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Study of a smartphone-delivered, therapist-supported mindfulness-based therapy program for depression in Finnish university students

Submission date
24/06/2018

Recruitment status
No longer recruiting

Registration date
01/08/2018

Overall study status
Completed

Last Edited
11/05/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a common mental disorder and a leading cause of disability in Western world. Effective treatments for depression exist, but their availability remains a significant problem. It is estimated that less than a half of people with depression receive any care for their symptoms. The recent information technology and mobile device revolution has enabled the development of digitally delivered mental health care, such as online therapies. The aim of this study is to test the efficacy of an online therapy program called Ascend, delivered via smartphone app, for depression.

Who can participate?
Finnish university students (age 18-40) with diagnosed depression

What does the study involve?
Participants are randomly allocated to an intervention group or a control group. Within both groups, there are about an equal number of participants with and without antidepressant medication. All participants receive regular treatment for depression by the Finnish Student Health Service. This regular treatment, i.e. treatment as usual, may include appointments with nurses, psychologists and/or physicians, laboratory tests, and it may or may not include antidepressant medication. In addition to the regular treatment provided by the Finnish Student Health Service, those in the intervention group receive an intensive 8-week online therapy program, Ascend, in a smartphone app. The program requires on average of 10-40 minutes of daily practice, six days a week, in addition to the time spent communicating with the therapist and the group via chat. The amount of chatting is completely optional, there are no recommended minimum or maximum amounts. The Ascend therapy program includes:
1. Educational material of depression and related symptoms (texts, videos, audios)
2. Audio-guided mindfulness practices (e.g. sitting, walking, body scanning)
3. Cognitive behavioral therapy (CBT)-styled thought reflection (e.g. thought diary)
4. Phone calls with a therapist (default: baseline, at the completion of therapy, and more often if

needed)
5. Chat with a therapist (therapist's response to participant is guaranteed within 24 hours)
6. Interaction with an anonymous peer-group undergoing the program simultaneously

What are the possible benefits and risks of participating?
Possible benefits of participating in the study include receiving help for depression symptoms beyond treatment as usual. As one emphasis of the therapy program is to teach participants new skills and ways to cope with their depressive symptoms in the future, it is possible that the participants will benefit from therapy program long after the study is over. Some people may experience anxiety when encountering their feelings, memories and potential fears. People may also experience stress because of the rather intensive program (recommendation of daily or almost daily practices). Risks of participating include the 50% possibility to be allocated to the control group, and not receive the Ascend online treatment in the course of the study. However, also individuals in the control group have the possibility to obtain the online Ascend therapy for free once the 6 months' follow-up is over. The Clinpal platform where patients report all confidential information, such as responses to the self-reported questionnaires, adheres to strict international data security guidelines, and will be kept in a safe (encrypted) storage within the eClinicalHealth Clinpal system. However, there is a theoretical risk of data hacking or other data violation act, which could at worst lead to the exposure of highly sensitive personal information. A burden from filling up the questionnaires is considered small, maximum 30 minutes per each timepoint within the course of 8 months.

Where is the study run from?
Finnish Student Health Service (FSHS or in Finnish, YTHS) and Meru Health Inc. The participants are recruited via the Finnish Student Health Service's centers in four Finnish cities; Tampere, Turku, Jyväskylä and Helsinki

When is the study starting and how long is it expected to run for?
April 2018 to December 2019

Who is funding the study?
Meru Health Inc.

Who is the main contact?
Dr Anu Raevuori

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R17128

Study information

Scientific Title
Randomized controlled study of a smartphone-delivered, therapist-supported, mindfulness-based intervention for depression in Finnish university students

Study objectives
Primary hypothesis:
Symptoms of depression, measured by PHQ-9, will gradually decrease in patients in the online therapy group across the online therapy program. The difference compared to the control group will be statistically and clinically significant at week 8, i.e. at the completion of online therapy program (minimal clinically important difference of PHQ-9, Löwe et al. 2004). During the follow-up (3 and 6 months after the online therapy program), depressive symptoms in online therapy group will on average increase slightly compared to the level at week 8, but will remain in a significantly lower level through the follow-up when compared to the control group and baseline PHQ-9 scores of online therapy group.

Secondary hypotheses:
1. Anxiety symptoms, sleep problems and perceived stress will gradually decrease in patients in online therapy program group across the program, and remain in a lower level at the follow-up when compared to controls and online therapy group individuals' own baseline scores. Quality of life, resilience and mindfulness will gradually increase in patients in online therapy program group across the program, and remain in a higher level at the follow-up when compared to controls and online therapy group individuals' own baseline scores.
2. There is a dose-response effect between the quantity of mindfulness practice (frequency x duration of sessions) and the reduction of depressive and anxiety symptoms. We assume that this effect is modified by the internalization of mindfulness skills as measured by Five Facet Mindfulness Questionnaire. We expect the online therapy program to be highly feasible, and to have a positive effect of medication adherence of potential antidepressive medication among individuals in the online therapy program group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Tampere University Central Hospital, 01/11/2017, ref: 09/2017 (ETL-code R17128)

Study design
Randomized-controlled single-center intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Acute depressive disorder (ICD-10 codes F32.0, F32.1, F32.2, and F33.0, F33.1, F33.2, F33.4, F33.8, F33.9)

Interventions
This is a randomized controlled study testing the efficacy of the Ascend program for depression. The program is delivered through a smartphone application, and guided by a therapist. Approximately 120 patients with depression from Finnish Student Health Service (YTHS) are recruited and divided according to the use of antidepressant medication, and then randomized to:

1. The intervention group receiving the Ascend therapy program and treatment as usual (TAU + therapy program arm)
2. The control group receiving only the treatment as usual (TAU arm)

Within both groups, stratification, i.e. random division into two equal-size subgroups, is conducted based on antidepressant medication use. Randomization is done by the Clinpal-platform, and the trialists are unaware of the details (on purpose). Also the above mentioned random stratification is conducted by the Clinpal.

Only participants in the intervention group receive intensive 8-week Ascend therapy program during the study. Those in the control group have the possibility to attend the 8-week Ascend therapy program free of charge once the study is completed.

Total duration of the whole study for both intervention group and control group is 8 months. The duration of the intervention is 2 months and the follow-up after the intervention is 6 months. Those in the control group are followed (simultaneously) for the whole 8 months. They are entitled to attend the therapy program after the follow-up is completed if they wish so.

The Ascend therapy program is an online mindfulness- and cognitive behavioral therapy -based intervention that lasts 8 weeks and is delivered via a smartphone application provided by Meru Health Inc. The therapy program is approved by a Finnish healthcare official (Valvira approval, dnro V/25535/2017). It requires on average of 10-40 minutes of daily practice, six days a week, in addition to the time spent communicating with the therapist and the group via program chat. All information and introductions to the practices will be given inside the application. The Ascend program follows high data security standards, and adheres to General Data Protection Regulation (GDPR) requirements. All participants receive oral and written directive for the potential abrupt depressive symptom worsening, where contacting physician/going to the emergency is recommended, along with contacting one's own Ascend program therapist.

The Ascend therapy program includes:
1. Educational material of depression and related symptoms (texts, videos, audios)
2. Audio-guided mindfulness practices (e.g. sitting, walking, body scanning)
3. Cognitive behavioral therapy (CBT)-styled thought reflection (e.g. thought diary)
4. Phone calls with a therapist (default: baseline, and more often only if needed)
5. Chat with a therapist (therapist's response to participant is guaranteed within 24 hours): there are no requirements for the amount (minimum or maximum) of chatting.
6. Peer-group: program participants constitute an anonymous peer-group of 8-15 individuals that undergo the program simultaneously; participants are able to see each other's chat messages with the therapist (group chat), but they are not able to comment each other's messages. Also, there is a private chat option with the therapist, and participants choose themselves whether they wish to use private chat or group chat.

Ascend therapists are healthcare professionals with training in Mindfulness Based Stress Reduction (MBSR)/Mindfulness Based Cognitive Therapy (MBCT) and with cognitive behavioral therapy skills. Within the therapy program, a therapist has a group of 8-15 individuals for the 8 week course. The participants do not meet each other physically but form an online peer-group within the Meru Health application. Participants' identities remain hidden from each other, and the peer-group interaction happens with nicknames. The therapist is aware of the personal identity information of all participants.

All participants will receive treatment as usual for depression by the Finnish Student Health Service. Treatment as usual may include appointments with nurses, psychologists and/or physicians, laboratory tests, and it may or may not include antidepressant medication. Frequency of the appointments is modified according to patients' individual needs. Treatment as usual does not involve any psychotherapy, and those receiving psychotherapy are excluded from the study.

Information of depressive symptom evolution, as well as other mental health and ill-health symptoms, are gathered at start, and during and after the program up to follow-ups of 3 and 6 months after the program completion.

Intervention Type
Mixed

Primary outcome measure
Depressive symptoms, measured using the Patient Health Questionnaire 9 (PHQ-9) at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention

Secondary outcome measures

1. Anxiety symptoms, measured using Generalized Anxiety Disorder 7 (GAD-7) at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
2. Sleep problems, measured using the Insomnia Severity Index (ISI) at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
3. Quality of life, measured using EUROHIS-Qol 8-item index at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
4. Internalization of mindfulness skills, measured using Five Facet Mindfulness Questionnaire - Short Form, FFMQ-SF at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
5. Experienced stress symptoms, measured using Perceived Stress Scale (PSS) at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
6. Resilience, measured using Resilience Scale at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 3 months and 6 months post-intervention
7. User-friendliness of the mobile phone (online therapy program) application, measured using System Usability Scale at 8 weeks

Overall study start date
01/04/2018

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Diagnosis of a depressive disorder (ICD-10 F32 or F33) at the time of enrollment
2. Willingness to commit to the 8-week online therapy program
3. No prior established mindfulness practice/meditation experience
4. Aged 18-40 years
5. Living in Finland
6. Has a smartphone with iOS or Android mobile operating system
7. Access to mobile internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
120

Total final enrolment
130

Key exclusion criteria
1. Previous suicide attempts
2. Severe suicidal ideation
3. Other serious mental disorders such as psychosis or severe personality disorders
4. Active substance abuse
5. Ongoing psychotherapy

Date of first enrolment
10/04/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Finland

Study participating centre
Finnish Student Health Service, FSHS, YTHS
Finland
40100

Sponsor information

Organisation
Meru Health

Sponsor details
Lapinlahdenkatu 16
Helsinki
Finland
00180

Sponsor type
Industry

Website
https://www.meruhealth.com/

Funder(s)

Funder type
Other

Funder Name
Lifeline Ventures Inc

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	11/05/2021	Yes	No