INFORMATION SHEET FOR PARTICIPANTS

IRAS No: 305830

You will be given a copy of this information sheet.

Title of project:

An Integrated Psychosexual Intervention for Sexual Difficulties in People with Multiple Sclerosis (PIMS): A Feasibility Study

Invitation for participation

We would like to invite you to participate in this research project aimed at developing a psychological intervention for managing sexual difficulties in people with Multiple Sclerosis.

- This study is being sponsored by King's College London and South London and Maudsley NHS Foundation Trust. It is funded by the National Institute for Health Research (NIHR).
- Before you decide whether to take part:
    - it is important for you to understand why the research is being done and what participation will involve
    - please take time to read the following and discuss it with others if you wish
    - contact the study team if you have any questions or would like more information

We are recruiting participants until **January 31st, 2023**.

Why have I been invited?

You have been invited to take part as you have a diagnosis of MS and have reported experiencing challenges related to sex.

You do not need to be in relationship to participate.

In order to ensure you are eligible, you will need to complete a brief screening questionnaire with a member of the research team.

Why are we doing this research?

Sexual challenges can be a hidden and difficult symptom associated with MS – 50-80% of people with MS are affected by this. Previous research has indicated that psychological interventions can be beneficial for managing sexual challenges in

those with MS. However, no interventions have been designed to be used within the NHS.

This initial study aims to assess whether it is possible to conduct a larger main study. To do this, we will collect important information that is needed to design a larger study. This includes questionnaires and interviews with participants.

What will happen if I take part?

For each participant, the study will take 14 weeks. Participation will involve the following:

1. Completing a brief **consent** form – this can be done on Qualtrics, a GDPR compliant survey software.
2. Completing an online **questionnaire** (about 20-30 minutes) about your MS symptoms, mental health, and sexual function/satisfaction. The questionnaire will be on Qualtrics.
3. Being **randomly allocated (like a coin flip) to one of two treatment approaches** by King's Clinical Trail Unit. You will not be able to choose the treatment approach you are assigned to. We do this to ensure results are reliable. Details on each approach is below.
4. Completing the same **questionnaire** (via Qualtrics) at the end of your time participating in the study.
5. Being invited for **one-to-one interviews** via Microsoft Teams (or telephone) with study team members about your experiences during the study. Taking part in the interview is not essential to your participation in the study. This interview is to:
    - Understand your experience of the intervention and study process
    - Hear your feedback on what you found helpful (or not helpful)
    - Gain insight on possible improvements in the future
    - If you participate in the interview, we will be using audio and video recording and transcribing via Microsoft Teams. These recordings/transcriptions will only be accessible by the research team. We may use directs quote from these interviews in our results; these will be de-identified so that no one can know who you are by reading the quotes.

The two treatments are:

1. A single one-to-one session with an MS clinician

You will receive a one-off appointment (15-20 minutes) with a MS healthcare practitioner specifically to discuss the role MS plays in sexual challenges and to determine which treatment options might work best for you.

2. PIMS intervention for sexual challenges in MS

If allocated to this group, you will be asked to participate in 6 self-directed and 2 facilitator led 'modules' (8 in total) targeting different aspects of sex/intimacy in relation to MS over 10 weeks. This is called the **P**sychosexual **I**ntervention for Sexual Difficulties in People with **M**ultiple **S**clerosis (PIMS).

Each of the eight sessions should take no more than 50 minutes.

This treatment group includes a manual, which includes:

- self-guided exercises
- information about the relationship between sex and MS
- ways to manage your emotional and sexual wellbeing

Two of these eight sessions will be done with MS healthcare practitioners, who will be trained to help guide and support you throughout your time in the study. Sessions with MS healthcare practitioners will be approximately 30-minutes.

Both treatment groups are equally important to the research as they will tell us which approach people find best.

All sessions with healthcare practitioners will be provided via your trust's preferred secure video call network or face-to-face, depending on availability and health guidelines.

At the end of the treatment, you may be asked to be interviewed by a researcher to understand your experience with the study. The researcher will be a different person than the MS healthcare practitioner you work with. The interviews will take place over video or over the phone.

Do I have to take part?

No. Participation is completely voluntary. You should only take part if you want to. Choosing not to take part will not disadvantage your or affect your treatment in any way. If you decide to take part, we will ask you to sign a consent form and give you a copy to keep.

What are the possible risks?

- Participation will require some time commitment to attend sessions with healthcare practitioners and work through self-guided material as described above
- It is possible that completing the questionnaires may cause you some distress, but this is rare. If the questions cause you any concerns or upset you, please stop answering the questions and speak to the researcher.
- Some of the questionnaires ask you about your mood. Depending on your responses, the researcher may ask you questions to assess your safety and make appropriate support services available to you if needed.

- This study is being largely run remotely, including sessions with healthcare practitioners. It may be possible for you to have face-to-face sessions with healthcare practitioners if this is mutually agreed. If attending face-to-face sessions, there may be a risk of transmission of COVID-19 from attending a hospital setting.
- Given the topic of the PIMS intervention, the interview may involve discussing intimate issues around sex, relationships, and intimacy which may be distressing. However, you will not be directly asked or required to share personal experiences.

What are the possible benefits?

- All participants will receive treatments that will potentially improve their sexual challenges
- Both groups may benefit from discussing their sexual challenges and treatment options with healthcare practitioners
- We anticipate the results from this study will allow us to:
    - Improve the knowledge of how MS affects sexuality and intimacy
    - Inform healthcare practitioners about how to help people with MS manage their condition
    - Inform future research on sexual challenges in MS

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your:

- NHS number
- Initials
- Name
- Date of birth
- Contact details
- Medical diagnoses

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will only contact your GP about your involvement in the study if we determine that you require additional mental health support. This will occur if you indicate risk of self-harm of suicidal ideation on certain questions in the baseline and follow-up measures. We will first meet with you to discuss this in more detail, and then send your GP a letter. You will get a copy of this letter, along with some resources for general mental health support.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

- You can find out more about how we use your information
- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research
- by asking one of the research team
- by sending an email to the Data Protection Officer, Albert Chan, info-compliance@kcl.ac.uk

Research data will be kept for 10 years after the study has ended.

What will happen with the results?

- We will write to you via email at the end of the research and inform you of the main findings
- Results will be written up for publication in scientific journals and presented at international conferences
- We will hold a public engagement event at the end of the project to share findings with the wider community
- Results will also be disseminated through relevant MS charities and organisations
- Results are due to be shared at the end of 2023.
- Any results will be anonymised so that participants cannot be identified

Who should I contact for further information?

If you have any more questions or require more information about the project, please contact the project manager:

Dr Ashley Brown

Email: ashley.brown@kcl.ac.uk

What if I have further questions, or something goes wrong?

If this project has harmed you in any way or if you wish to make a complaint about the conduct of the project you should first contact the research team at King's College London using the details below for further advice and information. If something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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You can also contact your local PALS service for the place at which you are recruited for this study.