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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

Registration date
07/01/2013

Overall study status
Completed

Last Edited
10/07/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
Patient Health Questionnaire (PHQ-9) at 6 months

Secondary outcome measures
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

Overall study start date
01/07/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Offer of treatment: 162. Control group (usual care alone): 323

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
England

United Kingdom

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

Sponsor information

Organisation
University of Sheffield (UK)

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Sponsor type
University/education

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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

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