Destigmatizing Mental Illness

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Hypotheses of the study:Psycho-education coping skills training is effective in reducing the negative consequences of stigma in people with SMI, in a way thata) quality of life of people with SMI improves;b) social functioning of people with SMI...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON37949

Source
ToetsingOnline

Brief title
D-STIGMI

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychiatric disorders, severe mental illness

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,FP-7 EU-subsidie

Intervention

Keyword: coping, empowerment, psychiatry, stigmatization

Outcome measures

Primary outcome

Quality of life

Secondary outcome

Care needs and social functioning

Study description

Background summary

Stigmatization is a social phenomenon in which people are approached using attributes that are assumed to be right but are not always applicable to the individual. Research has shown that stigmatization can have many negative consequences in multiple domains of daily life of people with a severe mental illness (SMI). It's therefore very important to improve the skills of these people in coping with this phenomenon.
Main hypothesis: Psycho-education coping skills training is effective in reducing the negative consequences of stigma in people with SMI, in a way that quality of life of people with SMI improves.

Study objective

Hypotheses of the study:
Psycho-education coping skills training is effective in reducing the negative consequences of stigma in people with SMI, in a way that
a) quality of life of people with SMI improves;
b) social functioning of people with SMI improves;
c) care needs of people with SMI diminish.

Study design

A Randomized Controlled Trial (RCT; N=140) is executed in an open design. Evaluation takes place by means of interviews with questionnaires, and the Experience Sampling Method (ESM) at baseline, post-treatment (no ESM) and follow up.

Intervention

The intervention group (N=70) participates in a psycho-education coping skills

training. The control group (N=70) participates in a newspaper reading group. Both groups take place in 10 weekly sessions of 1-1,5 hours in groups of 8-10 participants.

Study burden and risks

Participants from both conditions each get 10 weekly sessions of 1-1,5 hours. The measurements at baseline, post-treatment and follow up (interviews with questionnaires) take a maximum of 3 hours each (together 9 hours). The two ESM measurements each take a week (investment 30 minutes/day - together 7 hours). Participation in neither the experimental nor control condition is associated with significant risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

People with a severe mental illness and in particular psychosis of the schizophrenic or affective type. It involves patients with a non-organic psychosis (according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)) and a longterm course of disease (>2 years) and invalidating handicaps in daily functioning. In people with other diagnoses, such as a depressive disorder without psychosis; a severe anxiety disorder; or autism, treatment must not have had the desired effect and the problems in functioning have to be explicit (GAF<40).
Age 18-65.
Sufficient command of Dutch.
Participants are competent to make their own informed consent (no juridical regime restricts their autonomy) and can voluntarily participate in the study. They are able to comprehend the scope of the study, as well as risks and limitations.

Exclusion criteria

Not fulfilling inclusion criteria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31794.068.10