

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	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

**Source(s) of monetary or material Support:** eMen;Interreg

## **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