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Can people with substance misuse and depression benefit from brief psychological therapies?

Submission date
12/01/2012

Recruitment status
No longer recruiting

Registration date
27/02/2012

Overall study status
Completed

Last Edited
26/08/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Psychological therapies (talking therapies) are effective in reducing depression (low mood). A treatment programme called Increasing Access to Psychological Therapies has been established to offer short term psychological therapy based to people who have symptoms of depression. Depression is common in people who are being treated for substance misuse problems. However, this group of people often find it difficult to access psychological therapies for their mental health issues, as substance misuse is often been seen as reason for exclusion from accessing therapy for depression and other mental health issues. Those with substance misuse problems can also benefit from accessing therapy whilst in treatment for substance misuse as well as those who do not have substance misuse problems.
The aim of this study is to find out whether psychological therapies are effective for people with substance misuse. This study will investigate how many people with substance use problems and depression are willing to engage with brief psychological therapy, how many complete this, and what participants think about this psychological treatment. We also want to find out if participants who benefit from treatment have certain things in common; for example their use of alcohol or drugs or their level of dependence on substances.

What is involved?
The study will compare two treatments for depression:
1. Behavioural Activation delivered over 10 sessions with a primary care psychological therapist (based in the mental health team)
2. A self-help booklet accompanied by a session with the persons own key-worker in the community drug and alcohol service. This worker has been trained in assisting people with the use of self-help for depression booklets.
Both therapies have been shown to be effective for the treatment of depression, but they have not been tried out with people who also have a substance use problem. Although both options may be helpful, we dont know if one is better than the other or if there is no real difference between them when it comes to helping participants to improve their mood. Therefore people

who are interested in participating will be randomly allocated (like tossing a coin) to one or the other. The participants will not have the option to choose as we want to compare the two types of treatment without the influence of peoples own preferences.

Who can participate?
Anyone already being treated by the Leeds Community Substance Misuse Services who has been identified as having depressive symptoms.

What does the study involve?
The participants will complete initial brief questionnaires, and then be offered one of the treatments described above. This will be explained in detail by the study co-ordinator before they start treatment. As part of the study, member of the research team will ask the participants to complete brief symptom questionnaires related to mental health and substance misuse three times during the course of treatment: once at the start, once after 6 weeks and once after 12 weeks. The questionnaire should take approximately five minutes of their time on each occasion.

What are the possible benefits and risks of participating?
Participation in the study could help to improve their mood and reduce depressive symptoms and by taking part in the study they will be helping to improve knowledge about treatment for depression in community drugs services and help to develop new treatment approaches for the future.
Unfortunately participants will not be able to choose which of the 2 treatments to receive. The researchers will offer one treatment to one group of participants and the other treatment to another group. This will ensure there are equal numbers of participants in each treatment, and that personal preference or other individual factors do not influence who is in each treatment group. This is to ensure that any differences found between the two groups will be down to the differences in therapy, not differences in the groups that received it.
The questionnaires will ask people to rate how often they have experienced some key symptoms of depression and anxiety over the previous two weeks. This may be uncomfortable for some people as it may bring up difficult or unpleasant feelings. However, these will be questions that participants will have been asked before as part of routine treatment. In addition, all the workers and researchers involved will be able to offer support if people get upset, and refer to appropriate services or help as required. There is a risk management protocol in place for the study.

Where is the study run from?
Leeds community substance misuse services and Leeds Primary Mental Health Service, with collaborators from University of York, Durham University and University of Greenwich.

When is the study starting and how long is it expected to run for?
The start of the project will be March 2012 and will run for 1 year until March 2013

Who is funding the study?
National Health Service (NHS) Feasibility and Sustainability Fund

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
R006

Study information

Scientific Title
COmorbidity and Brief Interventions for Depression: The COBID Study

Acronym
COBID

Study objectives
1. To evaluate the feasibility of brief psychological therapy with people who have co-morbid substance misuse and depression quantified as engagement and completion rates (versus dropout rate)
2. A 12-week behavioural activation therapy will show improvement on measures of mood and substance misuse when compared with a minimal self-help treatment for depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee, 02/03/2012, ref: 12/YH/0096

Study design

Open label two arm randomised controlled trial

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
Mild to moderate substance misuse and depression

Interventions
Comparing behavioural activation with a minimal treatment intervention (1 session self-help and bibliotherapy)

Behavioural Activation (BA) is a structured psychological intervention for depression based on principles of operant conditioning, functional analysis of behaviour and problem solving (Martell et al., 2001; Hopko et al., 2003). Essentially, it consists of:
1. Self-monitoring to identify depressive and maladaptive behaviours
2. Scheduling activities aiming to reinforce adaptive behaviour patterns
3. Reducing the frequency avoidant behaviours, rumination and maladaptive coping strategies.

The intervention delivered in this pilot feasibility trial will follow a published BA protocol developed by Kanter et al. (2009) structured BA treatment manual developed by our collaborators for a previous RCT (Ekers et al., 2011), which integrates and summarises the main theoretical principles, techniques and intervention strategies presented in the above cited versions of BA. Most importantly, the Kanter protocol outlines key problems that impede effective treatment and presents alternative therapeutic strategies to address such barriers to activation follows the conventional BA theory and treatment model by Martell et al. (2001). The BA intervention will be based on a 12 session treatment manual.

BA will be delivered by qualified mental health practitioners based in the Primary Care Mental Health Service. Mental health practitioners will maintain contact with the participants' key workers and General Practitioners who are based in the community drugs treatment services and manage patients' care and treatment plans. Therefore, the intervention is considered collaborative care between mental health and community drugs services. The therapists delivering the BA intervention have already had training in this type of therapy as part of their professional qualification; in addition the research team will organise a full-day training event to orientate therapists to this study's BA manual.

The control intervention will involve usual care in a community drugs treatment service or addiction recovery programme, with the additional provision of a self-help booklet for depression which will be introduced by a key worker based in the community drugs servicepractitioner during a single session. Bibliotherapy is an educational self-help approach in which patients apply principles of Cognitive Behavioural Therapy (CBT) using bibliographical materials (booklets). Such self-help approaches are recommended for mild-to-moderate depression in the NICE guidelines (2009). A group of keyworkers in the Leeds community drugs services have received basic training in the use of self-help materials for common mental health problems as part of routine practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient Health Questionnaire (PHQ-9)
Measured at baseline, then 6 weeks post therapy and 12 weeks post therapy.

Secondary outcome measures
1. Generalised Anxiety Disorder (GAD-7)
2. Treatment Outcomes Profile (TOP)
3. Substance misuse section of PRISM

Measured at baseline, then 6 weeks post therapy and 12 weeks post therapy.

Overall study start date
19/03/2012

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Are currently engaging with a community drugs treatment, detox, maintenance or addiction recovery focused service in Leeds. Engagement is defined by:
1.1. Being currently registered with a formal addiction focused service or programme
1.2. Having had planned contact with the service within the last month
2. Meet criteria for a current depressive disorder as defined by a score of 12 or more on the PHQ-9 questionniare. Comorbid anxiety disorders are not exclusion criteria, as long as depression is the primary disorder
3. Meet criteria for mild-to-moderate severity of drug dependence, as defined by a score between 0 10 on the Severity of Dependence Questionnaire
4. Have used alcohol, drugs, or methadone maintenance medication within the last month

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Are not currently engaging in a formal addiction treatment or support programme in Leeds
2. Do not currently meet criteria as clinically significant for depressive disorder as defined by the PHQ-9 questionnaire score
3. Meet criteria for depression and a comorbid anxiety disorder, as identified by the GAD-7 questionnaire. Where the anxiety disorder is more severe, has been of longer duration than depressive symptoms and is the patient's main concern.
4. Meet criteria for a severe mental disorder including bipolar affective disorder, schizophrenia or other psychotic disorders. Patients with severe mental health problems who are already involved in psychiatric or secondary care mental health services.
5. Are free of substances of dependence and/or maintained on disulfiram, acamprosate or naloxone.
6. Those who have a severe drug or alcohol dependence, as defined by a score above 10 on the Severity of Dependence Questionnaire.

Date of first enrolment
19/03/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Research and Clinical Audit Lead
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.leeds.nhs.uk/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Feasibility and Sustainability Fund (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