Moodbuster Lite

No registrations found.

Ethical review   Not applicable
Status   Pending
Health condition type   -
Study type   Interventional

Summary

ID

NL-OMON24187

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Low mood

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam, Department of Clinical-, Neuro-, and Developmental Psychology
Source(s) of monetary or material Support: eMen, Interreg

Intervention

Outcome measures

Primary outcome

Adherence

Secondary outcome

Feasibility, User perceptions of virtual coach

Study description

Background summary

Internet-based cognitive-behavioral therapy (iCBT) is more effective when it is guided by human support than when it is unguided. This may be attributable to higher adherence rates that result from a positive effect of the accompanying support on motivation and on engagement with the intervention. This study aims to start bridging the gap between guided and unguided interventions. It will test an intervention that includes automated support delivered by an embodied conversational agent (ECA) in the form of a virtual coach or personalised automated motivational support messages. It will employ a pilot two-armed randomized controlled trial design. The primary outcomes of the trial will be (1) the effectiveness of iCBT, as supported by a virtual coach or personalised automated motivational support messages, in terms of improved intervention adherence in comparison with unguided iCBT; and (2) the feasibility of a future, larger-scale trial in terms of recruitment, acceptability, and sample size calculation. Secondary aims will be to assess the effect of the virtual coach and the personalised automated motivational support messages on motivation, users' perceptions of the virtual coach, and the general feasibility of the intervention as supported by a virtual coach or personalised automated motivational support messages. We will recruit N = 105 participants from the general population who wish to learn how they can improve their mood by using Moodbuster Lite, a 4-week cognitive-behavioral therapy course. Candidates with symptoms of moderate to severe depression will be excluded from study participation. Included participants will be randomized in a 1:1:1 ratio to either (1) Moodbuster Lite with automated support delivered by a virtual coach, or (2) Moodbuster Lite with personalised automated motivational support messages or (3) Moodbuster Lite without automated support. Assessments will be taken at baseline and post-study four weeks later.

Study objective

Following Moodbuster Lite with guidance provided by a virtual coach or personalised automated motivational support messages leads to higher adherence rates than following Moodbuster Lite unguided.

Study design

Baseline (T1), Post-study (T2)

Intervention

(1) Moodbuster Lite with guidance by a virtual coach; (2) Moodbuster Lite with personalised automated motivational support messages; (3)Moodbuster Lite without guidance

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Eligibility criteria

Inclusion criteria

18 years or older, comprehension of Dutch language, having expressed desire to improve mood, smartphone and computer with internet

Exclusion criteria

moderate to severe depression, having thought of suicide or hurting oneself several times during the past 2 weeks

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):   01-05-2021

Enrollment: 105

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL8110
Other	METc VUmc : 2019.388

Study results