

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/12/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

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

United Kingdom

England

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)

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

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	01/10/2013		Yes	No
Protocol article	protocol	14/04/2011		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes