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

III: Follow-up and economic evaluation at 18 months†

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Background A randomised controlled trial of cognitive–behavioural therapy (CBT) for people with medication-resistant psychosis showed improvements in overall symptomatology after nine months of treatment; good outcome was strongly predicted by a measure of cognitive flexibility concerning delusions. The present paper presents a follow-up evaluation 18 months after baseline.

Method Forty-seven (78% of original *n*=60) participants were available for follow-up at 18 months, and were reassessed on all the original outcome measures (see Part I). An economic evaluation was also completed.

Results Those in the CBT treatment group showed a significant and continuing improvement in Brief Psychiatric Rating Scale scores, whereas the control group did not change from baseline. Delusional distress and the frequency of hallucinations were also significantly reduced in the CBT group. The costs of CBT appear to have been offset by reductions in service utilisation and associated costs during follow-up.

Conclusions Improvement in overall symptoms was maintained in the CBT group 18 months after baseline and nine months after intensive therapy was completed. CBT may be a specific and cost-effective intervention in medication-resistant psychosis.

†Part I, 'Effects of the treatment phase', published in October 1997 (**171**, 319–327); part II, 'Predictors of outcome', published in November 1997 (**171**, 420–426).

Evidence is accumulating for the effectiveness of cognitive–behavioural therapy (CBT) for the more intractable problems of psychosis. Three randomised controlled trials have now been published (Tarrier *et al*, 1993; Drury *et al*, 1996*a*; Kuipers *et al*, 1997) and other trials are ongoing. So far there are only limited data on maintenance effects of any gains after treatment (Tarrier *et al*, 1993; Drury *et al*, 1996*b*). There is also a paucity of evidence on the economic impact of psychological interventions for psychosis (Tarrier *et al*, 1991; Healey *et al*, 1997). Thus, questions about the persistence of any gains and the cost-effectiveness of CBT for psychosis remain unanswered. Our three-centre study of CBT for psychosis, based in London and East Anglia, has been reported previously (Kuipers *et al*, 1997; Garety *et al*, 1997). In this paper we present the results of the 18-month follow-up and the economic evaluation.

METHOD

Design

The study was designed as a randomised controlled trial in which 60 participants received CBT and standard care, or standard care alone. Evaluators were independent of the treatment but were not 'blind' to the treatment condition because we felt that this was not feasible given the intensity of the assessments at baseline, during treatment, post-treatment and at follow-up. Further details of methodology and participants are described by Kuipers *et al* (1997).

Participants

Sixty people with at least one distressing symptom of psychosis, had been entered into the treatment trial. Participants who were evaluated (*n*=54) had diagnoses of schizophrenia (*n*=39), delusion disorder (*n*=13) or schizoaffective disorder (*n*=2). Treatment was given according to our manual (Fowler *et al*, 1995). Once the intensive therapy stage was completed after nine months, all participants were re-assessed by independent evaluators and then again nine months later (18 months after the initial assessments).

Measures

Measures taken at initial assessment were repeated as itemised below. In addition we completed an economic evaluation of services used. Assessments were completed by interviewing subjects in their local clinic or at home.

Symptom and functioning measures

The Brief Psychiatric Rating Scale (BPRS, 19 item version, 0–6 scale; Overall & Gorham, 1962) was readministered to assess overall mental state at the end of the 18–month follow-up period. Personal Questionnaires (Brett-Jones *et al*, 1987) were used to measure changes in key psychotic symptoms previously identified at baseline by the Present State Examination (PSE–10) as incorporated in version 1.0 of SCAN (World Health Organization, 1992). We measured the conviction, preoccupation and distress of delusions and the frequency, intensity and distress of hallucinations. We used Hustig & Hafner's (1990) assessment of hallucinations, and the Maudsley Assessment of Delusions Schedule (MADS; Buchanan *et al*, 1993). We measured insight (Amador *et al* 1993), and used the Beck Depression Inventory (BDI; Beck *et al*, 1961), the Beck Anxiety Inventory (BAI; Beck *et al*, 1988) and the Beck Hopelessness Scale (BHS; Beck *et al*, 1974) to measure disturbances of affect. We administered the Self Concept Questionnaire (Robson, 1989), a self-report measure of disturbances of self-esteem, and the Dysfunctional Attitudes Scale (DAS; described in Williams, 1992) to investigate changes in underlying beliefs about the self. We repeated the Social Functioning Scale (SFS; Birchwood *et al*, 1990) to look at any changes in social performance. The measures are described in more detail by Kuipers *et al* (1997).

Medication

As part of the request for referrals from clinical teams we asked them to be conservative in modifying medication once patients had been entered into the trial, and at least to notify us of worries that

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might lead to an increase. Despite this, medication regimes were sometimes complex and information incomplete. We calculated chlorpromazine equivalents following the guidelines in the *British National Formulary*. We classified regimes into no medication, low (equivalent to less than 300 mg chlorpromazine per day), medium (300–600 mg/day) and high (more than 600 mg). We also divided participants into those receiving constant, fluctuating, increasing and decreasing doses. Full data were available for the London participants, but information concerning East Anglian subjects was unobtainable or unreliable in some cases. We made particular requests that, if at all possible, participants should not be changed to clozapine during the trial, and we had complete data about transfers to this drug.

Service utilisation and cost measures

The conduct of an economic evaluation did not comprise part of the original design of this study, hence only in-patient hospital service utilisation data were available (via case records) at baseline and at the nine-month assessment point. The cost of CBT was calculated for the treatment period between these two assessment points, based on the number and average duration of CBT sessions and the unit cost per hour of direct therapist contact time. Unit costs per hour of direct therapist contact time were based on a face-to-face subject contact : non-subject contact ratio of 1:1.27 and the sum of the mid-point of relevant salary scales, London weighting activities (where applicable) and overheads (Netten & Dennett, 1996).

Service utilisation and accommodation data for the follow-up period (9–18 months) were collected using a variant of the Client Service Receipt Inventory (CSRI; Beecham & Knapp, 1992), which covers a range of key health and social care services that together comprise an individual's 'package' of care. The cost associated with each person's care package was derived by attaching unit costs to their particular use of services (as well as their living situation) and aggregating these components to give a total cost estimate. Unit cost figures were calculated to represent long-run marginal opportunity costs, and were drawn from national estimates, adjusted for London where applicable (Netten & Dennett, 1996). Informal care-giver support by family or friends and the indirect consequences of psychosis (such as lost employment) were not costed in this study.

STATISTICAL ANALYSIS

All analyses were carried out using SPSS for Windows (version 6.1.3). All significance test results are quoted as two-tailed probabilities. Typically, this involved independent group *t*-tests on summary trend measures calculated for each individual (Matthews *et al*, 1990). In the more complex analyses involving potential predictors, such as the MADS, a two-way ANOVA was carried out, again using summary trend measures as the dependent variable in the analysis. Analysis of cost differences was performed on logarithmically transformed data in order to adjust for the positively skewed distribution observed in service use costs.

RESULTS

Participants

Details of the subjects who took part in the follow-up are given in Table 1.

Of the 60 people initially randomised, 47 (78%) completed the 18-month assessments. Of the drop-outs, 11 withdrew during the treatment phase (0–9 months), one (in the standard treatment only group) had committed suicide, and one withdrew (from the standard treatment group) between nine and 18 months. There was one standard treatment only subject, however, who provided information for the 18-month assessment who had been too unwell to be assessed at nine months (explaining why there were 24 subjects in this group at both nine and 18 months, despite the person who dropped out after nine months).

Analysis of baseline characteristics (other than those already reported; Kuipers *et al*, 1997) revealed that the two groups were similar in terms of employment (70% unemployment) and living situation (70% independent housing, 30% sheltered housing/residential care). IQ differed by chance between the groups, but did not predict outcome, as we reported in Garety *et al* (1997). There was also similarity with respect to psychiatric history: the CBT group had a mean number of 124 in-patient days over the last five years (n=24; s.d.=190), compared with 110 for the standard treatment only group (n=27, s.d.=254).

Extra sessions

Six people in the CBT group received some extra sessions between 9–12 months. One person continued to receive active therapy between nine and 12 months, so that the follow-up was 15 months. Two received three appointments, two received two appointments, one received one appointment. The latter were not active therapy appointments but were designed to be supportive while reducing contact with the therapist gradually after the period of intensive therapy sessions. They were all negotiated with the subject according to individual preference. The cost of these extra sessions was included in the economic evaluation via the CSRI.

Outcome measures

The main outcome measure was the total BPRS score. Details are given in Table 2.

We did not attempt to do an intention-to-treat analysis at this stage (unlike the treatment study, Kuipers *et al*, 1997) as this is not possible without follow-up information on all subjects. However, as we had

Table 1 Demographic data on subjects available at follow-up. The cognitive–behavioural group comprised 12 men and 11 women; the standard treatment only group comprised 17 men and 7 women

	Cognitive–behavioural group			Standard treatment only group		
Variable	*n*	Mean	Range	*n*	Mean	Range
Age (years)	23	39.9	22–65	24	42.1	18–63
Duration of illness (years)	22	12.3	1–26	24	13.9	1–33
Predicted IQ (NART)	21	105.6	77–129	22	95.6	71–131
Current IQ (Quick test)	21	102.5	72–130	24	88.8	70–116

NART, National Adult Reading Test (Nelson, 1982).

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Table 2 Total Brief Psychiatric Rating Scale scores at baseline, nine months (after active treatment) and 18 months follow-up

	Cognitive–behavioural therapy group			Standard treatment only group		
	n	Mean	s.d.	*n*	Mean	s.d.
Baseline	27	26.44	6.54	26	24.46	7.14
9 Months	23	19.87	8.46	24	22.67	7.43
18 Months	23	18.78	8.19	24	23.50	7.42
Baseline for those with follow-up	23	26.35	6.87	24	23.96	7.21
Change[1] (baseline–18 Months)	23	7.57	6.02	24	0.46	3.86

1. Significance of difference between groups: $P<0.001$.

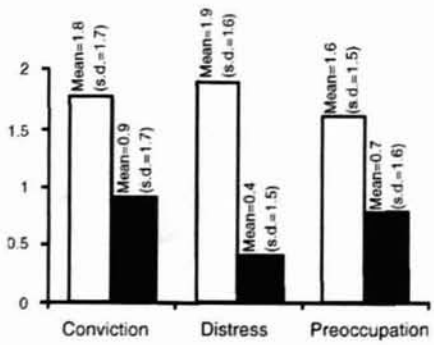

Fig. 1 Change in delusional variables: □, cognitive–behavioural therapy group (n=17); ■, standard treatment only group (n=24).

information on most participants, we decided to analyse the observed data; we analysed all the data available to us.

As already reported (Kuipers *et al*, 1997), there was a considerable improvement in the CBT group during the treatment phase (0–9 months), but very little change in the standard treatment group. There was little sign of any change during the follow-up period (9–18 months) in either group but the improvement in the CBT participants is maintained (with a hint that they might still be improving over this period) whereas the standard treatment group participants may have deteriorated very slightly. If we calculate a change score (baseline–18 months) for the BPRS total as the main indicator of outcome at the follow-up, then the mean for the CBT group is 7.57 (s.e.=1.26) and the mean for the standard treatment group is only 0.46 (s.e.=0.79). The difference between these means is 7.11 and the corresponding 95% confidence interval is 4.15–10.06 ($P<0.001$). The effect size of these changes (mean pre-treatment–mean post-treatment/s.d. pre-treatment) was 1.16 for the CBT group and 0.06 for the standard treatment group.

Of the participants showing delusional symptoms, as indicated in their responses to the Personal Questionnaire (Table 3), the above findings are mirrored for delusional distress (difference in mean change is 1.59 with corresponding 95% CI of 0.62–2.55; P=0.002), delusional conviction (difference in mean change is 0.89 with 95% CI of −0.21–1.99; P=0.11) and delusional preoccupation (difference in mean change is 0.94 with 95% CI of −0.05–1.93; P=0.06), although the differences for distress are the only ones which are statistically significant. These changes are illustrated in Fig. 1. We found a similar pattern in hallucinations. Of those who had hallucinations (n=17 in the CBT group, n=13 in the standard treatment group) there was a significant change in frequency (difference in mean change 1.35 with corresponding 95% CI of 0.29–2.42, P=0.015).

Intensity also reduced (difference in mean change is 0.79 with 95% CI of −0.35–1.929, P=0.17) as did distress (difference in mean change is 0.79 with 95% CI of −0.65–2.23, P=0.27) but these were not statistically significant. These changes are illustrated in Fig. 2. No interesting differences between the groups were found for other outcome measures.

Returning to the BPRS total score, we have previously shown that the MADS

Table 3 Changes in delusions

	Cognitive–behavioural therapy group			Standard treatment only group			Significance
	n	Mean	s.d.	*n*	Mean	s.d.	
Delusional distress							
Baseline for those with follow-up	17	4.08	0.82	24	3.49	1.17	
18 months	17	2.15	1.80	24	3.15	1.64	
Change	17	1.93	1.57	24	0.35	1.46	P=0.002
Delusional conviction							
Baseline for those with follow-up	17	4.47	0.77	24	4.62	0.68	
18 Months	17	2.66	1.93	24	3.69	1.65	
Change	17	1.81	1.78	24	0.92	1.68	P=0.11
Delusional preoccupation							
Baseline for those with follow-up	17	3.93	0.97	24	3.69	1.10	
18 Months	17	2.31	1.64	24	3.01	1.49	
Change	17	1.62	1.50	24	0.68	1.57	P=0.06

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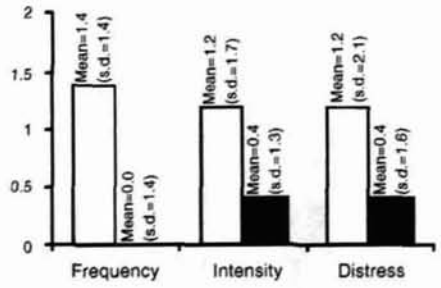

Fig. 2 Change in hallucinations: □, cognitive–behavioural therapy group (n=17); ■, standard treatment only group (n=13).

item, 'possibility of being mistaken', when measured at baseline, was a statistically significant predictor of response to CBT (i.e. there was a statistically significant predictor by treatment group interaction in a two-way ANOVA). CBT seemed to be particularly beneficial for those subjects who admitted that they might be mistaken (Garey *et al*, 1997). The purpose of the present analysis was to discover whether this still holds at follow-up. Visual inspection of the results given in Table 4 show that the relationship is now less clear. Not everyone in the trial provided responses to the MADS, resulting in quite low numbers in some groups, and there may be some biases arising from this. However, it appears from Table 4 that by 18 months the interaction between the treatment group and the MADS possibility of being mistaken had more or less disappeared. An analysis of variance with the linear trend (change in BPRS total from baseline to follow-up equivalent, in the case of three equally spaced assessments, to a linear trend) shows a highly statistically significant effect of treatment group ($F_{1,36}$=12.63; P=0.001), a just significant effect of MADS possibility of being mistaken ($F_{1,36}$=4.03; P=0.052), but with no evidence of an interaction between the two factors ($F_{1,36}$=0.017; P=0.897). A similar ANOVA for the quadratic trend in BPRS totals (i.e. the departure of the progress curve from a straight line) provided the following test statistics for the three effects respectively; for treatment group $F_{1,35}$=1.60 (P=0.214), for MADS possibility of being mistaken $F_{1,35}$=8.05 (P=0.008) and for the interaction effect $F_{1,35}$=3.09 (P=0.87).

The quadratic trend is highly significant only for the MADS possibility of being mistaken effect and it appears that for those subjects admitting to the possibility that they may be mistaken concerning their beliefs, there is a greater decrease in the BPRS total within the first nine months when compared with those who do not admit to the possibility of being mistaken (irrespective of treatment allocated). These subjects stabilise or even slightly deteriorate during the follow-up phase. None the less in the CBT group, the group who admit the possibility that they might be mistaken still show a (non-significantly) higher rate of improvement at 18 months of 8.29 BPRS points compared with those who did not admit the possibility (BPRS change 4.89). Those subjects admitting the possibility that they may be mistaken respond more quickly and to a greater extent to CBT than the others, although the others appear to benefit in the end, albeit to a lesser extent, from the CBT. The hint of deterioration in at least a proportion of the group who changed most quickly is clinically relevant; in our initial study (Garety *et al*, 1997) we noted that this group intriguingly showed abnormal reasoning on the cognitive estimates task – we speculated that a greater flexibility on the MADS may be associated with other cognitive biases which may be implicated in delusion formation. We further speculated that CBT may provide compensatory methods to assist in re-evaluating beliefs resulting from reasoning biases. A loss of improvement in some subjects may indicate that these compensatory methods may need to be offered over a longer time period to maintain gains in this group. Clearly these are matters that warrant further investigation.

Clinical outcome

We defined reliable clinical change as a five or more point difference in BPRS scores, as in our previous study (Kuipers *et al*, 1997). On this basis 65% (15/23) of the CBT group showed a reliable clinical improvement, compared with 17% (4/24) of the standard treatment group, at follow-up.

Medication

All available, although incomplete, data on medication are presented in Table 5. As would be expected under effective randomisation, there were no differences between the standard treatment and CBT groups in medication levels at induction. As time went on there was a tendency for doses to increase in the standard treatment group although this was only significant at the 11–13% level of probability, depending on the chosen basis of analysis.

As can be seen from Table 5, one person in the CBT group and two in the standard treatment group were changed to clozapine between nine and 18 months. In total, two of the subjects in the CBT group were changed to clozapine after randomisation and five in the standard treatment group. There were six participants who had been stabilised on clozapine prior

Table 4 Brief Psychiatric Rating Scale total scores as a function of Maudsley Assessment of Delusions Schedule (possibility of being mistaken) and treatment group

	Quadratic trend[1]		Baseline		9 Months		18 Months		Linear trend[2]	
	Mean	(s.d.)	Mean	(s.d.)	Mean	(s.d.)	Mean	(s.d.)	Mean	(s.d.)
No possibility										
Cognitive–behavioural therapy group (n=9)	−1.33	4.58	28.56	(5.10)	26.78	6.65	23.67	7.63	4.89	5.84
Standard treatment only group (n=17)	0.25[3]	11.86	24.65	(8.07)	24.88[3]	8.01	25.06	7.51	−0.41	2.96
Possibility										
Cognitive–behavioural therapy group (n=7)	13.43	8.64	27.71	(9.60)	16.86	5.76	19.43	7.32	8.29	6.13
Standard treatment only group (n=7)	3.71	8.36	22.29	(4.57)	19.14	4.06	19.71	6.07	2.57	5.13

1. Baseline+18 months −2 × 9 months.
2. The change score: baseline–18 months.
3. Based on n=16.

https://doi.org/10.1192/bjp.173.1.61 Published online by Cambridge University Press

to randomisation, three being allocated to each of the treatment arms of the trial. Post-randomisation change to clozapine was broken down by treatment group. There were actually more changes in the standard treatment only group (five *v.* two) and there was no evidence that clozapine alone might account for the improvement in BPRS.

Analysis of participants receiving extra sessions

Participants who received extra sessions were studied as a separate group. Those receiving CBT during the first nine months (CBT_1, n=17), the extra session group (CBT_2, n=6) and the standard treatment group (n=24) were compared on their mean change scores on the BPRS at 18 months, using a one-way ANOVA. The change scores were: 8.12 for CBT_1, 6.00 for CBT_2 and 0.46 for the standard treatment group. A least significant difference *post-hoc* test showed that CBT_1 and CBT_2 were both significantly better than the standard treatment group but not different to each other (P=0.05). Thus, it seems to be the case that despite some extra sessions, CBT_2 did not appear to improve more than the main CBT group.

Economic evaluation

Treatment phase

The comprehensive collection of service utilisation data and associated costs did not comprise part of the treatment phase assessments. The focus of the economic analysis was therefore to observe the extent to which the additional costs of CBT in the treatment phase might result not only in improved or maintained clinical outcomes but also in a reduced need for service inputs over the follow-up period. In the treatment phase, CBT group participants had had an average of 2.1 sessions per month lasting one hour each. The mean cost of CBT per month (at 1996 prices) was £123 (s.d.=£71, median=£105).

Follow-up phase

Analysis of costs and service use was only possible for 32 of the 47 subjects clinically assessed at follow-up, owing to refusal to complete the CSRI (eight subjects) and insufficient information or time (seven subjects). We also had a considerable amount of missing data, particularly on medication use, from East Anglian subjects, so we were not able to cost drug usage reliably. However, from the data we do have in Table 5, we have no reason to assume (because of randomisation) that drug use differed between the groups, it did not predict good outcome (Garety *et al*, 1997), and clozapine was not used more often in the CBT group. To test for follow-up bias, a series of t-tests were carried out, which revealed no significant differences ($P<0.05$) between completers and non-completers of the CSRI for a range of variables, including length of illness, length of admissions, severity of illness and social functioning. The resulting sample removes our ability to present findings with (statistical) confidence. However, it is still possible to highlight a number of trends in service use and costs.

Service use patterns

Table 6 gives the proportional and mean use of a range of hospital and community services over the duration of the follow-up period. The most noticeable differences between the two groups (though not statistically significant) relate to psychiatric in-patient days (CBT group: 14.5 days, s.d.=31.0; standard treatment group: 26.1 days, s.d.=53.6) and day care (CBT group: 23.5 attendances, s.d.=49.2; standard treatment group: 36.7 attendances, s.d.=48.9).

Care package costs

The component costs of care packages (per month) are summarised in Table 7. Accommodation costs can be seen to be similar for the two groups, which is a reflection of the similar number of subjects (five per arm) in specialist, non-domestic accommodation. Mean service use costs, by contrast, are less in the CBT group, particularly with reference to hospital-based care costs (CBT group: £360, s.d.=591; standard treatment group: £486, s.d.=878). Similarly the mean care package cost was less in the CBT group (£1220, s.d.=736) than the standard treatment group (£1403, s.d.=887). However, the small sample sizes and the skewed data make inference hazardous, as evidenced by the non-significant P-values (after log-transformation).

Table 5 Medication levels based upon chlorpromazine equivalents

	Cognitive–behavioural therapy group	Standard treatment only 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	9
Fluctuating	1	3
Increasing	2	7
Decreasing	2	0
Level of neuroleptic dose throughout the trial		
None	4	0
Low	2	2
Medium	4	8
High	6	9
Changes to clozapine		
Change occurs 0–9 months	1	3
Change occurs 9–18 months	1	2

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

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Table 6 Use of hospital and community services (follow-up phase)

	Cognitive–behavioural therapy group (n=17)			Standard treatment only group (n=15)			Significance
Service	%[1]	Mean	s.d.	%[1]	Mean	s.d.	*P*
Hospital							
In-patient days (psychiatric)	23	14.5	31.0	17	26.1	53.6	0.472
In-patient days (general)	12	2.5	7.0	0	0	0	0.163
Out-patient appointments (psychiatric)	88	4.0	3.2	93	4.9	4.0	0.502
Out-patient appointments (general)	12	0.5	1.5	17	0.4	0.8	0.869
Day patient attendances	6	0.1	0.24	0	0	0	0.332
Community							
Day care attendances	41	23.5	49.2	67	36.7	48.9	0.453
Community psychiatric nurse contacts	59	12.1	12.5	80	14.2	13.3	0.643
General practitioner contacts	76	7.1	9.7	80	4.5	5.3	0.353
Social worker contacts	41	3.4	9.6	40	1.7	3.4	0.505

1. Percentage of participants who used these services.

DISCUSSION

Main findings

The main finding at this stage of the study was that the improvement in symptoms in the CBT group was maintained at 18-month follow-up compared with the standard treatment group. The CBT group had a 29% reduction in symptomatology (on the BPRS) compared with a 2% reduction in the standard treatment group. Further, we were able to show a significant reduction at follow-up in a specific aspect of delusions and hallucinations (delusional distress and hallucination frequency) in the CBT group; two of our original therapeutic aims. Changes in other dimensions of delusions (conviction and preoccupation) and in hallucinations (distress and intensity) failed to reach significance but were continuing to reduce in the CBT group. The fact that the CBT group still showed significant gains at follow-up, nine months after active intervention suggests that improvement was not due to an 'attention effect'. This adds weight to the argument that improvement was due to specific treatment benefits of CBT, not to non-specific factors.

Methodological issues

The fact that other measures did not show differences at follow-up, or post-treatment, is disappointing. In particular, we had specifically targeted negative cognitions for treatment effort in those people who were depressed or had low self-esteem. However, CBT did not seem specifically effective in this area, unlike the results of our previous, waiting list control trial, where depression did improve in the CBT group (Garety *et al*, 1994). Thus, we have not been able to replicate this result with a larger sample and employing a randomised controlled trial design.

The fact that our evaluators were not blind to treatment condition is a methodological problem that we acknowledge and have discussed in our earlier paper (Kuipers *et al*, 1997). We had decided *a priori* that it was not feasible to do this, and our evaluators confirmed at the end of the trial that participants had volunteered therapy details during the multiple assessment sessions. With a two-treatment condition, an 'experimental' and an alternative treatment, there would have been less likelihood of this occurring, but we would still argue, as does Shapiro (1996), that such information is likely to emerge in trials of psychological treatments.

There are also methodological problems arising from the fact that some clients continued to see therapists for occasional sessions between nine and 12 months. Only one received active therapy, a decision dictated by clinical need, and the other five were seen infrequently for sessions that were supportive. While it could be argued that for these six people some therapeutic contact continued for 12 months, we have no convincing evidence that the outcome of this group differed from the outcome of the rest of the CBT group.

Medication

A further problem was that we were unable to control for the prescribing of medication, and the data were incomplete, being mainly from the London sample. The issue of medication is complicated, as levels are subject to several contradictory influences.

Table 7 Summary of costs per month (£)

	Cognitive–behavioural therapy group (n=17)			Standard treatment only group (n=15)			Significance
	Median	Mean	s.d.	Median	Mean	s.d.	*P*[1]
Accommodation cost	680	697	193	685	727	191	0.518
Service use costs	177	524	738	259	676	858	0.188
Hospital	50	360	591	50	486	878	0.932
Community	145	163	206	157	190	188	0.577
Care package cost	958	1220	736	1139	1403	887	0.416

1. Significance test performed on log transformed data.

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People with severe disorders are likely to be on high doses, and so dose and severity should be associated. On the other hand, high doses are prescribed precisely because they are thought to be more effective and therefore should reduce the level of symptoms. Parallel considerations apply to the relationship between increasing levels of medication and deteriorating symptoms. On balance, however, we expected that an effective psychological treatment should reduce the need for medication or at least not require an increase. We also thought that it would lead the responsible clinicians to introduce clozapine less often in the CBT group. If these predictions are right, the tendency for subjects in the standard treatment group to have more medication or to be changed to clozapine would tend to reduce the difference in outcome between the groups and therefore act against our research hypothesis.

In fact, these predictions were confirmed. In any case, as reported by Garety *et al* (1997), medication was not a predictor of good outcome at nine months as both groups were reasonably well maintained on it. We did have one case where clozapine was added to CBT at the end of treatment and one during follow-up, and both of these individuals showed dramatic reductions in their BPRS scores. It is possible that new neuroleptics and CBT are a particularly useful combination for treating the symptoms of subjects who had previously been medication-resistant. However, this remains to be tested empirically.

CLINICAL IMPLICATIONS

- Gains made using CBT for medication-resistant symptoms of psychosis persisted at 18-month follow-up, by which time delusional distress had improved and the frequency of auditory hallucination had reduced. Clinical improvements were found in 65% of the CBT group and only 17% of the standard treatment only group.
- The fact that improvements were still apparent at 18-month follow-up favours a treatment-specific change and not an attention effect.
- Adding CBT to standard care does not appear to increase the overall costs of care.

LIMITATIONS

- Assessors were independent but not blind to treatment conditions.
- The economic evaluation was based on small numbers, which seriously limited significance testing.
- We were not able to control medication prescribing and have limited data on it; however, there was no evidence that change was due to medication effects as both groups were well controlled on it.

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(First received 14 October 1997, final revision 11 March 1998, accepted 11 March 1998)

Cost effectiveness

The economic analysis, although limited by poor completion and small sample sizes, does show that CBT is not a particularly costly intervention (£123 per month on average), and provides encouraging, though not definitive, evidence that these additional therapy costs are offset by a reduction in service utilisation and associated costs in the intervention group. Since there are improvements in clinical outcomes, and overall costs for this sample are at least no greater than the for standard treatment only group, there is evidence to suggest that CBT is likely to be a cost-effective intervention for this subject group. This has potentially important implications for the planning and resourcing for services for this population (a shift from responsive care towards secondary prevention), and also for training in CBT itself.

However, there are a number of study design limitations that militate against more unequivocal statements regarding CBT's cost-effectiveness. An economic evaluation was not included in this study at its inception, resulting in a lack of service data for the treatment phase, the absence of a conflated outcome measure for the purposes of cost–utility/comparative analysis, and a sample size with insufficient power to detect statistically significant cost differences (due to the highly skewed distribution of these kind of data as well as non-completion of the CSRI). Further, the scope of the economic analysis was restricted to a range of key service areas; other costs including drugs, informal care inputs and forgone employment, each of which may exert a differential effect on overall costs in the two groups, were either not incorporated or not available.

IMPLICATIONS

We have demonstrated that gains made during nine months of CBT for psychosis were maintained and even augmented nine months later. The extra costs of this therapy appear to be offset by reduced utilisation of health and social care services. Therapeutic gains were specific to the positive symptoms of psychosis, particularly delusions and hallucinations. There was a clearly significant reduction in delusional distress and in the frequency of hallucinations when measured by self-report. There were some indications that other dimensions of delusions (conviction and particularly preoccupation) and hallucinations (intensity and distress) had also improved, although these were non-significant changes. Thus we have evidence that CBT can be of benefit to those with

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medication-resistant symptoms of psychosis, that these gains persist and are not expensive to provide.

The basic skills of CBT are potentially widely available in adult mental health teams, particularly among clinical psychologists. Many would be able, relatively easily, to extend their expertise to dealing with patients with psychosis, given the guidance available in manuals. The further dissemination of expertise would have greater training and therefore resource implications. This treatment appears to be cost-effective, once the costs of training are covered, and represents a new and useful extension of the treatments for psychosis.

We have demonstrated effectiveness in a treatment-resistant group with long-standing and persistent positive symptoms. Future research should consider offering these interventions at an earlier stage, in order to improve the long-term outcome in psychosis.

ACKNOWLEDGEMENTS

We thank all the participants in the study, and the clinicians and clinical teams in London and East Anglia who referred them. This research was supported by a Research and Development grant from the Department of Health.

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