

COGNITIVE THERAPY IN EARLY PSYCHOSIS: A PILOT RANDOMIZED CONTROLLED TRIAL

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Abstract. A pilot RCT of cognitive therapy (CT; based on Fowler, Garety, & Kuipers, 1995) for early psychosis adjunctive to treatment as usual (TAU) compared to TAU alone is presented. Recruitment is problematic and numbers are small. Levels of symptomatology are low at baseline; and both CT ($n = 12$) and TAU ($n = 9$) groups improve, with few significant group differences and high levels of individual variation. This pattern is common to other studies (Jackson et al., 1998; Lewis et al., 2002). The body of evidence to date seems to suggest that CT for early psychosis is not strongly indicated as an adjunctive treatment for *all* people with early psychosis, but should perhaps focus on the sub-group of patients whose recovery is incomplete.

Keywords: Early psychosis, cognitive therapy, randomized control trials, pilot study.

Background

The rationale behind early intervention in psychosis is secondary prevention – the hypothesis that most of the deterioration that occurs as a result of psychotic illness occurs in the

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first two to five years or so following onset, and that this “critical period” may set the course for the lifetime development of the disorder (Birchwood, Todd, & Jackson, 1998). To date, outcome data on cognitive therapy interventions in early psychosis are variable, and studies differ in style of therapy, time of implementation, session frequency and targeted client group. There is a need, therefore, for further investigations of efficacy. The present study is a very small-scale pilot randomized controlled trial, aiming to give preliminary data on the efficacy of a modification of the London-East Anglia trial CT for psychosis (Fowler et al., 1995), as an adjunct to TAU, in early psychosis, with a view to informing a larger scale study.

The CT comprised 18 sessions over 6 months and was adapted to place more emphasis on areas identified in pre-pilot clinical work as important in early psychosis. These were i) processing the experiences of psychosis, and often of admission to hospital or other contact with services; Jackson and Birchwood’s (1996) work identifies a high prevalence of post-traumatic stress symptomatology following the initial psychotic episode; ii) making sense of these experiences in the context of a personal formulation, with emphasis on developing as non-stigmatizing as possible a view of the person’s difficulties; iii) coming to terms with the impact of psychosis on the person’s life – the losses and changes and the impact on the sense of self, the future, and relationships. Generating optimistic but realistic plans for the future, and discussing the possible course of the illness, and what this may mean in terms of future contact with services and care of self, but with an emphasis on recovery; iv) emphasis on the preservation, to the greatest extent possible, of social, occupational and educational links or rapid re-engagement in community activities. The aim was to cover the period of time when the individual would be expected to be starting the process of adjusting to their experiences, rather than concentrating input exclusively during the acute, in-patient phase.

Method

Participants were recruited through community and in-patient clinical teams in local South London catchment areas by screening all new admissions and referrals. Clinical inclusion criteria were: an ICD-10 schizophrenia spectrum disorder diagnosed < 5 years ago; 1st or 2nd episode (neither episode longer than 9 months duration); symptoms present within the previous 3 months, but not necessarily at entry. Exclusion criteria were: known organic aetiology; and alcohol or substance misuse *as a primary diagnosis*. The age range was 16–65. Participants were assessed prior to entry to the trial, then at 2, 4 and 6 months following entry on a comprehensive battery of standardized symptom measures, including mood, anxiety and cognitive functioning/reasoning style. Screening and assessment were carried out by a blind assessor.

Randomization took place after consent and assessment, and was managed in a separate location by GD. Therapy was carried out by a clinical psychologist with considerable experience of working with people with psychosis (SJ) with regular supervision from PAG. Therapy procedures were listed in a checklist, completed at the end of each session as a means of monitoring both adherence, and content of therapy sessions, with a view to more clearly defining a protocol for CT for early psychosis. Treatment as usual (TAU) was predominantly medical and social and varied from reasonably intensive community follow-up from a team, including home visits, family contact and individual meetings to outpatient follow-up only.

Results

Participants

Over an 18-month period from June 1998 to January 2000, 96 participants were identified who fulfilled initial screening criteria. Of these, 57 were willing to meet with the researcher, of whom only 26 gave informed consent to take part in the study. The groups differed in status and in age with those who refused consent significantly more likely to be in-patients ($X^2(1\text{ df}) = 12.5, p < .001$) and to be older ($t = 2.8, p = .007$). The groups did not differ in self-reported ethnicity, psychotic episode (first or second) or gender. Of the 26 giving informed consent, 5 became unavailable prior to random allocation. Thus 21 individuals were entered in to the study; 12 to CT and 9 to TAU.

Baseline assessment

The groups are very small and therefore between group statistical analyses are not reported; however, they are broadly similar in demographics and symptomatology. Overall, the groups show relatively low levels of psychotic symptomatology and depression/anxiety, but moderate degrees of conviction in, preoccupation with and distress about delusional beliefs. Just less than half of the CT group and two-thirds of the control group experienced auditory hallucinations at a moderate level of severity. Insight as measured by the David scale was moderate in both groups.

Therapy

Only 8 of the 12 participants allocated to CT engaged (4 received 1 or 0 sessions; of these 2 left the country prior to therapy starting, one lost contact with all services after one session, one attended only one session, but although remaining in telephone contact, attended no further sessions). The mean number of sessions at 6 months was 11.0 ($SD = 4.7$; range 5–17; median 11). Content of sessions was variable, but common to nearly all was work on developing a personal model of psychosis, CT for residual psychotic symptoms, work on personal relationships and social reintegration and CT for depression, self-esteem and anxiety. This last was by far the most common component of therapy, and was often closely linked to other aspects of the illness (e.g. depression and anxiety about psychotic symptoms, about having been unwell, impact of experience on self-esteem etc.).

Six-month assessment

At the 6-month assessment, despite assertive follow-up, one person in each group failed to attend or return a postal assessment. Two participants in the CT group and one in the control group completed postal assessments. Change scores (0 month score – 6 month score) for both groups show a trend towards improvement, but great individual variation occurred, evidenced by the large standard deviations of change scores. No difference in pattern of change in individual client profiles was found between groups, with both groups comprising some participants showing clear improvement, some showing no change and some showing deterioration. As so few group differences were apparent, change across the total sample was also examined. For both groups combined, a general trend towards improvement was

evident on measures of psychotic symptoms, with levels of depression remaining low and stable.

Readmissions at 6 months

Readmissions within the 6 month follow-up period totalled 5 (one-third of the follow-up sample; $n = 16$): 3 for the CT group ($n = 8$; all informal), and 2 for the control group ($n = 8$; one informal, one under MHA section)). Average length of admission was 25.3 (SD 20.8) days for the CT group and 76 (SD 8.5) days for the control group.

Medication levels and other intervention at 6 months

Medication levels were variable and general trends in each group over the 6-month period were difficult to identify. However, overall, medication levels were medium and atypical antipsychotics were used predominantly, as is recommended for this group. Few people received other treatment in addition to treatment as usual; this constituted family intervention by community team (one TAU participant, one CT participant), involvement in a first episode psychosis research project (one TAU, one CT), and involvement in a trial of cognitive remediation (one CT participant). In both groups average satisfaction levels with treatment at 6 months were between “satisfied” and “very satisfied”.

Discussion

Recruitment and access

We found a high level of failure to engage with services. Of those individuals identified, about half were willing to meet with a researcher. Most of those who were not willing to meet were not in regular contact with services (e.g. a referral to the emergency services; an initial assessment only). About half of those met with consented to take part in the project. The most common reason given for refusal was that the client did not believe they had a problem, or believed that their problem required intervention other than therapy (e.g. rehousing, police involvement). This pattern has not necessarily been found in other studies (e.g. Socrates), and may reflect the fact that we are working with an inner London sample and, in terms of access rather than consent, not restricting our sample to in-patients. The factors associated with consent to participate are age and in-patient status, but not ethnicity, unlike in the study by Drury, Birchwood, Cochrane and MacMillan (1996). Our early psychosis group is also very socially mobile with many individuals moving out of contact as a result of changed circumstances. We believe we made strenuous efforts within our resources to contact participants for follow-ups, and this suggests that future similar studies should perhaps be designed to allow for this degree of mobility of clients. In accord with current national policy, developed since this study, we would also suggest that interventions, whether psychological, pharmacological or social, are best offered within the context of a specialized early intervention service where engagement can be maximized.

Presentation at entry to the trial

Both CT and TAU groups showed relatively low levels of psychotic symptomatology and of depression at initial assessment, indicating that some recovery had already taken place.

This is similar to the group studied by Jackson et al. (1998); and different from the studies examining change more during the acute phase (Drury et al., 1996; Lewis et al., 2002).

Therapy and change at 6 months

The therapy delivered, from session records, was reasonably close to protocol, emphasizing work on concomitant emotional disorder and psychotic symptomatology. Participants reported levels of satisfaction between “satisfied” and “very satisfied”, and levels of symptomatology, in the main, improve slightly. Satisfaction in this study may not be a measure of the quality of the intervention, as many participants expressed a wish to be left alone as much as possible, and therefore would express satisfaction with a level of care that may, in terms of a service perception of their needs, be inadequate.

Medication levels and other interventions were not different between groups. Re-admission data are comparable, with a suggestion of shorter admissions for the CT group. There is an issue over the adequacy of number of hospital admissions as an outcome measure in a group for whom engagement with services is problematic – fewer admissions may indicate undetected relapse rather than no relapse, and more admissions may reflect closer and more attentive follow-up than higher levels of morbidity. A better measure is relapse, rather than admission; however, for those out of contact with services collecting data on relapse is difficult.

The group exhibits a general trend to recovery that seems independent of treatment. This is similar to the findings of the SOCRATES study, where participants were in a more acute stage of the illness, but showed an overall improvement irrespective of treatment condition.

The failure to find many differences in symptomatology in our study may in part be due to the relatively low baseline levels at entry to the trial. The study is also a pilot, inadequately powered to reach definitive conclusions on efficacy. However, if the general trend is towards improvement, this raises the question of whether there is a sub-group who would benefit differentially from a psychological intervention – perhaps a relapsing group, or those with persisting psychotic symptoms or affective disturbance. Our numbers are too small to examine this convincingly, however; the two people who showed great improvement during therapy both experienced their second relapse around the time of entry to the trial, and reported persisting affective disturbance and some residual psychotic symptoms.

Methodological issues

Clearly, this is a very small-scale study. The sample is not representative of the population of those early in a psychotic illness, as such a high degree of selection was imposed by potential participants both refusing to meet the researcher and not giving consent to participate. A fairly high level of dropout further rarefies the group. Although we made strenuous efforts to encourage participation and to follow-up, it is possible that this could be improved upon in future studies. Numbers are small and this reduces the power for detecting statistically significant changes.

Conclusions

The results of this study are relatively consistent with those of other, larger, studies and we have concluded that at this stage, a larger scale trial of our brief CT (less than 6 months)

for unselected participants with first episode psychosis is not strongly indicated. The data suggested both that many of this group recover symptomatically quite well and that they are difficult to engage at this stage in “formal” therapy. The group differences do not suggest benefits, at least in terms of symptoms, from this intervention. However, evidence to date does not suggest that a cognitively informed supportive approach during the first episode is counter-indicated. The data from SOCRATES (Lewis et al., 2002) indicate that both supportive counselling and CT in the acute stages of the first episode may confer some transient benefits. We hypothesize that those with persisting symptoms or affective disturbance may be differentially helped by CT; the re-admission data in our study are also consistent with the possibility that CT may reduce relapse. We are therefore now embarking on a rather longer intervention (9 months) targeted at relapse reduction as well as the treatment of persisting symptoms for those with second or subsequent episodes of psychosis.

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