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Developing and assessing the feasibility of a psychosexual treatment for sexual difficulties in people with multiple sclerosis.

Submission date
24/05/2022

Recruitment status
No longer recruiting

Registration date
28/02/2023

Overall study status
Completed

Last Edited
13/03/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Sexual difficulties are one of the key hidden and troubling symptoms of Multiple Sclerosis (MS); they affect up to 50-80% of people with MS and include sexual dysfunctions (e.g., erectile dysfunction), sexual distress (e.g., worry about sex due to pain), and loss of pleasure.

The burden of obtaining treatment for sexual difficulties often falls on the person with MS. NHS support, if available, is usually limited to education and medications. Additionally, healthcare professionals are not always experienced in or comfortable with talking about this subject. The people with MS we spoke to said they wanted sexual difficulties to be discussed routinely in appointments, and for a wider range of sexual difficulty management options to be offered.

A type of psychological intervention used to treat sexual difficulties, called 'psychosexual interventions' show promise in treating MS related sexual difficulties but have not been robustly evaluated. Psychosexual interventions combine education (e.g., knowledge about how common sexual difficulties are in MS), with other elements such as intimacy-specific practices (e.g., learning to focus on pleasurable sensations) and challenging unhelpful beliefs about body image, sexuality, and relationships.

This project will adapt a psychosexual intervention (called PIMS) so that it is appropriate for people with MS. The research will take place at King's College Hospital, Queen Elizabeth Hospital, and Milton Keynes Community Health Services. This will provide preliminary evidence about the feasibility of the intervention and inform a future larger study.

As this is a preliminary trial, the aim is to explore design/delivery and acceptability of the PIMS intervention and outcome measures to staff and participants. This is to gather information to establish if it is worthwhile to run a large randomised controlled trial or if any changes should be made to the intervention and/or trial procedures before running a large trial.

Who can participate?
Adults with Multiple Sclerosis who are experiencing sexual and/or intimacy difficulties and who

receive care at one of the trial sites. They must be willing and able to provide informed consent and be proficient in verbal and written English. Participants cannot be currently receiving other psychotherapy or be in other psychological intervention trials, experience a mental health disorder (e.g., psychosis) or have visual or hearing impairments that would prevent them from engaging in the intervention.

What does the study involve?
Fifty adults with MS experiencing sexual difficulties will be randomised (allocated by chance) to receive either 1) the (P)sychosexual (I)ntervention for Sexual Difficulties in People with (M) ultiple (S)clerosis (PIMS) or 2) a standardised MS psychosexual education package (PSE). NHS healthcare professionals who work with people with MS (e.g., MS specialist nurses, physiotherapists) will be trained to deliver both treatments. The PSE treatment will involve clinicians asking questions about sexual difficulties, discussing treatment, and directing to other resources during a one-off 20-minute appointment. PIMS will be comprised of 8 sessions that will be no more than 50 minutes long. Two of these sessions (session 3 and 7) will be facilitator led and will last approximately 30 minutes.

Participants will complete questionnaires about their mental health and sexual functioning, satisfaction, and communication before and after treatment. We will also conduct interviews with participants to get feedback and better understand their treatment experiences.

What are the possible benefits and risks of participating?
Benefits:
- All participants will receive treatments that will potentially improve their sexual challenges
- Both treatment 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

Risks:
- Participation will require some time commitment to attend sessions with healthcare practitioners and work through self-guided material.
- It is possible that completing the questionnaires (at baseline and follow-up) may cause some distress, but this is rare.
- This study is being largely run remotely, including sessions with healthcare practitioners. It may be possible for participants 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, participants will not be directly asked or required to share personal experiences.

Where is the study run from?
The day-to-day running and management of the project will be at the Health Psychology department King's College London (Guy's Hospital). The recruitment and intervention delivery will be done at our study sites: King's College Hospital, Queen Elizabeth Hospital, and Milton Keynes Community Health Services.

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
Funding to conduct the trial is provided by the National Institute for Health and Care Research (NIHR) (UK) Research for Patient Benefit (RfPB) funding stream.

Who is the main contact?
Dr Ashley Brown, ashley.brown@kcl.ac.uk
Professor Rona Moss-Morris, rona.moss-morris@kcl.ac.uk

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305830

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 305830, CPMS 53293, NIHR202006

Study information

Scientific Title
A randomised controlled feasibility trial comparing an integrated psychosexual intervention for sexual difficulties in people with Multiple Sclerosis to sexual education alone

Acronym
PIMS

Study objectives
The primary aim is to test the feasibility of conducting a larger scale RCT of a newly developed psychosexual intervention for people with Multiple Sclerosis. We will assess the acceptability of the 1) trial methods 2) psychosexual intervention (PIMS), 3 proposed outcome measures for patients receiving PIMS, and 4) HCPs delivery of PIMS.

Parameters for assessing feasibility include: eligibility rates, recruitment rates, follow-up /retention rates, treatment adherence, and satisfaction and acceptability of the novel intervention form both the patients and HCPs view points. Analysis of these variables, including data from a nested qualitative study, will inform the decision to proceed to a definitive trial.

Secondary objectives
1. To explore treatment effects on self-report outcomes to determine that 95% confidence intervals for the effects are consistent with anticipated effects and minimum clinically important differences
2. To estimate key elements that would inform a power calculation to inform a power calculation for an efficacy study

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2022, London - Harrow Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8246; harrow.rec@hra.nhs.uk), ref: 22/LO /0441

Study design

Two-armed parallel groups multicentre randomized controlled feasibility trial with nested qualitative process analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Adults with multiple sclerosis experiencing sexual difficulties

Interventions
Randomisation and blinding
Randomisation will be conducted by an independent clinical trials unit to ensure allocation concealment. Participants will be randomised using an online electronic system to the intervention or control group following a 1:1 ratio using randomly varying block sizes to maintain similar numbers across each group during the period of recruitment. Randomisation will be stratified by centre and three gender groups: 1) cisgender men, 2) cisgender women, and 3) transgender/nonbinary. There is an equal probability of being randomised to the PIMS or PSE arm for groups 1 and 2, and a 100% chance of being randomised to the PIMS treatment group for those in group 3.

Interventions
PIMS Intervention arm:
PIMS is an adapted psychosexual intervention that is primarily self-directed with support from trained MS HCPs. This is a theory based, integrative intervention combining education on primary and secondary MS specific sexual challenges, advice on available treatments for sexual difficulties, and techniques from sex/intimate relationship psychotherapy, acceptance and commitment therapy (ACT), and mindfulness. The purpose of this intervention is to target biological, cognitive, emotional, and behavioural aspects of sexual difficulties for people with MS.
PIMS is comprised of 8 sessions: 6 self-led sessions designed to take approximate 50 minutes and 2 facilitator led sessions (sessions 3 and 7) designed to take approximately 30 minutes. All sessions are supported by a therapy manual.

Psychosexual education (PSE) arm:
This treatment arm will be a one-off 20-minute session with a trained MS clinician. This will involve clinicians asking standardised questions about sexual difficulties, discussing medication (if relevant), and signposting to other resources available online. Education components will be similar to those appearing in the PIMS intervention, without the inclusion of psychological

components (e.g., identifying values). Content will be consistent with the latest NICE guidelines for managing Multiple Sclerosis and recommendations for managing sexual and intimacy challenges put forth by the MS Society and MS Trust. This arm will be acting as an enhanced standard care arm.

Intervention Type
Behavioural

Primary outcome measure
Feasibility will be assessed by collecting descriptive data on recruitment and retention rates and willingness to be randomised according to Consolidated Standards of Reporting Trials (CONSORT) feasibility and pilot trial guidelines. The outcomes will be collected by someone separate to the healthcare practitioners delivering the intervention. We will determine the following:
1. Eligibility and recruitment rates
2. Follow up/retention rates. Proportion of participants who were randomised that completed follow up assessment.
3. Treatment adherence rates
3.1. For both PIMS and PSE arms, we will record attendance at appointments.
3.2. For PIMS arm, we will record adherence to treatment using self-reported completion of activities and time spent on the content for each week
4. Time needed to collect and analyse data
5. Acceptability and satisfaction. This will be evaluated based on constructs identified as being part of a theoretical framework for acceptability that have been developed into an 8-item scale for use in feasibility trials (Sekkhon, Cartwright, and Francis, 2017; 2018; 2022). Items are on 5-point Likert response scales, though scale points differ based on the item. An average acceptability score is generated, with higher scores indicated greater acceptability. Wording of the items have been adapted for this study, as is directed by the scale authors. Participants in the PSE and PIMS arm will both respond to the scale.

We will also assess the acceptability of the four sexuality-related measures (see below) to determine which are most relevant and acceptable to patients. To do this, participants will be asked to 1) rate how well they believe each scale captured their sexual difficulties, and 2) pick which of the 4 scales they found to be the most relevant. This will inform future primary outcome measures.

Secondary outcome measures
At baseline and at 14-week follow up:
1. The Sexual Function Evaluation Questionnaire (SFEQ) will be used to assess level of sexual functioning. We will be calculating both subscales and general scores for use in between-group analyses.
2. The Multiple Sclerosis Intimacy and Sexuality Questionnaire (MSISQ-19) was designed to assess MS-specific sex and intimacy related difficulties. This assesses difficulties arising from three causal levels: 1) disease mechanisms (e.g., loss of mobility), 2) treatment effects and disease symptoms (e.g., muscle spasms, incontinence), and 3) psycho-social factors (e.g., body image difficulties).
3. The Female Sexual Distress Scale-Revised (FSDS-R) will be used to assess general sexual distress. This scale will be used for both male and female participants as it has also been validated in male samples.
4. The New Sexual Satisfaction Scale – Short form (NSSS-S) is a 12-item measure assessing overall sexual satisfaction.

5. Disability using the Guys Neurological Disability Scale
6. Quality of life using the EQ-5D-5L
7. Depression symptoms will be measured via the Patient Health Questionnaire-9 (PHQ-9) and anxiety symptoms will be measured via the Generalised Anxiety Disorders-7 questionnaire (GAD-7). Sum scores will be generated for both measures.
8. For mindfulness, we will use two sub-scales from the Five Facet Mindfulness Questionnaire (FFMQ). An average score will be computed for the two subscales being used for this study.
9. For health economics related to the study, the Adult Service Use Schedule (ADSUS) will collect information on the number of contacts the participant has with a range of primary and secondary health and social care services over a specified period. Service use data will be reported via descriptive statistics; no inferential tests will be performed.

Overall study start date
01/09/2021

Completion date
30/06/2024

Eligibility

Key inclusion criteria
For PwMS in the intervention study:
1. Confirmed diagnosis of Multiple Sclerosis (using McDonalds revised criteria)
2. Attending the neurology clinic at one of the participating research sites
3. Aged ≥18 years
4. Affirmative response to the following question: Are you currently experiencing any sort of sexual or intimacy difficulty?
5. Able and willing to provide informed consent

For facilitators participating in nested qualitative study:
6. Clinical staff at research sites that work with people with Multiple Sclerosis

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
For PwMS in the intervention study
1. Severe visual or hearing impairments which would impact the ability to engage in the

intervention
2. Severe mental health disorder (e.g., psychosis) which would impact the ability to engage in the intervention
3. Currently receiving psychotherapy or are participating in any other psychological intervention trial
4. Insufficient verbal and/or written proficiency in English

For facilitators participating in nested qualitative study:
5. Unable or unwilling to consent to participate in the follow up interviews

Date of first enrolment
01/11/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
Bletchley Community Hospital
Whalley Drive
Bletchley
Milton Keynes
United Kingdom
MK3 6EN

Study participating centre
Queen Elizabeth Hospital
Woolwich Stadium Road
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SE18 4QH

Sponsor information

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South London and Maudsley NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

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King's College London

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is expected that results will be fed back to participants and will be disseminated through public engagement events (arranged with our patient and public involvement working group), academic publications, and presented at international conferences.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The CI (Prof Rona Moss-Morris; rona.moss-morris@kcl.ac.uk) will be the contact to approve and send out copies of any data. Any data shared will be de-identified. Only data from participants who have consented to their data being shared/used in future research studies will be shared. A data file will be made at the end of the

trial where the possibility of identification has been minimized and includes only data from those who have consented to this. Both quantitative and qualitative data may be requested. Data will only be shared for the purpose of research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	For facilitators version 1.0	20/05/2022	06/06/2022	No	Yes
Participant information sheet	For patients version 1.0	20/05/2022	06/06/2022	No	Yes
HRA research summary			28/06/2023	No	No
Protocol article		11/03/2025	13/03/2025	Yes	No