

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

<b>Submission date</b> 03/11/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/02/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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](mailto:psych_trials@imperial.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Verity Leeson

### Contact details

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### Type(s)

Principal Investigator

### Contact name

Prof Mike Crawford

### ORCID ID

<http://orcid.org/0000-0003-3137-5772>

### Contact details

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2nd floor Commonwealth Building  
Du Cane Road  
London  
United Kingdom  
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**Type(s)**

Public

**Contact name**

Dr Trial Coordinating Office

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

315951

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 53799, IRAS 315951

## 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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **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 measure**

Social functioning measured using the Work and Social Adjustment Scale total score at 6 and 12 months

## **Secondary outcome measures**

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

## **Overall study start date**

01/04/2022

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 308; UK Sample Size: 308

**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**

England

United Kingdom

**Study participating centre**

**Central and North West London NHS Foundation Trust**

Trust Headquarters

350 Euston Road

Regents Place

London

United Kingdom

NW1 3AX

**Study participating centre**

**Oxford Health NHS Foundation Trust**

Warneford Hospital

Warneford Lane

Headington

Oxford

United Kingdom

OX3 7JX

**Study participating centre**

**Avon and Wiltshire Mental Health Partnership NHS Trust**

Bath NHS House  
Newbridge Hill  
Bath  
United Kingdom  
BA1 3QE

**Study participating centre**

**Mersey Care NHS Foundation Trust**

V7 Building  
Kings Business Park  
Kings Drive  
Prescot  
United Kingdom  
L34 1PJ

**Study participating centre**

**Lincolnshire Partnership NHS Foundation Trust**

St George's  
Long Leys Road  
Lincoln  
United Kingdom  
LN1 1FS

**Study participating centre**

**Coventry and Warwickshire NHS Trust**

Wayside House  
Wilsons Lane  
Coventry  
United Kingdom  
CV6 6NY

**Study participating centre**

**Middlesex University**

Department of Mental Health & Social Work  
Ground Floor Town Hall  
The Burroughs  
London  
United Kingdom  
NW4 4BT



**Study participating centre****Imperial College London**

Division of Psychiatry  
2nd Floor Commonwealth Building  
Du Cane Road  
London  
United Kingdom  
W12 0NN

**Study participating centre****Derbyshire Healthcare NHS Foundation Trust**

Trust Headquarters  
Kingsway Hospital  
Kingsway  
Derby  
United Kingdom  
DE22 3LZ

## **Sponsor information**

**Organisation**

Imperial College London

**Sponsor details**

C/o: Becky Ward  
215, Level 2, Medical School Building  
Norfolk Place  
London  
England  
United Kingdom  
W2 1PG  
+44 (0)207 594 9459  
[becky.ward@imperial.ac.uk](mailto:becky.ward@imperial.ac.uk)

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.imperial.ac.uk/>

**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

## Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Conference presentation
3. Publication on website

We will use a broad range of methods to communicate the results of this research to all stakeholders including both those who provide and use mental health services for people with a personality disorder. This will include written reports, presentations at conferences, social media, service user groups and professional bodies. We will publish our findings on the website of the National Institute for Health and Care Research and in widely read high-quality peer-reviewed open-access journals. We will present the results of the study at the leading conferences for mental health and personality disorder.

## Intention to publish date

30/11/2025

## 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?
<a href="#">Protocol file</a>	version 2.0	22/12/2022	31/01/2023	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Protocol file</a>	version 4	18/07/2023	26/07/2023	No	No
<a href="#">Protocol article</a>		25/06/2024	28/06/2024	Yes	No
<a href="#">Protocol file</a>	version 5.0	07/12/2023	06/11/2024	No	No