ISRCTN54234300 https://doi.org/10.1186/ISRCTN54234300

ThrIVe-B feasibility study

Submission date	Recruitment status	[X] Prospectively registered
14/07/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/07/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Bipolar disorders (BDs) are fairly common, affecting around 3-4% of people in the UK. They are very costly, both personally and economically. BDs often involve episodes of depression and mania lasting for weeks or months. Around half of people with BDs have more frequent swings in mood lasting for hours or days. These frequent mood swings impact on day-to-day coping and increase the chances of additional mental health conditions and full mania or depression. People with BDs often want psychological treatments, but so far these have focused mainly on the full bipolar episodes. A treatment that helps people with BDs to manage frequent mood swings could improve day-to-day mental health, and may even reduce the chance of a full episode developing. With input from patients and clinicians the ThrIVe-B programme has been developed to target frequent bipolar mood swings and the difficulties they can cause. There first needs to be a smaller study to help plan for a large study. The aim of this study is to assess the feasibility and acceptability of a future study evaluating the clinical and cost effectiveness of the ThrIVe-B programme for adults with frequent bipolar mood swings.

Who can participate?
Patients aged 18 or over with frequent bipolar mood swings across two locations (Exeter and Lancaster)

What does the study involve?
Participants are randomly allocated to receive either their usual treatment or usual treatment plus the ThrIVe-B programme. The ThrIVe-B programme involves a course of 16 two hour weekly sessions, with printed course notes, eight individual therapy sessions and use of a smartphone application. The course notes can be personalised and provide longer term support. In addition there is a "reunion" session three months after the programme has ended. The participants complete regular questionnaires and interviews to assess depression symptoms, mood swings, personal recovery and quality of life.

What are the possible benefits and risks of participating?
The results will help to plan for a full study that will ultimately test whether ThrIVe-B is effective and provides good value for money.

Where is the study run from?
1. University of Exeter (UK)

2. Devon Partnership Trust (UK)
3. Cumbria Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2017 to November 2019

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

Who is the main contact?
1. Dr Kim Wright
2. Dr Alexandra Newbold

Contact information

Type(s)
Public

Contact name
Dr Kim Wright

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Washington Singer Labs
Perry Road
Exeter
United Kingdom
EX4 4QG

Type(s)
Public

Contact name
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Henry Wellcome Building
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Exeter
United Kingdom
EX4 4QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.4

Study information

Scientific Title
The clinical and cost effectiveness of adapted Dialectical Behaviour Therapy (DBT) for Bipolar Mood Instability in primary care (ThrIVe-B programme): a feasibility study

Acronym
ThrIVe-B

Study objectives
To assess the feasibility and acceptability of a future definitive randomised controlled trial (RCT) evaluating the clinical and cost effectiveness of a psychological therapy programme (informed by Dialectical Behaviour Therapy: DBT) for adults with frequent bipolar mood swings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire REC, 25/04/2017, ref: 17/YH/0105

Study design
Feasibility study with a two-arm randomised parallel controlled trial design

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Frequent mood swings within the context of a Bipolar Spectrum Disorder

Interventions
Following completion of the baseline assessment, eligible participants will be randomised on a 1: 1 ratio (minimisation by trial site and medication status [currently prescribed medication for

depression or Bipolar Disorder versus not prescribed such medication]) to:
1. Treatment as Usual (TAU) [control arm]
2. Treatment as Usual plus ThrIVe-B programme (TAU + ThrIVe-B) [intervention arm]

The ThrIVe-B programme has been developed iteratively in consultation with ThrIVe-B patients and others with personal experience of BDs. It follows five key principles of DBT: i) clearly structured treatment; ii) application of behavioural therapy; iii) emphasis on validation of emotional response; iv) dialectical stance, balancing acceptance and change; v) integration of mindfulness practice. This is achieved structurally through a combination of group meetings (15, weekly) and up to 8 concurrent fortnightly individual sessions of up to 45 minutes delivered in person or by telephone.

Intervention Type
Behavioural

Primary outcome measure
From 12/10/2017:

The primary aim of this study is to establish the feasibility of a future definitive trial; as such its aims are:
1. To establish recruitment pathways and trial teams in two trial sites (Devon/Exeter and Cumbria/Lancaster).
2. To inform the recruitment and timeline of a future fully-powered trial, by establishing the number of participants identified, approached, consented, randomised and completed.
3. To refine future trial procedures by establishing the acceptability and experience of the trial process to participants, including randomisation and completion of outcome measures.
4. To determine the optimal primary outcome measure in a future trial by assessing the performance of selected candidate primary outcome measures with respect to level of acceptability to participants (completion rates, perceived burden) and participant-perceived relevance and value.
5. To inform estimation of sample size for a future trial by measuring data completeness at follow up (participant attrition), standard deviation of the likely primary outcome measure, and the variability of the comparator condition, treatment as usual, across individuals and sites.
6. To inform the measurement of health economic outcomes in a future trial through piloting the use of a tool for identifying resource use and costs associated with delivery of the intervention.
7. To further assess the acceptability of the treatment via qualitative interviews and, based on input from trial participants and clinicians, to further refine and develop the treatment manual and the procedures for training, supervising and assessing the competence of trial therapists.

We will also evaluate whether the following continuation criteria have been met, prior to planning a future definitive trial:
1. Trial participation does not lead to serious negative consequences (unexpected serious adverse reaction) for our participants.
2. Any serious concerns about the acceptability and feasibility of the trial procedures can be rectified prior to a full trial.
3. Follow up data at 9 months is available from at least 60% of participants.
4. At least 60% of patients complete treatment (attend at least 50% of possible sessions).

Prior to 12/10/2017:

Symptom level, completed at baseline and 3, 6, 9, 15 months post baseline:
1. Current depression level, measured using Patient Health Questionnaire– 9
Symptom variability:
2. Self-reported tendency to experience labile mood, measured using the Affective Lability Scale
Quality of life and recovery status, completed at baseline and at 3, 6, 9, 15 months post baseline:
3. Personal recovery, measured using the Bipolar Disorder Recovery Questionnaire
4. Quality of life, measured using the Brief Quality of Life in Bipolar Disorder Scale

Secondary outcome measures

From 12/10/2017:

The outcome measures that will be evaluated within this feasibility study are as follows:

Symptom level, completed at baseline and 3, 6, 9, 15 months post baseline:
1. Current depression level, measured using Patient Health Questionnaire– 9
Symptom variability:
2. Self-reported tendency to experience labile mood, measured using the Affective Lability Scale
Quality of life and recovery status, completed at baseline and at 3, 6, 9, 15 months post baseline:
3. Personal recovery, measured using the Bipolar Disorder Recovery Questionnaire
4. Quality of life, measured using the Brief Quality of Life in Bipolar Disorder Scale

Symptom level, completed at baseline and 3, 6, 9, 15 months post baseline:
1. Current mania symptoms, measured using the Bech Mania Rating Scale
2. Current depressive symptoms, measured using the Hamilton Depression Scale
3. Anxiety symptoms, measured using the General Anxiety Questionnaire – 7

Health-related quality of life outcomes, completed at baseline and at 3, 9, 15 months post baseline:
The EuroQoL 5-Dimension 5 level (EQ-5D-5L) and the Short-Form-36 item (SF-36v.2) will be used to obtain utility scores for deriving Quality-Adjusted Life Years (QALYs) in order to estimate incremental cost effectiveness ratio in the planned future randomised controlled trial. In addition participants will be asked to complete a record of their recent health service usage.

Quantitative Process Measurement
To inform process measurement in a definitive trial, measures of hypothesised mechanisms of change will be included, providing data on their performance and acceptability to participants. Hypothesised treatment targets include mood-related impulsivity and avoidance, emotional acceptance, emotional problem solving, interpersonal functioning and social rhythm stability. Measures of these are described below.

Candidate self-report measures of therapy process, completed at baseline and at 3, 6, 9, 15 months post baseline:
1. Impulsive responding to positive mood, measured using UPPS-P
2. Behavioural avoidance and rumination, measured using the Behavioral Avoidance in Depression Scale
3. Mindfulness skill, measured using Kentucky Inventory of Mindfulness Skills
4. Regularity of daily routines, measured using the Adapted Social Rhythm Metric

Candidate behavioural measures of therapy process:
1. Means Ends Problem Solving Task (adapted to include social/emotional problem-solving) – this describes a problem and an end state/resolution and asks participants to describe the steps they

would take to reach that end state (completed at baseline and at 9,15 months post baseline; at each point participants complete one of the four scenarios; these are counterbalanced across assessment points). Participants are given the option to complete this measure either with the researcher present (face to face or telephone) or on their own

Measures completed session by session by participants in ThrIVe-B + TAU condition:
2. Current manic symptom level, measured using the Altman Scale for Rating Mania
3. Current mania symptoms, measured using the Bech Mania Rating Scale

Prior to 12/10/2017:

Symptom level, completed at baseline and 3, 6, 9, 15 months post baseline:
1. Current mania symptoms, measured using the Bech Mania Rating Scale
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3. Anxiety symptoms, measured using the General Anxiety Questionnaire – 7

Health-related quality of life outcomes, completed at baseline and at 3, 9, 15 months post baseline:
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Measures completed session by session by participants in ThrIVe-B + TAU condition:
2. Current manic symptom level, measured using the Altman Scale for Rating Mania
3. Current mania symptoms, measured using the Bech Mania Rating Scale

Overall study start date
06/06/2017

Completion date
05/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/05/2018:
1. Aged 18 or over
2. Lifetime diagnosis of Bipolar Disorder (I,II, "other specified bipolar disorder") or Cyclothymic Disorder, according to DSM-V
3. Current bipolar mood instability (defined as per DSM-V criteria 1 and 2 for Cyclothymic Disorder or a score of 1.3 on the Bipolar subscale of the Affective Lability Scale, a self-report measure of mood instability)
4. Client wishes to engage in psychological therapy that focusses primarily on ongoing mood instability and its consequences
5. In lifetime must have experienced at least a two-day period in which symptom criteria for hypomania were met. This is to ensure that we are offering the intervention to individuals with a likely vulnerability to a Bipolar Disorder, rather than emotional instability solely attributable to Borderline Personality Disorder (as frequent mood swings seen in people experiencing Borderline Personality Disorder can sometimes be mistaken for Bipolar mood swings)
6. Sufficient competency in English to be able to complete study measures without the need for translation
7. Registered with a GP practice in the catchment area served by the NHS Trusts involved in the study
8. Able and willing to regularly attend the group therapy session as scheduled

Previous inclusion criteria:
1. Aged 18 or over
2. Lifetime diagnosis of Bipolar Disorder (I,II, "other specified bipolar disorder") or Cyclothymic Disorder, according to DSM-V
3. Current bipolar mood instability (defined as per DSM-V criteria 1 and 2 for Cyclothymic Disorder or a score of 1.3 on the Bipolar subscale of the Affective Lability Scale, a self-report measure of mood instability)
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6. Sufficient competency in English to be able to complete study measures without the need for translation

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Target number: 48. Final number recruited: 43

Total final enrolment
43

Key exclusion criteria
Current exclusion criteria as of 30/05/2018:
1. Current alcohol or substance dependence (as this would indicate other treatment would be more appropriate)
2. Currently receiving other psychological therapy for bipolar disorder
3. Current high risk of suicide, or recent, frequent, significant self-harming behaviour (more than one instance requiring some form of treatment by self or others in the past month)
4. Evidence the individual may pose a significant risk to other group members, or has a pattern of interpersonal behaviour likely to be severely disruptive within a group setting (clinicians will be asked to apply this criterion when considering whether to approach individuals on their caseload regarding trial participation)
5. The person lacks capacity to consent to treatment or research participation
6. Current DSM-V mania or major depression
7. Individual indicates at any time pre-randomisation that they are unable or unwilling to attend the group therapy session that are scheduled

Previous exclusion criteria:
1. Current alcohol or substance dependence (as this would indicate other treatment would be more appropriate)
2. Currently receiving other psychological therapy for bipolar disorder
3. Current high risk of suicide, or recent, frequent, significant self-harming behaviour (more than one instance requiring some form of treatment by self or others in the past month)
4. Evidence the individual may pose a significant risk to other group members, or has a pattern of interpersonal behaviour likely to be severely disruptive within a group setting (clinicians will be asked to apply this criterion when considering whether to approach individuals on their caseload regarding trial participation)
5. The person lacks capacity to consent to treatment or research participation
6. Current DSM-V mania or major depression
7. Individual is receiving ongoing coordinated care in secondary mental health services (as this intervention is aimed at individuals with difficulties not complex or severe enough to require ongoing multidisciplinary mental health support and care coordination)

Date of first enrolment
10/08/2017

Date of final enrolment
16/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sir Henry Wellcome Building for Mood Disorders Research
University of Exeter
Perry Road
Exeter
United Kingdom
EX4 4QG

Study participating centre
Devon Partnership Trust
Wonford House
Exeter
United Kingdom
EX2 5AF

Study participating centre
Cumbria Partnership NHS Foundation Trust
Voreda
Portland Place
Penrith
United Kingdom
CA11 7BF

Sponsor information

Organisation
Devon Partnership NHS Trust

Sponsor details
Wonford House
Dryden Road
Exeter
England
United Kingdom
EX2 5AF

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/04fkxrb51

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal by August 2021.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository within the University of Exeter by the end of 2019. Anonymised data may be accessed and analysed by members of the project team and with researchers collaborating with members of the project team on the analysis of these data. With the exception of anonymised quotes from research interviews, consent from participants was not sought for sharing raw data publicly. Therefore, external researchers seeking to access the data for use in future projects must do so via request to the Chief Investigator (or her delegate), and projects using the data must have been approved in accordance with contemporary U.K. ethical and regulatory processes pertaining to the release of anonymised data under these circumstances.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/10/2018		Yes	No
Results article		01/07/2021	05/07/2021	Yes	No
HRA research summary			28/06/2023	No	No