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REFRAMEd - REFRactory depression: Mechanisms and Effectiveness of radically open-dialectical behaviour therapy

Submission date
10/08/2011

Recruitment status
No longer recruiting

Registration date
10/08/2011

Overall study status
Completed

Last Edited
19/07/2019

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
Most depression is treatable. However, about one in three patients with major depression responds poorly to currently available treatments and endures severely disrupted family, social and working life. Many chronically and treatment-resistant depressed (TRD) patients suffer from a personality disorder (PD) or problems such as being perfectionist, rigid or avoiding risks. Personality disorders are difficult to treat and patients with both depression and a PD respond poorly to drug therapies and psychological treatments like Cognitive Behavioural Therapy (CBT). Standard Dialectical Behaviour Therapy (DBT) has proved to be effective in treating borderline PD. Radically Open DBT (RO-DBT), a new treatment approach with strong roots in standard DBT, has demonstrated promise for patients with difficult-to-treat depression and related overcontrolled disorders. The aim of the study is to compare RO-DBT to Treatment as Usual (or standard clinical care).

Who can participate?
Men and women aged 18 or over who are suffering from TRD. TRD is defined as having had two or more previous episodes of depression or meeting the criteria for chronic depression, and being currently depressed without any symptom relief after having taken antidepressant medication for 6 or more weeks.

What does the study involve?
Participants will be randomly allocated to either the RO-DBT group or the Treatment as Usual group. Participants in both groups will receive standard treatment; this generally involves antidepressant medication prescribed by the GP or psychiatrist. The RO-DBT group will at the same time also receive 27 individual sessions and 29 group sessions for the duration of 7 months. Participants will be asked to come in for a discussion prior to the start of treatment and 7, 12, and 18 months later, and to complete several questionnaires once a month or every 2 months for the duration of 1 year to monitor symptom relief and quality of life.

What are the possible benefits and risks of participating?
We hope that either the standard treatment or RO-DBT will help patients by relieving them of

their depression or significantly decrease symptoms of depression. The participants will be compensated for their time and effort while taking part in this study, provided they have completed all assessments. There are no risks associated with this study. Being part of this research will involve participants giving some of their time to complete the questionnaires and discuss with the researchers how they are feeling. Discussions and questionnaires may be upsetting if patients recall distressing events, but our previous work with depressed patients shows that most people return to their original emotional state following assessment.

Where is the study run from?
The study is coordinated from the University of Southampton, but assessments and treatment will take place at three NHS Psychological Therapy Services (Dorset, Hampshire and North Wales).

When is the study starting and how long is it expected to run for?
The study is expected to start in September 2011, and the duration of the study is 5 years. Recruitment for this study started in March 2012 and will continue until March 2015.

Who is funding the study?
This research grant has been awarded by the Efficacy and Mechanism Evaluation (EME) programme, which is funded by the Medical Research Council (MRC) and managed by the National Institute for Health Research (NIHR).

Who is the main contact?
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Study website
http://www.reframed.org.uk

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10234

Study information

Scientific Title
REFRAMEd - REFRactory depression: Mechanisms and Effectiveness of radically open-dialectical behaviour therapy: a randomised controlled trial

Acronym
REFRAMEd

Study objectives
Current hypothesis as of 17/06/2014:
Most depression is treatable. However, about one third of patients with major depression respond poorly to current treatments and endure severely disrupted family, social and working life. Psycho-social treatments for chronic and treatment-resistant depression (TRD) are currently limited in effectiveness and understudied. Many TRD and chronically depressed patients suffer from a personality disorder (PD) or problems such as being perfectionist or rigid or avoiding risks. PDs are difficult to treat and patients with both depression and a PD respond poorly to both drug therapies and psychological treatments like Cognitive Behavioural Therapy (CBT).

Standard Dialectical Behaviour Therapy (DBT) has proved to be effective in treating borderline PD. Radically Open DBT (RO-DBT), a new treatment approach with strong roots in standard DBT, has demonstrated promise for patients with difficult-to-treat depression and related overcontrolled disorders. In this study, we shall test RO-DBT for treatment of TRD and refractory depression. The aim of the study is to compare RO-DBT to Treatment as Usual (or standard clinical care).

We shall test this new RO-DBT protocol for participants with TRD in a large randomised controlled trial with two stages. At the beginning of the study we shall show that we can recruit suitable participants and that our therapists can work with the RO-DBT manual; following this we shall continue recruiting until we reach a total of 276 participants across three sites.

The trial will compare treatment as usual (TAU) with RO-DBT as a complement to TAU. Over 7 months the RO-DBT group will concurrently receive TAU plus 27 individual RO-DBT sessions and 29 group RO-DBT sessions, all from experienced therapists; and a second group will receive only TAU. We shall measure efficacy by comparing groups.

Previous hypothesis:
Most depression is treatable. However, about one third of patients with major depression respond poorly to current treatments and endure severely disrupted family, social and working life. Psycho-social treatments for chronic and treatment-resistant depression (TRD) are currently limited in effectiveness and understudied. Many TRD and chronically depressed patients suffer from a personality disorder (PD) or problems such as being perfectionist or rigid or avoiding risks. PDs are difficult to treat and patients with both depression and a PD respond poorly to both drug therapies and psychological treatments like Cognitive Behavioural Therapy (CBT).

However, Dialectical Behaviour Therapy (DBT), a type of CBT, has proven efficacy in treating Borderline PD, reducing suicide risk, and reducing symptoms of depression in patients with PD. DBT has also shown early promise for patients with difficult-to-treat depression, and seems to

reduce suicidality and symptoms of depression and anxiety in these patients. Small studies have found that DBT is effective for depressed patients for whom drug treatment has failed. Because of its efficacy in treating PD, DBT has become well established in the UK, and a treatment manual for patients with treatment-resistant depression (TRD) is now in press. We shall test this new DBT protocol for participants with TRD in a large randomised controlled trial with two stages. At the beginning of the study we shall show that we can recruit suitable participants and that our therapists can work with the DBT manual; following this we shall continue recruiting until we reach a total of 276 participants across three sites.

The trial will compare treatment as usual (TAU) with DBT as a complement to TAU. Over 6 months the DBT group will concurrently receive TAU plus 24 individual DBT sessions and 24 group DBT sessions, all from experienced therapists; and a second group will receive only TAU. We shall measure efficacy by comparing groups.

On 17/06/2014 the following changes were made to the trial record:
1. The public title was changed from 'REFRActory depression - Mechanisms and Efficacy of Dialectical behaviour therapy' to 'REFRAMEd - REFRactory depression: Mechanisms and Effectiveness of radically open-dialectical behaviour therapy'
2. The scientific title was changed from 'REFRActory depression - Mechanisms and Efficacy of Dialectical behaviour therapy: a randomised controlled trial' to 'REFRAMEd - REFRactory depression: Mechanisms and Effectiveness of radically open-dialectical behaviour therapy: a randomised controlled trial'

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 20/06/2011, ref: 11/SC/0146

Study design
Randomised interventional treatment trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Current interventions as of 17/06/2014:
Radically Open Dialectical Behaviour Therapy for over-controlled behaviours followed up at 12 months.

Previous interventions:
Dialectical Behaviour Therapy, for emotionally over-controlled behaviours followed up at 12 months

Intervention Type
Behavioural

Primary outcome measure
Hamilton Rating Scale for Depression measured before treatment, after treatment, 6 months after treatment, and 12 months after treatment

Secondary outcome measures
1. Depression remission
2. Suicide ideation and behaviour
3. Health economics

Overall study start date
01/01/2012

Completion date
01/09/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/08/2012:
1. Aged 18 years or over
2. Have a current diagnosis of major depressive disorder (MDD; as defined by SCID-I)
3. Have refractory depression (RD), operationalized as having had two or more previous episodes of depression or meeting the criteria for chronic depression
4. Currently taking antidepressant medication
5. Have received this medication for 6 weeks or more at BNF recommended doses
6. Have a Hamilton Depression Rating score of at least 15

Previous inclusion criteria until 15/08/2012:
1. Aged 18 years or over
2. Have a current diagnosis of major depressive disorder (MDD)
3. Have a HAMD score of at least 15
4. Have treatment resistant depression (TRD) as defined by two or more previous episodes of depression and in their current episode to have taken an adequate dose of ADM for more than 6 weeks without symptom relief
5. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 276; UK Sample Size: 276

Total final enrolment
250

Key exclusion criteria
Current exclusion criteria as of 15/08/2012:
1. IQ less than 70 or insufficient English to complete treatment and assessment
2. Meet DSM-IV criteria for dramatic-erratic PD (borderline, histrionic, antisocial or narcissistic PD), bipolar depression, or psychosis
3. Have a primary diagnosis of substance dependence or substance abuse disorder
4. Currently receiving standard DBT
5. On a waiting list for standard DBT
6. Have received standard DBT within the last 6 months (please note that patients who have completed a course of DBT more than 6 months ago are eligible if they meet all other criteria)

Previous exclusion criteria until 15/08/2012:
1. Have an IQ < 70 or insufficient English to complete treatment and assessment
2. Meet DSM-IV criteria for emotionally undercontrolled PD (borderline, histrionic, antisocial, narcissistic PD), bipolar depression or psychosis
3. Have a primary diagnosis of substance dependence or substance abuse disorder

Date of first enrolment
01/01/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Southampton
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Highfield Campus
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United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK), Ref: EME 09/150/12

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	17/07/2015		Yes	No
Results article	results	01/04/2020	19/07/2019	Yes	No