Storytelling and Training to Advance Individual Recovery Skills (STAIRS): a blended module for patients recovering from depression. A pilot study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON49975

Source
ToetsingOnline

Brief title
A pilot study to determine the applicability of STAIRS.

Condition

- Mood disorders and disturbances NEC

Synonym
depression

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Agis en VCVGZ

Intervention

Keyword: depression, online, peers, storytelling

Outcome measures

Primary outcome

User experiences with the program and measurements.

Secondary outcome

At T0, T1 and T2 several questionnaires are administered that assess the level of functional recovery (Outcome Questionnaire; OQ-45), severity of depressive symptomatology (Inventory of Depressive Symptomatology- self report; IDS-SR) and the level of the patient empowerment (Nederlandse Empowerment Lijst; NEL). These scales will not be used as study outcomes in this pilot study. Rather, we will evaluate the participants* experiences with these measurements.

Study description

Background summary

Almost all mental healthcare treatments of depression focus on symptomatic recovery. However, such recovery does not necessarily mean that a person has reached functional recovery. Consequently, many persons still experience functional impairments after recovery. As this increases the risk of recurrence of the depression, a new blended module (STAIRS) is developed to promote functional recovery.

Study objective

Prior to conducting an RCT to study the efficacy of STAIRS, we conduct a pilot to (1) investigate the usability, feasibility and acceptability of the program and (2) to investigate the feasibility and acceptability of the intended measurement method/scheme for the RCT.

Study design

A pilot trial (N=10) of the STAIRS program for 12 weeks. To evaluate the patients* experiences, a questionnaire will be administered after 10 weeks and at the end of the program. The answers are clustered into themes and discussed in a focus group with the participants to evaluate the users* experiences with the program*s contents, didactics and organisation; and to identify possible points for improvement. In addition, all questionnaires we intend to use in the full RCT (at intake [T0], 6 weeks [T1] and at the end [T3]) will be administered and feasibility (i.e. incomplete data, drop-out) and acceptability (participants* experiences) will be evaluated. To evaluate relevant others* (e.g. family or friends) experiences with the program*s content and organization, a questionnaire will be administered at the end of the program. Also an assessment of the social functioning of the participant is askes in this questionnaire. Trainers will be asked about their experiences with the program*s usability, feasibility and acceptability in separate interviews.

Intervention

STAIRS is a 12-week program in which 9 different themes are addressed. Each theme starts with a group meeting guided by a professional and expert by experience. In these meetings different exercises are done (e.g. filling out an actual and desired week schedule, roleplaying a difficult situation), information is given and experiences are shared. Between meetings, participants can choose from a range of homework exercises to practice their desired skills in a tailored way. In addition, participants can share experiences with the other group members and exchange reactions using a private online community.

Study burden and risks

Participants spend approximately 20 hours in group meetings and 40 hours on homework. Additional time may be spent on travel to and from the group meetings at the UCP. Assessment of the program takes approximately 3.5h (2h on questionnaires and 1.5h on focus-group). The study assessments at T0-T2 take approximately 3h in total. We expect no risk of participation. Participants can benefit from STAIRS by attaining higher levels of functional recovery, reduced levels of depression and higher levels of empowerment.

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

- Age 18 to 65 years old
- In treatment for a diagnosed Major Depressive Episode; psychological treatment is expected to end within three months.
- Minimal reduction of depression symptoms; at least a reduction into absent, or mild depression symptoms.

Exclusion criteria

- IDS >= 25 (still suffering from moderate/severe depression)
- Insufficient command of the Dutch language.
- Cognitive problems/indication of low IQ < 80
- Not in possession of pc and/or smartphone
- Being referred/to be referred to a different mental health service for other mental problems

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2020
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	16-09-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL72037.042.20