness in  
37 Medical House Staff via Smartphone App: A Pilot Study. *Acad Psychiatry.*  
38 2017;41(5):646-50.  
39  
40  
41  
42 49. Morrison Wylde C, Mahrer NE, Meyer RML, Gold JI. Mindfulness for Novice Pediatric  
43 Nurses: Smartphone Application Versus Traditional Intervention. *J Pediatr Nurs.*  
44 2017;36:205-12.  
45  
46  
47  
48 50. Lim D, Condon P, DeSteno D. Mindfulness and compassion: an examination of  
49 mechanism and scalability. *PLoS One.* 2015;10(2):e0118221.  
50  
51  
52  
53 51. Arean PA, Hallgren KA, Jordan JT, Gazzaley A, Atkins DC, Heagerty PJ, et al. The  
54 Use and Effectiveness of Mobile Apps for Depression: Results From a Fully Remote  
55 Clinical Trial. *J Med Internet Res.* 2016;18(12):e330.  
56  
57  
58  
59  
60

- 1  
2  
3 52. Gilbody S, Lewis H, Adamson J, Atherton K, Bailey D, Birtwistle J, et al. Effect of  
4 Collaborative Care vs Usual Care on Depressive Symptoms in Older Adults With  
5 Subthreshold Depression: The CASPER Randomized Clinical Trial. JAMA.  
6  
7  
8  
9  
10 2017;317(7):728-37.
- 11  
12 53. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A  
13  
14 systematic review of the impact of patient and public involvement on service users,  
15  
16 researchers and communities. Patient. 2014;7(4):387-95.  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

## APPENDIX 1

Feature	Positive aspects	Negative aspects	Solutions
<b>Voice</b>	Liked by some participants, considered soothing and even spiritual	<p>The voice was not relaxing. One had to listen carefully which meant you could not switch off; otherwise you could not hear instruction clearly during meditation.</p> <p>It was also too repetitive, after 10 times it felt like a chore and not something to look forward to.</p>	<p>Choice of different voices</p> <p>participants should be told it takes time to get into the rhythm of the instructions, but you can get used to it</p>
<b>General interface aesthetics</b>	colours really fresh, interface not too busy, with pleasing layout and aesthetics	one participant would prefer different, bright, colours such as purple	None needed
<b>Graphics</b>		<p>The pictures were often not appropriate as they focused on the problem (e.g. tooth pain logo) rather than something positive or soothing. Unanticipated problems could arise according to one participant; she found it hard to lose weight and felt the food icons a) did not represent success and b) reminded her of eating.</p> <p>One participant found the pictures hard to see.</p>	Psychological theory supports the view that positive images would be advisable

<b>Animations</b>	liked	poorly chosen	None needed
<b>Progress</b>	<p>One participant liked the way the app helped progress through the stages.</p> <p>Another participant, with cyclical pain and hence cyclical use, did not aim to progress but simply chose to use the baseline video each time.</p>	<p>Three participants were frustrated and even 'angry' and 'patronised' at having to do the same (basic) meditation several times before moving up a stage.</p> <p>There was no indication of goals, duration of each level or gamification rewards.</p>	<p>Goal setting is recommended by psychological theory and could be as simple as using "day 1 of 30" rather than simply Day 1.</p> <p>Changing emojis could show progress, for example from a sad face to a smiley face to a heart; the inbuilt progress function was not felt sufficiently motivating.</p>
<b>Introduction</b>		<p>Experienced app users suggested the introduction could be improved for initiates</p>	<p>overview of the entire app and its levels suggested for the start.</p> <p>One participant had done mindfulness before but thought an introduction to mindfulness might be helpful for others.</p>
<b>Enjoyment</b>	considered fun by some participants.	One said it was not very 'interesting'.	<p>Include examples of a patient's day with the app to cater for a greater variety of participants</p> <p>It would be good to have other features as drop down options that were fun and</p>



			did not involve meditation.
<b>Session intensity</b>		Would be good to choose the duration of the meditation.	15 or 20 mins would be better than 10, which is not enough time shut off and meditate deeply.  The option to control this was important as even 10 minutes was a difficult commitment for some busy participants (1074, 1075, 1078) or those battling with chronic fatigue (1074)
<b>Pain modules</b>		it can be hard to focus on something like using the app when you are in pain.	None needed

**Comments on app acceptability and usability made by n=13 patients. Two patients walked through the app with the researcher**

# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	6
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4 and 5
Purpose or research question	#4 Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The	7

rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

1			
2			
3			
4			
5			
6			
7			
8			
9			
10	Researcher characteristics	#6	19
11	and reflexivity		
12			
13			
14			
15			
16			
17			
18			
19			
20	Context	#7	7
21			
22	Sampling strategy	#8	7
23			
24			
25			
26			
27	Ethical issues pertaining	#9	6
28	to human subjects		
29			
30			
31			
32			
33	Data collection methods	#10	7
34			
35			
36			
37			
38			
39			
40			
41	Data collection	#11	8
42	instruments and		
43	technologies		
44			
45			
46	Units of study	#12	See note
47			1
48			
49			
50			
51	Data processing	#13	8
52			
53			
54			
55			
56			
57			
58	Data analysis	#14	8
59			
60			

		developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	
1			
2			
3			
4	Techniques to enhance trustworthiness	#15 Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
5			
6			
7			
8			
9	Syntheses and interpretation	#16 Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-16
10			
11			
12			
13			
14	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	See note 2
15			
16			
17			
18	Intergration with prior work, implications, transferability and contribution(s) to the field	#18 Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	16
19			
20			
21			
22			
23			
24			
25			
26	Limitations	#19 Trustworthiness and limitations of findings	19
27			
28			
29	Conflicts of interest	#20 Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	4
30			
31			
32			
33	Funding	#21 Sources of funding and other support; role of funders in data collection, interpretation and reporting	3
34			
35			
36			

## Author notes

1. 7,8,9 and especially 10
2. 8-16 and appendix

The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist was completed on 26. March 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in gynaecology outpatient clinics: Qualitative data analysis of user experience and lessons learnt

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030711.R2
Article Type:	Original research
Date Submitted by the Author:	30-Nov-2019
Complete List of Authors:	Ball, Elizabeth; Queen Mary University of London - Whitechapel Campus, Yvonne Carter Building Newton, Sian; QMUL Rohricht, Frank ; East London NHS Foundation Trust Steed, Liz; QMUL Birch, Judy Dodds, Julie; QMUL, Women'shealth Research Unit Cantalapiedra Calvete, Clara; QMUL, Women's Health Research Unit Taylor, Stephanie; QMUL, Center for Primary Care and Population Health Rivas, Carol; University College London
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Health informatics
Keywords:	Chronic pelvic pain, mHealth, mindfulness, patient engagement, health app, feasibility study

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 **Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in**  
4 **gynaecology outpatient clinics: Qualitative data analysis of user experience and**  
5 **lessons learnt**  
6

7 **Ball, Elizabeth**

8 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom,*  
9 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
10 *Queen Mary University of London, United Kingdom, Centre for Maternal and child Health*  
11 *Research, City University London*  
12

13 **Newton, Sian**

14 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
15 *Kingdom*  
16

17 **Rohricht, Frank**

18 *East London NHS Foundation Trust, United Kingdom*  
19

20 **Steed, Liz**

21 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
22 *Kingdom*  
23

24 **Birch, Judy**

25 *Pelvic Pain Support Network, UK*  
26

27 **Dodds, Julie**

28 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
29 *Queen Mary University of London, United Kingdom*  
30

31 **Cantalapiedra Calvete, Clara**

32 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom*  
33

34 **Taylor, Stephanie JC**

35 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
36 *Kingdom*  
37

38 **Rivas, Carol**

39 *Department of Social Science, University College London, United Kingdom*  
40

41 Corresponding author

42 Carol Rivas, Department of Social Science, University College London, United Kingdom  
43 E-mail: c.rivas@ucl.ac.uk  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Abstract

### Objective

To determine whether a pre-existing smartphone App to teach Mindfulness Meditation is acceptable to women with chronic pelvic pain (CPP) and can be integrated into clinical practice within NHS CPP pathways. To inform the design of a potential randomised clinical trial.

### Design

A pre-study patient and public involvement (PPI) group to collect feedback on the acceptability of the existing app and study design was followed by a three-arm randomised feasibility trial. In addition, we undertook interviews and focus groups with patients and staff to explore app usability and acceptability. We also obtained participant comments on the research process, such as acceptability of the study questionnaires.

### Setting

Two gynaecology clinics within Barts Health NHS, London, UK.

### Participants

Patients with CPP lasting  $\geq 6$  months with access to smartphone or PC and understanding of basic English.

### Intervention

The intervention was mindfulness meditation content plus additional pain module delivered by smartphone app, active controls received muscle relaxation content by the same app.

Passive (waiting list) controls received usual care.

### Main outcome measures

Themes on user feedback, app usability and integration and reasons for using/not using the app.

### Results

App use was low in both active groups.

Patients in the pre-study PPI group, all volunteers, were enthusiastic about the app (convenience, content, portability, flexibility, ease of use). Women contributing to the



1  
2  
3 interview or focus group data (n=14), from a 'real world' clinic, (some not regular app users)  
4  
5 were less positive, citing as barriers lack of opportunities/motivation to use the app, and lack  
6  
7 of familiarity and capabilities with technology. Staff (n=7) were concerned about the potential  
8  
9 need for extra support for patients and staff and considered the app needed organisational  
10  
11 backing and peer acceptance.  
12

### 13 14 **Conclusion**

15  
16 The opinions of pre-study PPI volunteers meeting in their private time may not represent  
17  
18 those of patients recruited at a routine clinic appointment.  
19

20  
21 It may be more successful to co-design/co-develop an app with typical users than to adapt  
22  
23 existing apps for use in real-world clinical populations.  
24  
25

### 26 27 **Trial registration and funding**

28  
29 The trial (ISRCTN 10925965) was funded by the UK National Institute of Health Research,  
30  
31 Research for Patient Benefit programme (RfPB PB-PG-1013-32025).  
32  
33

### 34 35 **Keywords**

36  
37 Chronic pelvic pain, mHealth, mindfulness, Headspace, PPI, patient engagement, feasibility  
38  
39 study, health app  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### Article Summary; 'Strengths and limitations of this study' (relating to methods)

- The study was designed with the help of a study design group of CPP patients
- Patient recruitment to the study was good
- Unusually our study focused on a deprived urban area of the UK and considered typical local clinical patients
- The qualitative evaluation included the perspectives of both patients and a variety of healthcare staff
- Patients in the qualitative evaluation preferred telephone interviews over the offered face to face focus groups.

The original protocol for the study has been published separately. The UK National Institute of Health Research supported this work (RfPB PB-PG-1013-32025). There are no competing interests.

### Introduction

Smartphone health apps, as one form of mhealth (1), are popular in the UK, our study setting. With more than two-thirds of the UK population using smartphones (2,3,4), health apps are one of the fastest growing app categories, thus numbers of users are still increasing (5). Currently these apps are usually developed either by researchers or (in the majority) by commercial companies, without collaboration between these groups (6,7). The lack of interaction between researchers and commercial developers in the field of pain-related apps has led to a situation where commercially available apps have not been scientifically validated and apps that have been developed from research projects are not commercially available (8).

1  
2  
3 We were interested in using an app to support women with chronic pelvic pain (CPP) in a  
4 clinical setting, where validation of an intervention is important to ensure best care. CPP is  
5 defined as a subjective physical and emotional experience of pain in the pelvic area that has  
6 been present for at least six months that may or may not have an identifiable pathology (9).  
7  
8 CPP affects up to 24% of women worldwide (10) and accounts for 20% of gynaecological  
9 clinic referrals. (11,12) It has considerable impact on patients' quality of life, including their  
10 mental health and their income (13) due to loss of working days and diminished work  
11 capacity. Annual costs to the NHS have been estimated at approximately £326 million (14).  
12  
13 For endometriosis alone, which is just one cause of CPP, a European study of over 900  
14 women showed average annual total costs per woman of €9579. Costs of productivity loss of  
15 €6298 were double the health care costs of €3113 per woman. The latter were due to  
16 surgery (29%), monitoring tests (19%) and hospitalization (18%) and physician visits (16%)  
17 (15).  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30  
31 Despite costly interventions, CPP is often resistant to surgical and medical treatment and  
32 appears to respond better to a multimodal, holistic approach, (16) with a focus on coping  
33 strategies. A systematic review of randomised controlled trials (RCTs) by authors has  
34 identified mindfulness meditation (MM) as an effective coping strategy in other chronic pain  
35 conditions (17). In addition, evidence from uncontrolled trials suggests positive effects of MM  
36 for CPP, such as an increased ability to control pain, improvements in mental health,  
37 emotional well-being, work and family life and social functioning (18,19), but these have  
38 never been examined in an RCT.  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 We therefore chose to evaluate MM delivered via an app to women with CPP as our  
50 intervention. CPP is especially common in younger women, who may be categorised as  
51 digital natives, making an app-based intervention particularly appropriate in this group.  
52  
53  
54  
55

56 In MM the aim is to keep focussed on one's own breathing. Whenever attention wanders to  
57 intrusive thoughts and feelings these are simply taken notice of in a neutral way, that is,  
58  
59  
60

1  
2  
3 without elaboration or judgements or consideration of action. They are then let go as  
4 attention is returned to the breath. The idea is to bring awareness back to the here and now  
5 whenever worries and troubles intrude into thoughts.(20)  
6  
7  
8  
9

10 Generally two main complementary approaches have been used for MM: 1) exercises  
11 focusing one's attention to the present moment, and 2) monitoring of experiences in the  
12 present moment. While systematic reviews show that MM may have positive effects on  
13 depression, quality of life and pain symptoms in patients with chronic pain (17,21,22) and  
14 apps with such a focus on chronic disease have been shown to be beneficial in various  
15 conditions (23) none of the reviewed papers included meditation delivered via mobile phone  
16 apps or in women with CPP.  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

29 Evaluation of an existing app is often appropriate (24) and is both quicker and more cost-  
30 effective than designing an app from scratch. We chose to evaluate an existing commercial  
31 app platform that teaches mindfulness by guided meditation (Headspace ®), with a ten day  
32 basic meditation module followed by a pain module specifically designed for the MEMPHIS  
33 (Mindfulness meditation using a smart-phone application for women with chronic pelvic pain)  
34 study. The Headspace app was publicly nominated favourite health app of 2013,(25) has a 5  
35 star user rating in the Apple™ app shop and has scored top in a systematic review of 23  
36 mindfulness apps using the Mobile Application Rating Scale (visual aesthetics, engagement,  
37 functionality or information quality) (26). Headspace had reportedly seen over 15 million  
38 downloads up to mid-2018 when our study began.(27) To our knowledge the Headspace  
39 app in its original or modified form has not been assessed in any other pain conditions.  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51

52 We undertook a three-arm parallel randomised feasibility trial (MEMPHIS) (28) to assess  
53 whether or not to proceed with a full randomised controlled trial of the modified Headspace  
54 meditation app for women with CPP. In the current paper we report on the qualitative interview  
55 and focus group data from this study; the protocol and quantitative results have been  
56  
57  
58  
59  
60

1  
2  
3 published/ submitted (29,30). Our aim for the qualitative part of this study was to determine  
4 whether a pre-existing smartphone app to teach MM is acceptable to women with CPP and  
5 can be integrated into clinical practice within NHS CPP pathways. Objectives were to consider:  
6  
7

8  
9 1) The acceptability, use and usability of the app in the intended service user population and  
10 for health care professionals (doctors, health care assistants, clinical and research nurses)  
11  
12

13  
14  
15 2) The feasibility of integrating such an app into existing healthcare pathways  
16  
17

18 3) The usefulness of having a distinct patient group to advise us on the study design.  
19  
20  
21  
22  
23  
24

## 25 **Methods**

### 26 **Outcomes**

27  
28  
29 The outcomes of this analysis were inductively derived descriptive themes on acceptability,  
30 use and usability of the app and feasibility of integrating it into existing pathways. We follow  
31 the ISO 9241-11 (<https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-2:v1:en>) concept of  
32 technology usability (user friendliness) as the extent to which the app could be satisfactorily  
33 used by participants to meditate. By acceptability we mean whether participants could see a  
34 reason for using the app when given in clinic, and would be happy to use it for meditation.  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

### 49 **Intervention Procedures**

50  
51  
52 Women in the mindfulness meditation group received access to a 60-day progressive  
53 mindfulness meditation course delivered via the Headspace app. The first 10 days of the  
54 course taught basics of mindfulness meditation. Following this, participants were able to  
55 access the module on meditation which was targeted at for chronic pain. This module had  
56  
57  
58  
59  
60

1  
2  
3 been specifically made for this study. Session length was 10 minutes for the first 10 days, 15  
4 min up to day 20 and 20 min up to day 60. The active control group received access to a  
5 series of muscle relaxation sessions. These sessions were identical every day, except that  
6 their duration increased to mirror the increasing duration of the meditation content being  
7 listened to by the intervention group. Usage data are reported elsewhere (30).  
8  
9  
10  
11  
12  
13  
14

### 15 **Patient and Public Involvement**

16  
17  
18 We held a Patient and Public Involvement (PPI) group workshop before the study to discuss  
19 acceptability of the Headspace app and help us design our study. Women attending the  
20 Royal London Hospital CPP clinic were invited to volunteer for a week of using the  
21 unmodified (normal commercially available) Headspace app (which did not have the pain  
22 module at the time we undertook our pre study workshop) and then feed back on their  
23 experiences with the app in an evening discussion group. Women were not involved in the  
24 design of the modified app. The focus for the PPI group was on the use of the generic MM  
25 app.  
26  
27  
28  
29  
30  
31  
32  
33  
34

35 Two patient representatives provided support from the study design stage through  
36 recruitment to the interpretation of the results and regularly attended Trial Management  
37 Group meetings.  
38  
39  
40  
41  
42  
43  
44  
45

### 46 **Study recruitment and eligibility**

47  
48 The trial recruited at two outpatient gynaecology clinics within Barts Health NHS trust in two  
49 separate deprived areas of inner East London. Female patients with new or follow-up  
50 gynaecology appointments were assessed for eligibility by a researcher in clinic, having  
51 been posted a Patient Information Sheet. Women were eligible if they had been suffering  
52 with CPP for 6 months or more and had at least a basic understanding of the English  
53 language, sufficient to follow instructions, as assessed during discussion about the study for  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 informed consent; no women were excluded on this basis. Women were excluded if they did  
4 not meet these criteria or they did not have access to a smartphone or personal computer or  
5 were currently using the Headspace app (there were very few of the latter, according to the  
6 impression of the recruiting nurses). All patients gave full and informed consent to be  
7 randomised and data were collected through all stages of the study. All healthcare  
8 professionals and research nurses involved in the two clinics were also invited to take part in  
9 the feasibility study as the only eligibility criterion for staff. Full enrolment data are provided  
10 in Forbes et al (30). A key difference of these patients from those in the PPI group was that  
11 their focus was on managing their pain, with the app given explicitly as part of their clinic  
12 management support.  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

26 For the study of quantitative data, 90 patients were allocated randomly in a 1:1:1 ratio to the  
27 mindfulness meditation app, a muscle relaxation app active control or the usual care arm (for  
28 full details see (29)). Patients in the two active arms were asked to download the modified  
29 app in the clinic with support from a research staff member and were sent a questionnaire  
30 about app usability, an analysis of which is reported in a companion paper.(30) We used  
31 data from the app usability questionnaire to inform topic guides for the qualitative part of the  
32 study. This outlined key usability issues that had been uncovered, to guide our semi-  
33 structured interviews and focus groups with patients and staff.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

46 All women in the intervention and active control arms were eligible for the qualitative  
47 component of the study, and all staff participating in the study.  
48  
49  
50

### 51 **Within-study interviews and focus groups**

52 All patients in the intervention and active control arms were invited to one of two focus  
53 groups at their own study site after the 6-month follow up. We offered telephone interviews  
54 as an alternative. Patients were asked to 'walk through' the app with researchers, articulating  
55 their thought processes while they did so and commenting on its different specific features,  
56  
57  
58  
59  
60

1  
2  
3 (31). Walkthroughs are often used in developing technologies such as mhealth. This helped  
4  
5 to identify app usability issues or barriers to use of the app from the users' points of view  
6  
7 without the need for technical discussions. Results for the walkthrough, showing comments  
8  
9 on different features specific to the usability of the intervention app used in our study are  
10  
11 shown in Appendix 1; walkthroughs were undertaken by two patients. Patients also  
12  
13 discussed with us their experiences around app usability and acceptability.  
14  
15

16 Staff were invited to attend a staff focus group overseen by the patient representative and  
17  
18 facilitated by a researcher. In addition to considering app usability and acceptability,  
19  
20 members of the staff focus group (consultants, health care assistants, clinical and research  
21  
22 nurses and a representative from the pelvic pain support network were eligible) were asked  
23  
24 about the ease of integration into existing NHS pathways. Part of the staff discussion was  
25  
26 free flowing with open-ended questions, which gave us patient-focussed information on app  
27  
28 acceptability, and part was structured using questions developed from the Normalisation  
29  
30 Process Theory (NPT) toolkit in the way recommended by the NPT developers (32). For  
31  
32 example, we asked whether staff could see a purpose to the app in clinical practice, as  
33  
34 adding something different, which corresponds to the NPT toolkit question 'Participants  
35  
36 distinguish the intervention from current ways of working'. Since this was a semi-structured  
37  
38 approach questions were not rigidly worded. This helped us to consider the feasibility of  
39  
40 integration of the app into practice. NPT is a theory of implementation practices that was  
41  
42 initially developed for consideration of technology implementation and is in common use  
43  
44 (32).  
45  
46  
47

48 All data were audio-recorded at point of collection and transcribed, with personal identifying  
49  
50 data removed from transcripts. Raw data were stored in a Primary Care Clinical Trial Unit  
51  
52 database to clinical trial standards.  
53  
54  
55

## 56 57 **Analysis** 58 59 60



1  
2  
3 Analysis of within-study focus groups and interviews was carried out blinded as to which  
4 study app was used, and deployed the immersion-crystallisation method (33). Thus, the lead  
5 qualitative researcher immersed herself in the data, reading transcripts carefully, then writing  
6 down articulated or crystallised patterns or themes that related to the aims and research  
7 questions of the study. These were discussed with another researcher from the team, and  
8 themes modified as appropriate. This process was repeated until all the data had been  
9 examined and all patterns that had been noticed were articulated, discussed and  
10 substantiated with exemplar extracts. This approach was considered appropriate since we  
11 had a small dataset and we were not aiming to develop conceptual themes but rather to  
12 inform the design and development of a randomised controlled trial for the modified app.  
13 We used the SRQR checklist when writing our report (34).  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

### 29 **Ethics**

30 The MEMPHIS trial was a three-arm parallel randomised feasibility trial approved by Camden  
31 and Kings Cross Research Ethics Committee in 2016 (15/LO/1967).  
32  
33  
34  
35  
36

### 37 **Results**

38 We screened 488 women between May and September 2016 for their eligibility to participate  
39 in the study. After exclusions, 90 women gave full consent to participate and were  
40 randomised to the intervention arm (31 women), the active control arm (30 women) or the  
41 usual care arm (29 women).  
42  
43  
44  
45  
46  
47  
48  
49

### 50 **Demographics**

51 Women in the main feasibility trial (30) were aged a mean of 35 years, 66% were employed  
52 and overall approximately 50% had stayed in full time education until at least the age of 20  
53 though the proportion was least, at 36.7% in the intervention arm. Overall 44% were of white  
54 ethnicity though the proportion was lowest in the intervention arm (35.7%) and highest in the  
55 usual care arm (53.6%). The second most common self-reported ethnic groups were  
56  
57  
58  
59  
60

1  
2  
3 'Southern Asian' and 'Black'. Women in the intervention arm were most likely to have  
4 experienced CPP for 3-5 years (40.3% of this group), women in the usual care group for  
5 over 10 years (42.9% of this group). More women had pain for longer than two years in the  
6 intervention arm than in either of the other two arms. All women reported a high pain  
7 intensity, with means of 6.8 to 6.9 in the previous week (on a scale from 1-10) (30). These  
8 and other demographic data are reported in more detail in Forbes *et al.* (30) Our qualitative  
9 sample was taken from the two active arms and was comprised of 16% of trial participants  
10 and 23% of those eligible for the qualitative study. We did not record separate demographic  
11 data for the women in this smaller sample.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### ***Pre-study PPI group***

The ten women in the pre-study PPI group were self-selected local women who were familiar with using apps and focused on app use per se. They anticipated no technical issues even in women who were not used to apps. They considered that the Headspace app would be successfully adopted by patients taking part in the study, given that a smartphone, like CPP, is 'always with you'. They praised the flexibility of the app, welcomed its portability and were unanimous in saying it was easy to slip off for 10 minutes when at work to use it. As a result, they found they could use it at times when they most needed pain relief as well as to prevent pain and found the app helpful in relieving pain and stress. The group reported being able to meditate without the app, once they had tried it with the app; however, they still preferred to use the app because they found the voice soothing.

### ***App usage in the study***

Patient usage of the app was less than expected from our pre-study PPI group discussions. Only 36% of meditation app patients and 46% of the active control patients used the app at least once. (30)

### ***Thematic analysis of within-study data***

Qualitative data were obtained from 14 study patients; 12 preferred a telephone interview, two attended face-to-face interviews, one participant at the University attached to one of the recruiting clinics and one participant at the other recruiting hospital. Patients chose not to attend focus groups. Four of the patients were from the active control arm and 10 from the intervention arm. The two women we met face to face had both used the intervention and neither had progressed beyond the training stage, something that we cannot discount for other participants and which may help to explain reports of lack of effect on pain. Seven people attended the staff focus group: two recruiting nurses, three clinic nurses one consultant and a representative from the pelvic pain support network.

1  
2  
3 The qualitative analysis revealed three main themes from all within-study interviews and  
4 focus groups combined regarding usability, and four subthemes:  
5  
6  
7

- 8 1. Familiarity and capabilities with app technology
- 9 2. Motivations to use the app
- 10     ○ Perceived benefits
- 11     ○ Relation to other therapies
- 12 3. Opportunities to use the app:
- 13     ○ Technology issues getting in the way
- 14     ○ Life getting in the way
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22

23 These are explored below. As the PPI group data were not research data we did not  
24 analyse them for themes.  
25

26 While we initially combined active control and intervention groups in our analysis, we then  
27 looked for instances where there was a difference between these two groups. Only where  
28 we found this difference in any theme or statement have we specified which group women  
29 belonged to.  
30

### 31 *Familiarity and capabilities with app technology*

32 Around half of the patients were sufficiently familiar with technology and apps to be  
33 comfortable using the study apps. However, six participants (all using the intervention, which  
34 was more complex than the active control) reported difficulty because they were “*not very*  
35 *good at technology*” (patient 1002, intervention), or were unsure how to get started or use  
36 the app effectively without help.  
37

38 *I am not good with technical some things that is why the problems I had arisen, right*  
39 *okay. So I consulted with my daughter and she helped me work it out... so I don't try*  
40 *everything. (patient 1002, intervention)*  
41

42 One further patient (1001, intervention) was not used to technical app language; ‘help’  
43 suggested emotional support to her, for example. Two more (one intervention, one active  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 control) changed handsets and therefore did not continue with the app. In all cases these  
4  
5 technical difficulties appeared to lead to abandoning of the app or restricted use of its  
6  
7 functionality.  
8  
9

10 Five patients having technical problems suggested possible solutions such as a 'class' or  
11  
12 group for first time users, a YouTube orientation video, or a pictorial leaflet. This might  
13  
14 include an introduction to meditation and mindfulness as well as the app itself. One woman  
15  
16 commented: *"If your market is targeting people who are not using apps then you are going to*  
17  
18 *have to get together and find ways to do this"*, (patient 1041, intervention); she also  
19  
20 suggested we could get ideas from other apps on the market in this regard.  
21  
22

23 Given their experiences in the study, staff were concerned about additional staff time needed  
24  
25 to support women in using the app. This would sit in tension with one of the original  
26  
27 rationales behind choosing an app as the mode of delivery, which was to increase the  
28  
29 effective use of staff contact time with patients. Language barriers might compound  
30  
31 problems.  
32  
33

### 34 35 36 37 *Motivations to use the app*

38  
39 Staff, though unaware of the low sustained app use in the study, felt it would be common  
40  
41 sense to hold occasional motivating meetings with patients if the intention was for them to  
42  
43 use the app long term. The patient data suggested the main motivators or lack of motivation  
44  
45 for using the app in our sample, which could be drawn on in such meetings, and which we  
46  
47 now consider.  
48  
49

### 50 51 52 53 Perceived benefits

54  
55 Three intervention arm patients said they only entered the trial to help others through  
56  
57 research but were already using alternative forms of pain control. They explained that this  
58  
59 meant they were not motivated to actually use the app, perceiving the relative benefit to be  
60

1  
2  
3 small. The failure of such altruism to extend to using the app is a recognised phenomenon in  
4 clinical trials and has been called ‘weak altruism’. (35) Thus, only one of these three patients  
5 persevered. Even though she was one of the women who experienced difficulties with the  
6 technology, she explained, “*with something that is as soul destroying as the pain, it is*  
7 *important to help others off the back of other people's misfortune as it were*” (1036,  
8 intervention). However, she wondered how relevant her data were:  
9  
10  
11  
12  
13  
14

15  
16 *I took steps to improve my situation from a weight loss perspective as well and I've lost a lot*  
17 *of weight which has significantly helped not 100% but it is has significantly helped so I felt a*  
18 *bit fraudulent the last time filling in the forms because , so everything had improved so much*  
19 *so from the medical study perspective it was more about the weight loss than the app. So I*  
20 *felt a bit bad that I was still taking part. (patient 1036)*  
21  
22  
23  
24  
25  
26  
27

28 There was no clear pattern regarding the impact of current pain on app use by patients. Six  
29 said they used it regardless of pain intensity – sometimes developing a daily routine – while  
30 four only used it when in severe pain or expecting to be (e.g. during menstruation). This  
31 cyclical or intermittent use in some patients – which was irrespective of study arm - should  
32 be considered when looking at our main study outcomes.(30) The Headspace app requires  
33 regular use to learn and benefit from psychological techniques. To address this, healthcare  
34 professional alerts have been effective in other studies, (36) whilst Headspace only has a  
35 reminder function that the user can set. This was often not sufficient, as one patient said  
36 even with this feature, “*To be quite honest I used it a couple of times and then forgot. And*  
37 *then I [remembered it and] used it more frequently.*” (patient 1036, intervention)  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 One patient said medication was not working but the app did, though she was not sure  
50 whether this was ‘*mind over matter*’ (1065, intervention), which was her term for a placebo  
51 effect. Three others said it did not reduce their pain; all three were using the intervention  
52 app. The remaining patients considered other benefits were good reason for using the app  
53 even when they did not feel that it reduced pain intensity. Alternative or unanticipated  
54 benefits were not formally measured or taken into account in the study’s effectiveness  
55  
56  
57  
58  
59  
60

1  
2  
3 outcomes (30). For example, ten patients valued the way the app helped them to relax or de-  
4 stress or focus and re-assess their life; three of these specifically said they used it to induce  
5 a relaxed state to get to sleep. Notably the active control was a relaxation app; however this  
6 benefit was also reported by many women in the intervention arm. One participant (active  
7 control) said she did not like the focus on pain per se as her condition impacted on various  
8 areas of her life. Even when the intervention app was positively received, women might stop  
9 using it because it was too powerful, and they had gained the change they wanted:  
10  
11  
12  
13  
14  
15  
16  
17

18 *I think it was day 3, I could see the change that was happening, I was able to speak up for*  
19 *myself .....I can't explain it, even now I am getting emotional... it's just a lack of focus, I just*  
20 *needed direction. To try and put it into words. To me it meant so much that I have gone back*  
21 *to church... I use it outside of the app now I have got from it what was missing, so it's done*  
22 *something to me and for me which is very positive, and I may try it to lose weight but those*  
23 *positive vibes are still there. I can't go back to it because I did not want to go any further*  
24 *because what I got at the time helped me to focus, to change my way of thinking. I used it for*  
25 *about two or three weeks. (patient 1001, intervention)*  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35

36 Three intervention app patients found the app put them more in tune with their bodies and  
37 their breathing, (two of these were among those who also found the app de-stressing) while  
38 another found yoga better for that. Six patients, like pre-study PPI group members, also  
39 learned to use techniques from the app to alter their stress patterns without the app, having  
40 tried it, for example in traffic or by sitting down and taking time out or for general relaxation.  
41  
42  
43  
44  
45  
46  
47  
48  
49

#### 50 Relation to other therapies

51 Two patients (both active control) preferred 'pure' meditation, another considered the app to  
52 be "*very much about meditation*" (1041, intervention), which is in keeping with the arms they  
53 were in. An alternative therapy practitioner and two further patients reported that they  
54 preferred yoga. One (active control) said this was because it focussed on each part of the  
55 body in turn.  
56  
57  
58  
59  
60

1  
2  
3 Three intervention app patients thought the app was useful as an adjunct to other methods  
4 rather than a replacement for them, for example physical interventions such as Pilates, or  
5 listening to classical music.  
6  
7  
8  
9

#### 10 *Opportunities to use the app*

##### 11 Technology issues getting in the way

12 Staff pointed out that not all patients had smartphones (not appreciating that PCs/tablets  
13 were alternatives allowed in this study). Some patients lacked the storage space to load the  
14 app on their phones. There were also issues with Wi-Fi connectivity when staff tried to help  
15 the patients load the app within the hospital sites. Possible solutions that staff suggested  
16 were to lend patients phones and to have group upload sessions in a location with good Wi-  
17 Fi signal – though they acknowledged the resource implications.  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

##### 30 Life getting in the way

31  
32 Seven patients revealed they preferred to use the app in the evenings because of other life  
33 commitments. This meant they did not always use it as a direct response to pain, reducing  
34 its potential for contemporaneous effect. One patient who used it in response to pain but  
35 only used it once or twice blamed this on having no spare time because of juggling work and  
36 children (active control); however, another patient (intervention) managed despite such  
37 commitments the fact that she was in the intervention arm may have played a role.  
38  
39  
40  
41  
42  
43  
44  
45

##### 46 **Barriers to integration for staff**

47  
48 Staff believed that the biggest barrier to clinical adoption of the app was a possible lack of  
49 support from the host organisation. It might also be hard to integrate the app within existing  
50 professional work practices if the staff in the position of offering the app to patients failed to  
51 see its relative advantage over other interventions. Collection of feedback on the app's  
52 effectiveness would be necessary for staff to support sustained use. It was felt that staff  
53 would need training on how to introduce the app to women in practice, and that complexity  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 and high staff turnover could impede sustained use. An app was also seen as impersonal  
4 compared with face-to-face contact, which was more favoured by staff.  
5  
6  
7  
8  
9

### 10 **Participant comments on the research process**

11  
12 The study questionnaires that were used for the main quantitative outcome measures (30)  
13 were acceptable to patients except for some discomfort with a question about sex, which  
14 patients considered a delicate question that was missing a 'no sex' option. Most preferred a  
15 paper form reflecting their lack of affinity with technology. There were no indications that the  
16 study design or study processes had contributed to the participants' lack of engagement with  
17 the apps – with a caveat around support with the technology as mentioned above - though  
18 we did not systematically consider this. A full summary of patient comments on the study  
19 design and procedures is given in Appendix 1.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

### 31 **Discussion**

32  
33 Our study adds to the limited evidence on mHealth app user behaviour and experience  
34 (36,37). The pre-study PPI group (young women, of a generation who were familiar with  
35 using apps and who were asked to focus on the study design use of the app) liked the idea  
36 of delivering the intervention via an app, praising the contemporary design and flexibility.  
37 Hence we expected a similar positive attitude from trial participants, who were of a  
38 comparable age, and we assumed would be keen on using apps. Participant feedback  
39 revealed that this assumption was too simplistic.  
40  
41  
42  
43  
44  
45  
46  
47

48 Using our qualitative data, we were able to explore reasons for low app usage that had been  
49 recorded in our feasibility study.(30) Our thematic analysis suggests that the low app use in  
50 the trial occurred because many patients were not familiar with apps in general or lacked  
51 capabilities with technology. This was particularly true for the more complex intervention  
52 app. The other themes we report did not differ between groups (although the three cases of  
53 weak altruism' all occurred in the intervention arm) which suggests more generic issues that  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 can be transferable to other app use situations. For example, women stated limited  
4 motivation to use the app because of a lack of perceived benefit, or a lack of opportunity to  
5 use the app due to Wi-Fi issues or due to other commitments.  
6  
7  
8  
9

10  
11 Similar findings were reported by Laurie *et al.*(38) who interviewed 16 healthy city-dwelling  
12 participants (25-38 years) about their user behaviour before and after 30-40 days of  
13 Headspace app exposure. Like us, they reported barriers of busy lives, failure to establish a  
14 routine and a lack of perceived benefit; all users in their study tried the app at least once  
15 hoping it could deliver a quick fix but were disappointed if this did not happen. In our study  
16 many patients failed to perceive a benefit from using the app. Hence excuses stating other  
17 commitments may mask a deeper lack of motivation linked to perceptions of benefits.(39)  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

28 The advantages and disadvantages of using the app stand-alone were also illustrated by our  
29 data. Some suggestions made by participants to improve usage, such as more guidance at  
30 the start, seem obvious in hindsight. But they had not been considered because of the  
31 feedback from the pre-study PPI group and the commercial success of Headspace. The use  
32 of community contacts may be a helpful alternative.(40) Social support can create a  
33 community of practice, help to clarify expectations,(41) and improve health outcomes (as  
34 shown for example in internet based psychological treatment for depression (42).  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

45 The data suggest that for successful app use we need to understand what motivates  
46 individuals with clinical need to use the app for clinical reasons (which our PPI group did not  
47 focus on) and target this, for example by setting appropriate expectations. Incentivisation  
48 might also improve motivation. This could be achieved through app gamification (7), or  
49 encouragement through integration with patient-clinician face-to-face encounters, which was  
50 lacking in our study since the app was used stand-alone. The present study provided  
51 extensive initial technical support but no coaching and incentivising, in keeping with the  
52 protocol. Future app studies should take this into account. Participants in our study may  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 have also have benefitted from training and support to improve their app use capabilities and  
4 guidance on how to create more opportunities for app use – such as through sharing  
5 experiences in clinic support groups. This is in keeping with the COM-B model of behaviour  
6 change (43) which our themes matched, though this was only realised after analysis. The  
7 COM-B model says that Capability, Opportunity and Motivation are key drivers of behaviour  
8 and has been used to develop a number of complex interventions including smartphone  
9 apps (e.g. 3).

10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20 Lack of engagement after recruitment, or good initial engagement but minimal or  
21 inconsistent use, have been reported in other studies (44,45), including in Headspace trials  
22 other than our own (46, 47). Settings were a university and a psychiatric inpatients clinic,  
23 both in the USA. Inconsistent app use was noted by Wen (48) in junior doctors who used  
24 self-guided Headspace. Morrison Wylde (49) compared face-to-face MM with headspace  
25 use in novice paediatric nurses. However, unlike our study there were no recorded  
26 dropouts/non-users and also no record of whether or how long the app was used for which is  
27 an important omission.

28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39 None of these studies included a qualitative component. Yet, each of the Headspace study  
40 groups were very different, and so will likely have differed in motivations, contexts for  
41 opportunity to use the app, and incentivisations (50). While these aspects were not  
42 considered in the other studies, our use of qualitative research has enabled us to explore  
43 these in more depth. Our findings suggest these are important considerations in any study  
44 of app use and therefore this study makes a contribution to the field. For example, some of  
45 the groups in other studies may have differed from ours in likelihood of using mhealth apps  
46 in the first place, and familiarity with technology. In-patients may have more time to use the  
47 app and more support – and may also have had specific barriers to app use, such as related  
48 to setting and to illness.

1  
2  
3 Patients in the qualitative part of our study tended not to use apps on a regular basis (or at  
4 least apps other than simple games), and in terms of our themes, also represented in the  
5 COM-B model, may be said to have few capabilities in technology use. They therefore do  
6 not represent the typical users of the Headspace app in a commercial setting. Accessing the  
7 app regularly requires energy, time and effort, but patients with CPP often suffer from fatigue  
8 and anxiety as co-morbidities, perhaps whilst having to juggle family life and work.

9  
10 Therefore, this may be seen as a challenging clinical population in which to trial an app.  
11  
12 Further Headspace trials with diabetic (NCT03274362) and pain (NCT03495726) outpatients  
13 are underway.  
14  
15

16  
17 Our study has also shown that clear consideration of unexpected benefits should be  
18 included in future studies and these can be informed by our finding that benefits for patients  
19 may be more diffuse than anticipated (e.g. app relieving stress rather than pain). Such  
20 benefits were found in the active control as well as the intervention arm and so it may be that  
21 they represent a placebo effect though the effect could equally be real. Our data also  
22 suggest that staff benefits may be less than anticipated, as participants sometimes needed a  
23 lot of support and scaffolding in technology use at least initially.  
24  
25

26  
27 Young age, co-morbid anxiety and low educational attainment are predictors for dropping out  
28 of web-based interventions according to studies in the field of depression. (51, 52) This may  
29 be true despite regular phone support (52) though our participants all considered active  
30 motivational support from staff or app support groups would have improved app use. Our  
31 intervention arm participants were particularly likely to be young and with low educational  
32 attainment.  
33  
34

35  
36 Our data suggest that it is important to involve real world end users in the agile design or  
37 development or modification of apps in close collaboration with researchers and commercial  
38 app developers.(7) Although the evaluation of existing apps has been recommended as a  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 cost-effective and rapid process, (24) our findings suggest that in actual clinical practice  
4 these may be problematic.  
5  
6  
7  
8

9 *Strengths and weaknesses of the study and in relation to other studies*

10  
11 One strength of this study is that it creates much-needed evidence in the field of evaluating  
12 existing health apps in a clinic population (6,8,24) and recording user experience. This  
13 provides us with lessons to be learned.  
14  
15  
16

17  
18 Researchers conducting interviews and focus groups were: a senior mixed methods medical  
19 sociology researcher, a recruiting nurse, a representative from the pelvic pain support  
20 network and an experienced health psychologist. Findings were similar across the data and  
21 the different backgrounds of the researchers therefore does not appear to have influenced  
22 findings. The main analysis was undertaken by the medical sociologist and so the  
23 concordance with the COM-B model is not due to background discipline bias.  
24  
25  
26  
27  
28

29  
30 We were able to recruit successfully, and we obtained valuable information from patients  
31 with CPP, who were recruited from a deprived urban area of the UK as typical local clinical  
32 patients.  
33  
34  
35  
36  
37  
38

39  
40 However, we report a marked discrepancy between the attitudes of the pre-study PPI group  
41 of volunteer patients from the local area, who actively put themselves forward for a 7-day  
42 trial of the app, and the participants asked to take part when they attended clinics. The  
43 opinions of pre-study PPI volunteers meeting in their private time may not be representative  
44 of the opinions of patients recruited at a routine clinic appointment. Women in the PPI group  
45 were used to using apps, which had led them to be interested in the study in the first place.  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71  
72  
73  
74  
75  
76  
77  
78  
79  
80  
81  
82  
83  
84  
85  
86  
87  
88  
89  
90  
91  
92  
93  
94  
95  
96  
97  
98  
99  
100  
101  
102  
103  
104  
105  
106  
107  
108  
109  
110  
111  
112  
113  
114  
115  
116  
117  
118  
119  
120  
121  
122  
123  
124  
125  
126  
127  
128  
129  
130  
131  
132  
133  
134  
135  
136  
137  
138  
139  
140  
141  
142  
143  
144  
145  
146  
147  
148  
149  
150  
151  
152  
153  
154  
155  
156  
157  
158  
159  
160  
161  
162  
163  
164  
165  
166  
167  
168  
169  
170  
171  
172  
173  
174  
175  
176  
177  
178  
179  
180  
181  
182  
183  
184  
185  
186  
187  
188  
189  
190  
191  
192  
193  
194  
195  
196  
197  
198  
199  
200  
201  
202  
203  
204  
205  
206  
207  
208  
209  
210  
211  
212  
213  
214  
215  
216  
217  
218  
219  
220  
221  
222  
223  
224  
225  
226  
227  
228  
229  
230  
231  
232  
233  
234  
235  
236  
237  
238  
239  
240  
241  
242  
243  
244  
245  
246  
247  
248  
249  
250  
251  
252  
253  
254  
255  
256  
257  
258  
259  
260  
261  
262  
263  
264  
265  
266  
267  
268  
269  
270  
271  
272  
273  
274  
275  
276  
277  
278  
279  
280  
281  
282  
283  
284  
285  
286  
287  
288  
289  
290  
291  
292  
293  
294  
295  
296  
297  
298  
299  
300  
301  
302  
303  
304  
305  
306  
307  
308  
309  
310  
311  
312  
313  
314  
315  
316  
317  
318  
319  
320  
321  
322  
323  
324  
325  
326  
327  
328  
329  
330  
331  
332  
333  
334  
335  
336  
337  
338  
339  
340  
341  
342  
343  
344  
345  
346  
347  
348  
349  
350  
351  
352  
353  
354  
355  
356  
357  
358  
359  
360  
361  
362  
363  
364  
365  
366  
367  
368  
369  
370  
371  
372  
373  
374  
375  
376  
377  
378  
379  
380  
381  
382  
383  
384  
385  
386  
387  
388  
389  
390  
391  
392  
393  
394  
395  
396  
397  
398  
399  
400  
401  
402  
403  
404  
405  
406  
407  
408  
409  
410  
411  
412  
413  
414  
415  
416  
417  
418  
419  
420  
421  
422  
423  
424  
425  
426  
427  
428  
429  
430  
431  
432  
433  
434  
435  
436  
437  
438  
439  
440  
441  
442  
443  
444  
445  
446  
447  
448  
449  
450  
451  
452  
453  
454  
455  
456  
457  
458  
459  
460  
461  
462  
463  
464  
465  
466  
467  
468  
469  
470  
471  
472  
473  
474  
475  
476  
477  
478  
479  
480  
481  
482  
483  
484  
485  
486  
487  
488  
489  
490  
491  
492  
493  
494  
495  
496  
497  
498  
499  
500  
501  
502  
503  
504  
505  
506  
507  
508  
509  
510  
511  
512  
513  
514  
515  
516  
517  
518  
519  
520  
521  
522  
523  
524  
525  
526  
527  
528  
529  
530  
531  
532  
533  
534  
535  
536  
537  
538  
539  
540  
541  
542  
543  
544  
545  
546  
547  
548  
549  
550  
551  
552  
553  
554  
555  
556  
557  
558  
559  
560  
561  
562  
563  
564  
565  
566  
567  
568  
569  
570  
571  
572  
573  
574  
575  
576  
577  
578  
579  
580  
581  
582  
583  
584  
585  
586  
587  
588  
589  
590  
591  
592  
593  
594  
595  
596  
597  
598  
599  
600  
601  
602  
603  
604  
605  
606  
607  
608  
609  
610  
611  
612  
613  
614  
615  
616  
617  
618  
619  
620  
621  
622  
623  
624  
625  
626  
627  
628  
629  
630  
631  
632  
633  
634  
635  
636  
637  
638  
639  
640  
641  
642  
643  
644  
645  
646  
647  
648  
649  
650  
651  
652  
653  
654  
655  
656  
657  
658  
659  
660  
661  
662  
663  
664  
665  
666  
667  
668  
669  
670  
671  
672  
673  
674  
675  
676  
677  
678  
679  
680  
681  
682  
683  
684  
685  
686  
687  
688  
689  
690  
691  
692  
693  
694  
695  
696  
697  
698  
699  
700  
701  
702  
703  
704  
705  
706  
707  
708  
709  
710  
711  
712  
713  
714  
715  
716  
717  
718  
719  
720  
721  
722  
723  
724  
725  
726  
727  
728  
729  
730  
731  
732  
733  
734  
735  
736  
737  
738  
739  
740  
741  
742  
743  
744  
745  
746  
747  
748  
749  
750  
751  
752  
753  
754  
755  
756  
757  
758  
759  
760  
761  
762  
763  
764  
765  
766  
767  
768  
769  
770  
771  
772  
773  
774  
775  
776  
777  
778  
779  
780  
781  
782  
783  
784  
785  
786  
787  
788  
789  
790  
791  
792  
793  
794  
795  
796  
797  
798  
799  
800  
801  
802  
803  
804  
805  
806  
807  
808  
809  
810  
811  
812  
813  
814  
815  
816  
817  
818  
819  
820  
821  
822  
823  
824  
825  
826  
827  
828  
829  
830  
831  
832  
833  
834  
835  
836  
837  
838  
839  
840  
841  
842  
843  
844  
845  
846  
847  
848  
849  
850  
851  
852  
853  
854  
855  
856  
857  
858  
859  
860  
861  
862  
863  
864  
865  
866  
867  
868  
869  
870  
871  
872  
873  
874  
875  
876  
877  
878  
879  
880  
881  
882  
883  
884  
885  
886  
887  
888  
889  
890  
891  
892  
893  
894  
895  
896  
897  
898  
899  
900  
901  
902  
903  
904  
905  
906  
907  
908  
909  
910  
911  
912  
913  
914  
915  
916  
917  
918  
919  
920  
921  
922  
923  
924  
925  
926  
927  
928  
929  
930  
931  
932  
933  
934  
935  
936  
937  
938  
939  
940  
941  
942  
943  
944  
945  
946  
947  
948  
949  
950  
951  
952  
953  
954  
955  
956  
957  
958  
959  
960  
961  
962  
963  
964  
965  
966  
967  
968  
969  
970  
971  
972  
973  
974  
975  
976  
977  
978  
979  
980  
981  
982  
983  
984  
985  
986  
987  
988  
989  
990  
991  
992  
993  
994  
995  
996  
997  
998  
999  
1000

1  
2  
3  
4  
5 To our knowledge the present observation on failure of PPI work to translate into practice in  
6 a trial has not been formally reported before, and is lacking from a recent comprehensive  
7 systematic review.<sup>(53)</sup> PPI involvement is a stipulated requirement when applying for some  
8 funding, and the present research findings should be taken into account when drafting  
9 guidelines for future PPI involvement in study planning. PPI groups are able to provide  
10 significant help and advice in any study but our findings shows the value of adding agile co-  
11 development as a requirement for app intervention development as likely to provide a more  
12 effective intervention than one informed by PPI alone. Moreover, there is a difference  
13 between app use for active clinical management (as with our study participants), and  
14 consideration of the potential for app use for this (as with our PPI group).

#### 27 28 *Implications for clinicians and policymakers*

29  
30 Given the patchy use of the app and the way that some participants did not manage to  
31 unlock its full functionality, and an indication of diffusion of benefit, more work is needed to  
32 see whether the app reduces pain per se. This study is a good example of the need to move  
33 away from 'one size fits all' behavioural interventions. Future studies should do more work  
34 on implementation before doing an effectiveness trial. This will enable researchers to be  
35 more nuanced about saying who the app is effective for, if at all.

36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46 Strategies to involve busy, less motivated, and less technologically experienced individuals  
47 in PPI and lay app design groups need to be further developed. These groups should  
48 include considerable scaffolding, which we have shown extends to study involvement by  
49 patients. More care is also needed to obtain PPI input that is representative of the target  
50 group, taking into account their capabilities, opportunities and motivational aspects. It may  
51 be useful to give the PPI group a small condition management task that emulates what trial  
52 participants will be required to do. Moreover, we can confirm a recent review suggesting  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 that health apps should be co- designed with users (7), rather than presenting them with a  
4 pre-existing app. These implications for our study are also generalisable to other  
5  
6  
7 technology studies.  
8  
9

### 10 11 **What the study adds**

- 12  
13  
14 1. A mindfulness meditation app may not necessarily be taken up by patients with CPP  
15 even when it is a commercial success in the general population. Considerable  
16  
17 supportive scaffolding may be needed.  
18
- 19  
20 2. Use of existing commercial apps in actual clinical practice may be problematic  
21 compared with the agile development of apps with collaboration between  
22  
23 researchers, clinicians, developers and end users.  
24
- 25  
26 3. Chronic Pain patients are interested in alternatives to drug or surgical treatments and  
27 further research is required in this area, including with MM, the benefits of which may  
28  
29 extend beyond pain relief itself.  
30
- 31  
32 4. PPI groups may be more motivated to use an intervention than a real world clinical  
33 group as they are volunteers who are interested in the research topic. This may be  
34  
35 particularly problematic for interventions that require considerable capability or  
36  
37 motivation in use.  
38  
39  
40  
41  
42

### 43 **Author contributions**

44  
45 EB led the study as the CI. EB and CR were the main authors of the grant application for  
46 this study, and co-lead authors of the current paper. FR, SJCT, JD, JB, SN and LS  
47 contributed to the study design and initial protocol. All authors provided support throughout  
48 the trial and contributed towards the final paper. CR led on the PPI and CR and LS led the  
49 interview and focus group field work and analysis reported here. CR, LS, SN, CCC, JD and  
50  
51 JB were all involved in the field work.  
52  
53  
54

### 55 **Role of the funding source**

56  
57 The UK National Institute of Health Research, Research for Patient Benefit (RfPB No. PB-  
58 PG1013-32025) funded the MEMPHIS study. The funder had no role in the study design, in  
59  
60

1  
2  
3 the collection, analysis, and interpretation of the data, in the writing of this report, or in the  
4 decision to submit the paper for publication. The first and last authors vouch for the integrity,  
5 completeness and accuracy of the data and analyses, and for the fidelity of this report to the  
6 protocol and statistical analysis plan. The views and opinions expressed herein are those of  
7 the authors and do not necessarily reflect those of the RfPB, NIHR, NHS or the Department  
8 of Health.  
9  
10  
11  
12

### 13 14 **Competing interests**

15 We have read and understood BMJ policy on declaration of interests.  
16  
17

### 18 19 **Data sharing**

20 The data are collected from a small number of people which could compromise their identity  
21 if shared with others. Therefore we are not making them available except under exceptional  
22 circumstances which will be determined by the custodian of the data (Elizabeth Ball) on an  
23 individual basis.  
24  
25  
26  
27  
28  
29

### 30 31 **Transparency**

32 The lead author confirms that the manuscript is an honest, accurate and transparent account  
33 of the study being reported; that no important aspects of the study have been omitted; and  
34 that any discrepancies from the study as planned and registered have been explained.  
35  
36  
37

### 38 39 **Acknowledgements**

40 We would like to thank all the researchers, consultant obstetricians and gynaecologists and  
41 data assistants at each of the recruiting clinics for their hard work in promoting the study,  
42 recruiting participants and for data entry. Our thanks go to the Trial Steering Committee;  
43 Andrew Horne, Sohinee Bhattacharya, Christina Lioffi, and Hulya Guzel for their constant  
44 support throughout the trial.  
45  
46  
47  
48

49 We thank the Pelvic Pain Support Network and Endometriosis UK for their promotion and  
50 guidance in developing the study design. We would also like to acknowledge the NIHR RfPB  
51 programme for their on-going support.  
52

53 Lastly, thank you to Headspace Ltd for providing our participants with access to the  
54 Headspace platform, designing novel content for the study, and for their continuous support  
55 and advice throughout the study.  
56  
57  
58  
59  
60



## References

1. Ali EE, Chew L, Yap KY. Evolution and current status of mhealth research: a systematic review. *BMJ Innovations* 2016;2:33-40
2. Ofcom. The Communications Market Report. Ofcom: United Kingdom 2015. <https://www.ofcom.org.uk/research-and-data/multi-sector-research/cmr/cmr15/uk> [accessed 21 March 2019]
3. Kayyali R, Peletidi A, Ismail M, Hashim Z, Bandeira P, Bonnah J. Awareness and Use of mHealth Apps: A Study from England. *Pharmacy* 2017, 5, 33.
4. Sezgin E, Yildirim S, Özkan-Yildirim S, Sumuer E. Current and Emerging mHealth Technologies: Adoption, Implementation, and Use: Springer International Publishing; 2018 2018.
5. Lunden I. 6.1B Smartphone Users Globally By 2020, Overtaking Basic Phone Subscriptions <https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015> [cited 2018 28 August 2018].
6. Subhi Y, Bube SH, Rolskov Bojsen S, Skou Thomsen AS, Konge L. Expert Involvement and Adherence to Medical Evidence in Medical Mobile Phone Apps: A Systematic Review. *JMIR Mhealth Uhealth*. 2015;3(3):e79.
7. Edwards EA, Lumsden J, Rivas C, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. *BMJ Open*. 2016;6(10):e012447. doi:10.1136/bmjopen-2016-012447.
8. de la Vega R, Miro J. mHealth: a strategic field without a solid scientific soul. a systematic review of pain-related apps. *PLoS One*. 2014;9(7):e101312.
9. Engeler D, Baranowski AP, Borovicka J, et al. European Association of Urology. Guidelines on chronic pelvic pain. <http://uroweb.org/wp-content/uploads/EAU-Guidelines-Chronic-Pelvic-Pain-2015.pdf>. Accessed Sept 19, 2019.

- 1  
2  
3  
4 10. Ahangari, A. Prevalence of chronic pelvic pain among women: an updated review.  
5  
6 Pain Physician. 2014 Mar-Apr;17(2):E141-7.  
7
- 8  
9 11. Latthe, P., Latthe, M., Say, L., Gülmezoglu, M., & Khan, K. S. (2006). WHO  
10  
11 systematic review of prevalence of chronic pelvic pain: a neglected reproductive  
12  
13 health morbidity. BMC public health, 6, 177. doi:10.1186/1471-2458-6-177  
14
- 15 12. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in  
16  
17 women: an epidemiological perspective. Womens Health (Lond). 2015;11(6):851-64.  
18
- 19 13. Howard F. The Role of Laparoscopy in Chronic Pelvic Pain: Promise and Pitfalls.  
20  
21 Obstetrical & Gynecological Survey. 1993;48(6):357-87.  
22
- 23 14. Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al.  
24  
25 Chronic pelvic pain in the community--symptoms, investigations, and diagnoses. Am  
26  
27 J Obstet Gynecol. 2001;184(6):1149-55.  
28
- 29 15. Curtis L. Unit Costs of Health and Social Care 2014 Personal Social Services  
30  
31 Research Unit, University of Kent, Canterbury.: University of Kent, Canterbury; 2014  
32  
33 [Available from: <https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2014/>.  
34  
35
- 36 16. Simoens S, Dunselman G, Dirksen C, The burden of endometriosis: costs and quality  
37  
38 of life of women with endometriosis and treated in referral centres. Hum Reprod.  
39  
40 2012 May;27(5):1292-9. doi: 10.1093/humrep/des073. Epub 2012 Mar 14.  
41
- 42 17. Peters AA, van Dorst E, Jellis B, van Zuuren E, Hermans J, Trimbos JB. A  
43  
44 randomized clinical trial to compare two different approaches in women with chronic  
45  
46 pelvic pain. Obstet Gynecol. 1991;77(5):740-4.  
47
- 48 18. Ball EF, Nur Shafina Muhammad Sharizan E, Franklin G, Rogozinska E. Does  
49  
50 mindfulness meditation improve chronic pain? A systematic review. Curr Opin Obstet  
51  
52 Gynecol. 2017;29(6):359-66.  
53
- 54 19. Kold M, Hansen T, Vedsted-Hansen H, Forman A. Mindfulness-based psychological  
55  
56 intervention for coping with pain in endometriosis. Nordic Psychology. 2012;64(1):2-  
57  
58 16.  
59  
60

- 1  
2  
3 20. Fox SD FE, Allen RH. Mindfulness meditation for women with chronic pelvic pain: a  
4 pilot study. *J Reprod Med* 2011;56(3-4):158-62.  
5  
6  
7 21. Bishop SR. Mindfulness: A proposed operational definition. *Clinical Psychology:*  
8 *Science and Practice*; Autumn 2004; 11, 3; Health Module, pg. 230)  
9  
10 22. Plaza I, Demarzo MM, Herrera-Mercadal P, Garcia-Campayo J. Mindfulness-based  
11 mobile applications: literature review and analysis of current features. *JMIR Mhealth*  
12 *Uhealth*. 2013;1(2):e24.  
13  
14 23. Hilton L, Hempel S, Ewing BA, Apaydin E, Xenakis L, Newberry S, et al. Mindfulness  
15 Meditation for Chronic Pain: Systematic Review and Meta-analysis. *Ann Behav Med*.  
16 2017;51(2):199-213.  
17  
18 24. Wang J, Wang Y, Wei C, Yao NA, Yuan A, Shan Y, Yuan C. Smartphone  
19 interventions for long-term health management of chronic diseases: an integrative  
20 review. *Telemed J E Health*. 2014 Jun;20(6):570-83. doi: 10.1089/tmj.2013.0243.  
21 Epub 2014 May 1.  
22  
23 25. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S.  
24 Evaluating and selecting mobile health apps: strategies for healthcare providers and  
25 healthcare organizations. *Transl Behav Med*. 2014;4(4):363-71.  
26  
27 26. My Health Apps [Available from: [http://myhealthapps.net/app/details/127/Headspace-](http://myhealthapps.net/app/details/127/Headspace-on-the-go)  
28 [on-the-go](http://myhealthapps.net/app/details/127/Headspace-on-the-go)] (Accessed 28 August 2018).  
29  
30 27. Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and Evaluation of  
31 Mindfulness-Based iPhone Apps. *JMIR Mhealth Uhealth*. 2015;3(3):e82.  
32  
33 28. App Annie 2018 [Available from: <https://www.appannie.com/en/>] (Accessed 28  
34 August 2018).  
35  
36 29. Ball E, Newton S, Kahan BC, Forbes G, Wright N, Cantalapedra Calvete C, et al.  
37 Smartphone App Using Mindfulness Meditation for Women With Chronic Pelvic Pain  
38 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*.  
39 2018;7(1):e8.  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 30. Forbes G, Newton S, Cantalapiedra C, Birch J, Dodds J, Steed E, Rivas C, Khan  
4 KS, Rohricht F, Taylor SJC, Kahan B, Ball E. A smartphone app using psychological  
5 approaches for women with chronic pelvic pain (MEMPHIS): a randomised feasibility  
6 trial. submitted  
7  
8  
9  
10  
11 31. Gerhardt-Powals J. Cognitive engineering principles for enhancing human-computer  
12 performance. *International Journal of Human-Computer Interaction*. 1996;8(2):189-  
13 211.  
14  
15  
16  
17 32. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al.  
18 Normalisation process theory: a framework for developing, evaluating and  
19 implementing complex interventions. *BMC Med*. 2010;8:63.  
20  
21  
22  
23 33. Borkan J. Immersion/Crystallization. In BF Crabtree and WL Miller (Eds) *Doing*  
24 *Qualitative Research* (2nd edition). Thousand Oaks, CA: Sage Publication; 1999. p.  
25 pp. 179-94.  
26  
27  
28  
29 34. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting  
30 qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245-  
31 1251.  
32  
33  
34  
35 35. McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating  
36 in randomised controlled trials: conditional altruism and considerations for  
37 self. *Trials*, 11, 31. doi:10.1186/1745-6215-11-31  
38  
39  
40  
41  
42 36. Palmer, M., Sutherland, J., Barnard, S., Wynne, A., Rezel, E., Doel, A., Grigsby-  
43 Duffy, L., Edwards, S., Russell, S., Hotopf, E., Perel, P. Free, C. (2018). The  
44 effectiveness of smoking cessation, physical activity/diet and alcohol reduction  
45 interventions delivered by mobile phones for the prevention of non-communicable  
46 diseases: A systematic review of randomised controlled trials. *PloS one*, 13(1),  
47 e0189801. doi:10.1371/journal.pone.0189801  
48  
49  
50  
51  
52 37. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D.  
53 The Impact of mHealth Interventions: Systematic Review of Systematic Reviews.  
54 *JMIR Mhealth Uhealth*. 2018;6(1):e23.  
55  
56  
57  
58  
59  
60

- 1  
2  
3 38. Laurie J, Blandford A. Making time for mindfulness. *Int J Med Inform*. 2016;96:38-50.  
4  
5 39. Collins M, Shattell M, Thomas SP. Problematic Interviewee Behaviors in Qualitative  
6  
7 Research. *Western Journal of Nursing Research*. 2016;27(2):188-99.  
8  
9 40. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The  
10  
11 behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques:  
12  
13 building an international consensus for the reporting of behavior change  
14  
15 interventions. *Ann Behav Med*. 2013;46(1):81-95.  
16  
17 41. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing  
18  
19 human support to enhance adherence to eHealth interventions. *J Med Internet Res*.  
20  
21 2011;13(1):e30.  
22  
23 42. Andersson G. Using the Internet to provide cognitive behaviour therapy. *Behav Res*  
24  
25 *Ther*. 2009;47(3):175-80.  
26  
27 43. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for  
28  
29 characterising and designing behaviour change interventions. *Implement Sci*.  
30  
31 2011;6:42.  
32  
33 44. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth Intervention  
34  
35 Using a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot  
36  
37 Study. *JMIR Mhealth Uhealth*. 2016;4(3):e109. Published 2016 Sep 22.  
38  
39 doi:10.2196/mhealth.5227  
40  
41  
42 45. Geraghty AW, Torres LD, Leykin Y, Perez-Stable EJ, Munoz RF. Understanding  
43  
44 attrition from international Internet health interventions: a step towards global  
45  
46 eHealth. *Health Promot Int*. 2013;28(3):442-52.  
47  
48 46. Mistler LA, Ben-Zeev D, Carpenter-Song E, Brunette MF, Friedman MJ. Mobile  
49  
50 Mindfulness Intervention on an Acute Psychiatric Unit: Feasibility and Acceptability  
51  
52 Study. *JMIR Ment Health*. 2017;4(3):e34.  
53  
54 47. Noone C, Hogan MJ. A randomised active-controlled trial to examine the effects of  
55  
56 an online mindfulness intervention on executive control, critical thinking and key  
57  
58 thinking dispositions in a university student sample. *BMC Psychol*. 2018;6(1):13.  
59  
60

- 1  
2  
3 48. Wen L, Sweeney TE, Welton L, Trockel M, Katznelson L. Encouraging Mindfulness in  
4 Medical House Staff via Smartphone App: A Pilot Study. *Acad Psychiatry*.  
5 2017;41(5):646-50.  
6  
7  
8  
9 49. Morrison Wylde C, Mahrer NE, Meyer RML, Gold JI. Mindfulness for Novice Pediatric  
10 Nurses: Smartphone Application Versus Traditional Intervention. *J Pediatr Nurs*.  
11 2017;36:205-12.  
12  
13  
14  
15 50. Lim D, Condon P, DeSteno D. Mindfulness and compassion: an examination of  
16 mechanism and scalability. *PLoS One*. 2015;10(2):e0118221.  
17  
18  
19  
20 51. Arean PA, Hallgren KA, Jordan JT, Gazzaley A, Atkins DC, Heagerty PJ, et al. The  
21 Use and Effectiveness of Mobile Apps for Depression: Results From a Fully Remote  
22 Clinical Trial. *J Med Internet Res*. 2016;18(12):e330.  
23  
24  
25  
26 52. Gilbody S, Lewis H, Adamson J, Atherton K, Bailey D, Birtwistle J, et al. Effect of  
27 Collaborative Care vs Usual Care on Depressive Symptoms in Older Adults With  
28 Subthreshold Depression: The CASPER Randomized Clinical Trial. *JAMA*.  
29 2017;317(7):728-37.  
30  
31  
32  
33  
34 53. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A  
35 systematic review of the impact of patient and public involvement on service users,  
36 researchers and communities. *Patient*. 2014;7(4):387-95.  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## APPENDIX 1

Feature	Positive aspects	Negative aspects	Solutions
<b>Voice</b>	Liked by some participants, considered soothing and even spiritual	<p>The voice was not relaxing. One had to listen carefully which meant you could not switch off; otherwise you could not hear instruction clearly during meditation.</p> <p>It was also too repetitive, after 10 times it felt like a chore and not something to look forward to.</p>	<p>Choice of different voices</p> <p>participants should be told it takes time to get into the rhythm of the instructions, but you can get used to it</p>
<b>General interface aesthetics</b>	colours really fresh, interface not too busy, with pleasing layout and aesthetics	one participant would prefer different, bright, colours such as purple	None needed
<b>Graphics</b>		<p>The pictures were often not appropriate as they focused on the problem (e.g. tooth pain logo) rather than something positive or soothing. Unanticipated problems could arise according to one participant; she found it hard to lose weight and felt the food icons a) did not represent success and b) reminded her of eating.</p> <p>One participant found the pictures hard to see.</p>	Psychological theory supports the view that positive images would be advisable

<b>Animations</b>	liked	poorly chosen	None needed
<b>Progress</b>	<p>One participant liked the way the app helped progress through the stages.</p> <p>Another participant, with cyclical pain and hence cyclical use, did not aim to progress but simply chose to use the baseline video each time.</p>	<p>Three participants were frustrated and even 'angry' and 'patronised' at having to do the same (basic) meditation several times before moving up a stage.</p> <p>There was no indication of goals, duration of each level or gamification rewards.</p>	<p>Goal setting is recommended by psychological theory and could be as simple as using "day 1 of 30" rather than simply Day 1.</p> <p>Changing emojis could show progress, for example from a sad face to a smiley face to a heart; the inbuilt progress function was not felt sufficiently motivating.</p>
<b>Introduction</b>		Experienced app users suggested the introduction could be improved for initiates	<p>overview of the entire app and its levels suggested for the start.</p> <p>One participant had done mindfulness before but thought an introduction to mindfulness might be helpful for others.</p>
<b>Enjoyment</b>	considered fun by some participants.	One said it was not very 'interesting'.	<p>Include examples of a patient's day with the app to cater for a greater variety of participants</p> <p>It would be good to have other features as drop down options that were fun and</p>



			did not involve meditation.
<b>Session intensity</b>		Would be good to choose the duration of the meditation.	15 or 20 mins would be better than 10, which is not enough time shut off and meditate deeply.  The option to control this was important as even 10 minutes was a difficult commitment for some busy participants (1074, 1075, 1078) or those battling with chronic fatigue (1074)
<b>Pain modules</b>		it can be hard to focus on something like using the app when you are in pain.	None needed

**Comments on app acceptability and usability made by n=13 patients. Two patients walked through the app with the researcher**

# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	6
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4 and 5
Purpose or research question	#4 Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The	7

rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

1			
2			
3			
4			
5			
6			
7			
8			
9			
10	Researcher characteristics	#6	19
11	and reflexivity		
12			
13			
14			
15			
16			
17			
18			
19			
20	Context	#7	7
21			
22	Sampling strategy	#8	7
23			
24			
25			
26			
27	Ethical issues pertaining	#9	6
28	to human subjects		
29			
30			
31			
32			
33	Data collection methods	#10	7
34			
35			
36			
37			
38			
39			
40			
41	Data collection	#11	8
42	instruments and		
43	technologies		
44			
45			
46	Units of study	#12	See note
47			1
48			
49			
50			
51	Data processing	#13	8
52			
53			
54			
55			
56			
57			
58	Data analysis	#14	8
59			
60			

		developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	
1			
2			
3			
4	Techniques to enhance trustworthiness	#15 Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
5			
6			
7			
8			
9	Syntheses and interpretation	#16 Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-16
10			
11			
12			
13			
14	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	See note 2
15			
16			
17			
18	Intergration with prior work, implications, transferability and contribution(s) to the field	#18 Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	16
19			
20			
21			
22			
23			
24			
25			
26	Limitations	#19 Trustworthiness and limitations of findings	19
27			
28			
29	Conflicts of interest	#20 Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	4
30			
31			
32			
33	Funding	#21 Sources of funding and other support; role of funders in data collection, interpretation and reporting	3
34			
35			
36			

## Author notes

1. 7,8,9 and especially 10
2. 8-16 and appendix

The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist was completed on 26. March 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in gynaecology outpatient clinics: Qualitative data analysis of user experience and lessons learnt

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030711.R3
Article Type:	Original research
Date Submitted by the Author:	04-Dec-2019
Complete List of Authors:	Ball, Elizabeth; Queen Mary University of London - Whitechapel Campus, Yvonne Carter Building Newton, Sian; QMUL Rohricht, Frank ; East London NHS Foundation Trust Steed, Liz; QMUL Birch, Judy Dodds, Julie; QMUL, Women'shealth Research Unit Cantalapiedra Calvete, Clara; QMUL, Women's Health Research Unit Taylor, Stephanie; QMUL, Center for Primary Care and Population Health Rivas, Carol; University College London
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Health informatics
Keywords:	Chronic pelvic pain, mHealth, mindfulness, patient engagement, health app, feasibility study

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3 **Mhealth – Providing a Mindfulness App for women with chronic pelvic pain in**  
4 **gynaecology outpatient clinics: Qualitative data analysis of user experience and**  
5 **lessons learnt**  
6

7 **Ball, Elizabeth**

8 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom,*  
9 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
10 *Queen Mary University of London, United Kingdom, Centre for Maternal and child Health*  
11 *Research, City University London*  
12

13 **Newton, Sian**

14 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
15 *Kingdom*  
16

17 **Rohricht, Frank**

18 *East London NHS Foundation Trust, United Kingdom*  
19

20 **Steed, Liz**

21 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
22 *Kingdom*  
23

24 **Birch, Judy**

25 *Pelvic Pain Support Network, UK*  
26

27 **Dodds, Julie**

28 *Women's Health Research Unit, Barts and the London School of Medicine and Dentistry,*  
29 *Queen Mary University of London, United Kingdom*  
30

31 **Cantalapiedra Calvete, Clara**

32 *Department of Obstetrics and Gynaecology, Barts Health NHS Trust, United Kingdom*  
33

34 **Taylor, Stephanie JC**

35 *Centre for Primary Care and Population Health, Queen Mary University of London, United*  
36 *Kingdom*  
37

38 **Rivas, Carol**

39 *Department of Social Science, University College London, United Kingdom*  
40

41 Corresponding author

42 Carol Rivas, Department of Social Science, University College London, United Kingdom  
43 E-mail: c.rivas@ucl.ac.uk  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Abstract

### Objective

To determine whether a pre-existing smartphone App to teach Mindfulness Meditation is acceptable to women with chronic pelvic pain (CPP) and can be integrated into clinical practice within NHS CPP pathways. To inform the design of a potential randomised clinical trial.

### Design

A pre-study patient and public involvement (PPI) group to collect feedback on the acceptability of the existing app and study design was followed by a three-arm randomised feasibility trial. In addition, we undertook interviews and focus groups with patients and staff to explore app usability and acceptability. We also obtained participant comments on the research process, such as acceptability of the study questionnaires.

### Setting

Two gynaecology clinics within Barts Health NHS, London, UK.

### Participants

Patients with CPP lasting  $\geq 6$  months with access to smartphone or PC and understanding of basic English.

### Intervention

The intervention was mindfulness meditation content plus additional pain module delivered by smartphone app, active controls received muscle relaxation content by the same app. Passive (waiting list) controls received usual care.

### Main outcome measures

Themes on user feedback, app usability and integration and reasons for using/not using the app.

### Results

App use was low in both active groups.

Patients in the pre-study PPI group, all volunteers, were enthusiastic about the app (convenience, content, portability, flexibility, ease of use). Women contributing to the



1  
2  
3 interview or focus group data (n=14), from a 'real world' clinic, (some not regular app users)  
4  
5 were less positive, citing as barriers lack of opportunities/motivation to use the app, and lack  
6  
7 of familiarity and capabilities with technology. Staff (n=7) were concerned about the potential  
8  
9 need for extra support for patients and staff and considered the app needed organisational  
10  
11 backing and peer acceptance.  
12

### 13 14 **Conclusion**

15  
16 The opinions of pre-study PPI volunteers meeting in their private time may not represent  
17  
18 those of patients recruited at a routine clinic appointment.  
19

20  
21 It may be more successful to co-design/co-develop an app with typical users than to adapt  
22  
23 existing apps for use in real-world clinical populations.  
24

### 25 26 27 **Trial registration and funding**

28  
29 The trial (ISRCTN 10925965) was funded by the UK National Institute of Health Research,  
30  
31 Research for Patient Benefit programme (RfPB PB-PG-1013-32025).  
32

### 33 34 35 **Keywords**

36  
37 Chronic pelvic pain, mHealth, mindfulness, Headspace, PPI, patient engagement, feasibility  
38  
39 study, health app  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### Article Summary: 'Strengths and limitations of this study'

- The study was designed with the help of a study design group of CPP patients
- Patient recruitment to the study was good
- Unusually our study focused on a deprived urban area of the UK and considered typical local clinical patients
- The qualitative evaluation included the perspectives of both patients and a variety of healthcare staff
- Patients in the qualitative evaluation preferred telephone interviews over the offered face to face focus groups.

The original protocol for the study has been published separately. The UK National Institute of Health Research supported this work (RfPB PB-PG-1013-32025). There are no competing interests.

### Introduction

Smartphone health apps, as one form of mhealth (1), are popular in the UK, our study setting. With more than two-thirds of the UK population using smartphones (2,3,4), health apps are one of the fastest growing app categories, thus numbers of users are still increasing (5). Currently these apps are usually developed either by researchers or (in the majority) by commercial companies, without collaboration between these groups (6,7). The lack of interaction between researchers and commercial developers in the field of pain-related apps has led to a situation where commercially available apps have not been scientifically validated and apps that have been developed from research projects are not commercially available (8).

1  
2  
3 We were interested in using an app to support women with chronic pelvic pain (CPP) in a  
4 clinical setting, where validation of an intervention is important to ensure best care. CPP is  
5 defined as a subjective physical and emotional experience of pain in the pelvic area that has  
6 been present for at least six months that may or may not have an identifiable pathology (9).  
7  
8 CPP affects up to 24% of women worldwide (10) and accounts for 20% of gynaecological  
9 clinic referrals. (11,12) It has considerable impact on patients' quality of life, including their  
10 mental health and their income (13) due to loss of working days and diminished work  
11 capacity. Annual costs to the NHS have been estimated at approximately £326 million (14).  
12 For endometriosis alone, which is just one cause of CPP, a European study of over 900  
13 women showed average annual total costs per woman of €9579. Costs of productivity loss of  
14 €6298 were double the health care costs of €3113 per woman. The latter were due to  
15 surgery (29%), monitoring tests (19%) and hospitalization (18%) and physician visits (16%)  
16 (15).  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30  
31 Despite costly interventions, CPP is often resistant to surgical and medical treatment and  
32 appears to respond better to a multimodal, holistic approach, (16) with a focus on coping  
33 strategies. A systematic review of randomised controlled trials (RCTs) by authors has  
34 identified mindfulness meditation (MM) as an effective coping strategy in other chronic pain  
35 conditions (17). In addition, evidence from uncontrolled trials suggests positive effects of MM  
36 for CPP, such as an increased ability to control pain, improvements in mental health,  
37 emotional well-being, work and family life and social functioning (18,19), but these have  
38 never been examined in an RCT.  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 We therefore chose to evaluate MM delivered via an app to women with CPP as our  
50 intervention. CPP is especially common in younger women, who may be categorised as  
51 digital natives, making an app-based intervention particularly appropriate in this group.  
52  
53  
54  
55

56 In MM the aim is to keep focussed on one's own breathing. Whenever attention wanders to  
57 intrusive thoughts and feelings these are simply taken notice of in a neutral way, that is,  
58  
59  
60

1  
2  
3 without elaboration or judgements or consideration of action. They are then let go as  
4  
5 attention is returned to the breath. The idea is to bring awareness back to the here and now  
6  
7 whenever worries and troubles intrude into thoughts.(20)  
8  
9

10 Generally two main complementary approaches have been used for MM: 1) exercises  
11  
12 focusing one's attention to the present moment, and 2) monitoring of experiences in the  
13  
14 present moment. While systematic reviews show that MM may have positive effects on  
15  
16 depression, quality of life and pain symptoms in patients with chronic pain (17,21,22) and  
17  
18 apps with such a focus on chronic disease have been shown to be beneficial in various  
19  
20 conditions (23) none of the reviewed papers included meditation delivered via mobile phone  
21  
22 apps or in women with CPP.  
23  
24  
25  
26  
27  
28

29 Evaluation of an existing app is often appropriate (24) and is both quicker and more cost-  
30  
31 effective than designing an app from scratch. We chose to evaluate an existing commercial  
32  
33 app platform that teaches mindfulness by guided meditation (Headspace ®), with a ten day  
34  
35 basic meditation module followed by a pain module specifically designed for the MEMPHIS  
36  
37 (Mindfulness meditation using a smart-phone application for women with chronic pelvic pain)  
38  
39 study. The Headspace app was publicly nominated favourite health app of 2013,(25) has a 5  
40  
41 star user rating in the Apple™ app shop and has scored top in a systematic review of 23  
42  
43 mindfulness apps using the Mobile Application Rating Scale (visual aesthetics, engagement,  
44  
45 functionality or information quality) (26). Headspace had reportedly seen over 15 million  
46  
47 downloads up to mid-2018 when our study began.(27) To our knowledge the Headspace  
48  
49 app in its original or modified form has not been assessed in any other pain conditions.  
50  
51

52 We undertook a three-arm parallel randomised feasibility trial (MEMPHIS) (28) to assess  
53  
54 whether or not to proceed with a full randomised controlled trial of the modified Headspace  
55  
56 meditation app for women with CPP. In the current paper we report on the qualitative interview  
57  
58 and focus group data from this study; the protocol and quantitative results have been  
59  
60

1  
2  
3 published/ submitted (29,30). Our aim for the qualitative part of this study was to determine  
4 whether a pre-existing smartphone app to teach MM is acceptable to women with CPP and  
5 can be integrated into clinical practice within NHS CPP pathways. Objectives were to consider:  
6  
7

8  
9 1) The acceptability, use and usability of the app in the intended service user population and  
10 for health care professionals (doctors, health care assistants, clinical and research nurses)  
11  
12

13  
14  
15 2) The feasibility of integrating such an app into existing healthcare pathways  
16  
17

18 3) The usefulness of having a distinct patient group to advise us on the study design.  
19  
20  
21  
22  
23  
24

## 25 **Methods**

### 26 **Outcomes**

27  
28  
29 The outcomes of this analysis were inductively derived descriptive themes on acceptability,  
30 use and usability of the app and feasibility of integrating it into existing pathways. We follow  
31 the ISO 9241-11 (<https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-2:v1:en>) concept of  
32 technology usability (user friendliness) as the extent to which the app could be satisfactorily  
33 used by participants to meditate. By acceptability we mean whether participants could see a  
34 reason for using the app when given in clinic, and would be happy to use it for meditation.  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

### 49 **Intervention Procedures**

50  
51  
52 Women in the mindfulness meditation group received access to a 60-day progressive  
53 mindfulness meditation course delivered via the Headspace app. The first 10 days of the  
54 course taught basics of mindfulness meditation. Following this, participants were able to  
55 access the module on meditation which was targeted at for chronic pain. This module had  
56  
57  
58  
59  
60

1  
2  
3 been specifically made for this study. Session length was 10 minutes for the first 10 days, 15  
4 min up to day 20 and 20 min up to day 60. The active control group received access to a  
5 series of muscle relaxation sessions. These sessions were identical every day, except that  
6 their duration increased to mirror the increasing duration of the meditation content being  
7 listened to by the intervention group. Usage data are reported elsewhere (30).  
8  
9  
10  
11  
12  
13  
14

### 15 **Patient and Public Involvement**

16  
17  
18 We held a Patient and Public Involvement (PPI) group workshop before the study to discuss  
19 acceptability of the Headspace app and help us design our study. Women attending the  
20 Royal London Hospital CPP clinic were invited to volunteer for a week of using the  
21 unmodified (normal commercially available) Headspace app (which did not have the pain  
22 module at the time we undertook our pre study workshop) and then feed back on their  
23 experiences with the app in an evening discussion group. Women were not involved in the  
24 design of the modified app. The focus for the PPI group was on the use of the generic MM  
25 app.  
26  
27  
28  
29  
30  
31  
32  
33  
34

35 Two patient representatives provided support from the study design stage through  
36 recruitment to the interpretation of the results and regularly attended Trial Management  
37 Group meetings.  
38  
39  
40  
41  
42  
43  
44  
45

### 46 **Study recruitment and eligibility**

47  
48 The trial recruited at two outpatient gynaecology clinics within Barts Health NHS trust in two  
49 separate deprived areas of inner East London. Female patients with new or follow-up  
50 gynaecology appointments were assessed for eligibility by a researcher in clinic, having  
51 been posted a Patient Information Sheet. Women were eligible if they had been suffering  
52 with CPP for 6 months or more and had at least a basic understanding of the English  
53 language, sufficient to follow instructions, as assessed during discussion about the study for  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 informed consent; no women were excluded on this basis. Women were excluded if they did  
4 not meet these criteria or they did not have access to a smartphone or personal computer or  
5 were currently using the Headspace app (there were very few of the latter, according to the  
6 impression of the recruiting nurses). All patients gave full and informed consent to be  
7 randomised and data were collected through all stages of the study. All healthcare  
8 professionals and research nurses involved in the two clinics were also invited to take part in  
9 the feasibility study as the only eligibility criterion for staff. Full enrolment data are provided  
10 in Forbes et al (30). A key difference of these patients from those in the PPI group was that  
11 their focus was on managing their pain, with the app given explicitly as part of their clinic  
12 management support.  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

26 For the study of quantitative data, 90 patients were allocated randomly in a 1:1:1 ratio to the  
27 mindfulness meditation app, a muscle relaxation app active control or the usual care arm (for  
28 full details see (29)). Patients in the two active arms were asked to download the modified  
29 app in the clinic with support from a research staff member and were sent a questionnaire  
30 about app usability, an analysis of which is reported in a companion paper.(30) We used  
31 data from the app usability questionnaire to inform topic guides for the qualitative part of the  
32 study. This outlined key usability issues that had been uncovered, to guide our semi-  
33 structured interviews and focus groups with patients and staff.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

46 All women in the intervention and active control arms were eligible for the qualitative  
47 component of the study, and all staff participating in the study.  
48  
49  
50

### 51 **Within-study interviews and focus groups**

52 All patients in the intervention and active control arms were invited to one of two focus  
53 groups at their own study site after the 6-month follow up. We offered telephone interviews  
54 as an alternative. Patients were asked to 'walk through' the app with researchers, articulating  
55 their thought processes while they did so and commenting on its different specific features,  
56  
57  
58  
59  
60

1  
2  
3 (31). Walkthroughs are often used in developing technologies such as mhealth. This helped  
4  
5 to identify app usability issues or barriers to use of the app from the users' points of view  
6  
7 without the need for technical discussions. Results for the walkthrough, showing comments  
8  
9 on different features specific to the usability of the intervention app used in our study are  
10  
11 shown in Appendix 1; walkthroughs were undertaken by two patients. Patients also  
12  
13 discussed with us their experiences around app usability and acceptability.  
14  
15

16  
17 Staff were invited to attend a staff focus group overseen by the patient representative and  
18  
19 facilitated by a researcher. In addition to considering app usability and acceptability,  
20  
21 members of the staff focus group (consultants, health care assistants, clinical and research  
22  
23 nurses and a representative from the pelvic pain support network were eligible) were asked  
24  
25 about the ease of integration into existing NHS pathways. Part of the staff discussion was  
26  
27 free flowing with open-ended questions, which gave us patient-focussed information on app  
28  
29 acceptability, and part was structured using questions developed from the Normalisation  
30  
31 Process Theory (NPT) toolkit in the way recommended by the NPT developers (32). For  
32  
33 example, we asked whether staff could see a purpose to the app in clinical practice, as  
34  
35 adding something different, which corresponds to the NPT toolkit question 'Participants  
36  
37 distinguish the intervention from current ways of working'. Since this was a semi-structured  
38  
39 approach questions were not rigidly worded. This helped us to consider the feasibility of  
40  
41 integration of the app into practice. NPT is a theory of implementation practices that was  
42  
43 initially developed for consideration of technology implementation and is in common use  
44  
45 (32).  
46  
47

48  
49 All data were audio-recorded at point of collection and transcribed, with personal identifying  
50  
51 data removed from transcripts. Raw data were stored in a Primary Care Clinical Trial Unit  
52  
53 database to clinical trial standards.  
54  
55

## 56 57 **Analysis** 58 59 60



1  
2  
3 Analysis of within-study focus groups and interviews was carried out blinded as to which  
4 study app was used, and deployed the immersion-crystallisation method (33). Thus, the lead  
5 qualitative researcher immersed herself in the data, reading transcripts carefully, then writing  
6 down articulated or crystallised patterns or themes that related to the aims and research  
7 questions of the study. These were discussed with another researcher from the team, and  
8 themes modified as appropriate. This process was repeated until all the data had been  
9 examined and all patterns that had been noticed were articulated, discussed and  
10 substantiated with exemplar extracts. This approach was considered appropriate since we  
11 had a small dataset and we were not aiming to develop conceptual themes but rather to  
12 inform the design and development of a randomised controlled trial for the modified app.  
13 We used the SRQR checklist when writing our report (34).  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

### 29 **Ethics**

30 The MEMPHIS trial was a three-arm parallel randomised feasibility trial approved by Camden  
31 and Kings Cross Research Ethics Committee in 2016 (15/LO/1967).  
32  
33  
34  
35  
36

### 37 **Results**

38 We screened 488 women between May and September 2016 for their eligibility to participate  
39 in the study. After exclusions, 90 women gave full consent to participate and were  
40 randomised to the intervention arm (31 women), the active control arm (30 women) or the  
41 usual care arm (29 women).  
42  
43  
44  
45  
46  
47  
48  
49

### 50 **Demographics**

51 Women in the main feasibility trial (30) were aged a mean of 35 years, 66% were employed  
52 and overall approximately 50% had stayed in full time education until at least the age of 20  
53 though the proportion was least, at 36.7% in the intervention arm. Overall 44% were of white  
54 ethnicity though the proportion was lowest in the intervention arm (35.7%) and highest in the  
55 usual care arm (53.6%). The second most common self-reported ethnic groups were  
56  
57  
58  
59  
60

1  
2  
3 'Southern Asian' and 'Black'. Women in the intervention arm were most likely to have  
4 experienced CPP for 3-5 years (40.3% of this group), women in the usual care group for  
5 over 10 years (42.9% of this group). More women had pain for longer than two years in the  
6 intervention arm than in either of the other two arms. All women reported a high pain  
7 intensity, with means of 6.8 to 6.9 in the previous week (on a scale from 1-10) (30). These  
8 and other demographic data are reported in more detail in Forbes *et al.* (30) Our qualitative  
9 sample was taken from the two active arms and was comprised of 16% of trial participants  
10 and 23% of those eligible for the qualitative study. We did not record separate demographic  
11 data for the women in this smaller sample.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### ***Pre-study PPI group***

The ten women in the pre-study PPI group were self-selected local women who were familiar with using apps and focused on app use per se. They anticipated no technical issues even in women who were not used to apps. They considered that the Headspace app would be successfully adopted by patients taking part in the study, given that a smartphone, like CPP, is 'always with you'. They praised the flexibility of the app, welcomed its portability and were unanimous in saying it was easy to slip off for 10 minutes when at work to use it. As a result, they found they could use it at times when they most needed pain relief as well as to prevent pain and found the app helpful in relieving pain and stress. The group reported being able to meditate without the app, once they had tried it with the app; however, they still preferred to use the app because they found the voice soothing.

### ***App usage in the study***

Patient usage of the app was less than expected from our pre-study PPI group discussions. Only 36% of meditation app patients and 46% of the active control patients used the app at least once. (30)

### ***Thematic analysis of within-study data***

Qualitative data were obtained from 14 study patients; 12 preferred a telephone interview, two attended face-to-face interviews, one participant at the University attached to one of the recruiting clinics and one participant at the other recruiting hospital. Patients chose not to attend focus groups. Four of the patients were from the active control arm and 10 from the intervention arm. The two women we met face to face had both used the intervention and neither had progressed beyond the training stage, something that we cannot discount for other participants and which may help to explain reports of lack of effect on pain. Seven people attended the staff focus group: two recruiting nurses, three clinic nurses one consultant and a representative from the pelvic pain support network.

1  
2  
3 The qualitative analysis revealed three main themes from all within-study interviews and  
4 focus groups combined regarding usability, and four subthemes:  
5  
6  
7

- 8 1. Familiarity and capabilities with app technology
- 9 2. Motivations to use the app
- 10     ○ Perceived benefits
- 11     ○ Relation to other therapies
- 12 3. Opportunities to use the app:
- 13     ○ Technology issues getting in the way
- 14     ○ Life getting in the way
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22

23 These are explored below. As the PPI group data were not research data we did not  
24 analyse them for themes.  
25

26 While we initially combined active control and intervention groups in our analysis, we then  
27 looked for instances where there was a difference between these two groups. Only where  
28 we found this difference in any theme or statement have we specified which group women  
29 belonged to.  
30

### 31 *Familiarity and capabilities with app technology*

32 Around half of the patients were sufficiently familiar with technology and apps to be  
33 comfortable using the study apps. However, six participants (all using the intervention, which  
34 was more complex than the active control) reported difficulty because they were “*not very*  
35 *good at technology*” (patient 1002, intervention), or were unsure how to get started or use  
36 the app effectively without help.  
37

38 *I am not good with technical some things that is why the problems I had arisen, right*  
39 *okay. So I consulted with my daughter and she helped me work it out... so I don't try*  
40 *everything. (patient 1002, intervention)*  
41

42 One further patient (1001, intervention) was not used to technical app language; ‘help’  
43 suggested emotional support to her, for example. Two more (one intervention, one active  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 control) changed handsets and therefore did not continue with the app. In all cases these  
4  
5 technical difficulties appeared to lead to abandoning of the app or restricted use of its  
6  
7 functionality.  
8  
9

10 Five patients having technical problems suggested possible solutions such as a 'class' or  
11  
12 group for first time users, a YouTube orientation video, or a pictorial leaflet. This might  
13  
14 include an introduction to meditation and mindfulness as well as the app itself. One woman  
15  
16 commented: *"If your market is targeting people who are not using apps then you are going to*  
17  
18 *have to get together and find ways to do this"*, (patient 1041, intervention); she also  
19  
20 suggested we could get ideas from other apps on the market in this regard.  
21  
22

23 Given their experiences in the study, staff were concerned about additional staff time needed  
24  
25 to support women in using the app. This would sit in tension with one of the original  
26  
27 rationales behind choosing an app as the mode of delivery, which was to increase the  
28  
29 effective use of staff contact time with patients. Language barriers might compound  
30  
31 problems.  
32  
33

### 34 35 36 37 *Motivations to use the app*

38  
39 Staff, though unaware of the low sustained app use in the study, felt it would be common  
40  
41 sense to hold occasional motivating meetings with patients if the intention was for them to  
42  
43 use the app long term. The patient data suggested the main motivators or lack of motivation  
44  
45 for using the app in our sample, which could be drawn on in such meetings, and which we  
46  
47 now consider.  
48  
49

### 50 51 52 53 Perceived benefits

54  
55 Three intervention arm patients said they only entered the trial to help others through  
56  
57 research but were already using alternative forms of pain control. They explained that this  
58  
59 meant they were not motivated to actually use the app, perceiving the relative benefit to be  
60

1  
2  
3 small. The failure of such altruism to extend to using the app is a recognised phenomenon in  
4 clinical trials and has been called ‘weak altruism’. (35) Thus, only one of these three patients  
5 persevered. Even though she was one of the women who experienced difficulties with the  
6 technology, she explained, “*with something that is as soul destroying as the pain, it is*  
7 *important to help others off the back of other people's misfortune as it were*” (1036,  
8 intervention). However, she wondered how relevant her data were:  
9  
10  
11  
12  
13  
14

15  
16 *I took steps to improve my situation from a weight loss perspective as well and I've lost a lot*  
17 *of weight which has significantly helped not 100% but it is has significantly helped so I felt a*  
18 *bit fraudulent the last time filling in the forms because , so everything had improved so much*  
19 *so from the medical study perspective it was more about the weight loss than the app. So I*  
20 *felt a bit bad that I was still taking part. (patient 1036)*  
21  
22  
23  
24  
25  
26  
27

28 There was no clear pattern regarding the impact of current pain on app use by patients. Six  
29 said they used it regardless of pain intensity – sometimes developing a daily routine – while  
30 four only used it when in severe pain or expecting to be (e.g. during menstruation). This  
31 cyclical or intermittent use in some patients – which was irrespective of study arm - should  
32 be considered when looking at our main study outcomes.(30) The Headspace app requires  
33 regular use to learn and benefit from psychological techniques. To address this, healthcare  
34 professional alerts have been effective in other studies, (36) whilst Headspace only has a  
35 reminder function that the user can set. This was often not sufficient, as one patient said  
36 even with this feature, “*To be quite honest I used it a couple of times and then forgot. And*  
37 *then I [remembered it and] used it more frequently.*” (patient 1036, intervention)  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48

49 One patient said medication was not working but the app did, though she was not sure  
50 whether this was ‘*mind over matter*’ (1065, intervention), which was her term for a placebo  
51 effect. Three others said it did not reduce their pain; all three were using the intervention  
52 app. The remaining patients considered other benefits were good reason for using the app  
53 even when they did not feel that it reduced pain intensity. Alternative or unanticipated  
54 benefits were not formally measured or taken into account in the study’s effectiveness  
55  
56  
57  
58  
59  
60

1  
2  
3 outcomes (30). For example, ten patients valued the way the app helped them to relax or de-  
4 stress or focus and re-assess their life; three of these specifically said they used it to induce  
5 a relaxed state to get to sleep. Notably the active control was a relaxation app; however this  
6 benefit was also reported by many women in the intervention arm. One participant (active  
7 control) said she did not like the focus on pain per se as her condition impacted on various  
8 areas of her life. Even when the intervention app was positively received, women might stop  
9 using it because it was too powerful, and they had gained the change they wanted:  
10  
11  
12  
13  
14  
15  
16  
17

18 *I think it was day 3, I could see the change that was happening, I was able to speak up for*  
19 *myself .....I can't explain it, even now I am getting emotional... it's just a lack of focus, I just*  
20 *needed direction. To try and put it into words. To me it meant so much that I have gone back*  
21 *to church... I use it outside of the app now I have got from it what was missing, so it's done*  
22 *something to me and for me which is very positive, and I may try it to lose weight but those*  
23 *positive vibes are still there. I can't go back to it because I did not want to go any further*  
24 *because what I got at the time helped me to focus, to change my way of thinking. I used it for*  
25 *about two or three weeks. (patient 1001, intervention)*  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35

36 Three intervention app patients found the app put them more in tune with their bodies and  
37 their breathing, (two of these were among those who also found the app de-stressing) while  
38 another found yoga better for that. Six patients, like pre-study PPI group members, also  
39 learned to use techniques from the app to alter their stress patterns without the app, having  
40 tried it, for example in traffic or by sitting down and taking time out or for general relaxation.  
41  
42  
43  
44  
45  
46  
47  
48  
49

#### 50 Relation to other therapies

51 Two patients (both active control) preferred 'pure' meditation, another considered the app to  
52 be "very much about meditation" (1041, intervention), which is in keeping with the arms they  
53 were in. An alternative therapy practitioner and two further patients reported that they  
54 preferred yoga. One (active control) said this was because it focussed on each part of the  
55 body in turn.  
56  
57  
58  
59  
60

1  
2  
3 Three intervention app patients thought the app was useful as an adjunct to other methods  
4 rather than a replacement for them, for example physical interventions such as Pilates, or  
5 listening to classical music.  
6  
7  
8

9  
10 *Opportunities to use the app*

11  
12 Technology issues getting in the way

13 Staff pointed out that not all patients had smartphones (not appreciating that PCs/tablets  
14 were alternatives allowed in this study). Some patients lacked the storage space to load the  
15 app on their phones. There were also issues with Wi-Fi connectivity when staff tried to help  
16 the patients load the app within the hospital sites. Possible solutions that staff suggested  
17 were to lend patients phones and to have group upload sessions in a location with good Wi-  
18 Fi signal – though they acknowledged the resource implications.  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30 Life getting in the way

31  
32 Seven patients revealed they preferred to use the app in the evenings because of other life  
33 commitments. This meant they did not always use it as a direct response to pain, reducing  
34 its potential for contemporaneous effect. One patient who used it in response to pain but  
35 only used it once or twice blamed this on having no spare time because of juggling work and  
36 children (active control); however, another patient (intervention) managed despite such  
37 commitments the fact that she was in the intervention arm may have played a role.  
38  
39  
40  
41  
42  
43  
44  
45

46 **Barriers to integration for staff**

47  
48 Staff believed that the biggest barrier to clinical adoption of the app was a possible lack of  
49 support from the host organisation. It might also be hard to integrate the app within existing  
50 professional work practices if the staff in the position of offering the app to patients failed to  
51 see its relative advantage over other interventions. Collection of feedback on the app's  
52 effectiveness would be necessary for staff to support sustained use. It was felt that staff  
53 would need training on how to introduce the app to women in practice, and that complexity  
54  
55  
56  
57  
58  
59  
60



1  
2  
3 and high staff turnover could impede sustained use. An app was also seen as impersonal  
4 compared with face-to-face contact, which was more favoured by staff.  
5  
6  
7  
8  
9

### 10 **Participant comments on the research process**

11  
12 The study questionnaires that were used for the main quantitative outcome measures (30)  
13 were acceptable to patients except for some discomfort with a question about sex, which  
14 patients considered a delicate question that was missing a 'no sex' option. Most preferred a  
15 paper form reflecting their lack of affinity with technology. There were no indications that the  
16 study design or study processes had contributed to the participants' lack of engagement with  
17 the apps – with a caveat around support with the technology as mentioned above - though  
18 we did not systematically consider this. A full summary of patient comments on the study  
19 design and procedures is given in Appendix 1.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

### 31 **Discussion**

32  
33 Our study adds to the limited evidence on mHealth app user behaviour and experience  
34 (36,37). The pre-study PPI group (young women, of a generation who were familiar with  
35 using apps and who were asked to focus on the study design use of the app) liked the idea  
36 of delivering the intervention via an app, praising the contemporary design and flexibility.  
37 Hence we expected a similar positive attitude from trial participants, who were of a  
38 comparable age, and we assumed would be keen on using apps. Participant feedback  
39 revealed that this assumption was too simplistic.  
40  
41  
42  
43  
44  
45  
46  
47

48 Using our qualitative data, we were able to explore reasons for low app usage that had been  
49 recorded in our feasibility study.(30) Our thematic analysis suggests that the low app use in  
50 the trial occurred because many patients were not familiar with apps in general or lacked  
51 capabilities with technology. This was particularly true for the more complex intervention  
52 app. The other themes we report did not differ between groups (although the three cases of  
53 weak altruism' all occurred in the intervention arm) which suggests more generic issues that  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 can be transferable to other app use situations. For example, women stated limited  
4 motivation to use the app because of a lack of perceived benefit, or a lack of opportunity to  
5 use the app due to Wi-Fi issues or due to other commitments.  
6  
7  
8  
9

10  
11 Similar findings were reported by Laurie *et al.*(38) who interviewed 16 healthy city-dwelling  
12 participants (25-38 years) about their user behaviour before and after 30-40 days of  
13 Headspace app exposure. Like us, they reported barriers of busy lives, failure to establish a  
14 routine and a lack of perceived benefit; all users in their study tried the app at least once  
15 hoping it could deliver a quick fix but were disappointed if this did not happen. In our study  
16 many patients failed to perceive a benefit from using the app. Hence excuses stating other  
17 commitments may mask a deeper lack of motivation linked to perceptions of benefits.(39)  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27

28 The advantages and disadvantages of using the app stand-alone were also illustrated by our  
29 data. Some suggestions made by participants to improve usage, such as more guidance at  
30 the start, seem obvious in hindsight. But they had not been considered because of the  
31 feedback from the pre-study PPI group and the commercial success of Headspace. The use  
32 of community contacts may be a helpful alternative.(40) Social support can create a  
33 community of practice, help to clarify expectations,(41) and improve health outcomes (as  
34 shown for example in internet based psychological treatment for depression (42).  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

45 The data suggest that for successful app use we need to understand what motivates  
46 individuals with clinical need to use the app for clinical reasons (which our PPI group did not  
47 focus on) and target this, for example by setting appropriate expectations. Incentivisation  
48 might also improve motivation. This could be achieved through app gamification (7), or  
49 encouragement through integration with patient-clinician face-to-face encounters, which was  
50 lacking in our study since the app was used stand-alone. The present study provided  
51 extensive initial technical support but no coaching and incentivising, in keeping with the  
52 protocol. Future app studies should take this into account. Participants in our study may  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 have also have benefitted from training and support to improve their app use capabilities and  
4 guidance on how to create more opportunities for app use – such as through sharing  
5 experiences in clinic support groups. This is in keeping with the COM-B model of behaviour  
6 change (43) which our themes matched, though this was only realised after analysis. The  
7 COM-B model says that Capability, Opportunity and Motivation are key drivers of behaviour  
8 and has been used to develop a number of complex interventions including smartphone  
9 apps (e.g. 3).

10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20 Lack of engagement after recruitment, or good initial engagement but minimal or  
21 inconsistent use, have been reported in other studies (44,45), including in Headspace trials  
22 other than our own (46, 47). Settings were a university and a psychiatric inpatients clinic,  
23 both in the USA. Inconsistent app use was noted by Wen (48) in junior doctors who used  
24 self-guided Headspace. Morrison Wylde (49) compared face-to-face MM with headspace  
25 use in novice paediatric nurses. However, unlike our study there were no recorded  
26 dropouts/non-users and also no record of whether or how long the app was used for which is  
27 an important omission.

28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39 None of these studies included a qualitative component. Yet, each of the Headspace study  
40 groups were very different, and so will likely have differed in motivations, contexts for  
41 opportunity to use the app, and incentivisations (50). While these aspects were not  
42 considered in the other studies, our use of qualitative research has enabled us to explore  
43 these in more depth. Our findings suggest these are important considerations in any study  
44 of app use and therefore this study makes a contribution to the field. For example, some of  
45 the groups in other studies may have differed from ours in likelihood of using mhealth apps  
46 in the first place, and familiarity with technology. In-patients may have more time to use the  
47 app and more support – and may also have had specific barriers to app use, such as related  
48 to setting and to illness.

1  
2  
3 Patients in the qualitative part of our study tended not to use apps on a regular basis (or at  
4 least apps other than simple games), and in terms of our themes, also represented in the  
5 COM-B model, may be said to have few capabilities in technology use. They therefore do  
6 not represent the typical users of the Headspace app in a commercial setting. Accessing the  
7 app regularly requires energy, time and effort, but patients with CPP often suffer from fatigue  
8 and anxiety as co-morbidities, perhaps whilst having to juggle family life and work.

9  
10  
11 Therefore, this may be seen as a challenging clinical population in which to trial an app.

12  
13  
14 Further Headspace trials with diabetic (NCT03274362) and pain (NCT03495726) outpatients  
15 are underway.  
16  
17

18  
19  
20 Our study has also shown that clear consideration of unexpected benefits should be  
21 included in future studies and these can be informed by our finding that benefits for patients  
22 may be more diffuse than anticipated (e.g. app relieving stress rather than pain). Such  
23 benefits were found in the active control as well as the intervention arm and so it may be that  
24 they represent a placebo effect though the effect could equally be real. Our data also  
25 suggest that staff benefits may be less than anticipated, as participants sometimes needed a  
26 lot of support and scaffolding in technology use at least initially.  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40

41 Young age, co-morbid anxiety and low educational attainment are predictors for dropping out  
42 of web-based interventions according to studies in the field of depression. (51, 52) This may  
43 be true despite regular phone support (52) though our participants all considered active  
44 motivational support from staff or app support groups would have improved app use. Our  
45 intervention arm participants were particularly likely to be young and with low educational  
46 attainment.  
47  
48  
49  
50  
51  
52  
53  
54

55 Our data suggest that it is important to involve real world end users in the agile design or  
56 development or modification of apps in close collaboration with researchers and commercial  
57 app developers.(7) Although the evaluation of existing apps has been recommended as a  
58  
59  
60

1  
2  
3 cost-effective and rapid process, (24) our findings suggest that in actual clinical practice  
4 these may be problematic.  
5  
6  
7  
8

9 *Strengths and weaknesses of the study and in relation to other studies*

10  
11 One strength of this study is that it creates much-needed evidence in the field of evaluating  
12 existing health apps in a clinic population (6,8,24) and recording user experience. This  
13 provides us with lessons to be learned.  
14  
15  
16

17 Researchers conducting interviews and focus groups were: a senior mixed methods medical  
18 sociology researcher, a recruiting nurse, a representative from the pelvic pain support  
19 network and an experienced health psychologist. Findings were similar across the data and  
20 the different backgrounds of the researchers therefore does not appear to have influenced  
21 findings. The main analysis was undertaken by the medical sociologist and so the  
22 concordance with the COM-B model is not due to background discipline bias.  
23  
24  
25  
26  
27  
28  
29

30 We were able to recruit successfully, and we obtained valuable information from patients  
31 with CPP, who were recruited from a deprived urban area of the UK as typical local clinical  
32 patients.  
33  
34  
35  
36  
37  
38

39 However, we report a marked discrepancy between the attitudes of the pre-study PPI group  
40 of volunteer patients from the local area, who actively put themselves forward for a 7-day  
41 trial of the app, and the participants asked to take part when they attended clinics. The  
42 opinions of pre-study PPI volunteers meeting in their private time may not be representative  
43 of the opinions of patients recruited at a routine clinic appointment. Women in the PPI group  
44 were used to using apps, which had led them to be interested in the study in the first place.  
45 Whereas women in the PPI group had all trialled the app at home and work without support  
46 from us, many patients from clinic were unable to use their phone beyond calls, texts and  
47 photos. Moreover, most of the women we interviewed used the intervention app. We can  
48 only speculate as to why this is so but it does mean that concordances and divergences  
49 across the intervention and active control arm do need to be treated with circumspection.  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5 To our knowledge the present observation on failure of PPI work to translate into practice in  
6 a trial has not been formally reported before, and is lacking from a recent comprehensive  
7 systematic review.<sup>(53)</sup> PPI involvement is a stipulated requirement when applying for some  
8 funding, and the present research findings should be taken into account when drafting  
9 guidelines for future PPI involvement in study planning. PPI groups are able to provide  
10 significant help and advice in any study but our findings shows the value of adding agile co-  
11 development as a requirement for app intervention development as likely to provide a more  
12 effective intervention than one informed by PPI alone. Moreover, there is a difference  
13 between app use for active clinical management (as with our study participants), and  
14 consideration of the potential for app use for this (as with our PPI group).

#### 27 28 *Implications for clinicians and policymakers*

29  
30 Given the patchy use of the app and the way that some participants did not manage to  
31 unlock its full functionality, and an indication of diffusion of benefit, more work is needed to  
32 see whether the app reduces pain per se. This study is a good example of the need to move  
33 away from 'one size fits all' behavioural interventions. Future studies should do more work  
34 on implementation before doing an effectiveness trial. This will enable researchers to be  
35 more nuanced about saying who the app is effective for, if at all.

36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46 Strategies to involve busy, less motivated, and less technologically experienced individuals  
47 in PPI and lay app design groups need to be further developed. These groups should  
48 include considerable scaffolding, which we have shown extends to study involvement by  
49 patients. More care is also needed to obtain PPI input that is representative of the target  
50 group, taking into account their capabilities, opportunities and motivational aspects. It may  
51 be useful to give the PPI group a small condition management task that emulates what trial  
52 participants will be required to do. Moreover, we can confirm a recent review suggesting  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 that health apps should be co- designed with users (7), rather than presenting them with a  
4 pre-existing app. These implications for our study are also generalisable to other  
5  
6  
7 technology studies.  
8  
9

### 10 11 **Author contributions**

12 EB led the study as the CI. EB and CR were the main authors of the grant application for  
13 this study, and co-lead authors of the current paper. FR, SJCT, JD, JB, SN and LS  
14 contributed to the study design and initial protocol. All authors provided support throughout  
15 the trial and contributed towards the final paper. CR led on the PPI and CR and LS led the  
16 interview and focus group field work and analysis reported here. CR, LS, SN, CCC, JD and  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
JB were all involved in the field work.

### 24 25 **Role of the funding source**

26 The UK National Institute of Health Research, Research for Patient Benefit (RfPB No. PB-  
27 PG1013-32025) funded the MEMPHIS study. The funder had no role in the study design, in  
28 the collection, analysis, and interpretation of the data, in the writing of this report, or in the  
29 decision to submit the paper for publication. The first and last authors vouch for the integrity,  
30 completeness and accuracy of the data and analyses, and for the fidelity of this report to the  
31 protocol and statistical analysis plan. The views and opinions expressed herein are those of  
32 the authors and do not necessarily reflect those of the RfPB, NIHR, NHS or the Department  
33 of Health.  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### 40 41 **Competing interests**

42 We have read and understood BMJ policy on declaration of interests. We have no  
43 competing interests to declare.  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

### 46 47 **Data sharing**

48 The data are collected from a small number of people which could compromise their identity  
49 if shared with others. Therefore we are not making them available except under exceptional  
50 circumstances which will be determined by the custodian of the data (Elizabeth Ball) on an  
51 individual basis.  
52  
53  
54  
55  
56  
57  
58  
59  
60

### 57 58 **Transparency**

1  
2  
3 The lead author confirms that the manuscript is an honest, accurate and transparent account  
4 of the study being reported; that no important aspects of the study have been omitted; and  
5 that any discrepancies from the study as planned and registered have been explained.  
6  
7  
8

### 9 **Acknowledgements**

10 We would like to thank all the researchers, consultant obstetricians and gynaecologists and  
11 data assistants at each of the recruiting clinics for their hard work in promoting the study,  
12 recruiting participants and for data entry. Our thanks go to the Trial Steering Committee;  
13 Andrew Horne, Sohinee Bhattacharya, Christina Lioffi, and Hulya Guzel for their constant  
14 support throughout the trial.  
15  
16  
17  
18

19 We thank the Pelvic Pain Support Network and Endometriosis UK for their promotion and  
20 guidance in developing the study design. We would also like to acknowledge the NIHR RfPB  
21 programme for their on-going support.  
22  
23  
24

25 Lastly, thank you to Headspace Ltd for providing our participants with access to the  
26 Headspace platform, designing novel content for the study, and for their continuous support  
27 and advice throughout the study.  
28  
29  
30  
31  
32  
33  
34

### 35 **References**

- 36  
37  
38  
39  
40 1. Ali EE, Chew L, Yap KY. Evolution and current status of mhealth research: a  
41 systematic review. *BMJ Innovations* 2016;2:33-40  
42  
43 2. Ofcom. The Communications Market Report. Ofcom: United Kingdom 2015.  
44 <https://www.ofcom.org.uk/research-and-data/multi-sector-research/cmr/cmr15/uk>  
45 [accessed 21 March 2019]  
46  
47  
48 3. Kayyali R, Peletidi A, Ismail M, Hashim Z, Bandeira P, Bonnah J. Awareness and  
49 Use of mHealth Apps: A Study from England. *Pharmacy* 2017, 5, 33.  
50  
51 4. Sezgin E, Yildirim S, Özkan-Yildirim S, Sumuer E. Current and Emerging mHealth  
52 Technologies: Adoption, Implementation, and Use: Springer International Publishing;  
53 2018 2018.  
54  
55  
56  
57  
58  
59  
60



- 1  
2  
3 5. Lunden I. 6.1B Smartphone Users Globally By 2020, Overtaking Basic Phone  
4 Subscriptions [https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-](https://techcrunch.com/2015/06/02/6-1b-smartphone-users-globally-by-2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015)  
5  
6 2020-overtaking-basic-fixed-phone-subscriptions/?guccounter=12015 [cited 2018 28  
7  
8 August 2018].  
9
- 10  
11 6. Subhi Y, Bube SH, Rolskov Bojsen S, Skou Thomsen AS, Konge L. Expert  
12  
13 Involvement and Adherence to Medical Evidence in Medical Mobile Phone Apps: A  
14  
15 Systematic Review. *JMIR Mhealth Uhealth*. 2015;3(3):e79.  
16
- 17  
18 7. Edwards EA, Lumsden J, Rivas C, et al. Gamification for health promotion:  
19  
20 systematic review of behaviour change techniques in smartphone apps. *BMJ Open*.  
21  
22 2016;6(10):e012447. doi:10.1136/bmjopen-2016-012447.  
23
- 24  
25 8. de la Vega R, Miro J. mHealth: a strategic field without a solid scientific soul. a  
26  
27 systematic review of pain-related apps. *PLoS One*. 2014;9(7):e101312.  
28
- 29  
30 9. Engeler D, Baranowski AP, Borovicka J, et al. European Association of Urology.  
31  
32 Guidelines on chronic pelvic pain. [http://uroweb.org/wp-content/uploads/EAU-Guidelines-](http://uroweb.org/wp-content/uploads/EAU-Guidelines-Chronic-Pelvic-Pain-2015.pdf)  
33  
34 [Chronic-Pelvic-Pain-2015.pdf](http://uroweb.org/wp-content/uploads/EAU-Guidelines-Chronic-Pelvic-Pain-2015.pdf). Accessed Sept 19, 2019.  
35
- 36  
37 10. Ahangari, A. Prevalence of chronic pelvic pain among women: an updated review.  
38  
39 *Pain Physician*. 2014 Mar-Apr;17(2):E141-7.  
40
- 41  
42 11. Latthe, P., Latthe, M., Say, L., Gülmezoglu, M., & Khan, K. S. (2006). WHO  
43  
44 systematic review of prevalence of chronic pelvic pain: a neglected reproductive  
45  
46 health morbidity. *BMC public health*, 6, 177. doi:10.1186/1471-2458-6-177  
47
- 48  
49 12. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in  
50  
51 women: an epidemiological perspective. *Womens Health (Lond)*. 2015;11(6):851-64.  
52
- 53  
54 13. Howard F. The Role of Laparoscopy in Chronic Pelvic Pain: Promise and Pitfalls.  
55  
56 *Obstetrical & Gynecological Survey*. 1993;48(6):357-87.  
57
- 58  
59 14. Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, et al.  
60  
Chronic pelvic pain in the community--symptoms, investigations, and diagnoses. *Am J Obstet Gynecol*. 2001;184(6):1149-55.

- 1  
2  
3 15. Curtis L. Unit Costs of Health and Social Care 2014 Personal Social Services  
4  
5 Research Unit, University of Kent, Canterbury.: University of Kent, Canterbury; 2014  
6  
7 [Available from: <https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2014/>.  
8  
9  
10 16. Simoens S, Dunselman G, Dirksen C, The burden of endometriosis: costs and quality  
11  
12 of life of women with endometriosis and treated in referral centres. *Hum Reprod*.  
13  
14 2012 May;27(5):1292-9. doi: 10.1093/humrep/des073. Epub 2012 Mar 14.  
15  
16 17. Peters AA, van Dorst E, Jellis B, van Zuuren E, Hermans J, Trimbos JB. A  
17  
18 randomized clinical trial to compare two different approaches in women with chronic  
19  
20 pelvic pain. *Obstet Gynecol*. 1991;77(5):740-4.  
21  
22 18. Ball EF, Nur Shafina Muhammad Sharizan E, Franklin G, Rogozinska E. Does  
23  
24 mindfulness meditation improve chronic pain? A systematic review. *Curr Opin Obstet*  
25  
26 *Gynecol*. 2017;29(6):359-66.  
27  
28 19. Kold M, Hansen T, Vedsted-Hansen H, Forman A. Mindfulness-based psychological  
29  
30 intervention for coping with pain in endometriosis. *Nordic Psychology*. 2012;64(1):2-  
31  
32 16.  
33  
34 20. Fox SD FE, Allen RH. Mindfulness meditation for women with chronic pelvic pain: a  
35  
36 pilot study. *J Reprod Med* 2011;56(3-4):158-62.  
37  
38 21. Bishop SR. Mindfulness: A proposed operational definition. *Clinical Psychology:*  
39  
40 *Science and Practice*; Autumn 2004; 11, 3; Health Module, pg. 230)  
41  
42 22. Plaza I, Demarzo MM, Herrera-Mercadal P, Garcia-Campayo J. Mindfulness-based  
43  
44 mobile applications: literature review and analysis of current features. *JMIR Mhealth*  
45  
46 *Uhealth*. 2013;1(2):e24.  
47  
48 23. Hilton L, Hempel S, Ewing BA, Apaydin E, Xenakis L, Newberry S, et al. Mindfulness  
49  
50 Meditation for Chronic Pain: Systematic Review and Meta-analysis. *Ann Behav Med*.  
51  
52 2017;51(2):199-213.  
53  
54 24. Wang J,Wang Y, Wei C, Yao NA, Yuan A, Shan Y, Yuan C. Smartphone  
55  
56 interventions for long-term health management of chronic diseases: an integrative  
57  
58  
59  
60

1  
2  
3 review. *Telemed J E Health*. 2014 Jun;20(6):570-83. doi: 10.1089/tmj.2013.0243.

4  
5 Epub 2014 May 1.

6  
7 25. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S.

8  
9 Evaluating and selecting mobile health apps: strategies for healthcare providers and  
10  
11 healthcare organizations. *Transl Behav Med*. 2014;4(4):363-71.

12  
13 26. My Health Apps [Available from: [http://myhealthapps.net/app/details/127/Headspace-](http://myhealthapps.net/app/details/127/Headspace-on-the-go)  
14  
15 [on-the-go](http://myhealthapps.net/app/details/127/Headspace-on-the-go)] (Accessed 28 August 2018).

16  
17 27. Mani M, Kavanagh DJ, Hides L, Stoyanov SR. Review and Evaluation of  
18  
19 Mindfulness-Based iPhone Apps. *JMIR Mhealth Uhealth*. 2015;3(3):e82.

20  
21 28. App Annie 2018 [Available from: <https://www.appannie.com/en/>] (Accessed 28  
22  
23 August 2018).

24  
25 29. Ball E, Newton S, Kahan BC, Forbes G, Wright N, Cantalapiedra Calvete C, et al.  
26  
27 Smartphone App Using Mindfulness Meditation for Women With Chronic Pelvic Pain  
28  
29 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*.  
30  
31 (MEMPHIS): Protocol for a Randomized Feasibility Trial. *JMIR Res Protoc*.  
32  
33 2018;7(1):e8.

34  
35 30. Forbes G, Newton S, Cantalapiedra C, Birch J, Dodds J, Steed E, Rivas C, Khan  
36  
37 KS, Rohricht F, Taylor SJC, Kahan B, Ball E. A smartphone app using psychological  
38  
39 approaches for women with chronic pelvic pain (MEMPHIS): a randomised feasibility  
40  
41 trial. submitted

42  
43 31. Gerhardt-Powals J. Cognitive engineering principles for enhancing human-computer  
44  
45 performance. *International Journal of Human-Computer Interaction*. 1996;8(2):189-  
46  
47 211.

48  
49 32. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al.  
50  
51 Normalisation process theory: a framework for developing, evaluating and  
52  
53 implementing complex interventions. *BMC Med*. 2010;8:63.

54  
55 33. Borkan J. Immersion/Crystallization. In BF Crabtree and WL Miller (Eds) *Doing*  
56  
57 *Qualitative Research* (2nd edition). Thousand Oaks, CA: Sage Publication; 1999. p.  
58  
59 pp. 179-94.  
60

- 1  
2  
3 34. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting  
4 qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-  
5 1251.  
6  
7  
8  
9 35. McCann, S. K., Campbell, M. K., & Entwistle, V. A. (2010). Reasons for participating  
10 in randomised controlled trials: conditional altruism and considerations for  
11 self. *Trials*, 11, 31. doi:10.1186/1745-6215-11-31  
12  
13  
14 36. Palmer, M., Sutherland, J., Barnard, S., Wynne, A., Rezel, E., Doel, A., Grigsby-  
15 Duffy, L., Edwards, S., Russell, S., Hotopf, E., Perel, P. Free, C. (2018). The  
16 effectiveness of smoking cessation, physical activity/diet and alcohol reduction  
17 interventions delivered by mobile phones for the prevention of non-communicable  
18 diseases: A systematic review of randomised controlled trials. *PloS one*, 13(1),  
19 e0189801. doi:10.1371/journal.pone.0189801  
20  
21  
22 37. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D.  
23 The Impact of mHealth Interventions: Systematic Review of Systematic Reviews.  
24 *JMIR Mhealth Uhealth.* 2018;6(1):e23.  
25  
26  
27 38. Laurie J, Blandford A. Making time for mindfulness. *Int J Med Inform.* 2016;96:38-50.  
28  
29  
30 39. Collins M, Shattell M, Thomas SP. Problematic Interviewee Behaviors in Qualitative  
31 Research. *Western Journal of Nursing Research.* 2016;27(2):188-99.  
32  
33  
34 40. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The  
35 behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques:  
36 building an international consensus for the reporting of behavior change  
37 interventions. *Ann Behav Med.* 2013;46(1):81-95.  
38  
39  
40 41. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing  
41 human support to enhance adherence to eHealth interventions. *J Med Internet Res.*  
42 2011;13(1):e30.  
43  
44  
45 42. Andersson G. Using the Internet to provide cognitive behaviour therapy. *Behav Res*  
46 *Ther.* 2009;47(3):175-80.  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 43. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for  
4 characterising and designing behaviour change interventions. *Implement Sci.*  
5 2011;6:42.  
6  
7  
8  
9 44. Walsh JC, Corbett T, Hogan M, Duggan J, McNamara A. An mHealth Intervention  
10 Using a Smartphone App to Increase Walking Behavior in Young Adults: A Pilot  
11 Study. *JMIR Mhealth Uhealth.* 2016;4(3):e109. Published 2016 Sep 22.  
12  
13  
14  
15  
16  
17  
18 45. Geraghty AW, Torres LD, Leykin Y, Perez-Stable EJ, Munoz RF. Understanding  
19 attrition from international Internet health interventions: a step towards global  
20 eHealth. *Health Promot Int.* 2013;28(3):442-52.  
21  
22  
23  
24 46. Mistler LA, Ben-Zeev D, Carpenter-Song E, Brunette MF, Friedman MJ. Mobile  
25 Mindfulness Intervention on an Acute Psychiatric Unit: Feasibility and Acceptability  
26 Study. *JMIR Ment Health.* 2017;4(3):e34.  
27  
28  
29  
30 47. Noone C, Hogan MJ. A randomised active-controlled trial to examine the effects of  
31 an online mindfulness intervention on executive control, critical thinking and key  
32 thinking dispositions in a university student sample. *BMC Psychol.* 2018;6(1):13.  
33  
34  
35  
36 48. Wen L, Sweeney TE, Welton L, Trockel M, Katznelson L. Encouraging Mindfulness in  
37 Medical House Staff via Smartphone App: A Pilot Study. *Acad Psychiatry.*  
38 2017;41(5):646-50.  
39  
40  
41  
42 49. Morrison Wylde C, Mahrer NE, Meyer RML, Gold JI. Mindfulness for Novice Pediatric  
43 Nurses: Smartphone Application Versus Traditional Intervention. *J Pediatr Nurs.*  
44 2017;36:205-12.  
45  
46  
47  
48 50. Lim D, Condon P, DeSteno D. Mindfulness and compassion: an examination of  
49 mechanism and scalability. *PLoS One.* 2015;10(2):e0118221.  
50  
51  
52  
53 51. Arean PA, Hallgren KA, Jordan JT, Gazzaley A, Atkins DC, Heagerty PJ, et al. The  
54 Use and Effectiveness of Mobile Apps for Depression: Results From a Fully Remote  
55 Clinical Trial. *J Med Internet Res.* 2016;18(12):e330.  
56  
57  
58  
59  
60

- 1  
2  
3 52. Gilbody S, Lewis H, Adamson J, Atherton K, Bailey D, Birtwistle J, et al. Effect of  
4 Collaborative Care vs Usual Care on Depressive Symptoms in Older Adults With  
5 Subthreshold Depression: The CASPER Randomized Clinical Trial. JAMA.  
6  
7  
8  
9  
10 2017;317(7):728-37.
- 11  
12 53. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A  
13  
14 systematic review of the impact of patient and public involvement on service users,  
15  
16 researchers and communities. Patient. 2014;7(4):387-95.

17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

## APPENDIX 1

Feature	Positive aspects	Negative aspects	Solutions
<b>Voice</b>	Liked by some participants, considered soothing and even spiritual	<p>The voice was not relaxing. One had to listen carefully which meant you could not switch off; otherwise you could not hear instruction clearly during meditation.</p> <p>It was also too repetitive, after 10 times it felt like a chore and not something to look forward to.</p>	<p>Choice of different voices</p> <p>participants should be told it takes time to get into the rhythm of the instructions, but you can get used to it</p>
<b>General interface aesthetics</b>	colours really fresh, interface not too busy, with pleasing layout and aesthetics	one participant would prefer different, bright, colours such as purple	None needed
<b>Graphics</b>		<p>The pictures were often not appropriate as they focused on the problem (e.g. tooth pain logo) rather than something positive or soothing. Unanticipated problems could arise according to one participant; she found it hard to lose weight and felt the food icons a) did not represent success and b) reminded her of eating.</p> <p>One participant found the pictures hard to see.</p>	Psychological theory supports the view that positive images would be advisable

<b>Animations</b>	liked	poorly chosen	None needed
<b>Progress</b>	<p>One participant liked the way the app helped progress through the stages.</p> <p>Another participant, with cyclical pain and hence cyclical use, did not aim to progress but simply chose to use the baseline video each time.</p>	<p>Three participants were frustrated and even 'angry' and 'patronised' at having to do the same (basic) meditation several times before moving up a stage.</p> <p>There was no indication of goals, duration of each level or gamification rewards.</p>	<p>Goal setting is recommended by psychological theory and could be as simple as using "day 1 of 30" rather than simply Day 1.</p> <p>Changing emojis could show progress, for example from a sad face to a smiley face to a heart; the inbuilt progress function was not felt sufficiently motivating.</p>
<b>Introduction</b>		Experienced app users suggested the introduction could be improved for initiates	<p>overview of the entire app and its levels suggested for the start.</p> <p>One participant had done mindfulness before but thought an introduction to mindfulness might be helpful for others.</p>
<b>Enjoyment</b>	considered fun by some participants.	One said it was not very 'interesting'.	<p>Include examples of a patient's day with the app to cater for a greater variety of participants</p> <p>It would be good to have other features as drop down options that were fun and</p>



			did not involve meditation.
--	--	--	-----------------------------

<b>Session intensity</b>		Would be good to choose the duration of the meditation.	15 or 20 mins would be better than 10, which is not enough time shut off and meditate deeply.  The option to control this was important as even 10 minutes was a difficult commitment for some busy participants (1074, 1075, 1078) or those battling with chronic fatigue (1074)
<b>Pain modules</b>		it can be hard to focus on something like using the app when you are in pain.	None needed

**Comments on app acceptability and usability made by n=13 patients. Two patients walked through the app with the researcher**

# Reporting checklist for qualitative study.

Based on the SRQR guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med.* 2014;89(9):1245-1251.

	Reporting Item	Page Number
	#1 Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	6
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4 and 5
Purpose or research question	#4 Purpose of the study and specific objectives or questions	5
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The	7

rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

1			
2			
3			
4			
5			
6			
7			
8			
9			
10	Researcher characteristics	#6	19
11	and reflexivity	Researchers' characteristics that may influence the research,	
12		including personal attributes, qualifications / experience,	
13		relationship with participants, assumptions and / or	
14		presuppositions; potential or actual interaction between	
15		researchers' characteristics and the research questions, approach,	
16		methods, results and / or transferability	
17			
18			
19			
20	Context	#7	7
21		Setting / site and salient contextual factors; rationale	
22	Sampling strategy	#8	7
23		How and why research participants, documents, or events were	
24		selected; criteria for deciding when no further sampling was	
25		necessary (e.g. sampling saturation); rationale	
26			
27	Ethical issues pertaining	#9	6
28	to human subjects	Documentation of approval by an appropriate ethics review board	
29		and participant consent, or explanation for lack thereof; other	
30		confidentiality and data security issues	
31			
32			
33	Data collection methods	#10	7
34		Types of data collected; details of data collection procedures	
35		including (as appropriate) start and stop dates of data collection	
36		and analysis, iterative process, triangulation of sources / methods,	
37		and modification of procedures in response to evolving study	
38		findings; rationale	
39			
40			
41	Data collection	#11	8
42	instruments and	Description of instruments (e.g. interview guides, questionnaires)	
43	technologies	and devices (e.g. audio recorders) used for data collection; if /	
44		how the instruments(s) changed over the course of the study	
45			
46	Units of study	#12	See note
47		Number and relevant characteristics of participants, documents,	
48		or events included in the study; level of participation (could be	1
49		reported in results)	
50			
51	Data processing	#13	8
52		Methods for processing data prior to and during analysis,	
53		including transcription, data entry, data management and	
54		security, verification of data integrity, data coding, and	
55		anonymisation / deidentification of excerpts	
56			
57			
58	Data analysis	#14	8
59		Process by which inferences, themes, etc. were identified and	
60			

		developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	
1			
2			
3			
4	Techniques to enhance trustworthiness	#15 Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	8
5			
6			
7			
8			
9	Syntheses and interpretation	#16 Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	8-16
10			
11			
12			
13			
14	Links to empirical data	#17 Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	See note 2
15			
16			
17			
18	Intergration with prior work, implications, transferability and contribution(s) to the field	#18 Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	16
19			
20			
21			
22			
23			
24			
25			
26	Limitations	#19 Trustworthiness and limitations of findings	19
27			
28			
29	Conflicts of interest	#20 Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	4
30			
31			
32			
33	Funding	#21 Sources of funding and other support; role of funders in data collection, interpretation and reporting	3
34			
35			
36			

## Author notes

1. 7,8,9 and especially 10
2. 8-16 and appendix

The SRQR checklist is distributed with permission of Wolters Kluwer © 2014 by the Association of American Medical Colleges. This checklist was completed on 26. March 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)