Protocol: The influence of cognitive behavioural therapy for insomnia on self-reported endocrine therapy adherence: a mixed methods pilot study

University of Strathclyde: UEC23/09

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1. Introduction

Breast cancer (BC) is the most common type of cancer in the UK, and the highest cause of cancer-related death in women(1). Approximately 70% of BC cases are hormone-receptor positive, which means the cancer cells grow in response to hormones oestrogen and/or progesterone. Following primary treatment (usually surgery, chemotherapy and/or radiotherapy), these cases are treatable with endocrine therapy. This is prescribed in the form of daily tablets for 5-10 years. This treatment works by either reducing the volume of oestrogen produced in the body (Aromatase inhibitors) or preventing oestrogen from binding to its receptors (Tamoxifen) (2).

When it is taken as prescribed, endocrine therapy is successful in reducing the risk of breast cancer recurrence and mortality. Tamoxifen can reduce the risk of recurrence by up to 50%, and aromatase inhibitors can reduce the chance of recurrence by a further third in comparison(3). Despite the clinical advantages of ET, compliance with this medication is often not optimal. Research indicates that up to half of those prescribed ET take their medication less than 70% of the time(4). This reflects suboptimal adherence (the extent to which patients take the medication as prescribed) and persistence (the duration of medication use, from initiation to discontinuation) (Wasserman et al., 2017). Nonadherence and nonpersistence are related to increased risk of BC recurrence and mortality(5). Therefore, to further improve BC outcomes, adherence to this medication should be maximised.

Predictors of ET adherence include younger and older age, switching ET medication type, comorbidities, and out of pocket medication costs(6). Another major factor which makes adherence challenging is side effects, which have severe impacts on quality of life and sense of identity and returning to normality after cancer treatment(7,8). These recent studies indicate that side effects may present a means of improving adherence as BC survivors express a desire for support in managing them, and they are amenable to improvement than demographic and clinical predictors.

One side effect which may present an appropriate target is insomnia. Characterised by difficulty falling and staying asleep, insomnia common in cancer patients and especially among those diagnosed with BC(9). This is debilitating to carrying out daily activities and has further effects on mental health and ability to move on from BC treatment(8). Importantly, sleep problems are influenced by other treatment side effects such as hot flashes, night sweats, and musculoskeletal pain, and related to depression and anxiety in BC survivors(10,11). Insomnia is therefore a transdiagnostic symptom with the potential to

reduce the burden of several different ET side effects and overall quality of life. Unlike hot flashes and pain, sleep can be treated non-pharmacologically using cognitive behavioural therapy, which is considered the gold standard treatment for insomnia (12). This has been found to improve not only insomnia symptoms but also depression, anxiety, and fatigue in BC survivors(13), and can be delivered efficiently to groups of people and treat these symptoms non-pharmacologically(14,15).

Thus far, interventions to improve ET adherence have focused on patient education and reminders to take medication, which have had little success in improving adherence (Ekinci et al., 2018; Heiney et al., 2019). Recent protocols include components of side effect management(16), which addresses research finding that BC survivors express a desire for support and willingness to try new strategies with the aim of better side effect management (7,8). However, to the best of our knowledge, there have been no attempts to improve adherence by targeting a specific ET side effect. Sleep may present an opportunity here as it is a transdiagnostic target which is highly prevalent in this population, and can be effectively treated non-pharmacologically using CBT-I.

This study will utilise a randomised, waitlist-controlled design. We will aim to recruit 40 BC survivors who experience sleep problems and struggle to take their ET medication as prescribed. The main objective of this study is to explore the effect of CBT-I (delivered through videoconferencing) on sleep problems and adherence to ET in BC survivors.

2. Methods

2.1. Design

The study is a randomised, waitlist-controlled trial of CBT-I. The advantages of a waitlist control group are: this ensures all participants have the opportunity to receive the recommended treatment for insomnia, and that by utilising control participants as intervention participants after their participation in the control condition, we can increase the statistical power of the study. The immediate intervention group will complete assessments at baseline, post-intervention (approximately 4 weeks after baseline), and after a further 8 weeks (12 weeks post-randomisation follow-up). The waitlist group will complete these assessments at the same timepoints, then 2 additional assessments after they receive the intervention, and after a further 8 weeks. The study is expected to take approximately 12 weeks from baseline

to completion (follow-up assessment). This study has been granted ethical approval has been granted from the University of Strathclyde ethics committee (UEC23/09).

2.2. Participants

Participants will include BC survivors who: experience symptoms of insomnia, self-report to be nonadherent to their ET medication, are fluent in English, and have access to videoconferencing software. Treatment nonadherence and insomnia symptoms will be established first during the screening interview, and at baseline, by responses to the Medication Adherence Report Scale (MARS-5) and Sleep Condition Indicator (SCI), respectively, using established cut-off scores.

Exclusion criteria include: individuals who are currently pregnant or breastfeeding, have received CBT-I within the past 12 months, have received chemotherapy or radiotherapy within the past 4 weeks or have plans for future treatment, struggle with substance misuse, or have an unstable physical or mental health condition (e.g. psychosis) which would be incompatible with CBT-I treatment.

Participants will not be excluded on the basis of other sleep disorders, if they report that these are stable and well-managed. Participants will not be excluded on the basis of a palliative BC treatment plan. However, during the screening interview the nature of CBT-I treatment will be explained to them, as this treatment can be difficult to implement, and they will be asked if they feel well enough to participate.

2.2.1. Recruitment

We will aim to recruit a sample of 40 participants. A-priori power analysis was conducted using G*Power version 3.1.9.7 (Faul et al., 2007) to determine the minimum sample size required to test the study hypothesis using a repeated measures ANOVA (within-between interaction). Results indicated the required sample size to achieve 80% power for detecting a medium effect (significance criterion α=.05) was N=18. Therefore, the target sample size of N=40 is adequate to test the study hypothesis.

Recruitment will involve emailing participants of a previous study (UEC21/29) who indicated that they would be interested in participation in future research studies. We will contact individuals from this sample whose responses indicated they are nonadherent to their ET medication and experience significant sleep problems, informing them of the opportunity to take part in this study.

The initial email will briefly outline the nature of the study and include an information sheet with full study details. Those who are interested will be asked to respond to this initial email so that a screening interview can be scheduled.

2.3. Procedure

Those who indicate interest in participation will be emailed a link to a virtual consent form via Qualtrics survey platform. Following informed consent, a screening interview will be scheduled. They will then be interviewed to ensure eligibility criteria are met. Screening interviews will be carried out by the PhD student: if there are any points of uncertainty, clarification will be sought through discussion with academic supervisors. Those who meet inclusion criteria following screening will be sent a link to the baseline assessment, then randomised to either the intervention or waitlist control group. All further assessments will be sent via email and carried out through Qualtrics survey platform.

2.4. Randomisation

Participants will be allocated on a 2:1 basis to the waitlist or intervention group. The study team will have no influence over the randomisation process. Participants will be randomised using block randomisation in blocks of 10. The advantage of this method is that it maintains balance between intervention and control group, as significant imbalance would reduce the power of the study in a small sample (Lim & In, 2019; Pinto et al., 2022).

Upon providing informed consent, participants will be assigned a unique identifier (UID). A PhD student unrelated to the study will be given a list of these UIDs and use an online randomisation tool to generate an allocation sequence, which will be used to assign each group's participants. They will then pass the list of UIDs assigned to each group to the PhD student for the study, who will establish which participants are in each group. Following randomisation, the intervention group will be emailed a recurring link to access CBT-I sessions via videoconferencing.

2.5. Intervention

CBT-I is a multi-component, evidence-based intervention which incorporates both cognitive and behavioural techniques to address symptoms of insomnia, aiming to improve satisfaction with the duration and quality of sleep by reducing trouble falling and/or staying asleep. Its main components include: sleep restriction, stimulus control, and cognitive restructuring. Sleep restriction aims to reduce discrepancy between time spent in bed and time actually sleeping by improving 'sleep efficiency' (SE), which is the time spent sleeping expressed as a

percentage of time spent in bed. The individual is given a prescribed bedtime and waketime to match their time spent in bed with time sleeping, which is adjusted accordingly when their SE reaches 90%, or falls below 85%. Stimulus control involves strengthening the association between being in bed and being asleep, by minimising activity in the bed unrelated to sleep or intimacy, getting out of bed if unable to initiate sleep or get back to sleep after waking up, and only returning to bed when sleepy. Cognitive restructuring challenges maladaptive beliefs about sleep and concerns about the daytime consequences of poor sleep, to reduce arousal and anxiety associated with insomnia.

CBT-I will be delivered over 4 weekly 1-hour sessions, via videoconferencing. Session 1 will include psychoeducation about sleep (the relationship between sleep and mental health, the '3P' model of insomnia), and begin to explain components of CBT-I (sleep restriction and relaxation). Session 2 will reinforce previous learning about these components and introduce stimulus control. Session 3 will introduce sleep hygiene and its importance in preventing poor sleep. Session will 4 discuss cognitive therapy techniques and relapse prevention.

Participants in the waitlist condition will receive the CBT-I intervention after completing the 12-week follow-up assessment. This will then be used as a baseline measure for these participants to compare to their post-intervention and follow-up after receiving the treatment.

The intervention will be delivered by a PhD student, who will receive extensive CBT-I training from supervisors who have over 15 years' experience in delivering CBT-I. The student will receive continuous supervision throughout. Sessions will be recorded and 10% will be assessed by supervisors to monitor treatment fidelity.

2.6 Measures

2.6.1. Primary outcome

Medication Adherence Report Scale (5 item) (MARS-5). The MARS-5 will be used to measure self-reported nonadherence to ET medication. This includes 5 items which measure nonadherence behaviours, scored from 1 'Always' to 5 'Never'. Item 1 measures unintentional nonadherence (i.e., forgetting to take medication), whereas 2-5 represent intentionally not taking medication as prescribed (e.g., altering the dose of medication), with higher scores meaning better adherence. In past research, a total score ≤ 4 (on the unintentional nonadherence subscale) and ≤ 19 (on the intentional nonadherence subscale) have been used to classify participants as nonadherent. Scores are summed to create a total ranging from 1-5.

2.6.2. Secondary outcomes

The Sleep Condition Indicator (SCI) measures insomnia symptoms with 8 items, scored from 0-4. Responses are summed to create a total score ranging from 0-32, with higher scores meaning better sleep. A total score of ≤ 16 indicates probable insomnia disorder.

The Patient Health Questionnaire (PHQ-9) measures depressive symptoms using 9 items which each measure a different symptom. This measure is scored from 0-3, with higher scores indicating more severe symptoms. A score of ≥ 10 is recommended as a threshold for moderate to severe depression.

The Generalised Anxiety Disorder Assessment (GAD-7) measures symptoms of General Anxiety using 7 items scored from 0-3. Responses are summed to create a total score: a score of ≥ 10 indicates moderate-severe anxiety.

The Flinders Fatigue Scale (FFS) measures how often participants have felt bothered by fatigue, with 7 items where higher scores indicate worse fatigue. Six items are scored from 0-4, whereas item 5 includes a checklist which is scored from 0-7. Responses are summed to create a total score of 0-31. A score of ≥ 16 indicates moderate to severe (≥ 21=severe) fatigue.

The Breast Cancer Eight Symptom Scale (BESS) includes 3 subscales: this study will use the vasomotor symptoms and musculoskeletal pain subscales. These subscales include 3 items, scored from 1-3. Scores are summed, multiplied by the number of items in the subscale, and then divided by the number of questions answered, with higher scores indicating worse symptoms.

The consensus sleep diary will be to collect self-reported data about variations in sleep for each participant. These will be completed daily (to reflect the previous night's sleep) for one week at a time. Sleep diary data will include SE, sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TIB), time in bed (TIB), and number of night-time awakenings. All participants (intervention and control group) will complete a baseline sleep diary for one week prior to the intervention period, then complete sleep diaries throughout the 4-week intervention period.

2.7 Analytic approach

Participants demographics and clinical characteristics will first be presented. Descriptive data will be presented for each outcome measure (MARS-5, SCI, GAD-7, PHQ-9, FFS and BESS subscales) and sleep diary variables at each of the 3 timepoints (baseline, post-intervention, and 12-week follow-up).

Hypotheses will be tested using a 2x3 mixed factorial ANOVA. Between-subjects factor will be group (intervention or control), and within-subjects factor will be timepoint (baseline, post-intervention, and 12-week follow-up). We will examine the main effect of group, timepoint and interaction of group and timepoint. If a significant main effect is found, subsequent comparisons will be made applying Bonferroni correction.

3. Discussion

3.1. Study strengths and limitations

When taken as prescribed, ET is successful in reducing the risk of BC recurrence (EBCTCG, 2011). However, suboptimal adherence and persistence are an issue with this medication. To date, efforts to improve ET adherence have had little success, mostly focusing on patient education or reminders to reduce the risk of forgetting medication (Heiney, Ekinci). Side effects have been identified as a consistent predictor of ET nonadherence (Moon et al., 2019; Cahir et al., 2015; Pan et al., 2018), and are more amenable to change than demographic or clinical predictors. However, a recent systematic review (Fleming et al., 2022) reported a lack of consensus on the influence of specific side effects on ET nonadherence, which inhibits the identification of appropriate, targeted intervention strategies. This pilot study will explore the influence of a targeted intervention for sleep problems (CBT-I) on self-reported ET adherence in a sample of BC survivors.

Previous efforts to improve ET adherence have focused mostly on reminders or patient education, with little success (Ekinci et al., 2018; Heiney et al., 2019). However, recent studies report that participants express a desire for support with self-management of side effects (Arch et al., 2022; Hall et al., 2022; Jacobs et al., 2022). Jacobs et al. (2021) reported that participants found sessions focused on self-management of ET side effects such as sleep difficulties, hot flashes, and pain most useful. However, to the best of our knowledge, no studies have attempted to enhance adherence by targeting specific side effects. The current study will therefore directly address a perceived lack of support with side effects expressed by BC survivors (Peddie et al., 2021), and address a gap in the literature by investigating a specific, targeted intervention which may improve ET adherence.

Sleep problems are one of the most common ET side effects (Colleoni et al., 2018; Boldyrev et al., 2021), and have been associated with fatigue, musculoskeletal pain, and vasomotor symptoms (Desai et al., 2017; Leysen et al., 2019). Therefore, insomnia is a prevalent,

transdiagnostic side effect which may present an appropriate target for intervention to relieve overall side effect burden and improve ET adherence. CBT-I is considered the gold standard gold-standard treatment for insomnia (Ma et al., 2021), and has been effective in this population before in reducing not only sleep, but also depression, anxiety, and fatigue (D'arico et al., 2016).

The current study will administer CBT-I in groups of approximately 5 participants, through videoconferencing. A recent meta-analysis found no significant difference between remotely-delivered and conventional face-to-face CBT-I and reported that remotely-delivered CBT-I may be slightly more efficacious in comparison to in-person treatment (Ma et al., 2021). This format also has the advantage of widening accessibility, removing the financial and practical burden of travelling to in-person sessions. Delivering the intervention using a group (rather than individual) format presents a time-efficient and cost-effective intervention (Garland et al., 2022), and also addresses preferences expressed by BC patients to receive support with side effects in a group setting, so that they can learn from their peers' experiences (Jacobs et al., 2020). Despite being the gold-standard treatment for insomnia, clinician and patient-level barriers have limited access to this intervention (Koffel et al., 2018; Savard et al., 2021). The mode of delivery utilised in the current study therefore widens accessibility of the intervention. Furthermore, A recent systematic review by Peddie et al. (2021) reported that BC survivors showed high motivation to continue treatment, and willingness to make lifestyle changes to reduce the burden of side effects and persevere with ET. This willingness to try different strategies to reduce side effect burden indicates that they may be receptive to behavioural intervention such as CBT-I.

In addition to the mode of delivery of intervention, the design of the current study presents another strength. This study uses a repeated measures waitlist control, which is ethical as we will not be denying treatment to any participants. However, this could also be representative of real-world health services where patients frequently face extended waiting times (Garland et al., 2021; Koffel et al., 2018). A waitlist control design has been questioned due to the possibility of 'waiting effect' where participants may wait to change their behaviours until they receive an intervention, therefore delaying improvements, which is a potential ethical concern (Garland et al., 2021). However, insomnia tends to exist as a chronic, persistent issue in cancer patients, meaning participants are unlikely to improve without appropriate treatment (Savard et al., 2011).

3.2. Conclusions

The outcomes of this study will improve our understanding of potential targeted intervention strategies to reduce ET nonadherence, addressing a significant gap in the existing ET adherence literature (Fleming et al., 2022). By exploring the influence of improved sleep on self-reported nonadherence, we will investigate if sleep may be an effective target for intervention, and the potential for improving sleep to reduce overall side effect burden in BC survivors. If successful, these results will support the use of remote CBT-I to efficiently treat insomnia (a prevalent, burdensome issue among BC survivors), improve ET adherence, and potentially improve long-term BC outcomes in future.

References

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Informed consent form

University of Strathclyde: UEC23/09

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Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Feel free to contact us if you have any concerns, or you would like more information.

Who is conducting the research?

The research is being carried out as part of a PhD project within the Sleep Research Unit of Strathclyde University, supervised by Dr Leanne Fleming, Dr Megan Crawford, and Dr Iain MacPherson.

What is the purpose of the study?

The broad aim of this study is to test whether a cognitive behavioural treatment for insomnia helps improve adherence to hormone therapy medication in breast cancer survivors.

Why have I been invited?

We are contacting you as you previously took part in an online survey which was the first part of this PhD research project, and indicated you may be interested in future studies by leaving your email address. If you no longer wish to participate in research studies on this topic, please feel free to disregard this information sheet and accept our thanks for your previous participation. You have been invited to take part as you reported that you are prescribed hormone therapy medication and have also reported problems with your sleep.

Who can take part in the study?

People meeting the following criteria may be eligible to take part: aged 18 or over, prescribed hormone therapy treatment for breast cancer, problems with sleep, find it difficult to take hormone

therapy medication as prescribed, speak English, and have access to videoconferencing equipment/software.

Due to the nature of the study, people would be ineligible to participate if they: are currently pregnant or breastfeeding, undertake shift work (i.e., nightshift), have received chemotherapy or radiotherapy within the past 4 weeks (or will be receiving these treatments in the future), have trouble with substance misuse (such as alcohol or drugs), or an unstable mental health condition which could interfere with the study or make participation unsafe.

Do I have to take part?

No, you do not have to take part. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

What does taking part involve?

Once you have agreed to participate in the study, we will ask you to sign a consent form. There are 5 stages of this research study.

Stage 1: Screening First, we will conduct a screening evaluation via a video call using Zoom. During this screening, we will ask you some questions about your current physical and mental health, and your sleep. These questions may be of a sensitive nature, and you do not have to answer questions if you do not want to. That screening will take about 45-60 minutes.

Stage 2 Baseline assessment: We will ask you to complete a baseline assessment through an online questionnaire. This will ask some questions about your mental and physical health, your sleep, and how you take your hormone therapy medication. This will take about 15-20 minutes. We will also ask you to complete a daily sleep diary for one week. It will take you around 5 minutes to complete a diary entry each morning. Completing the diary before you start the study is routine procedure and provides us with a final check that you meet all of our study criteria. If we determine that you do not meet criteria for our study, we will have to exclude you from the study. If that is the case, we will provide you with some general information about how to improve your sleep.

Stage 3: Randomisation: If you eligible to take part in the study, you will be randomly allocated to one of two groups. This will not affect the treatment you receive, it will only affect whether you are in the group which receives the treatment first or second. Both groups will complete a series of questionnaires, and keep a diary of their sleep to record any changes over time. If you are assigned

to the second group, you will receive the treatment after 12 weeks. Depending on the group participants are randomised to, participation will last either 12 weeks or 24 weeks and participants will not know until they have consented how long participation will last for. Random allocation means neither you, nor the research team has control over which group you are assigned to.

Stage 4: Treatment and follow-up assessments:

The study will involve 4 sessions of cognitive behavioural therapy for insomnia, keeping a diary with some details about your sleep, and completing a series of questionnaires at different timepoints. Sessions will be delivered weekly for 4 weeks. These will last 45-60 minutes. The sessions will be delivered in groups, meaning there will be around 5 people in each session receiving the treatment. This will be delivered through video calls on Zoom. A member of the research team will email you an invitation to these meetings and contact you to confirm you are able to join.

During the 4-week intervention period, both the group receiving the intervention and the waitlist group will keep a diary of their sleep so that we can observe any changes over time. We will ask you to complete the same questionnaires as in the baseline assessment, 4 weeks after the baseline questionnaire, and 8 weeks after this. If you are assigned to the second group (meaning you receive the intervention after 12 weeks), you will be asked to keep a sleep diary again during the treatment, complete the questionnaires again after receiving the treatment, and again 8 weeks after this. The purpose of this to assess any changes to your scores over time.

Stage 5: Participant feedback

When you complete the questionnaires 8 weeks after finishing the treatment, you will be invited to take part in an exit interview to discuss your experience and things you found especially helpful/unhelpful about the intervention. You can opt out of this if you choose to. There will also be some open-ended questions in the post-treatment assessment where you can leave written feedback if you would like to.

What happens to the information?

The data are held in accordance with the Data Protection Act, which means that we keep it safely. If you decide to be in this study, the study researchers will gather information that identifies you, and about your personal health. All information will be kept on the University of Strathclyde's secure server (Strathcloud), in password-protected files, and only the study team has access to that folder.

The raw data from this study will be made available as "open data" through a research data

repository. This will not include any identifiable information (e.g., your name, date of birth, or email address). This means the de-identified study data will be publicly available and may be used for purposes not related to this study.

Identifiable information (e.g., name, date of birth, address): Information that might directly identify you, such as your name and address will be collected. This information will never be kept in the same place as the information about your health. Identifiable information will be kept for the length of the study and a fixed period afterwards (no more than 3 months). This is so we can contact you if we have any questions about your participation in the study. After that time, it will be confidentially destroyed.

Keeping the identifying and health information separate: All of your health information (e.g., about your sleep and mental health) will not be linked to your identifying information (e.g., your name). We will ensure this by assigning you a unique study ID. This is a process called de-identifying the data and means that personal information that could reasonably identify you will be removed or changed before data is shared with other researchers or the results are made public. A file that identifies you to your study ID, will be kept secure, separate from the rest of your data, and available only to the research team. Any information that can identify you will remain confidential.

Sensitive information: In cases, where you disclose information about suicidal ideation or physical/sexual abuse to you or others, the chief investigator will be obliged to contact the respective authorities (e.g., local mental health crisis team), even if you do not give consent for us to do so.

What if I withdraw: You can withdraw from the study at any time. If you choose to withdraw, we will ask your reason(s) why, so that we can better understand the experience of the participants. However, you do not have to give a reason if you do not want to. If you withdraw during the study, the data collected from you can be removed from the study records. If you wish to withdraw your data after completing the study, it can be removed from study records within 4 weeks after you have finished. At this point, the data from all participants will be assessed together, therefore individual data cannot be removed. However, no personal/identifiable data will be included the final report.

What are the possible benefits of taking part?

By taking part in this research, you will be providing valuable information regarding the treatment of insomnia in people who are prescribed hormone therapy. This will help us to investigate if is feasible to deliver this treatment on a larger scale study to people prescribed hormone therapy. While we cannot guarantee that you will experience improvements, we hope that you will see some changes in your sleep and your mental health.

What are the possible risks of taking part in the study?

We do not anticipate any serious risks associated with participation in this study. Some of the minor risks that we anticipate are:

- As you make changes to your sleep behaviours, you might experience side effects such as: fatigue, extreme sleepiness, reduced motivation/energy, irritability, and changes to hunger/appetite. These have been found to subside as treatment goes on. However, if any of these symptoms worsen, we advise you abstain from driving or operating heavy machinery and contact your health care provider if you become concerned.
- The questions asked during the screening evaluation might be personal and sensitive (for example about your current mood). You may stop the screening interview at any time.

What if there is a problem?

If you have any questions or concerns related to the study or the treatment, feel free to contact the research team using the contact information at the end of this form. Any changes in your health that you are concerned with should be shared with your GP.

Who has reviewed the study?

This study has been reviewed by the University of Strathclyde ethics committee.

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If you have any questions/concerns, during or after the research, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
University of Strathclyde
Graham Hills Building
50 George Street
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G1 1QE

Email: ethics@strath.ac.uk

Contact details for support organisations:

If you are worried about your own responses to the questions of this study, or if you are feeling distressed, we recommend that you contact your GP or one of the support organisations listed below.

· Breast Cancer Now
Free confidential phone and web-based service providing support and information from breast cancer nurses for people who have been diagnosed with breast cancer throughout the United Kingdom.
Weekdays: Monday to Friday — 9am to 4pm
Weekend: Saturdays — 9am to 1pm
Contact: 0808 800 6000
https://breastcancernow.org

· Local GP
Visit your local GP to discuss any issues you may be concerned about and for information of available local support services.
www.nhs.uk/service-search

· NHS 24
If you need urgent health advice when your GP Practice is closed.
Contact: 111
http://www.nhs24.scot/

· Samaritans
Free confidential phone and web-based service providing emotional support to anyone in emotional distress, struggling to cope, or at risk of suicide throughout the United Kingdom and Ireland.
This is a 24-hour service.
Contact: 116 123
www.samaritans.org

· Breathing Space
Free confidential phone and web-based service for people experiencing low mood, depression or anxiety.
Weekdays: Monday – Thursday 6pm – 2am
Weekend: Friday 6pm – Monday 6am
Contact: 0800 83 85 87
www.breathingspace.scot

· NHS Website

Free self-help tips on dealing with insomnia:
https://www.nhs.uk/conditions/insomnia/

Free self-help tips on dealing with fatigue:
https://www.nhs.uk/live-well/sleep-and-tiredness/self-help-tips-to-fight-fatigue/

Consent Form

Name of department: School of Psychological Sciences and Health
Title of the study:

- I confirm that I have read and understood the Participant Information Sheet for the above project and the researcher has answered any queries to my satisfaction.

- I confirm that I have read and understood the Privacy Notice for Participants in Research Projects and understand how my personal information will be used and what will happen to it (i.e. how it will be stored and for how long).

- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, up to the point of completion, without having to give a reason and without any consequences.

- I understand that anonymised data (i.e. data that do not identify me personally) cannot be withdrawn once it has been analysed.

- I understand that any information recorded in the research will remain confidential and no

information that identifies me will be made publicly available.

- I consent to being a participant in the project.

- Yes
- No