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Clinical effectiveness and cost-effectiveness of Structured Psychological Support for people with probable personality disorder in mental health services in England: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Evidence-based psychological treatments for people with personality disorder usually involve attending group-based sessions over many months. Low-intensity psychological interventions of less than 6 months duration have been developed, but their clinical effectiveness and cost-effectiveness are unclear.

Methods and analysis This is a multicentre, randomised, parallel-group, researcher-masked, superiority trial. Study participants will be aged 18 and over, have probable personality disorder and be treated by mental health staff in seven centres in England. We will exclude people who are: unwilling or unable to provide written informed consent, have a coexisting organic or psychotic mental disorder, or are already receiving psychological treatment for personality disorder or on a waiting list for such treatment. In the intervention group, participants will be offered up to 10 individual sessions of Structured Psychological Support. In the control group, participants will be offered treatment as usual plus a single session of personalised crisis planning. The primary outcome is social functioning measured over 12 months using total score on the Work and Social Adjustment Scale (WSAS). Secondary outcomes include mental health, suicidal behaviour, health-related quality of life, patient-rated global improvement and satisfaction, and resource use and costs. The primary analysis will compare WSAS scores across the 12-month period using a general linear mixed model adjusting for baseline scores, allocation group and study centre on an intention-to-treat basis. In a parallel process evaluation, we will analyse qualitative data from interviews with study participants, clinical staff and researchers to examine mechanisms of impact and contextual factors.

Ethics and dissemination The study complies with the Helsinki Declaration II and is approved by the London—Bromley Research Ethics Committee (IRAS ID 315951). Study findings will be published in an open access peer-reviewed journal; and disseminated at national and international conferences.

Trial registration number ISRCTN13918289.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Recruitment across seven large centres in England will increase the generalisability of the study findings.
⇒ The integrated process evaluation will increase the explanatory power of the study by generating a contextualised analysis of intervention delivery and outcome generation.
⇒ Study participants and clinical staff will not be masked to allocation status.
⇒ Gold standard quantitative measures for assessing treatment fidelity are not being used but will be explored qualitatively.
⇒ Patient outcomes will not be examined beyond 12 months.

INTRODUCTION

People with personality disorder have impaired social functioning and greatly reduced health-related quality of life.[1 2] People with 'borderline' personality disorder, the most frequently diagnosed pattern of personality-related mental health problems,[3] also have high rates of suicidal behaviour and contact with emergency medical and mental health services.[4] Concerns have repeatedly been expressed about the poor quality of healthcare that people with personality disorder receive.[5–7] There are no licensed

pharmacological treatments for personality disorder.[8] While psychological treatments can be effective, current evidence-based interventions are highly intensive,[9 10] and usually require people to attend many hours of group-based therapy over a period of a year or more. Many people with personality disorder are considered unsuitable for these intensive interventions, including those with the most severe difficulties.[11] Even when people are considered suitable, as many as half do not engage with them, or disengage before it has ended.[12] As a result, most people with personality disorder do not receive evidence-based psychological treatment.[13]

In recent years, 'low intensity' interventions of less than 6 months duration have begun to be developed with the aim of increasing the proportion of people with personality disorder who receive effective psychological support. However, the clinical effectiveness and cost-effectiveness of these interventions is currently unclear. A systematic review of randomised trials of low-intensity psychological interventions for people with borderline personality disorder found that most did not follow participants up after treatment had ended, and that costs and cost-effectiveness were rarely examined.[14] The authors concluded that fully powered studies with longer follow-up periods are required. In England, improving access to psychological interventions for people with personality disorder is a national priority.[15] The National Institute for Health and Care Excellence (NICE) have called for all people with borderline personality disorder to be offered choice in the duration and intensity of therapy they are offered.[16] But options for patients are currently limited by the lack of evidence-based low-intensity interventions.

Structured Psychological Support (SPS) is an intervention for people with personality disorder that was developed in collaboration with people with lived experience.[17] People are offered 6–10 sessions of person-centred psychoeducation, formulation and training in one or more psychological skill derived from high-intensity treatment approaches, notably dialectical behaviour therapy.[18 19] A feasibility trial of SPS, found evidence that the intervention is acceptable to patients and may be associated with improved social function and satisfaction with care, relative to treatment as usual (TAU).[20]

The aim of this new study is to examine the clinical effectiveness and the cost-effectiveness of SPS for people with personality disorder over a 1-year period. The primary hypothesis is that, for people with probable personality disorder, the offer of SPS will be associated with improved social functioning over a 1-year period, compared with the offer of enhanced TAU. The study includes a parallel process evaluation which aims to provide a contextualised analysis of intervention delivery and outcome generation. Should the trial generate evidence of patient benefit, we will use these qualitative data to support the wider delivery of this low intensity intervention in the future.

METHODS AND ANALYSIS

The SPS trial is a phase III, multicentre, individually randomised, parallel group, researcher-masked, randomised controlled superiority trial, including a parallel process evaluation and an integrated economic evaluation. The study will be conducted in two phases—an internal pilot phase and the full trial. The pilot phase will last for 4 months. During this period data will be collected on the number of centres that open to recruitment, the total number of participants that are recruited and update of the intervention in the active arm of the trial. Data from the internal pilot will be presented to the Trial Steering Committee, which will then recommend whether the trial continues to the second phase based on whether adequate progress is made in these areas.

Study participants will be followed up at 6 and 12 months after randomisation (figure 1). The trial is designed to be compliant with Standard Protocol Items: Recommendations for Interventional Trials guidelines.[21] The first study participant was recruited on 7 February 2023. Recruitment ended on 31 January 2024, by which time 336 had been enrolled in the study. Study participants are being followed up, with data collection due to be completed by 28 February 2025.

Study participants

Study participants will be recruited from primary and secondary care mental health services delivered by seven state-funded NHS centres in the North West, South West, Midlands, East and South East of England. These seven Trusts cover a combined population of over 20 million adults across a range of urban, rural and inner-city areas. To take part in the study potential participants must be aged 18 or over and be treated for probable personality disorder by mental health staff working in primary or secondary care services. We will exclude those who did not meet criteria for probable personality disorder according to the Standardised Assessment of Personality Disorder—Abbreviated Scale,[22] those who are unable or unwilling to provide written informed consent, those with a coexisting organic or psychotic mental disorder, those who are already receiving, or on the waiting list to receive, psychological treatment for personality disorder, and those who are already taking part in another clinical trial or interventional research study.

Study interventions

All study participants will have access to TAU. In addition to this, participants will be offered either SPS (active arm) or a single session of remotely delivered crisis planning (control arm). TAU will include follow-up from primary and secondary mental health services according to the participant's needs. Efforts will be made to avoid participants receiving psychological treatments that focus on personality and personality disorder during the 12-month follow-up phase of the study. However, participants will continue to be able to access psychological interventions

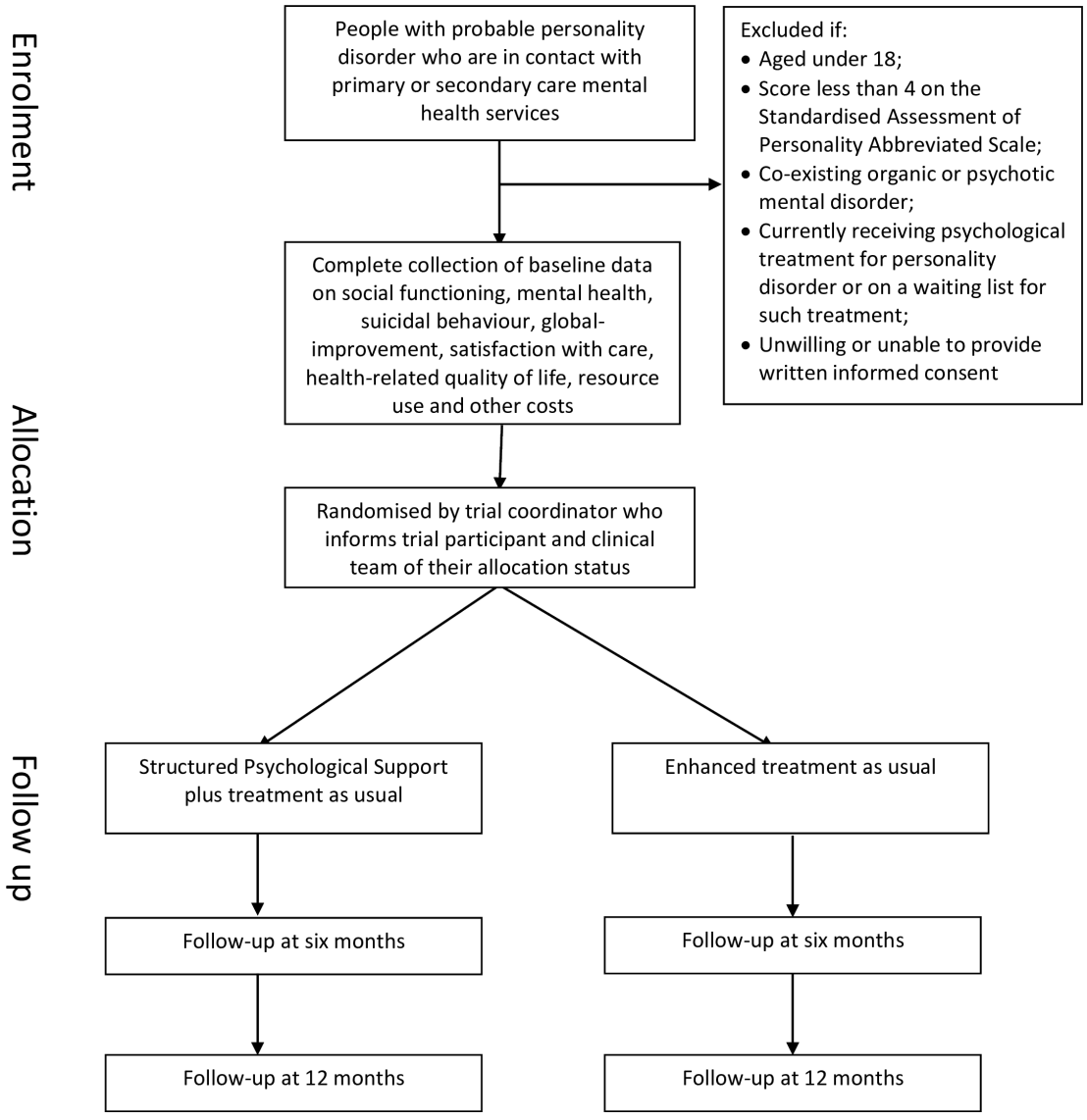

Figure 1 Study flow diagram.

for coexisting problems, such as anxiety, depression and substance misuse.

Structured Psychological Support

SPS is delivered in up to 10 individual 50 min sessions. Sessions can be delivered in-person or remotely. SPS is a person-centred approach, which allows practitioners to determine the number, frequency and duration of sessions based on clinical judgement and patient preference.[17] SPS draws on the longer-term evidence-based treatments for people with personality disorder including dialectical behaviour therapy and mentalisation based treatment[18 19 23 24] and has five key components (figure 2): providing information about personality and mental health and the role of health services; validation aimed at reducing self-blame and motivating self-efficacy; support to help the participant develop psychological skill(s) for managing their main difficulties; discussion of the role of relationships and structured activities in achieving better mental health, and the use of a 'mentalising stance'[25] to highlight mental states. During the first two sessions, practitioners assess the patient's understanding of their problems, and their coping strategies. They then use this information to provide tailored advice and validation and to formulate a treatment plan. The patient and the practitioner agree a focus for the remaining sessions and the practitioner summarises the plan in a letter, which is sent to the patient and if consent is given, shared with their general practitioner. After the planned sessions have been completed, patients are offered a follow-up review session within a 6-week period. This provides an opportunity for the patient to talk about their experience of using the skills they have learnt and for the practitioner to provide additional advice and support.

Each member of staff who delivers SPS is given a copy of a treatment manual, attends 9× hours of training (3×3-hour sessions), and completes a short assessment

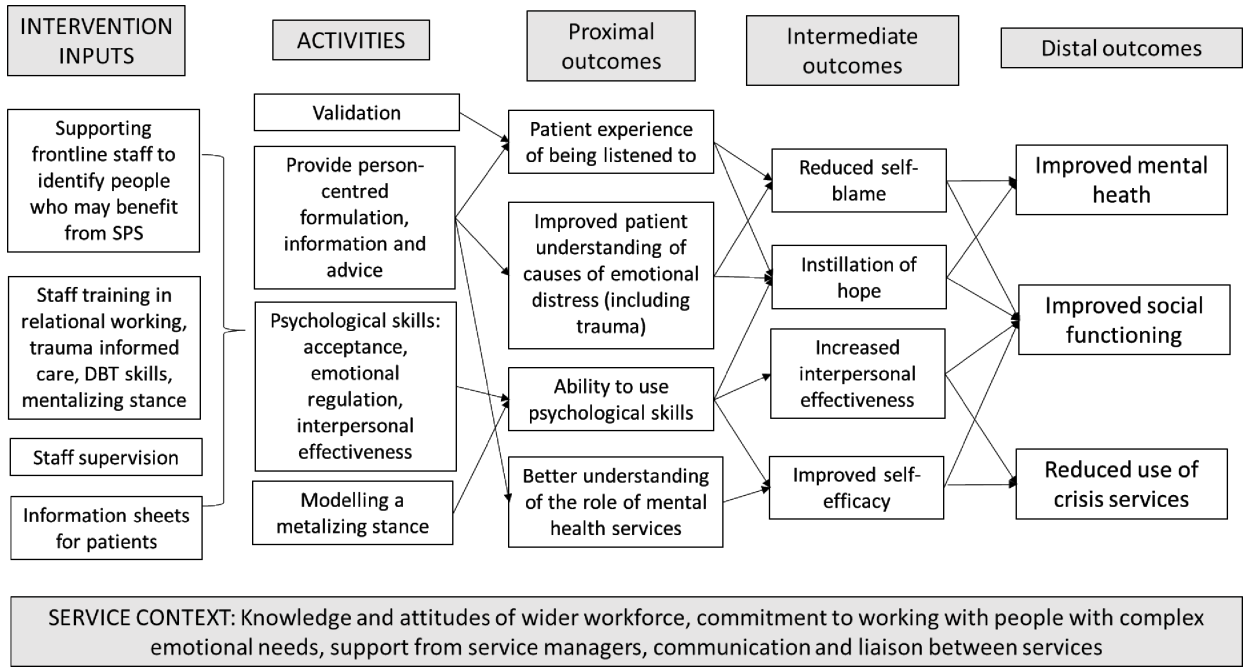

Figure 2 Logic model.

exercise before they treat their first study participant. They also attend fortnightly group supervision meetings. Supervision is delivered by a local clinician who has completed training in a high-intensity evidence-based treatment for people with personality disorder and has completed the 9-hour SPS training.

Treatment fidelity is maintained by regular clinical supervision. Staff delivering SPS are asked to complete a proforma for every participant, which records the number and length of sessions and remote contacts they have with patients. This will provide a measure of adherence to the study protocol in terms of the number and length of sessions and total treatment duration. We will also ask practitioners to record information on the content of sessions. These data will be used in conjunction with qualitative data from the process evaluation to explore the extent to which SPS is delivered in accordance with the treatment manual.

Control treatment

Participants in the control arm of the trial will be offered a single session of remotely delivered crisis planning. According to current NICE guidelines,[9] all people with borderline personality disorder should be offered a crisis plan, but evidence suggests that almost half do not receive this.[26] To try to ensure adherence to NICE-recommended care, we will offer all those in the control arm of the trial an opportunity to meet remotely with an experienced clinician to develop a person-centred crisis plan, which includes potential triggers for crises, things the participant can do to get through crises, and contact details for NHS and voluntary sector mental health helplines and crisis services.

Study procedures

Recruitment

Study researchers will meet with clinicians to publicise the study and encourage them to refer potential participants who either had a formal diagnosis of personality disorder or were being treated for emotional distress and interpersonal problems suggesting a probable diagnosis of personality disorder. Potential participants will be approached initially by a staff member and asked to provide verbal consent to be contacted by a member of the study team. If they agree, the researcher will meet the potential participant to explain the rationale for the study and give them a copy of the patient information leaflet. Potential participants may spend as much time as they want asking questions about the study and considering whether they want to take part. In all instances, potential participants will be given at least 24 hours before deciding whether they want to take part in the study (see online supplemental file). Potential participants sign an Informed Consent Form before being assessed for eligibility. If eligible, baseline data will be collected, and clinical records examined to check that they are not on a waiting list to receive psychological treatment for personality disorder. All participants who completed a baseline interview will be given a £10 gift voucher.

Randomisation

Eligible participants will be randomised via a secure fully automated service operated by the North Wales Clinical Trials Unit, University of Bangor. We will use a sequentially randomised dynamic adaptive algorithm stratified by gender and study centre, with a 1:1.15 (TAU:SPS) allocation ratio.[27] Within the algorithm, the likelihood of the participant being allocated to each treatment

group is re-calculated based on the participants already recruited and allocated. This recalculation is done at the overall allocation level and within stratification (gender and study centre). By undertaking this re-calculation the algorithm ensures that balance is maintained within acceptable limits of the assigned allocation ratio while maintaining unpredictability. A trial coordinator will then notify the participant and their clinical team including the person that would deliver the intervention or TAU locally, of their allocation status.

Follow-up

Study participants will be followed up at 3, 6, 9 and 12 months after randomisation. Outcome data will be collected at 6 and 12 months, and participants who complete a follow-up interview will be given a £20 gift voucher. At 3 and 9 months researchers will contact participants to thank them for their help with the study, enquire about adverse events and check their current contact details. After 12-month data have been collected and entered, the researcher that conducts the follow-up interviews will be asked to guess the participant's trial arm for sensitivity analysis. A final check of the participant's medical record will then be made to determine whether they received a psychological intervention for personality disorder during the previous 12 months (other than SPS in the context of the trial). Quantitative data from patient interviews will be recorded on paper Case Record Forms and then transcribed onto a web-based electronic database. This database will be stored on a dedicated web server on a network drive at Bangor University.

Measurement of costs and outcomes

All study measures are presented in table 1. We will use the self-report Standardised Assessment of Personality Abbreviated Scale (SAPAS) to check that potential participants have probable personality disorder. The SAPAS is a widely used measure to screen for personality disorder, which is reliable, valid and acceptable to patients.[22] In clinical populations, a cut point score of 4 on the SAPAS correctly classifies 85% of patients, with sensitivity of 0.82 and a specificity of 0.89.[22] While some studies use a cut point of 3 to identify people with probable personality disorder, we used a higher threshold of four to achieve a higher positive predictive rate. We will collect basic demographic and clinical data on age, gender, ethnicity, disability, relationship status, employment status and duration of contact with mental health services. We will assess the range of personality-related difficulties that participants have using the Personality Assessment Questionnaire for ICD-11 personality trait domains (PAQ-11)[28] and use items from the Structured Clinical Interview for Axis II Personality Disorders (SCID-II)[29] to determine whether they meet diagnostic criteria for borderline personality disorder. This will enable us to establish what proportion of participants meet the most prevalent form of the condition, with associated NICE guidelines.[9 16] Given high levels of trauma among people with personality

Table 1 Study assessment schedule

Assessments	Screening	Baseline	6-month follow-up	12-month follow-up	Unblinded 12-month follow-up
Structured Assessment of Personality—Abbreviated Scale	X (1)	–	–	X (4)*	–
Personality Assessment Questionnaire for ICD-11 Personality Trait Domains (PAQ-11)	X (2)	–	–	X (5)*	–
Structured Clinical Interview for Axis II Borderline Personality Disorders (SCID-II)	X (3)	–	–	–	–
International Trauma Questionnaire (PTSD items)	X (4)	–	–	X (12)*	–
Work and Social Adjustment Scale (WSAS)	-	X (1)	X (1)*	X (1)*	–
Difficulties in Emotion Regulation Scale (DERS)	–	X (2)	X (2)*	X (2)*	–
Patient Health Questionnaire (PHQ-9)	–	X (3)	X (3)*	X (3)*	–
Generalised Anxiety Disorder Scale (GAD-7)	–	X (4)	X (4)*	X (6)*	–
Suicidal Thoughts and Behaviour from the National Household Survey of Psychiatric Morbidity	–	X (5)	X (5)*	X (7)*	–
Patient-rated Global Improvement Scale	–	X (6)	X (6)*	X (8)*	–
Patient Satisfaction with Care*	–	X (7)	–	X (9)*	–
Adult Service Use Schedule (AD-SUS)	–	X (8)	X (8)*	X (10)*	–
EuroQoL EQ-5D-5L Level	–	X (9)	X (9)*	X (11)*	–
Trial Arm Allocation Guess	–	–	–	X (12)	–
Medical Records Check of Concomitant Psychological Treatment	–	–	–	–	X (1)

(Number) refers to the order in which the scales appear.
*Measure can be self-completed or completed at interview with researcher.

disorder,[30 31] we also included an assessment of complex post-traumatic stress at baseline using the International Trauma Questionnaire.[32] However, because this questionnaire asks people to recall past traumatic events, which some participants could find distressing, we gave participants the choice to opt out of answering these questions.

Primary outcome

The primary outcome is social functioning measured over 12 months using the total score on the Work and Social Adjustment Scale (WSAS).[33] This self-report scale has five items on: work functioning; home management; social roles, private leisure activities and relationships. Each item is rated on an 8-point ordinal scale. The WSAS is a widely used measure, which is short, reliable and sensitive to change.[34]

Secondary outcomes

Mental health will be assessed using the 16-item Difficulties in Emotion Regulation Scale,[35] the 9-item Patient Health Questionnaire[36 37] and the 7-item Generalised Anxiety Disorder Scale.[38 39] Incidence and severity of suicidal behaviour and self-harm, assessed using questions from the National Household Survey of Psychiatric Morbidity.[40] Health-related quality of life will be assessed using the EQ-5D-5L.[41] The EQ-5D-5L provides a brief and reliable measure of health-rated quality of life, which is responsive to change in people with personality disorder.[42] Patient experience will be measured using the patient-rated Global Improvement Scale[43] and Patient-rated Satisfaction with Care.[44] Personality status will be measured using the Standardised Assessment of Personality—Abbreviated Scale[22] at 6 and 12 months. We will collect data on use of resource using an adapted version of the Adult Service Use Schedule (AD-SUS).[45 46] The AD-SUS collects detailed data on use of all hospital and community health and social care services as well non-NHS costs such as accommodation costs and use of voluntary sector services.

Adverse events

Researchers will ask participants during any contact or scheduled visit about adverse events. Serious adverse events (ie, those that result in death, are life-threatening, require hospitalisation or prolongation of an existing hospitalisation, or result in persistent or significant disability or incapacity) and non-serious adverse events that require treatment on an urgent or emergency basis, defined as attendance at an emergency department, referral to a home treatment team or first responders team will be recorded from the time a participant gives consent.

Masking

All researchers who assess participant outcomes will be masked to allocation status. Participants and members of their clinical team will not be masked. Prior to follow-up interviews, participants will be asked not to reveal their treatment allocation. If any researcher becomes inadvertently unmasked, we will arrange for an alternative (masked) researcher to collect all further follow-up data. We will also ask the researcher that conducts the follow-up interviews to guess the participant's trial arm allocation at 12 months for sensitivity analysis.[47] The trial statistician running analysis will be unmasked, due to the unequal allocation ratio. The senior statistician approving Statistical Analysis Plan (SAP) will be masked.

Sample size

The sample size calculation is based on the primary hypothesis, that people with personality disorder who are offered SPS will have improved social functioning over a 1-year period, compared with those offered enhanced TAU. We have powered the study to detect a minimum clinically significant difference of 3.8 points (SD=9.5) on the WSAS, which, equates to an effect size of 0.4. This compares with an effect size of 0.63 found in our feasibility trial,[20] and 0.42 reported in a recent systematic review of small-scale trials of individual low-intensity interventions for people with personality disorder.[14] We will need to analyse data from 215 participants (approximately 115 receiving SPS and 100 receiving TAU), with a 0.5 correlation between baseline and follow-up scores, to have 90% power to detect a difference of 3.8 (SD 9.5) on the WSAS scale with a 5% significance level. We conducted the sample size calculation using the analysis of covariance method and PASS V.16 software (NCSS, Kaysville, Utah, USA). We used a variance inflation factor of 1.15 to account for clustering in the intervention arm of the trial assuming an average cluster size of four completers and an intraclass coefficient of 0.05. To take account of 30% loss to follow-up we set out to recruit 308 subjects (approx. 165 receiving SPS and 143 receiving enhanced TAU).

Process evaluation

Following MRC guidelines on the evaluation of complex interventions[48 49] and the application of process evaluation within trials of complex interventions,[50] we will embed a parallel process evaluation within this trial. The aim of the process evaluation is to provide a contextualised analysis of intervention delivery and outcome generation.

To assess the perspectives and experience of staff delivering both SPS and TAU interventions, semi-structured qualitative interviews will be conducted with a purposive sample of practitioners at each centre. We will also undertake a series of individual interviews with team managers, clinical leads and clinical supervisors to SPS practitioners (a total of approximately 45 staff interviews). These interviews will focus on the way that SPS is delivered and what arrangements are needed to support and sustain its delivery. Adapting techniques associated with normalisation process theory,[51] we will use these data to assess the extent to which SPS is engaged with by teams, achieves coherence within team processes, and is supported by collective action (eg, appropriate supervision and assessment of utility). In this way, we will aim to assess the

extent to which SPS becomes or may potentially become embedded into routine practice.

We will also interview participants (up to 50 interviews), to explore their experience of receiving SPS and enhanced TAU. We will select a purposive sample to ensure range and diversity of gender, age and ethnicity from across study centres. We will also purposively sample participants with a range of baseline WSAS scores, and prior to seeking informed consent we will confirm that each sampled participant had exposure to their allocated intervention. The interviews with participants randomised to SPS will have a strong focus on the experience of the key components of SPS, the perceived utility of any learnt psychological skills, whether participants have been able to use these skills and if they feel this is associated with any mental health benefit.

All interview topic guides will be developed with input from members of the Trial Management Group and the Lived Experience Advisory Panel (LEAP), which explore their experiences and encourage reflection.

Data analysis

A full SAP will be written by coapplicants, agreed with the Data Monitoring and Ethics Committee, and published online before data collection has been completed. The primary endpoint is 12 months. Our primary outcome is social functioning measured over 12 months using the total score on the WSAS. The primary analysis will compare WSAS scores across the 12-month period using a general linear mixed model adjusting for baseline scores, allocation group and study centre. Any additional covariates to be included in the model will be assessed for their appropriateness and defined a priori in the SAP. Data will be analysed on an intention-to-treat basis. Analysis of secondary outcomes will follow the same analysis model as the primary analysis where possible. Patterns of missing data will be assessed and predictors of missingness will be investigated and considered for inclusion in the models. Multiple imputation will be employed to address missing outcomes where appropriate. Test modelling and missing data assumptions via sensitivity analyses will be undertaken. All treatment effect estimates will be presented with 95% CIs.

Sensitivity analysis will also be undertaken for preplanned variables: (i) whether participants meet diagnostic criteria for borderline personality disorder, (ii) whether participants meet diagnostic criteria for complex post-traumatic stress disorder and (iii) differences in the modality and components of the intervention that participants receive. Participants will have variables indicating which elements of the intervention they received. These variables will be added into the models as factors to assess if there is a potential impact on the results.

Analysis of economic data

Prior to the completion of data collection, a full Health Economics Analysis Plan will be written and agreed by the coapplicants and approved by the Data Monitoring and Ethics Committee. The economic evaluation will take a broad approach encompassing NHS, personal social services (PSS) and relevant non-NHS/PSS costs such as accommodation and use of voluntary sector services.[52] Data on the service use will be collected using a modified version of the AD-SUS.[46] For each service use item, a relevant and suitable unit cost will be identified. Differences in service use over follow-up will be explored descriptively. While statistical differences in total costs by randomised group will be calculated using standard t-tests,[53] the focus of the analysis will be on the impact of costs and outcomes together. The primary cost-effectiveness analysis will consider costs alongside quality-adjusted life years (QALY) and will thus report on the incremental cost per QALY, in keeping with the requirements of analyses for use in NICE guidance.[52] A secondary cost-effectiveness analysis will report the incremental cost per unit improvement in social functioning measured using the WSAS. We will use data on number of hours worked per week and on out-of-pocket costs to study participants to widen the perspective to include non-health and social care costs as part of a secondary cost-effectiveness analysis. Statistical uncertainty around the estimates of cost-effectiveness will be explored using net benefit calculations and through the construction of cost-effectiveness acceptability curves.[54] Sensitivity analyses will be completed to test the assumptions used in the economic evaluation.

Analysis of qualitative data

Interviews will be transcribed verbatim and uploaded to the NVivo computer package (Scolari/Sage) to manage data and support analysis. We will employ a modified thematic analysis[55] which permits both deductive and inductive coding. After familiarisation with the data (reading transcripts) an initial (deductive) coding frame will be developed built on both a priori research questions (notably relating to the anticipated relationship between resources, actions, outputs and outcomes described in the logic model) and themes developed in the data. This coding frame will be developed and refined (inductively) as data collection and analysis progress. The coding will be applied to the data with the aim of allocating all data to a theme (either already defined or emergent at this point). While full copies of transcripts are retained to ensure context is maintained, NVivo supports the allocation to themes of disaggregated data. At the analytical stage constant comparison is used to discern patterns and divergences in the data and to support the identification of concepts and categories that enable a comprehensive and detailed response to the research questions.

Patient and public involvement

People with lived experience of personality disorder were involved in the development and refinement of the study intervention[17] and the development of the study protocol. A person with lived experience of recovery from personality disorder is a core member of the study team (FK-T). FK-T chairs our LEAP.

Members of this group include a mix of women and men from different parts of England who have experience of using and providing a range of voluntary and NHS services for people with personality disorder. Members of the panel helped us refine patient-facing study documents, advised on the structure and content of the topic guides used in the process evaluation and helped us develop our strategy for recruiting and follow-up procedures. LEAP members will also play an active part in interpreting the results of the study and communicating the study findings.

ETHICS AND DISSEMINATION

We obtained Research Ethics Committee approval from the London - Bromley Research Ethics Committee (IRAS ID 315951) in advance of the start of the study. Only those who have capacity and agree to provide written informed consent will be included in the study. Each potential participant will be provided with a copy of a Patient Information Sheet that will include a contact number and email address for the study team. The trial will be conducted in accordance with Good Clinical Practice guidelines. All participants will be offered a £10 honoraria at baseline and £20 following completion of the six and 12 month follow-up interview. In accordance with the current revision of the Declaration of Helsinki, a participant will have the right to withdraw from the trial at any time and for any reason and is not obliged to give his or her reasons for doing so.

Two independent oversight committees (Trial Steering Committee and Data Monitoring and Ethics Committee) oversee the study. In addition, monthly meetings of a Trial Management Group oversee study progress. The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act. All case Record Form data entered into a web-based online survey tool or collected during the process evaluation will be pseudonymised. Access to the data will be limited to individuals delegated the role, with these users allocated an identifier and password for login. The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

Results of the study will be communicated through publications in peer-reviewed open-access journals and presentations at national and international conferences. All study participants will be asked if they would like to receive a summary of the main study findings. The summary will be prepared in collaboration with members of the studies' LEAP. Should the intervention demonstrate benefit for patients, we will host an interactive free-to-access webinar on the use of SPS for people with personality disorder. In addition to summarising the results of the study, we will provide copies of the treatment manual and a guide to the implementation of the intervention in mental health services. The study sponsor is Imperial College London.

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Contributors MC is the chief investigator on the study and led the design of the study and the preparation of this manuscript. VL and SPP coordinate the trial, contributed to the development of the study protocol and preparation of this manuscript. RE and NG developed plans for the analysis of quantitative data, contributed to the design of the study and the study protocol and preparation of this manuscript. TW and AT developed plans for the collection and analysis of qualitative data for the process evaluation and contributed to the preparation of this manuscript. BMB developed plans for the economic evaluation, contributed to the design of the study and the study protocol and preparation of this manuscript. FK-T coordinates service user involvement in the study and contributed to the design of the study protocol. KES, GL, DW, HS, TG, VN are a principal investigators. KB contributed to the design of the study and the study protocol and preparation of this manuscript. All authors read and approved the final manuscript. The sponsor and funder played no role in the preparation of this manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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