Assessment of the effectiveness of a program for the reduction of stigma towards people with severe mental disorders in primary care workers.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/03/2018		[X] Protocol		
Registration date 29/03/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 10/11/2021	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

People with severe mental disorders (SMD) have higher disease and death rates than the general population. Stigma (negative attitudes and perceptions) contributes to an unfairness in the access to health services and a lower quality of assistance in this population. Stigma is translated into negative attitudes, social distance and discrimination towards this social group. For these reasons, healthcare workers are a priority groups for anti-stigma interventions. This study aims to assess the effectiveness of a program specifically designed to decrease negative attitudes and social distance and increase inclusive behaviors of health workers towards people with severe mental disorders.

Who can participate?

Adult health workers from Family Health Centers

What does the study involve?

Participants are randomly allocated by their health centre to one of two groups. Those in the first group receive a program delivered weekly by a psychologist. The program includes education, development of behavior skills and contact with somebody diagnosed with a severe mental disorder.

Those in the second group do not receive any additional program until after the study is finished.

What are the possible benefits and risks of participating?

All participants have the opportunity to learn how to reduce the stigma surrounding people diagnosed with severe mental disorders. There are no identifiable risks for those taking part in the study.

Where is the study run from?

Family Health Center Santa Sabina and 13 other Family Health Centers in Chile

When is the study starting and how long is it expected to run for? March 2017 – December 2018

Who is funding the study?
National Commission for Scientific and Technological Research, CONICYT (Chile)

Who is the main contact?
Dr Pamela Grandon (Scientific)
pgrandon@udec.cl

Contact information

Type(s)

Scientific

Contact name

Dr Pamela Grandon

Contact details

Pinares 20 Chiguayante Concepcion Chile 4100000 +56 41 220 4323 pgrandon@udec.cl

Additional identifiers

Protocol serial number

FONDECYT 1171287

Study information

Scientific Title

Assessment of the effectiveness of a program for the reduction of stigma towards people with severe mental disorders in primary care workers: A randomized trial.

Study objectives

The "Igual-mente" ("Equally") Program will decrease negative attitudes and social distance and it will increase inclusive behaviors from the health workers towards people with severe mental disorders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Ethical and Scientific Committee from Servicio de Salud de Concepción, 24/10/2017, ref: 16-08-44
- 2. Servicio de Salud de Talcahuano, 04/07/2017, ref: Act N° 67

Study design

Clinical cluster randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Mental illness

Interventions

Health workers from different primary care centers are randomized by center to experimental or control groups. All the workers from each center are invited to participate and those that accept receive the pre-test assessment. All of those that have received the pre-test assessment are randomly assigned to one group or another by random numbers. Randomization is carried out by an external person, blind to the other aspects of the research.

Those in the intervention group receive a program called Igual-mente (Equally). The program lasts two months with weekly sessions including education strategies, contact with people diagnosed with severe mental disorders and the development of well-behavior skills towards people with a SMD. The program is carried out by a psychologist and a person who has received the diagnosis of severe mental disorder. Both receive previous training and must pass a competence test. They are weekly both personally and distance supervised.

The control group do not receive the program for assessment during the study, but can receive it after the study is completed.

Intervention Type

Behavioural

Primary outcome(s)

- 1. Social Distance is assessed using Social Distance Scale.
- 2. Negative attitudes to people with mental health are assessed using "Scale of Attitudes of Health Professionals towards People with Severe Mental Illness" which is built by a doctoral thesis based on the "Mental Illness Clinicians Attitudes" (Gabbidon et al., 2013) and Community Attitudes to Mental Illness (Grandón, et al., 2016; Taylor, & Dear, 1981). Both will be evaluated up to 15 days after the end of the program.

Key secondary outcome(s))

Behaviour toward consulting with severe mental health disorders is assessed using a the Checklist of Inclusive Behaviours (a scale developed by the authors of this research) up to 15 days after the end of the program.

Completion date

31/12/2018

Eligibility

Key inclusion criteria

Workers from the Family Health Centers considering both:

1.1. Professionals (nurses, physicians, medical technicians, psychologists and social workers, professional midwife, nutritionists, occupational therapists, pharmacists, matron) 1.2.medical technicians.

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

316

Key exclusion criteria

No exclusion criteria

Date of first enrolment

10/03/2018

Date of final enrolment

31/03/2018

Locations

Countries of recruitment

Chile

Study participating centre Health Familiar Center Santa Sabina Concepción

Concepcior Chile 4030000

Study participating centre Health Familiar Center O'Higgins

Concepción Chile 4030000

Study participating centre Health Familiar Center Juan Soto Fernández

Concepción Chile 4030000

Study participating centre Health Familiar Center Lorenzo Arenas Concepción Chile 4030000

Study participating centre
Health Familiar Center Tucapel
Concepción
Chile
4030000

Study participating centre
Health Familiar Center Chiguay
Chiguayante
Concepción
Chile
4100000

Study participating centre
Health Familiar Center Leonera
Chiguayante
Concepción
Chile
4100000

Study participating centre
Health Familiar Center Pinares
Chiguayante
Concepción
Chile
4100000

Study participating centre Health Familiar Center Paulina Avendaño

Talcahuano Concepción Chile 4260000

Study participating centre Health Familiar Center Los Cerros

Talcahuano Concepción Chile 4260000

Study participating centre Health Familiar Center Hualpencillo

Hualpén Concepción Chile 4600000

Study participating centre Health Familiar Center La Floresta

Hualpén Concepción Chile 4600000

Study participating centre Health Familiar Center Talcahuano Sur

Hualpén Concepción Chile 4600000

Study participating centre Health Familiar Center Tome

Tomé Chile 4160000

Sponsor information

Organisation

Universidad de Concepcion

ROR

https://ror.org/0460jpj73

Funder(s)

Funder type

Government

Funder Name

Comisión Nacional de Investigación Científica y Tecnológica

Alternative Name(s)

National Commission for Scientific and Technological Research, CONICYT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Claudio Bustos, clbustos@udec.cl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2021	10/11/2021	Yes	No
Protocol article	protocol	07/03/2019		Yes	No

Basic results27/10/202027/10/2020NoParticipant information sheetParticipant information sheet11/11/202511/11/2025No