Effectiveness of psychological and psychosocial interventions on quality of life of patients with schizophrenia and related disorders: a systematic review protocol

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Abstract

The objective of this review is to synthesize the best available evidence on the effectiveness of psychological and psychosocial interventions on quality of life of patients with schizophrenia and related disorders. This review will consider studies that include patients with schizophrenia or related disorders (schizotypal and delusional disorders) in all stages of their illness and in all treatment settings. The review will consider studies that evaluate psychological or psychosocial interventions. Included interventions will be family interventions, psychoeducation / patient education, cognitive-behavioral therapy, cognitive remediation, social skills training, and supported employment / vocational rehabilitation. The format of the intervention may be individual or group-based. The providers of interventions may include nurses, physicians, psychologists, social workers or other allied health providers. The control comparison will be any other psychological or psychosocial intervention or standard care (also called “treatment as usual”). The review will consider studies that include quality of life as an outcome measure. Studies will be reviewed for evidence of standardized valid and reliable tools measuring subjective quality of life, such as the Quality of Life Scale, the World Health Organization Quality of Life, the Lehmans Quality of Life Interview or the Manchester Short Assessment of Quality of Life.
Review objective

The objective of this review is to synthesize the best available evidence on the effectiveness of psychological and psychosocial interventions on quality of life (QoL) of patients with schizophrenia and related disorders.

Review questions

In patients with schizophrenia and related disorders:

- what is the effect of a psychological intervention as compared to usual care on QoL?
- what is the effect of a psychological intervention as compared to another psychological or psychosocial intervention on QoL?
- what is the effect of a psychosocial intervention as compared to usual care on QoL?
- what is the effect of a psychosocial intervention as compared to another psychosocial intervention or psychological intervention on QoL?

Background

More than 450 million people suffer from mental health disorders worldwide and many more have mental problems. These disorders and problems affect all sections of society and every age group. It has also been estimated that the burden of mental disorders will rise significantly over the next decades. Thus, mental health disorders are of international concern.

Schizophrenia is a major mental disorder with considerable impact on individuals and their families. It is estimated that worldwide 24 million people at any point of time suffer from schizophrenia. Schizophrenia typically starts in early adulthood or late adolescence. It is associated with relapses with high hospitalization rates, loss of ability to work and mortality in younger age than a general population. Nearly every patient is disabled in multiple functional domains and they have significantly more problems in everyday functioning than the general population. Patients with schizophrenia are also stigmatized, which leads to discrimination which may affect these people's life opportunities, such as social relationships, education, employment, housing and health care services. Moreover, the economic costs of schizophrenia are remarkable. Costs are caused, for example by loss of ability to work, relapses with high hospitalization rates and family burden.

Besides antipsychotic treatment, clinical practice guidelines for schizophrenia recommend psychosocial interventions that are relevant to sufferers’ needs and focus on issues of specific relevance to the patient. Psychosocial interventions have been developed to address the impact of the illness on an individual’s well-being, psychosocial functioning and life opportunities.
Family interventions, psychoeducation/patient education, cognitive behavior therapy, cognitive interventions, social skills training and supported employment represents typical psychosocial interventions\textsuperscript{16,17}.

Jung and Newton\textsuperscript{20} reviewed Cochrane Reviews of psychosocial and psychological interventions for either schizophrenia, psychosis, schizoaffective or bipolar disorder. They identified 28 interventions with assertive community treatment (ACT), crisis intervention, music therapy and psychoeducation assessed as having strong support that merits application. Moreover, four interventions for patients with schizophrenia or severe mental illness were found to have moderate support that warranted consideration of application. These interventions being cognitive behavior therapy, family intervention, prompts to encourage appointment attendance and token economy. Interventions that were not supported were case management, compulsory community and involuntary outpatient treatment, distraction techniques as well as psychosocial treatment programs for people with both severe mental illness and substance misuse. The authors concluded that in many reviews the data was inconclusive. Moreover, the authors argued that the validity of randomized controlled trials (RCTs) may be questionable to investigate the effectiveness of varying psychotherapies.\textsuperscript{20}

Woodward\textsuperscript{21} produced an evidence summary related to psychological and psychosocial interventions for patients with schizophrenia. Based on the summary, cognitive behavior therapy should be available and cognitive remediation, social skills training and vocational interventions should be considered for patients with schizophrenia to improve social outcomes. Psychoeducation and music therapy were also identified as useful interventions whilst there was insufficient evidence to recommend psychoanalytic or psychodynamic psychotherapy for use in routine treatment.\textsuperscript{21}

Many research findings have confirmed that the presence of schizophrenia is related to poorer QoL\textsuperscript{22,23,24}. There is a number of factors that potentially are related to impaired QoL. For example various kinds of psychiatric symptoms,\textsuperscript{22,25,26,27,28,29} side effects of medication\textsuperscript{25} and perceived stigma\textsuperscript{13,29} may impair QoL of these patients. Reduced QoL can also be attributed to a weakened physical state, problems in psychosocial functioning\textsuperscript{30}, high level of unmet needs\textsuperscript{26,31} and low number of daily activities\textsuperscript{28}. Moreover, impaired QoL may be associated with weak social support\textsuperscript{26}, loneliness\textsuperscript{30,31,32}, unsatisfied amount of contact with family members\textsuperscript{28,32}, unemployment\textsuperscript{32} and insufficient financial means\textsuperscript{27}. Thus there is a need to develop a holistic approach to care in which patients’ QoL is of central concern\textsuperscript{33,34}. As a result, improving the QoL of these patients is emphasized in clinical practice guidelines all over the world\textsuperscript{16,17,18,19}.

With regards to psychological and psychosocial interventions effectiveness on QoL of patients with schizophrenia and related disorders (schizotypal and delusional disorders), several Cochrane reviews have included the QoL as a secondary outcome whilst other studies have QoL as a primary outcome. Jones et al.\textsuperscript{35} reviewed RCTs where cognitive behavior was investigated. Only one small study reported effectiveness on QoL and found no differential effect of cognitive behavior therapy. This was
also found in the review by McIntosh et al.\textsuperscript{36} related to compliance therapy. Dieterich et al.\textsuperscript{37} concluded that based on few skewed data intensive case management confers no advantage over standard care. Tungpunkom et al.\textsuperscript{38} concluded that it is unclear whether life skills programs improve QoL. The same was also concluded in the reviews by Ruddy et al.\textsuperscript{39} when related to art therapy, in Mössler et al.\textsuperscript{40} and Xia et al.\textsuperscript{41} regarding psychoeducation and Crowther et al.\textsuperscript{42} regarding vocational rehabilitation. These authors concluded that more research is needed to be confident of the effectiveness of psychoeducation on QoL.

There is an urgent need to determine the psychological and psychosocial interventions by which the QoL of patients with schizophrenia and related disorders is best supported. Thus, the purpose of this review is to synthesize the existing body of research evidence on the effectiveness of psychosocial and psychological interventions on QoL of patients with schizophrenia and related disorders. Prior to commencement of this systematic review, the Cochrane Library, Medline, Joanna Briggs Institute (JBI) database, DARE database and PROSPERO database were searched and no previous systematic reviews or reviews currently underway on this specific topic were located.

**Keywords:** Effectiveness; psychological intervention; psychosocial intervention; quality of life; schizophrenia

**Inclusion criteria**

**Types of participants**

This review will consider studies that include patients with schizophrenia or related disorders (schizotypal and delusional disorders) in all stages of their illness and in all treatment settings. We will include studies where the majority of participants are adults (18 years or over) and were the majority of participants have a diagnosis of schizophrenia or a related disorder (schizotypal disorder, persistent delusional disorder, F20-F22; schizoaffective disorder, F-25) based on International Statistical Classification of Diseased and related health Problems 10\textsuperscript{th} Revision (ICD-10).

**Types of interventions**

This review will consider studies that evaluate psychological or psychosocial interventions. Included interventions will be family interventions, psychoeducation / patient education, cognitive-behavioral therapy, cognitive remediation, social skills training, and supported employment / vocational rehabilitation. These interventions are most often recommended in practice guidelines for the treatment of patients with schizophrenia\textsuperscript{16,17,18,19}. The format of the intervention may be individual or group-based. The providers of interventions may include nurses, physicians, psychologists, social workers or other allied health providers.

The control comparison will be any other psychological or psychosocial intervention or standard care (also called “treatment as usual”) defined as the care a person would normally receive if they would not
been included in the research. Standard care includes any appropriate mental health care as deemed necessary by the clinician without program of the types described above.

**Types of outcomes**

This review will consider studies that include QoL as an outcome measure. Studies will be reviewed for evidence of standardized valid and reliable tools measuring subjective QoL, such as the Quality of Life Scale\(^43\), the World Health Organization Quality of Life\(^44\), the Lehmans Quality of Life Interview\(^45\) or the Manchester Short Assessment of Quality of Life\(^46\).

**Types of studies**

This review will consider any experimental study designs including randomized controlled trials, non-randomized controlled trials, quasi-experimental and before and after studies, for inclusion.

**Search strategy**

The search strategy aims to find published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified studies will be searched for further relevant studies.

Studies published in English will be considered for inclusion in this review. Because QoL instruments have been used as an outcome in clinical trials in psychiatry research since the 1990s\(^47\), studies published from 1990 to 2012 will be considered for inclusion in this review.

The databases to be searched include: CINAHL, Cochrane Library, Joanna Briggs Library, MEDLINE, PsiTri, PsycINFO, PsycArticles, SCOPUS and Social Sciences Collection. The search for unpublished studies will include MedNar, PsyDok and SCIRUS.

Initial keywords to be used will be:

- Schizophrenia, schizotypal disorder, persistent delusional disorder, schizoaffective disorder
- Family intervention, psychoeducation, patient education, cognitive-behavioral therapy, social skills training, cognitive remediation, vocational rehabilitation, supported employment
- Quality of life, life quality
- Randomized controlled trial, non-randomized controlled trial, quasi-experimental study, pre and post test, experimental study
Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

None.

Acknowledgements

The reviewers would like to acknowledge their employers Pirkanmaa Hospital District and Satakunta Hospital District for proving an opportunity to take part in the JBI's Comprehensive Systematic Review course. The Department of Psychiatry in Tampere University Hospital provided funding for protocol process.
References


Appendix I: Appraisal instruments

MAStARI Appraisal instrument

### JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

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<thead>
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<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocator?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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<td>7. Were groups treated identically other than for the named interventions</td>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<td>10. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include □ Exclude □ Seek further info. □

Comments (Including reason for exclusion)

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Appendix II: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for Experimental / Observational Studies**

- Reviewer: ____________________________ Date: ____________________________
- Author: ____________________________ Year: ____________________________
- Journal: ____________________________ Record Number: ____________________________

**Study Method**

- RCT: [ ]
- Quasi-RCT: [ ]
- Longitudinal: [ ]
- Retrospective: [ ]
- Observational: [ ]
- Other: [ ]

**Participants**

- Setting:
- Population:

**Sample size**

- Group A: ____________________
- Group B: ____________________

**Interventions**

- Intervention A:
- Intervention B:

**Authors Conclusions:**

- ____________________
- ____________________
- ____________________

**Reviewers Conclusions:**

- ____________________
- ____________________
- ____________________
Study results

### Dichotomous data

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### Continuous data

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