





BMJ Open Psychosocial interventions for community-dwelling individuals with schizophrenia: study protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Despite the recent global mental health movement of the transition from hospital-centred to integrated community-based services, comprehensive evidence of psychosocial interventions focusing on community-dwelling individuals with schizophrenia is still lacking. To overcome this gap in the current knowledge, we will conduct a systematic review and meta-analysis to assess the efficacy of all types of psychosocial interventions for community-dwelling (non-hospitalised) individuals with schizophrenia when compared with non-active control conditions (eg, treatment as usual).

Methods and analysis This study protocol has been developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines. By March 2022, the following sources will have been searched, without restrictions for language or publication period: Embase, PubMed, PsycINFO, CINAHL, the Cochrane Central Register of Controlled Trials, ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform. We will also try to identify other potentially eligible studies by searching the reference lists of included studies, other relevant systematic reviews and grey literature. All relevant randomised controlled trials from both high-income and low-income to middle-income countries will be allowed. Two independent reviewers will conduct the selection/screening of studies, data extraction and methodological quality assessment of included studies. The primary outcomes are quality of life and psychiatric hospital admission. Standard pairwise meta-analyses with a random-effects model will be conducted. Subgroup and sensitivity analyses will be performed to assess the robustness of the findings. Risk of bias will be assessed with the Revised Cochrane Risk-of-Bias Tool for Randomised Trials. The Grades of Recommendation Assessment, Development and Evaluation approach will be used to assess the quality of evidence.

Ethics and dissemination Ethics approval is not required for this study. The study findings will be disseminated through conference presentations as well as peer-reviewed publications.

PROSPERO registration number CRD42021266187.

Strengths and limitations of this study

- This study will only include relevant randomised controlled trials in order to avoid sources of bias that are commonly seen in quasiexperimental clinical trials.
- This study will accept all relevant trials from both high-income and low-income to middle-income countries, without placing restrictions on language of publication.
- Findings of this study may be limited by publication bias, study heterogeneity, the measurements used to assess quality of life (primary outcome) and the methodological quality of included studies.

INTRODUCTION

Schizophrenia is one of the most painful and costliest mental disorders for individuals and their families and for wider society. Schizophrenia and related disorders are usually diagnosed based on the presence of positive and/or negative symptoms and functional impairment.¹ Positive symptoms include psychotic manifestations, such as hallucinations, delusions, disorganised thought and speech, and disorganised/catatonic behaviour. Negative symptoms include blunted affect, avolition, anhedonia, asociality and avolition.² The accumulating evidence suggests that negative symptoms have more impact on everyday functioning and quality of life than positive and other symptom factors.^{3 4} Globally, schizophrenia is generally regarded as a low prevalence mental disorder (the global age-standardised point prevalence is 0.28%), but it creates a considerable economic deficit to society due to losses in productivity by individuals, costs for treatment and significant burdens on health and welfare systems.^{5 6}

Although antipsychotic medication is a global-standard effective treatment option

for treating/managing psychotic symptoms (especially for positive symptoms),⁷ 20%–30% of people with schizophrenia are resistant to antipsychotics,⁸ and 27% of individuals who had been treated with antipsychotics experienced a psychotic relapse within 1 year.⁹ Furthermore, antipsychotics are of less benefit for negative symptoms.¹⁰ However, limited evidence has suggested that psychosocial interventions are effective for managing treatment-resistant schizophrenia¹¹ and for ameliorating negative symptoms.¹² In this context, to assist in promoting recovery, there is consensus that treatment for schizophrenia should offer a full range of pharmacological and psychosocial interventions (including social and occupational interventions).¹³ Furthermore, in many countries (especially economically developed countries), mental health services have been transformed from hospital-centred to integrated community-based services by reducing the size of hospitals (eg, the number of hospital beds) and developing community-based services. Thus, effective psychosocial interventions for community-dwelling individuals with schizophrenia are in high demand around the world.

Based on systematic reviews and meta-analyses of randomised controlled trials (RCTs), there is now an increasing body of evidence concerning the efficacy of a range of psychosocial interventions for schizophrenia (mostly on positive symptoms and relapse prevention), such as psychoeducation,¹⁴ social skills training,¹⁵ cognitive-behavioural therapy,^{16–18} family intervention¹⁹ and assertive community treatment.²⁰ A recent network meta-analysis has evaluated the efficacy of psychological interventions for positive symptoms in schizophrenia and has found higher efficacy for cognitive behavioural therapy in comparison with an inactive control condition for positive symptoms and treatment response.²¹ McDonagh and colleagues²² have also conducted an updated systematic review, based on existing systematic reviews and additional trials, and reported that most psychosocial interventions for adults with schizophrenia were more effective in improving several outcomes (eg, functional outcomes, quality of life and core illness symptoms) when compared with treatment as usual. However, most of the systematic reviews and meta-analyses did not consider the type of intervention setting/context (ie, efficacy of psychosocial interventions conducted in the inpatient and outpatient settings were combined/complex). Some of the studies have performed subgroup or sensitivity analyses according to intervention setting, but most compared or stratified intervention settings in these studies were hospital based (ie, inpatient vs outpatient settings).^{23–27} One meta-analysis²⁸ investigated the efficacy of community-based psychosocial interventions for schizophrenia, but this study only focused on low-income and middle-income countries where there are severe shortages of mental healthcare resources (ie, limited available facilities and healthcare professionals).²⁹

To summarise, despite the recent global mental health movement of the transition from hospital-centred to

integrated community-based services, comprehensive evidence of psychosocial interventions focusing on community-dwelling individuals with schizophrenia is still lacking. To overcome this gap in the current knowledge, we will perform a systematic review and meta-analysis to assess the efficacy of all types of psychosocial interventions for community-dwelling individuals with schizophrenia when compared with non-active control conditions (eg, treatment as usual and waiting list). We are specifically interested in community-based psychosocial interventions, but it is difficult to define ‘community-based’ or ‘community-setting’ because healthcare/welfare systems and available facilities/services are widely varied across countries. Thus, we decided to focus only on psychosocial interventions that target community-dwelling individuals with schizophrenia (eg, outpatient, day care and outreach settings) and that cover all intervention settings/contexts except inpatient settings. We will allow studies from both high-income and low-income to middle-income countries. A better understanding of the meta-analytic efficacy of these psychosocial interventions would be important for clinical practice and for planning meaningful mental healthcare resource allocation.

This review focuses on quality of life and hospital admission as primary outcome measures. We set our key outcome measures based on the standard set of outcomes for psychotic disorders, defined by an international group of leading psychiatrists, psychologists, mental health experts, measurement experts and lived experience experts (International Consortium for Health Outcomes Measurement (ICHOM)).³⁰ The belief that ‘recovery’ is a key concept in mental health policy across different settings is now gaining wide acceptance around the world. In the ICHOM’s standard outcome set,³⁰ the domain of ‘recovery’ consists of two key outcomes: quality of life and personal recovery. Among these two outcomes, we focus on quality of life as a primary outcome because: (1) quantitative research assessing personal recovery is rapidly increasing,^{31–33} but a limited number of studies are available that used personal recovery as an outcome to evaluate community-based psychosocial interventions (quality of life is the most frequently used outcome);³⁴ and (2) quality of life is the most strongly associated enabling factor for personal recovery in the community setting.³⁵ We also focus on hospital admission as the other primary outcome because: (1) this outcome is also included in the ICHOM’s outcome set;³⁰ (2) preventing or reducing hospital admission is one of the key aims (targeted outcomes) in most community-based psychosocial interventions for schizophrenia;²² and (3) hospital admission is one of the commonly-used outcomes for evaluating community-based interventions/services in previous studies.³⁴

METHODS AND ANALYSIS

This systematic review and meta-analysis has been developed according to the Preferred Reporting Items for

Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines,³⁶ and the study protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42021266187). The PROSPERO record will be updated with any amendments/revisions made.

Types of studies

All relevant RCTs, including cluster RCTs, will be included. We will accept open and blinded RCTs. This choice is particularly relevant in trials on psychosocial interventions, in which only the outcome assessor can be blind but not the providers or participants (ie, Prospective Randomised Open, Blinded End-point trials). In the case of cross-over studies, we will use only the first cross-over phase. Where people are given additional treatments as well as psychosocial intervention plus standard care, we will only include data if the adjunct treatment is evenly distributed between groups, and it is only the psychosocial intervention that is randomised. We will include studies from both high-income and low-income to middle-income countries.

Types of participants

Community-dwelling individuals aged 18 years or older with a primary diagnosis of schizophrenia or related disorders, including schizophreniform disorder, schizoaffective disorder and delusional disorder, will be considered. Any version of the International Classification of Diseases, Diagnostic and Statistical Manual of Mental Disorders, Research Diagnostic Criteria, Feighner criteria, as well as clinical judgement are accepted.

We will not include participants deemed to be ‘at-risk’ of developing schizophrenia and who have a developmental impairment, intellectual disability or organic psychosis. Studies including participants diagnosed with other mental disorders will be included only if: (A) data on participants with a diagnosis of schizophrenia or related disorders can be extracted separately or (B) participants with a diagnosis of schizophrenia or related disorders constitute more than 80% of the participants in each arm.

Types of interventions and comparators

We will include any psychosocial intervention as long as it targets community-dwelling (ie, non-hospitalised) individuals with schizophrenia and related disorders. Psychosocial interventions are defined as any structured intervention focusing on individuals’ psychological and/or social factors as opposed to biological factors (eg, pharmacological intervention). We will consider the nodes for the psychosocial interventions displayed in online supplemental appendix 1. However, we expect a huge number of studies and categories of interventions to be included. If we find interventions of interest that do not fit in the prespecified nodes, we will define an additional category ‘Other’ or add new categories if there are a sufficient number of studies.

Interventions could be implemented through a range of modes (eg, face to face, telephone, internet delivered). Psychosocial interventions may also target just individuals with schizophrenia, or schizophrenic individuals and their partners/family members. Unguided self-help interventions at home (eg, self-help books and online self-help programmes) will also be allowed. Interventions that take place in inpatient settings will be excluded. Interventions that take place in both inpatient and other settings will be included only if the interventions that take place outside of inpatient settings constitute more than 80% of the total sessions or the intervention period. We will accept any cointervention to psychosocial intervention only if there is a comparison group that received the cointervention alone, regardless of whether the cointervention is active or non-active. No limit is set for the study duration or number of sessions provided in an intervention.

Comparators (ie, control conditions) will include treatment as usual, waiting list, as well as non-active interventions (eg, psychological placebo). As for psychological placebo, it is regarded as those interventions intended to control for non-specific aspects of the intervention by the researchers (eg, befriending, recreation and support, social activity therapy and supportive counselling). When treatment as usual is used as a waiting list, we will classify this condition as a waiting list. Cointervention alone will be classified as treatment as usual. Examples of appropriate designs are as follows:

- ▶ Psychosocial intervention versus control (treatment as usual; waiting list; non-active interventions).
- ▶ Psychosocial intervention plus medication versus medication.
- ▶ Psychosocial intervention A plus psychosocial intervention B versus psychosocial intervention B.

Types of outcome measures

Primary outcomes

1. Quality of life, as measured using a validated clinical instrument (eg, the WHO Quality-of-Life Scale, the Medical Outcomes Study Short-Form, EuroQoL, the Centers for Disease Control and Prevention Health-Related Quality of Life, the Flanagan’s Quality of Life Scale, Heinrich’s Quality of Life Scale and the McGill Quality of Life Questionnaire). If an identified study does not measure quality of life, we will use a validated clinical instrument measuring ‘well-being’, which has closely related constructs with quality of life (eg, the WHO Well-Being Index, Warwick-Edinburgh Mental Well-being Scale and Quality of Well-Being Scale).²⁷
2. Proportion of psychiatric hospital admission.

Primary outcomes will be divided into short term (6 months or less), medium term (seven to 12 months) and long term (over 12 months). If multiple time points are given, we will use those points closest to 6 months (for short term: primary time point), 12 months (for medium term), and 24 months (for long term).

Secondary outcomes

1. Personal recovery, as measured using a validated clinical instrument (eg, the Recovery Assessment Scale and the Questionnaire about the Process of Recovery).
2. Overall functioning, as measured using a validated clinical instrument (eg, the Global Assessment of Functioning and the Psychosocial Performance Scale).
3. Overall psychotic symptoms, as measured using a validated clinical instrument (eg, the Positive and Negative Syndrome Scale and the Brief Psychiatric Rating Scale).
4. Positive symptoms, as measured using a validated clinical instrument (eg, positive symptom subscale of the Positive and Negative Syndrome Scale, positive symptom subscale of the Brief Psychiatric Rating Scale and the Scales for Assessment of Positive Symptoms).
5. Negative symptoms, as measured using a validated clinical instrument (eg, the Clinical Assessment Interview for Negative Symptoms, the Brief Negative Symptom Scale, negative symptom subscale of the Positive and Negative Syndrome Scale, negative symptom subscale of the Brief Psychiatric Rating Scale and the Scales for Assessment of Negative Symptoms).

6. Tolerability, defined as the proportion of participants experiencing severe adverse events (eg, deaths, attempts at suicide, suicide ideation and serious violent incidents).
7. Acceptability, defined as the proportion of premature discontinuation (dropout rate) for any reason.

For secondary outcomes, we will use outcomes collected at the given endpoint of each study. If multiple time points are set, we will use those points that are 6 months or less and the closest to 6 months.

Search strategy

The following sources will be searched without restrictions for language or publication period: Embase, PubMed, PsycINFO, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL), ClinicalTrials.gov and WHO International Clinical Trials Registry Platform. [Table 1](#) presents an example of a search strategy for PubMed (see online supplemental appendix 2 for a full search strategy in different databases). The date of the last search update will be provided in the final publication.

We will also try to identify other potentially eligible studies or ancillary publications by searching the

Table 1 An example of a search strategy for PubMed

Line	Query
#1	"schizophrenia spectrum and other psychotic disorders"(MeSH Terms] OR "schizo"(Title/Abstract)OR "psychotic"(Title/Abstract)OR "psychosis"(Title/Abstract)OR "psychoses"(Title/Abstract)
#2	"psychotherapy"(MeSH Terms] OR "psychoanalysis"(MeSH Terms] OR "counseling"(MeSH Terms] OR "community mental health services"(Mesh Terms] OR "psychiatric rehabilitation"(Mesh Terms] OR "acceptance and commitment therap"(Title/Abstract)OR "assertive communit"(Title/Abstract)OR "behavior modificat"(Title/Abstract)OR "behavior regulat"(Title/Abstract)OR "behavior therap"(Title/Abstract)OR "behaviour modificat"(Title/Abstract)OR "behaviour regulat"(Title/Abstract)OR "behaviour therap"(Title/Abstract)OR "behavioral modificat"(Title/Abstract)OR "behavioral regulat"(Title/Abstract)OR "behavioral therap"(Title/Abstract)OR "behavioural modificat"(Title/Abstract)OR "behavioural regulat"(Title/Abstract)OR "behavioural therap"(Title/Abstract)OR "cognitive behavio"(Title/Abstract)OR "cognitive intervent"(Title/Abstract)OR "cognitive rehabilitat"(Title/Abstract)OR "cognitive remediat"(Title/Abstract) OR "cognitive technique"(Title/Abstract)OR "cognitive therap"(Title/Abstract)OR "cognitive treatment"(Title/Abstract) OR "compassion focused"(Title/Abstract)OR "conversational therap"(Title/Abstract)OR "conversion therap"(Title/Abstract)OR "counseling"(Title/Abstract)OR "counselling"(Title/Abstract)OR "emotion focused"(Title/Abstract)OR "emotionally focused"(Title/Abstract)OR "emotional focused"(Title/Abstract)OR "exposure therap"(Title/Abstract)OR "family intervent"(Title/Abstract)OR "family therap"(Title/Abstract)OR "group intervent"(Title/Abstract)OR "group therap"(Title/Abstract)OR "meditation"(Title/Abstract)OR "metacognitive therap"(Title/Abstract)OR "metacognitive training"(Title/Abstract)OR "meta-cognitive therap"(Title/Abstract)OR "meta-cognitive training"(Title/Abstract)or "mindfulness"(Title/Abstract)OR "morita therap"(Title/Abstract)OR "narrative therap"(Title/Abstract)OR "problem solv"(Title/Abstract)OR "psychoanaly"(Title/Abstract)OR "psychodynamic"(Title/Abstract)OR "psychoeducat"(Title/Abstract)OR "psychological treatment"(Title/Abstract)OR "psychological intervent"(Title/Abstract)OR "psychosocial treatment"(Title/Abstract)OR "psychosocial intervent"(Title/Abstract)OR "psychotherap"(Title/Abstract)OR "socioenvironmental therap"(Title/Abstract)OR "social skills training"(Title/Abstract)OR "supportive therap"(Title/Abstract)OR "psychiatric rehabili"(Title/Abstract)OR "psychosocial rehabili"(Title/Abstract)OR "token economy"(Title/Abstract)OR "peer support"(Title/Abstract)OR "peer deliver"(Title/Abstract)OR "supported employment"(Title/Abstract) OR "crisis plan"(Title/Abstract)OR "wellness recovery action planning"(Title/Abstract)OR "illness management"(Title/Abstract)OR "refocus"(Title/Abstract)OR "individual placement and support"(Title/Abstract)OR "supported housing"(Title/Abstract)OR "open dialogue"(Title/Abstract)
#3	"randomized controlled trials as topic"(MeSH Terms] OR "controlled clinical trial"(Publication Type] OR "random"(Title/Abstract)OR "RCT"(Title/Abstract)or "control"(Title/Abstract)OR "trial"(Title/Abstract)OR "condition"(Title/Abstract)
#4	#1 AND #2 AND #3
#5	#4 NOT ("animals"(MeSH Terms] NOT "humans"(MeSH Terms))

reference lists of included studies, other relevant systematic reviews and grey literature (OpenGrey).

Screening and data extraction

Screening

All search results will be catalogued using EndNote. After removing duplicates, screening and selection of studies will be managed using Rayyan. Eligibility of each study will be determined with the aid of a two-step screening procedure. First, screening of titles and abstracts will be conducted. Second, full-text screening of studies selected in the first screening will be performed. Both the first and second screenings will be performed by two independent, blinded reviewers. We will include studies that both reviewers judge to be 'included'. Prior to the formal screening, our review team will work together to screen a small sample of studies to ensure accuracy and consistency among reviewers. If both reviewers disagree even after discussion, we will consult another reviewer to make a decision. If there are any uncertainties about eligibility for this study, we will ask the authors of the original studies to provide further information. Details of selection process will be presented in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart.

Data extraction

Two reviewers will independently extract data from each selected study using a predesigned form in Microsoft Excel. The following data will be extracted from each included study:

- ▶ Publication information: author's name and publication year.
- ▶ Study characteristics: country in which the study was conducted, study design (type of RCT), number of arms, number randomised to each arm and randomisation method.
- ▶ Participant demographics: mean age, proportion of female/male, proportion of ethnicity, proportion of first-episode cases, details on diagnosis and method of diagnostic assessment.
- ▶ Intervention/comparator characteristics: type of intervention (eg, social skills training and cognitive behavioural therapy), setting/context (outpatient clinic, other facilities, home or combination), format (individual, group or combination), intensity and type of contact/support (therapist led and self-help (no contact/support) or combination; face to face, remote (eg, telephone, email and internet) or combination), inclusion of intervention for partners/family members, expertise of therapist (eg, doctor, nurse and psychologist), intervention dose (number and frequency of sessions/contacts, time span of the intervention), type of comparator (non-active intervention (eg, treatment as usual), waiting list or other non-active interventions (eg, psychological/pill placebo)).
- ▶ Outcome measures: primary and secondary outcomes specified and collected, method of collection

(self-reported or assessor-rated) and time points reported.

- ▶ Others: potential conflicts of interest and funding agencies.

Before extracting data, a calibration exercise will be undertaken to ensure accuracy and consistency among reviewers. If there is any discrepancy between reviewers even after discussion, we will consult another reviewer in order to reach consensus. If needed, we will ask study authors to obtain additional data and/or further clarification.

Risk of bias assessment

The risk of bias for the included studies will be assessed with Revised Cochrane Risk-of-Bias Tool for Randomised Trials (RoB 2). Two reviewers will independently assess the following bias domains:

- ▶ Bias arising from the randomisation process.
- ▶ Bias due to deviations from intended interventions.
- ▶ Bias due to missing outcome data.
- ▶ Bias in measurement of the outcome.
- ▶ Bias in selection of the reported result.
- ▶ Other biases.

Assessments will be classified into three levels according to the quality classification standards: low risk, some concerns and high risk of bias. Any disagreements/discrepancies will be resolved through discussion. If necessary, we will contact the study authors for further information. Effects of studies with a high risk of bias in the overall domain will be evaluated by sensitivity analyses.

Strategy for data synthesis and statistical analysis

Characteristics of the included studies

We will produce descriptive statistics and study population characteristics across all included studies, describing the types of comparisons and other clinical or methodological variables mentioned previously.

Measurement of intervention effect

The extracted data will be synthesised into a meta-analysis where possible. We will perform standard pairwise meta-analyses with a random-effects model for every comparison with at least two studies. Statistical analysis will be carried out using the Cochrane Collaboration's Review Manager (RevMan) software (V.5.4 for Windows). Acknowledging heterogeneity in psychosocial interventions for schizophrenia, we will perform random effects meta-analyses for each intervention type separately. For continuous outcomes (quality of life, personal recovery, overall functioning, overall psychotic symptoms and positive/negative symptoms), standardised mean differences with 95% CIs will be calculated. For dichotomous outcomes (eg, hospital admission, severe adverse events and premature discontinuation), risk ratios with 95% CIs will be calculated. The data for each meta-analysis will be presented in a forest plot.

Dealing with missing data

We will assess levels of attrition for included studies and conduct sensitivity analysis of the impact of including

studies with missing data of 20% or more. For all outcomes, we will conduct intention-to-treat analysis wherever possible.

Assessment of heterogeneity

Heterogeneity will be evaluated by using the inconsistency index (I^2) statistic to describe the percentages of total variation across studies ($I^2 \leq 50\%$ =low; $I^2 > 50\%$ =moderate to high). Where appropriate for pooling effect sizes, a fixed-effects model will be used when heterogeneity is low, and a random-effects model will be used when heterogeneity is moderate to high. If any substantial heterogeneity is observed, we will perform further subgroup analysis.

Assessment of publication bias

If a sufficient number of studies (10 or more) are eligible for meta-analysis, funnel plots will be used to assess reporting bias.

Analysis of subgroups or subsets

If any substantial heterogeneity is identified, the following potential effect moderators of primary outcomes will be explored by subgroup analyses:

- ▶ Intervention setting/context (facility-based (eg, outpatient clinic) vs others (eg, home)).
- ▶ Intervention format (individual vs group).
- ▶ Intensity of contact/support (therapist led vs self-help (no contact/support)).
- ▶ Mean age of participants (aged ≤ 35 versus > 35 years).
- ▶ Country categories (high-income vs low-income to middle-income countries (based on World Bank income group)).

If possible, we will perform some extra subgroup analyses according to the results of heterogeneity and inconsistency. Subgroup differences will be assessed by interaction tests. The results of subgroup analyses will be reported quoting the I^2 statistic and p value, and the interaction test I^2 value.

We also plan to perform sensitivity analysis on primary outcomes to observe the effects of excluding studies with high risk of bias in the overall domain, studies focused on first episode cases and studies focused on treatment-resistant cases.

Assessment of the confidence in cumulative evidence

The Grades of Recommendation Assessment, Development and Evaluation (GRADE) approach will be used to rate the overall evidence. Data will be imported from RevMan to the GRADE profiler (GRADEpro) software to produce 'summary of findings' tables. These tables will provide key information regarding evidence quality, intervention effect and a summary of available data on the outcome variables. The quality of the body of evidence will be assessed based on five factors: study limitations, consistency of effect, imprecision, indirectness and publication bias. Assessments will be judged/categorised as 'high', 'moderate', 'low' and 'very low'.

ETHICS AND DISSEMINATION

This study will consist of secondary analyses of existing anonymous data (ie, primary data will not be collected); hence, no formal ethical review/assessment is required. We plan to disseminate the study findings through conference presentations as well as publications in peer-reviewed journals.

DISCUSSION

There are two key methodological strengths. First, this study will only include relevant RCTs in order to avoid sources of bias that are commonly seen in quasiexperimental clinical trials, particularly when employing pre-post study design without control groups. Second, this study will accept all relevant trials from both high-income and low-income to middle-income countries, without placing restrictions on language of publication. The main strengths listed previously will make the study findings applicable to a wide range of countries, have the potential to inform and influence clinical decision making and serve as a guide for planning meaningful mental health-care resource allocation.

The following methodological limitations must also be taken into consideration. First, we will only include RCTs in our study. Since many low-income to middle-income countries still lack sufficient capacity to conduct RCTs (mainly due to limited available funds, facilities and health-care professionals), evidence from non-RCTs is important in these countries. Case-control studies or even observational studies are also important as they reflect real-world data in the community setting. However, since our study will focus on a wide range of psychosocial interventions and accept all relevant trials from both high-income and low-income to middle-income countries, there is a risk of obtaining too many records and including too many studies in the analysis if we accept non-randomised trials; this would have a serious negative impact on the feasibility of our study. In addition, several existing systematic reviews, focusing on psychosocial interventions for schizophrenia in low-income and middle-income countries have also only accepted RCTs in their analyses.^{28 37} Thus, we decided to limit the scope of our study to RCTs. Nevertheless, when interpreting the results, we need to be aware that the exclusion of non-RCTs may lead to a loss of data from the real world of clinical practice. Second, our secondary outcome regarding negative symptoms will be based on data from validated clinical instruments, but some of the commonly used instruments (eg, negative symptom subscale of the Positive and Negative Syndrome Scale and the Scale for the Assessment of Negative Symptoms) include some aspects not relevant to the current conceptualisation of negative symptoms (blunted affect, alogia, anhedonia, asociality and avolition).² Thus, this study cannot properly assess some of the core symptomatic outcomes, especially negative symptoms.

Findings of this study may be limited by publication bias, study heterogeneity, the measurements used to

assess quality of life (primary outcome) and the methodological quality of included studies. These limitations will be addressed with the RoB 2, and the credibility of the results will be assessed using the GRADE approach.

To the best of our knowledge, this proposed systematic review and meta-analysis will be the first to focus on the efficacy of all types of psychosocial interventions for community-dwelling individuals with schizophrenia and related disorders. Through this review, an overall picture of available evidence on the efficacy of psychosocial interventions in this population will be available. Additional analyses will also identify effective psychosocial interventions for specific populations, intervention types (including delivery methods) and so on, associated with intervention effectiveness. Such findings will serve to augment existing evidence that can inform service users, mental health professionals and policy makers about choices in treatment/care, the development of new interventions and the meaningful allocation of mental healthcare resources for managing community-dwelling individuals with schizophrenia.

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Contributors YS, HT, HI and NY designed the study protocol and drafted the manuscript. HN, FY, TG, YK, AT, HS and YI contributed with clinical and methodological input in planning the protocol. All authors critically revised the draft and contributed to and have approved the final manuscript.

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Competing interests HI has received consulting fees from Mitsubishi-Tanabe Pharma; honoraria for lectures from Mochida Pharmaceutical, Otsuka Pharmaceutical and Kyowa Pharmaceutical. TG has received honorarium for writing from Igaku-Shoin. AT has received honoraria for lectures from Mitsubishi-Tanabe Pharma, Sumitomo Dainippon Pharma and Otsuka Pharmaceutical. HS has received honoraria for lectures/presentations from Pfizer, Sanofi, Alexion Pharmaceuticals, Novo Nordisk Pharma, Sumitomo Dainippon Pharma, JCR Pharmaceuticals, Miyazaki City and Country Medical Association, Children's Cancer Association of Japan and Miyazaki Health Promotion Association; payment for expert testimony from Kyushu Conference for School Physical Examination, Miyazaki City and Country Medical Association and Miyazaki Prefectural Health Foundation; he is a leader of Committee for Growth Charts at School of Miyazaki City and Country Medical Association and Specialist Committee on Newborn Screening Tests of Miyazaki Prefectural Health Foundation. YI has received contracts from Tsumura; honoraria for lectures from Otsuka Pharmaceutical, Sumitomo Dainippon Pharma, Meiji Seika Pharma, Tsumura, Yoshitomyakuin Corporation, Takeda Pharmaceutical, Eisai, Mochida Pharmaceutical, Kyowa Kirin, MSD and Towa Pharmaceutical. NY has received a book royalty from Medical Friend; honoraria for lectures from Gakken Medical Support, Eisai, Meiji Seika Pharma, Mitsubishi-Tanabe Pharma and Mochida Pharmaceutical; honoraria for writings from Igaku-Shoin, Nikkei Business Publications and Maruzen Publishing; he is a Diplomat of

the Academy of Cognitive and Behavioral Therapies, Secretary Board Member of the Japanese Association for Cognitive Therapy and Member of the Japan Clinical Guideline Development Group for Anxiety Disorders and Obsessive-Compulsive Disorder.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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