ISRCTN46464036 https://doi.org/10.1186/ISRCTN46464036

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

Submission date
12/03/2018

Registration date
29/03/2018

Last Edited
10/11/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Nº 67

Study design
Clinical cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures
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.

Overall study start date
10/03/2017

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

Age group
Adult

Sex
Both

Target number of participants
The minimum number of participants will be 105 in the experimental group and 105 in the control group.

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
Chile
4030000

Study participating centre
Health Familiar Center O'Higgins
Concepción
Chile
4030000

Study participating centre
Health Familiar Center Juan Soto Fernández
Concepción
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4030000

Study participating centre
Health Familiar Center Lorenzo Arenas
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Study participating centre
Health Familiar Center Tucapel
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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
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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
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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

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?
Protocol article	protocol	07/03/2019		Yes	No
Basic results		27/10/2020	27/10/2020	No	No
Results article		01/11/2021	10/11/2021	Yes	No