



Improving psychological adjustment following a first episode of psychosis: A randomised controlled trial of cognitive therapy to reduce post psychotic trauma symptoms

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ABSTRACT

There are few evaluated psychological interventions or theoretical approaches which are specifically aimed at reducing problems related to adjustment and adaptation following a first episode of psychosis. The present study tests the efficacy of a form of CBT (Cognitive Recovery Intervention; CRI) in reducing trauma, depression and low self esteem following a first episode of psychosis, in a single-blind randomised controlled trial. A total of 66 patients who had recently experienced a first episode of psychosis were randomly assigned to CRI or treatment as usual (TAU) and followed up at 6 and 12 months. People receiving CRI tended to have lower levels of post-intervention trauma symptoms and demonstrated greater improvement than those receiving TAU alone. This was especially the case at 6 months for those with high pre-treatment levels of trauma. There was, however, no advantage for the CRI group with regards to reduced depression or improved self esteem. In conclusion, CRI appears to be an effective intervention to help young people adapt to the traumatic aspects of a first episode of psychosis although further evaluation in a larger study is warranted.

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Introduction

Psychological adjustment following a first episode of psychosis remains an important but poorly understood area (Jackson & Iqbal, 2000). Whilst a significant minority of people experiencing a first episode may naturally adjust to the psychological impact of such a life event (May, 2004), many may struggle and go on to develop a number of psychological and emotional dysfunctions such as PTSD, depression, social anxiety disorder, low self esteem and suicidality (Birchwood, Fowler, & Jackson, 2001; Morrison Frame, & Larkin, 2003). The treatment of choice for such emotional dysfunctions is predominantly CBT (Birchwood, Iqbal, Jackson, &

Hardy, 2004). Yet, despite this, there have been relatively few psychological interventions specifically developed in the context of psychosis in general (Birchwood & Trower, 2006) and even less for young people experiencing the onset of psychosis for the first time. Hall and Tarrier (2003) evaluated the efficacy of a simple cognitive-behavioural intervention designed to improve low self esteem in people with multiple episode psychosis and bipolar disorder. Results indicated that when used as an adjunct to treatment as usual (TAU), the intervention resulted in increased self esteem, reduced psychotic symptomatology and improved social functioning. These gains were maintained over 3 months. In another evaluation of the impact of CBT on self esteem in people with psychosis, Gumley et al. (2006) using a CBT protocol aimed at the early signs of relapse, also found greater increases in self esteem (as measured by the Rosenberg Self Esteem Questionnaire) for those receiving CBT than TAU. Unfortunately the generalisability of these studies to younger first episode populations is difficult to ascertain as both studies included a large number of older people with

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multiple admissions and a history of relapse. This may be particularly important given recent evidence that suggests that age-specific factors may influence the efficacy of CBT for people with psychosis (Haddock et al., 2006).

In a recent review of 33 RCTs of CBT for Schizophrenia (Wykes et al., 2008), not one selected depression as a primary outcome measure. In the 15 studies that did measure mood secondary to the primary target symptom (usually positive psychotic symptoms), the average effect size was 0.36 (95% CI, 0.08–0.65). This, however, was greatly influenced by the methodological rigour of the trial, with those studies scoring highly on the clinical trial assessment measure (CTAM; Tarrier & Wykes, 2004) tending to produce the lower effect sizes. Again, very few of these studies exclusively sampled first episode cohorts making it difficult to draw any firm conclusions about how effective CBT is for reducing depression or distress in young people adapting to the onset of a psychotic illness.

To date, only one CBT intervention conducted under RCT conditions has addressed the reduction in PTSD and trauma in people with psychosis as the primary outcome measure. Mueser et al. (2008) in an intention-to-treat analysis demonstrated that clients assigned to a CBT intervention improved significantly more in terms of PTSD symptoms than did clients in TAU at blinded post treatment and 3 and 6 month follow-up. The effects of CBT on PTSD were strongest in clients with severe PTSD. Again, however, it is difficult to establish how much the findings from this study can inform psychological interventions with a young first episode sample. Only 15% met the diagnostic criteria for schizophrenia or schizoaffective disorder (the vast majority were diagnosed with major mood disorder) and were a predominantly older, multiple episode cohort.

Of the larger, better controlled studies which have focussed on first episode psychosis and which have been conducted under RCT conditions (SOCRATES: Lewis et al., 2002; ACE: Jackson et al., 2008) many have concentrated on the amelioration of psychotic symptoms and/or social and occupational functioning. Neither of these two studies report on the use of CBT to reduce emotional dysfunction and enhance adaptation and adjustment to early psychosis. First episode studies which have addressed issues of trauma, post psychotic depression, suicidality and self esteem have tended to produce mixed results (Power et al., 2003; Bernard, Jackson, & Jones, 2006). Jackson et al. (1998, 2005) who developed cognitive-oriented psychotherapy for early psychosis (COPE), a phase specific cognitive therapy intervention aimed at reducing the impact of early psychosis on an individual's identity and sense of self, report few significant differences between their intervention group and control groups (one receiving treatment as usual from a specialised early intervention service and one group who were receiving neither COPE nor any other form of specialised early intervention). This study, however, was not an RCT and did not include outcome measures on important variables such as trauma/PTSD, suicidality and self esteem.

In view of this and drawing upon previous developmental work in the area (Jackson & Iqbal, 2000), the authors developed a new cognitive therapy designed to help people psychologically adjust and recover following a first episode of psychosis (CRI). This approach is theoretically grounded in work on pathways to emotional dysfunction framework in first episode psychosis (Birchwood, 2003) which embraces: (a) psychological reactions to psychosis, particularly shame (Gilbert, 2003), appraisals of loss (Birchwood et al., 2000), appraisals of threat (Jackson et al., 2004); and (b) developmental vulnerability (Janssen et al., 2004). In the present paper, we describe a single-blind, intention-to-treat, randomised controlled trial in which we compare the efficacy of CRI plus treatment as usual (TAU) with TAU alone, in a sample of participants who had recently experienced a first episode of

psychosis in the previous 18 months. The primary aim of the intervention was the reduction of trauma symptoms and depression which are often co-morbid with one another (Bleich et al., 1997); secondly, improvements in self esteem in the CRI group were also predicted.

Method

Recruitment and procedure

Patients with a first episode of non-affective psychosis conforming to ICD-10 criteria (F20, F22, F23, F25) as verified by experienced Consultant Psychiatrists were recruited from four Mental Health Services throughout the West Midlands in the UK. The four sites served a total catchment area of approximately 1.5 million. All candidates for inclusion to the study were required to have experienced a first episode of psychosis within the previous 6–18 months and were aged between 16 and 35 years old. Patients were not admitted to the study if they could not speak English or were unable to give informed consent.

All aspects of recruitment, screening and outcome assessment were organised by experienced research associates (KB, JJ, KR and RR). Frequent contact by telephone and in person was maintained with the relevant community mental health teams to identify potential recruits. Clinical notes were then screened and those meeting the inclusion criteria were offered an interview to obtain written consent and then a further interview for assessment, including outcome measures (see below). Patients were informed, consistent with local research ethical committee procedure, that they were entitled to withdraw from the study at any time and that any treatment they were receiving would be unaffected by whether they chose to take part in the trial or not. Eligible and consenting patients were then randomly assigned to CRI or TAU by means of a computerised random number generator administered by the Birmingham University Clinical Trials Unit independent of the research team. In addition, to maintain blindness, therapists and clients were asked not to discuss with the research associates which group they were allocated to and research staff did not attend treatment meetings or access case notes following randomisation. Assessors were asked to record any loss of masking to treatment allocation. This occurred on only one occasion. Participants were tested at baseline, 6 months (post treatment) and 12 months follow-up.

Power calculations were based on previous cognitive therapy for psychosis trials which have reported effect sizes for changes in depression up to 0.34 at 9 months follow-up (Birchwood et al., 2004). To detect such a moderate effect size in the current study would require a sample size of 160 in each of the two groups to achieve a power of 0.8 ($\alpha = 0.05$) assuming full data on all cases.

Assessment and measures

In addition to demographic information which was collected from all participants prior to randomisation, seven measures of psychopathology, emotional dysfunction and cognitive appraisals were taken at baseline, post-intervention (6 months) and follow-up (12 months). Results on the following three outcome measures are reported in this paper.

Impact of Events Scale

The Impact of Events Scale (Sundin & Horowitz, 2002) is a self report questionnaire used to measure post traumatic phenomena on two dimensions: (1) intrusive repetitive images and thoughts; and (2) avoidance of situations, thoughts and feelings that remind the

person of the event. In this instance, the event in question (i.e. a first episode of psychosis) was cued in memory by asking patients to think back to their “breakdown”, “illness” or psychotic symptoms (depending on their personal frame of reference) and providing them with an approximate date. The 15 item scale is scored from 0 to 5 indicating the extent to which each item was experienced in the preceding 7 days. Sundin and Horowitz (2002) report satisfactory internal reliability (Cronbach’s alpha = 0.86 for intrusion and 0.82 for avoidance) and test–re-test reliability ($r = 0.94$ for intrusion and 0.89 for avoidance). Because the outcome variable of interest was intrusions (and avoidance of intrusions) related to the first episode of psychosis the IES was used instead of the IES-R because it was briefer. It has also been used in previous research on first episode psychosis (McGorry et al., 1991; Jackson et al., 2004).

Calgary Depression Scale

The Calgary Depression Scale (CDSS; Addington et al., 1993) is specifically designed to measure depression in schizophrenia without contamination by negative symptoms. It is a nine item semi-structured interview based measure which gives a score ranging from 0 to 27. Scores of 3 and above signify ‘clinically significant depression’ with those greater than 7 signifying ‘severe depression’ (Addington et al., 1993). It is widely used and has good psychometric characteristics including high test–re-test reliability (intraclass correlation = 0.9), internal consistency (Cronbach’s alpha = 0.79) and convergent and discriminant validity (Addington et al., 1993).

Robson Self Concept Questionnaire

The Robson Self Esteem Questionnaire (SCQ; Robson, 1989) is a widely used self report measure of self esteem. Internal ($r = 0.93$) and test–re-test reliability ($r = 0.87$) are satisfactory as are its convergent, clinical and discriminant validity (Robson, 1989). It has been used extensively with people experiencing psychosis and schizophrenia (Hall & Tarrrier, 2003).

Treatment groups

Consenting patients were randomly assigned to receive either the cognitive therapy (CRI) plus TAU or TAU alone for a period of up to 6 months.

CRI

The cognitive therapy based recovery intervention (CRI) was designed to be delivered on a weekly basis over a 6 month period (i.e. it was limited to a maximum of 26 sessions) and followed a protocol based modular approach. In essence, the intervention arose from an individual formulation, which was translated, into an “individual recovery plan”. This approach has been described previously in more detail in Jackson and Iqbal (2000). There were three key components: (a) engagement and formulation; (b) trauma processing; and (c) appraisals of psychotic illness (shame, loss and entrapment). The intervention, therefore, is not just designed for those who could be described as ‘traumatised’ by their experiences of psychosis. It is intended to be helpful for all first episode patients adjusting to and recovering from a first episode of psychosis. All participants completed the core component (engagement and formulation) and those pertinent to their problem list and goals (i.e. trauma processing and/or addressing appraisals of shame, loss and/or entrapment). Trauma processing evolved from the exploration of the primary appraisals of the first episode of psychosis including their symptoms (voices, paranoia), their management (hospital admission) and the social context in which they occurred (interpersonal reactions of others). A relapse prevention framework; ‘back in the saddle’ (Plaistow & Birchwood, 1996) was used to aid this process.

Appraisals of psychotic illness and its consequences were explored within the context of social rank theory as giving rise to shame (emotional reaction to perceived reduction of status or social rank; Gilbert, 2003), loss (of a valued role or goal) and/or entrapment (‘blocked escape’ or an inability to reaffirm an identity or sense of belonging; Rooke & Birchwood, 1998). Social rank theory (Gilbert & Allen, 1998) proposes that how people appraise their psychotic experiences is often a product of a core self perception of low rank with the person often seeing themselves as being in an unwanted subordinate position compared to others. Standard cognitive therapy techniques (Socratic questioning, guided discovery, identifying and targeting beliefs and behaviours, developing alternative beliefs and reinforcing through behavioural change etc) were utilised in order to affect change in these appraisals. The CRI was delivered according to the protocol by four clinical psychologists and a cognitive behavioural psychotherapist. All clinicians had over 4 years experience in the practice of cognitive therapy for early psychosis and received regular case supervision.

Fidelity to protocol and adherence to the principles of CT were checked by means of audiotape and the CTS-Psy (Haddock et al., 2001). All tapes were rated by an experienced researcher who was independent of the delivery of CRI. Each therapist submitted at least two tapes from different stages of therapy. The mean rating for all tapes was 47 for total skills (range 39–53) indicating an acceptable level of CBT skills and their use across all therapists. Adherence to protocol was also assessed by an additional item and again found to be more than acceptable for both core and optional modules.

In addition to CRI those in the experimental group also received treatment as usual (TAU) according to their local mental health service practice.

TAU

Those assigned to the control group received treatment as usual (TAU) from their local mental health services. Although the TAU interventions across the four sites were not standardised, they were closely monitored and documented. In both conditions (control and CRI), TAU usually consisted of a combination of case management and anti-psychotic medication.

Neuroleptic medication

Dosages were recorded from clinical case notes at baseline and converted to chlorpromazine (CPZ) equivalents using the conversion described in the British National Formulary (British Medical Association and Royal Pharmaceutical Society of Great Britain, 2003). Although conversion from atypical to typical (CPZ) equivalents can be arbitrary, there was a consistent use of the tariff across both groups.

Statistical analysis

Scores on the primary outcome variable IES plus the CDSS and SCQ were individually submitted to three analyses: a summary measure analysis was applied to the two post random values on each measure, using the mean of the available values as the summary measure for each participant (see Everitt & Pickles, 2004). The summary measure analysis, however, gives us no information as to how an outcome measure changes over time in each intervention group, or how the response is related to other variables of interest (Proudfoot et al., 2004). In view of this a second set of analyses were performed which involved fitting linear mixed effects models at 6 and 12 months (also known as random effects models; Landau & Everitt, 2003). These are similar to regression models in which random effects are included to model possible subject heterogeneity of the outcome measures over time

(Proudfoot et al., 2004). For each outcome variable a random intercept model (see Everitt & Pickles, 2004) was fitted using the following fixed effects:

- (a) Time (coded 0 at 6 months and 1 at 12 months).
- (b) Gender (coded 0 for male and 1 for female).
- (c) DUP (converted to base log10 to overcome the problem of a positively skewed distribution, see Lewis et al., 2002).
- (d) Pre-randomisation value of outcome measure (i.e. baseline).
- (e) Condition (treatment, coded 0 for TAU and 1 for CRI).
- (f) Condition \times baseline interaction.
- (g) Condition \times time interaction.
- (h) Condition \times DUP.

Results

The sample

A total of 357 individuals were screened from which 166 patients met the inclusion criteria. Of these, 60 (37%) refused consent; 25 could not be contacted and 11 were thought to be unsuitable to be contacted by their care teams at the time of the

study. This left a sample of 70 consenting to randomisation. One person then withdrew their consent, two were deported and one person no longer fulfilled the criteria for the trial (i.e. their diagnosis was changed). In total 66 people were randomised to the two conditions (Fig. 1). The sample included 49 men and 17 women with a mean age of 23.3 years (SD 4.6). Ethnically the sample comprised 48 (72.7%) white, three (4.5%) black Caribbean/black African, 10 (15.1%) South Asian and four (7.7%) other/mixed race. Clinical (including baseline PANSS scores) and demographic characteristics of the treatment and control groups are shown in Table 1.

Those refusing to consent were significantly more likely to be black African–Caribbean/African or South Asian ($p < 0.001$). However, there were no differences with regard to age, gender, duration of illness or research site.

No changes were made to medication regimes in either the experimental or control conditions. In terms of prescribed medication, neuroleptic use was converted to CPZ equivalents. These are given in Table 1. Here it can be seen that the majority of patients in both groups (90 vs 92%) were prescribed atypical neuroleptic medication. Of these a small number (two/30 in the TAU group but none in the CRI group) were prescribed clozapine.

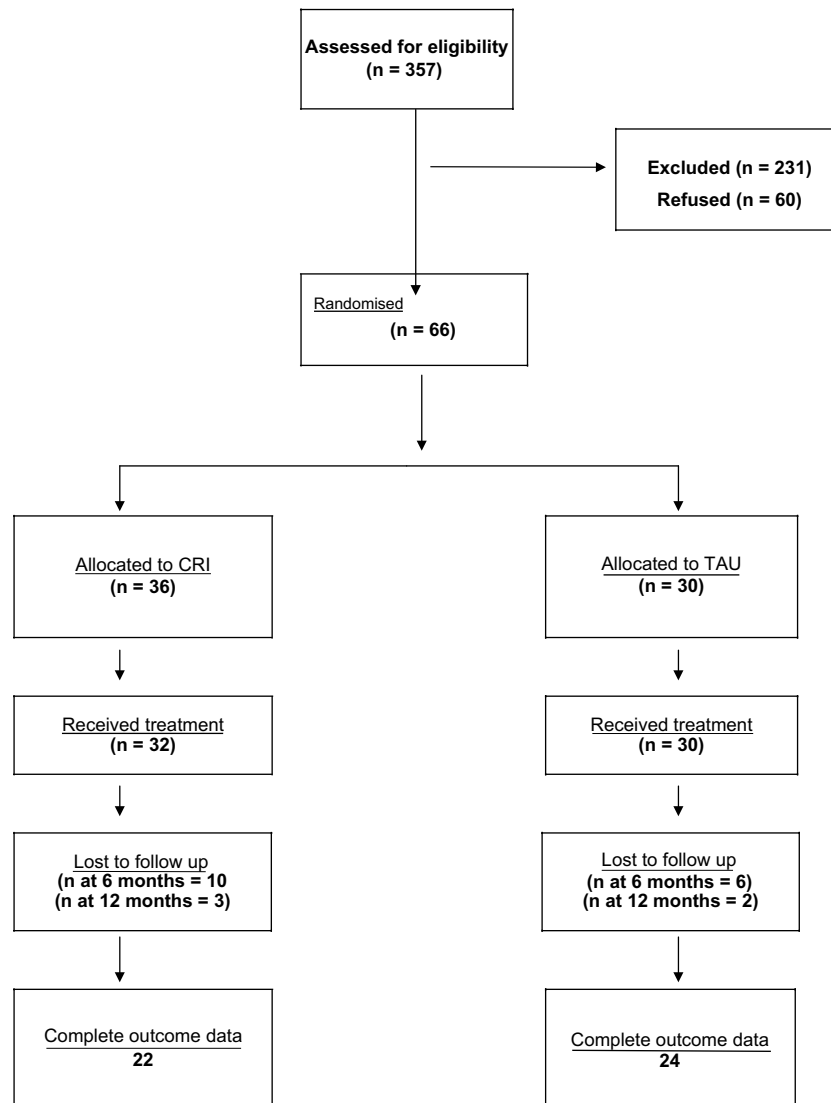


Fig. 1. CONSORT diagram.

Table 1
Clinical and demographic characteristics of the treatment and control groups.

	CRI	TAU
	(n = 36)	(n = 30)
Age, years		
Mean (SD)	24.1 (4.7)	22.3 (4.4)
Range	16–38	16–31
Gender, n		
Male	31	18
Female	5	12
Ethnicity, n		
White	26	21
Black	2	1
Asian	6	4
Other/mixed	2	4
Diagnosis		
PANSS score		
Positive scale		
Mean (SD)	13.1 (5.3)	11.9 (4)
Range	7–28	7–22
Negative scale		
Mean (SD)	13.7 (4.4)	14.6 (5.5)
Range	7–25	8–26
General psychopathology		
Mean (SD)	29.8 (5.9)	29.1 (7.4)
Range	19–45	18–49
Duration of untreated psychosis, weeks		
Means (SD)	17.4 (25.9)	23.7 (58.4)
Neuroleptic medication		
CPZ equivalents, mg/day	442.4 (231.8)	316.4 (236.1)
Prescribed atypicals	90%	92%
No. not taking any meds	5	1

Baseline 'trauma', depression and self esteem

Trauma symptomatology within the total sample, according to Horowitz's (1982) original criteria for the IES, indicated that 13/66 (20%) were experiencing significantly 'high' levels of intrusive re-experiencing of images arising from their first episode of psychosis (i.e. a score ≥ 20); and 20/66 (30%) were displaying 'high' levels of avoidance of these intrusions. Overall 15/66 (23%) had total scores on both scales exceeding 40 or above, a score which is a strong indication of a diagnosis of PTSD (Selley et al., 1997). These scores were similar to those found in traumatised groups such as those experiencing shipping disasters (Joseph et al., 1993), cancer (Brewin Watson, McCarthy, Hyman & Dayson, 1998), war trauma (Deahl, Gillham, Thomas, Searle, & Srinivasan, 1994) but marginally lower than other first episode samples (McGorry et al., 1991; Jackson et al., 2004; Tarrier et al., 2006).

According to scores on the CDSS (Addington et al., 1993), 44/66 (67%) of the total sample could be classified as 'significantly' depressed. Of these nine/44 (20%) were 'mildly' depressed (CDSS 3–4), 15/44 (34%) 'moderately' depressed (CDSS 5–7) and 20/44

(46%) 'severely' depressed (CDSS >7). In addition, 13/66 (20%) admitted to some degree of suicidal ideation according to responses to the relevant question on the CDSS (CDSS Q8; 1, 2 or 3)

Total scores on the Robson Self Esteem scale (SCQ) indicated that 50/66 (76%) had scores below the lower limit of the range that would be expected for the 'normal' population (i.e. below 132; Robson, 1989; Hall and Tarrier, 2003).

Allocation and flow of participants

As can be seen in the CONSORT diagram (Fig. 1), of the 66 participants who were randomly allocated, 36 were assigned to the treatment (CRI) arm and 30 to the control (TAU) arm.

The treatment group completed a median of 13 sessions (mean = 11, SD = 5.0). Of the 32 that started treatment, ten participants (31%) dropped out before they completed their 6 month assessment, attending between six and 20 sessions. This drop out rate is slightly higher than the control group where six/30 (20%) were unavailable for their 6 month follow-up assessments.

A further three people in the treatment group were lost at 12 months compared to two more in the control group. We therefore report outcomes for the IES, CDSS and SCQ on 46 (22/46 = CRI, 24/46 = TAU) of the 66 recruited patients. There were no significant differences in baseline measures (age, gender, ethnicity, PANSS positive symptoms, PANSS general psychopathology, CDSS, IES, SCQ, medication) between those completing ($N = 46$) and those not completing ($N = 20$) the study apart from one: baseline PANSS negative symptoms were found to be significantly higher in those dropping out of the study than those who completed it.

The impact of CRI

Summary measures analysis

Table 2 shows the means and SDs for 'trauma' (IES), depression (CDSS) and self esteem (SCQ) across the study's three time points.

Table 3 presents the results of applying t -tests to the chosen summary measures and the associated 95% confidence intervals. For the primary outcome measure total IES, there were 46 patients who had at least one post randomisation total IES value and so contributed to the analysis; the 20 patients not in the analysis are those for whom both post randomisation total IES values were missing (Fig. 1: CONSORT). The numbers of included patients and missing data were similar for the other outcome measures (CDSS and SCQ).

Although the full reasons for non-participation in therapy were difficult to ascertain because of ethical considerations (they were informed on their consent form that they could terminate therapy without having to give a reason), those who were willing to discuss this tended to give three main reasons: (a) it was too much trouble to attend; (b) they did not think they had a problem in the first

Table 2
Mean scores (SD) showing impact of CRI compared to TAU on measures of depression (CDSS), PTSD (IES), PANSS, Robson SCQ, Social Comparison Scale (SCS), Insight and PBIQ.

	CRI			TAU		
	Baseline	6 months	12 months	Baseline	6 months	12 months
Depression (CDSS)	5.6 (4.2)	3.9 (3.5)	3.7 (3.9)	5.9 (4.8)	4.9 (3.4)	3.9 (3.3)
Intrusions (IES)	9.5 (8.6)	6.2 (6.5)	4.6 (5.1)	12.1 (10.4)	9.5 (10.5)	6.2 (5.7)
Avoidance (IES)	12.7 (9.6)	9.2 (8.7)	6.3 (7.3)	14.7 (9.7)	13.5 (11.6)	11.2 (11.0)
Total IES	25.0 (19.5)	16.1 (14.2)	11.9 (11.8)	27.3 (18.2)	22.5 (21.3)	18.8 (16.3)
Robson SCQ (attract)	4.2 (1.1)	4.5 (1.1)	4.7 (1.1)	4.3 (1.3)	4.1 (1.0)	4.5 (1.0)
Robson SCQ (worth)	3.0 (1.4)	3.5 (1.5)	3.5 (1.7)	3.1 (1.2)	3.0 (1.4)	3.5 (1.4)
Robson SCQ (auto self-reg)	4.2 (1.2)	4.3 (1.4)	4.7 (1.4)	4.1 (1.3)	4.4 (1.0)	4.5 (0.9)
Robson SCQ (comp)	4.3 (1.2)	4.3 (1.1)	4.7 (1.3)	4.0 (1.2)	3.7 (1.0)	4.1 (1.0)
Robson SCQ (value of exist)	3.7 (1.1)	4.0 (1.5)	4.3 (1.5)	4.1 (0.9)	4.1 (1.2)	4.3 (1.3)
Total SCQ	55.94 (18.1)	54.9 (19.4)	58.4 (20.6)	51.10 (16.7)	54.5 (13.0)	59.6 (12.6)

place; and (c) they did not think therapy was helpful for their particular problem.

There was a borderline significant difference between the two conditions on the IES: patients receiving CRI scored on average between -0.1 and 14 points lower than those given treatment as usual (TAU). There was no difference between the two groups, however, for depression (CDSS) or self esteem (SCQ).

Linear mixed effects models

The means and standard deviations for both outcome variables in each treatment group at each time measurement are shown in Table 2; for the primary outcome measure, the IES, the means and standard errors are also shown in Fig. 2. For each of the outcome measures, a series of mixed effects regression models were considered. For each dependent variable a series of models were considered by the addition of terms to a basic model including pre-treatment scores and time. Additional models were judged for inclusion by the significance level of a likelihood-ratio test (Pinheiro & Bates, 2000). Full details of the analysis are shown only for the IES; results for the CDSS and SCQ are summarised below.

Impact Events Scale

Fitting a random intercept model including all the effects listed above showed that the best model fit was one that included the interaction terms condition \times IES pre ($p = 0.02$) and condition \times dup (log base 10; $p = 0.02$). The results of fitting the selected model (including estimated regression coefficients) are shown in Table 4.

The findings of most interest are:

- There is no significant change in outcome between 6 and 12 months.
- The pre-randomisation IES score is highly predictive of the post randomisation score.
- Those with the highest levels of pre-treatment IES benefited most from CRI.
- There is a significant effect of gender: females were likely to have post IES scores which on average were 7 points higher than male IES scores.
- On average, those with the lowest pre-treatment DUP scores tended to benefit the most from CRI.

An informal investigation of the interaction between baseline IES and condition revealed that below a pre-randomisation value 40 (caseness cut-off) on the IES, there was little or no difference between CRI and TAU. However, above this value the intervention resulted in an estimated average decrease of 28 points in the CRI group against a reduction of only 6 points in the TAU group. A further ANCOVA revealed that this interaction was, however, only significant at 6 months ($p = 0.03$).

In order to further ascertain the number of patients in the TAU and CRI groups who made a clinically significant improvement in

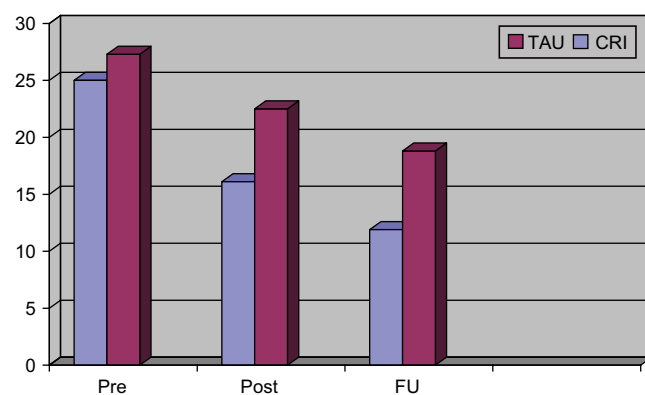


Fig. 2. Mean Scores on the IES (total).

terms of reductions in trauma symptoms over the 12 month trial period (defined as a reduction of 25% or greater from their baseline scores; Lipsey & Wilson, 1993), further post hoc chi squared analyses were performed. These indicated that for trauma symptoms, at 6 months, significantly more people (15/22; 68%) in the CRI group made improvements of 25% or better from their baseline scores compared to the eight/24 (33%) in the TAU group ($\chi^2 = 5.57$, $p < 0.05$). This signified a small to modest effect size for the treatment condition ($\phi = 0.35$) and an odds ratio (OR) of 1.92 (CI = 1.02–3.62). This advantage for the therapy condition was also evident at 12 months follow-up ($\chi^2 = 6.08$, $p < 0.05$; $\phi = 0.39$; OR = 1.93, CI = 1.11–3.36).

That is, those receiving the cognitive therapy condition (CRI) were nearly twice as likely to have substantially reduced trauma symptoms.

Calgary Depression Scale (CDSS)

Fitting similar models as for the IES (see Method), the results for the CDSS reveal that there were no significant interactions for condition \times time ($p = 0.41$), condition \times baseline CDSS ($p = 0.33$), condition \times dup (base10; $p = 0.46$) or condition \times gender ($p = 0.84$). These terms were therefore excluded from the final model which required a random intercept term for subject. Overall the model revealed no effect of time ($p = 0.27$) or CRI ($p = 0.67$) but a significant effect for pre-randomisation depression ($p < 0.0001$). That is, unsurprisingly, people were much more likely to have high post-intervention depression scores if they were more depressed at baseline. Post hoc analyses also revealed there were no significant differences between the two groups in terms of the numbers of people improving (i.e. 25% or greater reduction) on CDSS scores at 6 ($\chi^2 = 0.91$, $p > 0.05$) or 12 months ($\chi^2 = 0.1$, $p > 0.05$).

Table 3

Summary measures analysis of post randomisation values.

Outcome measure	TAU	CRI	t-test	95% CI
IES (total)	20.7 (15.3)	13.6 (8.7)	$t = 1.98$; $p = 0.05$	-0.14 to 14.35
Score: mean (SD)*	24	22		
CDSS	4.1 (2.7)	3.6 (3.3)	$t = 0.48$; $p = 0.6$	-1.36 to 2.20
Score: mean (SD)*	24	22		
SEQ (Robson)	119.2 (24.5)	124.8 (31.4)	$t = -0.71$; $p = 0.5$	-21.9 to 10.6
Score: mean (SD)*	24	22		

* = mean of the post randomisation values for each participant.

Table 4

Parameter estimates, standard errors and confidence intervals for main effects model fitted to scores on the IES.

Term	Estimated regression coefficients	SEM	p	95% CI
Intercept	13.25	5.37	0.01	2.72 23.77
Time	-4.33	2.88	0.14	-9.97 1.31
Gender	7.0	3.44	0.04	.21 13.7
DUP logbase10	-8.6	4.05	0.03	-16.54 -0.67
IES pre	0.57	0.11	<0.001	0.35 0.79
Condition	-13.22	8.23	0.11	-29.36 2.92
Condition \times IES pre	-0.39	0.16	0.02	-0.70 -0.07
Condition \times Time	-1.70	5.60	0.77	-10.78 24.50
Condition \times DUP log10	19.62	8.11	0.02	3.71 35.5

Robson Self Esteem Questionnaire (SCQ)

As for the CDSS no significant interactions of main effects were necessary; treatment \times time, treatment \times baseline self esteem and treatment \times DUP (logbase10) had p values of 0.3 or greater. Only the treatment \times gender interaction approached significance at $p = 0.05$. Therefore, as for depression, a model containing only main effects models were fitted to one that contained a random intercept term. This, once again, indicated that pre-randomisation levels of self esteem were highly predictive of post treatment self esteem ($p = 0.002$). However, unlike for depression and trauma, time had a significant effect on self esteem across both groups ($p = 0.02$). This signified an average 7 point increase. Lastly, post hoc analyses revealed there was no significant difference between the CRI and control group in terms of the numbers of people whose self esteem significantly improved at 6 months (Fisher's exact test = 0.59, $p > 0.05$) or 12 months follow-up ($\chi^2 = 0.78$, $p > 0.05$).

Discussion

This is one of the first reported randomised controlled trials of cognitive therapy aimed at helping people to adapt and psychologically adjust to the onset of psychosis. Data from the present study suggests that reductions in symptoms of trauma, attributable to the onset of psychosis, were more likely to occur in those receiving a targeted cognitive therapy intervention (CRI) than treatment as usual (TAU). The intervention appears to be especially beneficial for those who met the caseness criteria for PTSD which is consistent with the findings from Mueser et al. (2008) in their older more mixed diagnostic group. However, numbers were small and this would need to be tested in further studies. Post hoc analyses point to significant improvements over 6 months (of 25% or better) in those receiving CRI compared with those in the control condition. More specifically only seven/22 people (31%) in the CRI group reported that their trauma symptoms had either *not* substantially changed or had worsened over the course of the year compared to 16/24 (66%) in the TAU group. This would imply that not intervening early with a CBT based intervention would put more than twice as many people at risk of their trauma symptoms substantially worsening (or at least not improving) over the course of 6 months. This study, along with that of Bernard, Jackson, and Jones (2006) are the only two studies to demonstrate that the traumatic sequelae that follows a first episode of psychosis can be significantly reduced through psychological intervention. On average, levels of trauma symptoms in the present study were slightly lower than other studies surveying similar samples (Jackson et al., 2004; McGorry et al., 1991; Tarrier et al., 2006). The fact that only 23% of the present sample met the 'caseness' criteria for the IES would suggest that there were fewer people with severe trauma symptoms than the more usual one in three found in other first episode (McGorry et al., 1991; Jackson et al., 2004; Tarrier et al., 2006) and multiple episode studies (Seedat et al., 2004). Meeting 'caseness' criteria on the IES is, of course, not the same as a diagnosis of PTSD (although highly correlated; Rothbaum et al., 1992). As pointed out previously, the IES was selected because, in addition to being used in other studies of PTSD and psychosis (McGorry et al., 1991; Jackson et al., 2004; Chisholm et al., 2006), it measures the two aspects of trauma which were deemed to be most relevant to the study of traumatic reactions to the onset of psychosis (i.e. intrusive re-experiencing and avoidance of cues and reminders). The high concordance between IES intrusion and avoidance and PTSD diagnosis noted in a number of studies validates the usage of the IES in the present study. More importantly, a number of studies have demonstrated that the IES is a good, low-cost, practical way to assess outcome from intervention studies (Sundin & Horowitz,

2002). Despite this, the most recent factor analytic studies suggest that PTSD may be best conceptualised as a four factor model which in addition to intrusions and avoidance also incorporates arousal and dysphoria (Elklit & Shevlin, 2007). It is possible, therefore, that caseness cut-offs on the IES may misrepresent the numbers of people who fulfil the criteria for PTSD and trauma.

It is also conceivable that those refusing consent may have had high levels of trauma symptoms which could have inhibited them from accepting psychological help in the first place (Brewin, 2003). Jackson et al. (2004) found that those with a "sealing over" recovery style (and hence those denying they are unwell and avoiding services) were significantly more likely to admit to trauma symptoms related to avoidance of cues, emotions and reminders of the traumatic aspects of the first episode. It remains unclear whether CRI would have benefited this particular sub-sample of patients or whether a different approach such as written disclosure would have been more efficacious (Bernard et al., 2006).

It is also unclear because of a lack of an active control group, whether those who benefited from CRI in terms of reduced trauma symptoms did so because of increased contact with a mental health professional. This would have allowed an increased opportunity to talk about their first episode and scope for emotional processing (Brewin, 2003). On the other hand, many of the TAU group were in regular contact with one or more mental health professionals who would have afforded them the opportunity to discuss the circumstances surrounding the onset of their psychosis.

Overall there was no evidence that depression significantly reduced in either group across the course of the study. The best predictor of post-intervention depression was the level of pre-intervention depression. Although this is a disappointing finding it points to how resilient depression can be in some people following a first episode of psychosis. In general, however, average levels of depression on the CDSS fell from 'moderate' (5–6) at baseline to 'mild' (3–4) at the post-intervention point. The fact that this reduction was not significant may ultimately reflect the fact that the study was statistically underpowered and unable to detect small changes in effect size.

Despite significant reductions in mean levels of self esteem for both the CRI and TAU groups, average scores on the SCQ remained below the lower limit of the range that would be expected for the 'normal' population (i.e. below 132; Robson, 1989; Hall & Tarrier, 2003). This would appear to signify that although self esteem spontaneously increases following a first episode of psychosis this was not significantly accelerated by cognitive therapy as delivered in the current study. This would suggest that with, or without, a specific psychological intervention some people may draw upon their own resources to help them adapt and adjust to the onset of psychosis (May, 2004). Despite this, a number of people may remain feeling entrapped and shamed with a relatively poor sense of contentment and self acceptance (Birchwood et al., 2000). Similar findings have been noted from other CBT trials with older, multiple episode cohorts (Kuipers et al., 1997). Due to constraints of space, however, a detailed analysis of people's appraisals (Birchwood et al., 2003; Garety, Bebbington, Fowler, Freeman, & Kuipers, 2007) in the present study, will not be reported here but in a second paper.

Overall, those with the lowest levels of DUP tended to benefit most from CRI. Whilst the relationship between long DUP and poor outcome is now well established (Marshall et al., 2005), less is known about the influence of DUP on more specific outcomes in psychological interventions for first episode psychosis.

A large number of people (58%) either refused to consent, were deemed to be unlikely to consent by their care team or were not contactable prior to randomisation. Recruiting people who have recently experienced a first episode of psychosis into an RCT of CBT

within the context of a multi-ethnic, inner city area (as was the case in many of the research sites in the current study) can be notoriously difficult but not unusual for CBT trials (Tarrrier & Wykes, 2004; Jolley et al., 2003).

Despite the best intentions of the study to recruit from a wide range of ethnic groups representative of the populations sampled, there was a disproportionate number of people refusing to consent who described themselves as South Asian or African–Caribbean. This is consistent with other findings of a lower take up of psychological therapies amongst non-white minority groups in general (Lasser et al., 2002) and for those diagnosed with psychosis in particular (Rathod et al., 2005). It is also in line with more robust data, which suggests that African–Caribbean and black African patients are less likely to seek help from health professionals at the first episode (Morgan et al., 2005). The finding that people from ethnic minorities are less willing than white people to take up offers of cognitive therapy following a first episode of psychosis again has implications for the delivery of psychological interventions to diverse populations within the context of early intervention services (Commander, O'Dell, Surtees, & Sashidharan, 2003).

Approximately one in three of those in the experimental group withdrew from the study after randomisation. Whilst 20% also dropped out from the control group this figure, although large, is comparable with other similar studies (Jackson et al., 1998; Jolley et al., 2003) and again highlights some of the difficulties of sustaining psychological treatments over a relatively long period of time with first episode populations. Those who dropped out had significantly higher baseline negative symptom scores than those who continued in the study. It is possible that the motivational and cognitive difficulties that are associated with negative symptoms may have impeded their ability to participate in the intervention over a long period of time. Moreover, Lewis et al. (2002) reported that their optimum treatment of 15–20 h of CBT was rarely taken up by first episode patients even within a relatively contained hospital setting (most patients in the study were either in-patients or were attending day hospital facilities) with most only receiving a median of 8.6 h. All patients in the current study were engaged in the community. Many people in the SOCRATES trial refused sessions because they had to contend with many other issues, were experiencing high levels of distress, and had a fear of being intruded upon (Siddle & Haddock, 2004). This is likely also to be the case in the current study with the added complications of working in a less structured community setting. Again, this is not unique to psychological interventions with similarly high dropout rates also being reported in RCTs of drug interventions (CATIE; Lieberman et al., 2005; McGlashan et al., 2006). It may also be feasible to reduce the length of the intervention in order to retain a higher percentage of patients. We have obtained similar results from a shorter 4 week intervention using emotional disclosure through repeated writing about the first episode with much more favourable retention rates (Bernard et al., 2006).

Illicit drug misuse was not formally documented in the current study. Although this would make it difficult to ascertain whether the use of illicit substances such as cannabis, heroin and cocaine had a detrimental effect on outcomes, there is nothing to suggest that this effect would be different between the two groups. This is rarely studied in CBT trials in psychosis and probably needs to be taken into account in future research. As this was a pragmatic trial there was also no attempt to standardise routine care. Although this would reduce the chances of demonstrating an experimental effect, it does make the results more generalisable and consistent with what people typically receive in routine clinical practice (Lewis et al., 2002).

Despite some of the above shortcomings, analysis of the methodological quality of the trial using the Clinical Trials Assessment

Measure (CTAM; Tarrrier & Wykes, 2004) revealed that the quality of the methodology in the present study was of a high standard. Overall, the study can be considered a good quality pilot which justifies further trials and provides a solid basis for power calculations. There are encouraging results from the current study regarding the reduction in 'PTSD' symptoms in those meeting caseness criteria. In a further trial we intend to only pre-select those with high levels of trauma symptoms. Generally, however, the evidence base for psychosocial interventions and first episode psychosis remains limited (Haddock & Lewis, 2005). This is especially the case for issues of psychological adjustment, adaptation and emotional dysfunction (i.e. depression, suicide, self esteem, trauma, etc.). Larger more adequately powered RCTs are needed to test the applicability of CRI to different first episode populations in a variety of geographical regions.

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