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North Wales randomized controlled trial of cognitive behaviour therapy for acute schizophrenia spectrum disorders: outcomes at 6 and 12 months

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ABSTRACT

Background. Recent reviews of randomized controlled trials have concluded that cognitive behaviour therapy (CBT) is effective, as an addition to standard care, in the treatment of people suffering from schizophrenia. Most of the trials have been conducted with stabilized out-patients. The aim of this trial was to evaluate the effectiveness of CBT for in-patients suffering acute psychotic episodes, when delivered under conditions representative of current clinical practice.

Method. Consecutive admissions meeting criteria were recruited. After screening, 43 were assigned at random to a treatment-as-usual (TAU) control group and 47 were assigned to TAU plus CBT. At baseline, 6 months and 12 months, patients were rated on symptoms and social functioning. CBT (maximum 25 sessions) began immediately after baseline assessment.

Results. The CBT group gained greater benefit than the TAU group on symptoms and social functioning. A larger proportion of the CBT group (60%) than the TAU group (40%) showed reliable and clinically important change, and none of them (*v.* 17%) showed reliable deterioration compared with baseline.

Conclusions. CBT for patients suffering acute psychotic episodes can produce significant benefits when provided under clinically representative conditions.

INTRODUCTION

Recent reviews of randomized controlled trials (RCTs) have concluded that there is evidence that cognitive behaviour therapy (CBT) is effective, as an addition to standard care, in the treatment of people suffering from schizophrenia spectrum disorders (Dickerson, 2000; Bustillo *et al.* 2001; Gould *et al.* 2001; Rector & Beck, 2001; Pilling *et al.* 2002). Probably the most rigorous of these reviews is that by Pilling *et al.* (2002) who confined their review to high quality RCTs in which CBT had been compared either with standard care or with other active interventions. They concluded that 'CBT produced higher rates of "important improvement" in mental state and demonstrated positive effects on continuous measures of mental state at follow-up' (p. 763).

Most of the trials of CBT have been conducted with stabilized out-patients who were suffering from persistent residual psychotic symptoms, but the results of two trials have now been published in which CBT was offered at the time of admission to hospital due to acute psychotic episodes. These trials reported widely differing results. In the first of them, Drury *et al.* (1996*a*, *b*) found that, compared with a control group who received matched hours of therapist input, the acute patients in this trial who received CBT showed a marked decrease in recovery time, and a far smaller proportion of them

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(5% *v.* 56%) showed moderate or severe residual symptoms after 9 months. By contrast, Lewis *et al.* (2002) found only trends towards faster improvement in patients who received CBT compared with those who received routine care alone, and no indication of faster improvement compared with a control group who received supportive counselling. Only improvements in auditory hallucinations, among a subsample who were suffering hallucinations at baseline, were faster among those who received CBT.

The most obvious explanation for the differences in the results of these two trials is that Lewis *et al.* (2002) employed an intention-to-treat analysis, whereas Drury *et al.* (1996*a*, *b*) did not. Indeed, Drury *et al.* deliberately excluded one-third of the patients who had been allocated to CBT because they were considered unsuitable, either because they took less than half of their prescribed medication, they did not disclose any psychotic symptoms, or they would not engage in the treatment. Thus, their results may generalize only to patients who are compliant with certain requirements of this kind of treatment. Another factor that probably contributes to the different results in these two trials is that Drury *et al.* (1996*a*, *b*) assessed outcomes at 9 months after baseline, whereas Lewis *et al.* (2002) have so far followed up patients for only 70 days. In their trial comparing CBT with a befriending control intervention, Sensky *et al.* (2000) found there were no differences in outcome between their two groups at the end of treatment but at 9-month follow-up the CBT group had continued to show improvements while the befriending group had lost some of their former gains. Thus, Lewis *et al.* might yet find clear benefits of CBT at longer-term follow-up.

Another possible reason Lewis *et al.* (2002) did not obtain better results is that the treatment they provided may have been too intense, or not sufficiently sustained, or both. Their aim was to provide 15–20 hours of CBT during the inpatient hospital stay, within a 5-week treatment envelope or until the patient was discharged (Haddock *et al.* 1999). Considering that the patients were suffering acute psychotic episodes at the beginning of treatment, many of them may have been too ill to derive much benefit from CBT within the first 5 weeks and, in the event, most patients received even less than this (Lewis *et al.* 2002). Moreover, although booster sessions were offered, regular therapeutic sessions ended at discharge. Thus, the patients would not have had the continuing help of a therapist over the period of discharge, a time of transition when patients are particularly vulnerable, at least to judge by the greatly increased risk of suicide at that time (Rossau & Mortensen, 1997).

If Lewis *et al.* should find clear benefits of CBT when they follow up their participants in the longer term, their decision to provide an intensive, short-term treatment would be vindicated. It would still be unclear, however, to what extent such outcomes would generalize to routine clinical practice since such intense treatments are not normally offered. It may be that nothing less would be effective, in which case services may need to be reorganized accordingly, but the experience with behavioural family interventions in schizophrenia has been that novel psychosocial treatments that require special training of staff and reorganization of services are not readily adopted even when the evidence in their favour is strong (Anderson & Adams, 1996). The main aim of the present study was to evaluate the effectiveness of CBT for acute schizophrenia and related disorders when delivered under conditions that are representative of current clinical practice. The primary outcomes of interest were positive and negative symptoms and social functioning.

METHOD

Participants

On the basis of the existing literature, effect sizes of 0·6 S.D. were expected. A power analysis then indicated that a total sample of 90 would give adequate power (0·8) to detect an effect of this size.

Consecutive admissions to three acute psychiatric hospitals were considered eligible for inclusion if they were aged between 18 and 65 years, were resident within the catchment area, had received a clinical diagnosis of schizophrenia, schizophreniform or schizo-affective disorder, appeared to be suffering an acute psychotic episode, were not already receiving psychological treatment, and showed no evidence of organic mental disorder. The 279 patients who were considered to be eligible were

invited to participate when their psychiatrists declared them to be capable of informed consent. The invitation was declined by 100, and 38 were excluded because, by that time, more than 28 days had passed since they had been admitted (one of the exclusion criteria). Those who accepted were then excluded if, during a baseline assessment, they were found not to be suffering an acute psychotic episode ($N=13$), their diagnoses could not be confirmed according to DSM-IV (American Psychiatric Association, 1994) criteria ($N=7$), they had been dependent on alcohol or illicit drugs according to DSM-IV criteria during the past year ($N=12$), or their IQs, assessed by the Quick Test (Ammons & Ammons, 1962), were below 80 ($N=19$). Of those who remained at the conclusion of the assessments, 43 were assigned at random by inviting the patient to toss a coin in front of the assessor, to a treatment-as-usual (TAU) control group, and 47 were assigned to TAU plus CBT. Characteristics of these patients at baseline are shown in Table 1. The two groups did not differ significantly on any of these characteristics.

Table 1. *Characteristics* (*mean*, *s.d. unless stated otherwise*) *of patients at baseline*

	CBT group			TAU group		
	Mean	s.d.	*N*	Mean	s.d.	*N*
Age	30·5	8·7		31·3	9·6	
Years of FT education	11·9	1·8		11·5	1·3	
Age at onset*	23·5	5·6		24·4	6·0	
No. of admissions†	4·0	4·0		4·9	6·6	
IQ	93·3	8·5		93·4	8·4	
Gender						
Male			37			31
Female			10			12
Marital status						
Single‡			40			40
Married§			7			3
Diagnosis						
Schizophrenia			39			39
Schizo-affective			6			1
Schizophreniform			2			3
Employment status						
Unemployed			31			31
Employed¶			16			12
Section of MHA‖						
None			29			26
Section 2			9			11
Section 3			8			6

* Age at first contact with psychiatric services.
† Including the current admission.
‡ Includes divorced and separated.
§ Includes cohabiting and widowed.
¶ Includes FT and PT student, sheltered work, retired and houseperson.
‖ MHA, Mental Health Act (involuntary admission).

Measures

At baseline assessment and at both 6 months and 12 months after baseline, patients were rated following structured interviews by trained assessors, on the Scale for the Assessment of Positive Symptoms (SAPS) (Andreasen, 1984), the Scale for the Assessment of Negative Symptoms (SANS) (Andreasen, 1989) and the Expanded Brief Psychiatric Rating Scale (BPRS-E) (Lukoff *et al.* 1986). In accordance with a principal components analysis of the SANS and SAPS by Andreasen *et al.* (1995), the items of the SAPS were divided so that the global ratings for hallucinations and delusions were summed to form a score for positive symptoms and the global ratings for bizarre behaviour and positive formal thought disorder were summed to form a score for disorganization symptoms. Global ratings for the SANS items, affective flattening, alogia, avolition–apathy and anhedonia–asociality were summed to form a score for negative symptoms. Although the BPRS-E contains 24 items, in order to facilitate comparisons with other research, only the 16 items of the original version were summed to form a total score. In order to assess the reliabilities of the ratings, 12 interviews with patients were sampled at random at each assessment point, with the constraint that no patient was sampled more than once, and recordings of these interviews were rated while blind to the interviewer's ratings. Inter-rater reliabilities were at least adequate (range 0·71 to 0·97) for all of the summary scores from these measures at the three assessments (Startup *et al.* 2002*a*).

Following structured interviews with 'best informants', usually qualified mental health professionals who were the patients' care managers, the patients were rated by the interviewers on the Social Functioning Scale (SFS) (Birchwood *et al.* 1990). Scores for each of the seven sections of the SFS were first converted to scaled score equivalents and then summed. At the end of this interview, the patients were rated by both interviewer and informant independently, blind to each other's ratings, on the Global Assessment of Functioning (GAF) (American Psychiatric Association, 1994). All interviews referred

to the preceding month. Intraclass correlations for the agreement between the interviewer and the informant for ratings on the GAF were 0·89, 0·94 and 0·95 for the baseline and two follow-up assessments, respectively. Since these levels of agreement are excellent, averages of the two sets of ratings were used in all subsequent analyses involving the GAF. The third author (S.B.) conducted most of these assessments and also trained the other assessor.

Treatment conditions

Treatment as usual (TAU) in the three participating Trusts of the UK National Health Service consists of pharmacotherapy, nursing care during hospitalization and community care after discharge. Each patient has a keyworker, a mental health professional, who devises and implements a care plan that might include any or all of the following: day-hospital or day-centre attendance, home visits with counselling, support worker involvement, sheltered work, social clubs and outings, help obtaining benefits and accommodation, carer support. No attempt was made to influence the course of psychiatric or community care.

CBT, provided as an addition to TAU, followed the objectives, strategy and techniques of the manual published by Fowler *et al.* (1995). This is a highly individualized, needs-based form of CBT for psychotic disorders and is based on collaborative empiricism and (evolving) cognitive-behavioural formulations. It has been shown to be an effective adjunct to standard treatment for out-patients with residual psychotic symptoms (Kuipers *et al.* 1997, 1998) but has yet to be evaluated with acutely ill in-patients.

Appointments for treatment, up to a maximum of 25 sessions, were provided at weekly intervals where possible, and the length of each appointment, up to a maximum of 90 min, was adjusted flexibly according to the patient's requirements. Patients were asked to commit themselves to at least 12 sessions because we believed that was the minimum required for a beneficial effect. Therapy began immediately after baseline assessment and continued without interruption following discharge. Ratings of adherence to the therapy manual were made on a representative sample of CBT sessions, using the Cognitive Therapy for Psychosis Adherence Scale, and the favourable results have been reported by Startup *et al.* (2002*b*).

Therapists

CBT was provided by the first two authors of this paper and one other clinical psychologist. The authors were employed as specialists in serious mental illness and conducted CBT for schizophrenia on a routine basis. They had had 10 years (M.S.) and 2 years (M.C.J.) of post-qualification experience at the outset of the trial and had 28 and 17 clients, respectively, assigned to them for treatment in the current trial. The third therapist had recently undertaken 1-year specialist training in CBT for psychotic disorders. He had two clients assigned to him in the trial. The therapists met at least once a month for peer supervision and to maintain adherence.

Data analyses

The results were analysed on the basis of intention-to-treat, in two ways. First, mean differences between the groups were analysed in two multivariate analyses of covariance, followed by univariate tests, with treatment group as the independent variable (IV) and four of the outcome variables as dependent variables (DVs): the psychotic subscale of the SAPS, the SANS total, the Social Functioning Scale and the GAF. Baseline assessments on these four measures acted as simultaneous covariates. The BPRS was excluded from these analyses because of its redundancy against the SANS and the SAPS, and the disorganization subscale of the SAPS was excluded because the distribution of scores was highly skewed (see below). Since data were missing for some patients at 6-month but present at 12-month follow-up, and vice versa, separate analyses were conducted for each follow-up. Every effort was made to follow up all patients. Analyses were carried out using SPSS for OSF/1, release 6.1.4.

Results were also analysed for individual outcome in terms of reliable and clinically significant change. The GAF was chosen as the outcome variable for this analysis since it has been found to provide a valid summary of both symptoms and social functioning (Startup *et al.* 2002*a*) and results at 12 months were used because not all patients in the CBT group would have received all the CBT sessions they were to receive by 6 months. In order to assess

Table 2. *Means, S.D.s and sample sizes for outcome measures, for CBT and TAU groups, at three assessments*

	Baseline				6-month assessment						12-month assessment					
	CBT		TAU		CBT			TAU			CBT			TAU		
Outcome measure	Mean	S.D.	Mean	S.D.	*N*	Mean	S.D.	*N*	Mean	S.D.	*N*	Mean	S.D.	*N*	Mean	S.D.
SAPS: Psychotic	7·4	2·0	7·3	2·0	34	3·5	2·9	32	5·2	3·9	33	2·9	2·8	30	4·9	3·4
SAPS: Disorganization	3·3	2·6	3·4	2·2	34	0·9	1·5	32	1·5	1·9	33	0·6	1·2	30	0·9	1·6
SANS total	9·4	3·5	8·4	2·9	34	5·7	4·0	32	7·0	4·1	33	4·7	3·5	30	7·1	4·0
BPRS total	46·0	7·4	45·5	8·0	34	30·2	10·0	32	36·9	12·1	33	28·2	9·0	30	36·1	11·0
Social Functioning Scale	93·3	8·9	96·2	9·4	39	102·3	11·1	36	97·4	11·1	35	105·9	9·8	34	99·0	11·3
GAF	33·5	10·0	38·0	9·1	39	57·7	16·5	36	48·2	15·5	35	60·8	14·7	34	51·3	15·6

CBT, Cognitive behaviour therapy; TAU, treatment as usual; SAPS, Scale for the Assessment of Positive Symptoms; SANS, Scale for the Assessment of Negative Symptoms; BPRS, Brief Psychiatric Rating Scale; GAF, Global Assessment of Functioning.

reliable change, we selected the Christensen & Mendoza (1986) RC index, which is both conservative and makes few statistical assumptions (Hafkenscheid, 2000). For this calculation, the reliability of the GAF was estimated from an intraclass correlation of 0·89 for the agreement of two independent raters at baseline (Startup *et al.* 2002*a*) and 95% two-directional RC bounds of measurement error were used, giving bounds of $\pm 8{\cdot}7$ on the GAF. It was decided that suicide (but no other cause of death) would count as reliable deterioration.

Three main criteria for judging clinically significant change have been advocated by Jacobson & Truax (1991). All three gave similar cut-offs with our data, but since large amounts of change are to be expected in acutely psychotic patients as a result of standard treatment alone, we chose the most conservative criterion: change moving the patient to within 2 S.D.s of the normative mean. The normative data were drawn from research by Ferdinand *et al.* (1995), who found a mean GAF score of 76·5 (S.D. = 9·94) for a representative sample of the general population of young adults aged 19–24 (Ferdinand, personal communication, 10 May 2001). This gave a cut-off of 57 on the GAF for clinically significant change.

RESULTS

Means and S.D.s of the outcome variables for the three assessments are shown in Table 2. A series of *t* tests on baseline scores showed that the TAU group scored significantly higher on the Global Assessment of Functioning (t (88) = 2·19; $P < 0{\cdot}04$), but the two groups did not differ significantly on any other variable.

Patient attrition

The number of sessions of therapy received by patients assigned to the CBT group varied between 0 and 25 (mean = 12·9, S.D. = 9·4, median = 12) and showed a tri-modal distribution. Thus, patients typically stayed for only two to three sessions, or they stayed for just the 12 they had agreed to, or they continued up to the permitted limit of 25. Treatment was terminated prematurely by 21 of 47 (45%) for the following reasons: five patients moved away; one was deemed to be too dangerous; one entered a catatonic stupor; one was sent to prison; seven discharged themselves; three failed to keep appointments; and three did not attend for even one session of CBT. Nevertheless, every effort was made to complete follow-up assessments with these patients.

At 6-month and 12-month follow-up, interviews could not be conducted with 24 and 27 patients respectively for the following reasons (frequencies for 12-month follow-up in parentheses): 10 (10) refused; nine (11) had moved away; two (three) were detained in prison; two (one) were too ill or too dangerous; none (one) had withdrawn from the research; and one (one) had committed suicide. At 6-month and 12-month follow-up, informants were unable to provide information on 15 and 21 patients, respectively, for the following reasons: 10 (13) patients had moved away; two (three) were

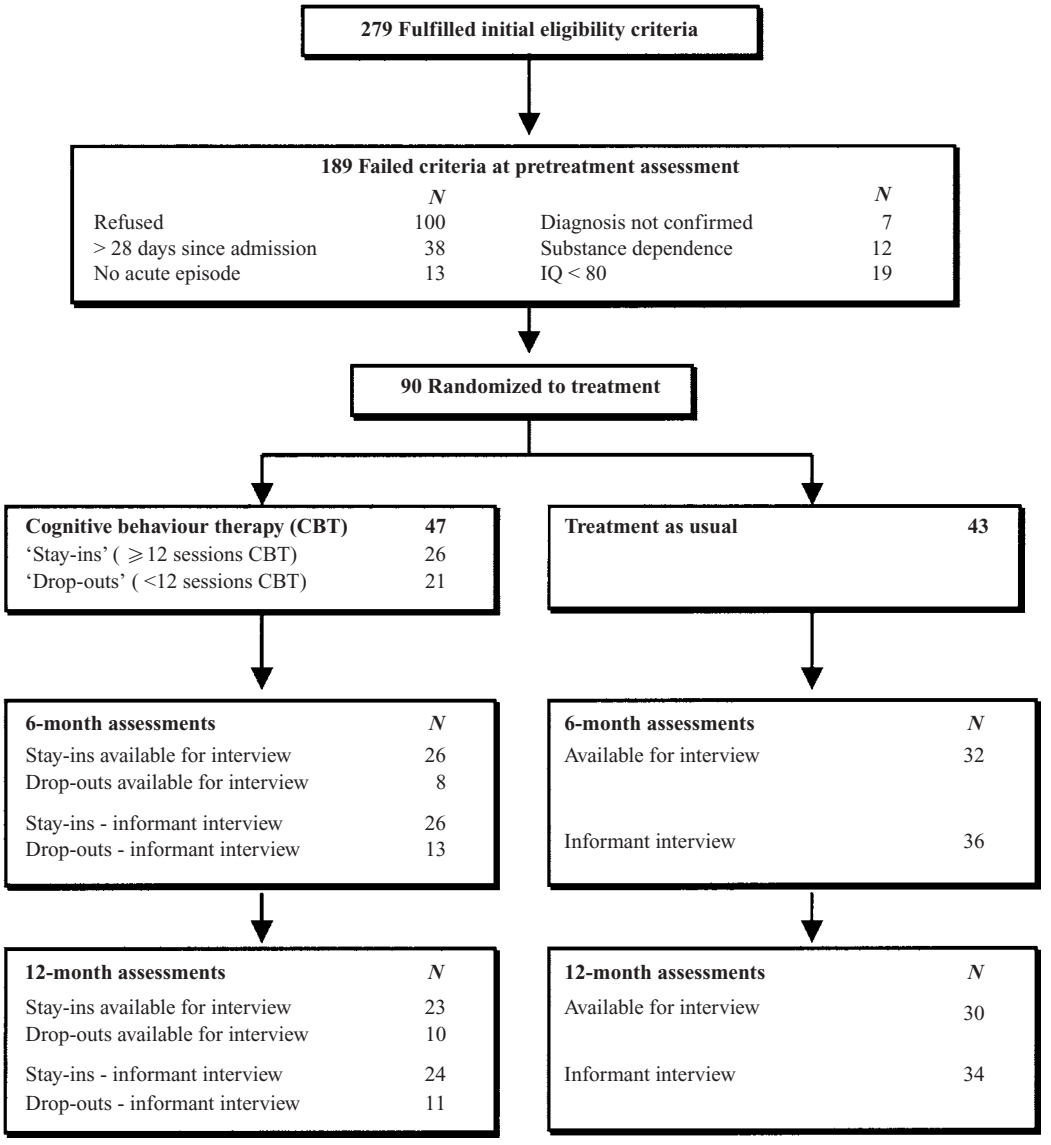

FIG. 1. Flow diagram: recruitment, allocation and follow-up of participants.

refusing to see the informant; one (two) was in prison; one (one) was too dangerous; none (one) had withdrawn from the research; and one (one) had committed suicide. The numbers in each group who were available for follow-up assessments are shown in Fig. 1. These numbers did not differ significantly between the two groups at either follow-up. Differences at baseline between those who were available for follow-up and those who were not were analysed in a series of univariate tests. As a control for the number of statistical tests, the threshold for significance was set at $P<0{\cdot}01$. None of the results was significant at this level.

Quantitative outcome

Mean differences between groups were analysed in two MANCOVAs. At 6-month follow-up, the multivariate difference between groups was not significant (exact $F(4, 56)=2{\cdot}02$, $P=0{\cdot}1$),

but at 12-month follow-up the difference between groups was highly significant (exact $F(4, 54) = 4{\cdot}84$, $P < 0{\cdot}002$). Univariate results from these analyses are presented in Table 3 as effect sizes (mean of the CBT group subtracted from the mean of the TAU group, then divided by the pooled S.D.). It can be seen that all of the results favour the CBT group and most of them are individually significant. The two-tailed probabilities associated with the results in the table were drawn from univariate results from the MANCOVAs.

The distribution of scores on the disorganization subscale of the SAPS was highly skewed because less than half of the patients showed any disorganization at follow-up. Therefore, the results on this variable were analysed by dividing the sample into those who showed at least mild disorganization (scored $\geqslant 2$ on either bizarre behaviour or thought disorder) at follow-up and those who did not. When the frequencies for these two groups were analysed by treatment group, 7/34 (21%) of the CBT group showed residual disorganization at 6 months, compared with 14/32 (44%) of the TAU group, which is a significant difference (Yates corrected $\chi^2(1, N = 66) = 3{\cdot}08$, $P < 0{\cdot}04$, $\phi = 0{\cdot}25$). However, this difference had disappeared by 12 months because by that time few patients in either group (6/33 (18%) of the CBT group, 8/30 (27%) of the TAU group) showed any disorganization (corrected $\chi^2(1, N = 63) = 0{\cdot}26$, $P = 0{\cdot}61$, $\phi = 0{\cdot}10$).

Table 3. *Effect sizes* (*standardized mean differences*) *between CBT and TAU groups* 6 *and* 12 *months after intake*

Outcome measure	Follow-up assessment	
	6 months	12 months
SAPS: delusions/hallucinations	0·51*	0·65**
SANS total	0·33	0·66**
BPRS total	0·62**	0·80**
Social Functioning Scale	−0·44*	−0·66**
GAF	−0·60*	−0·63**

For abbreviations, see Table 2.
* $P \leqslant 0{\cdot}05$; ** $P \leqslant 0{\cdot}01$ (two-tailed).

Table 4. *Categorical outcome*: *frequencies at* 12 *months*, *by treatment group*

Categorical outcome	Treatment group	
	CBT	TAU
Reliable deterioration	0	6
No reliable change	4	7
Reliable improvement	10	8
Reliable and clinically significant improvement	21	14

CBT, Cognitive behaviour therapy; TAU, treatment as usual.

Categorical outcome

Results on the Global Assessment of Functioning were analysed for individual outcome using bounds of $\pm 8{\cdot}7$ for reliable change and a cut-off of 57 for clinically significant change, as specified above. The results of applying these criteria are shown in Table 4, where the one suicide in the TAU group has been included among those showing reliable deterioration. It can be seen that a larger proportion of patients in the CBT group showed reliable and clinically significant improvement and a larger proportion of patients in the TAU group (none in the CBT group) showed reliable deterioration. The association between treatment group and categorical outcome was significant ($\chi^2(3, N = 70) = 8{\cdot}44$, $P < 0{\cdot}04$). We also converted these data into the number needed to treat (NNT) statistic. This gave an NNT of 5 (95% CI, 4·9 to 5·1) in order to obtain one reliable and clinically significant improvement, and an NNT of 5·8 (95% CI, 5·7 to 6·0) to prevent one reliable deterioration.

Medication

Although no attempt was made in this trial to influence the course of standard treatment, it is possible that the superior outcomes of the CBT group were due to differences in prescribed medication. This possibility was investigated in two ways. First, since there is some evidence that second-generation, atypical antipsychotic drugs are superior to conventional antipsychotic drugs in terms of both efficacy and tolerability, especially when the conventional drugs are prescribed in excessive doses (Geddes *et al*. 2000) and that clozapine confers even greater benefits than other atypical drugs (Chakos *et al*. 2001), the medication prescribed to the patients in our study at the time of each follow-up was categorized as conventional, atypical (olanzapine, quetiapine, risperidone, or amisulpride),

clozapine, or no medication. However, when the frequencies for these categories were analysed by treatment group, no significant differences were found at 6 months ($\chi^2(3) = 2{\cdot}36$, $P = 0{\cdot}5$) or at 12 months ($\chi^2(3) = 0{\cdot}83$, $P = 0{\cdot}84$). Secondly, dosages of antipsychotic medication during the 4 weeks preceding each assessment were converted to chlorpromazine equivalents using software designed for the purpose (Atkins *et al.* 1999). The distributions of these dosages were highly skewed and several outliers were identified even though patients taking no medication were excluded from the analysis. Therefore, the data were analysed with the Mann–Whitney *U* test. At 6 months, the dosages for the CBT group (mean = 488, S.D. = 631, median = 263 mg/day) and the TAU group (mean = 387, S.D. = 264, median = 300 mg/day) did not differ significantly ($U = 503$, $P = 0{\cdot}61$). At 12 months the mean dosages for the CBT group (mean = 566, S.D. = 645, median = 300 mg/day) and the TAU group (mean = 342, S.D. = 186, median = 300 mg/day) still did not differ significantly ($U = 374$, $P = 0{\cdot}18$).

DISCUSSION

The results of this trial showed that by 12 months after baseline, the CBT group had improved more on average than the TAU group, on all of the outcome measures including negative and psychotic symptoms, and social functioning. Moreover, the effect sizes on these measures at 12 months, which were in the range 0·6 to 0·8, were comparable to those found in previous trials of CBT for psychosis, the average of which is 0·65 at post-treatment (Gould *et al.* 2001). When the present results were analysed for individual outcome, it was found that a larger proportion of the CBT group (60%) than the TAU group (40%) showed reliable and clinically significant change in global functioning and none of them (*v.* 17%) showed reliable deterioration compared with baseline.

Some of these advantages appeared to be present already 6 months after baseline even though some of the CBT group had not at that time received all the CBT treatment that they would eventually receive. Since the multivariate analysis was not significant, we cannot have great confidence in the univariate results, but there were indications that psychotic and disorganization symptoms, and social functioning respond quite rapidly to CBT, though negative symptoms are slower to respond.

Methodological limitations

The chief methodological limitation is that the follow-up assessments were not conducted blind to group allocation. However, it should be noted that there was excellent agreement on the GAF between the independent assessments of the research interviewer and the informants, although there is no reason to suspect that the informants were biased in favour of CBT, and there was good agreement for the other ratings when a sample was rated independently by a second individual who was blind to the interviewers' ratings.

Another limitation is that there was no control for the amount of individual attention received by the patients in the CBT group. Thus, it is not clear whether the benefits enjoyed by the CBT group were due to the specific or non-specific aspects of the treatment.

Patients were randomized to groups by inviting the patients themselves to toss a coin and let it fall to the ground in front of the assessor. This method is unconventional, but it was chosen because our pilot work suggested that acutely ill patients tend to entertain suspicions about the research process if the basis of the randomization is not transparent to them. Moreover, analyses of baseline data showed that the two groups did not differ on any demographic or clinical variables except the GAF, and scores on this measure were higher for the TAU group, indicating better global functioning.

Although there was no reliable evidence that there were any differences in the medication received by the patients in the two treatment groups, there may have been differences in other aspects of standard treatment. Data are being collected on the amount and type of community care provided for the patients in this trial and the results will be reported in due course.

External validity

The external validity of this trial is likely to be high since it involved clinically representative conditions. Indeed, it met criteria for 'Stage 1' representative conditions, in the terminology of Shadish *et al.* (1997), in the following respects: consecutive admissions to hospitals meeting

lenient criteria were invited to participate (rather than patients specially solicited or selected for the research); therapy was conducted in psychiatric hospitals and community mental health centres (rather than a university clinic); and therapy was provided by professionals with regular caseloads (rather than therapists who received training specially for the research and conducted no other therapy). (It did not qualify for 'Stage 2' conditions, because a treatment manual was followed and adherence to the manual was monitored in supervision.) Furthermore, this trial was independent of the people who developed the form of CBT that was provided and the conditions under which treatment was provided were broadly representative of routine clinical practice, in the United Kingdom at least, in that sessions of CBT were conducted at weekly intervals and lasted about 1 hour. Thus, the results should generalize to other patients suffering from acute schizophrenia in other standard clinical settings.

Possibly this conclusion is constrained by the high rates of refusal and attrition but the extent to which these factors reduce the external validity of the study can probably be considered slight for the following reasons. First, although 36% of those considered eligible declined the offer to participate in this trial, it seems likely that these same individuals would have declined an offer of psychological treatment even if it had not been embedded in a research trial. They were not asked to give their reasons for declining, but it was the impression of the interviewers that most of them did not want to talk in detail about their illness to anyone. Thus, the refusal rate might be regarded as valuable information rather than a methodological limitation; it is likely to reflect rates that would be found in routine practice in the absence of research. Secondly, although 44% of the patients assigned to CBT terminated therapy prematurely (before session 12), such rates are typical of clinical practice. For example, Pekarik (1991) found that 76% of clients attending public clinics terminate after 10 or fewer sessions. Thus, there is no particular reason to think that the rate of drop-out in the present trial was influenced by the research.

Nevertheless, the rate of early termination from CBT does suggest that this form of treatment has limited acceptability among schizophrenic patients experiencing an acute episode. However, it is important to note that three of the patients assigned to CBT did not attend even one appointment, and therefore might be considered equivalent to the initial refusers, and that eight of them were unable to continue with CBT either because they moved away or they became too ill. Only 10 of them (21%), having started CBT, terminated prematurely of their own choice.

Probably the main constraint on the generalizability of the results of this trial is that there were only three therapists and two of them specialized in CBT for psychosis. Thus, the results may generalize to other settings only if CBT is provided by specialists.

Although the outcomes for the CBT group were better than for the TAU group at 12 months, this gives little indication of how durable these advantages might be since treatment for some in the CBT group was concluded only a few weeks before the 12-month assessment. However, identical assessments are being conducted at 24 months after baseline and these results will be reported in due course.

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