

Effectiveness of Community-Based Interventions for Patients with Schizophrenia: A Study Protocol for a Systematic Review

Soo-yeon Kim (✉ sooyeonkim@dhu.ac.kr)

Daegu Haany University

Ah Rim Kim

Far East University

Protocol

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Abstract

Background Schizophrenia requires a community-based intervention approach combined with standard treatment to prevent relapses. A literature review is required to understand the effectiveness of community-based interventions and to enhance quality in countries where they have not been fully established. This is a protocol for a systematic review of the effectiveness of community-based interventions for patients with schizophrenia.

Methods Only randomized and non-randomized controlled trials and cohort studies will be considered. Studies from September 2009 to September 2019 will be searched on five databases, with the primary words: “schizophrenia” and “community mental health services.” Studies on community-based interventions for patients with schizophrenia that originated from governmental programs will be considered. To assess bias, randomized and non-randomized trials will be analyzed via the Cochrane RoB 2.0 and the ROBINS-I, respectively. Results will be descriptively synthesized and statistically analyzed, and will be structured according to patients’ characteristics, intervention type and exposure, and outcome type. Discrete variables will be calculated via odds ratio, and continuous variables will be calculated via standardized mean difference using RevMan 5.3 software.

Discussion We will provide a summary of the available evidence on the effectiveness of community-based interventions and specific guidelines to improve their outcomes.

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Background

Recently, in Korea, as violent crimes performed by patients with schizophrenia began to rise and became a social issue, the social atmosphere created a negative bias related to this mental illness [1]. Even so, social issues related to patients with schizophrenia should be approached in a way that allows for the identification of blind spots in mental illness management, rather than just focusing on the crimes that occurred, and should also recognize the need for a closer look and care at the community level, which may ultimately help these individuals, when combined with regular treatment.

Schizophrenic episodes recur in patients at a high rate after diagnosis [2]. Relapse rates for schizophrenia are associated with the discontinuation of their respective antipsychotic drug treatments; therefore, symptoms such as violence are relatively well controlled—unlike social prejudice—when drug treatment is well adapted to the patient’s life [3]. Contrastingly, untreated schizophrenia tends to lead patients to repeated hospitalization due to frequent symptomatic relapses, a process that eventually leads to a general deterioration in individuals’ quality of life, provoked by difficulties related to cognitive skills, communication and interpersonal relationships, and significant social withdrawal [4–6].

Additionally, schizophrenia has been shown to have a higher requirement related to family care compared to other chronic conditions [6], mainly because it is difficult to maintain patients’ insight into their

treatment and drug compliance, as well as manage their symptoms, which is represented by high relapse rates. Thus, schizophrenia requires long-term comprehensive care combined with standard treatment, to prevent recurrence and improve the individuals' function on a daily basis.

Several studies have shown positive effects of interventions when used in parallel with the standard treatment for the management of schizophrenia. In groups who present low drug compliance and violent tendencies, symptoms were significantly reduced after more than 6 months of assisted outpatient treatment [8]. The results of a 2018 meta-analysis suggested that community-based interventions that are performed in the initial stages of the mental illness are effective to diminish the symptoms of schizophrenia, compared to the standard treatment [9]. Additionally, case management for more than 2 years has shortened the length of re-hospitalization [10].

Community-based interventions have shown to be effective not only in terms of the costs associated with hospitalization but also in terms of the quality of life and family burden of patients [11]. Particularly, it has been shown to help patients with schizophrenia in maintaining education and/or getting a job, which has resulted in their social reintegration and personal development [12].

Based on these positive effects of community involvement, many countries encourage community-based interventions, like the National Institute of Clinical Excellence Guidelines in the U.K., which emphasizes the need for community-based psychiatric intervention, such as cognitive therapy, counseling, and family intervention, in addition to standard treatment [13]. In Korea, since the enactment of the Mental Health Act in 1995, a policy of deinstitutionalization has been established with the help of the Mental Health Center, and community-based case management programs for various mental disorders have been developed and carried out [11,14]. However, to date, they have not been fully established, and community support systems are still vulnerable [15].

Thus, we deem that a systematic review on community-based intervention programs related to the treatment of schizophrenia is required. A similar prior study was conducted in 2017 [16]; however, this study was limited to low- and middle-income countries, and it cannot be considered an international standard, thereby creating barriers to use of its findings as strong evidence for how interventions should be performed in other countries.

1.1. Aims

Analyzing the effectiveness of community-based intervention studies developed and applied worldwide to date through a comprehensive systematic review proves a necessary step in developing community-based intervention programs for patients with schizophrenia. This systematic review allows for the planning of community-based interventions in countries where foundations for community-based interventions have not yet been established. Thus, this review will aim to:

- Identify the relapse and remission rates for patients with schizophrenia who have participated in community-based intervention programs.

- Identify the quality of life for patients with schizophrenia and their families who have participated in community-based intervention programs.

Materials And Design

Our search strategy, selection of studies, assessment of bias risk, and reporting of results for the review will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement [17].

2.1. Review Inclusion Criteria

2.1.1. Participants

This review will include all patients with schizophrenia who received/were subject to a community-based intervention program. Further, the results will be presented separately, based on the duration of the patients' illness (divided into the first episode or chronic status).

2.1.2. Intervention

This review will consider studies that evaluate any type of intervention programs that originated from the Community-based Intervention Program for patients with schizophrenia. Those interventions may include but are not limited to, case management, cognitive behavioral therapy, occupational rehabilitation, and physical intervention programs. In addition, the review will include the patients' symptomatic severity and quality of life as outcomes of the community-based intervention.

2.1.3. Comparators

The comparison groups will include patients with schizophrenia receiving standardized treatment that includes only medication. Additionally, cohort study designs will be included in this review, so studies without a comparison group will be included.

2.2. Outcomes

Schizophrenia causes frequent relapses and poor quality of life when treatment is ineffective or not sustained. In view of this, exploratory analysis will be conducted to identify relapse, recovery, and/or remission rates of psychotic symptoms. The patients' conditions will be verified by the number and duration of hospitalizations after the community-based intervention, by their scores on the Positive and Negative Syndrome Scale (PANSS), Brief Psychiatric Rating Scale (BPRS), and Global Assessment of Functioning (GAF). Quality of life will be defined by the patients' and their respective caregivers' Quality of Life Scale scores. Thus, any studies that report any of the above outcomes will be included.

2.3. Study Design

This review will consider randomized controlled trials (RCT), non-randomized controlled trials (non-RCT), and cohort studies, but will exclude single case studies and reviews. It will report the specific characteristics of all included studies, and the inclusion criteria are: studies must be written in either English or Korean, must have been published in the last 10 years (from 2009 to 2019), and must be a full paper (i.e., conference abstracts will not be considered).

2.4. Electronic Bibliographic Databases

Electronic searches will be conducted on the following databases: MEDLINE (PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, EMBASE and the Cumulative Index to Nursing and Allied Health Literature, Research Information Sharing Service (Korean database). Databases will be searched for studies from September 2009 to September 2019.

2.5. Search Strategy

The search strategy aims to find published studies that are in accordance with the Population Intervention Comparison and Outcome Process. An initial search of PubMed will utilize text words related to the systematic review research question: "schizophrenia" and "community based" or "community mental health services." Then, we will identify relevant keywords by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the relevant articles to refine our search. Specific search strategies are provided as attachments.

2.6. Study Screening and Selection

Search results will be downloaded using Endnote software, X9 version, and duplicate studies will be eliminated. In the first review, we will review the title and abstract of the selected studies to identify populations, intervention and outcome variables, and study designs to eliminate non-relevant literature; in the second review, a full-text review will identify the final literature of the selected studies. Each selected study will be independently reviewed by two researchers and will be cross-reviewed by both researchers. During the process, if opinions do not agree among researchers, the text will be reviewed together until the researchers reach an agreement.

2.7. Data Extraction

Data extraction will include specificities about populations, types of interventions, study designs, and outcome variables. Researchers will select five articles to create a pilot-format data extraction tool, and this tool will use the Excel software program (Microsoft).

In addition to the outcome data, descriptive details such as study designs (e.g., RCT or non-RCT), participants' characteristics (e.g., age, gender, disease status), methods used in the analysis, and methods of intervention (handling) will also be recorded and reviewed. The amount, duration, frequency, and intensity of each reported intervention will also be included in the record. The demographic

characteristics and types of interventions will also be specified to enhance the study analysis and synthesis.

If there are any missing or unclear data, we will contact the author of the original research to clarify.

2.8. Assessing Risk of Bias

For RCT studies, we will use the Cochrane RoB 2.0 tool [18]. RoB is a tool that combines both the checklist method and area evaluation method, and it is an important tool because its area evaluation randomizes sequence generation, which blinds parts of the study and study personnel, blinds the outcome assessments, and does not include incomplete outcome data, which helps us avoid selective reporting and other possible types of biased selection. To avoid the risk of biases in each question, they will be judged as “high,” “low,” and “uncertified” bias, in accordance with the specific presented guidelines.

Non-RCTs, including cohort studies, will use a Risk of Bias in Non-randomized Studies-of Interventions (ROBINS-I). ROBINS-I evaluation areas are related to the selection of target populations, confounding variables, measurement of exposure, blinding of outcome assessments, incomplete result data, and selective reporting [19]. Each area can be divided according to study type: cohort, comparative clinical trials, and before-after studies. This will be performed to determine the risk of warping in that specific area. To avoid the risk of biases in each question, they will be judged as “high,” “low,” and “uncertified” bias. Two reviewers will independently assess the methodological quality of selected studies, and any disagreement will be resolved by discussion.

Analysis

3.1. Descriptive Analysis

Our review results will be descriptively synthesized and analyzed. The structure of the studies will be described, and they will be structured according to the following characteristics:

- The characteristics of target populations
- The type of intervention
- Intervention exposure (e.g., intervention duration/times, individual or team approach)
- The type of outcome

3.2. Statistical Analysis

We will perform a meta-analysis that will first calculate summary estimates of individual studies. In this study, the results will be reported and divided into studies with discrete (hospitalization incidence rate) or continuous (hospitalization period; clinical scale involving PANSS, GAF, BPRS; quality of life) variables. The hospitalization rate will be calculated via odds ratio and other continuous variables (e.g., t, F, p), and

the standardized mean difference will be used to calculate effect sizes, which will be calculated by merging the effect sizes of individual studies using the RevMan 5.3 software.

Higgins's I^2 statistic will be used to confirm homogeneity. We have chosen this approach because I^2 statistics quantify the degree of heterogeneity and have features that are not sensitive to scales or number of studies [20]. Increasing heterogeneity increases the value of I^2 , which allows for the selection of a fixed-effect model or a random-effect model based on the I^2 50% rate [21]; a fixed effect model will be selected if it presents heterogeneity results below 50%, and if heterogeneity is higher than 50%, a random effect model will be selected, and subgroup analysis will be performed. Factors expected to contribute to heterogeneity include the clinical characteristics of the patients, including the severity of the disease, the comorbidity, the exact diagnosis, and the duration of the disease, which have all been reported to have an effect on treatment in previous studies [22–25]. Therefore, the subgroups will be set up in consideration of clinical characteristics and types of interventions, so that the likelihood of statistical errors are reduced. If quantitative synthesis is not appropriate due to high heterogeneity, we will perform descriptive synthesis only.

3.3. Confidence in Cumulative Evidence

For strength of evidence related to all outcomes, we will assess evidence using the GRADE method, and it will be judged as “high,” “moderate,” “low,” and “very low” [26].

Conclusions

This systematic review of the effect of community-based interventions on patients with schizophrenia will provide a detailed summary of the available evidence on the effectiveness of this type of intervention, and we intend to provide specific guidelines to help improve the outcomes of community mental health services.

Declarations

Author Contributions: Conceptualization, S.Y.K; design, S.Y.K.; writing—original draft preparation, S.Y.K. and A.R.K; writing—review and editing, S.Y.K. and A.R.K. All authors have read and agreed to the published version of the manuscript.

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Available of data and materials: The study protocol does not include the dataset, but the search strategy is included.

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List Of Abbreviations

BPRS: Brief Psychiatric Rating Scale

CINAHL: Cumulative Index to Nursing and Allied Health Literature

GAF: Global Assessment of Functioning

Non-RCT: Non-randomized control trials

PANSS: Positive and Negative Syndrome Scale

PICO: Population Intervention Comparison and Outcome

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses

QOLS: Quality of Life Scale

RCT: Randomized control trials

SMD: Standardized mean difference

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