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Cognitive behaviour therapy (CBT) for anxiety and depression in adults with mild intellectual disabilities (ID)

Submission date
02/02/2011

Recruitment status
No longer recruiting

Registration date
25/03/2011

Overall study status
Completed

Last Edited
05/12/2017

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Learning disabilities are common conditions which affect the way people's minds are able to process information and learn (intellectual ability). Even in a mild form, they can make everyday activities more difficult, causing problems with household tasks, socialising or managing money. It has been found that many people suffering from a mild learning disability also experience problems with their mood, such as depression (extreme sadness) and anxiety. Cognitive behavioural therapy (CBT) is a type of talking therapy, which works by teaching people more effective ways to deal with their problems by changing the way they think and behave. Many studies have shown that CBT can be an extremely effective therapy for people suffering from problems with their mood, however little research has been done to find out whether this type of treatment could be effective for someone with mild learning disabilities. Studies have shown that people with mild learning disabilities have the skills needed to take part in CBT. The aim of this study is to test the effectiveness of CBT in treating those with mild learning disabilities that are experiencing problems with their mood.

Who can participate?
Adults with mild learning disabilities who are also experiencing mental health problems that affect their mood (such as depression or anxiety).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive weekly one-to-one sessions of CBT for up to 16 weeks. These participants also continue to receive the usual service that they receive from the intellectual disability service, involving care management and emotional and social support. Participants in the second group continue to receive the usual service from the intellectual disability service, but do not receive any additional support throughout the 16 weeks of the study. At the start of the study and then again after 4 and 6 months, participants in both groups complete a number of questionnaires in order to find out whether the treatment has made any changes to their mood, quality of life or thinking ability (cognitive aspects).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Camden and Islington Mental Health and Social Care Trust (UK)

When is the study starting and how long is it expected to run for?
March 2010 to August 2011

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Angela Hassiotis
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Study website
http://www.ucl.ac.uk/mentalhealthsciences/researchthemesandinterests/cbt

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PB-PG-0807-14121

Study information

Scientific Title
Cognitive behaviour therapy (CBT) for anxiety and depression in adults with mild intellectual disabilities (ID): a randomised controlled trial

Study objectives
Is manualised cognitive behavioural therapy (CBT) treatment more clinically and cost effective than treatment as usual (TAU) for depression and/or anxiety for people with mild intellectual disabilities?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint UCL/UCLH Committees on Ethics of Human Research Committee Alpha approved on the 25th November 2008 (ref: 08AL 332)

Study design
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
Depression, anxiety

Interventions
1. CBT plus treatment as usual: Participants will receive up to 16 one-to-one manualised cognitive behavioural therapy treatment sessions over a period of 16 weeks (4 months) in addition to the usual service they receive from the intellectual disability service.
2. Treatment as usual (TAU): This is the standard treatment which would be available to any adult with an intellectual disability referred to the intellectual disability service. This includes care management, medical, non specific psychological input, nursing or social support.

Screening:
Potential participants will be screened for anxiety and/or depression using the Mini PAS-ADD (Psychiatric Assessment Schedules for Adults with Developmental Disabilities; Moss, 2002). Those identified as cases (greater than 10 for depression and greater than 7 for anxiety) will be

eligible for the study. The range of scores indicating severity is between 11 - 32 for depression and 7 - 18 for anxiety.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Participants will be assessed to measure the severity of their cognitive aspects of anxiety and/or depression using two subscales of the Beck Youth Inventories (BYI). These will be Beck Anxiety Inventory Youth (BAI-Y) and Beck Depression Inventory Youth (BDI-Y). Both sub-scales will be administered at baseline, end of treatment (i.e. four months) and at follow-up (i.e. six months).

Secondary outcome measures
1. Costs will be measured by administration of the Client Service Receipt Inventory, intellectual disability version (CSRI-ID version) at baseline and end of treatment (i.e. four months)
2. A quality of life questionnaire (Manchester Short Assessment of Quality of Life) that consists of 16-items. Each item is rated on a seven-point satisfaction scale, from 1 = 'Couldn't be worse' to 7 = 'Couldnt be better'. It will be administered at baseline and at the end of treatment (i.e. four months).
3. Satisfaction with treatment will be measured by using a modified client satisfaction questionnaire which will elicit the client's perception of the mental health service/intervention at baseline and end of treatment (i.e. four months)
4. There will also be an open question with prompts about the experience and process of therapy to both service users and their carers to gain a better understanding of how the intervention was perceived and valued

Overall study start date
01/03/2010

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Adults aged 16 years and over (either sex) who have mild intellectual disability (as determined on the service register)
2. A disorder with one of the following International Classification of Diseases, version 10 (ICD-10) codes: F32, F33, F34, F38, F40, F41 (anxiety, depression or mixed affective states)
3. Only participants with English as their main/spoken language

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Participants with co-morbid conditions of substance misuse, autism and those already receiving psychological treatment
2. Service users with moderate/severe intellectual disability

Date of first enrolment
01/03/2010

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
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Sponsor information

Organisation
Camden and Islington Mental Health and Social Care Trust (UK)

Sponsor details
Research and Development Office
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	14/04/2011		Yes	No
Results article	results	01/10/2013		Yes	No