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Adherence therapy following an acute episode of schizophrenia: A multi-centre randomised controlled trial

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ABSTRACT

Background: Non-adherence with antipsychotic medication is common in patients with schizophrenia.
Aims: To establish the efficacy of adherence therapy (AT) compared to treatment as usual (TAU) in improving medication compliance in patients following an acute episode of schizophrenia.
Method: The study was designed as a parallel group, single blind, randomised controlled trial. Fieldwork was conducted in four centres (3 in Germany and 1 in Switzerland) and involved a total of 161 patients. Patients received 8 sessions of AT in addition to treatment as usual. The main outcomes of this study were adherence and psychopathology at 12 weeks post discharge follow up.
Results: In total 80 patients received AT and 57 TAU. Intention-to-treat analysis included all randomised patients. Psychopathology, as determined using the PANSS-total, improved in the AT compared to TAU group by a mean of −6.16 points 12 weeks after discharge from hospital ($p<.05$). AT had no significant effects on patients' adherence, treatment attitudes or functioning. No significant adverse events were reported.
Conclusion: AT improves psychopathology in patients recovering from an acute episode of schizophrenia.

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1. Introduction

Improving adherence to treatment in patients with schizophrenia has the potential to reduce relapse rates and prolong remission, improve functioning and reduce health care costs (Robinson et al., 1999; David, 2010). Adherence therapy (AT) is a promising candidate intervention that utilises motivational and cognitive behavioural techniques to modify patients' beliefs about treatment to enhance medication adherence (Gray et al., 2004; Gray et al., 2006; Staring et al., 2010; Alhalaiqa et al., 2012; Anderson et al., 2010). The approach is cognisant with the National Institute for Health and Clinical Excellence and WHO guideline and review on promoting adherence in long term conditions (WHO, 2003; Nunes et al., 2009). To date there have been a number of trials of AT in severe mental illness that have produced conflicting findings. For example Gray et al. (2006) in a trial involving 409 patients with schizophrenia found that AT had no effect on the quality of life compared to a health education control intervention. Although a large, well-conducted trial the intervention was targeted at stable, largely adherent, community dwelling patients and has been criticised for a possible ceiling effect. AT trials that have focused on intervening with patients just after an acute episode (Kemp et al., 1998; Maneesakorn et al., 2007) have generally reported more favourable although not consistently positive outcomes (O'Donell et al., 2003). This observation is consistent with Caplan's crisis theory that suggests that people are more willing to look at alternative perspectives after a life event (such as being admitted to hospital) because they are in a state of confusion and disorganisation (Caplan, 1964). We hypothesised that AT initiated whilst patients with schizophrenia are inpatient and followed up in the community will be effective in enhancing adherence and reducing psychopathology compared to usual care.

Our randomised controlled trial aimed to test the hypotheses that compared to TAU 12 weeks after discharge from hospital AT:

1. reduces patient levels of psychopathology,
2. leads to an improvement in adherence to treatment,

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3. modifies patient's attitudes towards taking their medication,
4. improves global functioning.

2. Methods

A parallel-group randomised controlled trial of adherence therapy in patients with schizophrenia following an acute episode of illness comparing AT and TAU. Blood monitoring and assessment of symptoms and treatment attitudes were performed by researchers blind to group allocation.

2.1. Study participants

All patients that met our selection criteria and who were admitted for treatment of an acute exacerbation of a schizophrenia were recruited from 14th May 2007 to 6th July 2010 from three typical general adult psychiatric inpatient services serving catchment areas in three study sites in Germany (Bielefeld, Warstein and Lippstadt) and one in Switzerland (Bern). The four study sites have, in total 926 psychiatric beds and serve a population of around 1.1 million people.

Eligible patients were adults (≥18 years) with an ICD-10 schizophrenic disorder, were inpatients on one of the participating acute wards, were prescribed antipsychotic medication and were recommended to continue with treatment for at least one year after discharge by the treating clinical team. In addition, clinicians had to positively evaluate treatment including antipsychotic drug response and mental capacity of the patients to consent to participate. Patients were excluded if they had suicidal ideas or behaviours, did not speak German fluently, were prescribed long acting or depot antipsychotic medication, were homeless, or were under compulsory treatment. Co-morbid substance or alcohol dependence (excluding caffeine or nicotine), intellectual disability, or severe medical conditions (e.g. cancer) were additional exclusion criteria. We identified 256 eligible patients, 95 refused to participate. A total of 161 patients were consented and randomised, 137 patients completed baseline measures.

2.2. Ethical approval

All appropriate and necessary ethical approvals were obtained from the research ethics committees at the Universities of Muenster, Germany and Bern, Switzerland.

2.3. Sample size

We expected to observe an 8 point difference in PANSS-total scores between the groups. Assuming a sd of 15, a 2-tailed test of significance and 80% power we required 56 patients in each arm of the trial, resulting in a sample size of n = 112. We estimated from previous trials of adherence interventions in schizophrenia that approximately 30% of patients (n = 34) would withdraw. To adjust for this we increased the sample size to 160.

2.4. Randomisation

The research assistant (RA) in each of the four study centres checked patient eligibility and consent using a standardised checklist. Randomisation was undertaken by the Institute of Medical Epidemiology, Biostatistics and Informatics at the Medical Faculty, University of Halle-Wittenberg (Halle (Saale), Germany). The RA in each of the study centres faxed patient details to the randomization service which returned a unique study number and allocation to AT or TAU. The RA entered these details into a randomization log that was securely stored and could not be accessed by the therapists working on the study. Randomisation was on a 1:1 ratio to AT or TAU.

2.5. Intervention

TAU group: patients received TAU that followed national guidelines for the treatment of schizophrenia. Treatments were provided by a multidisciplinary team that included psychiatrists and nurses and were based on individualised plans developed together with the patients but generally included medication, psychotherapy and occupational therapy. Psycho-educational programmes were offered to each patient and included information and advice about medication and side effects.

AT group: patients in the intervention group received eight sessions of adherence therapy (AT) as an add-on to TAU. AT started whilst participants were inpatient (generally 5 sessions). Interventions were continued after discharge from hospital at the patients home (an additional 3 AT sessions were intended). Adherence therapy (AT) is rooted in the observation that patient beliefs impact on medication compliance (Horne et al. 1999; WHO, 2003; Nunes et al., 2009). A patient-centred manualised approach, AT is delivered as a course over a series of 8 one-to-one sessions, each with a different focus. The fundamental clinical skills of adherence therapy include agenda setting, using the patient's own language, collaborative working, linking sessions together and reflective listening. The four cornerstones of AT are keeping the patient engaged and minimising resistance to change, providing information required by the patient about medication and side effects, and using Socratic dialogue to generate discrepancies in patients' beliefs about treatment. Within this framework there are specific AT exercises:

1. Assessment: exploring patients' beliefs about treatment, practical problems with medication and side effects, medicine reconciliation (reviewing all medication, prescribed or otherwise patients are taking).
2. Structured medication problem solving to address practical issues with medication e.g. side effects or remembering to take medication.
3. Using a medication timeline to help patients review past experiences of illness and treatment.
4. Exploring patients' ambivalence about taking medication using a decisional matrix (the pros and cons of taking/not taking medication).
5. Testing patient beliefs about medication e.g. 'I can stop medication once I start to feel well', 'taking medication is unnatural', 'medication is a slow acting poison'.
6. Helping patients to move forward in their lives, to consider 'life goals' and the role medication may play in achieving these.

2.6. Training of therapists

AT therapists were experienced mental health nurses. They received five days additional training to deliver the intervention. The focus of the training was to ensure that therapists were skilled in delivering AT to a defined competence threshold. Therapists then underwent a two-month period of supervised practice followed by two further days of training to check and refine AT competencies. During the trial therapists received bi-monthly clinical supervision sessions to monitor fidelity to the AT model of working.

3. Outcome measures

3.1. Symptoms

3.1.1. The positive and negative syndrome scale

The PANSS is a gold standard instrument for measuring symptoms in schizophrenia research. Thirty items are rated on a seven point scale based on a 30–40 min structure clinical interview. The PANSS has very robust psychometric properties (Kay et al., 1987) and has been translated into German (Gerhold et al., 1999).

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