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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
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Study website
http://www.shef.ac.uk/scharr/sections/hsr/mh/mhresearch/practiced/info

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Depression severity and symptomatology measured by the PHQ-9 at 6 months and at 12-month follow-up.

Secondary outcome measures
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

Overall study start date
01/01/2014

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
550

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
England

United Kingdom

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

Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
CPSR
Health Services Research
The University of Sheffield
Regent Court
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Sponsor type
University/education

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

Publication and dissemination plan
1. December 2016: Protocol paper submit to Trials Journal
2. September 2019: Primary outcome paper (Clinical & Cost effectiveness)

Other planned papers at later date:
1. On patient drop-out
2. Patient experience of treatment
3. Comparison between trial patients & similar non-trial patients seen routinely by the service, 4) treatment adherence

Intention to publish date

01/05/2021

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?
Protocol article	protocol	01/03/2017		Yes	No
Results article		01/06/2021	18/05/2021	Yes	No
HRA research summary			28/06/2023	No	No