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The cognitive behavioural prevention of suicide in psychosis: A clinical trial

Nicholas Tarrier [a], James Kelly [b], Sehar Maqsood [b], Natasha Snelson [b], Janet Maxwell [c], Heather Law [b], Graham Dunn [c], Patricia Gooding [c,*]

[a] Department of Psychology, Institute of Psychiatry, London, UK
[b] Greater Manchester West Mental Health NHS Foundation Trust, UK
[c] Faculty of Human and Medical Sciences, University of Manchester, UK

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ABSTRACT

Background: Suicide behaviour in psychosis is a significant clinical and social problem. There is a dearth of evidence for psychological interventions designed to reduce suicide risk in this population.
Aims: To evaluate a novel, manualised, cognitive behavioural treatment protocol (CBSPp) based upon an empirically validated theoretical model.
Methods: A randomly controlled trial with independent and masked allocated and assessment of CBSPp with TAU (n = 25, 24 sessions) compared to TAU alone (n = 24) using standardised assessments. Measures of suicide probability, and suicidal ideation were the primary outcomes and measures of hopelessness, depression, psychotic symptoms, functioning, and self-esteem were the secondary outcomes, assessed at 4 and 6 months follow-up.
Results: The CBSPp group improved differentially to the TAU group on two out of three primary outcome measures of suicidal ideation and suicide probability, and on secondary outcomes of hopelessness related to suicide probability, depression, some psychotic symptoms and self-esteem.
Conclusions: CBSPp is a feasible intervention which has the potential to reduce proxy measures of suicide in psychotic patients.

1. Introduction

Suicide and suicide behaviour are of substantial public and social concern. It is well established that risk of suicide is considerably elevated in those suffering from schizophrenia and psychotic disorders (Caldwell and Gottesman, 1990; Cohen et al., 1994; Hawton et al., 2005; Bolton et al., 2007). Suicide ideation and suicide attempts are common with up to 50% of patients experiencing suicidal ideation at any point in time or having a history of previous attempts (Hawton et al., 2005; Palmer et al., 2005). It is assumed that there is a progressive continuum from ideation, intent, action and completion (Bolton et al., 2007). Thus, suicidal ideation is a risk factor for self-harm and completed suicide and a legitimate clinical target in its own right.

A meta-analysis of cognitive–behavioural interventions (CBT) to reduce suicide behaviour (Tarrier et al., 2008) demonstrated that individual, but not group, CBT, was effective in significantly reducing suicide behaviour in adults, although not adolescents, in the short and medium term. This result held despite considerable variability both in the target populations and in the CBT interventions. There is, however, a paucity of studies which have attempted to diminish suicide behaviour in psychosis, despite the well established high risk in this group. Cognitive behaviour therapy for psychosis (CBTp) reduces positive and negative symptoms of psychosis, depression, and anxiety but has less effect on hopelessness (Wykes et al., 2008) and suicidality (Tarrier et al., 2006).

Psychological interventions are most likely to be successful when they are clearly derived from a theoretical understanding of underlying mechanisms (Bolton et al., 2007; Johnson et al., 2008a). Advances in understanding the cognitive architecture underpinning suicidality have resulted in the development of empirically validated theoretical models, such as, the Schematic Appraisal Model of Suicide (SAMS) (Johnson et al., 2008a,b) which was modified from the Cry of Pain model (Williams, 1997). The SAMS has three core psychological components, namely, the presence of negative information processing biases, extensive 'suicide schema', and a negative and suicide focused appraisals system (Johnson et al., 2008a). To date, empirical evidence supports a multi-tiered appraisals system together with the operation

* Corresponding author at: School of Psychological Sciences, University of Manchester, M13 9PL, UK.

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of suicide schema in people experiencing suicidality, psychosis, and post traumatic stress disorder (Pratt et al., 2010; Taylor et al., 2010b,c; Panagioti et al., 2012c).

The Cognitive Behavioural Prevention of Suicide in psychosis protocol (CBSPp) (Tarrier et al., 2008; Tarrier et al., 2013) was founded on the SAMS. Thus, the specific cognitions targeted by CBSPp are information processing biases, and appraisals of defeat, entrapment, emotional dys-regulation, social isolation, and poor interpersonal problem solving (Tarrier et al., 2013). Although CBSPp arose from work with psychosis and post-traumatic stress disorder, it has the potential to be applied trans-diagnostically (Tarrier et al., 2013).

The aim of this study was to evaluate the CBSPp protocol. As far as we are aware this is the first evaluation of a suicide prevention intervention that has been intentionally derived from an empirically validated theoretical model of suicide (Johnson et al., 2010a,b; Pratt et al., 2010; Taylor et al., 2010b,c; Johnson et al., 2011; Taylor et al., 2011; Panagioti et al., 2012a,b,c).

Specifically, it was hypothesised that CBSPp in addition to Treatment As Usual (TAU) would have significant advantages over TAU alone in reducing 1) measures reflecting suicidal behaviour including hopelessness, and, 2) measures associated with other symptom clusters of psychosis including depression, thought disorder, and low self-esteem.

2. Method

This was a single blind randomised control trial, which aimed to test the feasibility and potential efficacy of a novel intervention (CBSPp) designed to reduce suicidal behaviours in those suffering from schizophrenia spectrum disorders. Participants assigned to the Treatment condition plus TAU were compared to those allocated to a TAU condition alone.

2.1. Participants

Ethical approval was obtained from Stockport Research Ethics Committee (08/H1012/97).

Between April 2009–October 2010 Community Mental Health Teams (CMHT), Early Intervention (EI) teams, and Assertive Outreach (AO) teams across four National Mental Health Service trusts including, Greater Manchester West, Manchester Mental Health and Social Care, Pennine Care and Five Boroughs in the North West of England, were approached to facilitate recruitment.

Participants were recruited into the study if they were: (a) aged between 18 and 65; (b) had a DSM IV diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychotic disorder not otherwise specified; (c) identified as having previous suicide attempts or experiencing current suicidal ideation; (d) under the care of an appropriate clinical team and currently in contact with mental health services; (e) receiving appropriate antipsychotic medication; and, (f) not currently receiving CBT or other empirically validated psychological treatments. Participants were excluded if they: (a) currently suffered serious suicidal intent and were currently considered a danger to themselves; (b) had a primary diagnosis of bipolar depression or substance induced psychosis; and, (c) suffered from an organic brain disease.

2.2. Procedure

Mental health staff identified potential participants on their case load who met the recruitment criteria. Once diagnosis was confirmed and written consent was obtained, the baseline assessments were administered by research assistants (RAs) independent of therapy. Following the baseline assessment, participants were randomised using a clinical data management system and allocated to either the experimental treatment group where participants were to receive CBSPp plus TAU or the control group where participants were to receive only TAU. Randomisation was controlled by staff not directly linked to the trial to ensure independence and blindness to the trial allocation arms.

Participants were informed of the randomisation outcome via a letter, which also contained a note reminding them not to disclose any information about their care or treatment during assessments which would break the blind requirement. In cases where the RAs were unblinded, protocols were followed whereby unblinding was documented and the assessment packs were scored by another RA. Masking was further maintained by ensuring that therapists and RAs were located in different offices so that therapy files and assessment data were stored separately. In addition, clinical staff were repeatedly instructed not to disclose any knowledge of therapy or group allocation to assessors. Participants who were allocated to the treatment arm were then contacted by one of the trial therapists to arrange their first session. Therapists were given a copy of the completed baseline assessments prior to starting therapy sessions to aid their clinical formulations and prevent unnecessary repetition of questioning of participants.

Participants were assessed at baseline, then at 4 and 6 month follow up time points. Prior to each assessment point, care coordinators were approached by a member of the research team to obtain a comprehensive risk assessment.[1]

A routine telephone follow up call was made the day after each assessment and seven days later to ensure that the assessments had not caused any distressing after-effects for the participant.

2.3. Measures/assessments

Standardised measures consisting of a short semi-structured clinical interview and self-report questionnaires were used.

2.3.1. Primary outcome measures

These were measures of suicidal thoughts and behaviours as follows:

1) The Beck Scale for Suicidal ideation; BSS (Beck and Steer, 1991).
   The BSS is a 21-item questionnaire with three response options assessing suicidal ideation, planning and intent in the past week, and previous attempt history.
2) The Adult Suicidal Ideation Questionnaire; ASIQ (Reynolds, 1991).
   The ASIQ is a 25 item scale, assessing suicidal intent in adults. Respondents report the frequency of thoughts about death in the last month using a 7 point Likert scale.
3) The Suicide Probability Scale; SPS (Cull and Gill, 1982).
   The SPS consists of 36 statements with 4 subscales (hopelessness, suicidal ideation, negative self-evaluation, and hostility). Responses are measured on a 4 point Likert scale.

2.3.2. Secondary outcome measures[2,3]

These were included to reflect mood and psychotic symptoms.

1) Calgary Depression Scale (Addington et al., 1990).
2) The Beck Anxiety Scale (Beck et al., 1988).
3) The Beck Hopelessness Scale (Beck et al., 1974).
4) The Positive and Negative Symptom Scale; PANSS (Kay et al., 1987).
5) The Psychotic Symptoms Ratings Scales; PSYRATS (Haddock et al., 1999).
6) Self Esteem Rating Scale (Lecomte et al., 2006).
7) Global Assessment of Functioning; GAF (DSM (IV), 1994) which provides a total score and two sub-scales of symptoms and disability, scores.

[1] History of self-neglect, environmental risk, relapse risk, self-harm, and harm to others.

[2] We acknowledge that primary and secondary outcome measures may be correlated as is often found in mental health research.

[3] Other measures relating to recovery were included in this pilot trial but have not been included in this data analysis because they were not relevant to suicidality. These were the Subjective Experiences of Psychotic Symptoms Scale and an unpublished scale about the process of recovery.

2.4. Training and monitoring/supervising trial therapists

Trial therapists were two clinical psychologists (JK, JM) who had extensive experience in delivering CBT for psychosis.

Prior to the commencement of the trial, the therapists received extensive training to familiarise them with the therapy manual. During the trial, group supervision with the treatment developer (NT) was provided fortnightly and peer supervision occurred weekly.

2.5. Intervention

CBSPp was based upon a treatment manual (Tarrier et al., 2008; Tarrier et al., 2013) and was derived from an explanatory model of suicide behaviour; the SAMS (Johnson et al., 2008a). The intervention consisted of three phases to address and change the three components of the SAMS. Modification of:

1) Information processing biases.
2) Appraisals, of defeat, entrapment, social isolation, emotional dysregulation and inter-personal problem solving.
3) Suicide schema.

In addition, the sessions focussed on the processes thought to underlie resilience to suicide.

The psychological therapy consisted of up to 24 individual therapy sessions delivered twice a week across 12 weeks at a convenient location for the participant (usually their home). Telephone contact or SMS messaging was utilised as appropriate, to support the therapy sessions.

2.6. Statistical analysis

All analyses used *Stata* version 11 (StataCorp, 2009). Random effects (i.e. random intercepts) models for repeated measures data were fitted to both 4- and 6-month outcome variables with the baseline value of the outcome variable being used as a covariate (allowing for a follow-up time by covariate interaction in all models). *Stata*'s *xtreg* command was used. After preliminary examination of the data, treatment effects were assumed to be the same for both follow-up times, the estimate of the effect of treatment arising from fitting the random effect model being that which is common to both follow-up times. Because most, if not all, of the outcomes were positively skewed, confidence intervals for the treatment effects were routinely estimated through the use of the bootstrap (Efron and Tibshirani, 1993) using the percentiles based on the results of 1000 replications (using the trial participant as the sampling unit).

3. Results

Of the 131 potentially eligible participants, 49 were randomised, 25 to CBSPp plus TAU and 24 to TAU alone (see Fig. 1). Of the CBSPp group,

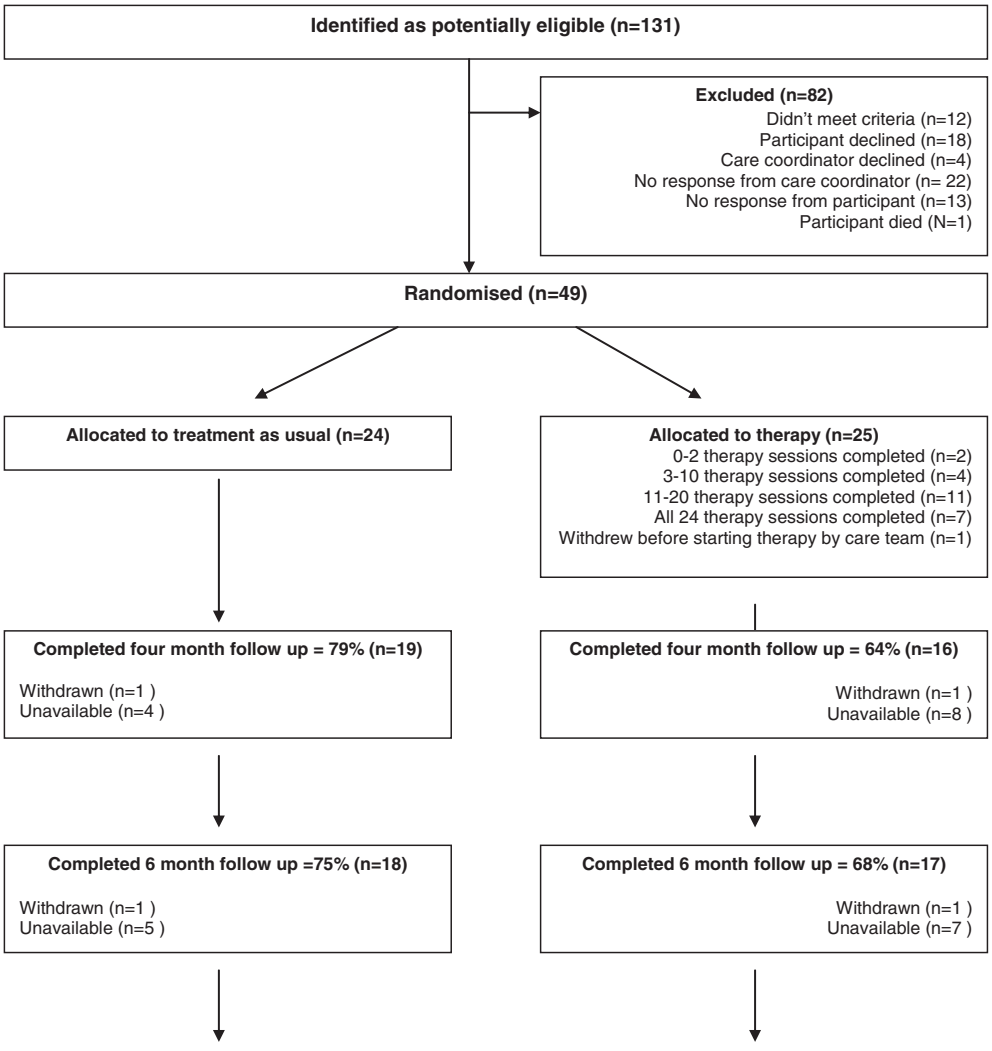

Fig. 1. Flow diagram of recruitment and treatment allocation Consort Diagram.

Table 1
Demographic characteristics of the sample.

Age	Mn (SD) = 34.9 (13.1)[a]
Male	31/49 = 63.3%
Ethnicity	
White (UK)	41
White (non-UK)	1
Black African (UK)	1
Black Caribbean African (UK)	1
Chinese	2
Mixed	2
Marital status	
Single	36
Married	2
Divorced	4
Common law marriages	7
Education (highest level of qualification)	
Primary	2
Secondary	30
Further	15
Higher	2
Religion	
Atheist	29
Christian	14
Hindu	1
Not specified	4
Missing	1

[a] The mean age of the participants in the CBSPp and TAU alone conditions were 32.6 (SD = 11.7) and 37.3 (SD = 14.2) respectively, a difference which was not significant.

16 and 17, and of the TAU alone group, 19 and 18 participants were re-assessed at 4 and 6 months respectively.

Demographic characteristics of the sample are shown in Table 1.

Fifteen participants attempted suicide once, 27 attempted suicide twice or more, and seven had not previously attempted suicide. Twenty two participants were recruited from EI services, 26 from CMHTs, and one from AO teams. Schizophrenia, Schizoaffective disorder, Persistent delusional disorder and Other were the primary diagnoses for 17, eight, three and ten participants respectively. Ten and 8 participants, respectively, had previously received CBT in the CBSPp plus TAU, and TAU alone, conditions.

As can be seen from Table 2, the repeated measures regression model indicated that there were significant improvements in the primary outcome measures of suicidal ideation (measured by the ASIQ but not as measured by the BSS) and suicidal probability (SPS) in the Treatment group compared to the TAU group.

Analysis of the secondary outcome measures yielded significant improvements in hopelessness, (measured with sub-scale of the SPS but not with the BHS), depression, self esteem, PANSS total scores, PANSS general symptoms scores, PANSS positive symptoms scores, and General Functioning (GAF) symptom scores. It should be noted that scores did not improve for the Treatment relative to the TAU group for anxiety (BAI), PANSS negative symptoms, the PSYRATS measures of delusions and hallucinations, the GAF total nor GAF disability measures.

The role of attrition indicated that, for most outcome variables, psychopathological indicators were worse for those who dropped out of the trial than for those who remained (see Table 3). There was only one significant interaction effect for the PSYRATS delusions which was because this measure increased for drop outs in the TAU group but was reduced for drop outs in the treatment group. For the all other outcome variables where there was a main effect of drop out status, there were no significant interactions meaning that worsening psychopathology for the drop outs was statistically equivalent across the treatment and TAU conditions. The random effects model used for the estimation of treatment effects, allowing for the corresponding baseline level of the outcome variable as a covariate, will produce unbiased estimates of intention-to-treat effects in the case of these patterns of attrition.

4. Discussion

There were improvements on a number of key measures over the trial. CBSPp in addition to TAU successfully, and significantly, reduced the estimated primary outcome measures of the probability of suicide and suicidal ideation (as measured by the ASIQ but not the BSS) compared to TAU alone. Associated secondary outcomes of depression, self esteem, psychotic symptoms overall, positive and general psychotic symptoms, and the GAF symptoms score were also improved as was hopelessness (as measured by the Suicide Probability Scale but not by the BHS). There were no significant group differences in anxiety, negative symptoms, or psychotic symptoms measured by the PSYRATS, nor on measures of overall functioning and disability using the GAF. Thus, it is important to note that the intervention not only improved suicidal thoughts and behaviours but also improved some of the known risk factors for suicide, such as, depression and some symptoms of psychosis.

Previous reports on the reduction of suicide behaviours have tended to be secondary reports of larger studies which have had more global clinical aims. For example, the OPUS study (Nordentoft et al., 2002) was an evaluation of an integrated community treatment including assertive community treatment, anti-psychotic medication, psycho-educational family treatment and social skills training with people experiencing first episodes of psychosis. Similarly, the SoCRATES trial (Tarrier et al., 2006) was an evaluation of CBT with recent onset schizophrenia aimed to speed recovery in those suffering an acute psychotic episode. Thus, both of these studies included retrospective evaluations of suicide behaviour in trials which did not have a sole and dedicated aim to reduce such behaviour. The current study, therefore, differed markedly from previous published studies in that the intervention was derived directly from a theoretical understanding and an empirically validated model of the psychological mechanisms underlying suicidality (Johnson et al., 2008a). The core mechanisms which have been identified involve negatively biased attentional processes, negative appraisals of defeat, entrapment, social support, emotional regulation, and problem solving, and the presence of an extensive suicide schema (Pratt et al., 2010; Taylor et al., 2010b,c; Panagioti et al., 2012c; Panagioti et al., 2013; Tarrier et al., 2013). The trial was carried out explicitly to target these underlying psychological mechanisms and so, reduce suicide behaviour (Tarrier et al., 2013). Evidence from other work has shown, in those experiencing psychosis, that CBT without this targeted development was disappointing in ameliorating suicidality (Tarrier et al., 2006). However, this issue should be investigated with a full scale RCT.

There are a number of major difficulties in evaluating suicidal prevention interventions. First, morbidity as a result of self harm, although all too frequent, is an impractical and ethically problematic outcome measure for a small clinical trial. Therefore, it was necessary to investigate suicide behaviour, by examining suicidal thoughts as a more frequently occurring proxy outcome measure. Moreover, suicidal ideation is subjectively distressing and, thus, can be considered a legitimate target in its own right. Second, the ethical requirements of administering a clinical study, especially one involving an untried therapeutic intervention, preclude the participation of those who are considered to be at current high probability of self-harm or acutely suicidal. Understandable as this is, it means that the study focused on risk factors, such as, history of past attempts or current ideation. A third, and related, issue is whether participation in suicide research is distressing or endangering to those with on-going suicidal thoughts. This is not supported by a study in which we elicited feedback from service-users who had participated in suicide related research. The results indicated that overall feedback was positive, and negative feedback was rare (Taylor et al., 2010a).

Table 2
Mean, (SD), for primary and secondary outcome measures at the three time points for the Treatment and Treatment As Usual (control) groups. Treatment effects, standard errors of the treatment effect, 95% confidence intervals, and effect sizes are also given. Significant outcome measures are marked with an asterisk (p< = .05).

	Baseline		4 months		6 months		Treatment Effect	SE	95% CI	Effect size
	Treat (n = 25)	TAU (n = 24)	Treat (n = 16)	TAU (n = 19)	Treat (n = 17)	TAU (n = 18)				
Primary outcomes										
Suicidal Ideation (Beck Scale for Suicidal ideation)	9.4 (8.9)	10.2 (10.2)	4.2 (6.0)	5.6 (9.0)	4.1 (6.5)	5.1 (7.2)	−1.31	1.36	−4.05–1.18	−.14
Suicidal ideation (ASIQ)*	54.1 (38.8)	57.4 (38.1)	37.1 (33.6)	40.9 (40.5)	29.6 (31.3)[a]	41.5 (34.9)	−12.3	6.3	−24.3 to −.14	−.32
Suicide probability (SPS)*	84.8 (23.1)	83.2 (24.6)	67.3 (23.3)	73.2 (21.8)	67.5 (19.6)	70.3 (20.4)	−6.96	3.89	−15.5–0	−.30
SPS suicidal ideation	23.0 (7.8)	20.8 (10.0)	15.6 (7.7)	16.7 (8.3)	16.7 (8.6)	15.9 (8.0)	−2.46	1.50	−5.59–0.37	−.28
SPS hopelessness*	27.5 (8.7)	26.4 (9.4)	19.9 (8.3)	22.8 (8.0)	20.0 (7.1)	22.9 (7.8)	−3.8	1.70	−7.3 to −0.5	−.42
SPS negative self-evaluation	18.5 (3.6)	19.9 (3.8)	16.8 (3.5)	17.9 (4.2)	16.0 (3.1)	18.2 (4.7)	−1.02	0.83	−2.70–0.71	−.27
SPS hostility	15.8 (7.3)	16.1 (5.8)	15.0 (6.8)	15.8 (6.8)	14.8 (5.2)	13.3 (5.5)	0.54	0.92	−1.40–2.22	.08
Secondary outcomes										
Depression (Calgary)*	8.6 (4.9)	9.4 (4.9)	4.2 (4.1)	8.5 (6.5)	4.0 (3.8)	7.2 (5.2)	−3.3	1.0	−5.3 to −1.4	−.68
Anxiety (Beck Anxiety Scale)	21.96 (13.31)	20.50 (12.94)	13.94 (9.65)	16.26 (10.13)	14.24 (11.42)	16.84 (13.28)[b]	−3.59	2.26	−7.77–1.00	−.28
Hopelessness (Beck Hopelessness Scale)	12.44 (5.55)	12.63 (5.70)	8.25 (5.53)	10.21 (6.80)	9.18 (5.16)	9.78 (5.79)	−1.04	1.05	−3.10–1.15	−.19
Self esteem*	68.0 (24.6)[c]	67.6 (25.3)	88.0 (27.0)[d]	77.3 (24.7)	90.3 (21.9)[e]	73.4 (25.3)	14.5	4.9	5.0–24.3	.59
PANSS total*	58.7 (10.4)	61.6 (16.4)	49.8 (12.3)	58.1 (17.1)	47.9 (11.9)	53.9 (12.8)	−7.1	2.1	−11.3 to −2.0	−.52
PANSS general*	31.3 (5.2)	31.5 (7.8)	24.3 (5.6)	29.0 (9.0)	24.4 (6.6)	27.1 (7.8)	−4.5	1.2	−6.8 to −2.1	−.69
PANSS positive*	14.8 (4.8)	16.1 (5.2)	14.0 (5.9)	15.2 (5.5)	12.4 (4.9)	14.9 (4.0)	−1.6	0.8	−3.0 to −0.1	−.32
PANSS negative	12.6 (2.6)	14.0 (5.5)	11.6 (2.9)	14.0 (5.6)	11.1 (2.3)	11.9 (3.1)	−1.33	0.76	−2.80–0.01	−.31
PSYRATS										
Hallucinations	18.79 (14.47)	19.08 (14.53)	17.81 (14.45)	12.00 (15.15)[f]	11.35 (14.21)	13.53 (15.76)[g]	2.74	2.74	−2.74–8.07	.19
Delusions	10.67 (6.60)	12.17 (8.57)	7.80 (8.50)[h]	9.74 (8.79)	7.19 (7.09)[i]	11.29 (8.12)[j]	−2.84	1.64	−5.87–0.40	−.37
GAF total	28.7 (7.5)	30.4 (9.1)	34.0 (8.5)	36.6 (15.6)	39.2 (19)[k]	35.7 (12.0)[l]	3.37	3.51	−3.01–10.11	.41
GAF symptoms*	31.2 (13.0)	33.9 (17.0)	42.8 (22.2)	43.2 (24.8)	47.5 (26.3)[m]	37.5 (15.5)	8.3	4.0	0.6–15.8	0.56
GAF disability	43.2 (11.1)	42.8 (9.3)	44.1 (5.4)	47.2 (12.3)	46.9 (15.5)[n]	44.9 (8.4)[o]	−.02	3.35	−5.90–6.37	−.0002

[a] N = 18.
[b] N = 19.
[c] N = 24.
[d] N = 17.
[e] N = 16.
[f] N = 18.
[g] N = 17.
[h] N = 15.
[i] N = 16.
[j] N = 17.
[k] N = 14.
[l] N = 17.
[m] N = 15.
[n] N = 15.
[o] N = 17.

Table 3
Mean (SD), baseline scores for primary and secondary outcome measures for participants who did and did not drop out in the Treated and Treatment As Usual (control) groups as analysed by univariate ANOVAs with two between subject factors of treatment status and drop out status, applied to baseline data for drop out status at each time point. Significant main effects ($p \leq .05$) are indicated with an asterisk. Significant interaction effects ($p <= .05$) are indicated with a #.

	4 months				6 months			
	No drop outs		Drop outs		No drop outs		Drop outs	
	TAU	Treated	TAU	Treated	TAU	Treated	TAU	Treated
Primary outcomes								
Suicidal ideation (BSS)	11.3 (9.2)	10.4 (9.5)	18.8 (14.4)	15.7 (8.7)	11.2 (9.4)	10.8 (9.1)	17.5 (13.5)	15.6 (9.6)
Suicidal ideation (ASIQ)	50.8 (38.2)	51.1 (39.5)	82.6 (28.5)	59.3 (39.2)	49.9 (39.3)	52.3 (38.3)	79.8 (25.1)	57.9 (42.2)
Suicide probability (SPS)	79.3 (25.7)	80.8 (25.6)	98.0 (13.0)	92.0 (16.5)	79.3 (26.4)	81.9 (25.5)	94.7 (14.2)	91.0 (16.6)
SPS suicidal ideation	19.2 (9.9)	22.3 (9.1)	26.6 (8.9)	24.4 (5.1)	18.6 (10.3)	22.5 (8.8)	27.3 (5.3)	24.3 (5.6)
SPS hopelessness	25.1 (9.7)	25.6 (9.8)	31.6 (6.5)	30.9* (5.0)	25.5 (10.0)	26.1 (9.7)	29.2 (7.6)	30.5 (5.2)
SPS negative self-evaluation	19.2 (3.9)	18.0 (3.8)	22.4 (2.1)	19.4 (3.1)	19.6 (4.3)	17.9 (3.5)	20.7 (2.2)	19.9 (3.6)
SPS Hostility	15.8 (6.2)	14.9 (6.9)	17.4 (3.8)	17.2 (8.0)	15.7 (6.3)	15.5 (7.2)	17.5 (3.7)	16.4 (8.0)
Secondary outcomes								
Depression (Calgary)	8.3 (4.8)	7.1 (4.8)	13.6 (2.5)	11.3* (4.0)	8.2 (4.9)	7.5 (4.9)	12.8 (2.9)	11.0* (4.1)
Anxiety (BAI)	17.7 (12.2)	20.7 (14.3)	31.2 (10.8)	24.2* (11.9)	18.5 (12.9)	22.1 (13.3)	26.5 (12.1)	21.8 (14.4)
Hopelessness (BHS)	11.7 (5.9)	11.4 (6.2)	16.2 (2.9)	14.2* (3.9)	12.1 (6.1)	11.4 (5.8)	14.3 (4.5)	14.8 (4.4)
Self esteem	70.9 (26.1)	71.8 (25.5)	55.2 (19.2)	60.4 (22.3)	69.3 (26.6)	71.5 (25.1)	62.7 (22.2)	59.4 (22.7)
PANSS total	58.2 (15.4)	58.0 (11.5)	74.6 (14.4)	60.0* (8.6)	58.8 (15.3)	58.0 (11.6)	70.0 (18.1)	60.3 (7.6)
PANSS general	30.0 (7.6)	30.6 (5.8)	37.2 (6.4)	32.7* (4.1)	29.8 (7.6)	30.5 (5.6)	36.5 (6.8)	33.0* (4.1)
PANSS positive	14.9 (5.0)	14.8 (5.4)	20.8 (2.9)	15.0* (3.6)	15.5 (4.7)	14.5 (5.4)	18.0 (6.5)	15.5 (3.3)
PANSS negative	13.3 (4.8)	12.7 (2.7)	16.6 (7.6)	12.3 (2.5)	13.5 (4.8)	12.9 (3.0)	15.5 (7.3)	11.8 (1.2)
PSYRATS hallucinations	18.1 (14.9)	16.3 (15.5)	22.8 (13.7)	23.8 (11.5)	19.1 (14.7)	16.6 (15.0)	19.0 (15.4)	24.1 (12.6)
PSYRATS delusions	10.8 (8.7)	11.8 (6.4)	17.4 (5.9)	8.4#[a] (6.9)	10.9 (8.6)	11.4 (7.0)	16.0 (8.1)	9.0 (5.6)
GAF total	32.2 (9.3)	29.6 (8.5)	23.6 (4.0)	27.2* (5.3)	31.8 (9.1)	29.7 (8.5)	26.0 (8.6)	26.8 (4.2)
GAF symptoms	36.6 (18.2)	32.5 (15.3)	23.6 (4.0)	29.0 (7.4)	35.3 (17.2)	32.8 (15.1)	29.7 (17.4)	28.0 (5.8)
GAF disability	43.7 (8.6)	43.8 (10.2)	39.6 (12.2)	42.0 (13.1)	43.4 (8.9)	43.4 (10.0)	41.l (11.0)	42.8 (13.8)

[a] $F(1,44) = 4.1$, $p = .05$.

This study has a number of weaknesses. The trial was small and attrition levels at follow up were high. However, attrition from samples that experience severe mental illnesses is often substantial because it is challenging to engage and treat such individuals. Furthermore, apart from delusions measured by the PSYRATS, there were no differential effects of drop out status across the TAU and Treatment conditions. We used a simple design where we compared CBSPp plus TAU with TAU alone. Future work would benefit from systematically comparing different forms of interventions, such as supportive counselling, to both a CBSPp condition and a waiting list control. The follow-up periods were relatively short at 4 and 6 months. Sample sizes did not permit clinically interesting variables, such as, the effect of command hallucinations, to be examined further.

On the positive side, this was an adequately powered pilot trial of a manualised novel treatment to address an important clinical life threatening problem, with independent and masked random allocation, and independent and masked assessments, using standardised measures with an at risk population recruited from a geographical cohort using public health services. Evidence was supportive of this intervention and there were no obvious adverse effects. The trial was the first of its kind and, thus, was an indication of feasibility as well as being indicative of the efficacy of the novel treatment.

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Contributors

Nicholas Tarrier designed this study and together with Patricia Gooding, James Kelly and Janet Maxwell developed the psychological intervention which was being trialled. Graham Dunn was responsible for the analysis of the data. Heather Law was the trial manager. Natasha Snelson and Sehar Maqsood were responsible for the day-to-day running of the trial. Nicholas Tarrier and Patricia Gooding wrote the paper. All authors have contributed to and approved the final manuscript.

Conflict of interest

None.

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