Scoping review protocol on non-pharmacological interventions for interpersonal and self-directed violence in adults with severe mental illness

Maria Concepcion Moreno-Calvete, Ivan Ruiz-Ibañez, Jose Juan Uriarte-Uriarte

INTRODUCTION

Individuals with severe mental illness “suffer from severe psychiatric disorders together with long-term mental disturbances, which entail a variable degree of disability and social dysfunction, and must be cared for by means of different social and health resources of the psychiatric and social healthcare network”. The conditions from the International Classification of Diseases, 10th Revision (ICD-10) included in severe mental illness are: schizotypal disorders, persistent delusional disorders, other non-organic psychotic disorders, other non-organic psychotic disorders, bipolar disorder, major depressive episode with psychotic features, recurrent major depressive disorders and compulsive obsessive disorder. Evidence shows an association between mental illnesses, such as schizophrenia and related disorders, and increased rates of convictions for a violent offence, suicide and premature mortality.

The WHO defines violence as “the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation”. The relationship between severe mental illness and violent behaviour is more complex.

METHODS AND ANALYSIS

This is a scoping review protocol. The review will include any randomised controlled trials (RCTs) and cluster RCTs that assess the efficacy of interventions on self-directed or interpersonal violence with no restrictions on the control treatment in people with severe mental illness in any setting. No restrictions will be applied in terms of language or date of publication. To identify studies, a search will be performed in the following databases: Embase, MEDLINE (via PubMed), PsycINFO, CINAHL, LILACS, SciELO, Cochrane Library, Web of Science, Scopus, ProQuest, Epistemionikes and databases of clinical trials. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement will be followed for reporting the findings, including the use of a PRISMA flow diagram. A standardised form will be used to extract data from studies. The findings will be classified using conceptual categories that will be specified in detail and a descriptive summary of the main results will be created. Moreover, it will be assessed whether the studies identified have been included in systematic reviews or meta-analyses and the results will be used to generate a conceptual map.

ETHICS AND DISSEMINATION

No patients or other participants will be involved in this study. We will prepare a manuscript for publication in a peer-reviewed journal and the results will be presented at mental health conferences.

ABSTRACT

Introduction Violence committed by people with mental illness has implications for mental health policy and clinical practice. Several strategies to reduce the risk of aggressive and violent behaviour have been proposed, and these include non-pharmacological interventions. There is, however, a need to identify which of these interventions are effective, and as a first step, we will conduct a scoping review to identify non-pharmacological interventions for self-directed or interpersonal violence in adults with severe mental illness across different conditions and settings.

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than it seems.\textsuperscript{6} In the USA, it has been found that while approximately 2% of the general population had perpetrated violence, the figure was as high as 7% to 8% among people with severe mental illness.\textsuperscript{2} Specifically, the prevalence rates of violence in psychiatric patients ranged from 2.3% to 13.0% in outpatients and from 16.0% to 23.0% during hospitalisation.\textsuperscript{8}

On the other hand, a high level of mental disorders has been found among prisoners with convictions for violent or non-violent crimes. Some studies in prison populations have suggested that the prevalence of psychosis is 1.8% to 3.7% and of major depression is 11.4% to 14.7%, while obsessive-compulsive disorder was diagnosed in 0.3%.\textsuperscript{3-11} Additionally, mental disorders have been associated with suicide risk and violence in prisoners.\textsuperscript{12,13}

A systematic review revealed that over 96% of offenders with severe mental illness convicted of homicide had psychiatric symptoms at the time of the crime and several risk factors have been associated with violence in people with schizophrenia such as substance abuse, insight, impulsiveness, psychopathy, motor speed, a global measure of cognition, baseline injurious violence and medication non-adherence.\textsuperscript{14-16} In addition to this, violence is associated with a history of violent victimisation and recent violent victimisation, and hence, victimisation could contribute to violence.\textsuperscript{16,17}

Despite the relationship between victimisation and violence, and the prevalence of victimisation being higher than that of violence in people with severe mental illness, the focus of the society is often on the violence.\textsuperscript{18,19} A study showed that the narratives about severe mental illness and violence increase the stigma, and the public is frequently exposed to portrayals of severe mental illness and violence in news media.\textsuperscript{20,21}

Further, the lifetime suicide risk for people with schizophrenia is estimated at about 4.9%.\textsuperscript{22} Risk factors implicated in suicide in people with schizophrenia include affective symptoms, history of a suicide attempt and number of psychiatric admissions, younger age, closeness to illness onset, older age at illness onset, male sex and substance abuse, while the period during or following psychiatric discharge has been identified as a high-risk time.\textsuperscript{23} Notwithstanding that suicide and interpersonal violence are not the same phenomena, they are observed together in people with schizophrenia, and offenders with psychosis who were at risk of suicide and violence had a history of more suicide attempts and more convictions for violent offences.\textsuperscript{24,25}

Several studies on pharmacological and non-pharmacological interventions have been found but there is heterogeneity in interventions, and no scoping review identifying the evidence on these interventions has been reported. Concerning pharmacological treatments, studies on interpersonal violence have focussed on treatments such as long-acting injectable antipsychotics, antipsychotic polypharmacy, high-dose monotherapy or antipsychotic dosage and studies on pharmacological interventions for self-directed violence have been related to treatments such as clozapine, lithium or anticonvulsants.\textsuperscript{26-31}

Regarding non-pharmacological interventions on interpersonal violence, several studies have evaluated interventions in various settings such as structured short-term risk assessment, cognitive-behavioural therapy, involuntary outpatient commitment, a community-based integrated intervention, integrated treatment plus assertive community treatment and metacognition-oriented social skills training.\textsuperscript{32-37} On the other hand, several studies have assessed non-pharmacological interventions on self-directed violence including cognitive-behavioural suicide prevention, ‘housing first’, a cognitive behavioural therapy worry-reduction intervention and psychoeducation.\textsuperscript{38-41}

A systematic review was conducted related to non-pharmacological interventions on interpersonal violence in people with severe mental illness;\textsuperscript{42} however, it did not include all diagnoses of severe mental illness, the search was limited in terms of language and databases and the search period was until June 2015, and hence, it does not consider more recently published studies such as those of Kang et al, Inchausti et al, Kingston et al.\textsuperscript{35,37,42} Additionally, an umbrella review was performed of interventions in general and forensic psychiatry on violence prevention.\textsuperscript{44} Nonetheless, this review is not focussed on severe mental illness and intervention studies included non-randomised as well as randomised controlled designs. No similar systematic reviews have been found related to non-pharmacological interventions on self-directed violence in the context of interest.

The intervention strategies for interpersonal and self-directed violence in people with severe mental illness vary across studies. In this situation, that is, when the body of knowledge is heterogeneous, scoping reviews allow assessment of the extent of the evidence on a topic and the value of conducting a systematic review or an overview of systematic reviews to summarise findings.\textsuperscript{45}

**Rationale**

The association between mental illness and interpersonal or self-directed violence has significance from a public health perspective and implications for mental health policy and clinical practice.\textsuperscript{6,8,46} Interpersonal violence is the factor with the most negative influence on the general population’s view of mental illness and one of the main contributors to the associated stigma.\textsuperscript{6} Denial of this association is not the best way for mental health practitioners to deal with the problem and hinders the setting up interventions for preventing and tackling violence in this context. Furthermore, the role of mental illness in suicide requires an effort to strengthen mental health care to prevent suicide in this population.\textsuperscript{47}

A combination of pharmacological and non-pharmacological treatment is necessary to manage interpersonal and self-directed violence in people with severe mental illness.

This review will be focussed on non-pharmacological interventions for interpersonal and self-directed violence.
in people with severe mental illness in any setting. The complexity and heterogeneity of non-pharmacological interventions on interpersonal and self-directed violence for people with severe mental illness, the existence of new evidence, the relevance of this topic and the absence of a scoping review warrant this study as the first step to decide whether it is necessary to conduct a systematic review or an overview of systematic reviews on this topic.

This study may be of interest to mental health practitioners and in particular might help in clinical practice by increasing the knowledge of strategies for interpersonal and self-directed violence in this population. Regarding future research, this scoping review will describe current research and provide information for designing additional studies or related projects such as a systematic review or overview. In the case of a lack of evidence, the information could stimulate research on this topic. On the other hand, in the case of finding RCTs and cluster RCTs included in systematic reviews, it would suggest the need to carry out an overview to synthesise the evidence from the systematic reviews while the absence of systematic reviews would suggest the need for a systematic review on this topic.

Objectives
This study aims to identify and describe non-pharmacological interventions for self-directed or interpersonal violence in people with serious mental illness in any setting.

Additionally, we will investigate whether each intervention found has been included in any systematic reviews or meta-analyses to decide whether it is necessary to conduct a systematic review or an overview of systematic reviews on this topic.

Review questions
What kinds of non-pharmacological interventions for self-directed or interpersonal violence in people with severe mental illness have been studied in any setting?

What are the durations, frequencies, settings and timings of non-pharmacological interventions for self-directed or interpersonal violence in people with severe mental illness?

What are the effects of these non-pharmacological interventions for self-directed or interpersonal violence described in the literature?

Which studies have been included in a systematic review/meta-analysis?

METHODOLOGY
Protocol design and registration
This protocol was developed considering the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) 2015 guidelines, with recommended material being included as indicated in online supplemental file 1. It has been registered with the Open Science Framework (https://osf.io/d56a2/).

Eligibility criteria
Studies will be selected using population, concept and context criteria:

Population
Inclusion criteria: adults with a diagnosis of severe mental illness or any condition included in severe mental illness: schizophrenia, schizoaffective disorder, bipolar disorder, obsessive-compulsive disorder, major depressive episode with psychotic features, recurrent major depressive disorders, atypical psychosis or other non-organic psychosis. Exclusion criteria: Instrumental treatments or brain stimulation treatments such as electroconvulsive therapy, transcranial direct current stimulation or transcranial magnetic stimulation.

Concomitant pharmacological interventions will be allowed, if they are administered in the same way in all study groups (intervention and control groups).

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Comparisons of interest: All interventions included will need a comparison group. The control treatment may be another treatment, placebo or treatment as usual for interpersonal or self-directed violence (‘treatment as usual’ being defined as the normal level of care provided in the area in which the study has been performed).
The outcomes of interest are:

**Main outcomes**

**Violent behaviour**
- Interpersonal violence: Physical or verbal aggression, physical or verbal threats, psychological or emotional abuse, criminal activity or property damage.
- Self-directed violence: Self-harm, suicide attempt or completed suicide.

**Additional outcomes**
- Agitation behaviour.
- Substance use: Drug use or alcohol use.
- Illness severity:
  - Psychiatric symptoms.
  - Functioning.
- Use of physical restraints or seclusion.
- Use of medication in an emergency.

The studies should include violent behaviour (interpersonal or self-directed violence) as an outcome to be included in the scoping review.

**Context elements**

This study will include any RCTs or cluster RCTs that assess the efficacy of non-pharmacological interventions on interpersonal or self-directed violence in people with severe mental illness in any setting. No restrictions will be applied on the control treatment (another treatment, placebo or treatment as usual) or in terms of language or date of publication.

**Information sources and search strategy**

The primary systematic literature searches will be conducted using a carefully designed search strategy. The combinations of keywords and search terms will be adapted for use with other databases in combination with database-specific filters, where these are available. The following electronic databases will be searched: Embase, MEDLINE (via PubMed), PsycINFO, CINAHL, LILACS, SciELO, Cochrane Library (the Cochrane Central Register of Controlled Trials(CENTRAL) and Cochrane Database of Systematic Reviews), Web of Science, Scopus, ProQuest, Epistemonikos and clinical trial databases (www.controlled-trials.com, www.ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform), among others. Further, the studies included in the clinical practice guidelines of various national health systems and the references of studies included will be reviewed to identify additional articles of interest. RefWorks reference management software will be used to manage the articles.49

As an example, the search strategy to be used on Web of Science is:

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TI=(schizophrenia OR schizophren* OR psychotic disorders OR psycho* OR schizoaffecive OR schizotypal personality disorder OR schizotyp* OR delirium OR severe mental illness OR severe mental disorder OR mental disorders OR bipolar and related disorders OR bipolar disorder* OR manic-depressive OR manic
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depressive OR bipolar affective OR mania* OR manic disorder OR obsessive-compulsive disorder OR obsessive-compulsive OR anankastic OR depressive disorder, major OR major depressi* OR diagnosis, dual (psychiatry) OR psychiatric dual OR dual diagnosis) AND TI= (violence OR violen* OR aggression OR agressi* OR damage OR prison* OR offens* OR suicid* OR self-harm OR self-injur*) AND TI= (randomized controlled trial OR controlled clinical trial OR randomized OR placebo OR randomly OR trial).

Further, a search will be performed to determine whether or not the RCTs and cluster RCTs selected for the scoping review have been included in systematic reviews. The information gathered from this process will contribute to the assessment of whether what is required subsequently is a systematic review, analysing data from primary studies which have not previously been included in any systematic reviews or an overview of systematic reviews, if numerous such reviews have already been carried out.

**Study selection and data extraction process**

The titles and/or abstracts of studies retrieved using the search strategy, and those from other sources, will be screened independently by two review authors (MCM and IR) to identify studies that potentially meet the inclusion criteria outlined above. Full texts of potentially eligible studies will then be retrieved and independently assessed for inclusion/exclusion by the same two authors, and any disagreements will be resolved through discussion and consensus. A standardised form will be used to extract data from the studies identified for final inclusion in the review.

All relevant data will be included to answer the scoping review questions. The information to be charted during the process will include: authors; publication year; country; study design; study population; settings; aim; details of the intervention and the control conditions; outcomes and times of measurement; findings and other relevant information. Two review authors (MCM and JJU) will extract the data independently; any discrepancies will be resolved through discussion and consensus. Any data found to be missing in the report of the studies, such as information about outcomes of interest or the population or any other information relevant to the scoping review will be requested directly from the study authors.

According to the scoping review’s methodology, the aim is to identify and describe the evidence; therefore, the quality of individual studies will not be assessed.

**Data synthesis and reporting of findings**

A descriptive summary of the main results will be reported. The results will be classified under conceptual categories such as author(s), year of publication, place or country where the study was conducted, study design, aim, study population, setting, description of the intervention and the control conditions, outcomes and details of key findings. Intervention subgroups will be assessed.
and a conceptual map will be generated with the findings. A PRISMA flow diagram will be created to illustrate the progress of studies through the selection process and screening (indicating the results from the search, removal of duplicate citations, and so on).

**Limitations**

Despite this being a scoping review on a complex and broad topic, violence is a very specific topic and we may find only a very small number of the studies. To maximise the number of publications found, several databases will be searched and no restrictions will be applied in terms of language or date of publication.

Another potential limitation is that the quality of the evidence will not be assessed. This is because it is to be a scoping review, the objective of which is not to conduct a critical appraisal but rather to identify and describe non-pharmacological interventions. Nonetheless, this scoping review will describe current research and provide information on which to base future research, especially related work such as a systematic review or an overview. Indeed, it will provide information to help decide whether to conduct a systematic review or an overview.

**Patient and public involvement**

No patients or other participants will be involved in this study.

**ETHICS AND DISSEMINATION**

This study does not require ethics approval. This scoping review will contribute to improve our understanding of violent behaviour in people with severe mental illness. A manuscript for publication in a peer-reviewed journal will be prepared and the results will be presented at mental health conferences.

**Contributors**

MCM was the major contributor in writing the manuscript. JUJ and JR critically revised the content and contributed to the manuscript. All authors gave their final approval of the version to be published.

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**Competing interests**

None declared.

**Patient consent for publication**

Not required.

**Provenance and peer review**

Not commissioned; externally peer reviewed.

**Open access**

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**ORCID iD**

Maria Concepcion Moreno-Calvete http://orcid.org/0000-0001-9712-2319

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