Brief individual psychological intervention for people with probable personality disorder: a multicentre, researcher-masked, randomised, controlled superiority trial in England

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Summary

Background Long-term psychological treatments are recommended for people with personality disorder. Brief interventions are increasingly delivered but are of uncertain benefit. We aimed to investigate the effectiveness of a brief individual psychological intervention for people with probable personality disorder over a 12-month period.

Methods The Structured Psychological Support (SPS) study was a multicentre, researcher-masked, randomised controlled superiority trial, conducted in seven mental health Trusts in England: Avon and Wiltshire Mental Health Partnership National Health Service (NHS) Trust, Central and North West London NHS Foundation Trust, Coventry and Warwickshire Partnership NHS Trust, Derbyshire Healthcare NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust, Mersey Care NHS Foundation Trust, and Oxford Health NHS Foundation Trust. Participants were aged 18 years or older and had probable personality disorder identified by meeting a threshold of 4 or more on the Standardised Assessment of Personality Abbreviated Scale. We excluded those who: did not consent; had a co-existing psychotic disorder; or were already receiving psychological treatment. We assessed whether participants met criteria for borderline personality disorder using the Structured Clinical Interview for Axis II Personality Disorders and whether they had co-existing complex post-traumatic stress disorder using the International Trauma Questionnaire. We randomly assigned participants to up to ten sessions of SPS plus treatment-as-usual or enhanced treatment-as-usual (allocation ratio 1·15:1), using an independent remote system. Researchers assessing outcomes were masked to group allocation. SPS comprises up to ten individual sessions of personalised psychological support, which includes psychoeducation and psychological skills derived from evidence-based treatments (dialectical behaviour therapy and mentalisation-based treatment). Sessions were usually delivered on a fortnightly basis by staff with previous experience of working with people with personality disorder. The primary outcome was social functioning at 12 months measured using the Work and Social Adjustment Scale (WSAS). Data were analysed using multilevel mixed effects general linear regression on an intention-to-treat basis. We used multiple imputation to address missing outcomes. We undertook a parallel health economic evaluation, which included cost-effectiveness and cost-utility analyses. People with lived experience were involved in the design of the research and in the writing process. The trial was prospectively registered (ISRCTN13918289) and is now complete.

Findings Between Feb 7, 2023, and Jan 31, 2024, 569 potential participants were referred for study inclusion, 34 were deemed ineligible, 56 declined to participate, and 127 were not approached. 352 potential participants provided consent, of whom 16 were deemed ineligible or withdrew. 336 participants were randomly assigned to either SPS (n=180) or treatment-as-usual (n=156). 251 (75%) participants were female, 75 (22%) were male, and ten (3%) were non-binary or other. The mean age was 34·8 years (SD 13·2; range 18–68) and 281 (84%) participants were White. 152 (84%) participants in the SPS group and 132 (85%) in the control group completed the 12-month follow-up. There was no difference between groups for the primary outcome of WSAS score (standardised coefficient 0·12 [95% CI –2·14 to 2·38]; p=0·92). The probability that SPS is cost-effective was 0·34–0·39. There were 36 serious adverse events affecting 17 participants in the SPS group and 16 in the treatment-as-usual group. None were judged to be related to study procedures. Two study participants died during the 12-month follow period, both in the SPS group.

Interpretation We found no difference in social functioning over the course of 1 year among people offered a brief psychological intervention, and no evidence of cost-effectiveness. These data highlight the importance of improving access to longer-term evidence-based psychological treatment programmes for people with personality disorder.

Funding National Institute for Health and Care Research.

Research in context

Evidence before this study

Before this trial, to our knowledge, there were no adequately powered randomised controlled trials investigating the effectiveness of individually delivered, brief psychological interventions for people with personality disorder. A previous systematic review of brief psychological interventions, lasting 6 months or less, for people with borderline personality disorder identified 27 randomised trials and found high levels of bias for attrition and reporting. Meta-analysis demonstrated reductions in symptoms of personality disorder and moderate effect sizes for social functioning and general mental health for interventions delivered to individuals. However, follow-up data were limited and cost-effectiveness was rarely examined. We updated this review by searching PubMed, PsychINFO, Embase, MEDLINE, CINAHL, and the Cochrane Register for trials of adults with a clinical diagnosis of personality disorder published in English between April 1 2020, and May 1 2025, using search terms related to 'psychotherapy*' OR 'intervention*' AND 'borderline$' OR 'personalit$' AND 'brief*' OR 'psychoeducation*'. We identified six new trials, which were generally small (median sample size of 90, range 42–240). Four did not follow participants up beyond the end of treatment and none examined cost-effectiveness. Three trials compared shorter-term versus longer-term group-based psychological treatments and found little difference between the two. The three other trials examined brief individual interventions. Two found no difference in their primary outcomes, while an exploratory trial of imagery rescripting (n=48) reported increased use in adaptive strategies over a 12-week period.

Added value of this study

This study demonstrated no difference in social functioning among people offered up to ten individual sessions of Structured Psychological Support and no evidence of cost-effectiveness. Although differences in emotional dysregulation and self-reported global improvement were seen, they were small. We did not detect reductions in self-harm or improvements in other outcomes that have been found in trials of longer-term psychological treatment programmes.

Implications of all the available evidence

Caution needs to be exercised when considering whether to offer brief psychological interventions to people with personality disorder. While some individuals might experience some benefit, this is likely to be small compared with the benefits that might be gained from receiving longer term psychological treatment programmes. The available evidence does not support the widespread use of brief individual psychological interventions for people with personality disorder.

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Introduction

People with personality disorder experience poor mental health, difficulties in relationships with others, and reduced quality of life.[1] People with borderline personality disorder, the type of personality disorder most commonly seen in mental health services, have high rates of suicidal behaviour and service use.[2] Although effective psychological treatment programmes have been developed for borderline personality disorder, they are highly intensive, typically requiring many hours of group-based therapy for a year or more.[3] With an estimated global prevalence of about 5%, the number of people with personality disorder seeking help far outweighs the numbers of staff trained to deliver these treatments.[4] Even when offered treatment, up to half of patients do not engage or drop out before completing the treatment.[3] Consequently, most people with personality disorder do not receive evidence-based treatment.

In the past 20 years, brief interventions lasting less than 6 months have been developed to try to increase the number of people with personality disorder who receive effective psychological support. However, the effectiveness of these treatments is uncertain. The PEPS trial, which was the largest study of a brief intervention until now, tested the effects of psychoeducation and group-based problem solving for people with personality disorder and showed no evidence of patient benefit.[5] A subsequent systematic review of randomised trials of brief psychological interventions of 6 months duration or less for people with borderline personality disorder found that most were conducted in Europe or North America, and three-quarters involved group-based sessions, usually delivered on a weekly basis. Most trials did not follow up with patients after treatment had ended, and cost-effectiveness was rarely examined.[6] The authors concluded that larger studies with longer follow-up periods were required.

Structured Psychological Support (SPS) is a psychological intervention for people with personality disorder that was developed in collaboration with experts by experience.[7] Following feedback from patients that it can be difficult to get their needs met in short-term group-based treatments, SPS is delivered in individual sessions. Patients are offered up to ten sessions of person-centred psychoeducation, formulation, and training in one or more psychological skills derived from higher-intensity treatment approaches, notably dialectical behaviour therapy and mentalisation-based treatment. A feasibility trial of SPS found that it was acceptable to patients and might be associated with improved social function and satisfaction with care compared with treatment-as-usual.[7]

The current trial aimed to generate evidence on the benefits, harms, and cost-effectiveness of SPS for people with probable personality disorder over a 12-month period. The primary hypothesis was that the offer of SPS would be associated with improved social functioning over 1 year, compared with the offer of enhanced treatment-as-usual. The study included a parallel process evaluation.

See Online for appendix 1
See Online for appendix 2
See Online for appendix 3

Methods

Study design

The SPS trial was a multicentre, two-arm, parallel group, researcher-masked, randomised, controlled superiority trial, which included a nested process evaluation and an integrated economic evaluation.[8] Study outcomes were assessed 6 months and 12 months after randomisation. Study participants were recruited from primary and secondary care mental health services delivered by seven state-funded National Health Service (NHS) centres across England: Avon and Wiltshire Mental Health Partnership NHS Trust, Central and North West London NHS Foundation Trust, Coventry and Warwickshire Partnership NHS Trust, Derbyshire Healthcare NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust, Mersey Care NHS Foundation Trust, and Oxford Health NHS Foundation Trust.

These seven Trusts cover a combined population of more than 20 million adults across a range of urban, rural, and inner-city areas. We obtained Research Ethics Committee approval from the London Bromley Research Ethics Committee (IRAS ID 315951) before the start of data collection. The full protocol (appendix 1), statistical analysis plan (appendix 2), and health economics analysis plan (appendix 3) are available and the statistical analysis plan was published at ISRCTN before the database was locked and data were analysed (March 15, 2025). The trial was registered with the ISRCTN registry (ISRCTN13918289) before data collection.

Following the start of the trial, we made two changes to the protocol. First, we broadened our inclusion criteria to allow people who were on a waiting list for psychological treatment for personality disorder but had no prospect of receiving it within the following 12 months to be recruited. This led to a small number of people at one site who were on a waiting list for psychological treatment to take part in the trial while they were waiting for longer-term treatment to start. Second, after instances in which researchers were unmasked when assessing satisfaction with the treatment between baseline and the 6-month follow-up interview, we removed this element from the 6-month follow-up interview.

Every stage of the study was guided by people with lived experience, including input from experts by experience who were members of the study team and the Trial Steering Committee. The contribution of people with lived experience led to changes in: the recruitment strategy; plans for retaining study participants; the content of semi-structured interview schedules used in process evaluation; the interpretation of the results of the study; and dissemination of the study findings.

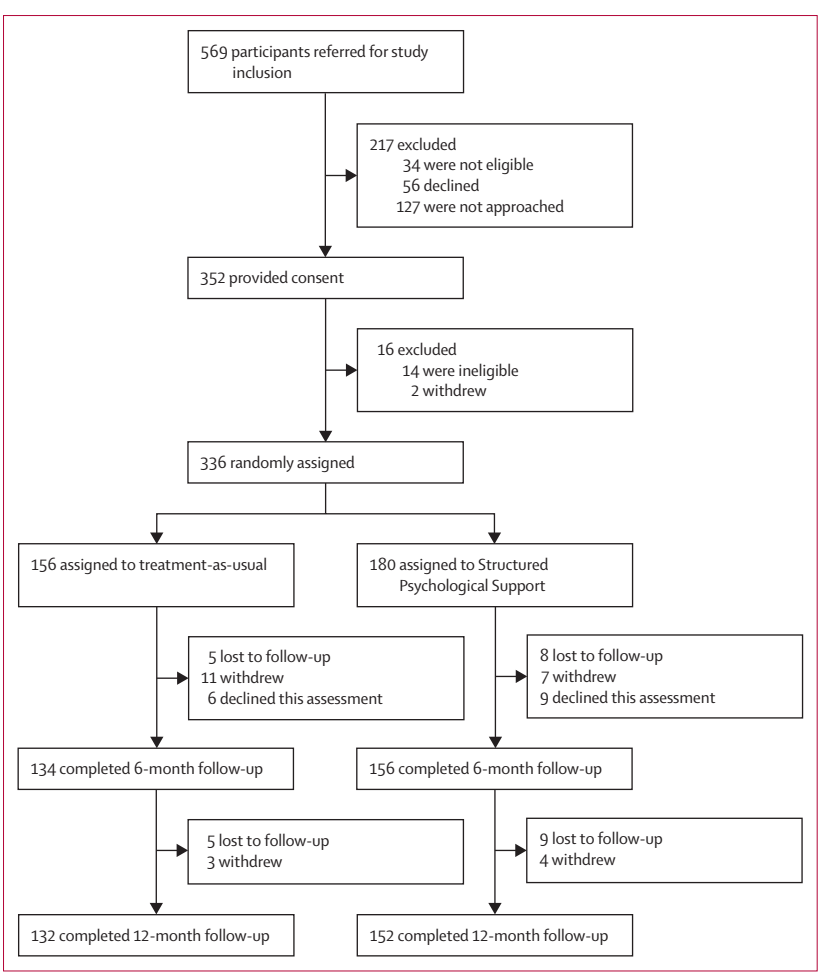

Figure 1: **Trial profile**

Participants

To take part in the study, potential participants had to be aged 18 years or older and have probable personality disorder, according to the referring clinician. We excluded those who did not meet criteria for probable personality disorder using a score of four or more on the Standardised Assessment of Personality Disorder Abbreviated Scale;[9] those who were unable or unwilling to provide written informed consent; those with a co-existing organic or psychotic mental disorder; those who were already receiving or about to receive psychological treatment for personality disorder (on a waiting list of less than 1 year); and those who were already taking part in another clinical trial or interventional research study.

Data on gender were collected via self-report questionnaires, with participants given the option of male, female, and non-binary or other. Data on ethnicity were also collected via self-report, with the options: White British, White Irish, White Other; Mixed: White and Black Caribbean, Mixed: White and Asian, any Mixed: Other; Asian or Asian British: Indian, Pakistani, Bangladeshi, other Asian; Black or Black British: Caribbean, African, Black other; Chinese; other ethnic group; or not known. Potential participants were asked to sign an informed consent form before being assessed for eligibility.

Randomisation and masking

Eligible participants were randomly assigned via a secure fully automated service operated by the North Wales Clinical Trials Unit, Bangor University. We used a sequentially randomised dynamic adaptive algorithm,[10] stratified by gender and study centre, to randomly assign participants to SPS plus treatment-as-usual or to enhanced treatment-as-usual, with a 1·15:1 allocation ratio. We used an unequal allocation ratio to account for clustering in the intervention group according to which therapist delivered the SPS intervention. Within the algorithm, the likelihood of a participant being allocated to each treatment group was re-calculated based on the participants already recruited and allocated. This recalculation was done at the overall allocation level and within stratification (gender and study centre). By undertaking this re-calculation, the algorithm ensured that balance was maintained within acceptable limits of the assigned allocation ratio while maintaining unpredictability.

All researchers who assessed participant outcomes were masked to allocation status. Participants and members of their clinical team were not masked. If any researcher became inadvertently unmasked, we arranged for an alternative masked researcher to collect all further follow-up data. When no masked researcher was available to conduct a follow-up assessment or the participant declined an assessment with the researcher, participants were asked to complete a web-based survey. The trial statistician running the analysis was unmasked, due to the unequal allocation ratio. The senior statistician approving the statistical analysis plan (RE) remained masked until the main analysis was completed.

Procedures

Researchers met with clinical teams to encourage them to refer potential participants who either had a formal diagnosis of personality disorder or were being treated for probable personality disorder. Potential participants were initially approached by a staff member and asked to provide verbal consent to be contacted by a study researcher. If they agreed, the researcher sent them a copy of the patient information leaflet and arranged a time to meet them.

We used the Standardised Assessment of Personality Abbreviated Scale, with a cutoff point of 4 of more, to check that potential participants had probable personality disorder.[9] We collected basic demographic and clinical data on disability, relationship status, employment status, and duration of contact with mental health services. We collected additional information on whether study participants met criteria for borderline personality disorder, using items on borderline personality disorder in the Structured Clinical Interview for Axis II Personality Disorders (SCID-II),[11] and we used the International Trauma Questionnaire[12] to assess whether they had co-existing complex post-traumatic stress disorder.

If potential participants were eligible, baseline data were collected, and clinical records were examined to check that patients were not already receiving, or about to receive, a psychological treatment for personality disorder. Following these checks, eligible participants were randomly assigned to the two groups. Treatment-as-usual included follow-up from primary care or support from secondary mental health services, or both, according to the participant's needs. Efforts were made to avoid participants receiving additional psychological treatments that focused on personality and personality disorder during the 12-month follow-up period.

SPS is delivered in up to ten individual sessions that typically last 45–50 min. The frequency of sessions was agreed with participants based on their preference. In most instances, sessions were delivered fortnightly, but some participants opted for weekly sessions. Sessions could be delivered in-person or remotely. SPS draws on the longer-term evidence-based treatments for people with personality disorder, particularly dialectical behaviour

	Enhanced treatment-as-usual group (n=156)	SPS plus treatment-as-usual group (n=180)	Overall (N=336)
Age, years	35·1 (13·6)	34·4 (13·0)	34·8 (13·2)
Gender			
Male	36 (23%)	39 (22%)	75 (22%)
Female	117 (75%)	134 (74%)	251 (75%)
Non-binary or other	3 (2%)	7 (4%)	10 (3%)
Ethnicity			
White	129 (83%)	152 (84%)	281 (84%)
Mixed	11 (7%)	8 (4%)	19 (6%)
Asian	9 (6%)	7 (4%)	16 (5%)
Black	6 (4%)	11 (6%)	17 (5%)
Other ethnic group	1 (1%)	2 (1%)	3 (1%)
Relationship status			
Single, never married	120 (77%)	132 (73%)	252 (75%)
Married or civil partnership	18 (12%)	23 (13%)	41 (12%)
Widowed	0	5 (3%)	5 (2%)
Divorced	10 (6%)	14 (8%)	24 (7%)
Separated	8 (5%)	6 (3%)	14 (4%)
Employment status			
Not working or in education	80 (51%)	82 (46%)	162 (48%)
Employed, voluntary work, or education	76 (49%)	97 (54%)	173 (52%)
Missing	0	1 (1%)	1 (<1%)
Source of referral			
Specialist personality disorder service	5 (3%)	4 (2%)	9 (3%)
General adult mental health service	62 (40%)	75 (42%)	137 (41%)
Mental health liaison service	18 (12%)	20 (11%)	38 (11%)
Primary care mental health service	71 (46%)	81 (45%)	152 (45%)
Mean length of time since first contact with mental health services, years	12·8 (9·6)	14·0 (10·9)	13·5 (10·4)

Data are n (%) or mean (SD). SPS=Structured Psychological Support.

Table 1: **Baseline characteristics**

	Baseline					6-month follow-up					12-month follow-up				
	Number of participants	Mean	SD	Minimum	Maximum	Number of participants	Mean	SD	Minimum	Maximum	Number of participants	Mean	SD	Minimum	Maximum
Primary outcome															
WSAS															
Total	333	29·86	6·4	7	40	286	27·30	7·88	0	40	284	26·58	8·71	1	40
Enhanced treatment-as-usual	155	29·67	6·84	7	40	133	27·72	7·06	10	40	132	27·04	8·15	5	40
SPS plus treatment-as-usual	178	30·02	6·01	14	40	153	26·93	8·54	0	40	152	26·18	9·18	1	40
Secondary outcomes															
DERS-16															
Total	331	65·45	9·97	28	80	283	60·33	11·75	19	80	280	58·38	12·9	20	80
Enhanced treatment-as-usual	154	65·13	10·02	33	80	133	61·77	10·7	20	80	129	59·54	12·57	29	80
SPS plus treatment-as-usual	177	65·72	9·95	28	80	150	59·05	12·5	19	80	151	57·39	13·14	20	80
PHQ-9															
Total	335	19·12	4·81	4	27	284	16·45	5·97	1	27	277	15·37	6·55	0	27
Enhanced treatment-as-usual	156	18·63	5·22	5	27	133	16·70	6·17	1	27	128	15·67	6·85	0	27
SPS plus treatment-as-usual	179	19·54	4·38	4	27	151	16·25	5·8	1	27	149	15·11	6·29	0	27
GAD-7															
Total	335	15·37	4·24	1	21	283	13·08	5·18	0	21	275	12·78	5·32	0	21
Enhanced treatment-as-usual	156	15·49	4·4	1	21	132	13·66	5·15	0	21	129	12·86	5·27	0	21
SPS plus treatment-as-usual	179	15·27	4·1	4	21	151	12·57	5·16	1	21	146	12·71	5·39	0	21
CGI															
Total	336	4·21	1·4	1	7	283	3·49	1·47	1	7	271	3·67	1·6	1	7
Enhanced treatment-as-usual	156	4·16	1·43	1	7	133	3·76	1·43	1	7	129	3·79	1·6	1	7
SPS plus treatment-as-usual	180	4·26	1·39	1	7	150	3·25	1·48	1	7	142	3·56	1·6	1	7
PSQ															
Total	328	6·85	3·73	0	12	..	..	..	..	..	265	7·23	3·93	0	12
Enhanced treatment-as-usual	154	7·07	3·78	0	12	..	..	..	..	..	126	6·48	4·07	0	12
SPS plus treatment-as-usual	174	6·64	3·69	0	12	..	..	..	..	..	139	7·92	3·68	0	12
SAPAS															
Total	341	6·35	1·16	4	8	..	..	..	..	..	275	5·7	1·42	2	8
Enhanced treatment-as-usual	156	6·29	1·2	4	8	..	..	..	..	..	127	5·71	1·44	2	8
SPS plus treatment-as-usual	180	6·42	1·13	4	8	..	..	..	..	..	148	5·69	1·41	2	8

(Table 2 continues on next page)

	Baseline					6-month follow-up					12-month follow-up				
	Number of participants	Mean	SD	Minimum	Maximum	Number of participants	Mean	SD	Minimum	Maximum	Number of participants	Mean	SD	Minimum	Maximum
(Continued from previous page)															
NSPM suicide attempts															
Total	65	1*	1 to 3†	1	60	37	1*	1 to 3†	1	30	28	1*	1 to 2·5†	1	9
Enhanced treatment-as-usual	41	2*	1 to 6†	1	60	22	1·5*	1 to 3†	1	30	14	1·5*	1 to 3†	1	9
SPS plus treatment-as-usual	24	1*	1 to 3†	1	7	15	1*	1 to 2†	1	6	14	1*	1 to 2†	1	9
NSPM self-harm															
Total	144	5*	2 to 13·5†	1	99	98	4·5*	2 to 20†	1	194	73	5*	2 to 20†	1	182
Enhanced treatment-as-usual	71	6*	3 to 20†	1	99	51	5*	2 to 24†	1	182	42	5*	2 to 22†	1	182
SPS plus treatment-as-usual	73	4*	2 to 10†	1	99	47	4*	2 to 20†	1	194	31	4*	2 to 15†	1	157
EQ5D-5L															
Total	336	0·42	0·30	0·29	0·98	244	0·45	0·32	0·38	0·99	220	0·47	0·31	−0·29	0·99
Enhanced treatment-as-usual	156	0·44	0·30	0·25	0·99	118	0·45	0·32	0·29	0·98	107	0·45	0·31	−0·29	0·98
SPS plus treatment-as-usual	180	0·40	0·30	0·29	0·99	126	0·48	0·31	0·38	0·99	113	0·49	0·30	−0·22	0·99

WSAS=Work and Social Adjustment Scale. SPS=Structured Psychological Support. DERS-16=16-item Difficulties in Emotion Regulation Scale. PHQ-9=Nine-item Patient Health Questionnaire. GAD-7=Seven-item Generalised Anxiety Disorder Scale. NSPM=National Household Survey of Psychiatric Morbidity (median number of episodes per participant over the previous 6 months). CGI=Clinical Global Impression–Improvement. PSQ=Patient Satisfaction Questionnaire. SAPAS=Standardised Assessment of Personality–Abbreviated Scale. *Median presented. †IQR presented.

Table 2: **Descriptive statistics of primary and secondary raw outcome data**

therapy and mentalisation-based treatment, and it has five key components: 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 skills for managing their main difficulties; discussion of the role of relationships and structured activities for achieving better mental health; and the use of a so-called mentalising stance to highlight mental states.[13] Patients were given written information about SPS at the start of their sessions (appendix 4 p 12). During the first two sessions, practitioners assessed the patient's understanding of their problems and their coping strategies. After these initial sessions, practitioners and participants agreed upon a psychological focus for future sessions, selecting one or more psychological skills (eg, mindfulness, interpersonal effectiveness, or mentalising) on which to focus. After the planned sessions were completed, patients were offered a follow-up review session. The treatment manual for SPS is provided in appendix 4 (pp 13–24).

See Online for appendix 4

Potential SPS practitioners were identified from existing staff by clinicians responsible for delivering local personality disorder treatment services. They were required to have had previous experience of providing psychological support to people with personality disorder and needed to complete training and be able to attend fortnightly supervision sessions. Each member of staff who delivered SPS was given a copy of a treatment manual, attended three 3-h training sessions, and completed a short assessment exercise before they treated their first study participant. They also attended fortnightly group supervision meetings, which were delivered by local clinicians who were experts in the treatment of people with personality disorder, who had completed SPS training and training in high-intensity evidence-based treatment for people with personality disorder.

Treatment fidelity was maintained by regular clinical supervision. Staff who delivered SPS were asked to complete a proforma for every participant, which recorded the number, length, and main content of in-person and remote contacts they had with the participant. We used these data together with qualitative data from the process evaluation to explore the extent to which SPS was delivered in accordance with the treatment manual.

Participants in the control group of the trial were offered enhanced treatment-as-usual, which involved treatment-as-usual plus a single session of remotely delivered crisis planning. To try to ensure adherence to National Institute for Health and Care Excellence (NICE)-recommended

	Maximum likelihood estimates for factor						Adjusted values per timepoint	
	Number of participants	Coefficient	95% CI	SE	p value	Cohen's effect size	Treatment-as-usual group (mean; SE)	SPS group (mean; SE)
Primary outcome								
WSAS	336	0·12	−2·14 to 2·38	1·14	0·92	0·10	6 months: 27·52 (0·85); 12 months: 26·68 (0·82)	6 months: 27·40 (0·79); 12 months: 26·46 (0·80)
Secondary outcomes								
DERS-16	336	4·29	0·96 to 7·63	1·69	0·012	0·19	6 months: 63·61 (1·26); 12 months: 61·04 (1·29)	6 months: 59·31 (1·22); 12 months: 57·57 (1·23)
PHQ-9	336	0·67	−0·93 to 2·28	0·82	0·41	0·08	6 months: 17·12 (0·60); 12 months: 15·99 (0·66)	6 months: 16·45 (0·59); 12 months: 15·41 (0·59)
GAD-7	336	1·19	−0·35 to 2·73	0·78	0·13	0·11	6 months: 13·97 (0·63); 12 months: 13·18 (0·60)	6 months: 12·78 (0·56); 12 months: 12·82 (0·58)
CGI	336	0·70	0·11 to 1·29	0·30	0·020	0·25	6 months: 3·93 (0·24); 12 months: 4·02 (0·23)	6 months: 3·23 (0·18); 12 months: 3·60 (0·19)
PSQ	336	−1·99	−4·01 to 0·03	1·00	0·050	0·37	12 months: 6·08 (0·89)	12 months: 8·07 (0·51)
SAPAS	336	0·22	−0·50 to 0·94	0·35	0·54	0·03	12 months: 5·95 (0·31)	12 months: 5·73 (0·14)
NSPM suicide attempts	336	1·97	−0·33 to 1·69	0·51	0·19	0·15	..	..
NSPM self-harm	336	0·85	−1·14 to 0·80	0·49	0·74	0·09	..	..
Subgroup and sensitivity analyses								
WSAS (per protocol)	275	2·77	−0·34 to 5·88	1·56	0·080	0·21	6 months: 28·90 (1·33); 12 months 26·59 (1·36)	6 months: 36·13 (1·05); 12 months: 25·16 (1·09)
WSAS borderline personality disorder criteria	336	0·92	−0·92 to 2·76	0·94	0·33	0·01	No borderline personality disorder: 28·23 (1·33); borderline personality disorder: 26·97 (0·82)	No borderline personality disorder: 26·06 (0·96); borderline personality disorder: 27·12 (0·72)
WSAS (no therapist random effect)	336	0·71	−0·90 to 2·32	0·82	0·39	0·10	6 months: 27·69 (0·70); 12 months: 26·76 (0·69)	6 months: 26·98 (0·65); 12 months: 26·24 (0·65)

WSAS=Work and Social Adjustment Scale. SPS=Structured Psychological Support. DERS-16=16-item Difficulties in Emotion Regulation Scale. PHQ-9=Nine-item Patient Health Questionnaire. GAD-7=Seven-item Generalised Anxiety Disorder Scale. NSPM=National Household Survey of Psychiatric Morbidity. CGI=Patient-rated Clinical Global Impression–Improvement. PSQ=Patient Satisfaction Questionnaire. SAPAS=Standardised Assessment of Personality–Abbreviated Scale.

Table 3: **Primary outcome, secondary outcomes, and subgroup and sensitivity analyses**

care,[14] we offered all those in the control group of the trial who did not have an up-to-date, person-centred, crisis plan an opportunity to meet remotely with an experienced clinician to develop one. All study participants continued to receive treatment-as-usual throughout the follow-up period, which included access to primary and secondary care mental health services, including access to urgent mental health care and inpatient treatment at times of crisis.

Outcomes

The primary outcome was social functioning at 12 months after randomisation, which was measured using the Work and Social Adjustment Scale (WSAS).[15] This measure was also taken at 6 months. Scores range from 0 to 40 with higher scores indicating greater disturbance in functioning. Secondary outcomes were mental health assessed using the 16-item Difficulties in Emotion Regulation Scale,[16] the nine-item Patient Health Questionnaire,[17] and the seven-item Generalised Anxiety Disorder Scale.[18] We assessed the incidence and severity of suicide attempts and self-harm, using questions from the National Household Survey of Psychiatric Morbidity (NSPM).[19]

We assessed patient experience using the patient-rated Clinical Global Impression–Improvement,[20] and we assessed patient-rated satisfaction with care using the four-item Patient Satisfaction Questionnaire.[21]

Health economic outcomes were health-related quality of life measured using the EuroQol-5 Dimension-5 Level[22] and converted to quality-adjusted life years (QALYs). We collected data on the use of health, social care, and criminal justice services using an adapted version of the Adult Service Use Schedule.[23] We assessed the primary outcome and most secondary outcomes at baseline, and at 6-month and 12-month follow-ups (appendix 4 p 25).[7] Researchers enquired whether participants had experienced adverse events at all follow-up appointments.

Choice of primary measure

We used the WSAS to measure the primary outcome because it measures social functioning, which is important to people with personality disorder and affects quality of life and other long-term outcomes. With five items, it is relatively brief and has been widely used in trials of psychological interventions, including the SPS feasibility study,[7] and has been widely used internationally. Secondary analysis of routine data from clinical samples has shown that it provides a reliable measure of social functioning and is sensitive to changes in mental health that are associated with the length and type of treatment that people receive.[15,24] No permissions are required to use the measure. A 4-point reduction in total WSAS score indicates a small improvement (eg, from severely impaired to markedly impaired) in two of the five domains of social functioning assessed by the scale.

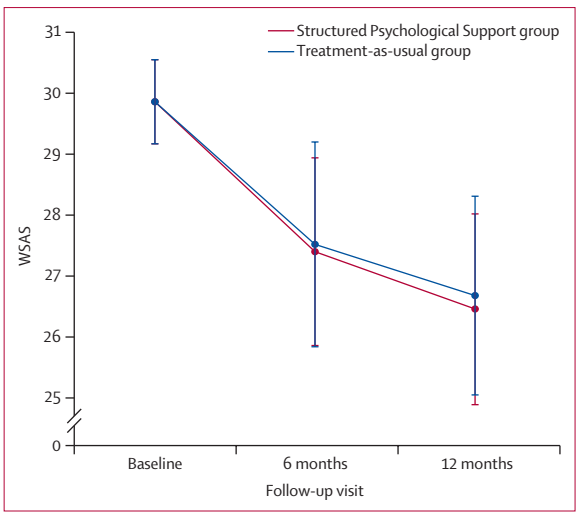

***Figure 2*: WSAS scores over time**
Data are adjusted means for the WSAS, baseline score is overall mean of raw data. WSAS=Work and Social Adjustment Scale.

Statistical analysis

The target sample size was calculated based on the primary hypothesis that, for people with probable personality disorder, the offer of SPS would improve social functioning over the course of 1 year compared with enhanced treatment-as-usual. Using a 5% significance level, we needed to analyse data from 215 participants, with a 0·5 correlation between baseline and follow-up scores, to have 90% power to detect a minimum clinically significant difference of 3·8 points (SD 9·5) in WSAS (equivalent to an effect size of 0·4).[6] We used a Variance Inflation Factor of 1·15 to account for clustering in the intervention group of the trial and an intraclass coefficient of 0·05. To account for 30% loss to follow-up, we aimed to recruit 308 participants (approximately 165 receiving SPS and 143 receiving enhanced treatment-as-usual).

The primary analysis compared WSAS scores across the 12-month period using multilevel mixed effects general linear regression, including gender and allocated treatment group as fixed effects, therapist nested within site as a random effect, and the baseline score and age as covariates. A time×group interaction term was also included. All participants with any follow-up data were included in the intention-to-treat analysis. Analysis of secondary outcomes followed the same approach where possible. To assess harms, the numbers of suicide attempts and episodes of self-harm from the NSPM were analysed. Adverse events, assessed in line with the study protocol, are presented descriptively and not compared statistically.

Patterns of missing data were assessed and predictors of missingness were identified. Missing data was deemed to be missing at random. We used multiple imputation to address missing outcomes. A complete case analysis was completed, as well as an analysis excluding those who died, to evaluate the effect of missing data.

	Treatment-as-usual group (n=101)	SPS group (n=56)	Total (N=157)
Psychiatric evaluation	17 (17%)	8 (14%)	25 (16%)
Suicidal ideation	15 (15%)	8 (14%)	23 (15%)
Intentional overdose	16 (16%)	2 (4%)	18 (11%)
Intentional self-injury	5 (5%)	5 (9%)	10 (6%)
Suicide attempt	7 (7%)	1 (2%)	8 (5%)
Anxiety	1 (1%)	4 (7%)	5 (3%)
Chest pain	3 (3%)	1 (2%)	4 (3%)
Back pain	1 (1%)	2 (4%)	3 (2%)
Dyspnoea	3 (3%)	0	3 (2%)
Ligament sprain	3 (3%)	0	3 (2%)
Bipolar disorder	1 (1%)	1 (2%)	2 (1%)
Cardiac disorder	0	2 (4%)	2 (1%)
Gastrointestinal pain	0	2 (4%)	2 (1%)
Hand fracture	1 (1%)	1 (2%)	2 (1%)
Hypoaesthesia	2 (2%)	0	2 (1%)
Limb injury	1 (1%)	1 (2%)	2 (1%)
Pain	1 (1%)	1 (2%)	2 (1%)
Self-injurious ideation	2 (2%)	0	2 (1%)
Abdominal pain	1 (1%)	0	1 (<1%)
Lower abdominal pain	1 (1%)	0	1 (<1%)
Upper abdominal pain	1 (1%)	0	1 (<1%)
Arthralgia	0	1 (2%)	1 (<1%)
Arthritis	0	1 (2%)	1 (<1%)
Autoimmune disorder	0	1 (2%)	1 (<1%)
Bladder operation	0	1 (2%)	1 (<1%)
Carbon monoxide poisoning	0	1 (2%)	1 (<1%)
Cardiac discomfort	0	1 (2%)	1 (<1%)
Deafness	1 (1%)	0	1 (<1%)
Depressed mood	1 (1%)	0	1 (<1%)
Ehlers-Danlos syndrome	1 (1%)	0	1 (<1%)
Epistaxis	1 (1%)	0	1 (<1%)
Fall	0	1 (2%)	1 (<1%)
Foot fracture	1 (1%)	0	1 (<1%)
Fracture	1 (1%)	0	1 (<1%)
Haematoma	1 (1%)	0	1 (<1%)
Head injury	0	1 (2%)	1 (<1%)
Headache	0	1 (2%)	1 (<1%)
Increased heart rate	0	1 (2%)	1 (<1%)
Hernia	0	1 (2%)	1 (<1%)
Hypertension	1 (1%)	0	1 (<1%)
Increased dose administered	0	1 (2%)	1 (<1%)
Infection	1 (1%)	0	1 (<1%)
Joint dislocation	1 (1%)	0	1 (<1%)
Localised infection	0	1 (2%)	1 (<1%)
Lower respiratory tract infection	0	1 (2%)	1 (<1%)
Mastoiditis	1 (1%)	0	1 (<1%)
Meningitis	0	1 (2%)	1 (<1%)
Menstruation delayed	1 (1%)	0	1 (<1%)
Migraine	1 (1%)	0	1 (<1%)
Nerve compression	0	1 (2%)	1 (<1%)
Neuropsychological symptoms	1 (1%)	0	1 (<1%)
Pain in extremity	1 (1%)	0	1 (<1%)
Palpitations	1 (1%)	0	1 (<1%)
Paralysis	0	1 (2%)	1 (<1%)
Pneumonia	1 (1%)	0	1 (<1%)
Post procedural complication	1 (1%)	0	1 (<1%)

(Table 4 continues in next column)

(Continued from previous column)

N represents the number of adverse events in each group. SPS=Structured Psychological Support.

Table 4: **Adverse events**

Additional analyses were conducted for the primary outcome measure. We undertook a planned, secondary, per-protocol analysis using the same methods as the primary analysis but excluding participants who received psychological interventions other than SPS as part of the trial. A planned subgroup analysis excluding participants from the active arm of the trial who did not attend five or more sessions of SPS was conducted. We did planned sensitivity analyses excluding participants who completed the 6 month follow-up outside the planned period of 28 days before and 56 days after the target date was completed, and including the number of intervention sessions that took place in person and the number of intervention sessions that took place online. The primary analysis model was repeated as a post-hoc analysis without including therapist as a random effect, to evaluate the stability of the primary findings, given the unusually high number of clusters (therapists).

We also undertook planned subgroup analyses according to whether participants: met criteria for Borderline Personality Disorder and met criteria for Complex Post Traumatic Stress Disorder. For secondary outcomes, if there was a significant effect of group in the analysis mode, these subgroup analyses were conducted, as well as the subgroup analysis to exclude participants who received psychological interventions other than SPS.

We also published a full health economics analysis plan before data analysis (appendix 3). The economic evaluation took a broad approach encompassing NHS, personal social services, and relevant non-NHS or personal social services costs, including accommodation and use of voluntary sector services. For each service use item, a relevant and suitable unit cost was identified. Differences in service use over follow-up were explored descriptively. The primary cost-effectiveness analysis considered costs alongside QALYs and the incremental cost per QALY.[25] A secondary cost-effectiveness analysis generated data on the incremental cost per unit improvement in social functioning. We used 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 the cost-effectiveness analysis. Statistical uncertainty around the estimates of cost-effectiveness was explored using net benefit calculations and through the construction of cost-effectiveness acceptability curves.[26] We used sensitivity analyses to test the assumptions used in the economic evaluation. All data were analysed using Stata (version 18).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Feb 7, 2023, and Jan 31, 2024, 569 potential participants were referred for study inclusion. 34 were deemed ineligible, 56 declined to participate, and 127 were not approached. 352 potential participants provided consent, of whom 16 were deemed ineligible or withdrew. 336 participants were eligible and randomly assigned: 180 to the SPS intervention group and 156 to the control treatment-as-usual group. 156 participants in the SPS group completed the 6-month follow-up and 152 completed the 12-month follow-up, and 134 participants in the treatment-as-usual group completed the 6-month follow-up and 132 completed the 12-month follow-up. Reasons for ineligibility are presented in the study flow chart (figure 1). The last follow-up assessment was completed on Feb 28, 2025.

Baseline characteristics of study participants are presented in table 1. 251 (75%) participants were female, with 75 (22%) men and ten (3%) transgender or non-binary people. The mean age was 34·8 years (SD 13·2; range 18–68), and 281 (84%) were White. Characteristics of the study participants appeared to be balanced across the two groups of the trial. A total of 247 (74%) participants met criteria for borderline personality disorder according to the SCID-II. Among the 292 people who completed the International Trauma Questionnaire, 190 (65%) met criteria for post traumatic stress disorder, and 181 (62%) met criteria for complex post traumatic stress disorder. We obtained primary outcome measure data from 286 (85%) participants at 6 months and 284 (85%) participants at 12 months. At 12 months, 223 (66%) follow-up assessments were conducted with a researcher and 61 (18%) were self-completed online. We included 336 participants in the primary, intention-to-treat analysis. There appeared to be approximate balance between trial groups in the baseline outcome data (table 1).

No difference was observed in the primary outcome, WSAS score, over 12 months (standardised coefficient 0·12 [95% CI −2·14 to 2·38]; p=0·92; table 2; table 3; figure 2). The intracluster correlation for the WSAS at follow-up was 0·008. No differences were seen in most secondary outcomes; however, small but statistically significant differences in favour of the intervention group were seen in emotional dysregulation (standardised coefficient 4·29 [95% CI 0·96 to 7·63]; p=0·012) and self-rated clinical improvement over 12 months (standardised coefficient 0·70 [0·11 to 1·29]; p=0·020; table 3). Differences in the primary outcome were not seen in the per-protocol analysis or the subgroup of participants who met diagnostic criteria for borderline personality disorder or complex post traumatic stress disorder. Complete case analysis, as well as analysis excluding those who died, showed no difference in conclusions of the results to the primary analysis, nor did sensitivity analysis excluding therapist as a random effect (appendix 4 pp 1–6). 157 adverse events and 36 serious adverse events were reported during the trial (table 4; table 5). Adverse events in men and women are presented in appendix 4 (p 11). Two study participants died during the 12-month follow-up period, both in the SPS group of the trial. Two adverse events and none of the serious adverse events were deemed to be related to participation in the study.

	Treatment-as-usual group (n=20)	SPS group (n=16)	Total (N=36)
Intentional overdose	5 (25%)	4 (25%)	9 (25%)
Suicidal ideation	2 (20%)	1 (6%)	3 (8%)
Death	0	2 (13%)	2 (6%)
Lower respiratory tract infection	1 (5%)	1 (6%)	2 (6%)
Alcohol misuse	0	1 (6%)	1 (3%)
Asthma	1 (5%)	0	1 (3%)
Cardiac disorder	0	1 (6%)	1 (3%)
Chest pain	0	1 (6%)	1 (3%)
Cholelithiasis	1 (5%)	0	1 (3%)
Crohn's disease	0	1 (6%)	1 (3%)
Eating disorder	1 (5%)	0	1 (3%)
Gastric bypass	1 (5%)	0	1 (3%)
Gastric haemorrhage	1 (5%)	0	1 (3%)
Gout	1 (5%)	0	1 (3%)
Decreased haemoglobin	1 (5%)	0	1 (3%)
Idiopathic intracranial hypertension	1 (5%)	0	1 (3%)
Kidney infection	0	1 (6%)	1 (3%)
Neoplasm malignant	0	1 (6%)	1 (3%)
Pharyngitis	1 (5%)	0	1 (3%)
Pneumonia	1 (5%)	0	1 (3%)
Psychiatric evaluation	1 (5%)	0	1 (3%)
Respiratory syncytial virus infection	0	1 (6%)	1 (3%)
Spinal decompression	0	1 (6%)	1 (3%)
Spinal fracture	1 (5%)	0	1 (3%)

N represents the number of serious adverse events in each group. SPS=Structured Psychological Support.

Table 5: **Serious adverse events**

SPS sessions were delivered by 76 practitioners, who each delivered SPS to a median of two participants (IQR 1–3; range 1–10). Practitioners were mainly psychologists (n=26 [34%]) and nurses (n=21 [28%]), with the remainder being psychiatrists, assistant practitioners, graduate psychologists, occupational therapists, mental health and wellbeing practitioners, and lived experience practitioners. Median time working in the NHS was 6 years (IQR 3–10). An audit of attendance at supervision meetings showed that, on average, 76% (95% CI 64·1–85·7) of practitioners who were expected to have attended a supervision meeting did so. Missing sessions was generally the result of annual leave and sickness absence. Participants in the active group of the trial received a median of seven SPS sessions (IQR 3–10) and 21 (12%) of 180 did not attend any sessions. The median time between randomisation and the first SPS session was 5 weeks (IQR 3–10). Most sessions were delivered in-person, with 23% delivered online. We did not see differences in outcomes between those who received face to face sessions and those who received online sessions. Data from treatment pro formas of 177 (98%) of 180 participants in the active group of the trial showed that all 177 received one or more psychological interventions, with a median of four per participant. The most widely used interventions were dialectical behavioural therapy skills (91 [64%] of 142), psychoeducation (55 [39%]), behavioural chain analysis (46 [32%]), cognitive behavioural therapy skills (29 [20%]), and mindfulness (30 [21%]). Crisis-planning sessions were generally delivered by psychiatrists. Among 156 participants allocated to the treatment-as-usual group of the trial, 16 (10%) did not require a new crisis plan, and 11 (6%) withdrew from study shortly after randomisation. Of the remaining 129 participants, 85 (65%) received an updated crisis plan and 44 (34%) declined the offer of a meeting.

The SPS intervention cost on average £878 per participant, and the crisis planning cost £86. The between-groups difference in cost in the raw data over the 12-month follow-up period was £136, suggesting the additional cost of the SPS intervention was offset by reductions in use of other services in the health system (appendix 4 pp 7–9). However, on statistical analysis with adjustments for baseline covariates, the difference in cost is small and in favour of the treatment-as-usual group, due to lower costs in the SPS group at baseline.

QALYs over follow-up were higher in the SPS group (0·46 QALYs for the SPS group *vs* 0·43 QALYs for the treatment-as-usual group), although the difference was very small and not statistically significant. Overall, costs were higher and outcomes better for the SPS group compared with the treatment-as-usual group. When examined in a cost-effectiveness analysis, the SPS intervention was not cost-effective, with a probability of 0·34–0·39 at the NICE threshold of £20–30k per QALY.

Discussion

To our knowledge, the SPS study is the first fully powered trial of a brief individual psychological intervention for people with personality disorder. We found that offering people up to ten sessions of person-centred psychological support was not associated with improved social functioning compared with offering them a single session of mental health crisis planning (enhanced treatment-as-usual). We also found no difference in levels of depression, anxiety, personality dysfunction, or suicidal behaviour between those offered SPS and those offered a crisis planning session. SPS did not provide a cost-effective use of resources. Although we detected reductions in emotional dysregulation and increases in self-rated global improvement among those in the SPS group, the differences were small. The results of this study contrast with those of clinical trials of longer-term psychological treatment programmes for people with borderline personality disorder, which have shown reductions in symptom severity, suicidal behaviour and depression, and improvements in psychosocial functioning.[3]

However, the findings support the only previous explanatory trial of a brief psychological intervention for people with personality disorder. The PEPS trial[5] found no evidence of patient benefit among those offered four sessions of psychoeducation and 12 group-based sessions of problem solving compared with those offered treatment-as-usual. Subsequent qualitative research among people with personality disorder who had received a brief intervention suggested that many felt it was unhelpful because the group-based format meant that their individual needs were not met.[13] The SPS study was designed in response to these findings and aimed to test whether a brief intervention would benefit people if it was delivered to them as individuals rather than in groups.

Both the SPS trial and the PEPS trial were preceded by smaller-scale phase 2 trials, which reported evidence of patient benefit. There are multiple reasons why promising findings from feasibility trials do not translate into positive results in phase 3 trials.[27] In both the SPS and PEPS trials, a key difference between the phase 2 and phase 3 trials was that the feasibility studies were conducted at sites where the intervention was initially developed and practised. The subsequent explanatory trials involved new staff in different areas where there was little or no experience of delivering these interventions.

Data from the parallel process evaluation will be reported separately, but interviews with study participants revealed that many previously had negative experiences of contact with mental health services and needed time to start to develop trust in their SPS practitioner. This might have meant that there was limited time for the acquisition or practice of the psychological skills offered, reducing the intervention's capacity to produce measurable benefits. Other participants voiced concerns about what would happen to them once sessions had finished. This concern was shared by members of the Lived Experience Advisory

Panel who spoke of feeling that they were going to "fall off a cliff edge" once contact with mental health services was ended. These observations highlight the importance of attachment and trust when working psychologically with people with personality disorder[28] and the inherent limitations of brief interventions, in which practitioners and patients spend limited time together.

The SPS study included a relatively large sample size and had relatively high retention. Strategies for recruitment and retention were greatly influenced by input from an active Lived Experience Advisory Panel, which helped us to achieve a higher rate of follow-up than has been reported in previous randomised trials of people with personality disorder.[29] Most participants were female, reflecting the predominance of women among people with personality disorder who use mental health services.[1] More than three-quarters of participants were White, reflecting the demographic characteristics of the local populations where the study was conducted. Previous randomised trials have generally been restricted to those who met criteria for borderline personality disorder. In keeping with changes to WHO's International Classification of Diseases, which classifies personality disorder according to severity rather than type of disorder,[1] we recruited a wider sample of people with a broader range of personality-related problems. However, it is unlikely that the characteristics of the study sample explain the differences between the SPS trial and those of previous studies of longer term interventions, because nearly three-quarters of people who took part in the SPS trial did meet diagnostic criteria for borderline personality disorder and we did not find evidence of patient benefit in a sensitivity analysis that was restricted to this group.

The study had several limitations, including the absence of high-quality information on treatment fidelity and the small number of participants that each SPS practitioner treated in the trial. We were unable to collect and analyse data from audio-recordings of SPS sessions. However, we were able to explore treatment fidelity qualitatively and practitioners completed a pro forma for each participant they met, which detailed the number and length of sessions they completed and the psychological interventions they delivered. These sources of data suggest that practitioners took longer to develop a therapeutic relationship than originally envisaged, and that there was limited time to rehearse psychological skills during the median of seven sessions that people in the active group of the trial received. We originally planned that each SPS practitioner would treat four or five participants.[8] In practice, high staff turnover meant that more than 70% of practitioners treated only one or two participants in the study. Practitioners in this study might not have been able to develop the experience and confidence in using SPS that would be needed to deliver benefits for patients. Training for staff was limited to 9 h over three sessions. It was followed by fortnightly supervision sessions with an experienced clinician with expertise in the psychological treatment of people with personality disorder. Additional training or supervision for practitioners could have increased the benefit that participants in the active group of the trial experienced. Study participants reported having had first contact with mental health services 13 years before taking part in the study. SPS might provide greater patient benefit if delivered to people at an earlier stage of their contact with services. The limited number of non-female participants restricts the generalisability of the findings.

The results of the SPS trial support NICE guidance that cautions against the use of brief psychological interventions for people with personality disorder.[14] Although short-term psychological interventions have been used to support people with personality disorder as a prelude to further treatment, the results of this study indicate that stand-alone, short-term, individual psychological interventions are unlikely to generate the improvements in mental health and social functioning that are seen with more intensive psychological treatment programmes. Previous research suggests that patients might benefit from shorter versions of these programmes, which last between 4 months and 6 months, in contrast to the 12-to-18-month periods of treatment that were originally recommended.[30] Future research is needed into how evidence-based psychological treatment programmes can be made accessible to more people and delivered in the most cost-effective way. Fully powered pragmatic trials of brief interventions which have shown promise in small-scale trials are also needed.

In conclusion, the brief individual psychological intervention for patients with probable personality disorder that we tested in this trial was not associated with improved social functioning or reductions in suicidal behaviour and is unlikely to provide a cost-effective use of resources. Available evidence does not support the widespread use of brief individual psychological interventions for people with personality disorder.

Contributors

The study was conceived by MJC (chief investigator) and by VCL, RE, FK-T, TW, BB, KS, GL, PM, DK, and KB who received funding. The study protocol was developed by MJC, VCL, RE, NG, TW, AT, BB, FK-T, SPP, GL, DW, HS, TG, VN, and KB. NG was the trial statistician and RE was the senior statistician. The health economic analysis was led by JA and BB. AT led collection of qualitative data, and the analysis was conducted by AT and TW. FK-T led Patient and Public Involvement in the study. KS, GL, DW, HS, TG, and VN supervised research teams at study sites. NG, RE, and MC accessed and verified the data. MJC is the study guarantor. All authors read and approved the final manuscript and confirm they had full access to study data and accept responsibility to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

Individual participant data and a data dictionary defining each field in the dataset will be made available upon reasonable request to the corresponding author.

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