Does compliance therapy improve use of antipsychotic medication?

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CRD summary
This mini-review assessed the effects of compliance therapy on compliance with antipsychotic medicine. The author concluded that there was insufficient evidence to assess compliance therapy and that further good-quality research is required. There were limitations to this review but, overall, the author's conclusions appear to reflect the poor quality of the included studies.

Authors' objectives
To assess the effects of compliance therapy on compliance with antipsychotic medicine.

Searching
The Cochrane Library, MEDLINE, PsycINFO (from 1985), EMBASE and CINAHL were searched for studies reported in English (1996 to March 2004) as compliance therapy was first developed in 1996. The search terms were reported. Unpublished studies were eligible.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared compliance therapy with a no-compliance therapy control were eligible for inclusion. The studies had to use compliance interventions that involved 4 to 6 compliance therapy sessions, each lasting between 20 and 60 minutes, and covered the three phases (patient's perception of illness and medication, exploration of ambivalence and stigma and maintenance issues) described by Kemp et al. (see Other Publications of Related Interest no.1). The interventions could be conducted in in-patient or community settings. Both included studies compared compliance therapy with non-specific counselling. One of the included studies offered 'booster' sessions of compliance therapy or non-specific counselling.

Participants included in the review
Studies of patients who were prescribed antipsychotic medication were eligible for inclusion. The included studies recruited a variable proportion of in-patients diagnosed with schizophrenia using the American Psychiatric Association's DSM-III-R criteria (58% in one study and 100% in the other).

Outcomes assessed in the review
Studies that measured compliance with prescribed medication and psychotic symptoms at baseline were eligible for inclusion. At least 80% of the participants had to have been followed up at one year. The included studies measured compliance using a 1 to 7-point scale based on information from main informants (relatives and health professionals). The included studies assessed psychotic symptoms using the 7-item version of the Brief Psychiatric Rating Scale (BPRS) or the Positive and Negative Symptom Scale (PANSS).

How were decisions on the relevance of primary studies made?
The author did not state how the studies were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The studies were assessed using criteria described by Greenhalgh and Donald (see Other Publications of Related Interest no.2). Aspects of validity reported included: method of randomisation; baseline similarity of the treatment groups; similarity of assessment measures used for the treatment groups; validity of methods used to assess compliance;
blinding of assessments at baseline and follow-up; power calculations; and the reporting and handling of drop-outs.

The author did not state who performed the validity assessment.

**Data extraction**

The author did not state how the data were extracted for the review, or how many reviewers performed the data extraction. For each study, the mean (with standard deviation, SD) baseline, post-intervention and 12-month scores of compliance and symptoms were extracted for continuous data; where reported, odds ratio (ORs) with 95% confidence intervals (CIs) were extracted for dichotomous data. Data for the outcome measures were extracted at baseline, post-intervention and follow-up.

**Methods of synthesis**

How were the studies combined?
The studies were combined in a narrative.

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

**Results of the review**

Two RCTs (n=130) were included.

Both studies were of poor quality. Methodological flaws included: lack of description of treatment regimens; inadequate information on patient characteristics; lack of clarity about the blinding of assessments; potential detection bias in methods used to assess compliance; potential observer bias in the assessment of symptoms; lack of information on the uptake of booster sessions; lack of power calculations; inadequate information on the scales used to assess compliance; lack of clarity about the handling of drop-outs; and potentially biased methods used to deal with drop-outs.

Both studies recruited patients from limited geographical areas and the generalisability of the results was limited.

Compliance.

One unblinded RCT (n=74 at baseline, n=66 at 12 months) reported that compliance therapy significantly improved compliance at 12 months compared with control. The ratings on a scale of 1 to 7 were 3.7 (SD=1.2) at baseline, improving to 5.5 (SD=1.8) at 12 months, with compliance therapy versus 4.1 (SD=1.2) at baseline, worsening to 3.6 (SD=2.1) at 12 months, with control; the mean difference the 19%. One subsequent report stated that the P-value for treatment difference was less than 0.001.

The other single-blinded RCT (the review author stated there were inconsistencies in the number analysed at 1 year: n=56 at baseline and 6 dropped out during follow-up, but 56 were analysed) reported no statistically significant difference between compliance and control for compliance. The OR of being compliant at baseline was 2.267 (95% CI: 0.47, 11.41), favouring the group allocated to compliance therapy, while the OR of being compliant at 12 months was 0.65 (95% CI: 0.2, 2.11), favouring the compliance treatment group.

Symptoms.

Neither study reported any statistically significant difference in symptoms between treatments. One study reported a mean BPRS (range: 7 to 49; reduction suggests improvement) of 20.3 (SD=7.6) at baseline, improving to 13.8 (SD=6.3) at 12 months, for the group allocated to compliance therapy versus 19.2 (SD=6.6) at baseline, improving to 15.3 (SD=6.2) at 12 months, for the group allocated to control. The second study reported a mean PANSS (range: 7 to 210; reduction suggests improvement) of 71 (SD=22) at baseline, improving to 58.2 (SD=17) at 12 months, for the group allocated to compliance therapy versus 66 (SD=17) at baseline, improving to 52.1 (SD=21) at 12 months, for the group allocated to control; this resulted in a non significant difference of 6.1 (95% CI: -4.7, 16.9, P=0.26) between treatment groups at 12 months.
Authors' conclusions
There was insufficient evidence to assess the effect of compliance therapy. Further good-quality research is required.

CRD commentary
This mini-review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched; unpublished studies were eligible but systematic methods used to locate unpublished studies were not described. By limiting the included studies to those in English, the author might have missed some relevant studies. The methods used to select studies, assess validity and extract the data were not described, so it is not known whether any efforts were made to reduce reviewer errors and bias. Validity was assessed using established criteria and the results of this assessment were reported.

The studies were appropriately combined in a narrative that took study quality into account. However, there were limitations in the reporting of results, and differences between the treatment groups in the change from baseline to follow-up were not clearly and consistently reported for all outcomes of interest; this made interpretation of the results difficult. However, the author stated that there was inadequate information in the primary studies to synthesise the data, which might explain the absence of the most useful results data. This was a mini-review with one author. The lack of reporting of review methods and the lack of clarity in reporting the results limit the reliability of the evidence. However, the author's conclusions appear to reflect the poor quality of the included studies. The need for further good-quality research seems to be supported.

Implications of the review for practice and research
Practice: The author did not state any implications for practice.

Research: The author stated that there is a need for further high-quality research into intervention influencing compliance.

Bibliographic details

PubMedID
16301926

Other publications of related interest

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Subject indexing assigned by NLM

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Antipsychotic Agents /therapeutic use; Cognitive Therapy; Humans; Patient Compliance; Schizophrenia /drug therapy; Schizophrenic Psychology

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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.