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Research Protocol: Online guided self-help intervention for sexual distress following sexual assault: A single case experimental study

PROTOCOL

Title: Online guided self-help intervention for sexual distress following sexual assault: A single case experimental study

Short Title: Guided Self Help Following Sexual Assault: SCED

IRAS Project ID: 313482

Sponsor:
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Study Synopsis

Full Title	Online guided self-help intervention for sexual distress following sexual assault: A single case experimental study
Short Title	Guided self-help following sexual assault - SCED
Protocol version number and date	V2 250722
Study duration	10 months
Study design	Single Case Experimental Design
Sponsor	Royal Holloway, University of London
Chief Investigator	Kimberley Khoo
IRAS Project ID	**313482**
Primary objective	To test the acceptability and feasibility of an online guided self-help intervention by female survivors of sexual assault who experience sexual distress
Secondary objective	To gain an initial indicator on the effectiveness of the intervention
Number of subject	6
Main inclusion criteria	Cis-female over the age of 18 with an experience of sexual assault that occurred over 12 months ago
Statistical methodology and analysis	Descriptive statistics, visual analysis, reliable change index.

1. Background & Aims of the project

1.1 Need for research in this area

Sexual assault (SA) is associated with enduring negative impacts, including interpersonal, psychological and physical difficulties (Maniglio, 2009; Chen et al., 2010). SA survivors develop a different relationship with sex (O'Callaghan et al., 2018) and report less interest in sex, reduced desire, fear of sex, arousal dysfunction and painful sex (Norris & Feldman-Summers, 1981; Weaver, 2009). They also experience high levels of shame, self-blame and decreased self-compassion and attachment-based difficulties (Hamrick & Owen, 2019).

Despite the prevalence of these difficulties, there is limited research identifying treatment. Systematic reviews investigating the effectiveness of psychological interventions in SA survivors do not mention sexual distress, suggesting that interventions are limited or do not consider sexual distress (Regehr et al., 2013; Parcesepe et al., 2015). Instead, they target generic distress related to trauma. Evidence from a meta-analysis suggests that psychological treatments for post-traumatic stress disorder following SA had no effect on sexual problems (O'Driscoll & Flanagan, 2015). On the other hand, traditional psychosexual therapy that aim to alleviate sexual distress does not consider the experience of SA trauma symptoms and how they may interact with standard psychosexual approaches (Althof et al., 2005). Meston and colleagues (2013) found that standard psychosexual therapy developed to alleviate sexual difficulties had inconsistent results among women with a history of SA, suggesting precedence for developing specific psychosexual intervention for SA survivors. Few studies explored specific interventions for sexual distress experienced by SA survivors; however, most of these studies do not adopt a formal model or follow a standard protocol (Gerwitz-Meydan, 2020).

This study proposes an online four-session guided self-help psychoeducational program for survivors of SA. Online guided-self-help is the chosen modality as it widens access to treatment in a population who may experience shame and stigma regarding help-seeking (Levin et al., 2018). Previous studies, such as a pilot RCT found online guided self-help effective in improving sexual functioning in women with vaginismus (Zarski et al., 2017). A treatment protocol for Internet-based guided self-help has already been developed for sexual pain but not for sexual distress after SA (Zarski et al., 2018). This intervention aims to normalise and build women's confidence on getting back to sex after experiencing SA. The objective is to reduce shame, self-criticism, sexual distress and improve sexual well-being. By exploring an individual's difficulties through a normalising framework, the intervention aims to increase their awareness of their difficulties and build confidence, skill and motivation to alleviate sexual distress. As this is a novel intervention, the study adopts a single-case experimental design (Morley, 2017). It aims to test the acceptability and feasibility and potential effectiveness of the intervention.

To our knowledge, no research projects have developed guided self-help materials for female survivors of sexual abuse targeting sexual distress. The project has taken guidance from experts by experience to develop materials collaboratively. Clinical psychologists from Bart's NHS Trust Sexual Wellbeing Service, where similar materials have been used in a group setting have also provided feedback.

1.2 Aims

- To investigate the feasibility and acceptability of a 4-session guided self-help psychosexual intervention for survivors of sexual abuse
- Initial indicator of effectiveness in reducing sexual distress

- Improving sexual satisfaction– specifically confidence in practicing strategies that will improve their relationship and experience of sex

1.3 Study objectives

Primary objectives

a. The objective of the study is to investigate the feasibility and acceptability of a 4-session guided self-help intervention for female survivors of sexual assault to gather an initial indicator of effectiveness in reducing sexual distress.

b. Is the intervention viewed as acceptable by female survivors of sexual assault? We will be defining 'acceptability' as how willing participants are to use the materials and its content (Bowen et al., 2009).

Secondary objectives

The secondary outcomes are whether the study suggest the intervention is effective. Is there an initial indicator that the intervention effective? Effectiveness is measured by reduction in the measure of sexual distress and improvement of sexual satisfaction – specifically confidence and motivation in practicing strategies that will improve their experience of sex.

2. Methods

2.1 Study design

The study adopts a single-case experimental design (SCED). This study design is helpful in testing the novelty and feasibility of an intervention.

Potential participants will be invited to follow a link to a Qualtrics survey. The Qualtrics survey provides detailed information about the study. Participants will undergo screening for eligibility and risk via Qualtrics. Should individuals wish to participate and are eligible, they can give informed consent by reading a set of statements on Qualtrics relating to the study

information. Eligible participants will fill in questionnaires such as the FSDI, FSFI, SCSS-S, at this point. Participants will undergo a baseline period known as phase A, varying between 5- 14 days where they will fill in visual analogue scales daily. The number of days participants will be in baseline will be randomly allocated by a randomiser. There are 6 visual analogue scales measuring shame, guilt, self-criticism, self-compassion, normalising and motivation.

After phase A, participants will undergo phase B, which is a 4-week intervention period where participants go through 1 module of the guided-self-help materials each week and complete the same visual analogue scales from baseline every day. After phase B, participants will be invited for a follow-up appointment one month after the intervention to fill in the FSDS, FSFI, client satisfaction questionnaire (Larsen et al., 1979) and feedback form developed with experts by experience.

2.2 Recruitment and participant screening

The study will be advertised through Barts NHS Trust Sexual Wellbeing Service with information put on leaflets circulated within the clinic. Clinicians may also provide an information sheet to clients with a weblink the study details and screening questionnaire.

Additional recruitment will be done on My Body Back, an organisation who works with women with experience of sexual assault, in London and Glasgow. My Body Back will advertise the study on its website and at its events, providing a web link to the study details and initial screening questionnaire. The intervention will be offered whilst women are on the waiting list. They will not lose their place on the waiting list if they take part.

General social media advertising will also be done through different charities and communities who work with female survivors of sexual assault. Potential participants will be encouraged to take some time to think about whether or not they would like to participate. Individuals will be

informed that participation is on a voluntary basis and consent can be withdrawn at any time. They will also not lose their place on the waiting list for services. Statistical power analyses have been underdeveloped for SCED (Arntz et al., 2013). For a SCED, only 1 participant is required for analysis but, Lanovaz & Rapp (2015) suggest a '3 point guideline' as the minimum requirement for control of study design. Having more than 3 participants will also improve the generalization of findings (Kratochwill et al., 2013). Considering this and to account for attrition, we aim to recruit 20 participants with a minimum sample size of 6 participants.

Should individuals wish to participate they will be invited to follow a link to a Qualtrics survey to initial screening questions to check for eligibility. Prior to completing the screening questionnaire participants will be provided the following text 'Thank you for being interested in this study. The next step is to complete a screening questionnaire. This questionnaire aims to determine if this study would be appropriate for you. The questionnaire does not ask you direct questions about your experience of sexual assault; however, it could potentially elicit difficult emotions. Please keep this in mind if you decide to proceed with the questionnaire as your wellbeing is a priority. There are no consequences if you decide to opt out of participating in this study. At the end of the questionnaire, we have included the chief investigator's email along with signposting information about services you can contact if you require additional support. Thank you for your time.' These questions will confirm if participants are experiencing difficulties with sex, have been sexually assaulted over 12 months ago, if they are currently receiving other forms of psychological intervention and have access to a smart phone or computer to access materials. The Patient Health Questionnaire 2-item (PHQ-2) and Generalised Anxiety Disorder 2-item (GAD-2) are incorporated in the screening questionnaire not to screen for depression and/or anxiety but provide an indication of participant demographic. There will also be a risk screen based on the PHQ-9 "Over the past two weeks,

how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?" - Not at all, Several days, More than half of the days, Nearly every day and a question about support from family and friends. Those who rate themselves as experiencing thoughts of death or self-harm and do not indicate that they have social support or psychological support will not be eligible to participate (see section. Those ineligible to participate will be redirected to a debrief page, 'debrief page for Qualtrics', which will include an explanation of why this is the case and signposting to relevant resources. They will also be provided with the chief investigators email or given the option to leave their telephone number for the chief investigator to call them and discuss why they were not appropriate for the study. Eligible participants will provide informed consent by reading statements relating to the study information and writing their initials if they consent to each statement. This includes confirming they have read the information, understanding participation is voluntary and being able to withdraw from the research at any time. Participants are asked to provide their GP details as part of informed consent. Participants will be informed that their GP will not be notified about their involvement in the study or provided any information contributed whilst participating. We will only contact their GP if there are identified risks. These risks include increased self-harm behaviour, increased suicidal risk or significant deterioration of mental health. Under these circumstances, confidentiality may be breached and, the chief investigator may contact the participants GP. As there is little to no professional contact as part of the study design, the chief investigator will only be made aware of increased risk if the participant raises it to the chief investigator by email.

Eligible participants who provide informed consent will have a screening call with the lead investigator, Kimberley Khoo to verify risk, confirm consent and answer any additional questions about the study. As the intervention is online, we hope that having a call at the

beginning will increase engagement through the study. After the screening call, participants will be asked to fill in a participant demographic sheet and provide their name, age, ethnicity, email address (for contact), region in the UK they live in, employment status and if they are currently or have previously accessed psychological therapy and what type of therapy they received. In addition, participants will complete the Female Sexual Distress scale – Revised (FSDS-R; Derogatis et al., 2002), Female Sexual Function Index (FSFI; Rosen et al., 2000) and State Self Compassion Questionnaire (SSCS-S; Neff et al., 2021).

2.2.1 Inclusion criteria

- Cis female experiencing sexual distress with a history of sexual trauma
- Willingness to complete guided self help
- Aged 18 and above
- Ability to read English to provide consent and meaningfully engage with the self-help materials
- Ability to access online guided self-help material through a computer or phone
- Not currently experiencing severe acute mental health problems
- Not currently suicidal or self-harming

2.2.2 Exclusion criteria

Participants will be excluded if they are experiencing severe acute mental health difficulties, sexual assault occurring within the last 12 months or currently experiencing more than fleeting suicidal thoughts or engaging in severe self-harming (individuals who have been sexually assaulted are likely to experience suicidal thoughts or self-harm behaviours, individuals with fleeting suicidal thoughts or superficial self-harm with strong protective factors may be

included however, since there is no contact with mental health professionals during the intervention unless participants reach out for triage, it is difficult to assess risk and participants have to be excluded if they do not have social support systems of are currently accessing psychological support*).*

2.2.3 Criteria for premature withdrawal

Participants will be able to withdraw from the study at any point by informing the chief investigator

2.3 Material provided to participants.

2.3.1 *Intervention*

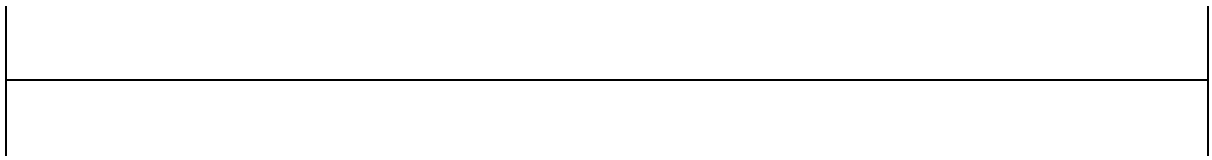
4 Sessions of guided self-help will be shared with the participants. These will be in the form of handout and video recordings that participant access through Qualtrics. The intervention is based on research on sexual trauma, psychosexual difficulties and materials developed by Bart's NHS Foundation Trust Sexual Wellbeing Service. It has been made in collaboration with clinicians within the service, experts by experience and the chief investigator. The intervention handout and scripts is in the document titled 'Intervention Manual V1'. Within the document there are scripts for each session which are read out in the video recordings. The handouts depict the visual images for the video and the materials provided to participant. Additional handouts for each session can be found in the appendix.

2.3.2 *Visual Analogue Scales*

Visual analogue scales are to be completed by participants. Visual analogue scales are scales with two ends where participants will be asked to rate how much they agree or disagree with the following statements as seen in figure 1 below:

- **Shame**
    - I feel shame when I experience sexual distress
- **Guilt**
    - I have feelings of guilt when I experience sexual distress
- **Self-criticism**
    - When I experience sexual distress, how often do I blame myself or my body?
- **Compassion**
    - When I experience sexual distress, I try to show myself warmth and comfort through my difficulties
- **Normalising**
    - I understand my difficulties in the context of my experience
- **Motivation**
    - I am motivated to put things in place to improve/ address the difficulties in my sex life

Figure 1: VAS Example



Disagree agree

2.3.3 Female Sexual Distress scale – Revised (FSDS-R; Derogatis et al., 2002)

The FSDS-R is used to assess distress related to sex in women (Derogatis et al., 2002). This 13-item self-report questionnaire is scored has four points, (0: never; 1: rarely; 2: occasionally; 3: frequently). In multiple studies involving more than 500 women, the FSDS-R has shown

high internal consistency (Dergostis et al., 2008) for women with and without sexual difficulties. A validation study demonstrate that the measure has discriminant and content validity (Dergostis et al., 2008). The FSDS-R is completed upon recruitment and at the 1 month follow up.

2.3.4 Female Sexual Function Index (FSFI; Rosen et al., 2000)

The FSFI is a 19-item questionnaire that measures six domains: desire, arousal, lubrication, orgasm, satisfaction and pain. The questionnaire has been used in different clinical trials and epidemiological studies and have shown to have high test-rested reliability and validity, it is scored from 1 to 5 with different response options. The FSFI is completed upon recruitment and at the 1 month follow up.

2.3.5 State Self Compassion Questionnaire (SSCS-S; Neff et al., 2021)

The SSCS-S is a 6-item questionnaire scored on a 5-point scale from 1 (not very true for me) to 5 (very true for me). In one study, Neff et al (2021) reports the SSCS-S had a strong correlation (r=.96) to the long version of the state self-compassion questionnaire and showed good reliability (α = .86). Another study found strong construct validity. The SCSS-S is completed upon recruitment and at the 1 month follow up.

2.3.6 Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979)

The CSQ is an 8-item questionnaire scored on a 4-point scale and will be provided to participants at follow up to ask the acceptability and satisfaction towards the intervention. The questionnaire has high construct validity and internal consistency. Permission has been seeked to adapt the questionnaire to focus on satisfaction for the intervention instead of service satisfaction. Awaiting response. The questionnaire is only used at follow up.

2.3.7 Feedback Form

A short qualitative feedback form will be provided to participants. This form has been developed with experts by experience and will have open ended questions for participants to provide more detailed feedback about the intervention. The questionnaire is only used at follow up.

2.4 Expert by experience (EbE) involvement

Survivors of sexual assault were consulted during the development of this study to provide feedback on the session materials and measures used throughout the study. EbE's helped develop the visual analogue scales as well as provide feedback on the intervention scripts and handouts which were implement in the final version.

3. Study procedure

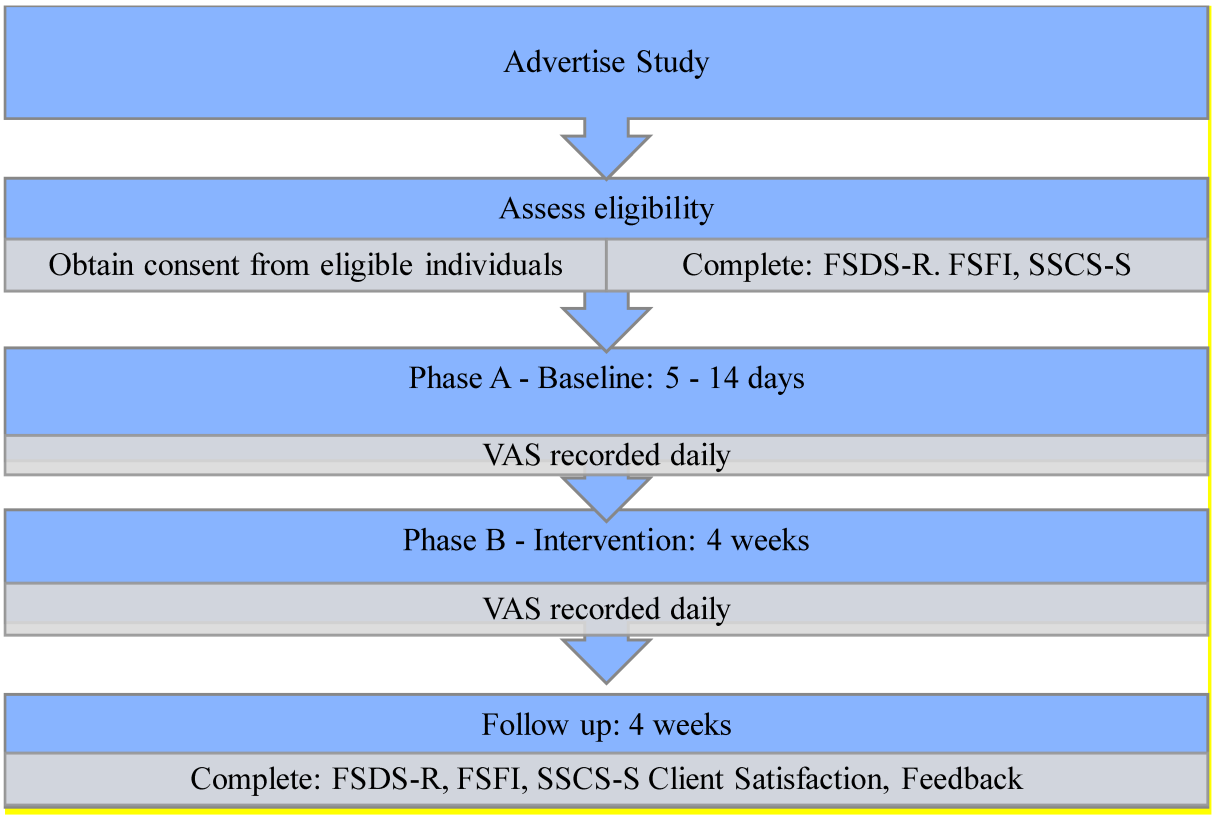


Figure 1. Flow chart of study procedures

The study is conducted via Qualtrics, an online survey platform. A survey link will be emailed to participants for them to complete in their own environment. This allows the study to be completed anywhere. The survey will be live for 5 months of data collection before being taken offline. Participants will also be sent handouts of each week's intervention. After completing the screening questionnaire, eligible participants will be asked to fill in the FSDS-R, FSFI and SCSS. These questionnaires are filled in once weekly during phase A and B.

During Phase A which varies between 5- 14 days, participants will be sent Qualtrics links to where fill in visual analogue scales daily. The number of days' participants will be in baseline will be randomly allocated. There are 6 visual analogue scales that measure shame, guilt, self-criticism, self-compassion, normalising and motivation.

During phase B participants go through 1 module of the guided-self-help materials each week and complete the same visual analogue scales from baseline every day. After phase B. participants will be invited for a follow-up appointment one month after the intervention to fill in the FSDS, FSFI, SSCS-S client satisfaction questionnaire and feedback form developed with experts by experience.

3.1 Informed consent procedures

Participants will be asked for informed consent via the Qualtrics survey which states they are aware of the consequence of taking part in the study and understand the information sheet provided to them. Participants are also provided with the email address of the Chief Investigator who they can reach out to with any queries before or after taking part. The study advertisement will provide brief information about the study. If interested, women will be directed to the online weblink to read through more detailed study information. It will be clearly stated that participation is voluntary and participants may drop out at any time and withdraw consent even after completing the project. It will be clearly stated that the intervention is

provided through online self-help that individuals work through on their own and does not entail personal support from a psychology team. Through a weblink, participant will tick boxes to provide informed consent, confirming they consent and understand these terms and asked to write their name as a way of providing consent.

3.2 Data collection methods

Data collection will be conducted through Qualtrics. During phase A and B, data is collected daily.

3.3 Statistical analysis of data

Descriptive statistics will be completed for demographic information. Visual analysis will be performed for daily VAS ratings to evaluate the reliability of treatment effects between the baseline and treatment phases. To investigate if there is pre-and post-difference between scores a reliable change index (RCI) will be calculated for each measure using Jacobson & Traux (1991) to test if changes are statistically significant. Tau-U test will be used on outcomes to analyse non-overlap of intervention scores. Guidance and procedures will be followed from What Works Clearing House (Kratochwill et al., 2010**).**

3.4 Risk and burdens

Participants will not be asked to disclose or directly think about their experience of sexual assault. The materials developed is to provide psychoeducation and build self-compassion through a normalising framework that will ask participants to reflect on their sex lives and how past experiences can affect their experience of sex. This may be difficult and upsetting for some participants. In order to counter this risk, information and signposting regarding crisis psychological support will be provided to participants at the beginning and end of each self-

help resource throughout the intervention. Participants will have access to Jane Vosper, Clinical Psychologist and two other clinicians at the Barts NHS Trust Sexual Wellbeing Service during the length of project for triage if adverse reactions are identified. Participants will be able to email the lead investigator and provide consent for the investigator inform Jane to get in touch with them. Participants will be informed they are able to reach the head investigator from 9am to 4pm on weekdays. Outside office hours they will be signposted to other support lines. It will be made clear to participants that besides this one appointment, the researchers cannot provide further advice or medical treatment

Participants should contact their GPs if they have concerns for their mental or physical health. Participants are required to provide GP details when providing informed consent. The GP will not be notified of the participants involvement in the study. We will only contact their GP if there are identified risk such as severe self-harming, suicidal risk or a significant deterioration in mental health. Under these circumstances, confidentiality may be breached. As the study is utilising a self-help intervention, there will be an expectation that participants will be able to make practical decisions about their readiness to begin the intervention, their ability to cope and access additional support if required. This expectation will be clearly outlined in the participant information sheet and consent form.

Participants will be assessed on their risk to self during screening and receive a follow-up screening call from the head investigator. Participants who disclose high risk who are not accessing mental health services will be excluded from participating to prevent further distress that may be triggered during the intervention. Participants will be made aware that the researcher cannot provide advice or medical treatment and that they should contact their GP as a first step if they have concerns regarding their mental or physical health. Participants will be

able to provide details of their GP who can be informed that they are taking part in the study, however this is not compulsory.

Overall, the potential benefits of this study are thought to outweigh the risk. The intervention content is based on compassion-focused therapy and content that is already used by Barts NHS trust Sexual Wellbeing Service to improve sexual wellbeing. Participants can access the materials while waiting to be seen by these services, both of which have a long wait time.

3.5 Study end definition

The study will be considered finished when the statistical analysis has been conducted and completed as seen as appropriate.

3.6 Pause criteria

If more than 4 participants within eight weeks get in contact with the chief investigator requesting a 1:1 support session provided by clinicians at Bart's NHS Foundation Trust Sexual Wellbeing Clinic due to adverse effects from the intervention, the study may be paused. This number was decided as it represents 25% of our recruitment goal. The study would have to be paused due to clinician availability. If this occurs, the researchers will have a meeting with the service lead at Bart's NHS foundation trust Sexual Well-Being Clinic. This meeting will discuss the feasibility of continuing the study and potentially pausing the study and changing the recruitment strategy.

4. Assessment of safety

As the study is utilising a self-help intervention, there will be an expectation that participants will be able to make practical decisions about their readiness to begin the intervention, their ability to cope and access additional support if required. This expectation will be clearly outlined in the participant information sheet and consent form. Participants will be able to email the lead investigator and provide consent for the investigator inform Clinicians at Bart's NHS Foundation trust to get in touch with them. Participants will be informed they are able to reach the head investigator from 9am to 4pm on weekdays. Outside office hours they will be signposted to other support lines.

If participants report identified risks, they will be supported through the 1:1 personal support session provided by Bart's NHS Foundation Trust, Sexual Wellbeing Service. However, confidentiality may be breached if the clinicians or the chief investigator are still concerned about risk. The chief investigator will first discuss this with the participant if this occurs. Subsequently, an urgent email (GP Letter V2) will be sent to the participant's GP via NHS email. A phone call will also be made to the GP to ensure the GP is informed.

5. Data security, management and confidentiality

5.1 Data storage, handling and confidentiality

All computerised data will be stores and encrypted on a password protected USB drive that adheres to the NHS confidentiality standards.

Participants will provide email address so that they can be sent links to the self-help materials each week as well as links to questionnaire and prompt emails. Names are only used when giving consent and for demographic information. Participants will then be allocated a participation ID number for reference to fill in questionnaires and not linked to names. A separate key associating the ID number with the participants' names will be stored apart from

the data and destroyed once it is no longer necessary to contact participants or obtain further information about them (e.g., once a journal article is published), this file will be password protected.

All information will be submitted through Qualtrics which is a secure and confidential platform. Data will be downloaded, password protected and kept on a secure USB stick, only accessible to the researcher.

Database containing any personal information will be deleted following the final write-up of the research.

No members of the research team will have access to participants' personal medical records or any clinical data beyond that voluntarily provided by the participants when they choose to participate in the study. This information provided will only be seen by the chief investigator and will be kept securely in a password protected database,

separately to the research data.

Data will be analysed on a personal laptop by the Chief Investigator at Royal Holloway, University of London. All data will be saved on a password protected encrypted USB (approved by RHUL and sponsor) that only the chief investigator has access to. This will not include any personally identifiable data. Data is anonymised and each participant is given a 4-digit participant code using random numbers and letters.

5.2 Data preservation

The research data will be kept in a database (as discussed in A36) which will be retained by Dr Andy Macleod, who is supervising this research on behalf of Royal Holloway, University of London, Data is kept for up to five years, for audit purposes.

This database will contain no personally identifiable information and will be password protected. Only Dr Andy MacLoed will hold the password. Consent forms will be kept for 2 years.

6. Publication of results

The study will be published as a doctoral thesis and may be published in peer reviewed scientific journals or presented in conferences.

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