A better treatment for depression with personalized just-in-time behavioral activation

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Our aim is to develop JITAIs focused on behavioral activation (BA) for depression in close collaboration with patients and therapists, and to examine their usability, feasibility, and preliminary effectiveness.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Depressed mood disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON57144

Source
ToetsingOnline

Brief title
Just-in-time behavioral activation for depression

Condition

- Depressed mood disorders and disturbances

Synonym
depressive disorder; depression

Research involving
Human

Sponsors and support

Primary sponsor: Dimence Groep
Source(s) of monetary or material Support: ZonMW

Intervention

- No intervention

Keyword: Adaptive interventions, Behavioral activation, Depression

Explanation

N.a.

Outcome measures

Primary outcome

Primary outcome is the feasibolity of the JITAIs as an add-on in the
 psychological treatment of depression.

Secondary outcome

Secondaire outcome are: Patient Health Questionnaire (PHQ-9), Mental Health
 Continuum-Short Form (MHC-SF), Questionnaire about the Process of Recovery
 (QPR), Client-satisfaction questionnaire (CSQ-8), System Usability Scale (SUS),
 TWente Engagement with Ehealth Technologies Scale (TWEETS) and the EuroQol-5
 Dimension (EQ-5D).

Study description

Background summary

Depression constitutes a significant public health issue, with rising prevalence and a negative impact on quality of life, mortality, and morbidity. Although psychological treatments*such as behavioral activation*are effective, they are only effective for half of the participants. The effectiveness can be improved by increasing adherence to activities between treatment sessions. Promising for improving adherence are 'Just-In-Time Adaptive Interventions' (JITAIs) that provide support 'at the right moment.' To date, JITAIs have not been studied in the context of behavioral activation for depression.

Study objective

Our aim is to develop JITAIs focused on behavioral activation (BA) for depression in close collaboration with patients and therapists, and to examine their usability, feasibility, and preliminary effectiveness.

Study design

Qualitative research with focus groups (design phase), followed by a quantitative quasi-experimental design in which JITAIs as an add-on to treatment as usual are compared with the outcomes of treatment as usual (evaluation phase).

Study burden and risks

Participants receive usual care throughout the study. The burden for participants in the design phase consists of participation in focus groups, and in the evaluation phase, it involves completing several questionnaires at 3 time points. If participants receive JITAIs as an add-on, the additional burden consists of: daily measurements (4 times a day, with 12 - 17 questions) and daily receipt of messages with a suggestion for a pleasant activity. There are no potential risks for the subjects during participation in the study.

Contacts

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Trial sites

Trial sites in the Netherlands

Universiteit van Twente
Target size: 121

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)
Adults (18-64 years)

Inclusion criteria

Healthy participants: Therapists working at Thubble and a patient representative

Patients: 1) age 18 years or older, 2) a diagnosis of a depressive disorder, and 3) in possession of an Android or iOS smartphone.

Exclusion criteria

1) Insufficient proficiency in the Dutch language

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-12-2024
Enrollment:	121
Duration:	2 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
Registration:	No

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO Date:	22-10-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-03-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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	NL87481.091.24
Research portal	NL-005185