London–East Anglia randomised controlled trial of cognitive–behavioural therapy for psychosis

I: Effects of the treatment phase

ELIZABETH KUIPERS, PHILIPPA GARETY, DAVID FOWLER, GRAHAM DUNN, PAUL BEBBINGTON, DANIEL FREEMAN and CLARE HADLEY

Background A series of small, mainly uncontrolled, studies have suggested that techniques adapted from cognitive–behavioural therapy (CBT) for depression can improve outcome in psychosis, but no large randomised controlled trial of intensive treatment for medication-resistant symptoms of psychosis has previously been published.

Method Sixty participants who each had at least one positive and distressing symptom of psychosis that was medication-resistant were randomly allocated between a CBT and standard care condition (n=28) and a standard care only control condition (n=32). Therapy was individualised, and lasted for nine months. Multiple assessments of outcome were used.

Results Over nine months, improvement was significant only in the treatment group, who showed a 25% reduction on the BPRS. No other clinical, symptomatic or functioning measure changed significantly. Participants had a low drop-out rate from therapy (11%), and expressed high levels of satisfaction with treatment (80%). Fifty per cent of the CBT group were treatment responders (one person became worse), compared with 31% of the control group (three people became worse and another committed suicide).

Conclusions CBT for psychosis can improve overall symptomatology. The findings provide evidence that even a refractory group of clients with a long history of psychosis can engage in talking about psychotic symptoms and their meaning, and this can improve outcome.

Traditionally, it has been thought that the experiences of psychosis were categorically different from normal experiences. Symptoms such as delusions have been defined in terms of being unresponsive to rational argument (Jaspers, 1963) and thus unamenable to 'talking' therapies. However, since the 1950s a small number of single case studies have indicated that if specific techniques are used, talking to people about their psychotic experiences can be productive and improve symptomatology (Beck, 1952; Watts *et al*, 1973). More recently, other studies have shown that gentle challenge of evidence, presenting alternative possible viewpoints, reality-testing and enhancing coping strategies may be helpful, particularly for those with distressing positive symptoms (Fowler & Morley, 1989; Chadwick & Lowe, 1990; Kingdon & Turkington, 1991; Fowler, 1992; Tarrier *et al*, 1993; Garety *et al*, 1994; Haddock *et al*, 1996), even for those with acute episodes (Drury *et al*, 1996).

Despite the promise of the studies so far published (Bouchard *et al*, 1996), there have been only two randomised controlled trials (RCTs) (Tarrier *et al*, 1993; Drury *et al*, 1996) neither of which offered long-term treatment. Therefore, we aimed to offer cognitive–behavioural therapy (CBT) for a period of nine months to those with persistent, distressing, medication-resistant symptoms of psychosis, and to evaluate any changes in outcome using multiple criteria, and an RCT design. A further aim was to engage as many clients in therapy as possible, as we did in our earlier study (Garety *et al*, 1994). This is because failure to engage clients in therapy, while a well documented problem for this client group, would obviously limit the usefulness of any psychological treatment for psychosis. In this paper we present the results of the treatment phase of a three-centre study, based in London and East Anglia.

METHOD

Participants

The study was conducted at three major sites; at the Maudsley Trust, London; at Addenbrooke's Hospital Trust, Cambridge; and at Norfolk Mental Health Trust, Norwich. Participants were catchment area clients who were recruited by asking for referrals from community teams and in-patient units.

Criteria for referral were: at least one current positive psychotic symptom (such as delusions or hallucinations) that was distressing, unremitting (at least the past six months) and medication resistant, that is had not responded to a previous trial of at least six months of appropriate neuroleptic medication. Clients prescribed clozapine needed to have been stable on this for at least one year (to allow time for all benefit to occur). People who had drug, alcohol or organic problems as primary features were excluded.

Procedures and randomisation

Once referred, all possible participants were seen for a screening interview by an independent evaluator to establish whether they met our criteria. Once this was confirmed and informed consent had been obtained, randomisation was carried out separately within each treatment centre by the trial statistician (G.D.), using randomised permuted blocking (Pocock, 1983) and a block size of six. Participants then entered either the control condition or the treatment group, and baseline assessments were carried out. Considerable efforts were made to collect data from all participants in the trial from the time of randomisation onwards.

Prior power calculations, based on the results of the pilot study (Garety *et al*, 1994), had indicated that a trial with a total of 60 people would have a power of at least 0.80 to detect an effect size of 0.516 using a two-group t-test with a 0.05 two-tailed significance level.

Assessments

A wide range of assessments was administered to participants at baseline, three months, six months, and nine months (which was the end of the treatment condition). A follow-up at 18 months after entry into the trial is still continuing. This paper will present only the results of the treatment phase of the trial. In a trial of psychological

treatment it is extremely difficult to make assessments that are totally blind to the treatment condition and this was not attempted. However, all assessments were carried out by independent research workers (D. Freeman and C. Hadley) who were not involved in the treatments.

Measures

Our previous study had established that participants were able to cope with our assessments. These were administered over several sessions. We wished to look in detail at symptoms, functioning, and cognitive and emotional variables because we wanted not only to monitor outcome, but also to find out whether there were predictors of good or poor treatment response and correlations between outcome measures. These will be reported separately (Garety *et al*, 1997).

Symptom and functioning measures

We used the Present State Examination (PSE–10; World Health Organization, 1992) to establish psychotic symptomatology, using the associated CATEGO–V programme to derive diagnostic categories according to DSM– III–R (American Psychiatric Association, 1987) at baseline. The Brief Psychiatric Rating Scale (19-item, 0–6 scale) (BPRS; Overall & Gorham, 1962) was administered to assess overall mental state (baseline and three-monthly). The research workers in the separate centres achieved a high level of interrater reliability on the BPRS (intra-class correlation coefficient= 0.92). We used Personal Questionnaires every three months to monitor changes in key symptoms identified by the PSE, as this methodology has proved to be both reliable and sensitive (Brett-Jones *et al*, 1987). For delusions we measured conviction, preoccupation and distress; for hallucinations we measured frequency, intensity and distress. We also assessed hallucinations (Hustig & Hafner, 1990) three-monthly, and used the Maudsley Assessment of Delusions Schedule (MADS; Buchanan *et al*, 1993) (baseline and nine months).

Insight (Amador *et al*, 1993) was measured at baseline and at nine months. The Beck Depression Inventory (BDI; Beck *et al*, 1961) (three-monthly) the Beck Anxiety Inventory (BAI; Beck *et al*, 1988) (baseline and nine months), Beck Hopelessness Scale (BHS; Beck *et al*, 1974) (baseline and nine months), and the Social Functioning Scale (Birchwood *et al*, 1990) (baseline and nine months) were also completed.

Cognitive measures

The National Adult Reading Test (NART; Nelson, 1982) and the Quick Test (Ammons & Ammons, 1962) are estimates of premorbid and current IQ, respectively. Cognitive deficits and biases were investigated using tasks involving cognitive estimations (Shallice & Evans, 1978), verbal fluency (Miller, 1984) and probabilistic reasoning (Garety *et al*, 1991). All of these were measured at baseline only.

Other measures

The Self Concept Questionnaire (Robson, 1989) is a measure of self-esteem (baseline and nine months). The Dysfunctional Attitudes Scale investigates underlying beliefs about the self (described in Williams, 1992) (baseline and nine months). The Autobiographical Memory Task (Williams & Dritschel, 1988) (baseline), the Recall of Adjectives Task (Bellew, 1990) (baseline), and a Satisfaction with Therapy Questionnaire (nine months) were also completed.

Treatment condition

Participants randomised into the treatment group received up to nine months of individual CBT for psychosis. Sessions were conducted weekly initially, and then fortnightly, for up to an hour. Therapy was designed to achieve the following aims:

(a) to reduce the distress and interference that can arise from the experience of psychotic symptomatology;

(b) to reduce emotional disturbance such as depression, anxiety and hopelessness, and to modify dysfunctional schemas if they existed; and

(c) to promote the active participation of the individual in the regulation of their risk of relapse and social disability.

The methods used to achieve these aims have been discussed in detail in our manual (Fowler *et al*, 1995). Specific interventions were individualised from the assessment phase of the treatment. Initial sessions were focused on facilitating engagement in treatment. Considerable effort was spent on building and maintaining a good basic therapeutic relationship, and this relationship was characterised by considerable flexibility on the part of the therapist. When necessary, treatment was arranged in locations convenient to the client, including home visits and proactive outreach following non-attendance. Within sessions the therapist was highly sensitive to changes in mental state and in particular the occurrence of paranoia. Active attempts were made to manage such problems so as to ensure that clients did not feel unduly pressured and to prevent treatment from becoming aversive. If necessary, sessions were cut short or rearranged. Difficult topics were discussed only when clients felt able to do so. During the early sessions the therapist conducted a detailed analysis of the client's problems. This involved eliciting in detail the client's interpretation of the development of their problems over time, in particular the development of delusional ideas and voices from their first emergence, and the client's appraisals of psychotic experiences occurring in different episodes. The therapist also attempted a detailed analysis of the current problems that the client had prioritised. Such analysis aimed to elucidate triggering factors, current coping responses and the context in which psychotic experiences were embedded. Following this, treatment involved the use of several of the following strategies according to an individualised case formulation.

Improving coping strategies and developing and practising new ones

This involved using a variety of widely known behavioural therapy techniques, including activity scheduling, relaxation and skills training. The aim was to build on the client's own coping repertoire to manage current problems. Such techniques were used primarily to assist clients to engage in functional activities such as going shopping or socialising, or to manage the behavioural consequences of psychotic symptoms such as impulses deriving from voice commands, or self-harm.

Clients' own coping repertoires were delineated, and they were encouraged to use strategies such as distraction or avoidance more specifically and consistently. Other strategies such as alcohol use and high levels of social withdrawal were discussed in terms of their long-term costs, and discouraged. New strategies such as reading aloud to combat auditory hallucinations were suggested for the client to try out and report back on.

Developing a shared model in collaboration with the client

Therapists engaged in collaborative discussion with clients about the nature of psychotic symptoms and the effects on their

lives. Information was offered to enable clients to understand what had happened to them in the context of current ideas about the basis of psychotic experiences. The aim was to assist clients to a new interpretation of their problems which had a less distressing meaning for them, and which was more likely to lead to engaging in health-promoting behaviour such as taking medication. Some clients wished for complex discussion of the interaction between biological, social and cognitive factors, others preferred using more basic concepts. The therapists were open-minded about the degree to which clients preferred or accepted a medical model of events, and tolerant of their rejection of diagnoses. In cases where clients were particularly resistant to changing delusional beliefs, therapists worked 'within' the delusional system by fostering less distressing and more functional specific meanings while not directly tackling the delusional belief itself.

Modifying delusional beliefs and beliefs about hallucinations

Therapists helped clients to review the evidence for their beliefs. Gentle challenge and the presentation of possible alternative explanations were used, together with reality-testing where appropriate. Beliefs held with less conviction were discussed first. Beliefs about hallucinations were looked at in detail in the same way, but more particularly, the meaning attributed to voices was examined. While links between current voices, especially distressing ones, and earlier incidents in clients' lives were not always evident, they could sometimes be uncovered and this was often helpful. If possible, voices and other hallucinations were discussed as internal events, which were experienced as real by clients, but were not part of the experience of others. If feasible, reality-testing was undertaken, such as testing out the actual rather than the feared consequences of not always obeying a command hallucination.

Modifying dysfunctional schemas (Beck et al, 1979)

In the context of a life review (Young, 1990) clients' negative views or dysfunctional assumptions about themselves were identified, and the evidence for their veracity was re-examined in light of a current review of their circumstances; for example, was it always true that the individual was a 'bad person' or 'worthless'?

Management of social disability and relapse

This included discussion of relapse signatures (Birchwood, 1996), issues of stigma and the need to make changes as small as possible, given the clients' history of vulnerability. The clients' ability to identify triggers that might exacerbate psychotic phenomena was discussed and they were encouraged to take appropriate avoidant or coping measures such as increased medication, seeking help, supportive discussion or distraction techniques. These issues were often discussed later on in treatment, after work on specific symptoms had either been completed or had proceeded as far as possible.

Therapists

Therapists in the trial were experienced clinical psychologists. They met regularly during the treatment phase (at least monthly), either for peer supervision (E. Kuipers, P. Garety, D. Fowler and Steve Jones) or for therapy supervision with D. Fowler (Nina Dick, Erik Kuiper, Michelle Painter and Mark Westacott). Strenuous attempts were made at all times to follow procedures as laid down in the treatment manual (Fowler *et al*, 1995).

All clients in the treatment condition also received routine care from their clinical teams. In most instances, this included case management and medication. Where the former was not routinely available, the therapist negotiated with the clinical team to provide the monitoring and review appropriate to case management. Thus, participants in the trial had a designated keyworker who saw them regularly and was responsible for coordinating their care. Clinical teams were asked, if at all possible, not to change clients' medication during the trial, and to inform us of changes that were unavoidable. This was monitored as closely as possible.

Control condition

Participants randomised into this condition received routine care from their clinical team, which as part of our entry criteria consisted of case management and medication. As above, the research team negotiated with the clinical team to ensure that clients had an allocated keyworker responsible for coordinating their care and setting goals for them. All control group keyworkers were also given feedback from the initial assessments, and were encouraged to review the client's progress every three months.

Measures of contact with the clinical team, days spent in hospital and other aspects of the costs of each group were collected and will be presented separately.

Statistical analysis

All statistical analyses were carried out using SPSS for Windows (Version 6.0) or BMDP PC–90. Changes over time (baseline, three, six and nine months) were assessed by the separate estimation of a linear trend for each person in the trial (using the data available for that person, even though they may not have provided data for all four assessments). These estimates were then used as the response variable in further analyses, as recommended by Matthews *et al* (1990). The linear trend was constructed (e.g. BPRS units/3 months) so that a negative value indicated an improvement (that is, there was an overall decrease in the measured score, BPRS total, say, over time) with a larger absolute value indicating a greater improvement (-5, for example, being a better outcome than -3). Typically we used a two-way analysis of variance (ANOVA) with the 'experimental' sums of squares option in SPSS; the two explanatory factors being treatment centre (London, Cambridge or Norwich) and treatment group (CBT or control).

RESULTS

Participants

One hundred and fifty-two people were referred for possible inclusion in the trial. Of these, 47 had no distressing positive symptom present at the screening interview. Ten had not been stabilised on medication, and 26 were not suitable for practical reasons such as living out of the catchment area. Nine people met the criteria but did not agree to participate (9 of 69; 8%). Thus a total of 60 people met the criteria, consented, and were entered into the trial. Of these, all were on medication apart from three whose symptoms had been medication-resistant in the past, but who consistently refused to take any at the beginning of the trial. After randomisation, 28 people entered the treatment group and 32 the control group. Demographic and clinical information on participants in the two groups are presented in Tables 1 and 2.

From Table 1 it can be seen that the total sample was middle-aged, had a preponderance of men, a long history of illness, and average scores on an estimate of current IQ. The only difference between the

Table 1 Demographic data on participants who entered the therapy trial

Variable	CBT group			Control group		
	n	Mean	Range	*n*	Mean	Range
Age (years)	28	38.5	19–65	32	41.8	18–63
Duration of illness (years)	25	12.1	1–26	30	14.0	1–33
Number of admissions	24	5.2	0–30	29	4.3	0–12
Predicted IQ (NART)	25	102.9	69–129	25	98.7	71–131
Current IQ (Quick Test)	25	99.8	72–130	29	91.5	70–116
Gender						
Male	15			23		
Female	13			9		

NART, National Adult Reading Test.

treatment and control groups was that the latter had a somewhat lower current IQ.

The clinical data presented in Table 2 show the scores on the symptoms and functioning measures that we used. As expected, the group as a whole was symptomatic, with moderate levels of depression, anxiety and hopelessness. By chance, the CBT group had lower levels of self-esteem than the control group at baseline, but both groups scored within the range for those with clinical problems. Social functioning was comparable to norms found in an unemployed group of people with schizophrenia (Birchwood *et al*, 1990).

Table 3 itemises the range of psychotic symptoms found in both groups, which did not differ appreciably. Most participants had delusions, and a majority also had hallucinations, particularly in the treatment group. Diagnostic classification showed a preponderance of paranoid schizophrenia.

Withdrawals

Out of the 60 people who gave their consent for the trial, a total of 11 people (18%) withdrew from assessments over nine months, four (14%) from the CBT condition and seven (22%) from the control group (five of whom withdrew immediately after randomisation). Of the four people who dropped out of the treatment condition by nine months, only three (11%) attended for fewer than 10 sessions.

Number of therapy sessions received

The median number of therapy sessions given to the treatment group was 15, and the mean was 18.6 (range 0–50). One person did not attend any therapy appointments, one had fewer than five sessions, six had 'brief therapy' (12 sessions or fewer). The rest of the treatment group (n=20) had what we defined as 'full therapy' (more than 12 sessions). Treatment sessions usually lasted for an hour, but were kept flexible (could be shortened) depending on a client's current mental state. Most sessions were conducted in out-patient clinic settings, but some were home visits or ward visits to maximise the likelihood of engagement in treatment, by offering sessions that were in a convenient location for clients (e.g. one client was physically disabled and was always seen at home).

Table 2 Clinical data on participants who entered the therapy trial

Variable	CBT group			Control group		
	n	Mean	s.d.	*n*	Mean	s.d.
BPRS	27	26.4	6.5	26	24.5	7.1
BDI	27	23.6	10.1	26	20.0	10.1
BHS	27	11.6	4.8	27	9.8	5.2
BAI	27	17.5	11.0	26	17.3	14.8
Self-esteem	25	90.1	29.6	28	107.3	23.3
Social Functioning Scale	27	103.3	7.2	30	101.6	9.0

BPRS, Brief Psychiatric Rating Scale; BDI, Beck Depression Inventory; BHS, Beck Hopelessness Scale; BAI, Beck Anxiety Inventory.

Outcome measures

Symptoms and functioning

All available data were analysed. The only participants who did not contribute either refused assessments after randomisation (withdrawals) or provided only one assessment and thus could not contribute to a trend estimate. Of the 53 people who did provide sufficient outcome data on the BPRS to estimate trends, two provided information on two time points, five provided three of the four BPRS total scores, and the remainder (46) provided complete data (that is, BPRS scores at all four times). The means for the BPRS linear trends and raw scores can be seen in Tables 4 and 5.

The CBT group did significantly better than the controls ($F_{1,47}$=7.41; P=0.009). There was little evidence that the difference between the CBT and control groups depended on centre (the test for the group by centre interaction: $F_{2,47}$=0.59; P=0.561). Although there seemed to be an improvement in the control clients, particularly in Norwich, neither the centre effect nor the overall change in the control group was statistically significant. It should, however, be noted that there appears to be a lack of homogeneity of the standard deviations (Cochrane's $C_{8,6}$=0.46; P=0.06), with both Cambridge groups being considerably more variable than the others. As there appears to be no simple relationship between the mean trend and its standard deviation, a simple transformation of the data would not remove this heterogeneity. The results appear to be robust, however, since dropping both the Cambridge groups from the analysis yields homogeneous standard deviations in the remaining four groups, and a statistically significant group effect remains (P=0.01).

The analysis was repeated after setting the BPRS trend at zero (i.e. no change) for those seven patients (two from the CBT group and five controls) for which a trend estimate was not available (i.e. they provided fewer than two of the repeated assessments) to provide a full 'decision to treat' analysis using the standard 'carry forward' method to impute missing values. A two-group t-test for the last row of Table 5 gave t=−2.55 with 51 d.f. (P=0.014). Inserting zeros for missing participants and repeating the t-test gave t=−2.70 with 58 d.f. (P=0.009). The mean

Table 3 DSM–III–R diagnoses and positive symptoms present in participants

Variable	CBT group (n=27)	Control group (n=27)
DSM–III–R diagnosis		
Schizophrenia (paranoid type)	19	20
Delusional disorder	6	7[1]
Schizoaffective disorder	2	0
	(n=27)	(n=29)[2]
Positive symptoms		
PSE: One or more delusions	20	28
PSE: One or more hallucinations	22	18
PSE: Perceptual disorders other than hallucinations	1	4
PSE: Subjective thought disorder and/or replacement of will	5	7

1. The diagnosis for one person was confirmed at the three-month assessment because of a lack of information from the initial assessment.
2. Information is included concerning positive symptoms present in two participants who withdrew from the research part-way through collection of PSE–10 data.

Table 4 Brief Psychiatric Rating Scale linear trends in each centre

Centre	CBT group			Control group		
	n	Mean	s.d.	n	Mean	s.d.
London	14	−1.49	1.57	12	0.18	1.66
Cambridge	6	−2.90	3.99	8	−0.35	3.08
Norwich	6	−2.37	1.60	7	−1.67	1.21
Combined	26	−2.02	2.31	27	−0.46	2.15

Significant difference between CBT and control groups (P=0.009).

Table 5 Mean Brief Psychiatric Rating Scale scores

Assessment	CBT group			Control group		
	n	Mean	s.d.	n	Mean	s.d.
Initial	27	26.4	6.5	26	24.5	7.1
Three-month	25	22.2	8.2	27	22.3	7.2
Six-month	25	21.2	7.3	27	22.9	6.2
Nine-month	23	19.9	8.5	24	22.7	7.6

trend for the CBT group (n=28) was then −1.87 (s.d. 2.89) and for the controls n=32) −0.38 (s.d. 1.98).

Visual inspection showed that items on the BPRS which changed most in comparison with the control group were suspiciousness (ideas of reference and persecution), unusual thought content (delusional ideas) and hallucinations. The self-reported reduction in delusional conviction, measured by linear trend, was −0.65 for the CBT group and −0.30 for the controls. Delusional distress was −0.61 for CBT and −0.39 for controls. The linear trend for the frequency of hallucinations was −0.24 for the CBT group and −0.01 for the control group. None of these reached significance at conventional levels, although all favoured the CBT condition. Change on all other symptom and functioning measures was not significantly different between conditions at this stage of the trial.

Clinical outcome

In comparison with others who have tended to determine indices of clinical response on arbitrary grounds, we decided to adopt an approach which aimed to take account of the degree of natural variability in BPRS scores over time. An estimate of the average variability in BPRS scores in the control group was therefore calculated (taken as the root mean sum of the squared standard deviation of individual BPRS scores for each case in the control group). This equated to five points. An improvement or worsening of greater than or equal to five points on the BPRS was then taken as indicating a reliable clinical change, and an improvement or worsening of greater than or equal to 10 points on the BPRS as indicating a large clinical change. (A five-point change on the BPRS is similar to the criterion of a 20% improvement taken to be an index of clinical response on the BPRS by Breier *et al* (1994)). In these terms, 6/28 (21%) achieved a large clinical improvement, and a further 8/28 (29%) of the treatment group achieved a reliable clinical improvement. One person of the 28 (3%) in the treatment group showed a reliable worsening of symptoms on the BPRS. In the control group, 1/32 (3%) showed a large clinical improvement and 9/32 (28%) of cases achieved reliable clinical improvements. Three of the 32 (9%) of the control group showed a clinically significant worsening of symptoms over the nine months.

If we widen the criteria to include clinically significant response in the client's primary presenting problem as measured by the Personal Questionnaires, then 18/28 (64%) of treatment and 15/32 (47%) of controls achieved clinically significant improvements. If cases with no clear linear trend in the scores are excluded (i.e. where there is little obvious evidence of trend), then the number in the control group who changed drops to 12/32 (37%).

One person in the control condition had committed suicide by the end of nine months. No one in the treatment condition had done this.

Medication

Medication regimes were complex and information was sometimes incomplete. We calculated chlorpromazine equivalents (CPZ) following the guidelines in the *British National Formulary*. Full data were available for the London participants, but data were more limited for East Anglia. We

classified these into no medication, low (less than 300 mg CPZ/day), medium (300–600 mg CPZ/day) and high (more than 600 mg CPZ/day). We also divided participants into those receiving constant, fluctuating, decreasing or increasing doses. Four clients were switched to clozapine before the final assessment. Three of these were in the control group, and the change occurred between the three and six month assessments. One person was in the CBT group and the change only occurred after the six month assessment.

Inspection of the data at baseline in Table 6, suggests that there were no particular differences in medication between the treatment and control conditions. However, over the nine months of the trial more control participants had their medication increased, whereas two of the CBT group and none of the controls had it decreased. This meant that as the trial progressed more of the control group moved into the high-dose category and fewer of them received low doses or no medication compared with the CBT group.

Table 6 Medication levels based on chlorpromazine equivalents

	CBT group	Control group
Level of neuroleptic dose at start of trial		
None	2	1
Low	5	4
Medium	3	10
High	8	5
Changes in medication during trial		
No change	11	10
Fluctuating	1	2
Increasing	2	7
Decreasing	2	0
Level of neuroleptic medication throughout the trial		
None	4	0
Low	2	2
Medium	4	8
High	6	9

Levels of neuroleptic medication: Low: less than 300 mg chlorpromazine; medium: 300 to 600 mg of chlorpromazine; high: greater than 600 mg chlorpromazine.
All available data on medication are included. These were predominantly from the London sample, which when considered on its own did not have a discernibly different pattern.

Table 7 Satisfaction with cognitive–behavioural therapy

	CBT group (n=20)
How satisfied are you with the therapy?	
Very satisfied	5
Satisfied	11
Indifferent	3
Dissatisfied	1
During therapy how much progress do you feel you actually made?	
Much progress	4
Some progress	13
No progress	2
Things got worse	1
In future, how much progress do you think you will be able to make in dealing with your problem?[1]	
Much progress	9
Some progress	8
No progress	1
Things will get worse	1

1. One participant did not answer this question.

Satisfaction

Twenty of the 28 in the treatment group completed a satisfaction with therapy questionnaire at nine months. As can be seen in Table 7, 16 (80%) were satisfied or very satisfied with the therapy, 17 felt they had made some or much progress, and 17 felt they would be able to make some or much progress in the future. One client reported that 'things got worse', and this person was also dissatisfied with treatment.

DISCUSSION

The results of this trial show that at the end of nine months of CBT it is possible to improve the overall symptomatology of people with medication-resistant, distressing symptoms of psychosis. This group still exists even after the introduction of the new neuroleptics (Kane, 1996). We showed a decrease in BPRS scores of 25% and this was produced mainly by changes in our targeted symptoms of delusions and hallucinations. There were no appreciable improvements in the level of depression. At this stage, the specific improvements observed in conviction for delusional ideas, were not statistically significant, in contrast to the results from our previous waiting list control trial. This is at least partly because of the more stringent methodology of an RCT design compared to uncontrolled or less well controlled trials. Further support for the specific effects of CBT is provided by a finding that only in the CBT group was outcome predicted by a cognitive measure linked to delusional thinking (Garety *et al*, 1997).

Engagement

The therapy was acceptable to clients, who expressed high levels of satisfaction and did not show demonstrable negative consequences. Our results illustrate that psychological treatments can be offered to clients

even when they have long histories of illness, and continuing distressing symptoms of psychosis. Our drop-out rates, which remained low, are particularly encouraging, and suggest that if engagement issues are dealt with, then even this client group can accept demanding interventions. This has also been demonstrated in a recent study of compliance therapy (Kemp *et al*, 1996), which addressed client-centred concerns in a similar way, but has often previously been problematic (e.g. Tarrier *et al*, 1993).

Rate of improvement

The rate of improvement in overall symptomatology (BPRS scores) that we have demonstrated, is around the same level as that found in studies on the effects on clozapine on clinically similar samples of people who have failed to respond to standard medication. While relatively few RCTs of clozapine have been completed, those in the literature are usually six-week trials, on large numbers of clients, comparing clozapine to chlorpromazine (Kane *et al*, 1988) or to haloperidol (Breier *et al*, 1994). These showed changes on the BPRS of between 11 and 26% in the clozapine group. Interestingly, the Kane *et al* study (n=268) showed a 26% change in the clozapine group, compared with an 8% change in the chlorpromazine group, that is both groups improved with intensive monitoring and optimal medication.

The advantage of a talking therapy is that it does not have physical side-effects, and can produce change that is both clinically noticeable and significant. The disadvantages of such treatments include intensive input by experienced clinicians (around 19 hours over nine months) and the extra training and supervision that is required to support therapists. A further disadvantage of this intervention so far, is that at this stage we have shown change only in BPRS scores, not in social functioning or any of our other measures.

Methodological problems

Our study suffered from methodological problems that are common to virtually all trials of psychological treatments. Most problematic was the view that we could not ensure our evaluators would remain blind to the treatment condition. Contacting and assessing 60 individuals over nine months requires considerable persistence and sensitivity, and from the experience of our pilot study we did not feel it was realistic or reasonable to assume that we could prevent details of therapy or control conditions emerging during assessment meetings with evaluators. We may have been mistaken about this, and it does weaken the methodology. However, we decided before the trial started that while we could maintain the independence of our evaluators by not involving them in treatment, we would not attempt to keep them blind to treatment type. This decision is endorsed by Shapiro (1996), who comments that blind evaluation is virtually impossible with psychological treatment trials: "Personnel employed to interview patients to assess their progress are seldom able to avoid exposure to information (especially within patients' accounts of their experiences) that gives away the nature of the treatment they have undergone" (p. 204).

Second, although we monitored medication and medication changes in both groups, it was not possible to keep all individuals stable or on the same medication regime. It remains a possibility that some improvements were due to medication effects, particularly in the control group. Clinicians increased standard medication or changed to clozapine more often for control patients.

Third, the selection of a viable control condition can be seen as problematic. In this study, we decided to compare CBT with the best current routine treatment, case management and medication. These cannot ethically be withdrawn from the treatment group (nor would we wish it), so in effect we evaluated CBT as added to the best standard treatment compared with this standard treatment alone. It is obviously a possibility that the extra 19 hours (mean) of treatment effected improvement because of non-specific attention. The fact that our results showed specific symptomatic change predicted by related cognitive measures (Garety *et al*, 1997) mitigates against this, but lack of change in delusional conviction or depression at this stage suggests that we cannot assume our CBT interventions were the effective ingredients in improvement. On the other hand, there is a case for arguing that the detailed assessments the control group received in itself comprised elements of an attentional control condition. The control group had equally sustained contact with the assessors over time; the assessors had to engage the patients, and at the beginning patients received a detailed assessment phase involving around six sessions. Patients then had regular assessment contacts at three-month intervals. Some patients reported that they believed the assessors were part of their treatment team. The process of conducting assessments involved specific discussion of symptoms in a supportive atmosphere, and it is possible that such assessments were themselves a minimal focusing intervention. However, this still does not control for the therapy time in the CBT condition, and further controlled studies are required to clarify the issue of specific versus non-specific effects of therapy.

Fourth, we did not aim in this study to examine which aspects of CBT were effective, or to look at an optimal number of sessions for this kind of treatment. Some patients would attend only for 'brief therapy', despite efforts to visit them at home or reorganise appointments. Others attended for maximum or even excessive numbers of sessions, without much apparent benefit. Thus, individuals varied considerably in how long they took to show change, and this issue remains to be clarified.

Clinical implications

Finally, it is clear that even though we demonstrated changes in our treatment group, only 50% of them were treatment responders. Assessing change in patients with very long-standing and treatment-resistant psychotic symptoms poses the problem that even clinically noticeable change does not place people back in the 'normal' range. On the other hand, even small changes in symptom levels might signify important differences in an individual's ability to cope with problems, or cope in the future. We will be able to discuss any maintenance or prevention effects when we have completed the follow-up phase of the study. Predictors of outcome are discussed in a subsequent paper (Garety *et al*, 1997). However, our research seems to indicate that talking to patients about psychotic symptoms and their meaning to the individual is a skill that clinicians working in this area should develop.

ACKNOWLEDGEMENTS

We thank all the patients who participated in this study and the clinicians and clinical teams in London and East Anglia who cooperated in referring and

CLINICAL IMPLICATIONS

- It is possible to improve outcome in psychosis using an adapted form of CBT.
- Drop-out rates for therapy were low and satisfaction was high, suggesting that clients with psychosis welcome this kind of intervention.
- Effects on symptoms were similar to those found in RCTs of clozapine.

LIMITATIONS

- The study did not control for attention effects.
- Assessors were independent but not blind to the treatment condition.
- Although changes in the treatment group were significant and clinically reliable, only 50% of these participants were treatment responders.

ELIZABETH KUIPERS, PhD, Department of Clinical Psychology, Institute of Psychiatry, London SE5 8AF; PHILIPPA GARETY, PhD, United Medical and Dental School, Department of Psychology, St Thomas' Hospital, London SE1; DAVID FOWLER, MSC, School of Health Policy and Practice, University of East Anglia, Norwich NR4 7TJ; GRAHAM DUNN, PhD, School of Epidemiology and Health Sciences, University of Manchester, Stopford Building, Oxford Road, Manchester; PAUL BEBBINGTON, PhD, University College London, Archway Wing 1st Floor, Whittington Hospital, Highgate Hill, London N19 5NF; DANIEL FREEMAN, BA, Department of Clinical Psychology, Institute of Psychiatry, London SE5 8AF; CLARE HADLEY, MSc, Department of Clinical Psychology, Leeds University, 15 Hyde Terrace, Leeds LS2 9LT

Correspondence: Dr E. Kuipers, Department of Clinical Psychology, Institute of Psychiatry, London SE5 8AF

(First received 18 November 1996, final revision 25 March 1997, accepted 14 April 1997)

supporting patients. We are grateful for the therapeutic input of Steve Jones, Nina Dick, Erik Kuiper, Michelle Painter and Mark Westacott. We also thank the members of our steering group for their support during the trial. This research was supported by a Research and Development grant from the Department of Health. We are grateful for a charitable donation from Janssen Pharmaceutica.

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