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Cognitive-Behavioural Therapy (CBT) for Adult Attention Deficit Hyperactivity Disorder (ADHD): a Randomised Controlled Trial

Submission date
01/04/2010

Recruitment status
No longer recruiting

Registration date
04/11/2010

Overall study status
Completed

Last Edited
16/10/2018

Condition category
Mental and Behavioural Disorders

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

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
R&D2009/051

Study information

Scientific Title
A Proof of Concept Randomised Controlled Trial to Examine the Potential Efficacy, Patient Acceptability and Feasibility of Cognitive-behavioural Therapy for Adults With Attention Deficit Hyperactivity Disorder (ADHD)

Study objectives
CBT plus treatment as usual will be more effective than treatment as usual alone in
1. reducing ADHD symptoms
2. improving functioning

Please note that as of 20/06/2013, the anticipated end date for this trial was updated from 20/04/2013 to 30/04/2014

20/06/2013: Please note that recruitment for this trial is closed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City Road and Hampstead approved on the 29th of July 2009 subject to clarifications, substantial amendments were approved on 27th January 2010, 4th August 2010 and 16th August 2011 (ref: 09/H0721/49)

Study design
Single centre interventional open label 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Adult Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
60 participants will be randomly allocated to either:
1. CBT plus treatment as usual

16 one-hour therapy sessions taking place over 30 weeks in addition to usual medical follow-up appointments - typically one 30-minute appointment every three to six months

2. Treatment as usual alone
Treatment as usual appointments at the Adult ADHD Service - typically one 30-minute appointment every three to six months - taking place over 30 weeks

The total duration of follow up will be 42 weeks (i.e. 12 weeks after the ends of the treatment period).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Adult Barkley Current Behaviour Scale (Barkley 2006)
An 18-item self-report measure assessing ADHD symptoms, rated on a 4-point Likert scale
2. Work and Social Adjustment Scale (Mundt et al 2002)
A reliable and valid self-report measure of impaired functioning attributable to an identified problem, consisting of 5 items, each rated on an 8-point scale

All outcomes will be assessed at baseline, 30 and 42 weeks. There is an assessment at the 30-week point also in case of attrition and for further analyses, but 30-week measures will not be used as the main outcomes.

Secondary outcome measures
Current secondary outcome measures as of 03/01/2012
1. Clinical Outcomes in Routine Evaluation Outcome measure (CORE-OM), (Evans et al 2002)
2. Hospital Anxiety and Depression Scale (HADS)
3. ADHD Beliefs Questionnaire
4. ADHD Behaviours Questionnaire
5. Rosenberg Self-Esteem Scale (Rosenberg 1965)
6. Autism Spectrum Quotient (Baron-Cohen et al 2001) *
7. Global Impression scales (improvement** and satisfaction**) (adapted from Guy 1976 and used previously in Deale et al 1997)
8. Frost Multidimensional Perfectionism Scale (Frost et al 1990), Doubts about actions, Concern over mistakes, Parental Criticism and Parental expectations subscales
9. Beliefs about Emotions Questionnaire (Rimes et al 2009)

Rated by nominated informant:
10. Adult Barkley Current Behaviour Scale
11. Global Impression scales (severity and improvement**) (adapted from Guy 1976 and used previously in Deale et al 1997)

Rated by independent evaluator:
12. Global Impression scales (severity and improvement**) (adapted from Guy 1976 and used previously in Deale et al 1997)
13. Global Assessment of Functioning (Axis V, DSM-IV-TR)

this is routinely administered during clinic assessments. This will only be included in the questionnaire pack if, for some reason, it has not already been completed
* baseline only
** 30 and 42 weeks only

Previous secondary outcome measures
1. Clinical Outcomes in Routine Evaluation Outcome measure (CORE-OM), (Evans et al 2002)
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3. ADHD Beliefs Questionnaire
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rated by nominated informant:
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rated by independent evaluator:
11. Global Impression scales (severity and improvement**) (adapted from Guy 1976 and used previously in Deale et al 1997)
12. Global Assessment of Functioning (Axis V, DSM-IV-TR)

All outcomes will be assessed at baseline, 30 and 42 weeks

Overall study start date
21/04/2010

Completion date
30/04/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/12/2012:
1. Men and women aged 18-65 with a diagnosis of adult ADHD according to NICE guidelines i.e. if there was evidence from both the participant and the informant (where available) that:
1.1. the participant met DSM-IV criteria for Adult ADHD both in childhood and adulthood
1.2. the participant experienced at least moderate psychological, social and/or educational or occupational impairment in multiple settings
1.3. symptoms occurred in two or more settings including social, familial, educational and/or occupational settings.
2. Participants will have received a diagnosis either from the Adult ADHD Service, Maudsley Hospital, London, UK or another specialist/secondary care service (in this case a copy of the diagnostic report will be required)
3. Participants will either already be attending follow-up clinics, including psychoeducation workshops, or will have been recently referred to the service for medication follow-up or psychological treatment

4. Currently score 6 or more on the inattentive or hyperactive/impulsive subscale of the Adult Barkley Current Behaviour Scale (self-rated)
5. Clinical severity of at least a moderate level (Clinical Global Impression score of 4 or above)

Previous inclusion criteria until 17/12/2012:
1. Men and women aged 18 to 65 who have received a diagnosis of adult ADHD in the Adult ADHD Service at the Maudsley Hospital, London, UK
2. Currently score 6 or more on the inattentive or hyperactive/impulsive subscale of the Adult Barkley Current Behaviour Scale (self-rated)
3. Clinical severity of at least a moderate level (Clinical Global Impression score of 4 or above)
4. If on medication to be on a stabilised dose as defined by no more than 10% change in medication dose over a two-month period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Clinically significant anxiety disorder
2. Current episode major depression, current suicidality or self-harm (score of moderate or high suicidality on the M.I.N.I.)
3. Acquired brain injury
4. Primary diagnosis of psychosis or bipolar disorder
5. Pervasive developmental disorder
6. Active substance misuse/dependence in last three months
7. Verbal IQ <80
8. Diagnosis of a personality disorder
9. Participant not willing to comply with the requirements of an RCT
10. If the assessor does not perceive ADHD to be the current primary problem

Date of first enrolment
21/04/2010

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adult ADHD Service
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust (UK)

Sponsor details
Bethlem Royal Hospital
Monks Orchard Road
Beckenham, Kent
England
United Kingdom
BR3 3BX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/015803449

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South London and Maudsley NHS Foundation 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?
Protocol article	protocol	03/09/2014		Yes	No
Results article	results	01/02/2018		Yes	No