Evaluation of the effectiveness of a newly developed blended module for patients recovering from depression (STAIRS): a mixed methods RCT

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

Summary

ID

NL-OMON54416

Source
ToetsingOnline

Brief title
Effect study of STAIRS: a mixed methods RCT

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: NWO,VCVGZ

Intervention

Keyword: blended training, depression, personal recovery, storytelling

Outcome measures

Primary outcome

The primary outcome of this study is personal recovery, measured in each group as the change on the Individual Recovery Outcome Counter (I.ROC) and the Recovery Assessment Scale Domains and Stages (RAS-DS) between baseline and T1 and T2.

Secondary outcome

Secondary quantitative outcomes in each group are: depression relapse between T1 and T2, change in depressive symptom severity, level of empowerment, sense of control, level of functional disabilities due to depression, costs associated with psychosocial problems and recovery of Quality of Life from baseline to end of treatment and 6 month follow-up.

Secondary qualitative outcomes in the experimental group are user experiences with the STAIRS-program.

Study description

Background summary

Almost all mental healthcare treatments of depression focus on symptomatic recovery. However, such recovery does not inherently mean that personal recovery is reached. In fact, many persons still experience functional impairments after symptomatic recovery. As this has a negative influence on daily life, a new blended module (STAIRS) was developed to promote personal recovery in persons that are in the final stage of symptomatic recovery from

depression. The current study will investigate the efficacy of STAIRS, by adding STAIRS to care as usual and comparing it with care as usual. It is hypothesized that STAIRS will have a positive effect on personal recovery and that this effect is larger than in the control group.

Study objective

The main objective of this study is to determine the efficacy of STAIRS. The secondary objectives are: (1) to investigate the association between improved personal recovery and depression relapse and (2) to gather qualitative insights into the elements contributing to (a) the effects and (b) the usability and acceptability of STAIRS.

Study design

Efficacy of STAIRS will be assessed by conducting a randomized controlled trial (N=140). In this trial, participants will be randomly assigned either to the experimental group receiving care as usual complemented with the STAIRS-training or the control group receiving care as usual. Measurement points are at T0 (baseline), T1 (post-treatment) and T2 (6 months after end of treatment). Qualitative semi-structured interviews will be held in the experimental group at T1 about the value that participants assign to the elements of the training, as well as the experienced acceptability, and perceived usefulness of the training.

Intervention

STAIRS is a 8-week program, in which 8 different themes are addressed. Coverage of 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 in the experimental group spend approximately 16 hours in group meetings and 8 hours on homework assignments. For the experimental group, additional time may be spent on traveling to and from the group meetings. The study assessments include questionnaires (3 x 60 minutes) and interviews (approximately 15 participants: 1,5 hour). This is time consuming and it might be experienced as boring and/or annoying. Furthermore, some questions could elicit some distress as these cover personal and emotional content. There is no

reason to expect any health risk of participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- age 18 to 65 years old; - in the last phase of treatment for a diagnosed Major Depressive Disorder; the acute phase of depression is over and a patient is in the process of regaining control over his life, or psychological treatment is ended in the last 6 months and an aftercare or maintenance antidepressant treatment is offered - Minimal reduction of depressive symptoms into moderate; an IDS-SR score of <38 - The willingness to participate in the study

Exclusion criteria

- Bipolar depression or depression with psychotic features. - Comorbid schizophrenia spectrum or other psychotic disorder. - Comorbid moderate or severe dependence of alcohol or drugs. - Neurological disorder (e.g., dementia). - Insufficient command of the Dutch language. - Cognitive problems or indication of low IQ (i.e.< 80). - Not in possession of a pc or smartphone. - Having been referred to a different mental health service for other mental problems.

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:	Recruiting
Start date (anticipated):	11-10-2022
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	05-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-11-2023
Application type:	Amendment
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	NL75317.042.21