MEMPHIS

Statistical Analysis Plan

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1. INTRODUCTION

1.1. Purpose of statistical analysis plan

The purpose of this document is to provide details of the statistical analyses and presentation of results to be reported within the principal paper(s) of the MEMPHIS trial. Any exploratory, post hoc or unplanned analyses will be clearly identified in the respective study analysis report. This document does not detail the qualitative analysis, and so aims and outcomes that are collected for qualitative analyses only are not included.

This document has been developed prior to examination of trial data and will not be implemented prior to final approval. Statisticians will be blinded to individual treatment allocations until this statistical analysis plan has been approved, all trial data has been collected and the trial is complete.

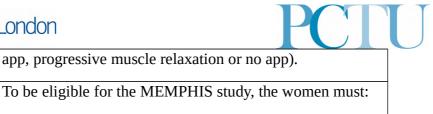This document is based on protocol version 8.0 (December 2016)

1.2. Members of the writing committee

Neil Wright (Statistician) was primarily responsible for writing the Statistical Analysis Plan, with input from Brennan Kahan (Senior Statistician). Neil Wright was responsible for writing the computer code to implement the analysis strategy. Elizabeth Ball (CI) and Julie Dodds also contributed to this Statistical Analysis Plan.

1.3. Summary

Short Title	MEMPHIS
Methodology	A randomised feasibility trial
Research Sites	This trial will be conducted at the Royal London and Whipps Cross Hospitals
Objectives/Aims	The overall aim is to assess the feasibility of implementing a trial of a mindfulness meditation intervention delivered by a mobile phone app for patients with chronic pelvic pain (CPP). The primary objectives are: To provide feasibility data for a large multicentre RCT aimed at rigorously testing mindfulness meditation in CPP To determine whether this app can be seamlessly integrated into clinical practice, especially CPP pathways
Number of Participants/Patients	90 women with CPP will be recruited and each randomised into one of the three trial groups (meditation

	app, progressive muscle relaxation or no app).
Main Inclusion Criteria	To be eligible for the MEMPHIS study, the women must:
	Be age 18 or over
	Have either organic or non-organic chronic pelvic pain lasting for 6 months or more
	Have access to a personal computer or smartphone.
	Understand simple spoken English
Statistical Methodology and Analysis	Feasibility outcomes will be summarised using descriptive statistics. Clinical outcomes will be analysed using linear mixed-effects models, and results will be presented as a difference in means and a 95% confidence interval.

1.4. Changes from planned analysis in the protocol

- In the protocol, the dropout rate is a feasibility outcome but is not defined. In this analysis plan, we define two feasibility outcomes as "the number and proportion of participants who never return or answer a follow-up questionnaire at 6 months post-randomisation" and "the number and proportion of participants who do not return a follow-up questionnaire, but do answer the questionnaire by phone at 6 month post-randomisation".

- In the protocol, duration of recruitment is described as "the number of days from the beginning to the end of recruitment". In this analysis plan, duration of recruitment is defined as "the number of days from the day recruitment opens until the day the 90th patient is randomised (inclusive of both end days)".

- In the protocol, "Sexual Health Outcomes score (as measured by Sexual Health Outcomes in Women Questionnaire (SHOW-Q))" is given as a clinical outcome. In this analysis plan, this is replaced by the SHOW-Q global score, for sexually active participants, and by the SHOW-Q pelvic interference score, for all participants.

1.5. Changes from SAP v1.0

- In section 1.4 of version 1.0 of the SAP we stated *"In the protocol, "Quality of life score (as measured by the RAND Short form (36) Health Survey (SF-36))" is given as a clinical outcome. In this analysis plan, this is replaced by four of the RAND SF-36 subscales: physical functioning, general health, social functioning, and pain."* This has now been removed from the SAP as the protocol has been updated to reflect the change in the way quality of life score is being measured.

- The definition of app use has been changed from "having completed at least 50% of a session" to "having completed at least 90% of a session" (section 3.1). The change was made due to Headspace, the data provider of the app usage data, only collecting data on sessions which were at least 90% complete.

1.6. Changes from SAP v2.0

- Added clarification to section 4.3 that data collected outside the recommended window for follow-up will still be included in analysis.

- In section 6.5.1, specified that the number of CRFs returned within the follow-up windows specified in section 4.3 will be summarised.

- Corrected scoring of CPAQ in Appendix A.

- Amended scoring of MYMOP in Appendix A so item scores are missing if the symptoms or activities are entered differently at follow up time points.

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2. STUDY METHODS

2.1. Study objectives

The overall aim is to assess the feasibility of implementing a trial of a mindfulness meditation intervention delivered by a mobile phone app for patients with chronic pelvic pain (CPP). The primary objectives are:

- To provide feasibility data for a large multicentre RCT aimed at rigorously testing Mindfulness meditation in patients with CPP.

- To determine whether this app can be seamlessly integrated into clinical practice, especially CPP pathways.

2.2. Overall study design and plan

MEMPHIS is a randomised feasibility trial. Eligible women will be randomised to one of the three treatment groups:

- Intervention: 60 days of the app delivering mindfulness meditation content (in addition to usual care).

- Active control: 60 days of the app delivering progressive muscle relaxation content (in addition to usual care).

- Treatment as usual: Usual care

2.3. Selection of study population

2.3.1. Inclusion Criteria

To be eligible for the MEMPHIS study, the women must meet the following criteria:

- Aged 18 or over

- Women with organic and non-organic chronic pelvic pain lasting for six months or more

- Be capable of understanding the information provided, with use of an interpreter if required and being able to understand simple English as is used in the app

- Give written informed consent

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2.3.2. Exclusion Criteria

Patients who meet the following criteria are ineligible to participate:

- No access to a Personal computer or smartphone

2.4. Method of treatment assignment and randomisation

After informed consent, patients will be randomised using a central, web-based system in a 1:1:1 ratio to one of the three treatment groups, using permuted blocks (of sizes 27, 30, 33) without stratification.

2.5. Sample size determination

30 participants will be recruited to each of the three treatment groups, giving a total of 90 participants. As this is a feasibility study, we have not performed a sample size calculation based upon the power to detect a significant treatment effect on a clinical outcome. However, 90 participants should provide a reliable estimate for the standard deviation of the primary clinical outcome (likely to be pain acceptance)[CITATION Lan04 \m Tea04 \l 2057], which can be used to inform the sample size calculation of the main trial.

3. STUDY OUTCOMES

3.1. Feasibility outcomes

- Duration of recruitment (measured from the day recruitment opens until the day the 90th patient is randomised)

- Estimates to be used for the sample size calculation of the phase III RCT:

  o The estimated SD at 60 days, 3 months, and 6 months post-randomisation for pain acceptance (as measured by the Chronic Pain Acceptance Questionnaire (CPAQ-8))

  o The number and proportion of participants who never return or answer a follow-up questionnaire at 6 months post-randomisation.

  o The number and proportion of participants who do not return a follow-up questionnaire, but do answer the questionnaire by phone at 6 month post-randomisation.

- Patient adherence to app use measured by the following outcomes:

  o Number of days (within the first 60 days from randomisation) a patient has used the app (with app use defined as having completed at least 90%% of a session).

  o Whether the patient has used the app on 22 or more days within the first 60 days from randomisation.

  o Number of weeks (within the first eight weeks from randomisation) a patient has used the app on three or more days.

  o Whether the patient has used the app on three or more days in 6 or more weeks (within the first eight weeks from randomisation).

  o Whether the patient has used the app on 22 or more days within the first 60 days from randomisation, AND used the app on three or more days in 6 or more weeks within the first eight weeks from randomisation.

3.2. App satisfaction questionnaires

At 60 days post-randomisation:

- System Usability Scale (SUS) score (0 [worst] – 100 [best])

- Reponses to the purpose made app satisfaction questionnaire

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3.3. Clinical outcomes

The following clinical outcomes at 60 days, 3 months, and 6 months post-randomisation:

- Pain acceptance score (as measured by the Chronic Pain Acceptance Questionnaire (CPAQ-8)) (0 [worst] – 48 [best])

- RAND Short form (36) Health Survey (RAND SF-36) scales:

  o Physical functioning (0 [worst] – 100 [best])

  o Pain (0 [worst] – 100 [best])

  o General health (0 [worst] – 100 [best])

  o Social functioning (0 [worst] – 100 [best])

- Depression score (as measured by the Hospital Anxiety and Depression Scale (HADS)) (0 [best] – 21 [worst])

- Anxiety score (as measured by HADS) (0 [best] – 21 [worst])

- Mindfulness score (as measure by the Cognitive and Mindfulness - Revised (CAMS – R) scale) (12 [worst] – 48 [best])

- Pain related disability score (as measured by the Chronic Pain Grade (CPG) disability subscale) (0 [best] – 100 [worst])

- Self efficacy score (as measured by the Pain Self-Efficacy Questionnaire (PSEQ)) (0 [worst] – 60 [best])

- Sexual Health Outcomes scores (as measured by the Sexual Health Outcomes in Women Questionnaire (SHOW-Q)):

  o SHOW-Q global score, for sexually active participants (0 [worst] – 100 [best])

  o SHOW-Q pelvic interference score, for all participants (0 [best] – 100 [worst])

- Subjective outcome score (as measured by the Measure Yourself Medical Outcome Profile (MYMOP)) (0 [best] – 6 [worst])

The following qualitative outcomes are not included in the Statistical Analysis Plan:

- Reasons for patient non-adherence to app use

- Obstacles to recruitment from participants and recruiting staff

- Usability/integration etc

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- Determining primary/secondary outcomes of interest

- App satisfaction questionnaires for service providers

4. DATA COLLECTION

This section describes the variables that will be collected during the trial to be used in the analysis described by this plan.

4.1. Collected at baseline only

The following variables will be collected for each participant at baseline only.

Demographic:

- Age

- Weight

- Height

- Living arrangements (Alone, With others)

- Employment status (Employed (full or part time, including self-employment), Unemployed and looking for work, At school or in full time education, Unable to work due to long term sickness, Looking after your home/family, Retired from paid work, Other)

- Age left full time education (I did not receive a formal education, Age 12 or less, Age 13 to 16, Age 17 to 19, Age 20 or over, I am still in full time education, Other)

- Ethnic group (White, Black, Central Asian, Middle Eastern, Southern Asian, Mixed, Other ethnic group, Do not wish to say)

- Do you smoke (Yes, No)

- Number of cigarettes per week

- Do you drink alcohol (Yes, No)

- Number of alcohol units per week

Prior and concurrent treatment:

- Treatment used in last six months: Acupuncture; Gabapentin; Amitriptyline; Biofeedback; Botox injection; Contraceptive pills/patch/ring; Exercise, yoga or pilates; Injections to suppress ovaries (e.g. Prostap, Zoladex); Herbal Medicine; Meditation or relaxation exercises; Massage; Nutrition/diet; Codeine or Morphine type painkillers; Nerve blocks; Over the counter medication; Physiotherapy; Psychological (talking) therapy; Transcutaneous Electrical Nerve Stimulation (TENS); Surgery; Other. (One variable for each: Yes, No.)

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- Currently using pain treatment (Yes, No)

Participants' pain:

- Length of pain (0-6 months, 7-12 months, 1-2 years, 3-5 years, 6-10 years, More than 10 years)

- Pain over the past week (0 [No pain] to 10 [Pain as bad as could be])

4.2. Randomisation details

The following variables for each participant will be held in the randomisation database.

- Date of randomisation

- Treatment group allocation

4.3. Collected at baseline and follow up

The following clinical outcome variables will be collected for each participant at baseline, 60 days, 3 months, and 6 months post-randomisation. We aim to collect 60 day follow up data between 46 and 74 days from randomisation, 3 month follow up date between 76 and 104 days and 6 month follow up data between 159 and 201 days. However, data collected outside these day ranges will be included in the analysis.

- Pain acceptance (as measured Chronic Pain Acceptance Questionnaire (CPAQ-8)) (4 variables)

- Short form (36) Health Survey (SF-36) (36 variables)

- Depression (as measured by the Hospital Anxiety and Depression Scale (HADS)) (7 variables)

- Anxiety (as measured by HADS) (7 variables)

- Mindfulness (as measure by the Cognitive and Mindfulness - Revised (CAMS – R) scale) (12 variables)

- Pain related disability (as measured by the Chronic Pain Grade (CPG) disability subscale) (3 variables)

- Self efficacy (as measured by the Pain Self-Efficacy Questionnaire (PSEQ)) (10 variables)

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- Sexual Health Outcomes (as measured by Sexual Health Outcomes in Women Questionnaire (SHOW-Q)) (12 variables)

- Subjective outcome (as measured by Measure Yourself Medical Outcome Profile (MYMOP)) (4 variables)

Date of visit / date completed and method of collection (return of postal questionnaire or via telephone) for each follow-up questionnaire will also be collected. When the follow-up questionnaire is answered via telephone, the variables for the Short form (36) Health Survey (SF-36), Self efficacy (as measured by the Pain Self-Efficacy Questionnaire (PSEQ)), and Sexual Health Outcomes (as measured by Sexual Health Outcomes in Women Questionnaire (SHOW-Q)) are not collected.

4.4. App usage data

App usage data will be received from Headspace, for all participants randomised to the Intervention or Active Control arms. The data will include variables for participant login token, duration of session, filename of session, date and time of completion. Each observation represents one user completing (at least 90% of) a mindfulness meditation or muscle relaxation session.

4.5. App satisfaction questionnaires

The following variables will be collected for participants randomised to an app arm, at 60 days post-randomisation:

- System Usability Scale (SUS) (10 variables)

- Purpose made questionnaire responses:

  o Nine statements with categorical response. (Totally disagree, Somewhat disagree, Neither agree nor disagree, Somewhat agree, Totally agree) (9 variables)

  o One question (Did you use the app every day? (Yes, No))

4.6. Unintentional unblinding of randomised treatment

After the participant has been randomised, the following variables will be collected from the researcher:

- Was the participant randomised to the app treatment arm? (Yes, No)

- If the participant was allocated to the app treatment arm, which app treatment do you believe the participant was randomised to? (Intervention app, Control app, Don't know)

At 6 months (between 159 and 201 days) post-randomisation, the following variables will be collected from the participant:

- Did you use the smartphone app for MEMPHIS? (Yes, No)

- Do you think you received the new treatment or comparison treatment? (New Treatment, Comparison Treatment, Don't Know)

5. DERIVED VARIABLES

5.1. Feasibility outcomes

A participant is counted as never having returned follow-up questionnaire at 6 months post-randomisation if date of visit / date completed and all other fields in the follow-up questionnaire are missing.

The patient adherence to app use outcomes listed in Section 3.1 will be calculated from the app usage data described in Section 4.4. Completing a session that is at least ten minutes on a day counts as having used the app on that day. Sample Stata code showing the calculation of these outcome variables is given in APPENDIX B: STATA CODE FOR GENERATING ADHERENCE OUTCOMES.

In the app usage data, date and timestamps will be provided in Coordinated Universal Time (UTC). These will be converted to UK time (BST/GMT as appropriate) before outcomes are derived.

5.2. Clinical outcomes

Details for how the clinical outcome scores list in Section 3.3 are derived from question responses (Section 4.2) are given in APPENDIX A: DERIVED AND COMPUTED VARIABLES.

5.3. System Usability Score (SUS) score

Details for how the System Usability Scale (SUS) score is derived from question responses is given in APPENDIX A: DERIVED AND COMPUTED VARIABLES.

6. STATISTICAL ANALYSIS

6.1. Analysis populations

All analyses will be carried out according to the intention-to-treat (ITT) principle: all patients with a non-missing outcome will be analysed according to the group to which they are randomised.

Summaries of patient adherence to app use will include all participants randomised to the intervention or active control treatment groups.

Sample means and SDs for clinical outcomes will include all participants with a non-missing outcome at that time point.

Analyses to estimate treatment effects for clinical outcomes (Section 6.4.2) will include all patients with a non-missing outcome for at least one of the three follow-up time points (60 days, 3 months, or 6 months) [CITATION Whi11 \l 2057]. Patients with a missing outcome at all follow-up time points for a clinical outcome are excluded from the analysis of that clinical outcome. A clinical outcome is non-missing if there are recorded responses at that time point for all individual questions required for the derivation of the clinical outcome. (Note that for the Subjective outcome score (MYMOP profile score), only symptom 1 score and wellbeing score are required.)

6.2. Baseline variables

Demographic, prior and concurrent treatment, and participants' pain baseline variables are listed in Section 4.1. Each variable (plus body mass index instead of height and weight) will be summarised for each treatment group by the mean (SD) or median (IQR) for continuous variables, and the number (%) for categorical variables. Draft tables are given in APPENDIX D: DRAFT TABLES.

6.3. Analysis of feasibility outcomes

Duration of recruitment will be stated. It is the number of days from the day recruitment opens until the day the 90th patient is randomised (inclusive of both end days).

The number of participants randomised in each one month period from the day recruitment opens will be presented.

The estimated SD in each treatment group at each follow-up time point for pain acceptance (as measured by the Chronic Pain Acceptance Questionnaire (CPAQ-8)) will be presented.

Each patient adherence to app use outcome listed in Section 3.1 will be summarised separately for the intervention and active control treatment groups. Each outcome will be presented as the mean

(SD) or median (IQR) for continuous variables, and the number (%) for categorical variables. Draft tables are given in APPENDIX D: DRAFT TABLES.

6.4. Analysis of clinical outcomes

6.4.1. Descriptive statistics

For each clinical outcome listed in Section 3.3 we will present:

- The number of patients in each treatment group with a non-missing outcome at each time point.

- The mean (SD) in each treatment group at each time point.

6.4.2. Statistical analysis

For each clinical outcome we will present estimated treatment effects for each follow-up time point, with a 95% confidence interval. Estimates of treatment effects will be presented comparing the intervention group (mindfulness meditation app) to the control (treatment as usual) group, the intervention group to the active control (progressive muscle relaxation app) group, and the active control group to the control group.

Outcomes will be analysed using linear mixed-effects models with outcome measurement (at three follow-up time points) as the dependant variable. The model will include fixed time effects, a fixed effect for treatment, time treatment interactions for 3 months and 6 months follow-up time points, and an unstructured correlation matrix for the residuals [CITATION Rab12 \l 2057]. The model will include baseline measure of the outcome as a covariate, assuming a linear relationship between baseline and outcome [CITATION Kah14 \l 2057]. The model will be fitted using restricted maximum likelihood. Example Stata code for this analysis model is given in APPENDIX C: STATA CODE FOR STATISTICAL ANALYSIS OF CLINICAL OUTCOMES.

If there are missing values for baseline measure of a clinical outcome, they will be replaced by the mean of the observed baseline values for all participants in all treatment arms (mean imputation) [CITATION Whi05 \l 2057]. Missing values of clinical outcomes at follow-up will not be imputed.

If the mixed effects models fail to converge, treatment effects will be estimated using separate linear regression models for each follow-up time point. Baseline measure of the outcome will be included as a covariate.

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6.5. Other analyses

6.5.1. Comparison of losses to follow-up

The number and proportion of patients in each treatment group who have returned, answered by phone, or never returned the follow-up questionnaire will be presented for each follow-up time point (60 days, 3 months, and 6 months post-randomisation). A patient is counted as having returned data unless date of visit / date completed and all other fields in the follow-up questionnaire are missing. A draft table is given in APPENDIX D: DRAFT TABLES.Summaries of the following baseline variables will be presented separately for patients who have returned, answered by phone, or never returned the follow-up questionnaire at the 6 month time point:

- Age at randomisation

- Body mass index

- Living arrangements

- Employment status

- Age left full time education

- Ethnic group

- Do you smoke

- Number of cigarettes per week

- Do you drink alcohol

- Number of units of alcohol per week

- Length of pain

- Pain over the past week

- Baseline values of clinical outcomes:

  o Pain acceptance score

  o Depression score

  o Anxiety score

  o Pain related disability score

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6.5.2. Unintentional unblinding of randomised treatment

For each participants in the intervention and active control arm, researcher response to the question "If the participant was allocated to the app treatment arm, which app treatment do you believe the participant was randomised to?" will be summarised by number and percentage.

For participants in the intervention and active control arms, response to the question "Do you think you received the new treatment or comparison treatment?" will be summarised by number and percentage. A draft table is given in APPENDIX D: DRAFT TABLES.

6.5.3. Summarising missing data in clinical outcomes

For each clinical outcome variable we will present the number and proportion of individuals for whom the outcome is complete for at least one of the three follow-up time points (60 days, 3 months, or 6 months).

For each clinical outcome variable, we will also present the number and proportion of individuals for whom the outcome is not completed (either because the questionnaire was not returned, or because the participant left all variables for that outcome blank), partially completed (one or more, but not all, variables used in its derivation are missing), or complete (no variables used in its derivation are missing) at each time point.

Completely missing and partially missing outcomes will be summarised separately according to whether follow-up was completed via the mail-in questionnaire or over the phone.

1.1.1. Summarising data returned outside of target follow up periods

The number and proportion of patients in each treatment group who had follow up questionnaires completed within the time periods specified in section 4.3 will be presented for each follow up point. These are between 46 and 74 days for 60 days follow up, between 76 and 104 days for 3 month follow up, and between 159 and 201 days for 6 month follow up.

6.5.4. App usability

The mean (SD) of the System Usability Scale (SUS) score will be presented separately for the treatment app and active control app arms.

The number and proportion of each response for each question in the purpose made app satisfaction questionnaire will be presented separated for the treatment app and active control app arms. The number and proportion responding "Yes" to the question "Did you use the app every day?" will also be presented for each app arm.

6.5.5. Serious adverse events

We will present the number of reported serious adverse events in each treatment arm.

6.6. Analysis software

The analysis will be carried out using Stata.

7. GRAPHS AND FIGURES TO BE PRODUCED

7.1. Participant flow

Participant throughput will be s | Randomised in RCT (n=..) | gram:

| Allocated to intervention (n=..) | Allocated to active control (n=..) | Allocated to TAU (n=..) |

| Data returned at 60 days: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 60 days: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 60 days: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. |

| Data returned at 3months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 3months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 3months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. |

| Data returned at 6 months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 6 months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. | Data returned at 6 months: No: n= Yes: n= → Questionnaire: n=.. → Via Telephone: n=.. |

| Included in analysis of pain acceptance score (n=..) | Included in analysis of pain acceptance score (n=..) | Included in analysis of pain acceptance score (n=..) |

7.2. Graphs

The following graphs will be created:

- Line graph showing mean CPAQ score at each time point for each treatment group. The graph will also include lines showing 95% confidence intervals for each mean CPAQ score.

- Line graph showing all estimated treatment effects (and 95% confidence intervals) on CPAQ score for each follow-up time point. (Estimates of treatment effects will be presented comparing the intervention group (mindfulness meditation app) to the control (treatment as usual) group, the intervention group to the active control (progressive muscle relaxation app) group, and the active control group to the control group.)

- Stacked bar chart showing the proportion of participants in each treatment group who have returned the follow-up questionnaire or answered the follow-up questionnaire by phone at each follow-up time point (60 days, 3 months, and 6 months post-randomisation).

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8. REFERENCES

CITATION Lan04 \m Tea04 \l 2057 : , [1, 2],

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CITATION Whi05 \l 2057 : , [6],

CITATION randsf36 \l 2057 : , [7],

 CITATION Zig83 \l 2057 : , [7],

 CITATION Gre07 \l 2057 : , [8],

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[13] [Online]. Available: http://www.bris.ac.uk/primaryhealthcare/resources/mymop/general-information/.

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9. APPENDIX A: DERIVED AND COMPUTED VARIABLES

Unless otherwise stated, if an individual response variable used in the derivation of an outcome is missing then the outcome variable is missing.

Variables names used in the example code correspond to the field names specified in the trial database "Requirements Specification Document".

Body mass index

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BMI is calculated as a person's weight (measured in kilograms) divided by the square of their height (measured in metres).

```
generate BMI = WEIGHT / ((HEIGHT / 100)^2)
```

RAND Short form (36) Health Survey (SF-36) scales scores [CITATION randsf36 \l 2057]

Responses to individual questions are recoded as shown in the first table below. Each scale score is the average score for the questions in that scale, as shown in the second table below.

Item numbers	Original response code	Recode to
GH1, GH2, GH6, GH8, GH11b, GH11d	1	100
	2	75
	3	50
	4	25
	5	0
GH3a, GH3b, GH3c, GH3d, GH3e, GH3f, GH3g, GH3h, GH3i, GH3j	1	0
	2	50
	3	100
GH10, GH11a, GH11c	1	0
	2	25
	3	50
	4	75
	5	100
GH7	1	100
	2	80
	3	60
	4	40
	5	20
	6	0

Scale	After recoding, average the following items
Physical functioning	GH3a, GH3b, GH3c, GH3d, GH3e, GH3f, GH3g, GH3h, GH3i, GH3j
Pain	GH7, GH8
General health	GH1, GH11a, GH11b, GH11c, GH11d
Social functioning	GH6, GH10

```
recode GH1 GH2 GH6 GH8 GH11b GH11d (1=100) (2=75) (3=50) (4=25)
(5=0)
```

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```
recode GH3a GH3b GH3c GH3d GH3e GH3f Gh3g GH3h GH3i Gh3j (1=0)
(2=50) (3=100)
recode GH10 GH11a GH11c (1=0) (2=25) (3=50) (4=75) (5=100)
recode GH7 (1=100) (2=80) (3=60) (4=40) (5=20) (6=0)
generate SF36_PHYSICALFUNC = (GH3a + GH3b + GH3c + GH3d + GH3e +
GH3f + GH3g + GH3h + GH3i + GH3j) / 10
generate SF36_SOCIALFUNC = (GH6 + GH10) / 2
generate SF36_PAIN = (GH7 + GH8) / 2
generate SF36_GENERALHEALTH = (GH1 + GH11a + GH11b + GH11c +
GH11d) / 5
```

Depression score (as measured by the Hospital Anxiety and Depression Scale (HADS))

[CITATION Zig83 \l 2057]

After appropriate recoding, the HADS depression score is the sum of scores for questions 2, 4, 6, 8, 10, 12 and 14.

```
recode HADS02 HADS04 HADS12 HADS14 (1=0) (2=1) (3=2) (4=3)
recode HADS06 HADS08 HADS10 (1=3) (2=2) (3=1) (4=0)
generate HADS_DEPRESSION = HADS02 + HADS04 +HADS06 + HADS08 +
HADS10 + HADS12 + HADS14
```

Anxiety score (as measured by HADS) [CITATION Zig83 \l 2057]

After appropriate recoding, the HADS anxiety score is the sum of scores for questions 1, 3, 5, 7, 9, 11 and 13.

```
recode HADS01 HADS03 HADS05 HADS11 HADS13 (1=3) (2=2) (3=1) (4=0)
recode HADS07 HADS09 (1=0) (2=1) (3=2) (4=3)
generate HADS_ANXIETY = HADS01 + HADS03 + HADS05 + HADS07 + HADS09
+ HADS11 + HADS13
```

Mindfulness score (as measure by the Cognitive and Mindfulness - Revised (CAMS – R) scale)

[CITATION Gre07 \l 2057]

After appropriate recording, the CAMS-R mindfulness score is the sum of scores for all questions 1 to 12.

```
recode CAMSR02 CAMSR06 CAMSR07 (1=4) (2=3) (3=2) (4=1)
```

```
generate CAMSR_SCORE = CAMSR01 + CAMSR02 + CAMSR03 + CAMSR04 +
CAMSR05 + CAMSR06 + CAMSR07 + CAMSR08 + CAMSR09 + CAMSR10 +
CAMSR11 + CAMSR12
```

Pain related disability score (as measured by the Chronic Pain Grade (CPG) disability subscale)
[CITATION Mic92 \l 2057]

THE CPG pain related disability score is the mean of the daily activities, social activities, and work activities scores, multiplied by 10.

```
generate CPG_DISABILITYSCORE = [(CPGd1 + CPGd2 + CPGd3) / 3 ] * 10
```

Self efficacy score (as measured by the Pain Self-Efficacy Questionnaire (PSEQ)) [CITATION mymop \l 2057]

The PSEQ self efficacy score is the sum of scores for all questions 1 to 10.

```
generate PSEQ_SCORE = PSEQ01 + PSEQ02 + PSEQ03 + PSEQ04 + PSEQ05 +
PSEQ06 + PSEQ07 + PSEQ08 + PSEQ09 + PSEQ10
```

Pain acceptance score (as measured Chronic Pain Acceptance Questionnaire (CPAQ-8))
[CITATION Ros10 \l 2057]

After reverse scoring, the CPAQ-8 pain willingness score is the sum of scores from questions 4, 5, 7 and 8. The CPAQ-8 activity engagement score is the sum of scores from questions 1, 2, 3, 5 and 6. The CPAQ-8 total score is the sum of the pain willingness score and the activity engagement score.

```
recode CPAQ CPAQ4 CPAQ5 CPAQ7 CPAQ8 (0=6) (1=5) (2=4) (3=3) (4=2)
(5=1) (6=0)
generate CPAQ_PAINWILL = CPAQ4 + CPAQ5 + CPAQ7 + CPAQ8
generate CPAQ_ACTIVITYENG = CPAQ1 + CPAQ2 + CPAQ3 + CPAQ6
generate CPAQ_TOTAL = CPAQ_PAINWILL + CPAQ_ACTIVITYENG
```

Sexual Health Outcomes score (as measured by Sexual Health Outcomes in Women Questionnaire (SHOW-Q))

Each response is rescaled to a score 0 to 100, with higher scores reflecting higher sexual functioning or fewer sexual problems. For a 5 response item, the scores are 0, 25, 50, 75 or 100. For a 4 response item, the scores are 0, 33.3, 66.7 or 100. The scoring for each question is shown in the table below.

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If a participant answers "I don't have a partner" or "I don't have sex without a partner" to question 2 or "I did not have sexual activity" to any of questions 3, 4, 6, 7 or 9, then the participant is classed as sexually inactive. Otherwise, the participant is classed as sexually active.

For sexually active participants, the SHOW-Q global score is calculated as the mean of all rescaled scores. Higher scores reflect higher sexual functioning or fewer sexual problems.

For all participants, the SHOW-Q pelvic problem interference score is the mean of response scores to questions 10, 11 and 12 after they are reverse scored. Higher scores reflect more interference.

Item number	Response text	Original response code	Recode to
SHOWQ01, SHOWQ02	Very satisfied	1	100
	Somewhat satisfied	2	75
	Neither satisfied nor dissatisfied	3	50
	Somewhat dissatisfied	4	25
	Very dissatisfied	5	0
SHOWQ10, SHOWQ11, SHOWQ12	Not at all	1	100
	Slightly	2	75
	Moderately	3	50
	Quite a bit	4	25
	Extremely	5	0
SHOWQ03, SHOWQ04	Never	1	0
	Rarely	2	25
	Sometimes	3	50
	Most of the time	4	75
	All of the time	5	100
SHOWQ08	Never	1	0
	Once or twice	2	25
	3-4 times	3	50
	5-6 times	4	75
	More than 6 times	5	100
SHOWQ05	Did not experience any orgasms	1	0
	Mild	2	33.3
	Moderate	3	66.7
	Strong	4	100
SHOWQ06, SHOWQ07, SHOWQ09	Not a problem	1	100
	Little of a problem	2	66.7
	Somewhat of a problem	3	33.3
	Very much of a problem	4	0

```
generate SHOWQ_ACTIVE = 1
replace SHOWQ_ACTIVE = 0 if SHOWQ02==6 | SHOWQ02==7 | SHOWQ03==6 |
```

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```
SHOW04==6 | SHOWQ06==5 | SHOWQ07==5 | SHOWQ09== 5
recode  SHOWQ01  SHOWQ02  SHOW10  SHOWQ11  SHOWQ12  (1=100) (2=75)
(3=50) (4=25) (5=0)
recode SHOWQ03 SHOWQ04 SHOWQ08 (1=0) (2=25) (3=50) (4=75) (5=100)
recode SHOWQ05 (1=0) (2=33.3) (3=66.7) (4=100)
recode SHOWQ06 SHOWQ07 SHOWQ09 (1=100) (2=66.7) (3=33.3) (4=0)
generate SHOWQ_GLOBAL = (SHOWQ01 + SHOWQ02 + SHOWQ03 + SHOWQ04 +

SHOWQ05 + SHOWQ06 + SHOWQ07 + SHOWQ08 + SHOWQ09 + SHOWQ10 +

SHOWQ11 + SHOWQ12)/12 if SHOWQ_ACTIVE == 1
generate SHOWQ_PELVPROBLEM = ((100 - SHOWQ10) + (100 - SHOWQ11) +

(100 - SHOWQ12))/3
```

Subjective outcome score (as measured by Measure Yourself Medical Outcome Profile (MYMOP))
[CITATION mymop2 \l 2057]

If the description for symptom 1, symptom 2, symptom 3 or activity does not match the description
given for the corresponding symptom or activity at baseline then the score for that symptom or
activity is missing.

If symptom 1 score or wellbeing score are missing, then MYMOP profile score is missing. The
MYMOP profile score is the mean of the symptom 1 score, symptom 2 score, activity score,
wellbeing score, and symptom 3 score. (Symptom 2 score, activity score and symptom 3 score are
only included if they are not missing)

```
egen  MYMOP_PROFILE  =  rowmean(SYMSCORE1,  SYMSCORE2,  ACTSCORE,
WELLBEING, SYMSCORE3)
```

System Usability Scale (SUS) score [CITATION htt \l 2057]

For questions 1, 3, 5, 7, and 9 the score contribution is the response number minus 1. For questions
2, 4, 6, 8, and 10 the score contribution is 5 minus the response number. The SUS score is the sum
of all score contributions multiplied by 2.5

```
recode SUS01 SUS03 SYS05 SUS07 SUS09 (1 = 0) (2 = 1) (3 = 2) (4 =
3) (5 = 4)
recode SUS02 SUS04 SUS06 SUS08 SUS10 (1 = 4) (2 = 3) (3 = 2) (4 =
1) (5 = 0)
generate SUS_SCORE  = 2.5 * (SUS01 + SUS02 + SUS03 + SUS04 + SUS05
+SUS06 + SUS07 + SUS08 + SUS9 + SUS10)
```

`countin60days`	Number of days (within the first 60 days from randomisation) a patient has used the app (with app use defined as having completed at least 90% of a session).	
`numberofweeksthreeplus`	Number of weeks (within the first eight weeks from randomisation) a patient has used the app on three or more days.	
`adhere_countin60days`	Whether the patient has used the app on 22 or more days within the first 60 days from randomisation.	1 = Yes 0 = No
`adhere_numberofweeksthreeplus`	Whether the patient has used the app on three or more days in 6 or more weeks (within the first eight weeks from randomisation).	1 = Yes 0 = No

Sample Stata code showing the calculation of these outcome variables is given in .

10. APPENDIX B: STATA CODE FOR GENERATING ADHERENCE OUTCOMES

Sample of Stata code for generating adherence outcomes from app usage data supplied by Headspace:

```
gen date_completed = date(datecompleted, "DMY")

format date_completed %td



gen date_rand = date(dateofrandomisation, "DMY")

format date_rand %td



gen date_fromrand = date_completed-date_rand



***
```

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```
* Drop sessions which are not part of intervention (i.e. short
duration)

drop if duration<5


* Remove multiple sessions in same day

duplicates report id date_fromrand

duplicates drop id date_fromrand , force


gen in60days = 1 if date_fromrand<61

bysort id: egen countin60days = count(in60days)


gen numberofweeksthreeplus = 0


forvalues week=1/8 {
    gen inweek`week' = 1 if date_fromrand>7*(`week'-1) &
date_fromrand<7*`week'+1

    gen threeplusinweek`week' = 0

    bysort id: egen countinweek`week' = count(inweek`week')

    assert countinweek`week'<8

    bysort id: replace threeplusinweek`week' = 1 if
countinweek`week'>2

    bysort id: replace numberofweeksthreeplus =
numberofweeksthreeplus +1 if countinweek`week'>2

}



bysort id: keep if _n==1
```

```
keep   id   countin60days   numberofweeksthreeplus   threeplusinweek*
countinweek*


gen adhere_countin60days = 0

replace adhere_countin60days = 1 if countin60days>21

gen adhere_numberofweeksthreeplus = 0

replace      adhere_numberofweeksthreeplus      =      1      if
numberofweeksthreeplus>5



tab adhere_countin60days adhere_numberofweeksthreeplus
```

11. APPENDIX C: STATA CODE FOR STATISTICAL ANALYSIS OF CLINICAL OUTCOMES

The following Stata shows the model that will be used to estimate treatment effects on clinical outcomes:

```
xtmixed outcome time##treat baseline || id: , noconstant
residuals(unstructured, t(time)) var reml
```

Estimates of treatment effects for each treatment arm comparison and time point will then be obtained using:

```
lincom 1.treat + 1.time#1.treat

lincom 1.treat + 2.time#1.treat

lincom 1.treat + 3.time#1.treat

lincom 2.treat + 1.time#2.treat

lincom 2.treat + 2.time#2.treat

lincom 2.treat + 3.time#2.treat
```

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```
lincom 2.treat + 1.time#2.treat - 1.treat + 1.time#1.treat

lincom 2.treat + 2.time#2.treat - 1.treat + 2.time#1.treat

lincom 2.treat + 3.time#2.treat - 1.treat + 3.time#1.treat
```

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12. APPENDIX D: DRAFT TABLES

12.1.1. Baseline demographics and medical history

Figures are mean (SD) unless stated otherwise.

	Intervention (n=…)	Active control (n=…)	Usual care (n=…)
Demographics			
Age at randomisation (Years)	XX (XX)	XX (XX)	XX (XX)
Body mass index	XX (XX)	XX (XX)	XX (XX)
Living arrangements – no. (%)			
Alone	XX (XX)	XX (XX)	XX (XX)
With others	XX (XX)	XX (XX)	XX (XX)
Employment status – no. (%)			
Employed	XX (XX)	XX (XX)	XX (XX)
Unemployed and looking for work	XX (XX)	XX (XX)	XX (XX)
At school or in full time education	XX (XX)	XX (XX)	XX (XX)

Unable to work due to long term sickness	XX (XX)	XX (XX)	XX (XX)
Look after your home/family	XX (XX)	XX (XX)	XX (XX)
Retired from paid work	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)

Age left full time education – no. (%)

I did not receive a formal education	XX (XX)	XX (XX)	XX (XX)
Age 12 or less	XX (XX)	XX (XX)	XX (XX)
Age 13 to 16	XX (XX)	XX (XX)	XX (XX)
Age 17 to 19	XX (XX)	XX (XX)	XX (XX)
Age 20 or over	XX (XX)	XX (XX)	XX (XX)
I am still in full time education	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)

Ethnic group – no. (%)

White	XX (XX)	XX (XX)	XX (XX)

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Black	XX	(XX)	XX	(XX)	XX	(XX)
Central Asian	XX	(XX)	XX	(XX)	XX	(XX)
Middle Eastern	XX	(XX)	XX	(XX)	XX	(XX)
Southern Asian	XX	(XX)	XX	(XX)	XX	(XX)
Mixed	XX	(XX)	XX	(XX)	XX	(XX)
Other ethnic group	XX	(XX)	XX	(XX)	XX	(XX)
Do not wish to say	XX	(XX)	XX	(XX)	XX	(XX)
Smoker – no. (%)						
Yes	XX	(XX)	XX	(XX)	XX	(XX)
No	XX	(XX)	XX	(XX)	XX	(XX)
If yes, number of cigarettes per week	XX	(XX)	XX	(XX)	XX	(XX)
Drink alcohol – no. (%)						
Yes	XX	(XX)	XX	(XX)	XX	(XX)
No	XX	(XX)	XX	(XX)	XX	(XX)
If yes, number of units of alcohol per	XX	(XX)	XX	(XX)	XX	(XX)

week

Baseline medical history

Length of pain – no. (%)

0-6 months	XX (XX)	XX (XX)	XX (XX)
7-12 months	XX (XX)	XX (XX)	XX (XX)
1-2 years	XX (XX)	XX (XX)	XX (XX)
3-5 years	XX (XX)	XX (XX)	XX (XX)
6-10 years	XX (XX)	XX (XX)	XX (XX)
More than 10 years	XX (XX)	XX (XX)	XX (XX)
Pain over the past week	XX (XX)	XX (XX)	XX (XX)

12.1.2. Prior and concurrent treatment

Figures are number (percentage).

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	Intervention (n=…)	Active control (n=…)	Usual care (n=…)
Treatment used in last six months			
Acupuncture	XX (XX)	XX (XX)	XX (XX)
Gabapentin	XX (XX)	XX (XX)	XX (XX)
Amitriptyline	XX (XX)	XX (XX)	XX (XX)
Biofeedback	XX (XX)	XX (XX)	XX (XX)
Botox injection	XX (XX)	XX (XX)	XX (XX)
Contraceptive pills/patch/ring	XX (XX)	XX (XX)	XX (XX)
Exercise, yoga or pilates	XX (XX)	XX (XX)	XX (XX)
Injections to suppress ovaries (e.g. Prostap, Zoladex)	XX (XX)	XX (XX)	XX (XX)
Herbal Medicine	XX (XX)	XX (XX)	XX (XX)
Meditation or relaxation exercises	XX (XX)	XX (XX)	XX (XX)
Massage	XX (XX)	XX (XX)	XX (XX)

Nutrition/diet	XX	(XX)	XX	(XX)	XX	(XX)
Codeine or Morphine type painkillers	XX	(XX)	XX	(XX)	XX	(XX)
Nerve blocks	XX	(XX)	XX	(XX)	XX	(XX)
Over the counter medication	XX	(XX)	XX	(XX)	XX	(XX)
Physiotherapy	XX	(XX)	XX	(XX)	XX	(XX)
Psychological (talking) therapy	XX	(XX)	XX	(XX)	XX	(XX)
Transcutaneous Electrical Nerve Stimulation (TENS)	XX	(XX)	XX	(XX)	XX	(XX)
Surgery	XX	(XX)	XX	(XX)	XX	(XX)
Other	XX	(XX)	XX	(XX)	XX	(XX)

Currently using pain treatment

Yes	XX	(XX)	XX	(XX)	XX	(XX)
No	XX	(XX)	XX	(XX)	XX	(XX)

Figures are mean (SD) unless stated otherwise.

	Intervention	Active control	Usual care
	(n=…)	(n=…)	(n=…)
SF-36 scales:			
Physical functioning	XX (XX)	XX (XX)	XX (XX)
Pain	XX (XX)	XX (XX)	XX (XX)
General Health	XX (XX)	XX (XX)	XX (XX)
Social Functioning	XX (XX)	XX (XX)	XX (XX)
Depression score	XX (XX)	XX (XX)	XX (XX)
Anxiety score	XX (XX)	XX (XX)	XX (XX)
Mindfulness score	XX (XX)	XX (XX)	XX (XX)
Pain related disability score	XX (XX)	XX (XX)	XX (XX)
Self efficacy score	XX (XX)	XX (XX)	XX (XX)
Pain acceptance score	XX (XX)	XX (XX)	XX (XX)
Sexual health outcomes:			

	Intervention	Active control	Usual care
SHOW-Q global score	XX (XX)	XX (XX)	XX (XX)
SHOW-Q pelvic problem interference score	XX (XX)	XX (XX)	XX (XX)
Subjective outcome score	XX (XX)	XX (XX)	XX (XX)

12.1.4. Loss to follow-up

	Intervention	Active control	Usual care
	(n=…)	**(n=…)**	**(n=…)**
Follow-up questionnaire returned – no. (%)			
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Follow-up questionnaire answered by phone – no. (%)			
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)

6 months	XX (XX)	XX (XX)	XX (XX)

Follow-up questionnaire never returned – no. (%)

60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)

12.1.5. Loss to follow-up

Figures are mean (SD) unless stated otherwise.

	6 months follow-up questionnaire returned (n=…)	6 months follow-up questionnaire answered by phone (n=…)	6 months follow-up questionnaire never returned (n=…)
Demographics			
Age at randomisation (Years)	XX (XX)	XX (XX)	XX (XX)
Body mass index	XX (XX)	XX (XX)	XX (XX)

Living arrangements – no. (%)

Alone	XX	(XX)	XX	(XX)	XX	(XX)
With others	XX	(XX)	XX	(XX)	XX	(XX)

Employment status – no. (%)

Employed	XX	(XX)	XX	(XX)	XX	(XX)
Unemployed and looking for work	XX	(XX)	XX	(XX)	XX	(XX)
At school or in full time education	XX	(XX)	XX	(XX)	XX	(XX)
Unable to work due to long term sickness	XX	(XX)	XX	(XX)	XX	(XX)
Look after your home/family	XX	(XX)	XX	(XX)	XX	(XX)
Retired from paid work	XX	(XX)	XX	(XX)	XX	(XX)
Other	XX	(XX)	XX	(XX)	XX	(XX)

Age left full time education – no. (%)

I did not receive a formal education	XX	(XX)	XX	(XX)	XX	(XX)

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Age 12 or less	XX (XX)	XX (XX)	XX (XX)
Age 13 to 16	XX (XX)	XX (XX)	XX (XX)
Age 17 to 19	XX (XX)	XX (XX)	XX (XX)
Age 20 or over	XX (XX)	XX (XX)	XX (XX)
I am still in full time education	XX (XX)	XX (XX)	XX (XX)
Other	XX (XX)	XX (XX)	XX (XX)

Ethnic group – no. (%)

White	XX (XX)	XX (XX)	XX (XX)
Black	XX (XX)	XX (XX)	XX (XX)
Central Asian	XX (XX)	XX (XX)	XX (XX)
Middle Eastern	XX (XX)	XX (XX)	XX (XX)
Southern Asian	XX (XX)	XX (XX)	XX (XX)
Mixed	XX (XX)	XX (XX)	XX (XX)
Other ethnic group	XX (XX)	XX (XX)	XX (XX)
Do not wish to say	XX (XX)	XX (XX)	XX (XX)

Smoker – no. (%)			
Yes	XX (XX)	XX (XX)	XX (XX)
No	XX (XX)	XX (XX)	XX (XX)
If yes, number of cigarettes per week	XX (XX)	XX (XX)	XX (XX)
Drink alcohol – no. (%)			
Yes	XX (XX)	XX (XX)	XX (XX)
No	XX (XX)	XX (XX)	XX (XX)
If yes, number of units of alcohol per week	XX (XX)	XX (XX)	XX (XX)

Baseline medical history

Length of pain – no. (%)			
0-6 months	XX (XX)	XX (XX)	XX (XX)
7-12 months	XX (XX)	XX (XX)	XX (XX)
1-2 years	XX (XX)	XX (XX)	XX (XX)

	Intervention	Active control	Usual care
3-5 years	XX (XX)	XX (XX)	XX (XX)
6-10 years	XX (XX)	XX (XX)	XX (XX)
More than 10 years	XX (XX)	XX (XX)	XX (XX)
Pain over the past week	XX (XX)	XX (XX)	XX (XX)

Baseline values of clinical outcomes

	Intervention	Active control	Usual care
Pain acceptance score (CPAQ-8)	XX (XX)	XX (XX)	XX (XX)
Depression score (HADS)	XX (XX)	XX (XX)	XX (XX)
Anxiety score (HADS)	XX (XX)	XX (XX)	XX (XX)
Pain related disability score (CPG)	XX (XX)	XX (XX)	XX (XX)

12.1.6. Follow up within target follow up period

	Intervention	Active control	Usual care

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	(n=…)	(n=…)	(n=…)
Follow-up questionnaire returned or answered by phone within target follow up period– no. (%)			
60 days (46 and 74days)	XX (XX)	XX (XX)	XX (XX)
3 months (76 and 104 days)	XX (XX)	XX (XX)	XX (XX)
6 months (159 and 201 days)	XX (XX)	XX (XX)	XX (XX)

12.1.7. Adherence to app use

Figures are mean (SD) unless stated otherwise.

	Intervention	Active control
	(n=…)	(n=…)
Number of days (within the first 60 days from randomisation) a patient has used the app	XX (XX)	XX (XX)
Number of weeks (within the first eight weeks from randomisation) a patient has used the app on three or more days	XX (XX)	XX (XX)

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Used the app on 22 or more days within the first 60 days from randomisation – no. (%)	XX (XX)	XX (XX)
Used the app on three or more days in 6 or more weeks (within the first eight weeks from randomisation) – no. (%)	XX (XX)	XX (XX)
Used the app on 22 or more days within the first 60 days from randomisation, AND used the app on three or more days in 6 or more weeks within the first eight weeks from randomisation – no. (%)	XX (XX)	XX (XX)

12.1.8. App usability questionnaire

Figures are number (percentage).

	Totally disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Totally agree	Not answered
It is easy to access the app whenever I wanted to use it						
Intervention:	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

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Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

After being shown, I understood how the app would work

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

It was fun to work with the app

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

The app worked well

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

It was easy to work through the modules

MEMPHIS Statistical Analysis Plan   Version 3.0

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

The number of modules was annoying

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

The modules were well-displayed on my smartphone

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Using the app was difficult because of my daily activities

Intervention: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

Active control: XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)   XX (XX)

MEMPHIS Statistical Analysis Plan   Version 3.0

Intervention:	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)
Active control:	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)

12.1.9. Clinical outcomes

	Intervention (n=…)				Active control (n=…)				
	n	**(%)**	**Mean**	**(SD)**	**n**	**(%)**	**Mean**	**(SD)**	**n**
Pain acceptance score									
Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX
Depression score									
Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX
Anxiety score									
Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX
Mindfulness score									
Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX

3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

Pain related disability score

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

Self efficacy score

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

SHOW-Q global score, for sexually active participants

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

SHOW-Q pelvic problem interference score, for all participants

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

Subjective outcome score

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Included in analysis †	XX	(XX)			XX	(XX)			XX

SF-36: Physical functioning

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
Included in analysis †	XX	(XX)			XX	(XX)			XX	

SF-36: Pain

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
Included in analysis †	XX	(XX)			XX	(XX)			XX	

SF-36: General Health

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
Included in analysis †	XX	(XX)			XX	(XX)			XX	

SF-36: Social Functioning

Baseline	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	
Included in analysis †	XX	(XX)			XX	(XX)			XX	

(† Included in analysis if outcome is available for at least one follow-up time point.)

	Intervention vs. Active control Adjusted mean difference (95% CI)		Invention vs. Usual care Adjusted mean difference (95% CI)		Active control vs. Usual care Adjusted mean difference (95% CI)	
Pain acceptance score						
60 days	XX	(XX to XX)	XX	(XX to XX)	XX	(XX to XX)
3 months	XX	(XX to XX)	XX	(XX to XX)	XX	(XX to XX)
6 months	XX	(XX to XX)	XX	(XX to XX)	XX	(XX to XX)

Depression score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

Anxiety score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

Mindfulness score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

Pain related disability score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

Self efficacy score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

SHOW-Q global score, for sexually active participants

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

SHOW-Q pelvic problem interference score, for all participants

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

Subjective outcome score

60 days	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
3 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)
6 months	XX (XX to XX)	XX (XX to XX)	XX (XX to XX)

SF-36: Physical Functioning

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60 days	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
3 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
6 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)

SF-36: Pain

60 days	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
3 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
6 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)

SF-36: General Health

60 days	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
3 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
6 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)

SF-36: Social Functioning

60 days	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
3 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)
6 months	XX	(XX to XX)	XX	(XX to XX)	XX (XX to XX)

12.1.10. Unintentional unblinding of randomised treatment

Figures are number (%) unless stated otherwise.

	Intervention (n=…)	Active control (n=…)
Researchers: Which app treatment do you believe the participant was randomised to?		
Intervention app	XX (XX)	XX (XX)
Control app	XX (XX)	XX (XX)
Don't know	XX (XX)	XX (XX)
Participants: Do you think you received the new treatment or comparison treatment?		
New treatment	XX (XX)	XX (XX)
Comparison treatment	XX (XX)	XX (XX)
Don't know	XX (XX)	XX (XX)

12.1.11. Partially missing clinical outcomes

	Not completed *	Partially Completed **	Fully completed ***
	n (%)	n (%)	n (%)
Pain acceptance score			

Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Depression score			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Anxiety score			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Mindfulness score			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Pain related disability score			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
Self efficacy score			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)
6 months	XX (XX)	XX (XX)	XX (XX)
SHOW-Q global score, for sexually active participants			
Baseline	XX (XX)	XX (XX)	XX (XX)
60 days	XX (XX)	XX (XX)	XX (XX)
3 months	XX (XX)	XX (XX)	XX (XX)

6 months	XX	(XX)	XX	(XX)	XX	(XX)

SHOW-Q pelvic problem interference score, for all participants

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

Subjective outcome score

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

SF-36: Physical Functioning

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

SF-36: Pain

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

SF-36: General Health

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

SF-36: Social Functioning

Baseline	XX	(XX)	XX	(XX)	XX	(XX)
60 days	XX	(XX)	XX	(XX)	XX	(XX)
3 months	XX	(XX)	XX	(XX)	XX	(XX)
6 months	XX	(XX)	XX	(XX)	XX	(XX)

* Questionnaire not answered or all variables used in the derivation of the outcome are missing.
** One or more, but not all, variables used in the derivation of the outcome are missing.

*** No variables used in the derivation of the outcome are missing.

	Questionnaire never returned		Questionnaire answered by telephone						Questionna...		
			Not completed †		Partially completed ††		Fully completed †††		Not completed †		Pa... comp...
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n
Pain acceptance score											
Baseline	XX	(XX)	n/a		n/a		n/a		XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Depression score											
Baseline	XX	(XX)	n/a		n/a		n/a		XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Anxiety score											
Baseline	XX	(XX)	n/a		n/a		n/a		XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Mindfulness score											
Baseline	XX	(XX)	n/a		n/a		n/a		XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
Pain related disability score											
Baseline	XX	(XX)	n/a		n/a		n/a		XX	(XX)	XX
60 days	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
3 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX
6 months	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX	(XX)	XX

Self efficacy score

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

SHOW-Q global score, for sexually active participants

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

SHOW-Q pelvic problem interference score, for all participants

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

Subjective outcome score

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX
3 months	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX
6 months	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX (XX)	XX

SF-36: Physical Functioning

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

SF-36: Pain

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

SF-36: General Health

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

SF-36: Social Functioning

Baseline	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
60 days	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
3 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX
6 months	XX (XX)	n/a	n/a	n/a	XX (XX)	XX

† Questionnaire answered, but all variables used in the derivation of the outcome are missing.
†† One or more, but not all, variables used in the derivation of the outcome are missing.
††† No variables used in the derivation of the outcome are missing.

13. APPENDIX E: DATA / FILE MANAGEMENT

13.1.1. Sources of data

Copies of CRFs are included in the Statistics Master File. Data is entered from these into a PCTU database. Extracts from the database are supplied by the data manager onto a secure environment.

App usage data will be received from Headspace.

13.1.2. Programming plan

The trial folder on secure environment will contain a folder for each analysis.

An analysis folder should contain the following folders (and their contents):

- analysis data (saved Stata data files for analysis)

- do files (Stata do files for data preparation and analysis)

- log files (Stata log files)

- output (any files output e.g. produced tables and graphs)

- raw data (data as extracted from database)

- temp (any temporary files needed during data preparation or analysis)

Folders containing do files should include a text directory explaining the role of each do file.

Field names specified in the database "Requirements Specification Document" will be the variable names in the data files. Where a variable is collect on more than one occasion, suffixes will be added to variables names (e.g. "_BASELINE", "_60DAYS", "_3MONTHS", "_6MONTHS").

Details of derived variables are given in Section , , and .

A complete data dictionary will be produced for the final analysis data set.