

The effectiveness and cost-effectiveness of treatment by homeopaths in addition to usual care for depressed patients

Submission date 01/12/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/01/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/07/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Depression affects a large number of people in the United Kingdom and in other countries. Many experience it more than once and some suffer from long-standing depression. Established therapies offered within primary care include especially psychological and psychotherapeutic treatment, and antidepressant drugs. These treatments may help many patients, but the effect is sometimes insufficient. Also, some patients do not want to use existing treatment such as antidepressant drugs. There may be many reasons for this, such as previously experienced side-effects. Some patients choose to consult with a homeopath. There is however insufficient research evidence to draw any final conclusions for such treatment for depressed patients.

Who can participate?

Participants will be selected among those who have already agreed to participate in the South Yorkshire Cohort (SYC). They have been recruited through their general practitioners. Participants will be aged 18 to 85, and of both genders. Those included will have self-reported significant depression symptoms.

What does the study involve?

Participants are randomly allocated to Individualised treatment provided by homeopaths in addition to usual care, or usual care alone. All participants are sent a questionnaire at 6 and 12 months. Results for these two groups are compared. Some participants are also invited for an interview with a researcher in order to learn from their experience with treatment.

What are the possible benefits and risks of participating?

Those randomly selected for free treatment provided by a homeopath are offered a first consultation which includes the prescription of a homeopathic remedy, and follow-up treatment for up to 9 months. Previous researchers have found that mild or moderate temporary side-effects may be experienced by some after taking homeopathic remedies, but no serious side-effects are expected. Treatment is individualised to suit each patient. This includes the length and frequency of consultations, and the type of homeopathic remedy prescribed for each patient. Homeopaths may also offer other advice, such as to consult with a counsellor or a

healthcare practitioner, or to use other supportive treatment. All included participants, whether offered treatment by a homeopath or not, may continue with other treatment as usual. All those who are taking conventional drugs must continue treatment as prescribed by their doctor.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
July 2013 to June 2014

Who is funding the study?
The project is self-funded. It has received funding from various funding organisations and individuals, European Central Council of Homeopaths, Homøopat Einar Larsens Minnefond (Norway), and Norske Homeopaters Landsforbund (Norway).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NCT 11/45

Study information

Scientific Title
A pragmatic cohort randomized controlled trial of the clinical and cost effectiveness of treatment of depression by homeopaths in addition to usual care, compared to usual care alone

Acronym

DEPSY (DEPRESSION in South Yorkshire)

Study objectives

To evaluate the acceptability and the comparative clinical and cost effectiveness of the offer of adjunctive treatment provided by homeopaths for patients with self-reported depression in addition to usual care, compared to usual care alone, as well as to explore their short and long term experiences.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. NRES Committee Yorkshire & The Humber - Leeds Central, 15/11/2012, ref: 12/YH/0379
2. NRES Committee Yorkshire & The Humber - Leeds Bradford, 31/07/2013, ref. 12/YH/0379

Study design

Pragmatic trial using the cohort multiple randomised controlled trial design and a qualitative interview study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Self-reported depression

Interventions

Individualised treatment provided by homeopaths in addition to usual care, compared to usual care alone.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Patient Health Questionnaire (PHQ-9) at 6 months

Key secondary outcome(s)

1. Patient Health Questionnaire (PHQ-9) at 12 months, and the following at 6 and 12 months
2. Generalized Anxiety Disorder 7-item (GAD-7) scale at 6 and 12 months
3. EuroQol (EQ-5D) at 6 and 12 months
4. Measure Yourself Medical Outcome Profile (MYMOP2) at 6 and 12 months
5. Body Mass Index (BMI) at 6 and 12 months
6. Life satisfaction score at 6 and 12 months

Completion date

30/06/2014

Eligibility

Key inclusion criteria

1. Patients with self-reported depression indicated by a minimum PHQ-9 score of 10 with a minimum of two symptoms scoring 2 points including at least either question 1 (little interest or pleasure in doing things) or question 2 (feeling down, depressed, or hopeless)
2. Aged 18 to 85 years
3. Are able to speak and read English
4. Have given informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with PHQ-9 scores below 10 or less than 2 symptoms scoring 2 points or neither question 1 nor question 2 scoring 2 points
2. Patients who report current or past psychiatric diagnosis (other than depression) including bipolar disorder, Alzheimer's disease, organic brain damage, schizophrenia, schizoaffective disorders, other psychotic disorders, or antisocial personality disorder
3. Patients who have received homeopathic treatment over the past 3 months
4. Patients who are currently involved in another health research project
5. Patients who due to reduced intellectual capacity or illiteracy are unable to read or understand study questionnaires and accompanying information

Date of first enrolment

01/07/2013

Date of final enrolment

30/06/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Sheffield (UK)

ROR
<https://ror.org/05krs5044>

Funder(s)

Funder type
Government

Funder Name
Investigator initiated and funded (UK)

Funder Name
European Central Council of Homeopaths (EU)

Funder Name
Homøopat Einar Larsens Minnefond (Norway)

Funder Name
Norske Homeopaters Landsforbund (Norway)

Results and Publications

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	30/06/2017		Yes	No
Results article	results	06/07/2017		Yes	No