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REDIT-CT: Improving Psychodynamic Psychotherapy in Primary Care: An Evaluation Study of Dynamic Interpersonal Therapy (DIT) in a High-Intensity Comparator Sub-study

Submission date
01/05/2014

Recruitment status
No longer recruiting

Registration date
01/05/2014

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a serious problem affecting millions of people worldwide. Research to date has shown that psychological therapies can be as effective as medication in its treatment. In the UK, the NHS has developed a programme called Improving Access to Psychological Therapies (IAPT), which aims to provide more easily accessible treatments for depression and anxiety. Within IAPT, dynamic interpersonal therapy (DIT) and cognitive behavioural therapy (CBT) are recommended as treatments for depression. DIT is a new form of short-term psychoanalytic psychotherapy and CBT is the most commonly used therapy in IAPT. While there is evidence that short-term psychodynamic psychotherapy is generally effective, the DIT package specifically continues to be perfected so it is important to test it through a full, large-scale research study. This study aims to find out the requirements for a full-scale study comparing DIT and CBT within IAPT.

Who can participate?
Patients aged over 18 with major depressive disorder can participate.

What does the study involve?
If you consent to join the study, and where the study is considered suitable for you after the first research assessment and clinical assessment, you will meet with a researcher three times in total (separately but in addition to your appointments with the therapist) to enable him/her to collect the necessary research information. The information that the research team will be interested in gaining from you will relate to your feelings, mood and depressive symptoms: this means that the researcher will ask questions and will also provide some questionnaires for you to complete. After the first meeting with the researcher, if you are eligible for the study, you will be randomly allocated to one of the treatment conditions in the study (DIT or CBT) and will then meet with the researcher twice more: 8 weeks after being allocated to treatment (i.e. half-way through the treatment course) and then again 17-18 weeks after allocation (i.e. at the end of the treatment course).

What are the possible benefits and risks of participating?
Whichever treatment you receive, you will be offered regular, structured support and you would be monitored closely throughout your time in the study. This study will help us to improve the way that these therapies are used in routine practice, which we hope will ultimately lead to better service provision for others in the future. You might feel good to know that you have been part of an important study and contributed to this. Some people can find it upsetting talking about their thoughts and feelings - both with their therapist and/or the researcher - but this usually gets better as treatment progresses. All information gathered by the researcher during your research appointment with them is strictly confidential, but if there is anything that you do not wish to discuss, or if you wish to interrupt the interview for any reason, the researcher will talk to you about this and pause or stop if asked to do so.

Where is the study run from?
Recruitment will take place in Camden Psychological Therapies Service, Camden & Islington NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
October 2013 to December 2017.

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

Who is the main contact?
Mrs Sally O'Keefe
Sally.OKeeffe@annafreud.org

Study website
http://www.redit.org.uk

Contact information

Type(s)
Scientific

Contact name
Miss Sally O’Keeffe

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16557

Study information

Scientific Title
An Evaluation Study of Dynamic Interpersonal Therapy (DIT) in a High-Intensity Comparator Sub-study: a randomised controlled trial

Acronym
REDIT-CT

Study objectives
REDIT-CT aims to assess the requirements for a full-scale trial comparing DIT and CBT within IAPT. In particular, the study will examine patients acceptability of random allocation to the treatment arms, if DIT and CBT therapists and IAPT service managers can collaborate on this shared protocol and if measurement outcomes independent of the therapies are compatible with service practices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London Stanmore,19/02/2014; ref. 14/LO/0183

Study design
Randomised, Interventional, Design type: Treatment

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Depression; Disease: Depression

Interventions
Participants are randomly allocated to receive Dynamic Interpersonal Therapy or Cognitive Behavioural Therapy over the course of approximately 16 weeks.

Cognitive-Behavioural Therapy: Cognitive-Behavioural Therapy (CBT) is a form of talking therapy delivered over 16 weeks. It aims to help identify individual patterns of thoughts, emotions, bodily feelings and actions that are unhelpful and make changes to these thoughts and behaviours to improve mood.

Dynamic Interpersonal Therapy: Dynamic Interpersonal Therapy (DIT) is a form of short-term psychoanalytic psychotherapy (16 sessions) developed for treating depression. It explores difficult things in the past that continue to affect the way people feel and behave in the present, and can help with emotional and relationship problems.; Follow Up Length: 4 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Updated primary outcome measures as of 03/05/2017:
Depression severity is measured using a semi-structured interview, the Hamilton Depression Rating Scale (HDRS-17) at baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks).

Previous primary outcome measure:
Treatment acceptability and feasibility. The main outcomes are recruitment rate, retention in treatment, treatment adherence, and adherence to research protocol. Acceptability will be indicated by the number of sessions attended, including the number of individuals who refuse treatment and feasibility by the number of patients failing to comply with the full clinical and research protocol, the burden of which will be similar to that which could be expected in a full study.

We will use the Hamilton Depression Rating Scale (HDRS-17) (17), a structured interview designed to quantify the severity of depressive symptoms in patients already diagnosed as suffering from depressive disorder.

Secondary outcome measures
Updated secondary outcome measures as of 03/05/2017:
1. Depression severity is measured using the Beck Depression Inventory (BDI-II) at baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks)
2. Psychological distress is measured using the Brief Symptom Inventory (BSI) at baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks)
3. Quality of life is measured using EuroQOL (EQ-5D) questionnaire at baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks).
4. Comorbidity of a range of psychiatric diagnoses are measured using the MINI+ interview (MINI International Neuropsychiatric Interview) at baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks)
5. Reflective functioning is measured using the Reflective Function Questionnaire (RFQ-54) at

baseline, mid-treatment (8 weeks), and end-of-treatment (approx. 16 weeks)
6. Social adjustment is measured using the Revised Social Adjustment Scale (SAS-r) at baseline, mid-treatment (8 weeks) and end-of-treatment (approx. 16 weeks)
7. Interpersonal difficulties are measured using the Inventory of Interpersonal Problems (IIP-64) questionnaire at baseline and end-of-treatment (approx. 16 weeks)
8. Adult attachment is measured using the Experiences in Close Relationships - Revised (ECR-R) questionnaire at baseline and end-of-treatment (approx. 16 weeks)

Previous secondary outcome measures:
General psychopathology outcomes, psychotherapy process outcome, health-related quality of life and measures of cost-effectiveness. The battery of instruments will include:
1. Brief Symptom Inventory (BSI)
2. Beck Depression Inventory (BDI-II)
3. EuroQol (EQ-5D)
4. Reflective Function Questionnaire (RFQ-54)
5. Self-Esteem Implicit Association Test (SEIAT)
6. Experiences in Close Relationships Questionnaire-Revised (ECR-R)
7. Revised Social Adjustment Scale (SAS-R)
8. MINI+ (Mini-International MINI international neuropsychiatric interview)

Measured at baseline, mid-treatment (8 weeks) and end-of-treatment (approx. 16 weeks).

Overall study start date
01/10/2013

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Age 18 or over
2. Current diagnosis of MDD with or without dysthymic disorder according to DSM-IV criteria
3. Hamilton Depression Rating Scale score above 14
4. PHQ score above 10
5. Confirmed need for high-intensity treatment either at triage, following referral, or by low-intensity worker and supervisor

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Current psychotic symptoms or bipolar disorder
2. Current use of antipsychotic medication
3. Complex Personality Disorder
4. Current self-injury
5. Historic severe or persistent self-injury
6. Two or more suicide attempts (lifetime)
7. One or more suicide attempt in the past 12 months
8. Current diagnosis of eating disorder according to DSM-IV criteria
9. Current diagnosis of drugs/alcohol abuse according to DSM-IV criteria
10. Non-English speaking
11. Previous unsuccessful CBT treatment
12. Clinical contra-indication to short-term psychotherapy (e.g. attachment history multiple - separations, serious ongoing trauma in childhood, multiple caregivers suggesting the need for longer term psychotherapy)
13. Evidence of pervasive use of help
14. Highly unstable or insecure life arrangements (e.g. domestic violence)

Date of first enrolment
04/04/2014

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anna Freud Centre
12 Maresfield Gardens
London
United Kingdom
NW3 5SU

Sponsor information

Organisation
The Tavistock and Portman NHS Foundation Trust (UK)

Sponsor details

The Tavistock Centre
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0610-22287

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

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	01/04/2020	21/06/2019	Yes	No
HRA research summary			28/06/2023	No	No