FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP APPLICATION FORM

Cover Page:

Title: Symptom Monitoring benefits physical and emotional outcomes during Menopause

Date submitted for review: October 2020

Date accepted: January 2021

FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP APPLICATION FORM

PART A

N.B. All questions should be addressed (e.g. provide an answer or state why not applicable).

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1. RESEARCH STUDY TITLE:

A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.

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2. NAME OF PRINCIPAL INVESTIGATOR: **Robin Andrews**
QUALIFICATIONS: **BSc Psychology**
JOB TITLE: **PhD student**
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ADDRESS (IF NOT STAFF OF USW): **N/A**

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3. CO-INVESTIGATOR(S):

Director of Studies and academic supervisor: Dr Deborah Lancastle

Second supervisor: Professor Bev John

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4. IMPERATIVE: Please provide the EFAS number for this project (available from the Research Governance Officer):

21059

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5. i) DOES THIS PROPOSAL REPRESENT PART OF AN EDUCATION/TRAINING PROGRAMME?
(If you answer YES to this question, please complete part ii below)

YES

ii) IF YES, WHAT QUALIFICATION WILL THIS THE PROJECT LEAD TOWARDS?

This research is part of a KESS-2 funded PhD project

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6. BACKGROUND AND CONTEXT / RATIONALE

Evidence suggests that up to 90% women in the UK will experience severe menopausal symptoms (Hunter et al., 2001). Despite this, it has been reported that few women will seek medical help, and most will not access treatment until their symptoms have become extremely bothersome (Constantine et al., 2016). Unfortunately, those that do seek treatment for menopause are likely to face barriers to effective healthcare, with some reports suggesting that many women struggle to adequately communicate the totality of their menopausal symptoms to health professionals (Ismail et al., 2016; Woods et al., 2015).

Robin Andrews recently conducted a systematic review (submitted for publication) which demonstrated that symptom monitoring reduced women's reports of menopausal symptoms, such as hot flushes, urinary incontinence, headaches, reduced libido, and depressed mood. The systematic review also demonstrated that symptom monitoring increased health awareness and facilitated patient-doctor communication, decision-making, and treatment goal setting, all of which are antecedents for improved medical treatment outcomes (Ha & Longnecker, 2010). In the randomised trials included in this review, however, symptom monitoring was used as a control intervention against which another intervention (e.g., paced respiration) was compared, and the findings of benefits in the symptom monitoring control group were largely under recognised and rarely discussed (Sternfeld et al., 2014; Carpenter et al., 2012).

7. AIMS AND OBJECTIVE(S) OF THE RESEARCH STUDY:

It is important to further our understanding of the extent to which symptom monitoring alone could be a useful intervention to support menopausal women. Should monitoring be beneficial, it has the potential to offer women a useful and economical way of improving their wellbeing when waiting for treatment, or for women who choose not to receive treatment for menopausal symptoms, or for whom medical treatment is contra-indicated. Thus, a randomised controlled trial (RCT) will be conducted in the proposed research because symptom monitoring as a stand-alone intervention for the menopause has not yet been evaluated experimentally.

The primary objective of the proposed study is to experimentally investigate symptom monitoring among menopausal women. The key outcome of interest will be whether daily symptom monitoring influences physical and emotional menopause symptoms, help-seeking, health and symptom awareness, willingness to engage in patient-doctor communication, and perceptions of efficacy in treatment decision-making and goal setting, compared to women who are not asked to monitor their symptoms.
To explore whether daily symptom monitoring can influence physical and emotional menopausal symptoms, this trial will employ the Daily Record Keeping form. The DRK was developed to assess women's daily reactions to IVF treatment (Boivin, 1997; Boivin & Takefman, 1995, 1996) and has since been employed in a number of fertility studies which have charted daily symptom changes (Lancastle, 2006; Ockhuijsen et al., 2014; Bailey et al., 2015). These studies have demonstrated symptom improvements following 2-weeks of using the DRK. The DRK was adapted for the present study to include physical and emotional menopause symptoms, based on the British Menopause Society's index of the most-commonly experienced menopausal symptoms (2016).
Care will be taken when interpreting the results of the DRK, because a number of factors influence symptom reports. For example, individuals who live alone are more likely to report a greater number of physical symptoms and succumb to physical illnesses than those who live with others (Pennebaker, 2012). Likewise, single, unemployed people are more likely to report a greater number of symptoms than individuals in a relationship and employment (Pennebaker, 2012). Because these factors interact with symptom reports, they will be relevant when assessing for covariates during this research (Pennebaker, 2012).
Evidence from the systematic review also indicated that symptom monitoring might induce health-related behavioural changes. Thus, help-seeking intentions will be explored as prior evidence suggests that symptom monitoring can lead to an increased intention to seek medical help (Shafran et al., 2019). Furthermore, difficulties in communicating symptoms can act as a barrier to help-seeking, and findings from the systematic review suggest that symptom monitoring may increase willingness to communicate with health providers (Salaheddin & Mason, 2016; Ismail et al., 2016; Woods et al., 2015). Decision-making

efficacy will also be explored as the systematic review demonstrated that symptom monitoring is related to improved efficacy in making medical decisions. This evidence also suggested that symptom monitoring may improve an individual's ability to identify which health improvements they would like to see in the future, therefore goal-setting efficacy will be assessed. Lastly, health awareness will be explored following evidence from the systematic review which suggested that symptom monitoring increased awareness of symptoms, which was subsequently associated with symptom improvements (Stensland & Malterud, 2001).

A secondary objective is to explore the potential moderators of the impact of symptom monitoring on physical or emotional symptoms. For example, the dispositional characteristic neuroticism has been shown in numerous studies to lead to reports of more frequent and/or severe symptoms (Ormel, Rosmalen, & Farmer, 2004; Lagoe & Atkin, 2015). Trait neuroticism is important to explore in this research as it has empirically been associated with increased reports of health anxiety. Increasing evidence suggests that the relationship between trait neuroticism and health anxiety is mediated by health information seeking (Lagoe & Atkin, 2015). Therefore, it's important to assess whether health information, as supplied by symptom monitoring, could instigate heightened health anxiety in individuals with high neuroticism scores. Moreover, neuroticism has been related to increased reports of physical symptoms in terms of both severity and frequency, even when comparing objectively healthy populations (Pennebaker, 2012). This suggests that individuals scoring high on trait neuroticism may tend to report an increased number of symptoms, and this effect will be important to explore in regard to evaluating the symptom monitoring intervention.
Monitoring and blunting coping tendencies have also been shown to influence the extent to which individuals prefer to pay close attention to their wellbeing or avoid thinking about it (Murris & Van Zuuren, 1992; Miller, 1987). Those who employ monitoring to cope with health problems will actively seek out health information, whereas those who employ blunting will adopt distraction strategies in order to actively avoid health information (Miller, 1995). This information seeking preference is important as evidence suggests that acquisition of health information can lead to increased health anxiety in individuals who exhibit monitoring coping preferences (Miller, 1995). In the case of menopausal symptom monitoring, women's attention is drawn to information about their menopausal wellbeing, which may be anxiety provoking. Therefore, this measure will help us understand whether symptom monitoring is more or less effective as an intervention for women, depending on their health information-seeking preferences.
It is important to establish for whom symptom monitoring might be most helpful, or conversely taxing or even harmful should it challenge a dispositional tendency to avoid focusing on wellbeing. Indeed, coping style and neuroticism have both been associated with increased health anxiety following the procurement of health information (Lagoe & Atkin, 2015; Miller, 1987). Therefore, health anxiety will also be measured during this research to explore whether symptom monitoring influences it, and whether this effect is related to neuroticism or coping preferences.

A third objective is to investigate whether participants attribute the act of monitoring to any perceived improvements, or whether participants attribute other elements of research participation to their improved health (i.e. increased menopausal awareness), or whether participants do not perceive any improvements whatsoever. Studies which have included symptom monitoring as a control intervention often speculate that involvement in research is responsible for the positive outcomes found in the control group, rather than symptom monitoring in itself (Borud et al., 2010). However, these studies rarely provide data on this assumption. Therefore, the present study aims to establish whether participation in menopausal research per se improves wellbeing, regardless of what that participation entails.

Summary of objectives:

- Investigate whether daily symptom monitoring influences psychological, physical and behavioural health outcomes compared to a non-monitoring control group.

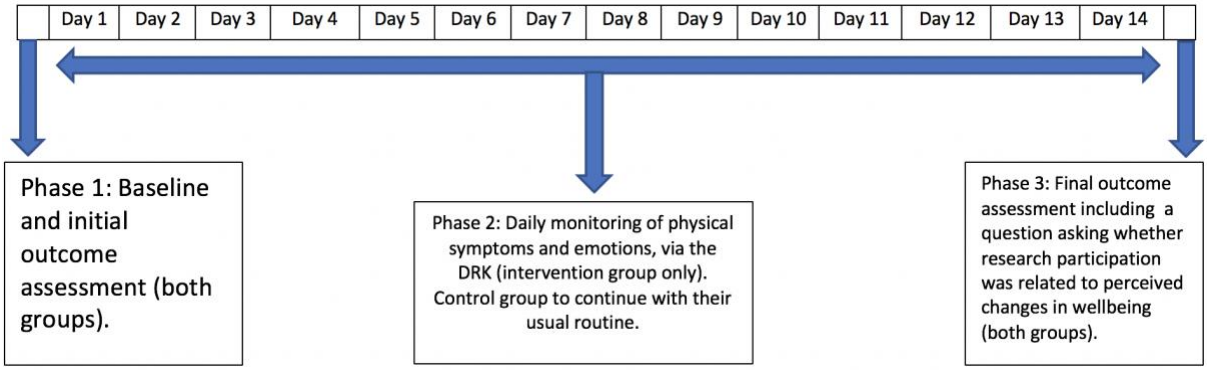
- Assess whether personality and coping style moderate the impact of symptom monitoring on physical or emotional health outcomes during the menopause.

- Identify whether participants attribute any health improvements to symptom monitoring, or other elements of their research participation.

8. STATEMENT OF STUDY DESIGN (E.g. RCT, Crossover, Cohort studies, Case control, Action research, etc. Max 700 words)

This study will employ a 2-arm randomised controlled trial, including 1 symptom monitoring intervention group and 1 non-monitoring control group. The main analysis will be a 2 by 2 mixed between/ within-subjects ANOVA. The between-subjects component will compare symptom differences between the symptom monitoring intervention group and the usual care control group. The within-subjects component will compare symptom changes between baseline and after 2-weeks of daily symptom symptom monitoring, and between baseline and after an interval of 2 weeks without monitoring, in the control group. The interaction will establish whether symptom changes differ over time according to whether women are in the symptom monitoring or control group. It is expected that improvements in well-being will occur over time in the symptom monitoring group, in comparison to the control group e.g., positive reactions will increase from baseline, whereas negative reactions will decrease. Symptom reports will be collected using the DRK (Boivin & Takefman, 1995). The intervention group will record their symptoms at baseline and every day for 2-weeks (although only baseline to follow up changes will be subject to analysis), the control group will record their symptoms at baseline and after an interval of 2-weeks with no daily monitoring. The DRK has been used previously in randomised trials of women's reproductive health (e.g., Boivin & Takefman, 1995; Ockhuijsen et al., 2014) to establish the effects of symptom monitoring. This research will take place electronically, questionnaires will be presented to participants in the form of JISC Online Surveys and accompanying information will be attached to emails as Word documents. This study has been designed in this way in response to the ongoing 2020 COVID-19 pandemic. The study admin will be managed by Robin via a dedicated USW email address: **theresearchteam@southwales.ac.uk.**

Research design figure:



All participants:

Both groups will complete a number of measures at baseline and at 2-week follow up, using surveys presented via JISC Online Surveys. Baseline measures will be: demographics, coping style, and trait neuroticism, as well as physical and emotional menopause symptoms (as measured using the DRK), health anxiety, help-seeking intentions, health and symptom awareness, willingness to engage in patient-doctor communication, and perceptions of efficacy in treatment decision-making and goal setting. Participants will be asked on the baseline questionnaire whether they would like to be sent text message reminders to help them remember to complete the surveys. Those who answer "Yes" will be asked to supply their mobile phone number. Participants will also be given the option of opting out of being sent text reminders throughout the duration of the study. This is in case participants find receiving daily text messages invasive, annoying, or not useful. Therefore, allowing participants to opt out gives them the option to change their

mind. **See Appendix 1 to view the baseline survey in Word document format.** Prior to being presented with the information sheet, consent form, and baseline survey questions, participants will be asked three screening questions which will assess study eligibility. **See Appendix 2 to view the screening questions. The screening questions with the information sheet and consent form and main baseline survey questions, as presented on JISC Online Surveys, can be viewed via this link: https://southwales.onlinesurveys.ac.uk/baseline-questionnaire-preview**

After 2 weeks, outcome questionnaires will be administered again (on the 15th day after the 14-day monitoring period) alongside a measure which will assess whether participants believe their research participation is related to any improvements in their health or wellbeing, and a single-qualitative item which will assess participant experiences of dealing with the menopause during the Covid-19 pandemic. The measures to be administered again include: the General help seeking questionnaire (GHSQ) which will assess help-seeking, health anxiety will be assessed using the Health Anxiety subscale extracted from The Health Orientation Scale (HOS), patient-doctor communication will be assessed using The Willingness to Communicate about Health (WTCH) Measure, decision-making will be assessed using the Decision Self-Efficacy Scale (DSE), goal-setting efficacy will be assessed using the General Self Efficacy Scale (GSE), health awareness will be assessed using the Health Consciousness (HC) subscale extracted from HOS, changes in physical symptoms after 2 weeks will be evaluated using the DRK, and 3 qualitative items will assess perceived effects of research engagement. A final qualitative item will also be used to assess participants' experiences in dealing with the menopause during the Covid-19 pandemic. Trait neuroticism and monitoring/ blunting coping styles will not be reassessed at follow-up as it is not expected that these dispositional variables will alter as a result of the intervention after 2 weeks. **See Appendix 3 to view the follow-up survey in Word document format. The follow-up survey as presented on JISC Online Surveys can be accessed via this link: https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview**

Intervention group:

Participants in the intervention group will be invited to monitor their physical and emotional symptoms every day for 14-days using the Daily Record Keeping form (DRK; Boivin & Takefman, 1995), administered via JISC Online Surveys. **See Appendix 4 to view the daily DRK survey in Word document format. The online DRK survey can be viewed as it's presented on JISC Online Surveys via this link: https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-preview.** At 10am each day of the intervention period, participants in the intervention group will be sent an email asking them to complete the DRK survey by the end of the day- they will also receive text message reminders to complete the DRK at 5pm each day, unless they opt out of reminders. Both the email and text reminders will include a link to the online DRK. Participants can opt out of text message reminders at any time by emailing Robin requesting to opt out. Once participants have returned DRK surveys every day for 14 days, on the 15th day they will be asked to complete the follow-up survey within 24 hours. Once they have returned the follow-up survey they will be sent their £20 gift voucher via email. **See Appendix 5, page 1 to view a template of the daily DRK email reminders, see Appendix 5, page 2 to view a template of the text message reminders. See Appendix 6, page 1 to view the email template advising intervention group participants of their group allocation, and instructing them to complete the DRK survey each day for 14 days.** The online text messaging platform ClickSend will be used to manage the scheduling of daily text message (www.clicksend.com) See the section below titled "Data collection tools" for a more detailed explanation of the measures used in this study.

Control group:

Participants in the control group will not monitor their symptoms daily for 14-days and will instead be instructed to carry on as usual during the 2-week period, while the intervention group are monitoring. This group will complete all measures (including the DRK) at baseline and at follow-up on the 15th day only. **See Appendix 6, page 2 to view the email template advising control participants of their group allocation, and instructing them to carry on as usual for 14 days. If they indicated on the baseline survey that they are**

interested in receiving text message reminders, participants in the control group will also be sent a reminder text message to complete the follow-up survey.

Hypotheses:

- Symptom monitoring will lead to significant improvements in symptoms after 2 weeks, in comparison to the non-monitoring control group.
- The monitoring group will report increased self-efficacy at follow up in patient-doctor communication, shared decision making, goal orientated behaviour, help-seeking intentions, and heightened health awareness, compared to the control group.
- Women in the intervention group who are monitors according to their scores on the blunting and monitoring scale will report higher negative emotions and physical symptoms than blunters at follow up.
- Greater Health anxiety at follow up will be predicted by symptom changes, demographics (living alone, employment, and marital status), coping style, neuroticism, and symptom monitoring.

9. MATERIALS AND METHODS

This study will use electronic means (online survey, email) and participants will receive a £20 Amazon voucher for completed participation. No face to face contact will occur between the research team and research participants. Participants will predominantly be recruited using JISC's online platform for connecting researchers with study participants (www.callforparticipants.com), as well as social media sites including Facebook and Instagram. Using these platforms, a research poster will be used to attract participants to the study and provide interested participants with a link to the screening questions, information sheet, consent form, and baseline survey. **See Appendix 7 to view the recruitment poster as it will be presented on www.callforpartcipants.com, and shared on social media sites.**

The baseline survey (**see Appendix 1**) will collect the email addresses of interested participants. After submitting the baseline questionnaire, participants will be contacted via email with details about their group allocation and further instructions i.e. intervention participants will be instructed to complete 5-minute daily surveys each day for 14 days (see **Appendix 6, page 1** for instruction email template for intervention participants), whereas control group participants will be asked to continue as usual for 14 days (see **Appendix 6, page 2** for instruction email template for control participants). After the 14-day period both groups will be asked via email to complete the follow-up survey (**see Appendix 6, page 3**). The information sheet (**see Appendix 8**) and consent form (**see Appendix 9**) will precede the baseline survey and will provide full information about the nature of the study and details about what the participants in each group will be asked to do, including eligibility for he £20 incentive for taking part. The methodology for supplying participants with vouchers via email has been used in a previously approved study with no problems raised (ethics reference: 200401HR).
To avoid participants being burdened unnecessarily by reading information about a study for which they are not eligible (e.g., too young or not experiencing the menopause) participants will answer screening questions which will assess their age, the number of hot flushes they experience per day, and their self-reported menopausal status. Participants will be screened out of the survey if they indicate that they are under 18, or report fewer than 2 hot flushes per day, and do not self-report peri- or post-menopausal status. **See Appendix 1, page 1 to view how the screening questions will be presented on the baseline survey. See Appendix 2 to view the screening questions.**

NICE guidance recommends clinicians diagnose menopause (without the use of laboratory testing) based on whether a woman is not using hormonal contraception and has gone over 12 months without a period. NICE advises that perimenopause be diagnosed based on the presence of irregular periods and vasomotor symptoms, in women without a uterus perimenopause is diagnosed based on symptoms alone. Therefore, it was decided to use presence of vasomotor symptoms as criteria for assessing symptomatic menopausal status as this

encompassed both symptomatic peri and postmenopausal women, as well as women who have undergone surgical menopause. Furthermore, numerous RCTs which have compared variances in symptom reports between intervention and control groups have used 2 hot flushes per day as a criterion for assessing menopausal symptomology and status, and for ensuring that groups are equal in terms of menopausal symptom burden (Carpenter et al., 2012; Otte et al., 2013; Fraser et al., 2005).

All questionnaires will be presented using the JISC online surveys platform: www.onlinesurveys.com. After completing the baseline questionnaire, and providing their email address, participants will be emailed within 24 hours of completion of the baseline survey with details of their group allocation and a unique username. See **Appendix 6, page 1** for the instruction email to intervention participants, and **Appendix 6, page 2** for the instruction email to control participants. Participants will be asked to confirm their username at the beginning of each subsequent survey they complete (i.e. the DRK or follow-up survey) and in any email contact with the researcher.

Materials:

Baseline measures:

Demographics and medical history (baseline only): Demographic variables to be measured are: age, town/country of residence, menopausal status, employment status, relationship status, living arrangements (i.e. are they living alone or with others?), date of last menstrual period, current medications being used (both for menopause and other conditions), and any current medical conditions. **See Appendix 1, page 2 to view how the demographic and medical history questions will be presented on the baseline survey.**

Blunting and monitoring coping preferences as measured using the Miller Behavioural Style Scale (MBSS; at baseline only): this will be used to assess dispositional monitor/blunter coping preferences, which might affect the extent to which women benefit from or feel uncomfortable with symptom monitoring. The MBSS asks the recipient to vividly imagine 4 different scenarios, and then choose how they would respond to each one from a list of statements. These statements give an indication of whether the respondent would react to the imagined situation by using a Monitoring or Blunting coping strategy. Three scores can be derived from the MBSS questionnaire. They are: (1) the total Monitoring score; (2) the total Blunting score; or (3) the total difference score- Monitoring minus Blunting. To create the total Monitoring and Blunting scores simply sum the Monitoring items (marked "M") and the number of Blunting items (marked "B") respectively. Once these individual scale scores are created, you can simply put them into the M-B equation to create the total difference score. **See Appendix 10, page 1 to view a copy of the original MBSS, see Appendix 1, page 13 to view how the MBSS will be presented on the baseline survey.**

Neuroticism as measured using the neuroticism scale (10 items; α = .86) from the International Personality Item Pool scales (NEO-IPIP-10; baseline only): this measure was chosen because it has a high reliability statistic, is freely available to use, is based on Costa and McCrae's NEO Personality Inventory (NEO-PI-R) of which it is highly correlated (α = .82), and has been used in numerous psychological articles, all of which are listed on the IPIP website (https://ipip.ori.org/newPublications.htm). The IPIP is a public domain collection of personality measures which are based on the 16PF Questionnaire and the Big Five personality traits. **See Appendix 10, page 3 to view a copy of the original NEO-IPIP-10, see Appendix 1, page 3 to view how the NEO-IPIP-10 will be presented on the baseline survey.**

Outcome measures:

Help-seeking intentions as assessed using The General Help Seeking Questionnaire (GHSQ; α = .85): help-seeking intentions will be assessed because prior evidence suggests that symptom monitoring can lead to an increased intention to seek medical help (Shafran et al., 2019). Furthermore, difficulties in identifying and communicating symptoms can act as a barrier to help-seeking and findings from our systematic review suggest

symptom monitoring may increase willingness to communicate with health providers (Salaheddin & Mason, 2016). Therefore, we endeavour to test whether help-seeking intentions can increase following symptom monitoring, as mediated by heightened willingness to communicate. The GHSQ has been designed to be adapted to the target population under assessment, therefore the following help-seeking source was added: "Internet sources including health websites, online forums (I.e. Mumsnet Quora Reddit), and social media accounts (I.e. Twitter, Instagram, Facebook)". "Parents" was removed as a help source, as the target population for this study might no longer be able to turn to their parents for help. Therefore "Other relative/ family member" was amended to: "Relative/ family member". **See Appendix 10, page 4 to view a copy of the original GHSQ, see Appendix 1, page 4 to view how the GHSQ will be presented on the baseline survey. See Appendix 3, page 1 to see how to GHSQ will be presented on the follow-up survey. On the baseline and follow-up surveys the GHSQ is titled "help-seeking questionnaire".**

Health anxiety subscale extracted from The Health Orientation Scale, α = .82 (HOS; to be assessed at baseline and follow-up): health anxiety will be assessed to explore whether symptom monitoring influences it, and whether this effect is related to neuroticism or coping preferences. The HOS was developed by William E. Snell, and includes 10 health-oriented subscales each containing five items. The items on the health anxiety subscale assesses anxious feelings associated with the status of one's health. More specifically, these
items were designed to tap people's feelings of tension, discomfort and anxiety about their physical health. People who endorse these items are those who experience chronic anxiety as a result of thinking about their physical health (Snell et al., 1991). The 5-item health anxiety subscale has good reliability, and has been used in numerous studies as a measure of health anxiety (Adejumo et al., 2017; Gordon et al., 2005; Snebby & Snell, 2002). **See Appendix 10, page 4 to view a copy of the original HOS including the Health Anxiety subscale, see Appendix 1, page 5 to view how the Health Anxiety subscale will be presented on the baseline survey. See Appendix 3, page 2 to see how to Health Anxiety subscale will be presented on the follow-up survey. On the baseline and follow-up surveys the health anxiety subscale is presented together with the health consciousness subscale and titled "Thoughts about health questionnaire".**

Patient-doctor communication will be assessed using the Willingness to Communicate about Health (WTCH) Measure, α = .70: this variable will be explored following evidence from the systematic review which suggested that willingness to communicate about one's health might increase following symptom monitoring. This was because individuals felt better able to describe the totality of their symptoms after summarising them using a symptom monitoring instrument (Ismail et al., 2016; Woods et al., 2015).
The 10-item WTCH measure uses a 5-point Likert scale which asks the responder to indicate how strongly they agree with each statement. These statements aim to capture how comfortable the respondent feels discussing their health and symptoms with others. The WTCH was chosen for this study because it has been found to have good reliability (α = .70) as well as convergent and discriminant validity (Wright et al., 2007). **See Appendix 10, page 6 to view a copy of the original WTCH, see Appendix 1, page 7 to view how the WTCH will be presented on the baseline survey. See Appendix 3, page 4 to see how to WTCH will be presented on the follow-up survey. On the baseline and follow-up surveys the WTCH is titled "health communication scale".**

Decision-making efficacy will be assessed using The Decision Self-Efficacy (DSE) Scale, α = 0.85: This variable will be explored following evidence from the systematic review which suggested that symptom monitoring is related to improved efficacy in medical decision making. This measure includes 11 items which assess self-confidence or belief in one's abilities in decision making, including shared decision making, in medical contexts. This instrument has been used in numerous studies which have explored whether certain health interventions have led to improvements in decision self-efficacy within health contexts (Minneci et al., 2019; Smith et al., 2019; Cuypers et al., 2018). Furthermore, this measure has been found to have good scale reliability (α = 0.85; Cuypers et al., 2018). **See Appendix 10, page 8 to view a copy of the original DSE, see Appendix 1, page 8 to view how the DSE will be presented on the baseline survey. See Appendix 3, page 5 to see how to DSE will be presented on the follow-up survey. On the baseline and follow-up surveys the Decision-making self-efficacy scale is titled the "decision making scale".**

Goal setting efficacy will be assessed using the General Self Efficacy Scale (GSE, α = 0.76 to 0.90): This variable will be explored following evidence from the systematic review which found that symptom monitoring may improve an individual's ability to identify which health improvements they would like to see in the future.
The GSE is a 10-item scale with a score for each question ranging from 1 to 4. The scale was created to assess a general sense of perceived self-efficacy. The construct of perceived self-efficacy reflects an optimistic self-belief that one can perform novel or difficult tasks, or cope with adversity in various domains of human functioning (Schwarzer, 1992). The 10 items on the GSE are designed to tap into the construct of perceived self-efficacy which has been positively related to goal-setting and health-related behavioural changes (Schwarzer, & Fuchs, 1996; Schwarzer & Jerusalem, 1995). Furthermore, several studies have shown that the GSE has high reliability, stability, and construct validity. **See Appendix 10, page 10 to view a copy of the original GSE, see Appendix 1, page 9 to view how the GSE will be presented on the baseline survey. See Appendix 3, page 6 to see how to GSE will be presented on the follow-up survey. On the baseline and follow-up surveys the GSW is titled the "self-efficacy scale".**

Health awareness was assessed using the Health Consciousness subscale extracted from The Health Orientation Scale (HOS, α = 0.82): This variable will be explored following evidence from the systematic review which suggested that symptom monitoring could increase health awareness. The items on the Health Consciousness subscale refer to an awareness of one's health. These items were designed to measure people's tendency to think about and to reflect about their health. People who endorse these items are those who think about that status of their physical health, and who in general are reflective about the nature of the health and wellness of their body (Snell et al., 1991). This measure was chosen for its simplicity, high reliability coefficient (α = 0.82) and because it has been employed in a number of studies (Adejumo et al., 2017; Gordon et al., 2005; Snebby & Snell, 2002). **See Appendix 10, page 5 to view a copy of the original HOS including the Health Consciousness subscale, see Appendix 1, page 5 to view how the Health Consciousness subscale will be presented on the baseline survey. See Appendix 3, page 2 to see how to Health Consciousness subscale will be presented on the follow-up survey. On the baseline and follow-up surveys the health consciousness subscale is presented together with the health anxiety subscale and titled "Thoughts about health questionnaire".**

The Daily record keeping form (DRK): participants in both groups will complete the DRK at baseline and at follow –up. Only the intervention group will complete the DRK every day of the 2-week period.

An RCT conducted by Lancastle compared outcomes of implementing a positive reappraisal coping intervention, with a positive mood induction control, and a daily monitoring control as measured using the DRK (Lancastle, 2006). This study evaluated emotional reactions and physical symptoms among women experiencing 14-day IVF waiting periods. This research found significant improvements in physical symptoms within the daily monitoring group across the 2-week waiting period which suggests that 2 weeks is an adequate amount of time to generate observable effects of an intervention, using daily symptom monitoring.

For the present study, the DRK will be amended to include a comprehensive list of 32 menopausal symptoms, as indexed by the British Menopause Society (2016), as well as emotional reactions. The original DRK was developed to measure emotional distress of women undergoing IVF waiting periods, thus valid and statistically reliable facets of the DRK have been shown to effectively track changes in emotions related to depression, anxiety, anger, uncertainty, and positive affect (Boivin, 1997). Whilst the majority of these emotions are highly relevant to midlife women, the present study also includes emotions associated with loneliness. This is because feelings of loneliness have frequently been reported among menopausal women (Bingol et al., 2019). The menopause is considered by some to be a taboo subject, leading many to undertake the burden of their symptoms alone; this stoic resolve can make many women feel isolated and disconnected from friends, family members, and their partners. Research has explored the influence loneliness has on menopausal symptoms, and these studies have reported strong, negative associations, suggesting that loneliness can worsen the felt experience of physical symptoms (Thurston et al., 2008; Fernández et al., 2012; Hu et al., 2017; Bingol et al., 2019).

Therefore, the present study will include items from previously validated measures of loneliness. The following emotional facets of loneliness will be included on the DRK: Isolated (as included in the UCLA loneliness scale), Rejected (as included in the De Jong Gierveld Scale), Lonely (as included in the direct measure of loneliness), Left out (as included UCLA loneliness scale). Cronbach's analyses will be conducted on these emotional facets to evaluate their reliability as a brief, daily, measure of loneliness.

In September 2020, the study was piloted by one woman who met eligibility criteria, completed the research materials and engaged in the 2- week symptom monitoring intervention. The DRK asks respondents to rate their emotions and symptoms from 0= Not at all (you have not experienced this symptom in the past 24 hours), 1= Mild (you have experienced this symptom but it does not interfere with you daily activities), 2= Moderate (you have experienced this symptom and it interferes with your daily activities to some degree), 3= Severe (you have experienced this symptom and it has had a markedly negative affect on how well you have performed your daily tasks). The pilot participant advised that they were not sure what to do when rating positive emotions such as happy or content as the instructions seemed inappropriate. Therefore, the wording on the DRK was amended to: 0= Not at all (you have not experienced this symptom or emotion at all in the past 24 hours) , 1= Mild (you've experienced this symptom or emotion but it has not impacted your daily activities or made you feel any different than usual) , 2= Moderate (you've experienced this symptom or emotion and it has impacted your daily activities to some degree or made you feel somewhat different than usual) , 3= Severe (you've experienced this symptom or emotion and it has heavily impacted your daily activities or made you feel extremely different than usual).
See Appendix 4 to view the daily monitoring survey which will be administered to intervention group participants for 14 days. See Appendix 1, page 10 to view the DRK as it will be presented on the baseline survey. See Appendix 3, page 7 to view the DRK as it will be presented on the follow-up survey. See Appendix 10, page 11 to view an original copy of the DRK.

Follow up:

The measures described above will be completed again at follow-up:

- **The General help seeking questionnaire (GHSQ)**
- **Health anxiety (HA) subscale extracted from The Health Orientation Scale (HOS)**
- **The Willingness to Communicate about Health (WTCH) Measure**
- **The Decision Self-Efficacy Scale (DSE)**
- **The General Self Efficacy Scale (GSE)**
- **Health Consciousness (HC) subscale extracted from The Health Orientation Scale (HOS)**
- **The Daily record Keeping form (DRK)**
- **Perceived effects of research engagement:** Three items (to be completed after the 2-week research period) will assess whether research participation has led to any perceived improvements in emotional and physical well-being: "Since your engagement in this research, what changes have you noticed in your physical or emotional well-being? "If you have experienced any changes, why do you think these changes occurred?" and "what impact has participating in this research had on your physical or emotional well-being?". These items will allow for more specific assumptions to be made about whether the use of symptom monitoring in research is attributed to perceived improvements, and whether researchers employing symptom monitoring as a control intervention should be wary of this occurrence. **To view how the research engagement questions will be presented on the follow-up**

survey, see Appendix 3, page 8.

- **Covid-19 experience question:** A final qualitative item will also be used to assess participants' experiences in dealing with the menopause during the Covid-19 pandemic: "Experiencing the menopause during the Covid-19 pandemic might be especially challenging for some women. Please use this space to tell us more about this experience if you wish. E.g., did you feel able to consult a GP when you needed to? Did any changes due to work restrictions or changes in home circumstances feel different because of the menopause? Did the menopause make you feel more or less able to cope?". This item was included in order to gain perspective on the wider context in which this research is taking place, in order to understand how the 2020 pandemic has impacted research findings. **To view the Covid-19 experience question as it will be presented on the follow-up survey, see Appendix 3, page 8.**

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10. PARTICIPANTS

Discuss the number of participants required, from where the participants will be recruited, and the exclusion and inclusion criteria. Please include power calculations where applicable.

Participants will be recruited using a research poster which will be presented both on JISC's research participant finder service: www.callforparticipants.com and social media sites: Facebook, Instagram and Twitter. **See Appendix 7 to view the recruitment poster as presented on www.callforparticipants.com, and shared on social media sites.** All participants who meet eligibility criteria and research terms will be provided with a £20 Amazon voucher after completing the study to thank them for their time.
Participants will be randomised using online resource: www.randomizer.org. Randomizer is a free resource for researchers in need of a quick way to generate random numbers or assign participants to experimental conditions. This site can be used for a variety of purposes, including psychology experiments, medical trials, and survey research. Randomizer works by generating a series of random unique numbers, therefore to allocate participants into the intervention group 1 set of 39 random numbers were generated using values ranging from 1-78. These figures were chosen following insights from the power analysis (see below).
Random number generation will be used to allocate participants into groups. Participants will be assigned a number when they join the study by submitting the baseline survey- this number will reflect the order in which they joined the study i.e. the first person to join will be assigned as number 1, the second will be assigned as number 2. This number will determine whether they are in the control or intervention group by using random numbers generated by randomizer.com. Randomizer works by generating a series of random unique numbers, therefore, to allocate participants into the intervention group, 1 set of 39 random numbers will be generated using values ranging from 1-78. If the participant's assigned number matches one of the 39 random numbers generated, they will be allocated into the intervention group. If their number is not on the random number list, they will be allocated into the control group.

Inclusion criteria: this study will involve adult females, who report at least 2 hot flushes per day, with self-reported peri- or post-menopausal status. Women taking menopause-specific treatments (e.g. HRT or anti-depressants) are included in this study provided they reach the criteria for hot flushes and are otherwise healthy.

Exclusion criteria: participants will be screened out of the survey if they answer no to the following questions, which will be presented before the information sheet, consent form and main survey: "Are you over the age of 18?", "Are you experiencing at least 2 hot flushes per day?", and "Are you experiencing either perimenopause or menopause?".

Additionally, care will be taken to identify and exclude outliers from analyses, especially when considering the data of those who say they have been diagnosed with chronic or severe conditions with symptoms overlapping with menopausal symptoms, including chronic fatigue syndrome, fibromyalgia, cancer, heart

disease, thyroid disorders, depression and other mental illnesses. As the research team is not medically trained, we are not able to ascertain definitively if women do have any medical conditions. However, women will be informed in the information sheet that they should not participate if they have these conditions for the reason stated above, and those who report such conditions in the demographic and medical history will be statistically assessed with caution using univariate and multivariate analyses, and data from these individuals will be excluded where necessary. Participants who do not complete all study materials or comply fully with the experimental protocol will also be excluded from analyses. Participants who report demographic characteristics that have been related to poorer health will also be assessed as covariates. Differences in symptoms between groups according to employment status, living status and relationship status will be analysed to understand variances in health between these groups. This is because unemployed, or single, or individuals who live alone are more likely to report poorer health than others.

Power analysis:

An a priori power analysis was conducted using G*Power 3 (Faul, Erdfelder, Lang, & Buchner, 2007) to test the difference between two independent group means (accounting for special, main effects, and interactions) using a two-tailed test, a medium effect size (d = .40) and an alpha of .05. Results suggested that a total sample of 52 participants with two equal sized groups of 26 was required to achieve a power of .80.

Medium effect sizes were estimated based on Cohen's (1962) conventional values because these values were derived from studies specific to psychological research (Aguinis, & Harden, 2009). Furthermore, medium effect estimates, rather than small estimates, were used for this research because this study is exploratory and small effects on symptom frequency might not be noticeable to participants. Small effects might imply that symptom monitoring as an intervention to help reduce menopausal symptoms may lack meaningful benefit.

Hoerger (2010) found evidence that at least 10% of participants will drop out of internet mediated research and such studies have high attrition rates. Furthermore, several studies have provided data on attrition rates of studies which employ a 2-week intervention period. Lancastle and Boivin's (2008) feasibility study aimed to establish whether a brief coping intervention (positive reappraisal coping intervention; PRCI) was acceptable and practical when evaluated in the context of a randomised trial. Of the 84 women who agreed to participate in the study 55 (65.5%) completed all measures, suggesting an attrition rate of 34.5%. Moreover, Lancastle's (2006) study also evaluated the PRCI alongside a positive mood inductive intervention, and a daily monitoring control group; this research reported a 31% attrition rate.

Therefore, taking into account average attrition rates from internet mediated research (10%), as well as studies which have utilised a 2-week intervention period (33%), it was decided that the proposed study will use a total sample of 78 participants with two equal groups of 39.

11. HAVE NATIONALLY APPROVED / REGULATORY BODY GUIDELINES BEEN FOLLOWED IN PREPARING THIS PROTOCOL?

(E.g. Association of the British Pharmaceutical Industry Guidelines (1983), Royal College of Physicians Guidelines, The Declaration of Helsinki, British Psychological Society guidelines, BERA, etc.). If so, please specify.

- Faculty of Life Sciences and Education Ethics Committee
- GDPR regulations (2018) and the Data Protection Act (2018)
- USW postgraduate researchers (PGR) code of practice

- British Psychology Society Code of Ethics for Research with Human Participants

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12. HAVE POTENTIAL PARTICIPANTS BEEN INVOLVED IN, PLEASE INDICATE. IF NO, PLEASE INDICATE WHY.

	YES
THE DESIGN OF THIS STUDY	One individual who matches the eligibility criteria has piloted this study, including completing all of the research materials and engaging in the 2-week symptom monitoring intervention. This was done to assess the practicality of delivering research materials and research interventions online, in order to highlight potential issues and identify best ways of working. These were the steps taken to pilot this study: 1. The baseline survey link was sent to the pilot participant. 2. Once the baseline survey was returned completed, emails were scheduled in advance to be sent out at set times and dates. 3. The first email was scheduled to be sent 24 hours after the baseline survey had been completed- it included the pilot's designated username, the pilot's group allocation (intervention group), full study instructions, the link to the first daily DRK survey (with the instruction that it is to be completed within 24 hours), terms and conditions for claiming the £20 voucher, and details on how to withdraw or opt out of receiving daily text message reminders. See **Appendix 6, page 1** for the email template. 4. The daily DRK reminder emails were scheduled to be sent each day for the next 13 days exactly 24 hours after the first email was sent. These emails included the pilot's designated username, a link to the DRK survey (with the instruction that it is to be completed within 24 hours), terms and conditions for claiming the £20 voucher, and details on how to withdraw or opt out of receiving text message reminders. See **Appendix 5, page 1** for the daily DRK email reminders. Because a text message management system was not purchased during the pilot study period, text message reminders were sent from Robin's personal phone to the pilot participant each day (this individual is a close personal friend of Robin's who already has her telephone number). These reminders included a link to the survey and advice on how to opt out of text message reminders (by emailing Robin). See **Appendix 5, page 2** to view the text message reminder template. 5. On the 15th day, scheduled exactly 24 hours after the final daily DRK email was sent, the follow-up survey email was sent. This email included the pilot's designated username, the link to the follow-up survey (with the instructions that it must be completed within 24 hours), and advice that the £20 Amazon voucher will be sent once the completed follow-up survey is received and all other terms and conditions have been met (I.e. all surveys have been completed within the specified time frames). **See Appendix 6, page 3 to view the follow-up survey template.**

	Once this user had piloted the research materials, they were asked to provide their opinion on the design of the study, the consent form items, the delivery of the data collection tools and information, as well as their thoughts on the data collection surveys. They confirmed that the surveys and the accompanying materials (i.e. the information sheet, debrief forms, and consent form) were easy to comprehend and complete. However, this participant advised that they were not sure what to do when rating positive emotions using the DRK, such as happy or content. This individual stated they did not have any problems with the length of time the surveys took to complete, with the baseline and follow-up surveys taking them "no more than half an hour each" and the daily DRK taking them "no more than 5 minutes each day". The DRK was amended in light of these comments (for more information (see above and Appendix 4 to view the amended daily record keeping form). This individual also stated that they did not find completing the DRK each day for 14 days intrusive and in fact found it beneficial, and that the daily text reminders were especially useful for keeping track of when surveys needed to be completed. This individual recommended that text message reminders be sent out later in the day rather than at the same time as the survey emails, as people may be settling down towards the end of the day and therefore may benefit more from a later reminder to complete the survey. They also recommended it be made clear from the text messages when the surveys need to be completed by (i.e. "please complete the survey by 10am tomorrow morning). These suggestions were incorporated into the design of this study. This participant will be compensated with a £20 Amazon voucher for their time.
INFORMED CONSENT DOCUMENTS	As above.
DATA COLLECTION TOOLS	As above.

13. DATA COLLECTION TOOLS

Have you tested the data collection tool(s) for face validity? Where **more than one tool** is being utilised please fill in the table.

YES, NO NA (ALL tools are already validated)

Title of DCT	Validated by you? (Y / N / NA - already validated)	Is permission necessary?	Do you have permission? (Supply permission separately)
Demographics and medical history (to be assessed at baseline only).	Y	NA	NA
Miller Behavioural Style Scale (MBSS; to be assessed at baseline only).	NA	Y	Y **(see Appendix 11, page 1)**

The neuroticism scale (10 items; α = .86) compiled from the International Personality Item Pool (to be assessed at baseline only).	NA	N	NA
General help seeking questionnaire (GHSQ; to be assessed at baseline and follow-up).	NA	Y	Y **(see Appendix 11, page 3**)
Health anxiety subscale adapted from The Health Orientation Scale (HOS; to be assessed at baseline and follow-up).	NA	N	NA
Patient-doctor communication will be assessed using the Willingness to Communicate about Health Measure (WTCH; to be assessed at baseline and follow-up).	NA	Y	Y **(See Appendix 11, page 4**)
The Decision Self-Efficacy Scale (to be assessed at baseline and follow-up).	NA	N	NA
The General Self Efficacy Scale (GSE; to be assessed at baseline and follow-up).	NA	NA	NA
Health Consciousness subscale adapted from The Health Orientation Scale (HOS; to be assessed at baseline and follow-up).	NA	N	NA
Two qualitative items (to be assessed at 2 weeks only) will assess whether research participation has led to improvements in	Y	NA	NA

emotional and physical well-being: "Since your engagement in this research, what changes have you noticed in your physical or emotional well-being? "If you have experienced any changes, why do you think these changes occurred?"			
Daily record keeping form (DRK). For participants in the intervention group, they will continually fill out the DRK each day throughout the 2-week research period- whereas the control group will complete this form at baseline and at 2 weeks only.	NA	Y	Y **(see Appendix 11, page 5)**

PART B

N.B. All questions should be addressed (e.g. provide an answer or state why not applicable).

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14. POTENTIAL RISKS AND BURDENS

Describe potential risks and burdens for your participants. Include any potential for distress, discomfort, with an explanation of why it is necessary. For any risk stated here please state what will be done to minimise such effects.

No physical risks from completing this research are anticipated, although participants may be alerted to issues with their physical or mental health through reflecting on their symptoms. Potential participants will be advised on the information sheet (**see Appendix 8**) that no diagnosis of physical or mental health problems can be made by the research team so that if they are concerned about their physical health or psychological well-being through taking part in the study, they should contact their GP or contact sources of advice and support provided on the information sheet (**Appendix 8**) and debrief sheets, **see Appendix 12, page 1 for debrief sheet presented at the end of the baseline survey, see Appendix 12, page 5 to see the debrief sheet presented at the end of the daily DRK survey, see Appendix 12, page 9 to see the debrief**

sheet presented at the end of the follow-up survey. Should data suggest that the DRK has a negative impact on some individuals, Robin's supervisors: Dr Deborah Lancastle and Professor Bev John, will be consulted in the first instance, and a joint decision will be made about the best way to solve the problem, with escalation to the USW research governance officer, Mr Jonathan Sinfield, if this isn't solved satisfactorily.

Although research participation will not be anonymous, as interested participants will provide their email addresses to the lead researcher via the baseline survey (which will be advertised on www.callforparticipants.com) participants will be assured that their responses to the research materials will be kept entirely confidential. Participants will be made aware that they cannot be identified in any write up, presentation or publication of results of the study. If participants are uncomfortable with sharing such information, they will be reassured that they do not have to take part, and that if they change their mind about their participation, they can close down the survey at any point before submission and any information collected will be deleted or destroyed. This information will be reiterated on the information (**Appendix 8**) and debrief sheets provided at the beginning and end of the research surveys (**see Appendix 12**).

Survey participants will be asked to provide sensitive data (i.e. email addresses, menopausal status, menopausal symptoms, date of last menstrual period), and they will be advised of this via the information sheet (**See Appendix 8**) that sensitive information (and the type of sensitive information) will be asked of them prior to taking part in the study. Participants will be advised that they can withdraw their data from the study at any point up until they receive their £20 Amazon incentive.

To withdraw, participants will be instructed to email Robin with confirmation that they wish to withdraw their data. This information will be included in the information sheet (**Appendix 8**) and repeated in the debrief sheets (**see Appendix 12**). On the consent form (**Appendix 9**) participants will be asked to confirm that they understand they can withdraw their data up until they receive their incentive.

The information sheet will also state that if participants drop out of the study, the information they have submitted up until that point will be retained unless the participant withdraws prior to data analyses. Potential participants will be notified of their rights to withdraw their data, and that data will be retained if they do not give notice of their withdrawal, using this using the following statement:

"If you change your mind about taking part while you are still completing the survey, close down the survey by clicking the x in the corner of the screen and all information provided by you will be removed and destroyed. To withdraw after submitting the survey, email Robin Andrews. You do not have to give a reason for withdrawing your data, and all your responses to every survey you have completed will be deleted. Please bear in mind, if you do withdraw your data it will no longer be possible for us to provide you with a £20 Amazon voucher and that once you have received your voucher it is no longer possible to withdraw. If you don't notify Robin Andrews that you wish to withdraw, all your data will be retained in the study, so it is important to let Robin know if you have chosen to withdraw".

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15. DISCLOSURE OF INFORMATION FROM INTERVIEW/QUESTIONNAIRE

Where research might lead to unexpected disclosure of information by participants that could require notification or other follow up action by the researcher, how will this be handled? This provision should also be explained clearly within the participant information sheet. This must be handled in accordance with the Data Protection Acts 1998 and 2018 (DPA), as well as the new General Data Protection Regulations (GDPR).

This study requires the lead researcher (RA) to contact participants regularly via email. Contact details of interested participants will be provided by www.callforparticipants.com.

There is a small risk that participants may use this mode of communication to consult Robin for help for physical or mental health problems, or they may disclose information which may require notification or follow up. To mitigate these risks, Robin will use a separate email address **(theresearchteam@southwales.ac.uk)** from her professional one to contact recruited participants, as agreed with USW IT. All emails sent from this email address will include a note at the end stating the following: *"Please do not reply to this email. If you would like to withdraw, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of text message reminders. If you have any questions or concerns about this study, please email:* [redacted]*"* It is anticipated that this instruction and the use of a study email address will minimise any chance of instantaneous nuisance replies to Robin. However, please note that Robin has not experienced any negative emails from participants in a recent menopause survey, so this is not anticipated in this study. The study email address will be used to advise recruited participants of their group allocation, their unique username, and provide further instructions **(see Appendix 6).** This email address will also be used to email a link to the DRK intervention to intervention group participants each day of the intervention period (**see Appendix 5 to view DRK link email template**), as well as a link to the follow-up survey to all participants (**see Appendix 6**).
Robin's personal USW email address will be provided on the information sheet (**Appendix 8**) and debrief forms (**see Appendix 12**) should participants have questions about the mechanics of completing the survey, it will be made clear on both forms that participants should only contact Robin's email address for this purpose. If participants have any questions about anything else related to the survey such as the menopause, or concerns about the study, they will be directed to the Director of Studies (Dr Deborah Lancastle) in the first instance. If participants have concerns or complaints that cannot be answered satisfactorily by Deborah on consultation with the wider research team then the issue will be referred to the research governance officer: Jon Sinfield. These contact details will be provided on the information and debrief sheets. It will also clearly be stated in the information sheet that the research team cannot provide medical advice and that any respondents who are concerned should contact their GP, and examples of help sources are made available to participants on the information and debrief sheets:

"Please note that we are not able to diagnose any physical or mental health problem from your responses to this survey. If you are at all concerned about your physical or mental health you should contact your own General Practitioner (GP) and/or other sources of help. We have provided some examples of help sources below.

"You may find the following sites helpful for information about the menopause and mental health problems:
NHS website: https://www.nhs.uk/conditions/menopause/
British Menopause Society: https://thebms.org.uk/
Samaritans: https://www.samaritans.org/."

If a participant does disclose information that requires follow-up, then Robin will consult with her supervisors DL and BJ who will decide on what action should be taken. Any information shared with Robin will be kept confidential and will be handled in accordance with the Data Protection Act 2018, as well as the new General Data Protection Regulations (GDPR, 2018). See **Appendix 8** information sheet for the following statement: "All personal data (sensitive and standard) will be collected, retained and stored in accordance with the Data Protection Act (2018) and the General Data Protection Regulations (GDPR, 2018)." **See Appendices 13 and 14 to view the researcher safety protocol and the risk assessment table to view more information on how potential risks to the researcher and research participants are being mitigated.**

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16. POTENTIAL RISKS TO THE RESEARCHER
Describe any potential risks to the safety and wellbeing of the researcher, such as lone working. Describe the measures proposed to address such concerns. Have the procedures been risk assessed in accordance with USW guidance?

Robin will use a separate email address (theresearchteam@southwales.ac.uk) from her professional one to

contact recruited participants. All emails sent from this address will include a note at the end stating the following: "Please do not reply to this email. If you would like to withdraw, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of text message reminders. If you have any questions or concerns about this study, please email: [redacted]". These methods will mitigate risks of a dialogue emerging between Robin and the participants, as replies to the no reply email address will not reach Robin. Participants will have to make active efforts to communicate with Robin by composing an email to a new address, which may discourage them from contacting her instantly without consideration. Because participants are directed to DL and BJ for any queries or concerns, the chance of Robin receiving distressing emails are reduced.
Robin will provide her official USW email address (robin.andrews@southwales.ac.uk) on the information and debrief sheets for participants to contact her for more information about the study, should they wish. This could mean that Robin may be approached by participants wishing to complain and pressurise her into providing remuneration for which they are not eligible, and she could be asked for advice she is not qualified to give. Such challenging communications put Robin at risk of worry and distress. The information sheet will direct participants to only contact Robin with questions about the mechanics of completing the survey. If participants have any questions about anything else related to the survey such as the menopause, or concerns about the study, they will be directed to the Director of Studies (Dr Deborah Lancastle) in the first instance. If participants have concerns or complaints that cannot be answered satisfactorily by Deborah on consultation with the wider research team then the issue will be referred to Jon Sinfield.

It will also be clearly stated in the information sheet that the research team cannot provide medical advice and that any respondents who are concerned should contact their GP.

In terms of complaints about eligibility for claiming the voucher, eligibility criteria will be clearly stated and repeated on the recruitment poster (**see Appendix 7)** presented by www.callforparticipants.com and on social media sites, and the information sheet (**Appendix 8**), minimising the likelihood that participants could state that they didn't know they had to satisfy certain criteria to be eligible for study participation and thus remuneration. Together, these controls should minimise any chance of Robin experiencing negative consequences from any potential issues an individual might have with the research. **See Appendix 13** for the researcher safety protocol, which provides detailed procedures for action, should problems arise. See **Appendix 14** for the risk assessment table, which summarises all potential risks to the research team and participants, including current practices in place to reduce said risks.

17. SCREENING OF IDENTIFIABLE PERSONAL INFORMATION
Give details of the sources (e.g. patient notes) of identifiable personal information that will be used to identify potential participants.

A recruitment poster (**see Appendix 7**) will be hosted on the JISC platform www.callforparticipants.com and social media accounts on Facebook, Twitter and Instagram. This poster will aim to attract potential participants and it will describe the nature of the study, including the eligibility criteria and details of what might be required of participants. The research team will not have direct contact with potential participants, as this will be facilitated by the JISC platform www.callforparticipants.com or verified USW/ KESS social media accounts. Once JISC has identified potential participants from their participant pool (which encompasses individuals who have given permission to be contacted about research participation by researchers), JISC will send these participants the baseline survey which will also encompass screening questions, the information sheet, and consent form. These individuals will be asked to provide their email address on the baseline survey (**see Appendix 1**). Those who complete baseline questionnaires will be emailed by the research team with details of their group allocation and further instruction.

18. ADVERTISEMENTS
All advertising material intended to recruit research participants must be reviewed by the Faculty ethics sub group. This includes but is not limited to: posters, letters, web pages and radio/TV broadcasts.

Are you intending to use any advertisements? **YES**

If yes, please list the documents appended to this application.

Appendix 7: Online recruitment poster as presented by JISC platform www.callforparticipants.com and social media accounts on Facebook, Twitter and Instagram.

19. APPROACHING PARTICIPANTS
Describe how potential participants will be approached and who will be involved.
In a clinical context, patients should be initially approached by a member of their clinical care team.

Copies of documentation used to approach potential participants should be enclosed with this application, such as a copy of the participant information sheet.

A recruitment poster (**see Appendix 7**) will be hosted on the JISC platform www.callforparticipants.com to attract potential participants and it will describe the nature of the study, including the eligibility criteria and a brief outline of the tasks to be completed. The research team will not have direct contact with potential participants, as this will be facilitated by the JISC platform www.callforparticipants.com. Once JISC has identified potential participants from their participant pool (which encompasses individuals who have given permission to be contacted about research participation by researchers), JISC will send these participants the baseline survey which will also encompass screening questions, the information sheet, and consent form. These individuals will be asked to provide their email address on the baseline survey (**see Appendix 1**). Those who complete baseline questionnaires will be emailed by the research team with details of their group allocation, their unique username, and further instruction (**see Appendix 6 to view instruction email templates**). This study will recruit participants on a rolling basis; therefore, participants will continuously be recruited until the required sample size has been reached. Therefore the 15-day study period will begin once the individual participant has submitted their baseline survey, which will be accessed via the research poster which will be advertised to potential participants from the point of obtaining ethical approval up until the required sample size has been recruited.

Participants who have confirmed their interest by completing the baseline measures and the accompanying consent form will be emailed from the USW email address (theresearchteam@southwales.ac.uk) specific to this study with further instructions. Individuals allocated into the intervention group will be advised that they will be emailed links to complete the DRK each day for 14 days and receive text reminders (should they have opted in to this and provided their mobile number in the baseline survey), those allocated into the control group will be advised that they will be contacted by in 14 days' time, when they will be asked to complete a follow-up questionnaire. **See Appendix 6, page 1 to view intervention group instruction email template, see Appendix 6, page 2 to view control group instruction email template**.

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20. INFORMED CONSENT
Describe the arrangements for taking consent from research participants prior to their participation in the research study. Describe the time allowed to decide to take part. Please include a copy of a written consent sheet (where used) with this application.

For consent to be ethical and valid in law participants must be 'capable' of giving consent. Please ensure you have adhered to current guidance on the attributes of a capable person and adhered to such guidance in your recruitment strategy.

The consent form will be included in the baseline survey (view the consent form as it will be presented on the online baseline survey via this link: https://southwales.onlinesurveys.ac.uk/baseline-questionnaire-

preview, **see Appendix 9 for the consent form only**). This consent form will ask participants to confirm that they understand the information sheet provided to them, that they are aware of what the study involves and that they consent to take part in the online study. Participants will be advised to take as long as they wish to decide, with the proviso that data analyses will commence in December 2020, so after this date the survey will be closed.

21. INFORMED CONSENT TOOLS

Please confirm the information sheet and consent form have been considered as appropriate for the target audience?

YES

The information sheet and consent form have been piloted by someone known personally to RA who meets the criteria for this study. They have confirmed that all aspects of the survey (including the information sheet and consent items) are easy to understand and interpret. Additionally, these items have been rigorously reviewed by supervisors DL and BJ who have extensive experience developing research studies. The other measures have been used in several previous peer-reviewed and published studies.
See Appendix 8 for the survey information sheet. See Appendix 9 to view the informed consent items. Use this link: https://southwales.onlinesurveys.ac.uk/baseline-questionnaire-preview to view the full baseline survey, which also includes the information sheet and consent form and initial screening questions.

22. DATA ANALYSIS / STATISTICS

Please describe the arrangements for analysing your data (qualitative and quantitative). Where appropriate discuss what data/statistical analysis will be completed. Where used, please remember to discuss sample size and how the sample size was decided upon.

2 x 2 mixed between-within ANOVA:

The main analysis will include a 2x2 mixed between-within ANOVA to assess differences in symptoms among the symptom monitoring and control groups before and after the 2-week research period. The between-subjects component will encompass the differences in symptoms between the control and intervention groups; the within-subjects variable refers to differences in symptoms before and after the 2-week study period. It is expected that after 2 weeks of symptom monitoring the intervention group will exhibit a greater reduction in symptoms in comparison to the control group (I.e., a significant group x time interaction). As discussed, a power analysis was calculated to identify the minimum sample size needed to detect moderate effects, resulting in the decision to recruit 78 participants, with 39 participants being randomised into each group.

Regressions:

Multiple regressions will explore whether help-seeking intentions as continuous variables as predicted by symptom monitoring group (dummy coded), self-efficacy in patient-doctor communication, self-efficacy in shared decision making, health and symptom awareness, and self-efficacy in goal orientated behaviour, health anxiety, and menopausal symptom changes.

Logistic regressions will establish whether control or intervention group membership (as measured as a dichotomous “Invention/Control” variable) is predicted by health anxiety, variances in emotions and symptoms, help-seeking intentions, self-efficacy in patient-doctor communication, self-efficacy in shared decision making, health and symptom awareness, and self-efficacy in goal orientated behaviour.

Correlations:

Correlations will also be computed to assess for associations between certain variables. For example, higher neuroticism X higher negative emotions.

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23. DATA CUSTODIAN
Please identify the person who is responsible for overall data security.

Dr Deborah Lancastle

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24. DATA MANAGEMENT
Please describe how research data will be stored, including the location and arrangements for data storage. Describe where/how your data will be securely stored during, and after the research study has completed. Describe how long data will be retained, and at what point will data be anonymised. Personal data should be discarded as soon as it is no longer needed.

All online data provided, and databases compiled, will be kept on password protected computers which only the researchers and supervisors can access. The email addresses of interested participants will be collected on the baseline survey. All email addresses will be stored separately from survey responses on password protected Excel documents, and will only be accessible to Robin and her supervisors.

To enable participants to withdraw their data should they wish, and ensure that personally identifiable information is not stored alongside responses to the intervention and follow-up materials, recruited participants will be provided with a unique username by email (i.e. 'Your username is: Participant1 please retain this information as you will be asked to confirm it on all surveys you complete') which they will be asked to confirm at the beginning of each research material they complete (i.e. the DRK surveys and the follow-up survey).

Should participants wish to withdraw their data from the study (before the data gets analysed) they will be instructed to email Robin confirming their decision to withdraw their data. The information sheet, consent from, and debrief sheets will all advise participants that their data can be removed provided they email Robin with confirmation of their desire to withdraw. Reminders on how to withdraw will be included on all emails sent to participants (**see Appendix 6 to view the instruction email templates and the follow-up survey email template, see Appendix 5 to view daily DRK reminder email template)**. Withdrawal information will be provided on the information sheet (**see Appendix 8**) and confirmed on the debrief sheets which will be provided at the end of each survey (**see Appendix 12).**

Dr Deborah Lancastle will be the custodian of the data. The data will not be passed on to anyone outside of the research team and will be kept for five years and then destroyed. Should the data be required for further studies other than described here, approval will be sought from the appropriate ethics panel at the University of South Wales. **See Appendices 13 (researcher safety protocol) and 14 (risk assessment)** for further information on steps being taken to reduce risks to the participant's privacy.

Are the data being collected regulated by the Data Protection Act as well as the new General Data Protection Regulations (GDPR)?

YES- please see **Appendix 8: Information sheet** which includes the following statement to participants: "All responses to this survey will be confidential and secure. All personal data (sensitive and standard) will be collected, retained and stored in accordance with the Data Protection Act and the General Data Protection Regulations (GDPR, 2018). All data provided will be kept on password protected computers which only the research team can access. Dr Deborah Lancastle will be the custodian of the data. The data will not be

passed on to anyone outside of the research team and will be kept for 5 years and then destroyed. Analysis of anonymised data will be carried out by members of the research team. Should the data be required for future studies, other than that described here, approval will be sought from the appropriate ethics panel at the University of South Wales."

Please see **Appendix 9: Consent form** to view an item assessing participants consent to their data being processed in accordance with DPA and GDPR regulations: "I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as confidential and will be handled in accordance with the Data Protection Act and the General Data Protection Regulations (GDPR) 2018 and will be destroyed after 5 years."

If YES, please confirm that the data will be retained and stored in accordance with the General Data Protection Regulation (2018) by initialling below.

Principal Investigator Initials: **RA**

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25. CONFIDENTIALITY OF DATA
Describe the provision for ensuring that the confidentiality of personal data is preserved, such as a strategy for anonymity.

Participants are not anonymous in this survey as their responses can be linked to their identity when they provide their email addresses on the baseline survey and cannot be anonymous because it is essential to link participants' responses throughout the study. However, participants' contributions are confidential as they cannot be identified in any publication or presentation of the results. Any potentially identifiable information provided in free text responses on the survey will be redacted.

All online data provided, and databases compiled, will be kept on password protected computers which only the researchers and supervisors can access. All saved records of email addresses will be kept on password protected Excel documents which only the lead researcher and her supervisors can access.

To enable participants to withdraw their data should they wish, and ensure that personally identifiable information is not stored alongside responses to the DRK and follow-up measures, recruited participants will be provided with a unique username which will be sent to them over email, and repeated in each subsequent email sent. At the beginning of the DRK intervention surveys and follow-up survey, participants will be asked to confirm the username they were provided with via email. If they forget their unique username, they are asked to contact Robin who will remind them of this.

Dr Deborah Lancastle will be the custodian of the data. The data will not be passed on to anyone outside of the research team and will be kept for five years and then destroyed. Should the data be required for further studies other than described here, approval will be sought from the appropriate ethics panel at the University of South Wales. **See Appendices 13 (researcher safety protocol) and 14 (risk assessment)** for further information on steps being taken to reduce risks to the participant's privacy.

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26. Please confirm that all participants being asked to provide personal data (sensitive and standard) will be told which legal basis is being cited for collecting and processing their personal information – this should be conveyed on the consent form and information sheet. In accordance with the new General Data Protection Regulations (GDPR)'

Yes see **Appendix 8 for the information sheet, and Appendix 9 for the consent form.**

27. PAYMENT TO RESEARCH PARTICIPANTS

Please note, participants should not be paid for taking risks. Payment should not be set to a level that would unduly influence potential participants. Information pertaining to participant payment should be included on the Participant Information Sheet.

Will participants be paid? YES

If yes, please give details.

All 78 participants will receive a £20 Amazon gift voucher. The £20 Amazon voucher will be emailed to respondents at the end of the 2-week research period pending they fully adhere to the instructions provided and do not withdraw. To adhere to the research instructions, all participants must fully complete the baseline and follow-up measures, and intervention participants must complete the DRK monitoring form each day for 14 days within 24 hours of receiving the links via email. All participants must complete the follow-up survey within 24 hours of receiving the link via email. This information will be provided on the information sheet, and the consent form will include items which will obtain confirmation that participants are aware that they must complete the requirements of the study in order to claim their Amazon voucher.

Some participants allocated into the control group may feel they would like to try the symptom monitoring intervention themselves. While it would be impractical to offer the exact intervention to control participants after the research period, a list of online symptom monitoring tools and mobile apps (e.g., Health and Her's online symptom tool, Clue's mobile app for period tracking) will be provided on the final debrief sheet which will be provided after the follow-up questionnaire is completed **(see Appendix 12, page 9 to view the follow-up debrief sheet, see this link: https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview to the follow-up survey which also presents the debrief sheet)**.

28. PAYMENT TO RESEARCHER

Describe any payment that the research team is receiving as part of carrying out this research study. Researcher payment should be recorded in the participant information sheet.

This research is part of a KESS-2 funded PhD.

29. CONFLICT OF INTEREST

Describe any conflict of interest that anyone in the research team might have.

No known conflicts of interest.

30. ENSURING ANONYMITY OF IDENTIFIABLE DATA IN PUBLICATIONS

Describe the provision for ensuring anonymity in any publication or publicly available output produced from this research study.

The results of this study could lead to conference presentations and academic publications, and possibly to reports that could be used to improve information provision or access to medical care in the NHS or private care. No individual will be able to be identified in any dissemination of the results of the study. Any potentially identifiable information provided in free text responses on the survey will be redacted.

Because this study is part of a KESS-2 studentship, the results will be available to the company to use to improve their provision; however, data will be summarised as results of analyses, anonymous, and participants cannot be identified. Participants will be informed in the information sheet that the results may be used by Health & Her to improve their services. The data will not be passed on to anyone outside of the research team and will be kept for five years and then destroyed. Should the data be required for further studies other than described here, approval will be sought from the appropriate ethics panel at the University of South Wales. **See Appendices 13 (researcher safety protocol) and 14 (risk assessment)** for further information on steps being taken to reduce risks to the participant's privacy.

31. SCIENTIFIC SCRUTINY AND RESOURCING

Has this research study been peer reviewed?

NO

If YES, please provide information about the review, including the reviewing body and date of review/approval.

NA

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32. INSURANCE INDEMNITY

i. Does this research study require indemnity/insurance cover from the University of South Wales?

Yes

ii. Will the research take place on University of South Wales' premises?

NO

If NO, give details of any offsite locations:

All data will be collected digitally online, analyses of data will take place off premises due to COVID-19 restrictions.

iii. DOES THE RESEARCH UTILISE ANY OF THE FOLLOWING (PLEASE INDICATE ALL THAT APPLY): No

Investigating or participating in methods of contraception?
Assisting with or altering the process of conception?
The use of drugs?
The use of surgery? (other than biopsy)
Genetic engineering?
Participants under 5 years of age? (other than activities above)
Participants known to be pregnant? (other than activities above)
Pharmaceutical product/appliance designed or manufactured by host institution?
Work outside of United Kingdom?

If YES to any of the above please contact the Research Governance Manager – jonathan.sinfield@southwales.ac.uk

N/A

FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP APPLICATION FORM

33.

Security Sensitive Material	
Will your project involve any of these? **NA to all**	Ministry of Defence-commissioned work on military equipment or policy
	EU security research including policy development
	All work related to extremist groups (e.g. related to animal rights campaigners)
	IT encryption design for public bodies or businesses
	All work related to terrorism
If you respond YES to any of the above please ensure your complete and attach the **USW PREVENT for RESEARCH registration** forms to this application	

I have read and agree to abide by the latest version of the document:
Research Ethics Policy, Terms of Reference and Operating Procedures for University Ethics Sub Group and Faculty Research Ethics Committees
This can be found at **https://www.southwales.ac.uk/research/research-expertise/research-governance/**

Research Governance | University of South Wales
The University is committed to the following principles of good research practice. These are laid out in our USW Research Good Practice Code of Conduct which stipulates: That our research is underpinned with common values of rigour and integrity
www.southwales.ac.uk

- At the time of signing this application, I consider it to be complete and accurate
- I will notify the faculty ethics sub group immediately if i subsequently consider the application requires any correction or qualification, or if there is any revision to the proposal.
- I understand that I may be invited to discuss my proposal with the faculty ethics sub group.

SIGNATURE OF INVESTIGATOR **Robin Andrews**

SIGNATURE OF SUPERVISOR **Deborah Lancastle**

DATE OF SUBMISSION Dlancastle .

SIGNATURE OF APPROVAL **……..**
(Chair/Secretary – FESG)

DATE OF APPROVAL **……**

Appendices

Appendix 1: The baseline survey in Word document format:

FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP APPLICATION FORM

Baseline questionnaire

Demographics:

4. Please type your email address (this is required to continue with this study)

……

5. How would you describe your physical and mental health in general?

- ❑ Good
- ❑ Okay
- ❑ Poor

6. What is your living status?

- ❑ I live alone
- ❑ I live with my family
- ❑ I live with friends
- ❑ I live with my partner
- ❑ I live in shared housing
- ❑ I live in a residential home

7. What is your relationship status?

- ❑ In a relationship
- ❑ In a relationship and living together
- ❑ Married
- ❑ Divorced or separated
- ❑ Widowed
- ❑ Single

8. What is your current occupation? Tick as many as apply:

- ❑ Working full-time
- ❑ Working part-time
- ❑ Student
- ❑ Military
- ❑ Volunteer
- ❑ Looking for work
- ❑ Homemaker
- ❑ Retired

- ❑ Unable to work due to illness or disability
- ❑ Full-time carer for a family member/ loved one
- ❑ Other

8b. If you selected Other, please specify:

……

9. What is your ethnicity?

- ❑ White
- ❑ Asian
- ❑ Black
- ❑ Mixed ethnicity
- ❑ Other

9a. If you selected Other, please specify:

……

10. What was the date of your last menstrual period? If you can't remember exactly please give your best estimate:

……

11. Please type the name of the country and the town/city you live in:

……

12. Are you currently using any medication or treatments for your menopause symptoms?

- ❑ No
- ❑ Yes

12a. If you selected Yes, please specify which medication or treatments you are using. Examples can include HRT, antidepressants, psychological treatments, counselling, or supplements.

……

13. Please describe any health conditions that you are currently being treated for:

……

14. Please describe any non-menopause-related medications or treatments you are currently using:

……

You are now going to be asked some questions about your health and you as a person, please work through them, giving the answer that best applies to you for each question.

Mood questionnaire:

15. Describe yourself as you generally are now, not as you wish to be in the future. Describe yourself as you honestly see yourself, in relation to other women of your age. Indicate for each statement whether it is:

1= Very Inaccurate, 2= Moderately Inaccurate, 3= Neither Accurate nor Inaccurate, 4= Moderately Accurate, or 5= Very Accurate, as a description of you.

	1. Very Inaccurate	**2. Moderately Inaccurate**	**3. Neither Accurate nor Inaccurate**	**4. Moderately Accurate**	**5. Very Accurate**
I often feel blue.					
I dislike myself.					
I am often down in the dumps.					
I have frequent mood swings.					
I panic easily.					
I rarely get irritated.					
I seldom feel blue.					
I feel comfortable with myself.					
I am not easily bothered by					

things.					
I am very pleased with myself.					

Help Seeking questionnaire:

16. If you were having a personal or emotional problem, how likely is it that you would seek help from the following people? Please indicate your response by selecting the number that best describes your intention to seek help from each help source that is listed. Use this scale to indicate your response: 1 = Extremely Unlikely, 3 = Unlikely, 5 = Likely, 7 = Extremely Likely.

	1	2	3	4	5	6	7
Intimate partner (e.g., girlfriend, boyfriend, husband, wife etc.)							
Friend (not related to you)							
Relative/family member							
Mental health professional (e.g. psychologist, social worker, counsellor)							
Internet sources including health websites, online forums (i.e. Mumsnet, Reddit, Quora) or social media (i.e. Facebook groups, Twitter, Instagram)							
Phone helpline							
Doctor/GP							
Minister or religious leader (e.g. Priest, Rabbi, Chaplain)							
I would not seek help from anyone							
I would seek help from another not listed above							

16b. Who else would seek help from? Type N/A if all of your help sources have been listed above.

……

Thoughts about health questionnaire:

17. Please read each item carefully and decide to what extent it is characteristic of you. Give each item a rating of how much it applies to you by marking your response by using the

following scale: 1 = Not at all characteristic of me, 2 = Slightly characteristic of me, 3 = Somewhat characteristic of me, 4 = Moderately characteristic of me, 5 = Very characteristic of me

	1 = Not at all characteristic of me	2 = Slightly characteristic of me	3 = Somewhat characteristic of me	4 = Moderately characteristic of me	5 = Very characteristic of me
I feel anxious when I think about my health.					
I'm worried about how healthy my body is.					
Thinking about my physical health leaves me with an uneasy feeling.					
I usually worry about whether I am in good health.					
I feel nervous when I think about the status of my physical health.					
I am very aware of how healthy my body					

feels.					
I notice immediately when my body doesn't feel healthy.					
I'm sensitive to internal bodily cues about my physical health.					
I know immediately when I'm not feeling physically well.					
I'm very aware of changes in my physical health.					

Health communication scale:

18. Please read through the following statements and indicate how strongly you agree with them.

	1 = Strongly Disagree	**2 = Mildly Disagree**	**3 = Undecided**	**4 = Mildly Agree**	**5 = Strongly Agree**
In general, I feel comfortable talking with physicians about my health.					
I usually feel relaxed when talking about my health problems with my family.					
I typically feel comfortable giving others information about my					

health status.					
In general, I don't mind discussing my health status with friends.					
I typically discuss emotional concerns I have about my health status with health providers.					
I usually feel awkward talking about my health problems with others.					
I would not have a problem talking to nurses about my health status.					
In general, I would not mind discussing my health with other people who have a similar health history.					
I am generally willing to engage in a conversation about information related to my health status if someone asks me a question about my condition.					
I would not be willing to discuss my fears about my health condition with others.					

Decision-making scale:

19. Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by circling the number from 0 (not at all confident) to 4 (very confident) for each item listed below.

	0 (Not at all confident)	**1**	**2**	**3**	**4 (Very confident)**
I feel confident that I can get the facts about the medication choices available to me					
I feel confident that I can get the facts about the benefits of each choice					
I feel confident that I can get the facts about the risks and side effects of each choice					

I feel confident that I can understand the information enough to be able to make a choice					
I feel confident that I can ask questions without feeling dumb					
I feel confident that I can express my concerns about each choice					
I feel confident that I can ask for advice					
I feel confident that I can figure out the choice that best suits me					
I feel confident that I can handle unwanted pressure from others in making my choice					
I feel confident that I can let the clinic team know what's best for me					
I feel confident that I can delay my decision if I feel I need more time					

Self-efficacy scale:

20. Please read through the following statements and indicate how accurately they apply to you:

	1 = Not at all true	**2 = Hardly true**	**3 = Moderately true**	**4 = Exactly true**
I can always manage to solve difficult problems if I try hard enough				
If someone opposes me, I can find the means and ways to get what I want.				
It is easy for me to stick to my aims and accomplish my goals.				
I am confident that I could deal efficiently with unexpected events.				
Thanks to my resourcefulness, I know how to handle unforeseen situations.				
I can solve most problems if I invest the necessary effort.				
I can remain calm when facing difficulties because I can rely on my coping abilities.				

When I am confronted with a problem, I can usually find several solutions.				
If I am in trouble, I can usually think of a solution.				
I can usually handle whatever comes my way.				

The Daily Record Keeping Form:

21. Please read through the following emotions and menopausal symptoms and indicate whether you have experienced them in the past 24 hours using this scale: **0= Not at all (you have not experienced this symptom or emotion at all in the past 24 hours) , 1= Mild (you've experienced this symptom or emotion but it has not impacted your daily activities or made you feel any different than usual) , 2= Moderate (you've experienced this symptom or emotion and it has impacted your daily activities to some degree or made you feel somewhat different than usual) , 3= Severe (you've experienced this symptom or emotion and it has heavily impacted your daily activities or made you feel extremely different than usual).**

	0= Not at all	**1= Mild**	**2= Moderate**	**3= Severe**
Nervous				
Positive				
Relieved				
Sad				
Hopeful				
Confident				
Disappointed				
Hesitant				
Happy				
Doubtful				
Discouraged				
Anxious				
Isolated				
Content				
Tense				
Rejected				

Fulfilled				
Uncertain				
Left out				
Lonely				
Encouraged				
Angry				
Worried				
Unsure				
Sleeping problems				
Weight gain				
Joint aches				
Low energy				
Hot flushes				
Stress/ anxiety				
Night sweats				
Low mood				
Brain fog				
Loss of sex drive				
Headaches				
Period changes				
Skin changes				
Vaginal dryness				
Urinary changes				
Painful sex				
Bloating				
Poor concentration				
Itchy skin				
Digestive issues				
Memory loss				
Irregular heartbeat				
Breast pain				

Brittle nails				
Hair loss				
Electric shock sensations				
Muscle tension				
Body odour				
Allergies				
Burning tongue				
Other				

21b. If you selected "other" in the question above, please type what it was (type N/A if this does not apply to you):

……

Health behaviour questionnaire:

22. Vividly imagine that you are afraid of the dentist and have to get some dental work done. Which of the following would you do? Check all of the statements that might apply to you.

- ❑ I would ask the dentist exactly what work was going to be done.
- ❑ I would take a tranquilizer or have a drink before going.
- ❑ I would try to think about pleasant memories.
- ❑ I would want the dentist to tell me when I would feel pain.
- ❑ I would try to sleep.
- ❑ I would watch all the dentist's movements and listen for the sound of the drill.
- ❑ I would watch the flow of water from my mouth to see if it contained blood.
- ❑ I would do mental puzzles in my mind.

23. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check all of the statements that might apply to you.

- ❑ I would sit by myself and have as many daydreams and fantasies as I could.
- ❑ I would stay alert and try to keep myself from falling asleep.
- ❑ I would exchange life stories with the other hostages.
- ❑ If there was a radio present, I would stay near it and listen to the bulletins about what the
- ❑ police were doing.
- ❑ I would watch every movement of my captors and keep an eye on their weapons.

- ❑ I would try to sleep as much as possible.
- ❑ I would think about how nice it's going to be when I get home.
- ❑ I would make sure I knew where every possible exit was.

24. Vividly imagine that, due to a large drop in sales, it is rumoured that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check all of the statements that might apply to you.

- ❑ I would talk to my fellow workers to see if they knew anything about what the
- ❑ supervisor evaluation of me said.
- ❑ I would review the list of duties for my present job and try to figure out if I had fulfilled them
- ❑ all.
- ❑ I would go to the movies to take my mind off things.
- ❑ I would try to remember any arguments or disagreements I might have had that would
- ❑ have resulted in the supervisor having a lower opinion of me.
- ❑ I would push all thoughts of being laid off out of my mind.
- ❑ I would tell my spouse that I'd rather not discuss my chances of being laid off.
- ❑ I would try to think which employees in my department the supervisor might have
- ❑ thought had done the worst job.
- ❑ I would continue doing my work as if nothing special was happening.

25. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check all of the statements that might apply to you.

- ❑ I would carefully read the information provided about safety features in the plane and
- ❑ make sure I knew where the emergency exits were.
- ❑ I would make small talk with the passenger beside me.
- ❑ I would watch the end of the movie, even if I had seen it before.
- ❑ I would call for the flight attendant and ask what exactly the problem was.
- ❑ I would order a drink from the flight attendant or take a tranquilizer.
- ❑ I would listen carefully to the engines for unusual noises and would watch the crew to
- ❑ see if their behaviour was out of the ordinary.
- ❑ I would talk to the passenger beside me about what might be wrong.
- ❑ I would settle down and read a book or magazine or write a letter.

26. If you are randomly assigned to the daily monitoring group, do you wish to receive text reminders to complete the questionnaire?

- ❑ Yes
- ❑ No

26b. Please type your mobile phone number:

……

To view the baseline survey as it will be presented on JISC Online Surveys (including the initial screening questions, information sheet, and consent items) please use this link: https://southwales.onlinesurveys.ac.uk/baseline-questionnaire-preview

Appendix 2: The initial screening questions, which will be presented on Online Surveys at the beginning of the baseline survey before the information sheet, consent items, and main baseline questions.

Appendix 2: Initial screening questions:

1. Are you over the age of 18?

- ❑ Yes
- ❑ No **(respondents who select this answer will be screened out of the survey)**

1b. If you selected yes, please type your age:

……

2. On average, how many hot flushes and/or night sweats are you currently experiencing every 24 hours? Tick the answer that most applies to you.

- ❑ I am not currently experiencing any hot flushes or night sweats **(respondents who select this answer will be screened out of the survey).**
- ❑ I am experiencing fewer than 2 hot flushes and/or night sweats per day **(respondents who select this answer will be screened out of the survey)**
- ❑ I am experiencing 2 hot flushes and/or night sweats per day.
- ❑ I am experiencing more than 2 hot flushes and/or night sweats per day. (say how many)

3. Which stage of the menopause best matches your current experience? Tick the answer which most applies to you:

- ❑ Premenopause: I do not have menopausal symptoms yet, and I continue to have my periods as usual **(respondents who select this answer will be screened out of the survey).**
- ❑ Perimenopause – Early Phase: I am currently experiencing menopausal symptoms. I have regular monthly periods, but the length or flow of each period varies.
- ❑ Perimenopause – Late Phase: I am experiencing menopausal symptoms and have not gone 12 months in a row without a period, but I sometimes have more than 2months between periods.
- ❑ Postmenopause – Symptomatic: I haven't had my period in over 12 months, and continue to have menopausal symptoms.
- ❑ Postmenopause – Asymptomatic: I haven't had my period in over 12 months, and I no longer have (or never had) menopausal symptoms **(respondents who select this answer will be screened out of the survey).**

Link to screening questions as presented at the beginning of the baseline survey (before the information sheet, consent form, and main survey questions):
https://southwales.onlinesurveys.ac.uk/baseline-questionnaire-preview

Appendix 3: The follow-up survey in Word document format (visit: https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview to preview the survey on JISC Online Surveys).

Follow-up questionnaire

1. Please confirm the username you were provided with by the research team, you will find it on the email you received

which included the link to this survey. **Please note that if you do not include this word, your response won't be valid because we can't match it with your earlier questionnaire response. This will affect your eligibility for your voucher. Therefore, if you are not sure of your username, please contact Robin Andrews at robin.andrews@southwales.ac.uk:**

……

Help Seeking questionnaire:

2. If you were having a personal or emotional problem, how likely is it that you would seek help from the following sources? Please indicate your response by selecting the number that best describes your intention to seek help from each help source that is listed. Use this scale to indicate your response: 1 = Extremely Unlikely, 3 = Unlikely, 5 = Likely, 7 = Extremely Likely.

	1	2	3	4	5	6	7
Intimate partner (e.g., girlfriend, boyfriend, husband, wife etc.)							
Friend (not related to you)							
Relative/family member							
Mental health professional (e.g. psychologist, social worker, counsellor)							
Phone helpline							
Internet sources including health websites, online forums (Mumsnet, Quora, Reddit) and social media (I.e. Facebook groups, Twitter, Instagram)							
Doctor/GP							
Minister or religious leader (e.g. Priest, Rabbi, Chaplain)							
I would not seek help from anyone							
I would seek help from another not listed above							

2b. Who else would seek help from? Type N/A if all of your help sources have been listed above.

……

Thoughts about health questionnaire:

3. Please read each item carefully and decide to what extent

it is characteristic of you. Give each item a rating of how much it applies to you by marking your response by using the following scale: 1 = Not at all characteristic of me, 2 = Slightly characteristic of me, 3 = Somewhat characteristic of me, 4 = Moderately characteristic of me, 5 = Very characteristic of me

	1 = Not at all characteristic of me	**2 = Slightly characteristic of me**	**3 = Somewhat characteristic of me**	**4 = Moderately characteristic of me**	**cha**
I feel anxious when I think about my health.					
I'm worried about how healthy my body is.					
Thinking about my physical health leaves me with an uneasy feeling.					
I usually worry about whether I am in good health.					
I feel nervous when I think about the status of my physical health.					
I am very aware of how healthy					

my body feels.					
I notice immediately when my body doesn't feel healthy.					
I'm sensitive to internal bodily cues about my physical health.					
I know immediately when I'm not feeling physically well.					
I'm very aware of changes in my physical health.					

Health communication scale:

4. Please read through the following statements and indicate how strongly you agree with them.

	1 = Strongly Disagree	**2 = Mildly Disagree**	**3 = Undecided**	**4 = Mildly Agree**	**5 = Strongly Agree**
In general, I feel comfortable talking with physicians about my health.					

I usually feel relaxed when talking about my health problems with my family.					
I typically feel comfortable giving others information about my health status.					
In general, I don't mind discussing my health status with friends.					
I typically discuss emotional concerns I have about my health status with health providers.					
I usually feel awkward talking about my health problems with others.					
I would not have a problem talking to nurses about my health status.					
In general, I would not mind discussing my health with other patients who have a similar health history.					

I am generally willing to engage in a conversation about information related to my health status if someone asks me a question about my condition.					
I would not be willing to discuss my fears about my health condition with others.					

Decision-making scale:

5. Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by circling the number from 0 (not at all confident) to 4 (very confident) for each item listed below.

	0 (Not at all confident)	**1**	**2**	**3**	**4 (Very confident)**
I feel confident that I can get the facts about the medication choices available to me					
I feel confident that I can get the facts about the benefits of each choice					
I feel confident that I can get the facts about the risks and side effects of each choice					
I feel confident that I can understand the information enough to be able to make a					

choice					
I feel confident that I can ask questions without feeling dumb					
I feel confident that I can express my concerns about each choice					
I feel confident that I can ask for advice					
I feel confident that I can figure out the choice that best suits me					
I feel confident that I can handle unwanted pressure from others in making my choice					
I feel confident that I can let the clinic team know what's best for me					
I feel confident that I can delay my decision if I feel I need more time					

Self-efficacy scale:

6. Please read through the following statements and indicate how accurately they apply to you:

	1 = Not at all true	**2 = Hardly true**	**3 = Moderately true**	**4 = Exactly true**
I can always manage to solve difficult problems if I try hard enough				
If someone opposes me, I can find the means and ways to get what I want.				
It is easy for me to stick to my aims and accomplish my goals.				
I am confident that I could deal efficiently with unexpected events.				

Thanks to my resourcefulness, I know how to handle unforeseen situations.				
I can solve most problems if I invest the necessary effort.				
I can remain calm when facing difficulties because I can rely on my coping abilities.				
When I am confronted with a problem, I can usually find several solutions.				
If I am in trouble, I can usually think of a solution.				
I can usually handle whatever comes my way.				

The Daily Record Keeping Form:

7. Please read through the following emotions and menopausal symptoms and indicate whether you have experienced them in the past 24 hours using this scale: **0= Not at all (you have not experienced this symptom or emotion at all in the past 24 hours) , 1= Mild (you've experienced this symptom or emotion but it has not impacted your daily activities or made you feel any different than usual) , 2= Moderate (you've experienced this symptom or emotion and it has impacted your daily activities to some degree or made you feel somewhat different than usual) , 3= Severe (you've experienced this symptom or emotion and it has heavily impacted your daily activities or made you feel extremely different than usual).**

	0= Not at all	1= Mild	2= Moderate	3= Severe
Nervous				
Positive				
Relieved				
Sad				
Hopeful				
Doubtful				
Confident				
Disappointed				
Happy				

Discouraged				
Unsure				
Anxious				
Isolated				
Content				
Tense				
Rejected				
Fulfilled				
Hesitant				
Left out				
Lonely				
Encouraged				
Uncertain				
Angry				
Worried				
Sleeping problems				
Weight gain				
Joint aches				
Low energy				
Hot flushes				
Stress/ anxiety				
Night sweats				
Low mood				
Brain fog				
Loss of sex drive				
Headaches				
Period changes				
Skin changes				
Vaginal dryness				
Urinary changes				
Painful sex				

Bloating				
Poor concentration				
Itchy skin				
Digestive issues				
Memory loss				
Irregular heartbeat				
Breast pain				
Brittle nails				
Hair loss				
Electric shock sensations				
Muscle tension				
Body odour				
Allergies				
Burning tongue				
Other				

7b. If you selected "other" in the question above, please type what it was (type n/a if this does not apply to you):

……

8. Since your engagement in this research, what changes have you noticed in your physical or emotional well-being?

……

8b. If you have experienced any changes, why do you think these changes occurred?

……

8c. What impact has participating in this research had on your physical or emotional well-being?

……

9. Experiencing the menopause during the Covid-19 pandemic might be especially challenging for some women. Please use this space to tell us more about this experience if you wish. E.g., did you feel able to consult a GP when you needed to? Did any changes due to work restrictions or changes in home circumstances feel different because of the menopause? Did the menopause make you feel more or less able to cope?

……

To view this survey as it will be presented on JISC Online Surveys, please follow this link: https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview

Appendix 4: The daily DRK survey in Word document format

The Daily Record Keeping Form

Main DRK survey

1. Please confirm the username you were provided with by the research team, you will find it on the email you received which included the link to this survey **Please note that if you do not include this word, your response won't be valid because we can't match it with your earlier questionnaire response. This will affect your eligibility for your voucher. Therefore, if you are not sure of your username, please contact Robin Andrews at robin.andrews@southwales.ac.uk:**

……

The Daily Record Keeping Form:

3. Please read through the following emotions and menopausal symptoms and indicate whether you have experienced them in the past 24 hours using this scale: **0= Not at all (you have not experienced this symptom or emotion at all in the past 24 hours) , 1= Mild (you've experienced this symptom or emotion but it has not impacted your daily activities or made you feel any different than usual) , 2= Moderate (you've experienced this symptom or emotion and it has impacted your daily activities to some degree or made you feel somewhat different than usual), 3= Severe (you've experienced this symptom or emotion and it has heavily impacted your daily activities or**

made you feel extremely different than usual).

	0= Not at all	1= Mild	2= Moderate	3= Severe
Nervous				
Positive				
Relieved				
Sad				
Hopeful				
Confident				
Disappointed				
Doubtful				
Happy				
Discouraged				
Anxious				
Hesitant				
Isolated				
Content				
Tense				
Rejected				
Fulfilled				
Uncertain				
Left out				
Lonely				
Unsure				
Encouraged				
Angry				
Worried				
Sleeping problems				
Weight gain				
Joint aches				
Low energy				
Hot flushes				
Stress/ anxiety				
Night sweats				

Low mood				
Brain fog				
Loss of sex drive				
Headaches				
Period changes				
Skin changes				
Vaginal dryness				
Urinary changes				
Painful sex				
Bloating				
Poor concentration				
Itchy skin				
Digestive issues				
Memory loss				
Irregular heartbeat				
Breast pain				
Brittle nails				
Hair loss				
Electric shock sensations				
Muscle tension				
Body odour				
Allergies				
Burning tongue				
Other				

3b. If you selected "other" in the question above, please type what it was (type n/a if this does not apply to you):

……

Page 2/2: DRK debrief sheet (see Appendix 29)

To preview the DRK as it will be presented via JISC Online Surveys, please visit this link: https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-preview

Appendix 5: Templates of the text message reminders and daily DRK email reminders

Appendix 5: Templates of the daily DRK email reminders and text message reminders

Daily DRK email reminder template:

Hi,
Welcome to Day 2 of the monitoring study.
Your username is: **pilot1**
Please remember this username as it will be used to provide you with your £20 voucher, you can contact robin.andrews@southwales.ac.uk if you forget it.
You may open the **Day 2 survey** in your web browser by clicking the link below:
https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-pilot-copy
If the link above does not work, try copying this link into your web browser:
https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-pilot-copy
This link is unique to you and should not be forwarded to others.
To claim your £20 Amazon voucher, **you must complete all 14 of the 5-minute surveys within 24 hours of receiving the links via email, and you must complete the final follow-up survey within 24 hours of receiving the link via email.**
Please do not reply to this email. If you would like to withdraw your data, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of receiving text message reminders.
If you have any questions or concerns about this study, please email: [redacted]
We thank you again for your participation,
The Research Team

Daily text message reminder template:
Today's survey has been sent to the email address you have provided. You can complete this survey now via this link: https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-pilot-copy. Please make sure you complete and return this survey by 10am tomorrow morning to be eligible for the voucher. We thank you for your participation in this research. To opt out of text message reminders please email: robin.andrews@southwales.ac.uk

Appendix 6: Participant information email templates

Appendix 6: Participant information email templates

Email template advising intervention group participants of their group allocation, and instructing them to complete the DRK survey each day for 14 days:

Hi,
Thank you for participating in our study.
You have been allocated into the intervention group.
Your username is: **pilot1**
Please remember this username as it will be used to provide you with your £20 Amazon voucher, you can contact robin.andrews@southwales.ac.uk if you forget it.
Starting from today, you will be asked to complete a 5-minute survey each day for the next 14 days. You must complete and return each survey within 24 hours of receiving the link via email. There will be a different link each day You may open the **Day 1** survey in your web browser now by clicking the link below:
https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-preview
If the link above does not work, try copying this link into your web browser:
https://southwales.onlinesurveys.ac.uk/daily-record-keeping-form-preview
This link is unique to you and should not be forwarded to others
Please do not reply to this email. If you would like to withdraw your data, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of receiving text message reminders.
If you have any questions or concerns about this study, please email: [redacted]
We thank you again for your participation,

The Research Team

The email template advising control participants of their group allocation, and instructing them to carry on as usual for 14 days:

Thank you for participating in our study.
You have been allocated into the **control** group.
Your username is: **pilot1**
Please remember this username as it will be used to provide you with your £20 Amazon voucher, you can contact robin.andrews@southwales.ac.uk if you forget it.
For the next 14 days, please continue with your life as usual.
Once the 14-day period has passed you will receive a link to a follow-up survey via email.
Once you have completed the follow-up survey you will be provided with your **£20 Amazon gift voucher via email**, provided you have completed it within the allocated time frame and have met the terms and conditions (see the information sheet attached for further guidance).
To be eligible for the £20 Amazon voucher, **you must complete the follow-up survey within 24 hours of receiving the link via email.**
Please do not reply to this email. If you would like to withdraw your data, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of receiving text message reminders. If you have any questions or concerns about this study, please email: [redacted]
We thank you again for your participation,
The Research Team

The follow-up email template sent to participants after 14 days of either usual care or completing daily DRK surveys:

Hi,

You have now reached the end of the study; all you need to do now is complete the final follow-up survey (see the link below).

Your username is: **pilot1**

Please remember this username as it will be used to provide you with your £20 voucher, you can contact robin.andrews@southwales.ac.uk if you forget it.

You may open the **follow-up survey** in your web browser by clicking the link below:

https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview

If the link above does not work, try copying this link into your web browser: https://southwales.onlinesurveys.ac.uk/follow-up-questionnaire-preview

This link is unique to you and should not be forwarded to others.

Once you have completed the follow-up survey you will be sent your **£20 Amazon gift voucher via email**, provided you have completed all surveys within the allocated time frames and have met the terms and conditions (see the information sheet attached for more information).

To be eligible for your £20 Amazon voucher, **you must complete the follow-up survey within 24 hours of receiving it.**

Please do not reply to this email. If you would like to withdraw your data, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of receiving text message reminders.

If you have any questions or concerns about this study, please email [redacted]

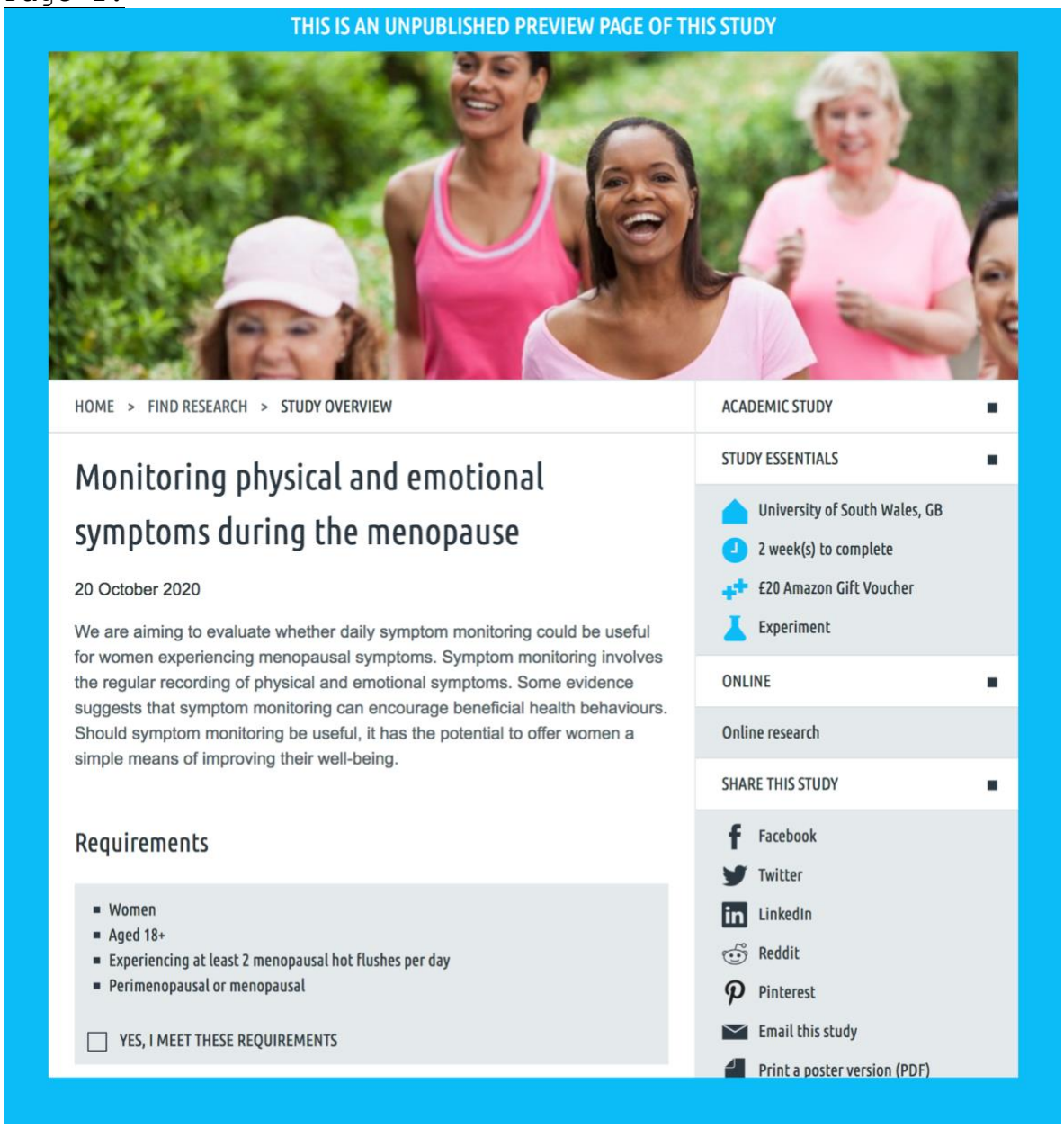
We thank you again for your participation,

The Research Team

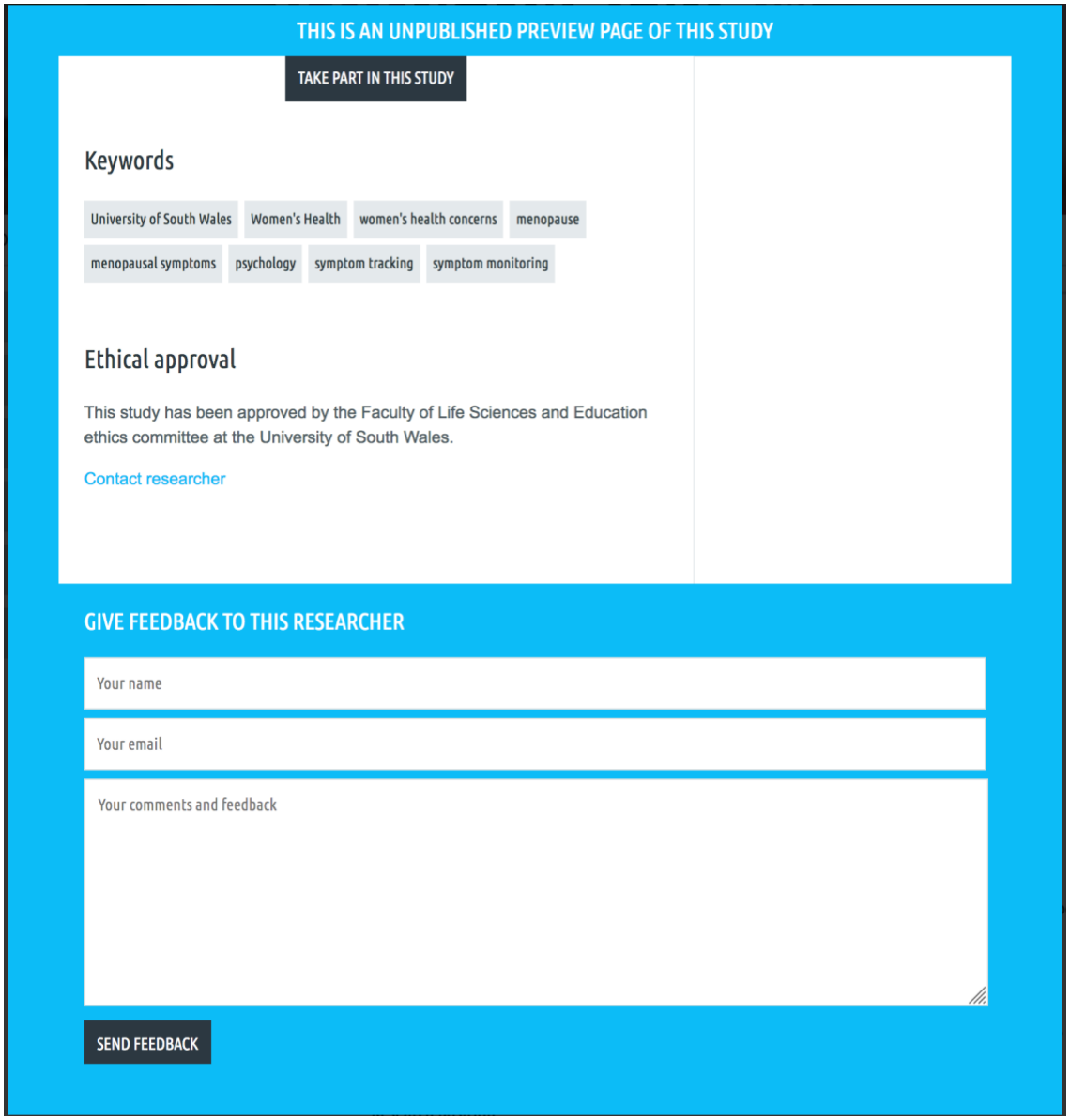
Appendix 7: The recruitment poster as presented on www.callforpartcipants.com

Poster preview link:
https://www.callforparticipants.com/study/get-feedback/OXR4U

Page 1:



Page 2:



Appendix 8: Information sheet

Information sheet

Study Title: A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.

You have been invited to take part in a research study about how a daily monitoring intervention could help women experiencing menopause-related symptoms. As part of this study, you may be asked to complete a brief, 5-minute survey about physical and emotional symptoms of the menopause each day for 14 days, which will be emailed to you at 10am every day.
Before deciding whether you wish to take part in this study, please read the following information about the research and what we would like you to do. If any of the information is not clear please feel free to contact the lead researcher Ms. Robin Andrews, or her supervisor Dr Deborah Lancastle, using the contact details provided. Please take your time to decide whether or not you would like to take part.

What is the purpose of the study?
This research is being carried out as part of a PhD thesis, with the goal of evaluating whether a daily monitoring intervention could influence menopause-related health outcomes.
This study is being carried out by Robin Andrews, who is a KESS-2 funded PhD student at the University of South Wales. This study is supervised by Dr Deborah Lancastle and Professor Bev John, who are both registered Health and Care Professions Council psychologists. Dr Lancastle has expertise in the psychological aspects of women's reproductive health, and Professor John is experienced in developing and evaluating complex health interventions.
As part of her PhD research, Robin Andrews is working with Health & Her, a UK-based company which provides advice and support for women with menopausal symptoms. The anonymised results of this study might be used by Health & Her to develop their provision for menopausal women.

Why have I been invited?

You have been invited to take part in this study because you are an adult female who is experiencing menopause symptoms, and are currently experiencing at least 2 menopausal hot flushes per day.

This study will involve comparing the health of two participant groups; therefore, we need all participants to be in good health and free from chronic physical or psychological conditions. Please do not take part if you have chronic or severe medical conditions including chronic fatigue syndrome, fibromyalgia, cancer, heart disease, thyroid disease, depression and other mental illnesses, or if you are not experiencing at least 2 menopausal hot flushes per day, or are under the age of 18.

Do I have to take part?

It is up to you to decide whether to take part. If you do, you will be asked to complete an online consent form to show that you understand what we would like you to do. Completing this survey confirms that you have consented to take part and are happy for us to use your data.

What will happen to me if I take part?

This research involves an online study which will investigate whether a daily monitoring intervention could improve health outcomes for menopausal women. You will be randomly assigned to one of two groups. Group 1 will be complete the daily monitoring intervention (the intervention group) for 14 days as well as a survey at the beginning and end of this period. Group 2 will complete the survey at the beginning and end of 14 days.

After you have read this information and have completed the consent form on the next page, we would like you to complete an online survey, this will take approximately 10-minutes. You will be asked multiple-choice questions about your health; your information will be kept confidential and you cannot be

identified from any publication of the results. If you are uncomfortable with the idea of sharing such information you do not have to take part.
When you have completed the online survey, you will receive an email from the research team. This email will explain to you which group you have been allocated into. You will be allocated at random into the intervention group, or the control group, as described above.
The intervention group:
If you are allocated into the intervention group, you will be asked to complete a brief, 5-minute survey each day for 14 days, which will be sent to you via email. After the 14 days have passed you will be asked to complete another 10-minute survey, sent to you via email. Once you have returned this survey you will be compensated with a **£20 Amazon gift voucher if you have met all the terms and conditions** (i.e. you have completed all surveys and returned them within 24 hours). If you choose, you may also be sent text message reminders to help you remember to complete the surveys. This is up to you and you can opt out of receiving reminders at any time.
The control group:
If you are allocated into the control group, you will simply complete the 10-minute surveys at the beginning and end of 14 days. Once you have completed this survey you will be compensated with a **£20 Amazon gift voucher if you have met all the terms and conditions** (i.e. you completed both surveys and returned them within 24 hours).

Expenses and payments
Respondents who fully complete this study will be eligible for a **£20 Amazon voucher, which they will receive when they return the final survey.**

Terms and Conditions:
To be eligible for the voucher you must satisfy the following criteria:

- You must not withdraw or drop-out from this study
- Regardless of the group you are in, you must complete and submit all surveys in the links that are sent to you within 24 hours of receiving them.
- You will be provided with a unique username to identify your responses. You must accurately confirm your username on each survey you complete so we can link your survey responses together.

What will I have to do?

If you decide to take part, please:

1. Complete the consent form on the following page and proceed to the survey.
2. Complete all questions on the survey, this will take you approximately 10 minutes.
3. You will receive an email from the research team within 24 hours, this will tell you your group allocation and provide instructions for the next steps of the study.
4. If you are allocated into the **intervention group:**

You will be asked to complete a brief, 5-minute survey about physical and emotional symptoms of the menopause each day for 14 days, which will be emailed to you at 10am every day. After 14 days have passed day you will be asked to complete a 10-minute follow-up survey. Once you have completed this survey, you will be sent your **£20 Amazon gift voucher.**

5. If you are allocated into the **control group**:

You will **not** be asked to complete any daily surveys. You will be asked to complete a 10-minute follow-up survey around 2 weeks from the day you received the email advising you of your group allocation. You will have 24 hours to complete this survey. Once you have completed this survey, you will be sent your **£20 Amazon gift voucher.**

It can help to complete surveys in a calm environment without time pressure or distraction. We are interested in your own opinions, so we would be grateful if you could complete this

survey without assistance from others.

What are the possible risks and disadvantages of taking part?

The menopause is a sensitive subject, and you might feel uncomfortable thinking about your health and symptoms. Please be reassured that you cannot be identified in the thesis or any presentations or publications of the study results. However, if you are uncomfortable with the idea of sharing such information you do not have to take part. You might feel you have a physical or psychological problem after reflecting on your symptoms. Please note that we cannot diagnose physical or mental health problems from your survey responses. If you are concerned about your health after taking part, please contact your GP. We have also provided some contact and information sources below. If you are allocated into the control group you may be disappointed in not being offered to take part in the symptom monitoring intervention. While we are not currently able to offer the intervention to control participants once the study period has finished we will supply a list of symptom monitoring resources, should you be interested in monitoring your symptoms after taking part in this study.

What are the possible benefits of taking part?

We cannot promise that the outcome of this research will help you, but we hope that the information will contribute to the development of ways of helping women experiencing menopausal symptoms to help themselves. This research could also improve the online support available for menopausal women.

What if there is a problem?

If you have questions about the study itself, please contact Robin Andrews. If there are any other issues, please contact Dr Deborah Lancastle. If you are unhappy with anything about this study and wish to make a formal complaint, you can contact **Jonathan Sinfield**. The contact details are below.

All responses to this survey will be kept confidential and

secure. **All personal data (sensitive and standard) will be collected, retained and stored in accordance with the Data Protection Act (2018) and the General Data Protection Regulations (GDPR, 2018).**

All data provided will be kept on password protected computers which only the research team can access. Dr Deborah Lancastle will be the custodian of the data. The data will not be passed on to anyone outside of the research team and will be kept for 5 years and then destroyed. Analysis of anonymised data will be carried out by members of the research team. Should the data be required for future studies, other than that described here, approval will be sought from the appropriate ethics panel at the University of South Wales.

Involvement of the General Practitioner (GP)
We will not be collecting information about your GP or contacting your GP. Therefore, if you are at all concerned about your physical or psychological wellbeing it is up to you to contact your GP.

What will happen if I don't carry on with the study?
If you change your mind about taking part while you are still completing the survey, close down the survey by clicking the x in the corner of the screen and all information provided by you will be removed and destroyed. To withdraw after submitting the survey, email **Robin Andrews**. You do not have to give a reason for withdrawing your data, and all your responses to every survey you have completed will be deleted. Please bear in mind, if you do withdraw your data it will no longer be possible for us to provide you with a £20 Amazon voucher and that once you have received your voucher it is no longer possible to withdraw. If you don't notify Robin Andrews that you wish to withdraw, all your data will be retained in the study, so it is important to let Robin know if you have chosen to withdraw.

What will happen to the results?

The results will form part of a doctoral thesis by Robin, and will be presented at academic conferences, and will be written up in research publications by Robin, Dr Lancastle and Professor John. You cannot be identified in any presentation of the results of this study. If you wish to find out about the outcome of the study you may contact the researchers (see contact details below).

Who is organising or sponsoring the research?

This research is sponsored by the University of South Wales, and is funded by USW, KESS-2, and Health & Her. KESS-2 is a collaboration between the Welsh Government and the European Social Fund.

Contact details

Robin Andrews:
Email: robin.andrews@southwales.ac.uk
Address: Ferndale building, Room 317
University of South Wales
Treforest
Pontypridd
CF37 1DL

If you are unhappy about any aspect of the study, please contact the University of South Wales Research Governance Officer, Jonathan Sinfield:

Email: jonathan.sinfield@southwales.ac.uk
Address: 8 Forest Grove building, Room 10
University of South Wales
Treforest
Pontypridd
CF37 1DL

Thank you for taking the time to read this information sheet. You may find the following sites helpful for

information about the menopause and mental health problems:
NHS website: https://www.nhs.uk/conditions/menopause/
British Menopause Society: https://thebms.org.uk/
Samaritans: https://www.samaritans.org/

Appendix 9: Consent form

Title of Project: A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women
Name of Researcher: Robin Andrews

Name of supervisor: Dr Deborah Lancastle

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw my data up I receive my £20 Amazon voucher, without any consequence to myself.	
3. I agree to my survey responses being recorded and I understand how this data will be stored, destroyed, anonymised, who will have access to it, and how long it will be kept.	
4. I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as confidential and will be handled in accordance with the Data Protection Act and the General Data Protection Regulations (GDPR) 2018 and will be destroyed after 5 years.	

5. I agree to my anonymised data being used in a PhD thesis and in conference presentations and articles for academic journals.	
6. I understand that by submitting all completed surveys implies that I consent to participate in this research.	
7. I understand that after I complete the first survey I will sent an email which will tell me whether I have been allocated into the intervention group, or control group.	
8. I understand that to claim my £20 Amazon voucher I must complete and return each survey within 24 hours of receiving them.	
9. I agree to take part in the above study.	

Appendix 10: Original copies of validated questionnaires

Appendix 10: Original copies of validated questionnaires

Monitor/Blunter Style Scale

1. Vividly imagine that you are **afraid** of the dentist and have to get some dental work done.

Which of the

following would you do? Check **all** of the statements that might apply to you.

___ I would ask the dentist exactly what work was going to be done.

___ I would take a tranquilizer or have a drink before going.

___ I would try to think about pleasant memories.

___ I would want the dentist to tell me when I would feel pain.

___ I would try to sleep.

___ I would watch all the dentist's movements and listen for the sound of the drill.

___ I would watch the flow of water from my mouth to see if it contained blood.

___ I would do mental puzzles in my mind.

2. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building.

Which of the following would you do? Check **all** of the statements that might apply to you.

___ I would sit by myself and have as many daydreams and fantasies as I could.

___ I would stay alert and try to keep myself from falling asleep.

___ I would exchange life stories with the other hostages.

___ If there was a radio present, I would stay near it and listen to the bulletins about what the police were doing.

___ I would watch every movement of my captors and keep an eye on their weapons.

___ I would try to sleep as much as possible.

___ I would think about how nice it's going to be when I get home.

___ I would make sure I knew where every possible exit was.

3. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check **all** of the statements that might apply to you.

___ I would talk to my fellow workers to see if they knew anything about what the supervisor evaluation of me said.

___ I would review the list of duties for my present job and try to figure out if I had fulfilled them all.

___ I would go to the movies to take my mind off things.

___ I would try to remember any arguments or disagreements I might have had that would

have resulted in the supervisor having a lower opinion of me.

___ I would push all thoughts of being laid off out of my mind.

___ I would tell my spouse that I'd rather not discuss my chances of being laid off.

___ I would try to think which employees in my department the supervisor might have thought had done the worst job.

___ I would continue doing my work as if nothing special was happening.

4. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check **all** of the statements that might apply to you.

___ I would carefully read the information provided about safety features in the plane and make sure I knew where the emergency exits were.

___ I would make small talk with the passenger beside me.

___ I would watch the end of the movie, even if I had seen it before.

___ I would call for the flight attendant and ask what exactly the problem was.

___ I would order a drink from the flight attendant or take a tranquilizer.

___ I would listen carefully to the engines for unusual noises and would watch the crew to see if their behavior was out of the ordinary.

___ I would talk to the passenger beside me about what might be wrong.

___ I would settle down and read a book or magazine or write a letter.

The 10-item neuroticism scale extracted from the International Personality Item Pool scales (NEO-IPIP-10)

The Items in Each of the Preliminary IPIP Scales Measuring Constructs Similar to Those in Costa and McCrae's (1992) five NEO-PI-R domains

Neuroticism 10-item scale (Alpha = .86)

+ keyed:

Often feel blue.

Dislike myself.

Am often down in the dumps.

Have frequent mood swings.

Panic easily.

– keyed:

Rarely get irritated.

Seldom feel blue.

Feel comfortable with myself.

Am not easily bothered by things.

Am very pleased with myself

Link to scale website and scale information:
https://ipip.ori.org/newNEOKey.htm#Neuroticism

The original General Help Seeking Questionnaire (GHSQ)

Note: Help sources should be modified to match the target population.

1. If you were having a personal or emotional problem, how likely is it that you would seek help from the following people?

Please indicate your response by putting a line through the number that best describes your intention to seek help from each help source that is listed.

1 = Extremely Unlikely 3 = Unlikely 5 = Likely 7 = Extremely Likely

a. Intimate partner (e.g., girlfriend, boyfriend, husband, wife, de' facto)	1	2	3	4	5	6	7
b. Friend (not related to you)	1	2	3	4	5	6	7
c. Parent	1	2	3	4	5	6	7
d. Other relative/family member	1	2	3	4	5	6	7
e. Mental health professional (e.g. psychologist, social worker, counsellor)	1	2	3	4	5	6	7
f. Phone helpline (e.g. Lifeline)	1	2	3	4	5	6	7
g. Doctor/GP	1	2	3	4	5	6	7
h. Minister or religious leader (e.g. Priest, Rabbi, Chaplain)	1	2	3	4	5	6	7
i. I would not seek help from anyone	1	2	3	4	5	6	7
j. I would seek help from another not listed above (please list in the space provided, (e.g., work colleague. If no, leave blank)_____	1	2	3	4	5	6	7

The Health anxiety subscale extracted from The Health Orientation Scale (HOS)

INSTRUCTIONS:
The items listed below refer to people's health. Please read each item carefully and decide to what extent it is characteristic of you. Give each item a rating of how much it applies to you by using the following scale: A = Not at all characteristic of me. B = Slightly characteristic of me. C = Somewhat characteristic of me. D = Moderately characteristic of me. E = Very characteristic of me.

Health Anxiety:
The items on the Health Anxiety (HA) subscale refer to anxious feelings associated with the status of one's health. More specifically, these items were designed to tap people's feelings of tension, discomfort and anxiety about their physical health. People who endorse these items are those who experience chronic anxiety as a result of thinking about their physical health.

I feel anxious when I think about my health.
ABCDE
I'm worried about how healthy my body is.

ABCDE
Thinking about my health leaves me with an uneasy feeling.
ABCDE
I usually worry about whether I am in good health.
ABCDE
I feel nervous when I think about the status of my physical health.
ABCDE
Link to full HOS as presented online:
https://www.midss.org/sites/default/files/hos.pdf

The Health Consciousness subscale extracted from The Health Orientation Scale (HOS)

INSTRUCTIONS:
The items listed below refer to people's health. Please read each item carefully and decide to what extent it is characteristic of you. Give each item a rating of how much it applies to you by using the following scale: A = Not at all characteristic of me. B = Slightly characteristic of me. C = Somewhat characteristic of me. D = Moderately characteristic of me. E = Very characteristic of me.
Health Consciousness:
The items on the Personal Health Consciousness (PHC) subscale refer to an awareness of one's health. These items were designed to measure people's tendency to think about and to reflect about their health. People who endorse these items are those who think about that status of their physical health, and who in general are reflective about the nature of the health and wellness of their body.
I am very aware of how healthy my body feels.
ABCDE
I notice immediately when my body doesn't feel healthy.
ABCDE
I'm sensitive to internal bodily cues about my health.
ABCDE
I know immediately when I'm not feeling in great health.
ABCDE
I'm very aware of changes in my physical health.
ABCDE
Link to full HOS as presented online:
https://www.midss.org/sites/default/files/hos.pdf

The original Willingness to Communicate about Health (WTCH) Measure

Please use the following scale to answer the items listed below:

1 = Strongly Disagree
2 = Mildly Disagree
3 = Undecided
4 = Mildly Agree
5 = Strongly Agree

_____ 1. In general, I feel comfortable talking with physicians about my health.

_____ 2. I usually feel relaxed when talking about my health problems with my family.

_____ 3. I typically feel comfortable giving others information about my health status.

_____ 4. In general, I don't mind discussing my health status with friends.

_____ 5. I typically discuss emotional concerns I have about my health status with health providers.

_____ 6. I usually feel awkward talking about my health problems with others.

_____ 7. I would not have a problem talking to nurses about my health status.

_____ 8. In general, I would not mind discussing my health with other patients who have a similar health history.

_____ 9. I am generally willing to engage in a conversation about information related to my health status if someone asks me a question about my condition.

_____ 10. I would not be willing to discuss my fears about my health condition with others.

Scoring: Add the scores together, reversing the scores for items 6 and 10. The higher the score, the more willing persons are to communicate about their health

Decision self-efficacy scale

My confidence in making an informed choice

Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by circling the number from 0 (not at all confident) to 4 (very confident) for each item listed below.

I feel confident that I can:

1. Get the facts about the medication choices available to me

not at all confident 0 1 2 3 4 very confident

2. Get the facts about the benefits of each choice

not at all confident 0 1 2 3 4 very confident

3. Get the facts about the risks and side effects of each choice

not at all confident 0 1 2 3 4 very confident

4. Understand the information enough to be able to make a choice

not at all confident 0 1 2 3 4 very confident

5. Ask questions without feeling dumb

not at all confident 0 1 2 3 4 very confident

6. Express my concerns about each choice

not at all confident 0 1 2 3 4 very confident

7. Ask for advice

not at all confident 0 1 2 3 4 very confident

8. Figure out the choice that best suits me

not at all confident 0 1 2 3 4 very confident

9. Handle unwanted pressure from others in making my choice

not at all confident 0 1 2 3 4 very confident

10. Let the clinic team know what’s best for me

not at all confident 0 1 2 3 4 very confident

11. Delay my decision if I feel I need more time

not at all confident 0 1 2 3 4 very confident

The General self-efficacy scale:

1 I can always manage to solve difficult problems if I try hard enough.
2 If someone opposes me, I can find the means and ways to get what I want.
3 It is easy for me to stick to my aims and accomplish my goals.
4 I am confident that I could deal efficiently with unexpected events.
5 Thanks to my resourcefulness, I know how to handle unforeseen situations.
6 I can solve most problems if I invest the necessary effort.
7 I can remain calm when facing difficulties because I can rely on my coping abilities.
8 When I am confronted with a problem, I can usually find several solutions.
9 If I am in trouble, I can usually think of a solution.
10 I can usually handle whatever comes my way.

Scoring key: 1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true

The Daily Record Keeping form

APPENDIX H
Daily Record Keeping form used in Study 2

Daily Monitoring Form

Personal code number.....

Date.....

Rating scale

☐ **Not at all: leave the box blank if you have not experienced that symptom**

1 **Mild: if you have experienced the symptom but it doesn't interfere with**

2 **Moderate: if you have experienced the symptom and it interferes to some**

3 **Severe: if the symptom has a markedly negative effect on how well you**

Part 3

Part 1							
Day of study							
Date							
Part 2: Emotions							
Nervous							
Positive							
Relieved							
Sad							
Hopeful							
Confident							
Disappointed							
Happy							
Discouraged							
Anxious							
Unsure							
Content							
Tense							
Hesitant							
Fulfilled							
Doubtful							
Uncertain							
Encouraged							
Angry							

	Not at all: leave the box blank if you have not experienced that symptom that	Worried						
		Optimistic: pregnancy						
1	Mild: if you have experienced the symptom but it doesn't interfere with	Pessimistic: pregnancy						
2	Moderate: if you have experienced the symptom and it interferes to some	**Part 3: Physical symptoms**						
		Breast tenderness						
3	Severe: if the symptom has a markedly negative effect on how well you	Chest pain/tightness						
		Menstrual cramps						
		Shortness of breath						
		Muscle tension						
		Sweatiness						
		Nausea						
		Abdominal bloating						
		Fatigue/tiredness						
		Cold hands/feet						
		Racing heart						
		Spotting / bleeding						
Part 4: Ways of coping with the waiting period								
I turned my attention away from treatment by thinking about other things or doing some activity								
I made a plan of action and followed it								
I accepted there was nothing I could do								
I did something with the implicit intention of relaxing								
I wished the situation would go away or somehow be over with								
I expressed my emotions								
I tried to make the most of the situation								
Part 5: Ways of thinking about the waiting period								
I perceive that the waiting period is stressful								
I can control what happens in the waiting period								
The waiting period could have a negative impact on me								
I have what it takes to cope with the waiting period								
The waiting period could have a positive impact on me								
Part 6: About the intervention card								
1. How many times did you read the card today? **(write the total number of times each day)**								
2. How did you feel after reading the card? **(1 = felt more negative, 2 = felt the same, 3 = felt more positive)**								

Appendix 12: The 3 debrief sheets:

Debriefing Form 1- Baseline Survey

Study Title: A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.

Thank you for participating in this survey!

The next steps:

Keep an eye on your inbox, as you will shortly receive an email from the research team. This email will be sent from this address: theresearchteam@southwales.ac.uk. If you do not receive an email within the next 24 hours, please check your junk/spam folder. This email will explain to you which group you have been allocated into. You will either be allocated into **the intervention group** or **the control group**. Full information on what you need to do next will be provided. Once you have completed this study you will be sent your £20 Amazon gift voucher.

Voucher eligibility details:

You will be sent your £20 Amazon voucher after you return the final 10-minute survey, which will be emailed to you in approximately 2 weeks' time. Only one £20 voucher will be provided per participant. Amazon vouchers will be sent to those who have fully completed and submitted the research materials sent to them via email, did not withdraw or drop-out from the study, and had accurately confirmed their username on each survey they submitted.

To be eligible for the voucher you must satisfy the following criteria:

- You must not withdraw or drop-out from this study.
- You must complete and submit all surveys in the links which are sent to you within 24 hours.
- You must accurately confirm your username on each survey you complete. Your username will remain the same throughout the duration of this study and will be provided on all emails sent to you from the research team.

We would appreciate it if you do not discuss your responses to the survey with others, to ensure that responses aren't influenced by other people's opinions.

What if I decide to withdraw?

You can withdraw your data any time before **you receive your £20 Amazon voucher**. To withdraw, email Robin Andrews (see contact details below). Withdrawal of your data will mean that your survey responses will be permanently deleted and destroyed. Please note that if you withdraw you will not be eligible for a voucher.

Please note that if you drop-out from this study by no longer completing surveys and ceasing contact with the research team, all data you have provided up until that point will be retained unless you contact Robin Andrews via email with your decision to withdraw your data from this study.

We thank you again for your contribution to this research!

What if I have questions or concerns about this research?

If you have any questions or concerns about this survey, please contact the lead researcher: Robin Andrews,

Email: robin.andrews@southwales.ac.uk

Address: Ferndale building, room 317
University of South Wales
Treforest
Pontypridd
CF37 1DL

If you are worried about this research or concerned about how

it is being conducted, please contact Robin's supervisor: Dr Deborah Lancastle,

Complaints procedure:

If you wish to make a formal complaint, contact the Research Governance Officer of the University of South Wales: Mr Jonathon Sinfield,

Email: jonathan.sinfield@southwales.ac.uk

Address: 8 Forest Grove, room 10
University of South Wales
Treforest
Pontypridd
CF37 1DL

Support and information services:

If you are concerned about your physical or psychological well-being, you should contact your GP or a healthcare professional. If you feel you require further support or information for menopause-related or mental health issues, please visit the following websites:

NHS website: https://www.nhs.uk/conditions/menopause/

British Menopause Society: https://thebms.org.uk/

Samaritans: https://www.samaritans.org/

Debriefing Form 2- Daily Record Keeping Form

Study Title: A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.

The next steps:

Keep an eye on your inbox, as you will shortly receive an email from the research team with a link to the next survey for you to complete within 24 hours. This email will be sent from this address: theresearchteam@southwales.ac.uk. If you do not receive this email within the next 24 hours please check your junk/spam folder, or email robin.andrews@southwales.ac.uk.

If you have opted in, you will also be sent text message reminders to help you remember to complete the questionnaires. You can opt out of receiving reminders at any time. To opt out of receiving text reminders, just email robin.andrews@southwales.ac.uk requesting to stop text reminders.

What if I decide to withdraw?

You can withdraw your data any time *before* **you receive your £20 Amazon voucher**. To withdraw, email Robin Andrews (see contact details below). Withdrawal of your data will mean that your survey responses will be permanently deleted and destroyed. Please note that if you withdraw you will not be eligible for a voucher.

If you decided to withdraw midway through completing a survey by clicking the X in the corner of the screen or closing your browser, all data you have provided on that specific survey up until that point will be destroyed. However, any data you have submitted by completing previous surveys will be retained. Please note that if you drop-out from this study by no

longer completing surveys and ceasing contact with the research team, all data you have provided up until that point will be retained unless you contact Robin Andrews via email with your decision to withdraw your data from this study.

Thank you again for your contribution to this research!

What if I have questions or concerns about this research?

If you have any questions or concerns about this survey, please contact the lead researcher: Robin Andrews,

Email: robin.andrews@southwales.ac.uk

Address: Ferndale building, room 317
University of South Wales
Treforest
Pontypridd
CF37 1DL

If you are worried about this research or concerned about how it is being conducted, please contact Robin's supervisor: Dr Deborah Lancastle,

Complaints procedure:
If you wish to make a formal complaint, contact the Research Governance Officer of the University of South Wales: Mr Jonathon Sinfield,

Email: jonathan.sinfield@southwales.ac.uk

Address: 8 Forest Grove, room 10
University of South Wales
Treforest
Pontypridd
CF37 1DL

Support and information services:
If you are concerned about your physical or psychological well-being, you should contact your GP or a healthcare professional. If you feel you require further support or information for menopause-related or mental health issues, please visit the following websites:

NHS website: https://www.nhs.uk/conditions/menopause/

British Menopause Society: https://thebms.org.uk/

Samaritans: https://www.samaritans.org/

Debriefing Form 3- Follow-up Questionnaire

Study Title: A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.
Thank you for participating in this survey!

The aim of this study was to explore whether daily monitoring of symptoms and emotions could lead to improvements in health or changes in behaviour. The findings from this research will help medical professionals understand whether a simple, cost-effective intervention could help women with menopausal symptoms get the treatment that they need.

Terms and conditions:
You will be emailed your £20 Amazon gift voucher within the next 24 hours. Make sure you check your junk/spam folder if you have not received it after 24 hours, if you have still not received it please email robin.andrews@southwales.ac.uk. Only one £20 voucher will be provided per participant. Amazon vouchers will be sent to those who fully completed the research

materials sent to them via email, did not withdraw from the study, and had accurately confirmed their username on each survey they submitted.

To be eligible for the voucher you must satisfy the following criteria:

- You must not withdraw or drop-out from this study
- You must complete and submit all surveys in the links which are sent to you within the stated time periods. You will have had 24 hours to complete the follow-up survey.
- If you were allocated into the intervention group you must have completed the 5-minute surveys each day (within 24 hours of the survey being received via email) for 14 days.
- You must have accurately confirmed your username on each survey you completed. Your username will remain the same throughout the duration of this study and will be provided on all emails sent to you from the research team.

What if I decide to withdraw?

You can withdraw your data any time before you receive your £20 Amazon voucher. To withdraw, email: robin.andrews@southwales.ac.uk. Withdrawal of your data will mean that your survey responses will be permanently deleted and destroyed. Please note that if you withdraw you will not be eligible for a voucher.

Please note that if you drop-out from this study by no longer completing surveys and ceasing contact with the research team, all data you have provided up until that point will be retained unless you contact Robin Andrews via email with your decision to withdraw your data from this study.

Thank you again for your contribution to this research!

What if I have questions or concerns about this research?
If you have any questions or concerns about this survey, please contact the lead researcher: Robin Andrews,

Email: robin.andrews@southwales.ac.uk
Address: Ferndale building, room 317
University of South Wales
Treforest
Pontypridd
CF37 1DL

If you are worried about this research or concerned about how it is being conducted, please contact Robin's supervisor: Dr Deborah Lancastle,

Complaints procedure:
If you wish to make a formal complaint, contact the Research Governance Officer of the University of South Wales: Mr Jonathon Sinfield,

Email: jonathan.sinfield@southwales.ac.uk
Address: 8 Forest Grove, room 10
University of South Wales
Treforest
Pontypridd
CF37 1DL

Support and information services:
If you are concerned about your physical or psychological well-being, you should contact your GP or a healthcare professional. If you feel you require further support or information for menopause-related or mental health issues, please visit the following websites:

NHS website: https://www.nhs.uk/conditions/menopause/

British Menopause Society: https://thebms.org.uk/

Samaritans: https://www.samaritans.org/

Symptom monitoring tools:

If you were allocated into the control group and did not get an opportunity to engage in the symptom monitoring intervention, please see the following online symptom monitoring tools and mobile apps. If you were in the intervention group but feel you have benefited from monitoring your symptoms and would like to continue you can also use the following online tools and mobile apps:

Health & Her online symptom tool:
https://healthandher.com/symptom-tool/

Health & Her mobile app (IOS & Googleplay):
https://apps.apple.com/gb/app/health-her-menopause-app/id1519199698

Symptom checker from WebMD:
https://symptoms.webmd.com/default.htm

Clue (a free period tracker app on IOS only):
https://helloclue.com/

Flaredown (a free web and mobile app on Android & iOS):
http://flaredown.com/

Appendix 13: The researcher safety protocol

Researcher safety protocol

Study name:

FACULTY OF LIFE SCIENCES AND EDUCATION
FACULTY ETHICS SUB GROUP APPLICATION FORM

A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.

What are the hazards?

This study poses no foreseeable risks of physical harm to the research team or to the research participants, because all research will be carried out online. Other potential risks are:

1. Participants with physical or mental health problems might consult Robin for help, and financial remuneration brings the risk that participants may complain to her if they do not meet the conditions for remuneration.
2. Part of the study requires participants to provide their email address in order to participate in this research and claim their incentive (a £20 Amazon voucher) for completing the study, which means that participants' personal contact details will be known to Robin. Participants who indicate that they would like to be sent text message reminders (which will prompt them to complete the surveys) will also be asked to provide their mobile phone number.
3. Survey respondents who have been allocated into the control group might be disappointed that they were not given an opportunity to engage in the daily symptom monitoring intervention.

Who might be harmed and how?

1. Robin could be approached by participants wishing to complain and pressurise her into providing remuneration for which they are not eligible, and she could be asked for advice she is not qualified to give. Such challenging communications put Robin at risk of worry and distress.

2. Survey respondents will be asked to provide personally identifiable information (email addresses and mobile phone numbers) in order to claim their remuneration or be sent daily reminders to complete the daily monitoring survey. Therefore, this presents the risk of privacy breaches that might harm them if these details became known to others.

3. Control participants might feel disappointed that they were not given an opportunity to engage in the daily monitoring intervention, and they may approach Robin wishing to complain or pressurise her into allocating them into the intervention group.

What is being done to control the risks?

1. There is a small risk that participants may consult Robin for help for physical or mental health problems, or they may disclose information which may require notification or follow up. To mitigate these risks, Robin will use a separate email address from her professional one to contact recruited participants. This is the email address: theresearchteam@southwales.ac.uk. All emails sent from this address will include a note at the end stating the following "Please do not reply to this email. If you have questions or concerns about this study, or you would like to withdraw, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of text message reminders." This email address will be used to advise recruited participants (that is participants who have returned the completed baseline survey, including the consent form) with their group allocation, their unique username, and provide further instructions. This email address will also be used to email the daily monitoring intervention to intervention group participants each day of the intervention period, as well as the follow-up survey to all participants. This method will mitigate risks of an instantaneous dialogue emerging between Robin and the participants, therefore reducing the chances of experimenter biases occurring should Robin feel the need to respond to any queries. This will also reduce the risks of participants disclosing information to Robin which may need further action.

2. The information sheet will direct participants to only to contact Robin (via her personal USW email address) with questions about the mechanics of completing the survey. If participants have any questions about anything else related to the survey such as Health & Her, the menopause, or concerns about the study, they will be directed to the Director of Studies (Dr Deborah Lancastle) in the first instance. If participants have concerns or complaints that cannot be answered satisfactorily by Deborah on consultation with the wider research team then the issue will be referred to Jon Sinfield. It is also clearly stated in the information sheet that the research team cannot provide medical advice and that any respondents who are concerned should contact their GP. In terms of complaints about eligibility for/claiming the voucher, the steps participants need to take to ensure they are eligible to claim the voucher are clearly stated on the information sheet and repeated in the final debrief sheet, minimising the likelihood that participants could claim they didn't know they had to satisfy certain criteria to be eligible for remuneration. Together, these controls should minimise any chance of Robin experiencing negative consequences from any potential issues a participant might have with the research, and provide a clear protocol for action should problems arise.

3. All email addresses and phone numbers will be stored separately from survey responses on password protected Excel documents, and will only be accessible to Robin and her supervisors. Text messages will be sent from the online text message management platform ClickSend (www.clicksend.com) which will be accessed by Robin via a USW password protected computed, therefore participant's phone numbers will not be stored on Robin's personal telecommunications devices. To enable participants to withdraw their data should they wish, and to ensure that personally identifiable information is not stored alongside responses to the intervention and follow-up materials, recruited participants will be provided with a unique username which will be repeated in all email correspondence: "Your username is: Participant1 please retain this information as you will be asked to confirm it on all surveys you complete". Participants will be asked to confirm their unique username at the beginning of each research material they complete (i.e. the daily monitoring surveys and the follow-up survey). The data will not be passed on to anyone outside of the research team and will be kept for five years and then destroyed. Should the data be required for further studies other than described here, approval will be sought from the appropriate ethics panel at the University of South Wales.

4. Participants who are disappointed with their group allocation will be reminded that their decision to engage in the study is voluntary and they are free to withdraw their data from the study at any point up until they receive their £20 Amazon voucher. They will be directed to read the information sheet which explains the importance of comparing the monitoring intervention group with a non-monitoring control group. On the third debrief sheet, which will be presented at the end of the final follow-up survey, all participants are given information on online tools and mobile apps which they can use to monitor their symptoms, should they wish.

What further action is necessary?

1. The strategies above are tried and tested methods of ensuring that student researchers are protected from the implications of inappropriate or distressing communication with participants. Deborah and Bev have many years of experience of managing applied research and student supervision and will take appropriate action as and when needed.
2. Robin has completed the necessary GDPR training so is already mindful of the correct way to manage data confidentially. Names and contact details for participants will be collected in the ways described above, to ensure that participants' identities are stored separately from their survey responses.

How will the actions be carried out?

1. Robin will use a separate email address from her professional one to contact recruited participants: (theresearchteam@southwales.ac.uk). All emails sent from this address will include a note at the end stating the following "Please do not reply to this email. If you have questions or concerns about this study, or you would like to withdraw, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of text message reminders." This email address will be used to advise recruited participants (that is participants who have returned the completed baseline survey, including the consent form) with their group allocation, their unique username, and provide further instructions. This email address will also be used to email the DRK intervention to intervention group participants each day of the intervention period, as well as the follow-up survey to all participants.

2. The information sheet will direct participants to only to contact Robin (via her personal USW email address) with questions about the mechanics of completing the survey. If participants have any questions about anything else related to the survey such as Health & Her, the menopause, or concerns about the study, they will be directed to the Director of Studies (Dr Deborah Lancastle) in the first instance. If participants have concerns or complaints that cannot be answered satisfactorily by Deborah on consultation with the wider research team then the issue will be referred to Jon Sinfield. The information sheet will include the following disclaimer, so that it is made clear to participants that medical advice should be sought from a GP or other help professional, and not the research team:

"Please note that we are not able to diagnose any physical or mental health problem from your responses to this survey. If you are at all concerned about your physical or mental health you should contact your own General Practitioner (GP) and/or other sources of help. We have provided some examples of help sources below."

3. All email addresses will be stored on password protected Excel documents separately from survey responses, which will only be accessible to Robin and her supervisors. To enable participants to withdraw their data should they wish, and ensure that personally identifiable information is not stored alongside responses to the intervention and follow-up materials, recruited participants will be provided with a unique username over email (i.e. 'Your username is: Participant1 please retain this information as you will be asked to confirm it on all surveys you complete') which they will be asked to confirm at the beginning of each research material they complete (i.e. the DRK surveys and the follow-up survey).

4. The third and final debrief sheet (see Appendix 30- Debrief 3 follow-up survey) will include the following information to all participants:

"Symptom monitoring tools:

If you were allocated into the control group and did not get an opportunity to engage in the symptom monitoring intervention, please see the following online symptom monitoring tools and mobile apps. If you were in the intervention group but feel you have benefited from monitoring your symptoms and would like to continue you can also use the following online tools and mobile apps:

Health & Her online symptom tool: https://healthandher.com/symptom-tool/

Health & Her mobile app (IOS & Googleplay): https://apps.apple.com/gb/app/health-her-menopause-app/id1519199698

Symptom checker from WebMD: https://symptoms.webmd.com/default.htm

Clue (a free period tracker app on IOS only): https://helloclue.com/

Flaredown (a free web and mobile app on Android & iOS): http://flaredown.com/"

When will the actions be carried out?
Once ethics approval has been granted.

This risk assessment will be retained for future reference and if there are any significant changes or new work practices then the assessment will be reviewed.

Appendix 14: The risk assessment table:

Risk Assessment

Assessment of: **A randomised controlled trial of the effects of monitoring physical and emotional symptoms among menopausal women.**	Name of Assessor: **Robin Andrews**	
Assisted by: **Dr Deborah Lancastle**	Assessment date: **14.10.2020**	Date of Next review: **31/11/2020**

Task/Activity	Hazards/Persons at Risk	Existing Control Measures	Risk Evaluation			Further Control Measures / Recommendations	Date Action Completed
			Likelihood (L)	Severity (S)	L x S		
Part of the study requires participants to provide their email address in order to engage in the study and receive their incentive (a £20 Amazon voucher) for completing the survey. Participants who opt in to being sent daily text message reminders	The participants could be at risk of data protection breaches, especially if their email addresses fall into the wrong hands from being stored improperly.	Robin will use a separate email address from her professional one to contact recruited participants: (theresearchteam@southwales.ac.uk). All emails sent from this address will include a note at the end stating the following "Please do not reply to this email. If you have questions or concerns about this study, or you would like to withdraw, please email robin.andrews@southwales.ac.uk. You can also email robin.andrews@southwales.ac.uk if you would like to opt out of text message reminders." All email addresses will be stored on password protected Excel documents separately from survey responses, which will only be accessible to Robin and her	2	2	4	This research team has conducted a prior study which supplied remuneration to participants via email (ethics reference: 200401HR) to good effect with no repercussions. An alternative method to providing users with the voucher anonymously (without need for their email addresses) would be by directing them to a website which will host the Amazon voucher, following input of a key word given to them at the end of the survey. However, this technology is not available to the research team at present. Therefore, no further control measures are recommended due to limited resources.	On receipt of approval for methodology (before surveys are made live)

will be asked to provide their mobile phone number.		supervisors. Text messages will be sent from the online text message management platform ClickSend (www.clicksend.com) which will be accessed by Robin via a USW password protected computed, therefore participant's phone numbers will not be stored on Robin's personal telecommunications devices. To enable participants to withdraw their data should they wish, and ensure that personally identifiable information is not stored alongside responses to the intervention and follow-up materials, recruited participants will be provided with a unique username over email (i.e. 'Your username is: Participant1 please retain this information as you will be asked to confirm it on all surveys you complete') which they will be asked to confirm at the beginning of each research material they complete (i.e. the DRK surveys and the follow-up survey).					
Having an open dialogue with Robin during the research period could put the lead researcher in a position where participants will make	Establishing a dialogue with survey participants over email could put the lead researcher in a position where she is uncertain on how best to approach requests made	As described above, most of the study will be administered via a separate email address to Robin's personal USW email. However, the information sheet will direct participants to contact Robin (via her personal USW email address) with questions about the mechanics of completing the survey. If participants have any questions about anything else related to the survey such as Health & Her, the menopause, or concerns about the study, they	2	2	4	The information sheet, which will be provided to participants prior to the undertaking the survey, will include a disclaimer which explains that no medical advice could be sought from the research team. A list of medical help resources will also be included in this information sheet, should any participants feel worried about their health following completion of the survey. This information will be repeated within the debrief sheet, at the end of the survey.	On receipt of approval for methodology (before surveys are made live)

requests that she is unable to grant. For example, participants will be answering health and medical type questions (i.e. "have your menopause symptom become better or worse?"). This may lead some to mistake the intent of the survey, and email the lead researcher to ask for medical advice. Participants might also email Robin wishing to complain to her if they do not meet the conditions for remuneration, or they	by survey participants, for example, survey respondents may request medical advice. Therefore, provisions will be made in the event that this occurs. Robin also could be approached by participants wishing to complain and pressurise her into providing remuneration for which they are not eligible, and control participants might feel disappointed that they were not given an opportunity to engage in the daily monitoring intervention, and they may approach Robin wishing to complain or pressurise her into	will be directed to the Director of Studies (Dr Deborah Lancastle) in the first instance. Participants will be asked only to contact Robin with questions about procedural points. If participants have any questions about anything related to the survey (i.e symptom monitoring or the menopause) they will be asked to contact the Director of Studies: Dr Deborah Lancastle. If any participants have questions which are not related to the survey or if they have objections, then the lead researcher will consult with her supervisors and a joint decision will be made about the best way to solve the problem, with escalation to the USW research governance officer if this isn't solved satisfactorily. It will be clearly stated in the information sheet that the research team cannot provide medical advice and that any respondents who are concerned should contact their GP. In terms of complaints about eligibility for/claiming the voucher, the steps participants need to take to ensure they are eligible to claim the voucher are clearly stated on the information sheet and repeated in the debrief sheets, minimising the likelihood that participants could claim they didn't know they had to satisfy certain criteria to be eligible for remuneration. Together, these controls should				The information sheet and debrief forms, as well as all emails sent to participants, will include the terms and conditions for voucher eligibility: You will be emailed your £20 Amazon gift voucher within the next 24 hours. Make sure you check your junk/spam folder if you have not received it after 24 hours, if you have still not received it please email robin.andrews@southwales.ac.uk. Only one £20 voucher will be provided per participant. Amazon vouchers will be sent to those who fully completed the research materials sent to them via email, did not withdraw from the study, and had accurately confirmed their username on each survey they submitted. "To be eligible for the voucher you must satisfy the following criteria: You must not withdraw or drop-out from this study You must complete and submit all surveys which are sent to you within the stated time periods. You will have had 24 hours to complete the follow-up survey. If you were allocated into the intervention group you must have completed the 5-minute surveys each day (within 24 hours of the survey being received via email) for 14 days. You must have accurately confirmed your username on each survey you completed. Your username will remain	

may be disappointed in their group allocation and request to be put into a different group.	allocating them into the intervention group.	minimise any chance of Robin experiencing negative consequences from any potential issues a participant might have with the research, and provide a clear protocol for action should problems arise. Participants who are disappointed with their group allocation will be reminded that their decision to engage in the study is voluntary and they are free to withdraw their data from the study at any point up until they receive their £20 Amazon voucher. They will be directed to read the information sheet which explains the importance of comparing the monitoring intervention group with a non-monitoring control group. On the third debrief sheet, which will be presented at the end of the final follow-up survey, all participants are given information on online tools and mobile apps which they can use to monitor their symptoms, should they wish.				the same throughout the duration of this study and will be provided on all emails sent to you from the research team." The third and final debrief sheet (see Appendix 30- Debrief 3 follow-up survey) will include the following information to all participants: "Symptom monitoring tools: If you were allocated into the control group and did not get an opportunity to engage in the symptom monitoring intervention, please see the following online symptom monitoring tools and mobile apps. If you were in the intervention group but feel you have benefited from monitoring your symptoms and would like to continue you can also use the following online tools and mobile apps: Health & Her online symptom tool: https://healthandher.com/symptom-tool/ Health & Her mobile app (IOS & Googleplay): https://apps.apple.com/gb/app/health-her-menopause-app/id1519199698 Symptom checker from WebMD: https://symptoms.webmd.com/default.htm Clue (a free period tracker app on IOS only): https://helloclue.com/ Flaredown (a free web and mobile app	

						on Android & iOS): http://flaredown.com/"	

Risk Evaluation

Likelihood

Given the control measures in place:	Rating
It is extremely unlikely to occur	2
It is not expect to happen	4
May occur under current circumstances	6
Likely to occur under current circumstances	8
Almost certain to occur under current circumstances	10

Severity

Potential outcome:	Score
Minor first aid/ minor property damage/ minor inconvenience	2
First aid (e.g. sprains, cuts, bruises) / repairable property damage / some disruption to activities	4
Lost time injury / fracture fingers/toes / stay in hospital / replacement of property required / significant disruption to activities	6
Fractures (other than fingers/toes), amputations etc. / partial loss of a building / postponement of activities	8
Fatality / cancellation of activities / complete loss of a building	10

Risk Rating

Less than 8	Low Risk
8 – 16	Low – Medium Risk

20 – 32	Medium Risk
36 – 48	Medium – High Risk
Above 48	High Risk