

Outcomes of an effectiveness trial of cognitive-behavioural intervention by mental health nurses in schizophrenia

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Background Little is known about the medium-term durability of cognitive-behavioural therapy (CBT) in a community sample of people with schizophrenia.

Aims To investigate whether brief CBT produces clinically important outcomes in relation to recovery, symptom burden and readmission to hospital in people with schizophrenia at 1-year follow-up.

Method Participants (336 of 422 randomised at baseline) were followed up at a mean of 388 days (s.d.=53) by raters masked to treatment allocation (CBT or usual care).

Results At 1-year follow-up, participants who received CBT had significantly more insight ($P=0.021$) and significantly fewer negative symptoms ($P=0.002$). Brief therapy protected against depression with improving insight and against relapse; significantly reduced time spent in hospital for those who did relapse and delayed time to admission. It did not improve psychotic symptoms or occupational recovery, nor have a lasting effect on overall symptoms or depression at follow-up.

Conclusions Mental health nurses should be trained in brief CBT for schizophrenia to supplement case management, family interventions and expert therapy for treatment resistance.

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Most meta-analyses concur that expert cognitive-behavioural therapy (CBT) has proven benefits in research settings in managing residual symptoms, poor insight and poor adherence to treatment regimens in schizophrenia (National Institute for Clinical Excellence, 2002; Pilling *et al*, 2002). However, randomised clinical trials only prove efficacy in research settings and with specialist therapists. If CBT is to be delivered to the full range of people with schizophrenia within community settings, then effectiveness trials are needed with clinically worthwhile outcomes (Turkington *et al*, 2003). The largest workforce in regular contact with people with schizophrenia are mental health nurses. Traditionally, these have used case management and psycho-education within a supportive relationship in the community to manage the disorder. Some nurses have been trained to deliver family interventions aimed at reducing relapse, although implementation has been difficult because of the time investment needed (Kuipers, 2000). The question arises of whether training nurses to deliver brief CBT would be of additional benefit. The null hypotheses being tested were that at 12-month follow-up there would be no difference between the two groups (CBT and usual care) in insight, overall symptoms, depression or suicidality, occupational recovery, time to and duration of hospital readmission, and psychotic or negative symptoms.

METHOD

The original results from this trial for end of therapy have already been published (Turkington *et al*, 2002). The original paper provides a full description of the method.

Study population

Lists of patients with ICD-10 schizophrenia (World Health Organization,

1992) in contact with healthcare services were constructed across six sites (Belfast, Glasgow, Hackney, Newcastle, Southampton and Swansea) in the UK. Lists were drawn from in-patient and out-patient case lists, depot injection and clozapine clinics, community mental health team case lists and case registers. These patients were not strictly treatment resistant as defined in other trials of CBT (Sensky *et al*, 2000) but most who agreed to enter the trial had ongoing positive and/or negative symptoms or were at risk of relapse. The group was representative of people who have not recovered from schizophrenia but who, with moderate levels of ongoing symptoms, are maintained in the community and in contact with a community mental health team or general practitioner (GP).

Sampling method

Patients were excluded from the lists if they were in the process of active relapse, had a primary diagnosis of substance or alcohol dependence, organic brain disease or learning disability severe enough to interfere with rating. Patients were approached for consent and randomised only after permission had been given by the responsible medical officer and community keyworker. Randomisation was performed by computer, using blocks of six random numbers, and stratification was by site on a 2:1 ratio (therapy *v.* usual care). This was to allow inter-site comparisons. All usual-care patients were offered the intervention of cognitive-behavioural therapy at the end of the final follow-up assessment. The results for the whole group will not be presented here, but will await further follow-up at 24 months from baseline. The study was initially powered using a pilot study of brief CBT (Turkington & Kingdon, 2000) to give a 90% chance of detecting a 25% level difference in overall symptoms at the 0.01 level of significance.

Assessments

Raters were trained in the use of the rating instruments before the beginning of the trial (intraclass correlation coefficient=0.71). To protect masking, therapists asked patients not to say anything about CBT to the raters, and raters were informed that a random sample of usual-care patients would be sent a sample of the CBT materials (this was not carried out in practice). The primary outcomes were measured by validated rating scales.

Overall symptoms using the Comprehensive Psychopathological Rating Scale (CPRS; Åsberg *et al*, 1978), insight using the Insight Rating Scale (IRS; David, 1990) and depression Montgomery-Åsberg Depression Rating Scale (MADRS; Montgomery & Åsberg, 1979) were all measured. Secondary outcomes measured included positive symptoms using the Psychotic Symptom Rating Scales (PSYRATS; Haddock *et al*, 1999) and negative symptoms using the Negative Symptom Rating scale (NSRS; Hansen *et al*, 2003). Occupational recovery was assessed from a full masked perusal of the case-notes over the follow-up period. Evidence was logged of return to work (full-time or part-time) or resumption of education or training. Relapse was defined as readmission to hospital. Time to and duration of readmission were logged masked to treatment group at the 12-month time point. Results were independently analysed following entry into a central database. Medication changes from end of therapy were recorded as was the number of atypical antipsychotic drugs used over the follow-up period.

Treatment groups

Mental health nurses were trained over a period of 10 days. Only one of these (J.P.) had a higher qualification in CBT for schizophrenia. He acted as a trainer/supervisor for the other nurses who, although experienced in working with schizophrenia in community settings, had no basic knowledge of CBT. Training involved a description of the key stages of therapy (Kingdon & Turkington, 1994, 2005), beginning with discussion with the nurses about formation of a therapeutic alliance with the patient and developing normalising explanations for psychotic symptoms. Next, nurses were taught how to make a therapeutic assessment and then develop a formulation of the onset and maintenance of psychotic symptoms. Thereafter, cognitive-behavioural techniques were demonstrated for managing troublesome psychotic symptoms (hallucinations, delusions and negative symptoms). Further sessions addressed improving concordance with antipsychotic medication, developing more functional beliefs concerning self and others, and developing a personalised relapse prevention plan. Thus, the nurses were being trained to achieve good engagement and then to work flexibly using cognitive-behavioural techniques to

improve the patients' understanding, develop their coping skills and help them to take more control over their illness. Role-play (and role-reversal) exercises were practised to develop confidence in technique application at each stage of therapy. Numerous case examples were worked through (Kingdon & Turkington, 2002). After training, weekly supervision was provided. A total of six therapeutic sessions were completed with each patient over 2–3 months. If the patient agreed, the main carer received three sessions of CBT training so that he or she could help with understanding the case formulation, managing psychotic symptoms and preventing relapse.

This brief intervention is technique-based and should not be confused with the formulation-based and schema-focused CBT described by the National Institute for Clinical Excellence (2002) for treatment resistance. Any patient who attended fewer than three therapeutic sessions was classified as having dropped out. Therapeutic sessions were supported by a series of informative booklets prepared specifically for the study. Treatment fidelity was confirmed independently by two psychologists who rated a randomised selection of taped sessions with the Cognitive Therapy Scale modified for psychosis (CTS-Psy; Haddock *et al*, 2001). The mean score was 38.4 (95% CI 35.78–41.9) with no statistically significant difference between general and specific sub-scales, indicating that cognitive-behavioural techniques were being used in these sessions. Although the scores on the CTS-Psy were relatively

lower than the score that might be expected from therapists who had received intensive training to carry out CBT with patients with treatment-resistant psychosis, these scores do indicate that the nurses were employing some CBT techniques in their intervention. Patients randomised to receive treatment as usual received their normal care plan as organised by the community keyworker. All such patients understood that they would be offered the CBT intervention at the end of the study period.

Statistical analysis

Results were analysed independently at the follow-up point using the Statistical Package for the Social Sciences, version 10 for Windows, on an intention-to-treat basis. Differences in symptomatic improvement between the two groups were assessed using analysis of covariance at 12-month follow-up. The covariates used were baseline measurements for the corresponding dependent variables. Tests of normality and skewness across continuous clinical variables were within acceptable limits. Missing data at follow-up were imputed using a group mean. The total number of days in hospital for each patient was calculated over the 12 months from baseline and compared between the two groups using parametric statistics. Time to relapse as measured by readmission was analysed using a survival analysis according to the Kaplan-Maier method. Differential rates of occupational

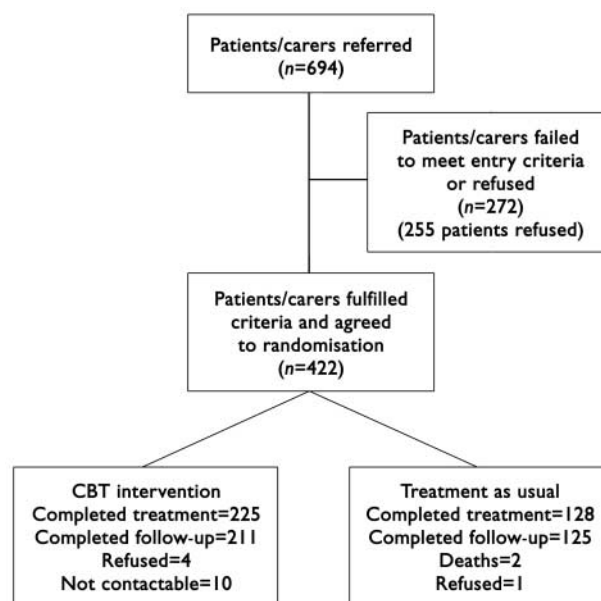


Fig. 1 Participants' flow through the study. CBT, cognitive-behavioural therapy.

recovery between the two groups were analysed using chi-squared testing.

RESULTS

The flow chart showing numbers of participants in each group and reasons for drop out is shown in Fig. 1.

The patients enrolled in this study were mostly men, unmarried, White and living independently in poor-quality accommodation (Rathod *et al*, 2005). There were no statistically significant differences between the groups at baseline. In particular, in terms of previous hospital admissions due to schizophrenia, the CBT group had a mean of 4.71 (95% CI 4.09–5.33) with a mean number of days in hospital of 48.52 (95% CI 37.84–59.21). The usual-care group had a mean of 5.18 (95% CI 4.03–6.33) readmissions and 52.01 (95% CI 37.94–66.07) days in hospital. These differences were not statistically significant, nor were baseline medication dosage or numbers of participants on atypical antipsychotic drugs. At baseline, the mean medication dosage in chlorpromazine equivalents was 746.88 mg in the therapy group (95% CI 602.79–890.96) and 886.58 mg in the usual-care group (95% CI 660.72–1112.44). In relation to atypical antipsychotic drugs, 55 people in the CBT group and 25 in the usual-care group were receiving these medications. During the course of the follow-up period, 14 CBT patients and 10 usual-care patients switched onto atypical antipsychotic drugs. During the follow-up period there was no statistically significant difference in medication parameters.

Durable, statistically significant improvements were seen at 12-month follow-up in insight and negative symptoms

in the CBT group compared with the usual-care group (Table 1). Actual scores are given, with mean change scores and confidence intervals on each scale, between baseline and 12-month follow-up. Primary negative symptoms, including alogia and affective blunting, were not improved by the intervention. A good clinical outcome was defined *a priori* as an improvement of 25% or more, giving a number-needed-to-treat for insight of 11 and for negative symptoms of 14. No significant difference was found between the two groups for positive symptoms, overall symptoms or depression.

A chi-squared test was carried out on 2 × 2 tables, comparing level of improvement of insight (<25% or ≥25%) with improvement or no change in depression or worsening of depression. These tests were carried out separately for CBT and usual care and then combined. This revealed a definite risk of worsening of depression in the usual-care group (relative risk=2.19, 95% CI 1.41–3.43) but not in the CBT group (RR=1.13, 95% CI 0.76–1.68) in those whose insight improved by >25%. This protective effect of therapy was highly significant ($P=0.001$), and the risk of not having CBT and worsening of depression with improvement in insight, perhaps caused by psychoeducation or an atypical antipsychotic medication, is clinically important. Significantly more patients in the usual-care group (38 out of 165) relapsed by 12-month follow-up than in the therapy group (36 out of 257) (chi-squared test, $P<0.05$). Patients in the usual-care group were significantly more likely to be readmitted to hospital earlier (mean time to relapse: usual care, 161 days (s.d.=97.19); CBT, 176 days (s.d.=98.29) ($P=0.018$, odds ratio=1.84, 95% CI 1.108–3.04)). Those patients who did

relapse in the CBT group tended to be back in hospital for a briefer period (mean, 50 *v.* 71 in-patient days ($P<0.05$)). Taken together, these results display a highly significant beneficial effect of brief CBT in relation to readmission to hospital in schizophrenia. Occupational recovery, as defined by return to work or education on a full- or part-time basis, was rare in both groups (11 out of 257 in the CBT group and 9 out of 165 in the usual-care group). There was no significant difference in outcome between the six sites on an intersite comparison on the primary outcome.

DISCUSSION

This study shows that training mental health nurses to deliver brief CBT is safe and effective. The durable effects of the intervention occurred across certain but not all outcome measures. Statistically significant improvement was found for both insight and secondary negative symptoms such as apathy, reduced volition and asociality. This is particularly encouraging in relation to the very modest benefits that can be achieved with negative symptoms even with atypical antipsychotic medication. A sustained improvement in insight would be expected to lead to improved adherence and the use of more effective coping strategies. Interestingly, some patients receiving the therapy showed increased reporting of positive symptoms when insight was improved. This may have been the reason why the eventual result overall for these symptoms was not significantly different between the two groups. Such increased reporting may have been a result of increased or worsening symptoms or it may also have been related to a willingness

Table 1 Baseline scores and change scores (mean, 95% CI) at 12-month follow-up

Measure	CBT intervention		Treatment as usual		Comparison of change scores (ANCOVA) mean difference
	Baseline score	Change score	Baseline score	Change score	
Overall symptoms	23.27 (21.64 to 24.9)	4.96 (3.56 to 6.36)	24.30 (22.11 to 26.49)	3.64 (1.80 to 5.47)	-1.716 (-3.76 to 0.33) ($P=0.099$)
Insight ¹	8.72 (8.33 to 9.1)	-0.50 (-0.95 to -0.05)	8.68 (8.18 to 9.18)	0.19 (-0.38 to 0.76)	0.711 (0.11 to 1.31) ($P=0.021$)
Depression	5.52 (4.93 to 5.94)	1.43 (0.98 to 1.88)	6.14 (5.38 to 6.79)	1.28 (0.68 to 1.88)	-0.47 (-0.89 to 0.59) ($P=0.128$)
PSYRATS (voices)	9.41 (6.72 to 12.13)	1.42 (0.07 to 2.78)	10.1 (7.88 to 12.92)	2.59 (0.97 to 4.2)	0.824 (-0.88 to 2.53) ($P=0.342$)
PSYRATS (delusions)	7.95 (6.47 to 9.98)	2.00 (1.08 to 2.92)	7.71 (6.02 to 9.47)	2.43 (1.37 to 3.5)	0.572 (-0.572 to 1.72) ($P=0.328$)
Negative symptoms	4.60 (3.95 to 5.12)	1.36 (0.98 to 1.74)	4.89 (4.09 to 5.53)	0.76 (0.23 to 1.30)	-0.773 (-1.27 to -0.28) ($P=0.002$)

CBT, cognitive-behavioural therapy; ANCOVA, analysis of covariance; PSYRATS, Psychotic Symptom Rating Scales.

1. A negative change score on this parameter indicates improvement and a positive mean difference score on ANCOVA indicates a positive result for therapy over treatment as usual.

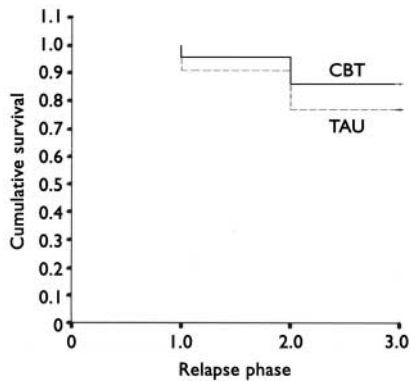


Fig. 2. Kaplan-Meier curve of time to relapse over 12 months according to treatment arm. TAU, treatment as usual; CBT, cognitive-behavioural therapy. Overall log-rank test $P=0.018$

to disclose symptoms, owing to normalising and reducing stigma and not being readmitted as a consequence. Depression and overall symptoms were shown to be significantly improved at the end of therapy but not significantly at follow-up. One of the most positive results in this study related to the protective effect of CBT on depression in relation to clinically significant improvements in insight. It may be safer for patients expected to make substantial improvements in insight, for example when commencing or recommencing anti-psychotic medication and psychoeducation, to consider providing CBT at the same time.

Relapse and recovery

Apart from the symptomatic improvements listed above, patients with schizophrenia treated with brief CBT showed a longer time to readmission (84% increased risk in the usual-care group). They were also significantly less likely to relapse over the follow-up period. When readmitted, they spent significantly less time in hospital (mean of 50 *v.* 71 days). This is most likely to relate to improved insight and more effective coping styles in the CBT group. In an earlier publication by our group (Rathod *et al*, 2005) we demonstrated that, following therapy, there was a statistically significant improvement in insight into the need for treatment in the intervention group at 12-month follow-up. Whether this translated into actual adherence was not tested. These levels of improvement are modest in symptomatic terms, although clinically important because of the benefits of reduced admission to hospital. The savings in terms of reduced

bed occupancy could repay resources spent on training in CBT and the provision of supervision. If the beds could have been closed to free the finance, £404 000 could have been saved across the six sites. For a medium-sized mental health trust this would equate to the closure of one acute ward, freeing monies to be spent in the community.

Unfortunately, brief CBT does not lead to any increase in occupational recovery. This is an important clinical outcome, and is now being assessed in clinical trials using CBT and vocational rehabilitation. It would seem, however, that this brief dose of therapy could lead to a more integrated discussion across the area of psychosocial management at care programme approach review meetings (Pelton, 2001). It allows wider availability of CBT to the many eligible patients (National Institute for Clinical Excellence, 2002) and prioritisation of patients for more long-term therapy for those requiring it. A further benefit is that the practical aspects of therapy, including reality-testing, shared formulation, graded activity scheduling and the use of a range of coping strategies, bring carers into the process of treatment. Training nurses in CBT has benefits for the patient, carer, the service delivery system and the nurses themselves, who often report improved job satisfaction.

Similar UK/USA pragmatic trials

These findings support those of Hogarty *et al* (1997), who showed that personal therapy, when delivered to patients with schizophrenia in the community with the support of a carer, showed benefits on symptom control and reduced readmission to hospital. The possible benefits of brief CBT in terms of improved adherence to drug treatment parallel the results of Kemp *et al* (1996, 1998), who demonstrated cost-effectiveness over the short and medium terms. This intervention differed from the above approaches in focus on improved insight into symptom causation and maintenance, with the development of focused coping strategies and lifestyle change. The therapeutic approach was able to blend the above techniques with the relapse prevention techniques of Gumley *et al* (2003) to produce an intervention which was flexible and effective. This paper supports our previous publication in showing that mental health nurses can safely and effectively use CBT with stable patients with

schizophrenia in community settings to deliver clinically important outcomes.

Critical appraisal

The problems in interpreting the findings presented here mostly relate to issues of protection of masking and generalisability. All studies which have not used an active therapy comparator struggle to fully preserve masking. Strategies were employed to attempt to protect masking, and suspected breaches did not appear to confirm loss of masking to any substantial degree. In relation to generalisability, the nurses were funded by the trial sponsor and liaised with community mental health teams rather than having emerged from within their ranks. It still needs to be proven in a further study that nurses can be trained and can practise CBT with patients with schizophrenia while in day-to-day working life. Also, although the sample is by and large representative of patients with schizophrenia with positive and negative symptoms on nursing case-loads, it may not be representative of the population with schizophrenia as a whole. Many of the more seriously ill patients, particularly with dual diagnosis, actively avoid or default from GP or nurse case-loads and are more likely to refuse to enter clinical trials. This study now needs to be followed up by a study which controls for the effect of therapist time. Appropriate controls would include befriending (Sensky *et al*, 2000), supportive counselling (Tarrier *et al*, 1998) or psychoeducation (Carroll *et al*, 1998). However, ideally and unlike the studies mentioned above, the control treatments should be delivered from a position of clinical equipoise using experts in that therapy to minimise the impact of investigator allegiance (Paley & Shapiro, 2002).

Implications for services

The more widespread implementation of CBT within mental health nursing would require an increased number of training places, particularly of the brief intensive kind employed here. Staff are more likely to be released for a brief intensive training course than for 1 day per week over several years. An increase in training courses for psychosocial interventions with a particular focus on cognitive-behavioural methods would also be needed. At the supervisory level we would need more postgraduate training courses. This paper supports the guidelines published by NICE, but also

points out the financial implications of this particular form of evidence-based practice. Encouragingly, brief CBT offered to patients with schizophrenia and their carers appears to have beneficial effects, which should encourage training providers to support the development of more training courses with continuing supervision from experienced therapists. This intervention would need to be supplemented by input from expert practitioners, who could deliver a minimum of 20 sessions for patients with more severe psychosis or comorbid psychiatric disorders such as substance use or comorbid personality disorders.

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