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# STEPS study: to find out if and how to carry out a large clinical trial on stepped care treatment for depression.

**Submission date**
01/06/2014

**Recruitment status**
No longer recruiting

**Registration date**
02/07/2014

**Overall study status**
Completed

**Last Edited**
05/10/2016

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Stepped care treatment for depression is a way of deciding who gets what therapy and when. It is widely used and recommended. Some talking (psychological) therapies are more intensive (time consuming and costly) than others. In stepped care, almost all patients start with a low intensity therapy. Only people who remain unwell go on to a high intensity therapy. Compared with other systems, stepped care is thought to benefit patients whilst saving money but we don't know if that is true. Ultimately, we would like to carry out a large clinical trial that will tell us if stepped care really is an efficient way to organise depression treatment. However, before we can do that, we need to find out if and how we can carry out such a trial. We need to test and develop potential trial methods and procedures in a small trial. We also need to find out what people think of stepped care. Once we have the information we need, our goal is to design the large trial. The large trial should help to improve treatment for depression.

Who can participate?
We are recruiting between 60 and 75 people with depression, aged >17 years from an NHS Increasing Access to Psychological Therapies (IAPT) service for common mental health problems in South West England.

What does the study involve?
Participants take part in a small clinical trial. They will be randomly allocated to receive either stepped care treatment for depression or intensive psychological therapy only. We meet with everyone before they begin treatment and 6 months later. When we meet, people tell us about how they are feeling by completing some questionnaires. People who have stepped care also speak with us in a separate meeting to tell us what they think of the therapy they have received.

What are the possible benefits and risks of participating?
Participants receive treatment which is known to help some people with depression. Long term, we hope that this study will benefit other patients. Our results on what people think of stepped care should help the NHS (and other organisations worldwide) decide how to put it into practice. We think that the information from the small trial will inform a large trial; the results from the

large trial should influence how we treat depression. We are not aware of any risks of taking part as a result of the treatment people receive. However, because people with depression are more likely than others to commit suicide, we follow tried and tested procedures to monitor people's suicidal thoughts and feelings. We routinely ask people about these thoughts and we involve other health professionals in people's care when we think they may be at risk of hurting themselves.

Where is the study run from?
This study has been set up by the University of Exeter and is being carried out with the support of our local IAPT service.

When is the study starting and how long is it expected to run for?
Recruitment began in September 2013 and is expected to last for about 1 year. Participants are involved in the study for about 6 months. We hope to collect all the information we need by April 2015 although the study will extend for longer than this whilst we look at the data and write up our findings.

Who is funding the study?
The cost of the study is being met by the University of Exeter and funding for patients' treatment is being provided by the NHS Northern Eastern and Western Devon Clinical Commissioning Group.

Who is the main contact?
Jacqueline J. Hill
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### Study website
http://medicine.exeter.ac.uk/research/healthserv/complexinterventions/projects/steps/

# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Developing stepped care treatment for depression: a pilot randomised controlled trial and embedded interviews

### Acronym
STEPS

### Study objectives
The purpose of this study is to prepare the ground for undertaking a fully-powered randomised controlled trial of stepped care compared with high intensity psychological therapy alone for the treatment of depression in adults.
Specific objectives are to:
1. Gather enough information on recruitment, retention, treatment pathways and clinical outcomes from a small randomised trial to design the proposed fully-powered trial
2. Find out what people think of stepped care to inform a stepped care clinical protocol for use in the large trial.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee South West - Frenchay, 24/07/2013; ref. 13/SW/0140

### Study design
Pilot randomised controlled trial and semi-structured interviews

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### 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
Major Depressive Disorder (Depression)

### Interventions
Participants are randomised to two arms: intervention arm and control arm
Clinical procedures in both groups are NICE-recommended treatments routinely delivered in IAPT services i.e. Cognitive Behaviour Therapy (CBT) in low and high intensity forms.

Intervention arm: Stepped care involves initial low-intensity CBT delivered using guided self-help materials and, dependent on treatment response, high-intensity CBT. Guided self-help material has been adapted from an online Wellbeing Course developed by the Centre for Emotional Health at Macquarie University, Australia (http://www.ecentreclinic.org/). Stepped care participants progress is monitored. People who show insufficient progress are offered high-intensity psychological therapy; participants who recover only receive low-intensity therapy. High-intensity psychological therapy comprises between eight and 20 consultations of CBT.

Control arm: Participants in the control arm of the trial receive high-intensity CBT that is identical to the intensive CBT for patients in stepped care.

The total duration of treatment is between 6 weeks and 6 months for stepped care participants and up to 4 months for patients in the control arm.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
A variety of patient-related data will be collected at baseline and 6 months post randomisation:
1. Severity of depressive symptoms (BDI-I)
2. Health-related quality of life (Short Form Health Survey-36)
3. Worry and anxiety (Generalised Anxiety Disorder-7)
In addition, we will collect data on the flow of participants through the trial (i.e., numbers of participants at each step) and patients' pathway through and adherence to treatment.

### Secondary outcome measures
Qualitative data from semi-structured interviews on what people think of our trial methods and procedures and their views of stepped care.

### Overall study start date
25/09/2013

### Completion date
25/09/2015

## Eligibility

### Key inclusion criteria

1. Age >17 years
2. Fulfilling criteria for DSM Major Depressive Disorder identified by standard clinical interview
3. Willing to receive either stepped care or intensive psychological therapy alone for depression
4. Registered with Improving Access to Psychological Therapies (IAPT)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
60-75

### Key exclusion criteria
1. Alcohol or drug dependence
2. Presenting at acute risk of suicide
3. Cognitively impaired determined by a brief assessment of cognitive function
4. A diagnosis of bipolar disorder, psychosis and/or psychotic symptoms

### Date of first enrolment
25/09/2013

### Date of final enrolment
25/09/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Sir Henry Wellcome Building for Mood Disorders Research**
Exeter
United Kingdom
EX4 4QQ

## Sponsor information

### Organisation
University of Exeter (UK)

### Sponsor details
c/o Gail Seymour
Research & Knowledge Transfer
The Innovation Centre
Rennes Drive
Exeter
England
United Kingdom
EX4 4RN

### Sponsor type
University/education

### Website
http://www.exeter.ac.uk

### ROR
https://ror.org/03yghzc09

## Funder(s)

### Funder type
University/education

### Funder Name
University of Exeter (UK)

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
United Kingdom

### Funder Name
NHS Northern, Eastern & Western Devon Clinical Commissioning Group (UK)

# 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 20/11/2014 | | Yes | No |
| Basic results | | 05/10/2016 | 05/10/2016 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |