

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

<b>Submission date</b> 01/05/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/06/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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.reidit.org.uk>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Miss Sally O'Keefe

### **Contact details**

Anna Freud Centre

12 Maresfield Gardens

London

United Kingdom

NW3 5SU

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Sally.OKeeffe@annafreud.org

## **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  
120 Belsize Lane  
London  
England  
United Kingdom  
NW3 5BA

**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?
<a href="#">Results article</a>	results	01/04/2020	21/06/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No