A systematic review of randomized controlled trials that attempt to identify interventions that improve patient compliance with prescribed antipsychotic medication

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Authors' objectives
To summarise efficacy of interventions that aim to improve patient compliance with prescribed antipsychotic medication regimes.

Searching
The following databases were searched between 1984 and 1999: CINAHL, BIDS, PsycLIT, the Cochrane Library, MEDLINE and Best Evidence. Studies were also sought from article bibliographies, handsearches of selected journals, and writing to principal authors identified in the review. Four subsets of keywords were used in the search (details were given). Non-English language articles were eligible.

Handsearches were conducted of ten listed key journals identified by the frequency of their appearance in the literature search.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) that reported on interventions aimed at improving patient compliance with prescribed medication were included. Studies were excluded for the following reasons: no suitable control group; very small sample size; failure to adequately randomise the participants; failure to report demographic details; and failure to include base-line scores.

Specific interventions included in the review
The following interventions designed to improve compliance with prescribed medications were included: psychoeducation; family interventions (family counselling, education, discussion of treatment and treatment issues, and medication management); individualized behaviour-tailoring (visible reminders, self-monitoring calendars, pairing of daily medication intake with individual's specific routines); and compliance therapy (motivational interviewing and cognitive behavioural therapy). Group based and individualized interventions were employed in a variety of settings including acute inpatients, rehabilitation, community and outpatients. Studies were reported from England, America, Germany and China.

Participants included in the review
Patients were receiving psychiatric care (hospital or community) aged 18 years or over with a diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, severe affective disorder, or psychotic disorder not otherwise specified, and were receiving antipsychotic medication. Diagnostic criteria for schizophrenia (when stated) included Chinese Medical Association (1985) criteria and American Psychiatric Association DSM-III-R criteria (1987). Male and female participants ranged in age from 18 to 65 years.

Outcomes assessed in the review
Definitions of compliance were diverse and included specific rating scales (Schedule for Assessment of Insight, and the 7-point Likert scale), subjective reporting from both the subject and other key persons, independent measures and scales, and pill counts. Short-term studies of interventions were defined as having less than six months follow-up and longer term studies defined as having follow-up periods of six months or greater.

How were decisions on the relevance of primary studies made?
The literature search was carried out independently by each reviewer and identified abstracts reviewed independently by two reviewers. Articles identified as requiring further scrutiny were independently reviewed according to inclusion criteria with a third reviewer acting as arbitrator when disagreements arose.
Assessment of study quality
No formal validity assessment was conducted though the following aspects of validity were addressed: randomisation; definitions of compliance; statistical methods and power; types of interventions; blinding of raters; and diagnostic criteria.

Data extraction
The following data were extracted by two reviewers with a third reviewer adjudicating on disagreements: study design; interventions; effect on compliance; and sample characteristics.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative review.

How were differences between studies investigated?
Differences between the studies were discussed.

Results of the review
Eight RCTs were included (543 patients).

Methodological quality: Only one study adequately described the process of randomisation. Definitions of compliance were diverse. Only one study was judged to have adequate statistical power. Not all raters were blinded. Self-reports of compliance were used in five studies. Details of interventions used and operational definitions were often imprecise.

Results were reported as statistically significant or not, without point estimates and 95% CI, making interpretation difficult.

Psychoeducational interventions (three RCTs, 228 patients): no statistically significant effect on compliance. Increases were reported in patient knowledge about drug treatment.

Family interventions (two RCTs set in China, 146 patients): no statistically significant effect on compliance though both studies showed increased compliance. Control subjects in one study saw a different doctor at each contact. Individualised behaviour tailoring regimes (one RCT, 12 patients received intervention): statistically significant increase in medication compliance rates though follow-up was short (3 months).

Compliance therapy (two RCTs conducted by same researcher, 94 patients): statistically significant increase in medication compliance rates. Individualised delivery was complex and time consuming though reported to be more cost-effective than non-specific counselling.

Cost information
Refers to study by Healey based on data from one of the included studies that reports compliance therapy was more cost-effective than non-specific counselling over 6, 12 and 18 months follow-up (see Other Publications of Related Interest no.1).

Authors' conclusions
Medication compliance can be improved by certain, sometimes complex interventions. Effective interventions included individualised behaviour tailoring regimes and compliance therapy. However further efforts are needed in developing effective interventions to assist patients in following prescribed treatment regimes.

CRD commentary
The aims and inclusion criteria were clearly stated. Full details were given of the search strategy and methods used to identify relevant studies and extract data. Attempts were made to locate unpublished material. Although no formal validity assessment was conducted, relevant aspects of validity were addressed in the text. Given the clinical heterogeneity among studies, a narrative review was appropriate. The discussion includes mention of the following limitations of the review: the doubtfulness of how representative the available data were; reliance on subjective data; impartiality, reliability and attribution style when considering outcomes from the studies; and the limited generalisability of results from studies set in research as opposed to clinical settings.

Results were not considered with respect to study validity.

The review was based on a small number of trials with variable validity and hence the conclusions must be considered with caution.

**Implications of the review for practice and research**

Practice: The authors state that the review emphasises the importance of combining medication education with personal idiosyncrasies of patients when planning care. They suggest a balance and mutual respect within the relationship between the medical practitioner, the patient and the psychiatric nurse. The evidence of the review supports using a combination of daily living activities and medication regimens combined as a behavioural reminder incorporated as a joint activity and not treated as a separate entity.

Research: The authors state that larger field studies are required to review factors that improve compliance and that a common definition of non-compliance needs to be agreed. They suggest that multicentre trials using the same methodology and operational definitions should be carried out.

**Bibliographic details**


**Other publications of related interest**


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Subject indexing assigned by CRD

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**Record Status**

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.