Moodbuster Lite: Study into the relationship between online support and adherence in an online course for improving mood

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

Summary

ID

NL-OMON49793

Source
ToetsingOnline

Brief title
Moodbuster Lite

Condition

- Mood disorders and disturbances NEC

Synonym
gloom, low mood

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Intervention

Keyword: behavioural activation, low mood, online intervention

Outcome measures

Primary outcome

The primary outcome measure is adherence, measured as intervention completion,

and number of mood registrations.

Secondary outcome

Secondary outcome measures are motivation (motivation for following the course

and motivation to continue using the course), the relationship with the virtual

coach (acceptance of the virtual coach and working alliance), and feasibility

(system usability, user satisfaction, mood ratings, mental health status, and

performed activities).

Study description

Background summary

Online interventions for common mental health disorders such as depression are considered effective. Guided interventions, however, are typically more effective than unguided ones, and show better adherence rates. Automated support by a virtual coach or personalized supportive messages could help bridge the gap between guided and unguided interventions.

Study objective

The primary aim of this study is to compare adherence rates between (1) people who receive a short course aimed at improving mood with automated support by a virtual coach, (2) people who receive the same course with personalized supportive messages and (3) people who receive the same course without automated support. Secondary aims are to evaluate the participants* motivation to follow and keep following the intervention, their acceptance of and

relationship with the virtual coach (intervention group with the virtual coach only), and the system*s feasibility in terms of usability, user satisfaction, and symptom improvement.

Study design

The study follows a three-armed pilot randomized controlled trial design. There are two measurement points: T0 (baseline), and T1 (end of study, 4 weeks after T0).

Intervention

Moodbuster Lite is a four-week online self-help course based on cognitive behavioral therapy that consists of three lessons and a smartphone application used to keep track of one's mood. The intervention group will also receive automated support by a virtual coach or by means of personalized supportive messages. The core elements of the course are motivational interviewing (lesson one), psychoeducation (lesson two), and behavioural activation (lesson three).

Study burden and risks

Participant burden involves completing online questionnaires at baseline and after four weeks. The risks involved in taking part in the study are considered minimal. Participants in all three conditions may benefit from taking part in the intervention by acquiring skills to improve their mood. Completion of the questionnaires may be slightly distressing for some participants.

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

1. Aged 18 years or older
2. Self-reported desire to improve one*s mood

Exclusion criteria

1. Not willing to sign the informed consent form
2. No adequate written proficiency in the Dutch language
3. No valid e-mail address or a computer with internet access
4. Does not possess a smartphone
5. A score of 15 or higher on the PHQ-9 (indicating moderate to severe levels of depression that warrant more serious treatment)
6. A score of 1 or higher on item 9 of the PHQ-9, indicating that this participant thought of suicide at least several times during the past two weeks.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	105
Type:	Anticipated

Medical products/devices used

Generic name:	Moodbuster Lite
Registration:	No

Ethics review

Approved WMO Date:	19-11-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL69433.029.19