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Protocol

A multicomponent intervention to reduce internalized stigma in persons with a diagnosis of severe mental disorder: protocol of a pilot randomized mixed trial

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ABSTRACT

Background: People with mental disorders face stigma as a social obstacle in multiple areas of their lives. Therefore, stigma toward this population is a priority for global public health due to its numerous consequences for those affected. One of its manifestations is internalized stigma, which also has severe implications for people with mental disorders. This study presents the protocol of a multicomponent intervention aimed at reducing internalized stigma in people with severe mental disorders.
Methods: The intervention is based on a mixed-method experimental design. The main design is an external randomized pilot trial with two arms, parallel, double-blind, equally randomized, and single-center. Qualitative data before and after the completion of the intervention are included as a secondary component of the main design. The study will be carried out in health service of the secondary level of care in Gran Concepción, Biobío Region, Chile. Twelve people will participate in the qualitative pre-intervention stage and 34 in the intervention stage, 17 in the experimental group, and 17 in the control group. The experimental group will receive the intervention plus the usual treatment, and the control group will only receive the usual treatment. The intervention is carried out in 10 sessions lasting 90 minutes each and is administered by a health service professional.
Conclusions: The study will provide evidence on the acceptability and feasibility of the intervention in the Chilean context, advancing knowledge and understanding in the field.
Trial Registration: The study has been registered with trial registration no. ACTRN12622000919718.

Keywords: Protocol, Multicomponent intervention, Internalized stigma, Mental disorder, Severe mental disorder, Psychiatric diagnosis

INTRODUCTION

People with mental disorders (MDs) often face stigma in multiple spaces of their lives.[1] Internalized stigma is a subjective and self-evaluative process generated because of the interrelation of socio-historical-cultural factors. People with MDs accept as valid for themselves and internalize the negative stereotypes and prejudices that predominate in society; that is, they self-stigmatize, which generates adverse emotional and behavioral reactions and transformations in their identity.[2,3]

Internalized stigma is relevant due to its multiple negative repercussions for stigmatized people, which has been corroborated in Chile.[4-6] Due to its consequences, a variety of interventions have been developed-mainly through randomized clinical trials (RCTs)- aimed at its reduction in people diagnosed with a severe mental disorder (SMD).[7-9]

Interventions can be grouped into six types: psychoeducational, cognitive-behavioral, disclosure-focused, multicomponent, social contact-based, and drama therapy-based.[10-12]

The most common interventions are psychoeducational or those that include some psychoeducational components integrated into the primary strategy.[10] However, cognitive restructuring and social skills training are typical.[12] The most effective interventions are multicomponent ones.[10]

In Latin America, as in Chile, there are few studies on stigma and how to reduce it.[13] Due to this, since stigma is contextual,[14] it is necessary to develop socio-culturally adapted interventions. On the other hand, interventions need a solid theory and methodology to support them, considering the central aspects of the stigmatization process.[15]

When people with a diagnosis of MDs incorporate the negative stereotypes linked to their diagnosis, their identity is negatively affected.[3] However, the literature on internalized stigma does not integrate into existing explanatory models and approaches a formal and validated theory of identity that allows explaining how this transformation occurs and that, in turn, supports interventions.[16] The intervention developed in the present study addresses this gap by incorporating a formal theory of identity applied to that of internalized stigma.

In addition, a few interventions include a preliminary exploratory stage that considers the participants' points of view and the contextual particularities of the internalized stigma. Therefore, there is a need to add qualitative information to the design phase of an intervention to achieve better results.[17] For these reasons, mixed methods in designing and implementing this type of intervention have been recommended.[2]

RCTs are a standard of methodological rigor. However, before its realization, it is recommended to develop a pilot test when there are areas of uncertainty, which would increase the probability of success in terms of feasibility and provide greater validity to the final study.[18,19]

Carrying out a group intervention to reduce internalized stigma in people diagnosed with SMD in Chile poses important challenges: the feasibility and acceptability of its implementation in the health system, its potential effectiveness, and compliance with the intervention protocol. In the country, there is a high demand for individual-focused mental health care, which leaves little time for interventions other than health consultation.[20] In this context, it is convenient to start by implementing a pilot intervention trial, not an RCT.

This research aims to evaluate a multicomponent pilot intervention's feasibility, acceptability, and potential effectiveness in reducing internalized stigma in people diagnosed with SMD. In the qualitative and design stage, the aim is to explore the experiences of internalized stigma from the participants' perspective and to design the multicomponent intervention. The study's primary objectives include assessing the number of people eligible to participate in the intervention, assessing the participants' retention, assessing the fidelity of the intervention's delivery, and exploring its acceptability from the participants' perspective. Secondary objectives are to examine the completeness and explore the acceptability of the data collection instruments from the participant's perspective and evaluate the changes in the clinical outcome measures produced by the intervention. The results will constitute a first and necessary step for the subsequent incorporation of an intervention of these characteristics as part of the country's public health policies.

METHODS

Trial design

For the development of the study, the recommendations of the extension of the CONSORT 2010 declaration for pilot and feasibility tests.[21] An experimental design of mixed methods will be used. The trial was registered with the Australian New Zealand clinical trials registry (ACTRN12622000919718).

The main design will be a randomized pilot trial with two arms (a multicomponent intervention + usual treatment vs. usual treatment), double-blind, equally randomized (1:1), and single-center, because the participants will be selected from the Leonor Mascayano Community Mental Health Center (COSAM, in Spanish), located in Gran Concepción, Biobío Region, Chile (Figure 1).[22] As a secondary component to the main design, qualitative data will be collected in two moments: before the intervention to support its design and after it is completed to explore the fidelity of its administration, its acceptability, and that of the instruments used.

Including the pre-intervention qualitative component will allow an approach and deepening of how internalized stigma is presented in the Chilean context. For its part, the post-intervention evaluation will make it possible to receive feedback from the facilitators and the participants to modify some elements of the study design with a view to a definitive RCT.[23]

Participants

Population

It will comprise people diagnosed with SMD who reside in Greater Concepción, Biobío Region, Chile.

Sample

The sample will be for convenience. Participants from the first qualitative phase will not be included in the

quantitative phase. The second qualitative phase will use the same sample as the quantitative phase.

Inclusion criteria

The following criteria of patients was included - people between 18 and 60 years old; with a diagnosis of SMD confirmed by the treating health team; diagnoses of: schizophrenia, schizotypal disorder, persistent delusional disorder, induced delusional disorder, schizoaffective disorder, non-organic psychoses, non-organic psychoses unspecified, manic episode, bipolar disorder type II, severe depressive episode with psychotic symptoms, recurrent depressive disorder, a severe current episode with psychotic symptoms, or other non-organic psychotic disorders, according to the ICD-11; clinically compensated according to the treating health team; have more than one year of treatment in health centers for the current diagnosis; and ability to consent assessed by a psychologist external to the treating health team using the MacArthur treatment capacity assessment tool (MacCAT-T).[24]

Exclusion criteria

Patients with the following criteria was excluded: the presence of organic deterioration, as indicated by the treating health team, and the presence of comorbidity with substance abuse and dependence; does not include tobacco and alcohol, as indicated by the treating health team.

Qualitative stage

For the initial qualitative stage, a maximum variation sampling will be used; the interview's heterogeneity criteria are diagnosis, sex, and age.[25]

The sample will be 12 people. This amount corresponds to the sample sizes that have used previous qualitative research on the subject (n=9; n=12; n=14).[26-28]

In the second phase of qualitative data collection, the facilitators of the intervention and the total number of participants in the experimental group of the quantitative stage will be interviewed.

Quantitative stage

As a trend, in pilot and feasibility studies, it is unnecessary to carry out formal calculations to establish the required sample size.[18] However, as one of the objectives of this research is to evaluate the potential effectiveness of the pilot intervention, the recommendations offered by Whitehead et al will be followed to calculate the required sample size.[29] Considering a design with a d=0.4, the number of participants per arm for the pilot trial should be 15 for 90% power and 5% two-sided significance.[30] Considering there could be a 10% sample loss, 17 people will be selected for each arm.

Intervention

The intervention was based on an integrative approach to offer an eco-systemic view of internalized stigma. This considers the relationship between identity and internalized stigma in understanding the phenomenon.[31] For this, the identity model of SMDs formulated by Yanos and colleagues, including elements of the situational model of personal response to stigma, of the labeling theory, self-labeling, and modified labeling.[31-35] Likewise, aspects of the moral theory of stigma, the reflex evaluation process, of resistance to stigma with the self-aspects model of identity (SAMI) are articulated.[14,36-38] The SAMI is the theory of identity that supports the intervention. The model considers that through self-interpretation (a socio-cognitive process by which people give coherence and meaning to their experiences and the links they maintain with their context), people build their identity, which acts on the cognitions, emotions, and behaviors of each individual.[38]

The "EncontrándoME" program aims to help people who live with an MD to learn to recognize internalized stigma, identify how it affects them, be able to face it, and develop new ways of thinking and seeing themselves.

The development of the program considered the experience of people with an MD who participated in an in-depth semi-structured interview. In addition, the program was based on the most effective interventions and other intervention programs such as "honest, transparent, proud: to eliminate the stigma of mental illness" by Corrigan and collaborators, "Ending self-stigma" by Lucksted and collaborators, "narrative development and cognitive therapy" by Yanos and collaborators, "program for coping and reduction of internalized stigma" by Díaz and in the "program of self-affirmation and disclosure: an intervention program for the reduction of internalized stigma" of Gonzalez and Muñoz. The program is characterized by combining techniques derived from narrative therapy (narrative development), cognitive-behavioral therapy (cognitive restructuring), as well as others focused on strengthening the facets of personal identity, the re-elaboration of life projects/goals, the resignification of occupations with meaning, education, diversion (positive internal dialogue), the revelation of the mental disorder and enhancing the recovery process.

It is a group program of ten sessions, structured and manualized, administered by a facilitator (health professional). An experienced expert accompanies you in two sessions. Sessions are weekly and last about an hour and a half. It is recommended that the groups be between five and twelve to facilitate group dynamics and the program's effectiveness.

Outcome measures

Two outcome measures will be included, some referring to the feasibility/acceptability such as the rate of recruitment,

retention, the fidelity of the administration of the intervention, the acceptability of the intervention, the completion of the data collection instruments, the acceptability of the data collection instruments, and other clinics such as internalized stigma, self-esteem, hopelessness, recovery, personal empowerment, and MD identity (Table 1).

Procedure

Stage 1: Qualitative (before the intervention)

At this stage, pre-intervention qualitative interviews were conducted, which were recorded and transcribed in full. The accuracy of the transcripts was cross-checked with the recordings by someone external to the researcher.

Stage 2: Design

In this phase, the qualitative results obtained from the interviews were combined with the integrated approach assumed and with the strategies that have shown greater effectiveness in planning and designing relevant activities for the participants.[39]

The first two stages of this study have already been carried out.

Stage 3: Intervention and evaluation

Once the possible participants have been contacted through the health team, they will be evaluated with the MacCAT-T. Those who can consent will be invited to participate in the study.

After recruitment, the initial quantitative evaluation (t1) will be carried out by an external evaluator trained to do so. Clinical measures, sociodemographic and clinical data of the participants, the completion rate of the data collection instruments, and the recruitment rate will be collected.

After the initial evaluation (t1), the participants will be randomly assigned to the experimental and control group (1:1) from a stratified random sampling based on diagnosis.[22]

An independent investigator will perform the randomization process electronically and remain hidden until the study's conclusion. The participants and the evaluator will not know the assignment to the groups (experimental and control), thus being a double-blind study.[22]

The intervention will be applied to the experimental group, who will also receive the usual treatment administered by the treating health team. In contrast, the control group will only have the usual treatment.

It will be ensured that the facilitators of the intervention are professionals who work in the participating health centers to ensure that the study conditions are as close to reality as possible. These will be previously trained, and after each session, they will complete a checklist designed to evaluate fidelity in administering the intervention. In addition, an external observer will complete an observation guideline for 20% of the sessions that are carried out.

Post-intervention evaluation (t2) of clinical outcome measures will be performed up to 7 days after completion of the intervention. Subsequently, a semi-structured interview will be applied to the participants to explore the acceptability of the data collection instruments. An interview with the facilitators will also be conducted to assess fidelity in administering the intervention. On the other hand, information on the completion rate of the data collection instruments and the retention rate will be recorded. Throughout the process, a follow-up and description of the losses and abandonments of the study will be carried out to avoid the so-called follow-up bias.[22]

Data collection, management and analysis

Description of data collection techniques and instruments:

Semi-structured in-depth interview applied to users: it will be used to explore the experiences of internalized stigma in the participants. The thematic script considers the following topics: the beginning of the MD, perceptions about the diagnosis, interaction with other people, disclosure of the diagnosis to others, coping strategies, life goals, and future projections.

Checklist: designed to assess fidelity in the delivery of the intervention. For its design, the fidelity scale described in the intervention manual "Fight against prejudice and discrimination through empowerment by PhotoVoice" by Gagne et al was taken as a reference.

The list contains two sets of items that assess each of the ten program sessions: content and process items. The former is specific to each session, while the process ones are relevant to the implementation of the program in general and practically do not vary between sessions. Items are scored on a 4-point scale.

Observation guideline: designed to assess fidelity in delivering the intervention by an external observer. Two sessions will be randomly selected to be evaluated using the checklist.

Semi-structured interview with the intervention facilitators: it was designed based on the interview used by Toomey et al and aimed to explore the opinions of facilitators about fidelity in the administration of the intervention.[40] It will be consulted for: experiences with the administration; structure and format; a context where it was administered; modifications; future implementation,

and other elements related to the impact of the external observer in some sessions.

Semi-structured interview for the evaluation of acceptability: evaluates the acceptability of the intervention and the data collection instruments from the participants' perspective. The first section will explore elements related to the intervention: structure/format; a context where it was administered; utility; applicability of the contents; benefits; derived consequences; similarity with other interventions; individual experiences with participation; modifications; facilitator; recommendation to third parties and other aspects related to the frequency of application. The second part will investigate factors related to the instruments: instructions, response options; reagents; filling process; length, and administration context.

Internalized stigma of mental illness scale (LA-ISMI): the Latin American version of the instrument designed and validated by Ritsher et al to measure the subjective experience of stigma in people with MDs.[41] It is a Likert-type self-report scale with four response options. This version has 12 items that assess three dimensions: social stigma (5 items), experiences of stigma (4 items), and internalized stigma (3 items). These dimensions explain 68% of the total variance. It presents adequate validity and internal consistency, with Cronbach's Alphas that vary from 0.77 to 0.88.[42]

Rosenberg self-esteem scale (RSES): the original scale was designed to assess the self-esteem of adolescents, but its use has spread to other populations that include people with SMI.[8,9,43] It is a unidimensional self-report instrument composed of 10 items and presented adequate validity and reliability (α=0.754).

Beck hopelessness scale (BHS): it was designed by Beck et al to identify pessimism and negative attitudes towards the future in people with depression and suicidal risk, as well as skills to face difficulties and achieve success in life.[44] It is made up of 20 items that have two response options (true or false). It was validated in Chile and presented good psychometric properties.[45] The Kuder-Richardson-20 reliability coefficient showed a high internal consistency (α=0.86). The scale presented the following four factors: pessimism about the future, expectations towards the future, motivation, and individual perception of the future.

The recovery assessment scale (RAS): is the most used to measure recovery.[46] It is a Likert-type scale with five response options. The Argentine version of the instrument has 21 items grouped into five factors: goals/success orientation and hope, dependence on others; self-confidence; no domination by symptoms, and willingness to ask for help.[47] As this scale is not validated in Chile, it was decided to use the Argentine version due to the cultural similarities between both countries.

The personal empowerment scale (PES): was initially developed by Rogers et al to measure personal empowerment in users of mental health services.[48] It is a 28-item Likert-type scale with four response options. It has five factors: self-esteem/self-efficacy, power/ powerlessness, community activism and autonomy, optimism and control over the future, and justified anger. These factors explain 54% of the variance. Since there are no adaptation and validation studies of this instrument in Chile, it was decided to use the Spanish version, which has adequate validity and high internal consistency.[49]

The scale of self-assessment and reflex assessments of stigmatizing characteristics associated with the identity of the mental disorder (EAER-CEITM): aims to explore how people with a psychiatric diagnosis see themselves and how they think others see them. The scale comprises two subscales, one focused on self-assessment and the other on reflexive assessments. Each one has 11 pairs of semantic differentials representing the positive and negative poles of stigmatizing characteristics associated with the identity of the mental disorder. Cronbach's Alpha of the self-evaluations subscale is 0.837 and 0.932 for the reflex evaluations.[50]

The scale to evaluate the perception of the effectiveness of intervention strategies (EEPEEI): this scale was designed to respond to one of the gaps in interventions to reduce internalized stigma: the non-identification of the differential effects of intervention strategies employed when used together.[30] It is a Likert-type scale composed of 39 items and nine subscales: narrative development, strengthening of facets of personal identity, cognitive restructuring, re-elaboration of life projects/goals, resignification of occupations with meaning, education, deviation-positive internal dialogue, disclosure of the mental disorder and enhancing the recovery process.

Data analysis

Qualitative stage

Semi-structured in-depth interview: a reflective thematic analysis of the interviews will be carried out.[51] The 6-step approach proposed by Braun and Clarke taking into account their most recent re-conceptualizations.[51-53] Thematic analysis has been used to identify "what matters most" that determines the predominant stigma domains in different cultures.[54,55] The principal investigator will carry out the analysis of the interviews. The analyzes will be carried out with the support of the MAXQDA software in its version 22.2 for Mac.[56]

Quantitative stage

Analyses in pilot and feasibility studies should be primarily descriptive or focus on estimating confidence intervals (CIs).[57] In addition, as these are not studies where hypotheses are tested, inferential statistical tests are not proposed, and therefore p values are not reported.[18,21]

Table 1: Outcome measures.

Aim	Result	Measurement
Feasibility and acceptability		
Assess the number of people eligible to participate in the intervention	Recruitment	Recruitment rate: proportion of participants referred by health staff to participate in the intervention who meet the inclusion criteria relative to the number of participants enrolled
Evaluate the retention of participants in the intervention	Retention	Retention rate: proportion of registered participants who attend all sessions of the intervention
Assess fidelity of intervention delivery	Fidelity of the administration of the intervention	Intervention checklist to be completed by facilitators at the end of each session Observation guidelines will be applied to 20% of the sessions by an external observer Semi-structured interview with the facilitators applied after the intervention concluded
Explore the acceptability of the intervention from the perspective of the participants	Acceptability of the intervention	A semi-structured interview will be applied after the intervention ended
Examine the completion of data collection instruments	Completion of data collection instruments	Completion rate of the data collection instruments in the pre- and post-intervention evaluations
Explore the acceptability of the data collection instruments by the participants	Acceptability of data collection instruments	A semi-structured interview will be applied after completing the post-intervention evaluation
Clinics		
Assess changes in clinical outcomes produced by the intervention	Internalized stigma: people with MDs accept as valid for themselves and internalize the negative stereotypes and prejudices that predominate in society; that is, they self-stigmatize.[2,62]	Scores will be obtained based on the Internalized Stigma Scale of Mental Illness (LA-ISMI) in the pre- and post-intervention evaluations.
	Self-esteem: positive or negative feeling towards oneself, which is built from the evaluation of one's own characteristics.[43]	Scores will be obtained based on the Rosenberg Self-Esteem Scale (RSES) in the pre- and post-intervention evaluations.
	Hopelessness: tendency to have negative expectations about oneself and the future.[44]	Scores will be obtained based on the Beck Hopelessness Scale (BHS) in the pre- and post-intervention evaluations.
	Recovery: experience of living successfully considering the limitations of the TM.[46]	Scores will be obtained based on the Recovery Assessment Scale (RAS) in the pre- and post-intervention evaluations.
	Personal empowerment: is constituted by the sense of self-esteem; the belief that one can control one's destiny and life events; the real power with which one counts, as well as community activism and turning powerlessness into action.[48]	Scores will be obtained based on the Personal Empowerment Scale (PES) in the pre- and post-intervention evaluations.
	Mental disorder identity: refers to the positive and negative poles of the characteristics associated with the mental disorder identity	Scores will be obtained based on the self-assessment scale and reflex evaluations of the stigmatizing characteristics associated with the identity of the mental disorder (EAER-CEITM) in the pre- and post-intervention evaluations.

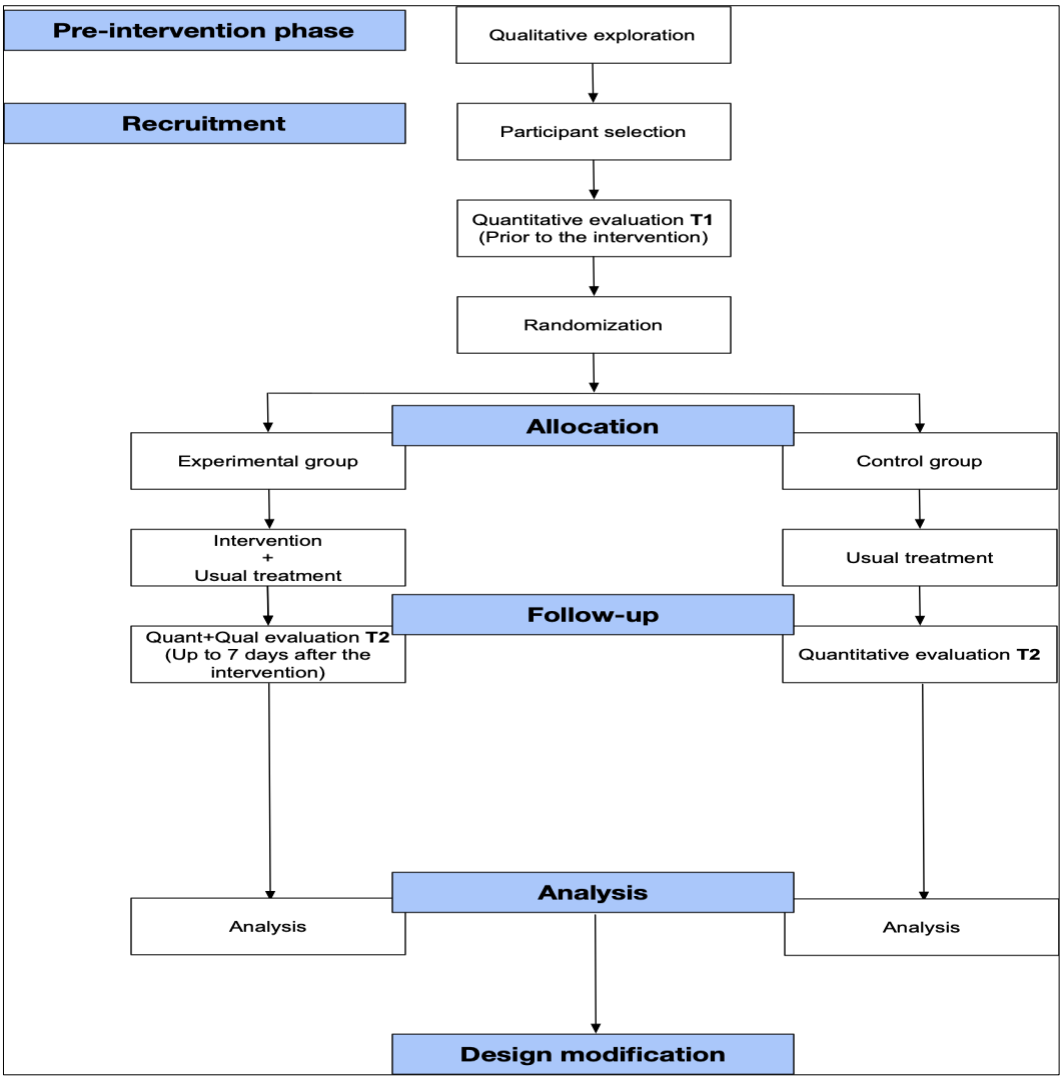

Figure 1: Mixed methods experimental design.

Table 2: Schedule of the stages of the randomized pilot trial.

Moment	Study period				
	Recruitment	Evaluation	Assignment	Intervention	Evaluation
	-t1	t1	0	1	t2
Recruitment					
Selection of participants	X				
Informed consent	X				
Pre-intervention evaluation					
Internalized stigma		X			
Self-esteem		X			
Hopelessness		X			
Recovery		X			
Personal empowerment		X			
Mental disorder identity		X			
Completion rate of data collection instruments		X			
Recruitment rate		X			
Randomization		X			
Assignment			X		

Continued.

Moment	Study period				
	Recruitment	Evaluation	Assignment	Intervention	Evaluation
	-t1	t1	0	1	t2
Interventions					
EncontrándoME+usual treatment				X	
Usual treatment				X	
Post-intervention evaluations					
Fidelity of the administration of the intervention					X
Internalized stigma					X
Self-esteem					X
Hopelessness					X
Recovery					X
Personal empowerment					X
Mental disorder identity					X
Perception of the effectiveness of intervention strategies					X
Acceptability of data collection instruments					X
Completion rate of data collection instruments					X
Retention rate					X
Acceptability of the intervention					X
Fidelity of the administration of the intervention					X

Considering the previous considerations, to answer primary objectives 1, 2, and 3 and secondary 1 of the pilot tests, descriptive analyzes will be used essentially (mean, standard deviation, frequencies, proportions, and percentages), while to answer the secondary objective 3, descriptive statistics (mean, standard deviation and cut-off analysis) and the estimate of the 95% CI for the mean score difference will be used. Intention-to-treat analysis will be used to assess the effects of the intervention.[58]

The statistical package for the social science (SPSS) software will be used in its version 28.0.0.0 for Mac.[59]

Ethics

The study was approved by the ethics, bioethics, and biosafety committee of the Vice President for research and development of the University of Concepción (CEBB 765-2020-M), of the scientific ethics committee of the concepción health service (CEC-SSC: 06-21-31) and by the Health Seremi of the Biobío Region (Exempt Resolution No. 1183), guaranteeing its independent evaluation.[60]

DISCUSSION

The intervention implementation is expected to be feasible in a health center. Likewise, the intervention is likely potentially effective in reducing internalized stigma and increasing hope, self-esteem, empowerment, recovery, and the positive characteristics associated with the identity of the MD of the participants, and that the latter use the tools learned during the sessions in their daily life as coping strategies to internalized stigma.

The evaluation of the implementation of the intervention is an essential first step since it will allow its effectiveness to be tested in a subsequent RCT and thus be transferred to the public health policy of Chile and other countries in Latin America that share cultural aspects.

A possible limitation of the study is that the integrative approach assumed does not have empirical validation of all the relationships between the variables it includes. This could influence the potential effectiveness of some of the strategies proposed to reduce/increase the intensity of some variables.

Therefore, it is suggested to validate the proposed approach based on a structural equation model with the data obtained from the study participants.[61]

CONCLUSION

This study will provide a culturally contextualized intervention to reduce internalized stigma in people with severe mental disorders in Chile, aligned with the demands of the Ministry of Health in terms of practical actions to reduce stigma.

Therefore, it will provide evidence on the acceptability and feasibility of the intervention in the Chilean context, advancing knowledge and understanding in the field. In this way, it constitutes one of the first experiences of this type in Latin America, solving the absence of interventions in low and middle-income countries.

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