Brief individual psychological intervention for people with probable personality disorder: a multicentre, randomised controlled superiority trial in England: Summary of study findings

Background

Long-term psychological treatments are recommended for people with personality disorder. Brief interventions are increasingly delivered but 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 multi-centre, researcher-masked, randomised controlled superiority trial, conducted in seven mental health Trusts in England. Participants were 18 years or older and had probable personality disorder identified by meeting a threshold of four or more on the Standardised Assessment of Personality Abbreviated Scale. We excluded those who: did not consent; had a co-existing psychosis; 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 randomised participants to up to 10 sessions of SPS 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 of up to 10 individual sessions of personalised psychological support, which includes psychoeducation and psychological skills derived from evidence-based treatments (Dialectical Behaviour Therapy and Mentalization Based Treatment). Sessions were usually delivered on a fortnightly basis by staff with previous experience of working with people with personality disorder who had completed three, three-hour training sessions and received fortnightly supervision from experienced supervisors. The primary outcome was social functioning at 12 months measured using the Work and Social Adjustment Scale. Data were analysed using multilevel mixed effects general linear regression on an intention-to-treat basis. We undertook a parallel health economic evaluation, which included a 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

Outcomes

Between 7th February 2023 and 31st January 2024, 569 people were screened. Of these, 336 were allocated to the active arm (180) or control arm (156) of the trial (see flow diagram at the end of this report).

Most participants were female (n = 257, 75, %), 75 (22%) were men and 10 (3%) were transgendered or non-binary. Mean age was 34.8 (Standard Deviation = 13·2), and 281 (77%) were white (see table 1).

The attrition rate was 15% at 12 months. There was no difference between groups on the primary outcome (Coefficient = 0·12, 95% CI = -2·1, 2·4, p = 0·91) (see table 2). No difference was observed in the primary outcome, WSAS score, over 12 months (Standardised coefficient = 0·12, 95% CI = -2·1, 2·4, p = 0·91; see table 3).

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 arm were seen in emotional dysregulation (Standardised coefficient = 4.29, 95% CI = 0..96, 7.63, p = 0·01) and self-rated clinical improvement over 12 months (Standardised coefficient = 0.70, 95% CI = 0.11, 1.29, p = 0·02) (see table 3). The probability that SPS is cost effective was between 34-39%. There were 36 serious adverse events affecting 17 participants in the active and 16 in the control arm of the trial. None were judged to be related to study procedures (see table 4).

Interpretation

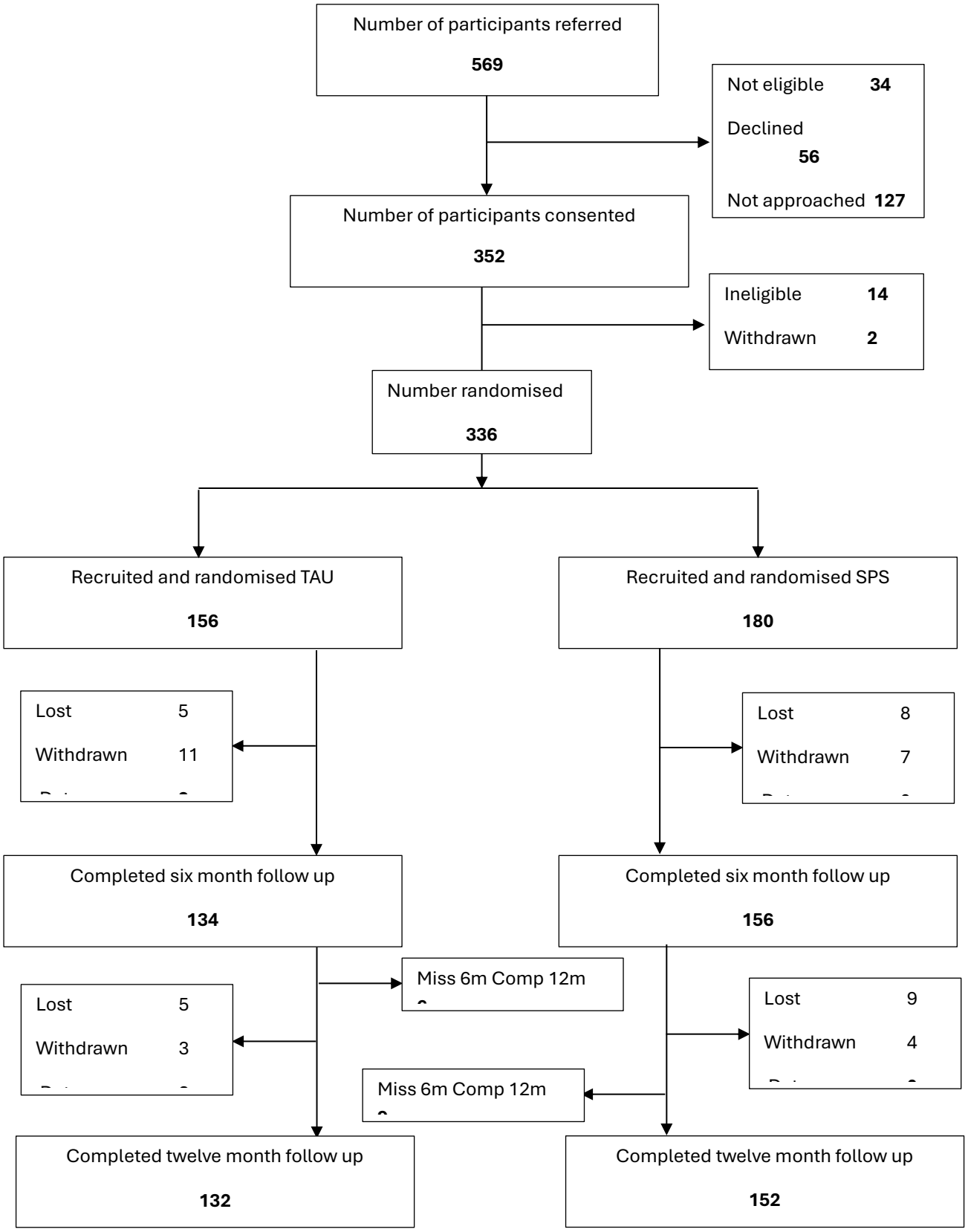
We found no difference in social functioning over one-year among people offered brief psychological intervention and no evidence of cost-effectiveness. These data highlight the importance of improving access to longer-term evidence-based psychological treatment programmes for people with personality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

Funding

National Institute for Health and Care Research.

Competing interests statement

We declare no competing interests.



Flow diagram

	Control group N=156	SPS group N=180	Overall N=336
Age, years			
Mean (SD)	35·1 (13·6)	34·4 (13·0)	34·8 (13·2)
Gender			
Male	36 (23%)	39 (21%)	75 (22%)
Female	117 (75%)	134 (74%)	251 (75%)
Non-binary/Other	3 (2%)	7 (4%)	10 (3%)
Ethnicity			
British	129 (81%)	152 (85%)	281 (84%)
Mixed	11 (7%)	8 (5%)	19 (6%)
Asian	9 (6%)	7 (4%)	16 (5%)
Black	6 (4%)	11 (6%)	17 (5%)
Other	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 (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 (52%)	82 (46%)	162 (48%)
Employed, voluntary work, or education	76 (48%)	97 (54%)	173 (52%)
Missing	0 (0%)	1 (1%)	1 (0%)
Source of referral			
Specialist personality disorder service	5 (3%)	4 (2%)	9 (3%)
General adult mental health service	62 (40%)	75 (41%)	137 (41%)
Mental health liaison service	18 (12%)	20 (11%)	38 (11%)
Primary care mental health service	71 (46%)	81 (45%)	152 (45%)
Length of time since first contact with mental health services (years)			
Mean (SD)	12·8 (9·6)	14·0 (10·9)	13·5 (10·4)

Table 1: Baseline characteristics of study sample

	Group	Baseline					6 Month Follow Up					12 Month Follow Up				
		N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max
Primary outcome																
WSAS	Total	333	29·86	6·4	7	40	286	27·3	7·88	0	40	284	26·58	8·71	1	40
	TAU	155	29·67	6·84	7	40	133	27·72	7·06	10	40	132	27·04	8·15	5	40
	SPS	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
	TAU	154	65·13	10·02	33	80	133	61·77	10·7	20	80	129	59·54	12·57	29	80
	SPS	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
	TAU	156	18·63	5·22	5	27	133	16·7	6·17	1	27	128	15·67	6·85	0	27
	SPS	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
	TAU	156	15·49	4·4	1	21	132	13·66	5·15	0	21	129	12·86	5·27	0	21
	SPS	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
	TAU	156	4·16	1·43	1	7	133	3·76	1·43	1	7	129	3·79	1·6	1	7
	SPS	180	4·26	1·39	1	7	150	3·25	1·48	1	7	142	3·56	1·6	1	7

	Group	Baseline					6 Month Follow Up					12 Month Follow Up				
		N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max
PSQ	Total	328	6·85	3·73	0	12	-	-	-	-	-	265	7·23	3·93	0	12
	TAU	154	7·07	3·78	0	12	-	-	-	-	-	126	6·48	4·07	0	12
	SPS	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
	TAU	156	6·29	1·2	4	8	-	-	-	-	-	127	5·71	1·44	2	8
	SPS	180	6·42	1·13	4	8	-	-	-	-	-	148	5·69	1·41	2	8
NHSPM Suicide attempts	Total	65	* 1	* [1 – 3]	1	60	37	* 1	* [1 – 3]	1	30	28	* 1	* [1 – 2·5]	1	9
	TAU	41	* 2	* [1 – 6]	1	60	22	* 1·5	* [1 – 3]	1	30	14	* 1·5	* [1 – 3]	1	9
	SPS	24	* 1	* [1 – 3]	1	7	15	* 1	* [1 – 2]	1	6	14	* 1	* [1 – 2]	1	9
NHSPM Self-harm	Total	144	* 5	* [2 – 13·5]	1	99	98	* 4·5	* [2 – 20]	1	194	73	* 5	* [2 – 20]	1	182
	TAU	71	* 6	* [3 – 20]	1	99	51	* 5	* [2 – 24]	1	182	42	* 5	* [2 – 22]	1	182
	SPS	73	* 4	* [2 – 10]	1	99	47	* 4	* [2 – 20]	1	194	31	* 4	* [2 – 15]	1	157
EQ5D-5L Quality of life	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
	TAU	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

	Group	Baseline					6 Month Follow Up					12 Month Follow Up				
		N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max	N	Mean * Median	SD * [IQR]	Min	Max
	SPS	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

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

WSAS = Work and Social Adjustment Scale. DERS-16 = 16-item Difficulties in Emotion Regulation Scale. PHQ-9 = Nine-item Patient Health Questionnaire. GAD-7 = Seven-item Generalised Anxiety Disorder (GAD-7). NSPM = National Household Survey of Psychiatric Morbidity (median number of episodes per participant over the previous six months). CGI = Patient-rated Global Clinical Improvement. PSQ = Patient-rated Satisfaction with Care. SAPAS = Standardised Assessment of Personality – Abbreviated Scale. EQ5-D-5L = EuroQol-5 Dimension-5 Level.

	Number of participants	Maximum likelihood estimates for factor					Cohen's effect size	Adjusted values per time				
		coefficient	SE	p-value	95% CI			time point	Control		SPS	
					lower	upper			mean	SE	mean	SE
PRIMARY OUTCOME												
WSAS	336	0·12	1·14	0·92	-2·14	2·38	0·10	6 month	27·52	0·85	27·40	0·79
								12 month	26·68	0·82	26·46	0·80
SECONDARY OUTCOMES												
DERS-16	336	4·29	1·69	0·01	0·96	7·632	0·19	6 month	63·61	1·26	59·31	1·22
								12 month	61·04	1·29	57·57	1·23
PHQ-9	336	0·67	0·82	0·41	-0·93	2·28	0·08	6 month	17·12	0·60	16·45	0·59
								12 month	15·99	0·66	15·41	0·59
GAD-7	336	1·19	0·78	0·13	-0·35	2·73	0·11	6 month	13·97	0·63	12·78	0·56
								12 month	13·18	0·60	12·82	0·58
CGI	336	0·70	0·30	0·02	0·11	1·29	0·25	6 month	3·93	0·24	3·23	0·18
								12 month	4·02	0·23	3·60	0·19
PSQ	336	-1·99	1·00	0·05	-4·01	0·03	0·37	12 month	6·08	0·89	8·07	0·51
SAPAS	336	0·22	0·35	0·54	-0·50	0·94	0·03	12 month	5·95	0·31	5·73	0·14
NHSPM suicide attempts	336	1·97	0·51	0·19	-0·33	1·69	0·15	Over 12 months	-	-	-	-
NHSPM self-harm	336	0·85	0·49	0·74	-1·14	0·80	0·09	Over 12 months	-	-	-	-
SUBGROUP AND SENSITIVITY ANALYSES												
WSAS per protocol	275	2·77	1·56	0·08	-0·34	5·88	0·21	6 month	28·90	1·33	36·13	1·05
								12 month	26·59	1·36	25·16	1·09

	Number of participants	Maximum likelihood estimates for factor					Cohen's effect size	time point	Adjusted values per time			
		coefficient	SE	p-value	95% CI				Control		SPS	
					lower	upper			mean	SE	mean	SE
PRIMARY OUTCOME												
WSAS met BPD criteria	336	0·92	0·94	0·33	-0·92	2·76	0·01	No BPD BPD	28·23 26·97	1·33 0·82	26·06 27·12	0·96 0·72
WSAS no therapist random effect	336	0·71	0·82	0·39	-0·90	2·32	0·10	6 month 12 month	27.69 26.76	0.70 0·69	26·98 26.24	0·65 0·65

Table 3. Primary, secondary outcomes, subgroup and sensitivity analysis

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

Adverse events	Control group N=101		SPS group N=56		Total N=157	
	N	%	N	%	N	%
Psychiatric evaluation	17	16·83	8	14·29	25	15·92
Suicidal ideation	15	14·85	8	14·29	23	14·65
Intentional overdose	16	15·84	2	3·57	18	11·46
Intentional self-injury	5	4·95	5	8·93	10	6·37
Suicide attempt	7	6·93	1	1·79	8	5·1
Anxiety	1	0·99	4	7·14	5	3·18
Chest pain	3	2·97	1	1·79	4	2·55
Back pain	1	0·99	2	3·57	3	1·91
Dyspnoea	3	2·97	0	0	3	1·91
Ligament sprain	3	2·97	0	0	3	1·91
Bipolar disorder	1	0·99	1	1·79	2	1·27
Cardiac disorder	0	0	2	3·57	2	1·27
Gastrointestinal pain	0	0	2	3·57	2	1·27
Hand fracture	1	0·99	1	1·79	2	1·27
Hypoaesthesia	2	1·98	0	0	2	1·27
Limb injury	1	0·99	1	1·79	2	1·27
Pain	1	0·99	1	1·79	2	1·27
Self-injurious ideation	2	1·98	0	0	2	1·27
Abdominal pain	1	0·99	0	0	1	0·64
Abdominal pain lower	1	0·99	0	0	1	0·64
Abdominal pain upper	1	0·99	0	0	1	0·64
Arthralgia	0	0	1	1·79	1	0·64
Arthritis	0	0	1	1·79	1	0·64
Autoimmune disorder	0	0	1	1·79	1	0·64
Bladder operation	0	0	1	1·79	1	0·64
Carbon monoxide poisoning	0	0	1	1·79	1	0·64
Cardiac discomfort	0	0	1	1·79	1	0·64
Deafness	1	0·99	0	0	1	0·64
Depressed mood	1	0·99	0	0	1	0·64
Ehlers-Danlos syndrome	1	0·99	0	0	1	0·64
Epistaxis	1	0·99	0	0	1	0·64
Fall	0	0	1	1·79	1	0·64
Foot fracture	1	0·99	0	0	1	0·64
Fracture	1	0·99	0	0	1	0·64
Haematoma	1	0·99	0	0	1	0·64
Head injury	0	0	1	1·79	1	0·64
Headache	0	0	1	1·79	1	0·64
Heart rate increased	0	0	1	1·79	1	0·64
Hernia	0	0	1	1·79	1	0·64
Hypertension	1	0·99	0	0	1	0·64
Increased dose administered	0	0	1	1·79	1	0·64
Infection	1	0·99	0	0	1	0·64
Joint dislocation	1	0·99	0	0	1	0·64
Localised infection	0	0	1	1·79	1	0·64
Lower respiratory tract infection	0	0	1	1·79	1	0·64

Mastoiditis	1	0·99	0	0	1	0·64
Meningitis	0	0	1	1·79	1	0·64
Menstruation delayed	1	0·99	0	0	1	0·64
Migraine	1	0·99	0	0	1	0·64
Nerve compression	0	0	1	1·79	1	0·64
Neuropsychological symptoms	1	0·99	0	0	1	0·64
Pain in extremity	1	0·99	0	0	1	0·64
Palpitations	1	0·99	0	0	1	0·64
Paralysis	0	0	1	1·79	1	0·64
Pneumonia	1	0·99	0	0	1	0·64
Post procedural complication	1	0·99	0	0	1	0·64
Serious adverse events	Control group N=20		SPS group N=16		Total N=36	
	N	%	N	%	N	%
Intentional overdose	5	25	4	25	9	25
Suicidal ideation	2	10	1	6·25	3	8·33
Death	0	0	2	12·5	2	5·56
Lower respiratory tract infection	1	5	1	6·25	2	5·56
Alcohol abuse	0	0	1	6·25	1	2·78
Asthma	1	5	0	0	1	2·78
Cardiac disorder	0	0	1	6·25	1	2·78
Chest pain	0	0	1	6·25	1	2·78
Cholelithiasis	1	5	0	0	1	2·78
Crohn's disease	0	0	1	6·25	1	2·78
Eating disorder	1	5	0	0	1	2·78
Gastric bypass	1	5	0	0	1	2·78
Gastric haemorrhage	1	5	0	0	1	2·78
Gout	1	5	0	0	1	2·78
Haemoglobin decreased	1	5	0	0	1	2·78
Idiopathic intracranial hypertension	1	5	0	0	1	2·78
Kidney infection	0	0	1	6·25	1	2·78
Neoplasm malignant	0	0	1	6·25	1	2·78
Pharyngitis	1	5	0	0	1	2·78
Pneumonia	1	5	0	0	1	2·78
Psychiatric evaluation	1	5	0	0	1	2·78
Respiratory syncytial virus infection	0	0	1	6·25	1	2·78
Spinal decompression	0	0	1	6·25	1	2·78
Spinal fracture	1	5	0	0	1	2·78

Table 4: Adverse events, and serious adverse events