Family interventions in schizophrenia and related disorders: a critical review of clinical trials

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Authors' objectives
To update evidence from studies on family intervention in schizophrenia looking carefully at methodological issues.

Searching
MEDLINE was searched from 1976 to 1998 using the keywords 'schizophrenia' and 'family therapy' in the title, abstract and subject headings, and 'clinical trials' in publication type. Reviews on the subject, published in recent years and in English, were examined and all journals included in the list published in Evidence-based mental health (see Other Publications of Related Interest no.1) were handsearched.

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

Specific interventions included in the review Psychosocial treatments targeted at families of patients with schizophrenia were eligible. These were compared to a control treatment, or to alternative family treatments. Most studies used a mix of psychoeducational and cognitive behavioural techniques involving a combination of information about schizophrenia and education on its management, along with strategies aimed at stress reduction, communication training, and collaborative problem-solving. Some treatments were based on underlying models including those of Falloon, McFarlane, or Malan and Balint. Interventions were carried out in clinics and at home. Control treatments included antipsychotic drugs.

Participants included in the review Patients diagnosed with schizophrenia, schizoaffective disorder or other non-affective disorder, based on a standardised diagnostic system, were eligible. The criteria used to diagnose schizophrenia included: New Haven Schizophrenia Index (NHSI); Present State Examination (PSE); American Psychiatric Association criteria (DSM-III or DSM-III-R); Research Diagnostic Criteria (RDC); and Chinese Medical Association criteria. Most schizophrenics were male (median rate of women was 32% overall). In most studies, patients were recruited in hospital or at discharge following an acute episode. Studies were conducted in several countries (USA, Canada, Australia, Germany, China, The Netherlands and Italy). Families included high expressed emotion families.

Outcomes assessed in the review The inclusion criteria were not defined in terms of the outcomes, apart from stating that outcome indicators had to be systematically described and measured. The following four types of outcomes were included: patient's relapse (defined as hospital admission or using a clinical definition) or readmission; patient's mental state measured using the Brief Psychiatric Rating System (BPRS), Psychiatric Assessment Scale (PAS), Schedule for Affective Disorders and Schizophrenia (SADS-C), Scale for Assessment of Negative Symptoms (SANS), Scale for Assessment of Positive Symptoms (SAPS), Global Assessment Scale (GAS), Arbeitsgemeinschaft fur Methodik und Dokumentation in der Psychiatrie (AMDP), Positive and Negative Syndrome Scale (PANSS), and the Covi Anxiety Scale; patient's social and work functioning assessed using the Katz Adjustment Scale, Personal Adjustment and Role Skills Scale (PARS), Vets Adjustment Scale (VAS), Social Adjustment Scale (SAS), Strauss-Carpenter Levels of Functioning Scale (SCLFS), community tenure, employment, living arrangements, GAS, family burden, Major Role Adjustment Inventory (MRAI), and Strauss-Carpenter Outcome Scale (SCOS); and family's well-being and other family-related variables measured using family emotional environment (FES), family functioning (FAM-III), expressed emotion status, relative's satisfaction with care, General Health Questionnaire (GHQ), Positive and Negative Affects Scale (PANAS), relatives coping behaviour, and family relationships.

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

**Assessment of study quality**
The included studies were limited to RCTs. No formal assessment of validity was undertaken though characteristics suggested by Collins et al. were considered (see Other Publications of Related Interest no.2).

**Data extraction**
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

Tables reported in the review included the following information: author and date of publication, intervention details, number of families per intervention group, patient characteristics, setting, outcome measures, and results.

Data from selected studies were re-analysed using the following criteria: patients were analysed according to the groups to which they were originally randomised; suicide was considered as relapse; and patients never discharged, or showing persistent symptoms at both baseline and follow-up, were considered as relapsed. Whenever possible, effect sizes were calculated for continuous outcome measures.

**Methods of synthesis**

How were the studies combined?
Relapse rates across the studies were combined quantitatively, but the methodology used was not described.

How were differences between studies investigated?
The influence of the following aspects of treatment on results were considered: technical model, subject of intervention, setting, and duration. Differences in some aspects of study methodology were discussed.

**Results of the review**

Twenty-five RCTs were included (1,744 patients).

Effect on relapse rate was relatively well-assessed though differences emerged, particularly in comparison with poor control treatments in older studies, and these differences disappeared in recent studies. Finding on patients' symptoms, social functioning or family variables were limited and affected by methodological pitfalls. No difference between intervention models emerged, though behavioural and psychoeducational approaches were better investigated. Patients' inclusion, greater frequency and length of treatment led to better results.

Patient's relapse or readmission (18 RCTs, including 15 RCTs with a control group and 3 RCTs comparing different treatments): results were inconsistent across studies. There were wide variations in relapse rate across studies in both treatment and control groups. At 1 year, median relapse rate in intervention group was 18% (range: 6 - 52) versus 44% (range: 15 - 67) in control. At 2 years, median relapse rate in intervention group was 33% (range: 15 - 50) versus 64% (range: 46 - 83) in control.

Concerns about the use of 'relapse' as an outcome included variable definitions of 'relapse', with criteria for definition of relapse often unclear inconsistent and poorly standardised across studies; definitions based on a threshold of symptoms may be misleading or useless for patients with high levels of psychopathology at baseline; schizophrenia often shows a fluctuating course and any division of patients into categories tend to be artificial; and relapsed patients usually left the trial, and data on the period following relapse were not collected.

Patient's mental state (8 RCTs, including 6 RCTs with a control group and 2 RCTs comparing different treatments): problems with the primary studies included high drop-out rates, and difficulties interpreting results because full data were provided on selected symptoms only or from non-relapsed patients only.
Patient's social and work functioning (11 RCTs, including 9 RCTs with a control group and 2 RCTs comparing different treatments): clearly positive results were seldom found, there was little consistency in the use of measurement tools, and a lack of accuracy in outcome criteria assessment.

Family's well-being and other family-related variables (14 RCTs): results were inconsistent. Problems included the use of a variety of outcome measures of uncertain validity.

Comparison of different intervention models.

Technical model (psychoeducational, behavioural, psychodynamic, systematic).

Interventions within these categories were not homogeneous. It was not possible to identify the effective components of family intervention.

Subject of intervention (single family with or without the patient, multiple family group): there was consistency of negative results from 4 RCTs with groups of relatives without the patient.

Setting (hospital, out-patient clinic, home): results were inconsistent.

Duration: 7 RCTs, in which the family intervention was provided on a short-term basis (no more than 10 sessions over less than 6 months), failed to show convincing and long-lasting results.

Other methodological issues.

Methodological problems included: small sample size without consideration of study power; few authors described the standard treatment fully or checked its application to the control group; inadequate investigator blinding; failure to consider reliability of outcome measures; and failure to perform analyses on an intention to treat basis.

Authors' conclusions
It remains unclear whether the effect depends on family treatment or on more intensive care. The failure to relate outcomes to family-mediating variables is a challenge to the rationale underlying family interventions.

CRD commentary
The aims were stated and the inclusion criteria were defined in terms of the study design, participants, and intervention. Material was sought from several sources, but it was not reported whether any language restrictions were applied and no attempt was made to locate unpublished articles, thus raising the possibility of publication bias. Methods used to select studies were not described. Validity was not formally assessed, although studies were restricted to RCTs and comment was made on some aspects of validity. Methods used to assess validity and extract data were not described. Details of the primary studies were presented in tabular format and some studies were further described in the text. It was unclear how studies were selected for more detailed description. Data were extracted on an intention to treat basis. Given the many differences between studies, a narrative review was appropriate. The evidence on which comments were made would have been easier to assess had separate tables of studies reporting specified outcomes been presented. Where heterogeneity in results was found, this was not explored and no attention was drawn to better sources of evidence.

The evidence as presented supports the authors' conclusions.

Implications of the review for practice and research
Practice: The authors state that the addition of family intervention to standard treatment of schizophrenia has a positive impact on outcome to a moderate extent; family intervention is effective in reducing the short-term risk of clinical relapse after remissions from an acute episode; and the elements common to most effective interventions were inclusion of patients in at least some phases of the treatment, long duration, and information education about the illness was provided within a supportive framework.
Research: The authors state that future research should address the identification of large community-based unselected samples; the use of control groups receiving good well-defined standard care; the definition of clinical significance of continuous outcome measures; the use of adequate measures of patients’ outcome in addition to relapse; and the systematic assessment of family burden and well-being as outcome variables. Research should also focus on patients with diverse cultural backgrounds and study intervening variables concerning the family unit’s functioning or interaction.

Bibliographic details

PubMedID
10937780

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Behavior Therapy; Family Therapy /methods /standards; Female; Humans; Male; Patient Education as Topic; Psychotic Disorders /therapy; Randomized Controlled Trials as Topic /standards; Research Design /standards; Schizophrenia /therapy; Secondary Prevention; Treatment Outcome

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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.