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Assessing psychological support for people with emotional distress and difficulties in relationships: The SPS study

Submission date
03/11/2022

Recruitment status
No longer recruiting

Registration date
11/11/2022

Overall study status
Completed

Last Edited
08/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with a diagnosis of personality disorder have high levels of contact with health services but the care they receive is often poor. National guidelines recommend that people are offered evidence-based psychological treatments. These treatments last between one to two years and require people to attend therapy groups on a regular basis, but these intensive treatments are not suitable for everyone with a personality disorder. In an effort to provide services that are more inclusive and to increase the number of people with a personality disorder that receive effective treatment, clinicians have begun to develop lower-intensity treatments. However, we do not have good quality evidence about whether they help patients in the long term or provide value for money. Structured Psychological Support (SPS) is an individual low-intensity intervention, which was developed in collaboration with people with lived experience of personality disorder. The aims of this study are to test whether SPS is a clinically and cost-effective intervention for improving mental health and social functioning in people with a probable personality disorder. The study also aims to conduct a parallel process evaluation where people that have been involved in the study tell us about their experiences. This will help the researchers gain a better understanding of the reasons for the study findings.

Who can participate?
Adults who are being treated by mental health staff working in a primary or secondary care NHS setting, and meet criteria for probable personality disorder

What does the study involve?
We plan to conduct a randomised trial of SPS compared to treatment as usual in people with a probable personality disorder. Participants will have their mental health, social function and service use assessed at the beginning of the study and again at follow-up 6 and 12 months later. For those allocated to receive the SPS intervention, 6 to 10 sessions of person-centred psychological support will be offered. This aims to help people develop a better understanding of their difficulties and techniques that they can use to improve their mental health and functioning. In parallel to the trial, trial participants, non-participants and clinicians or managers will be interviewed about their experience of the study processes.

What are the possible benefits and risks of participating?
By taking part in this study, participants will help trial researchers to find out whether SPS helps to improve the social functioning and mental health of people with emotional distress and difficulties in relationships. However, they will be required to give up some of their time to complete the interviews and the SPS sessions.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
April 2022 to February 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
Trial Coordinating Office, psych_trials@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315951

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
53799

Study information

Scientific Title
Assessing psychological support for people with emotional distress and difficulties in relationships: The SPS study

Acronym
SPS

Study objectives

Individuals with probable personality disorder who are offered Structured Psychological Support will have improved social functioning over a one-year period, compared to those offered enhanced treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/10/2022, London-Bromley REC (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8118; bromley.rec@hra.nhs.uk), ref: 22/LO/0631

Study design
Multicentre individually randomized parallel-group researcher-masked randomised-controlled trial with a parallel process evaluation and an integrated economic evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Personality disorder

Interventions
This is a multicentre, individually randomised, parallel-group, researcher-masked, randomised controlled trial, including a parallel process evaluation and an integrated economic evaluation. The trial will involve two linked phases. The first is an internal pilot study of four months of recruitment across all centres. Data from the internal pilot will be presented to the Trial Steering Committee (TSC) indexed against a priori stop/go criteria. The TSC will then advise the funder and the sponsor on whether the study should progress to phase 2. Phase 2 is the full trial, with further recruitment over a four-month period. All participants will be followed-up for 12 months.
Patients that are eligible and provide written informed consent will complete the screening assessment with a study researcher. Those that do not consent to take part will be asked if they would consider speaking to the process evaluation researcher later in the study about their reasons for declining, and this is noted on the screening log. If eligibility is confirmed they will then have their name and contact details passed to the trial coordinator who will randomise them to one of two treatment arms, with an equally likely chance of allocation. All trial participants will receive enhanced treatment as usual from mental health services, meaning that all have a jointly developed crisis plan. In addition, they will be receiving either no additional treatment (treatment as usual/TAU) or Structured Psychological Support (SPS).
As soon as practical after eligibility is confirmed, participants will also complete the baseline assessment which collects basic demographic and clinical data, social functioning, mental health, and quality of life.
Each participant will be contacted by the trial coordinator once they have been randomised, to inform them of their treatment allocation. We will also inform their clinical team of their allocation. If allocated to SPS, the participant's contact details will be given to an allocated therapist who will then make contact directly to initiate the treatment. Therapy sessions may be audio-recorded for therapist supervision and assessment of treatment fidelity. Therapists will complete a proforma for each therapy participant that details the number and length of sessions

and techniques used, but these will use the participant's study ID rather than name as an identifier.
Participants will be asked to complete further follow-up interviews at six and 12 months after randomisation. They will also be contacted by telephone at three and nine months to thank them for their participation in the study, remind them of their forthcoming follow-up interviews, confirm their contact details and inquire about any adverse events.
Some participants (50) and staff (up to 45) involved in the study will also be invited to interview for the process evaluation. Staff and patients will be selected purposively, to ensure that both men and women of different ages and ethnic and cultural backgrounds are included from a range of study sites. The qualitative researcher based at Middlesex University will work with the researchers at study sites to identify participants and staff that were involved in the study. The researcher that is based at the site and already known to the participant/staff member would approach them about the process evaluation interview and then either the site researcher or qualitative researcher will take consent. The qualitative researcher will carry out the interview either in-person or over the telephone/video call. Those that agree to take part will be audio-recorded and those recordings will be professionally transcribed verbatim prior to data analysis. For participants who wish to take part in the interview but do not want to be audio-recorded, the researcher will make contemporaneous notes, and then dictate as soon as possible after the interview has been completed.

Intervention Type
Behavioural

Primary outcome(s)
Social functioning measured using the Work and Social Adjustment Scale total score at 6 and 12 months

Key secondary outcome(s))
1. Mental health measured using the 16-item Difficulties in Emotion Regulation Scale, the nine-item Patient Health Questionnaire, and the seven-item Generalised Anxiety Disorder scale at 6 and 12 months
2. Suicidal thoughts and behaviour measured using items from the National Household Survey of Psychiatric Morbidity scale at 6 and 12 months
3. Health-related quality of life measured using the EQ-5D-5L at 6 and 12 months
4. Patient experience measured using the patient-rated Global Improvement scale and the patient-rated Satisfaction with Care scale at 6 and 12 months
5. Personality status measured using the Standardised Assessment of Personality – Abbreviated Scale at 6 and 12 months

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/08/2023:
1. Probable personality disorder on the Standardised Assessment of Personality Abbreviated Scale (score of 4 or more)
2. Age 18 years old and over
3. Being treated by mental health staff working in a primary or secondary care NHS setting

Process evaluation:
4. Involved in the trial in any way or have indicated an interest in talking about their reasons for declining as part of the process evaluation if they declined when initially approached

Previous inclusion criteria:
Trial involvement:
1. Age 18 years old and over
2. Being treated by mental health staff working in a primary or secondary care NHS setting

Process evaluation:
3. Involved in the trial in any way or have indicated an interest in talking about their reasons for declining as part of the process evaluation if they declined when initially approached

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
336

Key exclusion criteria
Current exclusion criteria as of 31/08/2023:
1. Unable or unwilling to provide written informed consent
2. Co-existing organic or psychotic mental disorder
3. In receipt of psychological treatment for personality disorder or are on a waiting list of <1 year for such treatment
5. Anyone currently a participant in a clinical trial or other interventional research will not be eligible to take part until their participation is complete

Previous exclusion criteria:
1. Probable personality disorder on the Standardised Assessment of Personality Abbreviated Scale
2. Unable or unwilling to provide written informed consent
3. Co-existing organic or psychotic mental disorder
4. In receipt of psychological treatment for personality disorder or are on a waiting list for such

treatment
5. Anyone currently a participant in a clinical trial or other interventional research will not be eligible to take part until their participation is complete.

Date of first enrolment
06/02/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents Place
London
England
NW1 3AX

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
England
OX3 7JX

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
England
BA1 3QE

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Kings Drive
Prescot
England
L34 1PJ

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
England
LN1 1FS

Study participating centre
Coventry and Warwickshire NHS Trust
Wayside House
Wilsons Lane
Coventry
England
CV6 6NY

Study participating centre
Middlesex University
Department of Mental Health & Social Work
Ground Floor Town Hall
The Burroughs
London
England
NW4 4BT

Study participating centre
Imperial College London
Division of Psychiatry
2nd Floor Commonwealth Building
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London
England
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Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Trust Headquarters
Kingsway Hospital
Kingsway
Derby
England
DE22 3LZ

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Mike Crawford (m.crawford@imperial.ac.uk). De-identified participant-level data including primary and secondary outcome measures and adverse events will be shared with researchers who provide a methodologically sound proposal by email to Prof. Crawford. The data will be available from 01/12/2024 with no fixed end date. Any data that could potentially be used to identify participants will not be provided in the dataset at the individual participant level e.g. ethnicity, and dates of service use. All participants gave written informed consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/06/2024	28/06/2024	Yes	No
Basic results		08/01/2025	08/01/2026	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version 2.0	22/12/2022	31/01/2023	No	No
Protocol file	version 4	18/07/2023	26/07/2023	No	No
Protocol file	version 5.0	07/12/2023	06/11/2024	No	No