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A randomised controlled trial of dialectical behavioural therapy skills for employment for people who experience difficulties in common with a personality disorder

Submission date
11/11/2019

Recruitment status
Suspended

Registration date
28/11/2019

Overall study status
Completed

Last Edited
20/04/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to find out whether a new psychological intervention, Dialectical Behavioural Therapy Skills for Employment (DBT-SE), is more effective than support provided by Mental Health Employment Services (MHES) in helping people who experience difficulties consistent with a personality disorder (PD) to gain and retain paid employment. The study is part of a wider research programme "Enabling and Motivating People (with a personality disorder) in Occupation Wellbeing Education and Responsibility (EMPOWER)" funded by the National Institute for Health Research (NIHR). It is important to develop recovery-focused services to help to tackle the challenges of employment for people with mental health problems. People with a PD have complex needs and while therapeutic interventions result in improved mental health, their vocational outcomes remain comparatively poor. This suggests that targeted vocational interventions are vital for improving the lives of people with a PD. DBT-SE is an intervention that focuses on identifying and modifying the emotional, cognitive, and behavioural factors which lead to poor self-management and interpersonal difficulties in the workplace. It will be delivered by healthcare professionals in NHS Trusts and Third Sector Organisations that provide mental health support services (e.g. Mind).

Who can participate?

Participants are eligible if they report difficulties consistent with a PD; are of working age but not currently working (or working limited hours for limited salary/medically certified unfit to work due to mental health); eligible for work in the UK; available for employment and able to verbally communicate in English.

What does the study involve?

Participants are randomly allocated to either DBT-SE plus Treatment as Usual (TAU) or MHES plus TAU. DBT-SE participants attend 3-hour group sessions for 17 weeks. The services MHES participants receive vary between organisations but typically include support in employment preparing activity, motivation, skills development, and managing mental health difficulties.

What are the possible benefits and risks of participating?
All participants will be invited to attend an employment workshop to discuss some of the practical skills needed for seeking or returning to work. All participants will be issued with an employment manual written by a vocational advisor. This manual contains advice on the practical aspects of employment. Participants getting DBT-SE will attend training sessions where skills to manage the challenging emotional aspects of looking for and applying for work, interviewing, and starting work will be discussed each week. Participants getting MHES will be supported by a vocational advisor who is an expert at helping people to gain employment or return to work. Regardless of the support received (DBT-SE or MHES) it is hoped that what participants will learn will help them to manage emotions and relationships better in their home life, which may also improve their wellbeing. Participants will be compensated for their time when they are contacted after the initiatives have ended. At the 6 and 12 month follow ups participants are given £20 in high street shopping vouchers (£40 in total). Participants will contribute to NHS research designed to support people into employment in the future. There may not be an immediate direct benefit to participants but it is hoped that participating will helps them on their path to employment. There is a possibility that participants could get upset when discussing their experiences or completing the research questionnaires. It is also possible that they may experience disappointment if they are not able to obtain employment quickly. Participants will be given information on how to stay safe if they do experience distress and are provided with the contact information of organisations they can telephone if they need to speak with someone. If their distress is ongoing they are encouraged to contact their healthcare professional (if they have one) or GP.

Where is the study run from?
North East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to July 2021

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

Who is the main contact?
Dr Anna Cattrell
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 39689

Study information

Scientific Title
A randomised controlled trial evaluating the efficacy of Dialectical Behavioural Therapy Skills for Employment (DBT-SE) compared with a referral to a mental health employment specialist for people with difficulties consistent with a personality disorder (PD)

Acronym
An RCT of DBT-SE for PD

Study objectives
The researchers plan to conduct a randomised controlled trial (RCT) to evaluate whether a new psychological intervention, Dialectical Behavioural Therapy Skills for Employment (DBT-SE), is more effective than support provided by Mental Health Employment Services (MHES) in helping people who experience difficulties consistent with a personality disorder (PD) to gain and retain paid employment. The RCT is part of a wider research programme "Enabling and Motivating People (with a personality disorder) in Occupation Wellbeing Education and Responsibility (EMPOWER)" funded by the National Institute for Health Research (NIHR).

It is important to develop recovery-focused services to help to tackle the challenges of employment for people with mental health problems. People with a PD have complex needs and while therapeutic interventions result in improved mental health, their vocational outcomes remain comparatively poor. This suggests that targeted vocational interventions are vital for improving the lives of people with a PD. DBT-SE is an intervention that focuses on identifying and modifying the emotional, cognitive, and behavioural factors which lead to poor self-management and interpersonal difficulties in the workplace. It will be delivered by healthcare professionals in NHS Trusts and Third Sector Organisations that provide mental health support services (e.g. Mind).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 26/10/2018, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)2071048052; Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net), ref: 18/EM/0262

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Personality disorder

Interventions
Participants will be allocated to either DBT-SE plus Treatment as Usual (TAU) or MHES plus TAU. DBT-SE participants will attend 3-hour group sessions for 17 weeks. The services MHES participants receive will vary between organisations but typically include support in employment preparing activity, motivation, skills development, and managing mental health difficulties.

Intervention Type
Other

Primary outcome measure
Number of hours of paid employment, measured using study-specific questionnaires for employment and income at baseline, 6 and 12 months and via an employment activity questionnaire administered to all participants at baseline, week 9, 17, 6 and 12 months and in DBT-SE participants weekly during the intervention (week 1-8 and 10-16)

Secondary outcome measures
1. Health economic data is measured using study-specific questionnaires for:
1.1. Service receipt at baseline, 6 and 12 months
1.2. Medication use at baseline, 6 and 12 months
1.3. Sociodemographic questionnaire at baseline
1.4. Employment and income at baseline, 6 and 12 months
1.5. European Quality of Life – 5 Dimensions (EQ-5D-5L)
2. Employment readiness measured via a study-specific employment continuum rating scale at baseline, week 9, week 17, 6 months and 12 months and a study-specific preparedness for

employment questionnaire at baseline, week 9, week 17, 6 months and 12 months
3. Mental health data are collected by validated questionnaires: the Brief Symptom Inventory and Clinical Outcomes in Routine Evaluations at baseline, 6 months and 12 months and via the study-specific modified scale for overt aggression at baseline, 6 months and 12 months
4. Emotional regulation measured using the difficulties in emotional regulation scale at baseline, week 9, week 17, 6 months and 12 months
5. Use of coping skills measured via the Ways of Coping Checklist at baseline, 6 months and 12 months
6. Interpersonal and social function assessed via the work and social adjustment scale at baseline, 6 months and 12 months, and the Inventory of Interpersonal problems at baseline, week 9, week 17, 6 months and 12 months

Overall study start date
17/01/2019

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Difficulties consistent with a PD: A score of 3 or more on the Standardised Assessment of Personality - Abbreviated Scale (SAPAS)
2. Registered with a UK GP: Willing and able to provide details of the GP practice they are registered with for safety reasons
3. Working age: Minimum 18 years old
4. Not currently working or working limited hours for limited salary:; (i) Unemployed, (ii) Certified medically unfit to work by GP for a minimum of 4 weeks (by randomisation date) with no planned return to work within the next 3 weeks or (iii) Fulfils the Government requirements for permitted work or supported permitted work, current guidance : working fewer than 16 hours per week, AND, earn less than £131.50 per week (N.B. this will be updated during the study in line with changes to UK government guidelines)
5. Eligible for employment in the UK: UK National or UK Resident with Residential/visa status approved for employment and a plan to remain in the UK for a minimum of 18 months
6. Available for employment: No commitments that preclude employment (e.g. sole carer for family member/infant who cannot be cared for by another person, full-time student)
7. Able to verbally communicate in English and basic reading and writing skills: The intervention is delivered in English so participants will need to be comfortable conversing with other group members. As the intervention uses handouts and homework sheets they will need to have basic reading and writing skills

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 432; UK Sample Size: 432

Key exclusion criteria
1. Florid Psychotic Disorder/symptoms of Psychosis: Measured through seven screening questions adapted from the SCID I. The presence of symptoms implies the volunteer is not suited to the programme and may not have the capacity to consent
2. Has received full or modified/adapted DBT during the last 12 months: It would not be appropriate to offer more DBT so soon after treatment ends
3. Suicide attempt within the last 12 weeks: Each participant will be questioned regarding suicidal behaviour, where there have been recent (< 12 weeks) incidents of suicidal behaviour the participant will not be permitted to volunteer for the study. This is because the needs of the participant are greater than the study is equipped to support
4. Incident of deliberate self-harm within the last 4 weeks: Each participant will be questioned regarding self-harming behaviour, where there have been recent (< 4 weeks) incidents of self-harm the participant will not be permitted to volunteer for the study. This is because the needs of the participant are greater than the study is equipped to support
5. Bipolar Disorder diagnosis/ currently in treatment for Bipolar Disorder (Includes being diagnosed with Bipolar Disorder but not currently receiving treatment): A diagnosis of Bipolar Disorder or pharmacological or Psychological treatment for bipolar disorder implies the participant has needs outside of the remit of the study
6. PD symptoms due to a head injury: Difficulties are not due to a mental health problem but an organic injury
7. Unable to travel to DBT-SE site or MHES site: Participants need to be willing and able to travel to either site
8. Receiving a psychological therapy as part of a research study unrelated to EMPOWER: Participants receiving a novel treatment as part of research will be excluded as it will not be possible to accurately quantify and characterise the treatment. If the research intervention will be over before the participant attends baseline data collection and randomisation they will be permitted to join the study but will not if the two could overlap

Date of first enrolment
19/02/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre

North East London NHS Foundation Trust
Block 8
Goodmayes Hospital
Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
Tees, Esk and Wear Valley NHS Foundation Trust
Research and Development
Flatts Lane Centre
Normanby
Middlesbrough
United Kingdom
TS6 0SZ

Study participating centre
Mind in the City, Hackney and Waltham Forest
8-10 Tudor Road
Hackney
London
United Kingdom
E9 7SN

Study participating centre
Betsi Cadwaladr University Health Board
Health Board
Research and Development Department
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Essex Partnership University NHS Foundation Trust
St Margaret's Hospital
The Plain
Epping
United Kingdom
CM16 6TN

Sponsor information

Organisation
North East London NHS Foundation Trust

Sponsor details
1st Floor Maggie Lilley Suite
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United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1212-20011

Results and Publications

Publication and dissemination plan
1. Planned publication of the protocol in April to June 2020
2. Peer-reviewed scientific journals
3. Conference presentation
4. Publication on website

Intention to publish date
01/07/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No