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Improving Psychodynamic Psychotherapy in Primary Care: Randomised Evaluation of Dynamic Interpersonal Therapy (DIT)

Submission date
22/06/2012

Recruitment status
No longer recruiting

Registration date
22/06/2012

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is a serious and growing global health problem and previous research has shown that psychological therapies are 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 widen patients choice of available therapies for depression and anxiety. The options offered by IAPT follow national recommendations (as outlined by the National Institute of Clinical Excellence [NICE] depression guidelines), which highlight short-term psychodynamic psychotherapy (STPP) as one of the treatment types that can be effective for adults with depressive illness. There are several forms of STPP, one of which is Dynamic Interpersonal Therapy (DIT). 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 investigate it through a full, large-scale research study and broaden the evidence for its effectiveness within IAPT services. The REDIT study is a research study designed precisely to investigate the effectiveness of Dynamic Interpersonal Therapy (DIT) as a depression treatment within IAPT services. The study will compare the outcomes of patients diagnosed with depression who are receiving immediate DIT with those of patients on an enhanced wait list (including elements of low-intensity routine care) followed by DIT after a period of approximately 16 weeks. The current study is a 'pilot' study, which will help prepare the way for an even larger trial of DIT to be conducted in the future.

Who can participate?
100 adults (aged 18 years and above) will be invited to join the REDIT study because they have a depressive illness and are attending IAPT services in one of the two sites in London where the study is being held (Newham and Tower Hamlets).

What does the study involve?
Each of these 100 eligible participants will be randomly allocated either to receive either immediate DIT for 16 weeks, or to be on the enhanced wait list for 16 weeks and then receive DIT.
Taking part in REDIT is voluntary at all times, so if you do decide to take part you can choose to

withdraw (either from their treatment, from the research appointments or both) at any time without providing a reason. If you consent to being in the study, and where the study is considered suitable for you after the first research assessment and clinical assessment, you would 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 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). REDIT participants will also be invited to take part in a sub-branch of the study if they would like to: this involves having some MRI pictures done of the brain while doing a few simple tasks on a computer. This part of the study is called fMRI-REDIT. The aim of it is to help us understand the relationship between how the brain works and depression. We are especially interested to see whether some patterns in the way the brain behaves might affect how well different people respond to treatment for depression within the main REDIT study. Studies like this one are important, because the more we can understand about the brain and how it works when a person experiences depression, the more suitable and effective therapies can then hopefully be developed. The fMRI in fMRI-REDIT stands for functional magnetic resonance imaging. This is a method used to scan a persons brain using a special scanner, in order to see how the brain reacts while he or she does various activities: for example, choosing between two objects on a screen, completing a puzzle, and so on. Typically, the pictures of your brain will show which parts are most active depending on the task you are doing. This is slightly different to magnetic resonance imaging MRI which produces a picture of how the brain is structured rather than how it behaves. This part of the study is also completely voluntary and participants can choose only to stick with the main REDIT study if they prefer, or consent separately to the MRI part as well.

What are the possible benefits and risks of participating?
Whichever treatment you receive within the REDIT study, you will be given regular, structured support and will be monitored closely throughout your time in the study. The REDIT study will help us to explore and improve the way that DIT is used in routine practice. It will also set the ground for an even bigger study in the future that will give us more information to monitor the effectiveness of this treatment. You might feel good to know that you have contributed to this research and that studies such as REDIT will ultimately lead to better service provisions for others in the future. Some individuals 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?
Two sites in London where the study is being held (Newham and Tower Hamlets).

When is the study starting and how long is it expected to run for?
December 2010 to December 2016

Who is funding the study?
The Department of Health is supporting the central coordination of the study through the Anna Freud Centre and University College London.

Who is the main contact?
Ms Sally Parkinson
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Contact information

Type(s)
Scientific

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Protocol serial number
11833

Study information

Scientific Title
Psychodynamic Psychotherapy in Primary Care: A Randomised Study to evaluate the effectiveness of Dynamic Interpersonal Therapy (DIT)

Acronym
REDIT

Study objectives
The aim of this study is to investigate the effectiveness of Dynamic Interpersonal Therapy (DIT) as a depression treatment within IAPT services.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City & East, 05/04/2011, ref: 11/LO/0250

Study design
Single-blind multi-site randomised controlled feasibility study

Primary study design

Interventional

Study type(s)
Treatment

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

Interventions
Participants were randomised to either the DIT or the 'enhanced waiting list' condition using a minimization algorithm with an 80% bias to minimize imbalance. Minimisation criteria included severity of depression (above or below median for site) and age (above or below median age for site).

Dynamic Interpersonal Therapy (DIT)
Dynamic Interpersonal Therapy (DIT) is a form of brief psychodynamic psychotherapy (16 sessions) developed for treating depression. It can help people with emotional and relationship problems. It explores difficult things in the past that continue to affect the way people feel and behave in the present. The therapy takes place over 16 weeks.

Enhanced Waiting List Condition
Enhanced waiting list participants will have contact with a psychological well-being practitioner once a fortnight. This will include help with general well-being & support, anxiety/panic management advice, sleep hygiene, employment support, learning cognitive restructuring techniques and other elements as necessary for 16 weeks.

Participants were followed up mid-treatment (8 weeks), at the end of treatment (approx. 16 weeks), and post-treatment (52 and 86 weeks).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Primary outcome as of 14/06/2016:
Depression severity is measured using a semi-structured interview, the Hamilton Depression Rating Scale (HDRS-17) at baseline, mid-treatment (8 weeks), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks).

Original primary outcome:
Hamilton Depression Rating Scale (HDRS-17) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)

Key secondary outcome(s))
Secondary outcome as of 14/06/2016:
1. Depression severity is measured using the Beck Depression Inventory (BDI-II) at baseline, mid-treatment (8 weeks), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks)
2. Psychological distress is measured using the Brief Symptom Inventory (BSI) at baseline, mid-

treatment (8 weeks), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks)
3. Quality of life is measured using EuroQOL (EQ-5D) questionnaire at baseline, mid-treatment (8 weeks), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 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), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks)
5. Reflective functioning is measured using the Reflective Function Questionnaire (RFQ-54) at baseline, mid-treatment (8 weeks), end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks)
6. Social adjustment is measured using the Revised Social Adjustment Scale (SAS-r) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks), and long-term follow-ups (52 and 86 weeks)
7. Interpersonal difficulties are measured using the Inventory of Interpersonal Problems (IIP-64) questionnaire at baseline, end-of-treatment (approx.. 16 weeks), and long-term follow-ups (52 and 86 weeks)
8. Adult attachment is measured using the Experiences in Close Relationships - Revised (ECR-R) questionnaire at baseline, end-of-treatment (approx.. 16 weeks), and long-term follow-ups (52 and 86 weeks)

Original secondary outcome measures:
1. Beck Depression Inventory (BDI-II) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)
2. Brief Symptom Inventory (BSI) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)
3. EuroQOL (EQ-5D) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)
4. MINI+ (Mini-International MINI international neuropsychiatric interview) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)
5. Reflective Function Questionnaire (RFQ-54) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)
6. Revised Social Adjustment Scale (SAS-r) at baseline, mid-treatment (8 weeks) end-of-treatment (approx. 16 weeks)

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged over 18 years, male or female
2. Current diagnosis of Major depressive disorder (MDD) with or without dysthymic disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria
3. Hamilton Depression Rating Scale score above 14
4. Patient Health Questionnaire (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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current psychotic symptoms or bipolar disorder
2. Current use of antipsychotic medication
3. Complex Personality Disorder
4. Historic or current self-injury/parasuicide
5. Historic or current eating disorder
6. Current excessive use of drugs/alcohol
7. Non-English speaking
8. Participation in another depression clinical trial within the last year where subject has received CBT
9. Previous unsuccessful CBT treatment
10. Clinical contra-indication to short-term psychotherapy (e.g. attachment history - multiple separations, serious ongoing trauma in childhood, multiple care-givers - suggesting the need for longer term psychotherapy)
11. Evidence of pervasive use of help
12. Highly unstable or insecure life arrangements (e.g. domestic violence)

Date of first enrolment
01/11/2012

Date of final enrolment
28/01/2015

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Tavistock and Portman NHS Foundation Trust (UK)

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR (UK) -Research for Patient Benefit Programme
Grant Codes: PB-PG-0610-22287

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	results	01/04/2020	21/06/2019	Yes	No