ISRCTN06461651 https://doi.org/10.1186/ISRCTN06461651

Pragmatic, randomised controlled trial assessing the non-Inferiority of counselling and its effectiveness for depression

Submission date
18/07/2014

Recruitment status
No longer recruiting

Registration date
24/09/2014

Overall study status
Completed

Last Edited
18/05/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
There is good evidence showing that a talking therapy called Cognitive Behaviour Therapy (CBT) can and does help many people. However, it does not help everyone all the time. For people experiencing moderate or severe depression there is an alternative treatment called counselling for depression (CfD). CfD is as effective as CBT but we need to test whether this is really the case by conducting a scientifically rigorous study. This is the purpose of the study and the findings may help to inform patient choice in the future.

Who can participate?
Adults from the Sheffield Health and Social Care NHS Foundation Trust's Improving Access to Psychological Therapies (IAPT) service who have been referred for step 3 treatment and who have a primary diagnosis of moderate or severe depression.

What does the study involve?
Participants are randomly allocated to either Counselling for Depression (CfD) or Cognitive Behaviour Therapy (CBT). Once people are screened and accepted into the study, they complete some forms about how effective the therapy is for them. Once treatment has finished, clients are sent a questionnaire pack 6 and 12 months after their entry into the study. With their agreement, they are also contacted by telephone to carry out a short interview on their experience of treatment, whether they have terminated treatment with the agreement of their practitioner or by their own decision.

What are the possible benefits and risks of participating?
Participants stand an equal chance of receiving either CBT or CfD, and there is currently little evidence to suggest that one treatment is better than the other for depression. There is little or no risk to participants who are part of the study. This is because they continue with their treatment as they would normally.

Where is the study run from?
Sheffield Health and Social Care NHS Foundation Trust (UK) - Improving Access to Psychological Therapies (IAPT) service

When is the study starting and how long is it expected to run for?
Recruitment began in August 2014 and will recruit for a period of around 18 months

Who is funding the study?
The British Association for Counselling and Psychotherapy (BACP) Research Foundation (UK)

Who is the main contact?
Prof. Michael Barkham
m.barkham@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr David Saxon

Contact details
ScHARR
University of Sheffield
Regents Court
Regents Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 222 0718
d.saxon@sheffield.ac.uk

Additional identifiers

Protocol serial number
0001

Study information

Scientific Title
A pragmatic non-inferiority randomised trial of the clinical and cost-effectiveness of counselling for depression versus cognitive-behaviour therapy, for clients in primary care meeting a diagnosis of moderate or severe depression

Acronym
PRaCTICED

Study objectives

Determining the clinical and cost-effectiveness of counselling for depression (CfD) compared with cognitive behaviour therapy (CBT) as delivered in primary care for clients with moderate or severe depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - South Yorkshire, 27/03/2014, ref: 14/YH/0001

Study design
Non-inferiority randomised controlled trial embedded within a comprehensive cohort design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate and severe depression

Interventions
Participants are randomised to two arms:

1. Counselling for Depression (CfD): the intervention being evaluated is Counselling for Depression (CfD). CfD is a form of Person-Centred/Experiential (PCE) therapy derived from the competences required to deliver effective humanistic psychological therapies. CfD is drawn from those humanistic approaches with the strongest evidence for efficacy, based on outcomes of controlled trials. CfD is specifically designed to address depression and is delivered within IAPT and related programmes. The comparator intervention will be high-intensity Beckian CBT as delivered within the Sheffield IAPT service. Both interventions will offer up to 20 sessions for participants.
2. Cognitive Behavioural Therapy (CBT)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Depression severity and symptomatology measured by the PHQ-9 at 6 months and at 12-month follow-up.

Key secondary outcome(s))
1. CORE-OM, BDI-II, EQ-5D-5L, WSAS and GAD-7
2. Healthcare utilisation, measured using an adaptation of the Client Service Receipt Inventory
3. Patient satisfaction, measured using the Client Satisfaction Questionnaire (CSQ), at 6 months

Taken at baseline, 6 and 12 months

Completion date
30/08/2019

Eligibility

Key inclusion criteria
Aged 18 or over

Stage 1:
1. An initial indication by the client that depression is a major focus (ascertained by the PWP during initial assessment of presenting issues)
2. Weekly PHQ-9 scores are greater or equal to 12 at the 3rd or 4th appointment with the PWP
3. Client states no strong objection to either treatment sufficient for them to be unwilling to enter the trial should they be allocated to the alternate treatment

Stage 2:
4. Client meets an ICD-10 diagnosis of moderate or severe depression using the Clinical Interview Schedule-Revised (CIS-R) carried out by an independent assessor

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
510

Key exclusion criteria
Stage 1:
1. Presence of prior diagnosis of personality disorder, bipolar disorder, schizophrenia as indicated in the IAPT Outcomes Toolkit within the service data or from GP referral notes to the service
2. Organic origin of presentation (e.g., dementia) as indicated on referral to the service by the GP
3. Long-term physical condition as denoted in service notes

Stage 2:
4. Elevated risk of suicide: if active thoughts of suicide are indicated from the CIS-R, we will implement a risk protocol to inform the PWP or identified practitioner

5. Alcohol or substance dependency: these will be determined by Questions 1 and 2 from Section I (Alcohol) and Section II (Drug) of the Mini-International Neuropsychiatric Interview (M.I. N.I.), which yield diagnoses of current alcohol or drug dependency

Date of first enrolment
16/10/2014

Date of final enrolment
30/08/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Sheffield (UK)

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research organisation

Funder Name
The British Association for Counselling and Psychotherapy (BACP) Research Foundation (UK) (Ref: 0001)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	18/05/2021	Yes	No
Protocol article	protocol	01/03/2017		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes