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Can 'self-confidence workshops' for depression help the implementation of the NICE Guidelines?

Submission date
26/04/2010

Recruitment status
No longer recruiting

Registration date
06/10/2010

Overall study status
Completed

Last Edited
15/02/2019

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

By 2030, it is predicted that depression will be the leading cause of disease burden across the world. However, people are often reluctant to seek help. In the UK, 54% of people who were depressed did not contact their general practitioner (GP). In addition, although the public prefer psychological treatment to medication for depression, psychological services have been very small. In the UK, people used to need to be referred to psychological treatment services. Despite a recent increase in funding, the capacity of psychological treatment services remains limited, particularly for people with more severe problems. In addition, black and minority ethnic (BME) groups are often under-represented in psychological treatment services. Cognitive behaviour therapy (CBT) is as effective as medication for moderate to severe depression, and has long-term benefits. The NICE clinical guidelines in the UK recommend intensive individual CBT for those with moderate or severe depression, whereas individuals with mild to moderate depression are offered a range of treatments including computerised CBT, guided self-help and group CBT. Traditional CBT groups tend to be small, with 8-10 participants meeting for 10-12 two-hour sessions. Another alternative approach is to offer larger scale psycho-educational CBT groups that can reach more people. Psycho-educational means that techniques are adapted into a teaching format so that larger numbers of people, say 25-30 people, can be reached. However, psycho-educational interventions advertised as depression workshops attracted few people, and most people had already used specialist services. Changing the name of the workshops to a more user-friendly label of self-confidence workshops led to a more people self-referring, with 39% of self-referrers never having previously seen their GP for depression. When one-day self-confidence workshops, to which people could refer themselves, were compared with a waiting list control group in a small study, it was found that the workshops were effective in reducing depression and improving self-esteem after 12 weeks. A 2-year follow-up study found that the benefits were maintained but only for those who were depressed. Our study aimed to assess whether the self-confidence workshops were effective clinically, and also to measure their cost and value for money in different parts of South London, focussing just on people with depression. We also wanted to assess access by difficult to engage groups such as black and minority ethnic (BME) groups and those who had not consulted their GPs. If shown to be successful, this could provide an alternative effective psychological intervention that was good

value for money for people with depression in the community, given the low take-up for treatment for depression and peoples preference for psychological treatment.

Who can participate?
Depressed people aged 16 years or over, either sex.

What does the study involve?
Publicity about the workshops was sent round to the community and anyone with problems of low self-confidence was invited to self-refer to the workshops. All individuals who phoned or emailed to register were invited to a one-hour group introductory talk where further information about the workshops was given and informed consent obtained before participants completed assessments at the beginning of the study. For those people who could not attend the talk, the researchers offered an individual telephone assessment. Participants were randomly allocated either to receive the one-day self-confidence workshop after 3 weeks or to wait for 12 weeks for the same workshop (waiting list group). At follow-up for those who had attended the immediate workshop, a two-hour group meeting was held when outcome measures were completed. Participants in the waiting list group were advised to see their GP as usual during the 12-week waiting period. When they were invited to attend their workshop, outcome measures were collected immediately before they attended the workshop. Study participants who did not complete the assessments were posted outcome assessment questionnaires. Participants who completed the forms got feedback about changes they had made on the assessment forms. Those participants who were not depressed were not included in the study and but did get a place on a separate workshop.

What are the possible benefits and risks of participating?
Participants who attended the self-confidence workshops could have benefited from improvements in their symptoms of depression. We think there were few risks. There were no side effects from the CBT. We tried to safeguard confidentiality risks by ensuring data was kept confidential. We were keen to ensure people were making fully informed decisions to participate in the study. If people were distressed at the workshop, we had a backup clinical arrangement so that they could speak to a clinician. At follow-up, if participants still felt they needed help, they were advised about where to go.

Where is the study run from?
Kings College London (UK).

When is the study starting and how long is it expected to run for?
The study ran from April 2010 to November 2011.

Who is funding the study?
National Institute for Health Research (NIHR), Sutton and Merton Primary Care Trust, Wandsworth Primary Care Trust, Lewisham Primary Care Trust, Kingston Primary Care Trust, and Maudsley Charitable Trust.

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
PB-PG-1207-15154

Study information

Scientific Title
Can 'self-confidence workshops' for depression help the implementation of the NICE Guidelines: a randomised controlled trial with repeated measures of a clinical and health economic evaluation

Study objectives
Do these workshops help the implementation of the NICE Guidelines for depression by providing a clinically effective and cost-effective low intensity psychological intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College London Ethics Committee, 14/04/2010, ref: PNM/09/10-65

Study design
Two group multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Quality of life

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
One-day workshop utilising material from Melanie Fennel's 'Overcoming Low Self-Esteem'. The aim is to help participants understand problems of low self-esteem and to teach different techniques to help them improve their self-confidence to enable them to handle their resulting feelings of depression and anxiety. The programme is broken down into four sessions:
1. Model of self-confidence and emotional aspects of self-confidence, including depression and anxiety
2. Cognitive aspects
3. Behavioural aspects
4. Action planning and homework assignments

Introductory talk (1 hour) then 1-day treatment 3 weeks later (9.30 am - 4.30 pm), then 2-hour booster session at 3 weeks post-workshop and postal follow-up at 3 months. Other participants are on the waiting list for 3 months before the intervention begins. Workshops take place within eight boroughs in South-East London (Wandsworth, Merton, Kingston, Sutton, Hammersmith, Hounslow, Lambeth and Lewisham).

The control group is a waiting list who wait 3 months before receiving the intervention.

Follow-up period is 3 months for the experimental group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Client Service Receipt Inventory (CSRI): a specially designed short self-report version will be developed and used to assess service use and lost employment
2. Beck Depression Inventory (BDI) for assessment of severity of depression. 4-point Likert scale to measure the extent to which the person is experiencing symptoms of depression.

Both measures completed at baseline and 3-month follow-up.

Secondary outcome measures
1. GAD-7 measure to assess how much the person has been bothered by various symptoms of anxiety on a 4-point Likert scale (0 not at all, 3 nearly every day)
2. Rosenberg Self-Esteem Scale to assess feelings about self on a 4-point Likert scale (0 strongly

disagree, 3 strongly agree)
3. The EQ-5D measure of health outcome to enable health-related quality of life and quality-adjusted life-years to be calculated. Participants indicate how they are coping in terms of mobility, self-care, anxiety/depression, pain and completion of usual activities. Also uses a visual analogue scale for indicating health state (0 worst imaginable health state, 100 best imaginable health state).

All measures completed at baseline and 3-month follow-up.

Overall study start date
10/04/2010

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Depressed people, classified as only those with a Beck Depression Inventory (BDI) score of 14 and above
2. Aged 16 years or over, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320

Key exclusion criteria
1. Aged less than 16 years
2. Attention problems or organic brain syndrome

Date of first enrolment
10/04/2010

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychology (PO77)
London
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-1207-15154)

Funder Name
Sutton and Merton Primary Care Trust (UK)

Funder Name
Wandsworth Primary Care Trust (UK)

Funder Name
Lewisham Primary Care Trust (UK)

Funder Name
Kingston Primary Care Trust (UK)

Funder Name
Maudsley Charitable 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No
Results article	results	13/02/2019		Yes	No