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A feasibility study to analyse the psychological benefits of green exercise (GE) in comparison to cognitive behavioural therapy (CBT) with patients with mild to moderate depression

Submission date
28/09/2007

Recruitment status
Stopped

Registration date
28/09/2007

Overall study status
Stopped

Last Edited
22/02/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0628179879

Study information

Scientific Title

Study objectives
To establish how a 6 week green exercise programme compares to a cognitive behavioural therapy course as a treatment for patients suffering with mild to moderate depression.

As of 22/02/2012, the anticipated end date of trial was updated from 31/12/2008 to 01/08/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Essex Local Research Ethics Committee, REC reference number 06/Q0302/15, 15/02/2006.

Study design
Randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Depression

Interventions
The aim of the study is to evaluate the effectiveness of two different six week group programmes in the treatment of mild to moderate depression. There will be one group programme focusing on green exercise (a series of short countryside walks) and one focusing on cognitive behavioural therapy.

The target population will be individuals who are suffering from mild to moderate depression (in particular reactive depression e.g. a reaction to a traumatic event- due to redundancy, bereavement, divorce, accident etc0 and they have become depressed as a result. Subjects will be referred to the research study by their GP, whereby they will be given sufficient information to make an informed decision regarding their participation.

The GPs will be informed of the research via " Time to learn" session and will be provided with an information leaflet for future reference. Participants may be on a waiting list for referral to a counsellor and take part in this research whilst waiting, but at no point will they be refused alternative treatment. Subjects may have indicated to their GP that they do not wish to have a prescription of any medication but are happy to try other forms of treatment and a research place will be offered. However, we will not recruit subjects who are seeing a separate counsellor during the research or who are changing their medication.

16 participants will be recruited in total, 8 of which will be allocated to the green exercise group and 8 to the cognitive behavioural therapy group (CBT). Participants will be partially randomly allocated within the constraints of it being matched pairs design, as we need to match the groups for age, gender and medication.

Each group programme will comprise of a two hour session once a week for a period of 6 weeks and a detailed programme for the series of CBT and green exercise sessions is included. CBT activities will primarily involve small group discussions and a mini lecture. Green exercise activities will involve one hour of moderate walking in the countryside or country park in a nearby location. A series of 3 walks will be designed which will be repeated twice within the 6 week period. The approximate energy expenditure of the walks will be measured using calorie mapping technique and all 3 will be an equivalent intensity, duration and terrain. The walk leader will set the pace and wear a pedometer to measure the number of steps completed. This will provide us with an estimation of the number of calories expended. A certain level of social interaction will also be encouraged.

The CBT course leader will act as secondary leader in the green exercise programme and the green exercise course leader will attend the CBG sessions to ensure consistency of personalities.

An assistant will also be recruited to attend every session on both courses and they will be fully trained in first aid and CPR. They will have a supportive role and will not be actively involved in the proceedings.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Beck Depression Inventory (BDI) score will decrease after participation in the programme, in comparison to the initial value. This will imply that the participants are less depressed after having participated in either the CBT or the green exercise programme.

Secondary outcome measures
The secondary outcome measures will involve analysing the fluctuations in mood and self esteem over the duration of the course. There will be a comparison of the change in GHQ scores

and SAS values and a comparison of all outcome measures between the two groups of subjects ie CBT group versus green exercise group.

Overall study start date
01/03/2006

Completion date
01/08/2008

Reason abandoned (if study stopped)
"Lack of staff/facilities/resources"

Eligibility

Key inclusion criteria
1. Participants suffering from reactive depression
2. Over 18 years of age
3. Meet the DSM 1v criteria for mild to moderate depression
4. Participants will not suffer any co-morbidity and the participant's GP must have declared them fit to take part in the exercise programme

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
16

Key exclusion criteria
1. Patients that do not meet the DSM 1v criteria
2. Suffer from co-morbitity
3. Are unable to participate in one hour of moderate walking
4. Are unable to communicate using the English Language

Date of first enrolment
01/03/2006

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Environment and Society
Colchester
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CO4 3SQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
South Essex Partnership NHS Trust (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