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Exploratory pilot trial of Help4Mood

Submission date
21/10/2013

Recruitment status
No longer recruiting

Registration date
17/12/2013

Overall study status
Completed

Last Edited
19/10/2016

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
The aim of the Help4Mood project is to develop an interactive computer based system for upporting the treatment of people with major depressive disorder in the community. Help4Mood is designed to facilitate recovery from depression through monitoring activity, mood and thoughts, and by using this information to help patients and their clinicians work together. The current system of Help4mood has already been tested via focus groups and case studies with non-patients as well as with patients who have experienced depression (but are recovered from it). The aim of this initial study is to test the feasibility of the online Help4Mood system with a small number of people who currently have depression and to help design a larger study.

Who can participate?
Participants aged up to 30 and treated for depression.

What does the study involve?
Participants will be randomly allocated to one of two groups: a treatment as usual group and a treatment as usual plus Help4Mood intervention.
Participants allocated to the treatment as usual plus the Help4Mood intervention will be asked to use Help4Mood system every day for 4 weeks (for example to log details about their mood, thoughts, quality of sleep etc).

What are the possible benefits and risks of participating?
Nor provided at time of registration

Where is the study run from?
A total of 18 participants in Scotland will be recruited.

When is the study starting and how long is it expected to run for?
November 2013 to March 2014.

Who is funding the study?
European Commission

Who is the main contact?
Prof Brian McKinstry

Study website
http://help4mood.info/site/default.aspx

Contact information

Type(s)
Scientific

Contact name
Prof Brian McKinstry

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0

Study information

Scientific Title
Exploratory pilot trial of Help4Mood: randomised controlled trial

Acronym
Help4Mood T6.8

Study objectives
The aim of this study is to evaluate the feasibility and acceptability of a randomised controlled trial of Help4Mood for patients with major depressive disorder in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Ethics Committee 01, 14/11/2013, REC reference: 13/SS/0207

Study design
Two centre feasibility study. Blocked randomization (1:1) for each site (e.g. GP practice) with variable sized blocks (2 or 4). Concealed allocation. The study is not blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Depression

Interventions
Help4Mood + Treatment as usual will be compared to Treatment as usual.
The duration of the intervention is 4 weeks.
The duration of the follow up is 1 day post intervention.

Help4Mood has been designed as an intervention to support clinical management of depression which has persisted after initial treatment, potentially while awaiting more specialised care. It aims to extend CBT-based guided self help by:
1. Providing a more interactive interface
2. Breaking CBT tasks into smaller daily chunks rather than longer workbook sessions
3. Adding additional data on physical activity, sleep and speech delivery (though not content)
4. Compiling data from interactions with the system into an easily readable and informative report for the patient and their usual clinicians

The Help4Mood System consists of a laptop or computer with some special software on it. The laptop and the data on it are completely secure. No one apart from the participant's doctor and the researcher on the study will be able to see any information about participants which is in it. Participants will be asked to use the Help4Mood system on the computer every day for 4 weeks. This involves doing the following activities:
1. Doing a mood check (daily)
2. Evaluating any negative and positive thoughts (daily)
3. Rate sleep quality (daily)
4. Wearing an activity monitor which can be worn on the wrist or the waist
5. To choose a rewarding activity (weekly) and report on whether they have done it (twice a

week)
6. To do a relaxation exercise (twice a week)
7. To provide a speech sample of up to one minute in length (up to three times a week)
8. To do a depression questionnaire - PHQ-9 (once a week)

Participants will be asked to make an appointment to see their usual doctor where they can discuss the results from the Help4Mood system. The Help4Mood system will generate a one-page report that will be emailed to their doctor.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To evaluate the feasibility and acceptability of a randomised controlled trial of Help4Mood for patients with major depressive disorder in primary care.

Secondary outcome measures
To examine:
1. The demographic characteristics (age, sex, working and domestic status) of trial participants
2. The baseline depression characteristics (severity, duration of current episode, number of past episodes, past and current treatment) of these individuals
3. The acceptability, to clinicians and patients of the identification, recruitment, randomisation and related trial procedures
4. Adherence to the intervention and trial protocol among pilot study participants, specifically:
4.1. Proportion in the active arm who use the Help4Mood system regularly (daily)
4.2. Patterns of less frequent use / cessation among those in the active arm
4.3. Completion of baseline and short term follow up measures in both arms
5. Changes in the proposed outcome measures while this study will not be powered to show statistical significance, these data will be used to power a full trial
6. Subjective experiences and opinions of participants including:
6.1. Personal experience of using Help4Mood during the pilot study
6.2. Perceived effects of Help4Mood on thoughts or behaviour
6.3. Effect of using Help4Mood on relationship between patients and healthcare providers from the point of view of the patient
6.4. Suggestions for modification either of Help4Mood or study procedures

Overall study start date
15/11/2013

Completion date
28/03/2014

Eligibility

Key inclusion criteria

1. Aged up to 30 years old inclusive
2. Under the supervision of a clinician and being treated with antidepressant medication which has not been changed (dose or agent) in the four weeks prior to recruitment
3. Patients prescribed additional hypnotics or anxiolytics for symptom relief will also be eligible

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
18

Key exclusion criteria
1. A Beck Depression Inventory (BDI) II score indicative of severe depression (≥30)
2. Significant risk of self harm or suicide based on either clinical assessment or item 9 of BDI -II (excluded answers I would like to kill myself and I would kill myself if I had the chance)
3. Current or recent (last month) self-harm behaviour
4. Current or past bipolar disorder
5. Current or past psychotic disorder
6. Current panic disorder
7. Current substance abuse, organic brain syndrome or mental learning difficulty
8. Augmented antidepressant treatment (multiple antidepressants, concurrent antipsychotic drug or lithium)
9. Currently receiving psychological therapy (e.g. structured CBT, but not including general psychological supportive treatment)

Date of first enrolment
15/11/2013

Date of final enrolment
28/03/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

Centre for Population Health Sciences
Edinburgh
United Kingdom
EH8 9AG

Sponsor information

Organisation
The University of Edinburgh (UK)

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Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) Ref: 24765

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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

Intention to publish date
01/09/2016

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	01/09/2016		Yes	No
HRA research summary			28/06/2023	No	No