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An SMS-assisted mindfulness-based intervention for relapse prevention in depression

Submission date
10/04/2014

Recruitment status
No longer recruiting

Registration date
06/06/2014

Overall study status
Completed

Last Edited
04/05/2017

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
Mindfulness-based interventions aim at promoting an intentional, non-judgemental attention to the present moment and have been shown to be helpful in preventing the reoccurrence of depression. Mobile communication technologies (such as short message service, SMS) can be used to maintain treatment gains and achieve long-term behaviour changes. Mindfulness-based interventions have rarely been studied in inpatient settings. Therefore, we have developed a low intensity program for psychiatric inpatients with depression which combines mindfulness exercises with SMS-assistance. The aim of this pilot study is to inform the planning of a full-scale trial and examine whether the study design is feasible, i.e. how many patients are willing to participate in the study, fill in the questionnaires, use the SMS-assistance and are satisfied with the intervention. Furthermore, we will examine the usability of the questionnaires.

Who can participate?
Adult inpatients of the Clinic of Psychiatry and Psychotherapy II (Guenzburg), Ulm University, with symptoms of depression. Participants should have a mobile phone and sufficient knowledge of the German language.

What does the study involve?
The intervention consists of two steps. First, in addition to standard inpatient care, participants will be invited to attend a group introduction to three mindfulness exercises during their hospital stay. Second, after discharge from hospital, participants will be randomly allocated to either receive the SMS-assistance or recieve no additional support. Over a period of four months after discharge, participants will be asked to report via SMS whenever they have practiced a mindfulness exercise, and in return receive reinforcing feedback. Assessment points are at study intake, at discharge from hospital and four-months follow-up.

What are the possible benefits and risks of participating?
Research indicates that mindfulness interventions can be helpful in preventing the reoccurrence of depression. SMS-interventions have been shown to support long term behaviour changes. Thus, possible benefits are a decreased risk of depressive relapse and an improvement of

general well-being. Overall, negative outcomes are rarely reported. The mindfulness exercises are introduced during the inpatient stay of the patient. Therefore, any adverse reactions can immediately be responded to.

Where is the study run from?
Enrolment takes place at the Clinic for Psychiatry and Psychotherapy in Guenzburg (lead centre MIND-S-study). Technical and methodological support is provided by the Center of Psychotherapy Research, University of Heidelberg.

When is the study starting and how long is it expected to run for?
The study started in September 2013. Data acquisition will last approximately until the end of 2014

Who is funding the study?
"Innovationsfonds Medizin", a research fund provided by the Ministry of Science, Research and Art of the State of Baden-Wuerttemberg, Germany.

Who is the main contact?
Dr Bernd Puschner
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Study website
http://www.uni-ulm.de/psychiatrieII/en_projects/mind_s.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An SMS-assisted mindfulness-based intervention for relapse prevention in depression: a pilot randomized controlled trial

Acronym
MIND-S

Study objectives
The study examines the feasibility of the study design and the intervention. Research questions are:
1. Feasibility of the study design in terms of recruitment, randomisation, retention, and usability of the measures.
2. Feasibility of the intervention in terms of adherence and acceptability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ulm University Ethics Committee; 13/08/2013; ref. 231/13

Study design
Pilot study prospective single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Depressive symptoms, relapse prevention

Interventions
1. During inpatient psychiatric treatment: Manualized group session introducing three mindfulness-based exercises (mindful breathing, mindful walking, mindfulness of the body).

Study participants should attend the group at least once.
2. After discharge (t1) for participants allocated to intervention group: Assistance of mindfulness practice at home, using positive reinforcement via the mobile phone SMS-technology and weekly reminders (until 4-month follow-up, t2)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility and acceptability of the study design and procedures:
1. Number of patients recruited (at study intake, t0) and randomized (at hospital discharge, t1), drop-out rates until follow up (four months after discharge, t2)
2. Homework compliance (questionnaire at t2)
3. Use of the SMS-assistance during the four months after hospital discharge (objective measure)
4. Satisfaction with the interventions (questionnaires at timepoints: t1, t2)

Secondary outcome measures
Usability of the selected questionnaires (measuring homework compliance, depressive symptoms etc), assessed at all measurement-points (t0-t2)

Overall study start date
24/09/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Age: 18 to 75 years
2. Symptoms of depression during the current illness episode
3. Mobile phone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Psychotic symptoms, or a history of schizophrenia
2. Current manic state
3. Acute risk of a dissociative crisis
4. Severe cognitive deficit/impairment
5. Persistent severe substance abuse
6. Acute risk of suicidality or self-harm
7. Insufficient command of the German language

Date of first enrolment
24/09/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Ulm University
Guenzburg
Germany
89312

Sponsor information

Organisation
The Ministry of Science, Research and Art of the State of Baden-Wuerttemberg (Germany)

Sponsor details
Ministerium fuer Wissenschaft, Forschung und Kunst Baden-Wuerttemberg
Koenigstr. 46
Stuttgart
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70173

Sponsor type
Government

ROR

https://ror.org/01hc18p32

Funder(s)

Funder type
Government

Funder Name
The Ministry of Science, Research and Art of the State of Baden-Wuerttemberg (Germany) - Innovationsfonds Medizin - Kompetenzzentrum Praevention psychischer und psychosomatischer Stoerungen in der Arbeits- und Ausbildungswelt (PPAA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/05/2017		Yes	No