

# Preparing people with difficulties consistent with a personality disorder for employment

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/10/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In January 2013, 1.43 million people in the UK received incapacity benefit, many because of mental health difficulties. There is a complex relationship between employment and mental health; poor mental health predicts unemployment, whilst employment leads to improvements in mental wellbeing. Therefore, assisting people with mental health difficulties to get into employment is a priority for the NHS and social care organizations. Personality disorders (PDs) are mental health conditions which affect the way people manage feelings and relate to other people. They are often characterised by intense emotional responses and impulsive high-risk behaviours, meaning that people with a PD often have difficulties developing and sustaining relationships, a necessary skill for both wellbeing and employment. Dialectical behavioural therapy (DBT) is a type of treatment designed to help people who have difficulties managing their emotions through changing thought patterns and behaviour. It is well recognised as an effective treatment for PD. The aim of this study is to test a new treatment programme based on the principles and techniques of DBT can help prepare people with difficulties relating to a PD to find employment. The programme targets areas of difficulty such as managing intense emotions, problematic interpersonal relationships, self-criticism and poor self-management through the development and evaluation.

### Who can participate?

Unemployed adults with a personality disorder.

### What does the study involve?

Suitable participants are invited to a 60-minute enrolment session where they complete a number of questionnaires about their wellbeing, mood and social functioning. If the participant is still willing to enrol after this session they will be offered a place in one of four DBT-SE groups. All participants who participate in the enrolment session are offered compensation for their time. The DBT-SE groups run for three hours per week (including two 10-minute breaks) for 16 weeks. In between each group participants are given tasks to practice to help consolidate (sum up) what they have learnt during each session. Participants are also asked to fill out a questionnaire and a diary card to help the study team to monitor their employment-related activity. Every four weeks participants are asked to complete additional questionnaires online which take around 30-40 minutes to complete. At the end of the study, participants are invited

to take part in a 60-minute interview, to give feedback on their experience of being involved in the study. All participants who participate in the feedback session are offered compensation for their time.

What are the possible benefits and risks of participating?

There is a chance that participants will benefit from taking part by better learning to manage the challenging emotional aspects of looking and applying for work, interviewing, and starting work. Additionally, by learning the skills with a group of people who experience similar difficulties, participants will may benefit from feeling less alone in their own experiences and will have the opportunity to practice their interpersonal skills in a safe and supportive space. It is possible that during the study, participants might get upset if they have recently experienced difficulties in obtaining a job, have recently lost a job, or are having difficulties at work when they enrol. All of the staff working on this study are experienced in facilitating or co-facilitating standard adult DBT skills groups and are trained in how best to support participants if they become upset.

Where is the study run from?

1. Goodmayes Hospital (UK)
2. Larkswood Centre, Thorpe Coombe Hospital (UK)
3. Mind City, Hackney and Waltham Forest (UK)
4. Wood Lane Baptist Church (UK)

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

May 2016 to August 2016

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Anna Cattrell

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## Contact information

**Type(s)**

Public

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Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

190743

**ClinicalTrials.gov number**

**Secondary identifying numbers**

30744, IRAS 190743

## **Study information**

**Scientific Title**

A feasibility study of dialectical behavioural therapy skills for employment (DBT-SE) for individuals with difficulties consistent with a personality disorder (PD)

**Study objectives**

The aim of this study is to investigate the feasibility of a 16 week Dialectical Behaviour Therapy Skills for Employment (DBT-SE) intervention to support individuals with difficulties consistent with a personality disorder in obtaining and retaining employment in preparation for a full randomised control trial.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

London - Harrow Research Ethics Committee, 11/03/2016, ref: 16/LO/0227

## **Study design**

Non-randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

## **Primary study design**

Interventional

## **Secondary study design**

Non randomised study

## **Study setting(s)**

Other

## **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**

Specialty: Mental Health, Primary sub-specialty: Personality disorder; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

## **Interventions**

DBT-SE Attendees:

Participants will be screened over the telephone for suitability and if eligible, will be invited to attend a one-hour enrolment session where baseline clinical, psychometric and demographic information will be recorded.

All participants will be offered a place in one of the four DBT-SE groups based at community and hospital locations across the North East London NHS Foundation Trust (NELFT). The intervention will run for 16 weeks and each session will last for 3 hours including two 10-minute breaks. The groups will have staggered start dates, commencing as soon as 12 participants have been recruited.

During the intervention weekly reports of the types of employment seeking activity and the use of DBT-SE skills will be collected from participants. Risk taking behaviour will be monitored weekly in line with standard clinical practice. Participants will also be asked to complete short clinical and psychometric questionnaires every four weeks (duration 30-40 minutes). Four weeks after the end of the intervention participants will be invited to take part in a semi-structured interview to give feedback on their experience of the intervention, psychometric and clinical measures and the referral process.

DBT-SE Attendee Supporters:

Supporters of people with a PD may play a key role in the success (e.g. supportive) or failure (e.g. critical) of their loved one during their search for employment, or during periods when they are unable to work. Furthermore, Supporters may report they experience a burden (financially and /or emotionally) that may reduce their own wellbeing when supporting their loved one through these periods. During the enrolment session, each DBT-SE participant will be asked whether they have a Supporter, and if so, if they think their Supporter would also like to take part in the

study. DBT-SE Supporters that take part will be asked to complete a postal survey of demographic, wellbeing and support measures at baseline, i.e. before the DBT-SE participant enters the intervention and at the end as part of the feedback.

## **Intervention Type**

Other

## **Primary outcome measure**

Feasibility outcomes:

1. Referral site and source will be evaluated by analysing the number and speed of referrals received are measured once all DBT-SE groups have started (approximately week 4)
2. Retention rate will be evaluated by analysing the attendance records of each DBT-SE group, logged weekly during the intervention weeks 1-16 and analysed at the end at week 16
3. Willingness of participants to be randomly allocated to a group as part of the main randomised controlled trial is measured via a semi-structured interview at 20 weeks
4. Suitability and acceptability of patient-centered outcomes are measured via a semi-structured interview at 20 weeks
5. Effectiveness and acceptability of an internet-based delivery method for completion of the assessment and outcome measures is assessed via semi-structured interview at 20 weeks
6. Willingness of participants to allow their supporters to be involved in the study measured via a semi-structured interview at 20 weeks

## **Secondary outcome measures**

Patient-centred outcomes:

1. Hours of employment (and employment-related activity) are measured weekly using a diary card from weeks 2-16 and the New Employment Questionnaire (developed for this study) if participants gain employment during the intervention
2. Mood is measured using a number of instruments administered at different time-points across the study:
  - 2.1. Generalised Anxiety Disorder Scale-7 screens for anxiety symptoms, collected at baseline, weeks 4, 8, 12, 16 and at follow-up
  - 2.2. Patient Health Questionnaire-9 screens for depression symptoms, collected at baseline, weeks 4, 8, 12, 16 and at follow-up
  - 2.3. State-Trait Anger Expression Inventory-2 measures the experience, expression and control of anger, collected at baseline, weeks 4, 8, 12, 16 and at follow-up
  - 2.4. Inventory of Interpersonal Problems-PD Version provides detailed information on the interpersonal difficulties experienced by the individual, collected at baseline and at week 16
  - 2.5. Risk Assessment Questionnaire captures rates of self-harm, suicide attempts, and acts of violence, recorded weekly
  - 2.6. Wellbeing is measured using the Warwick-Edinburgh Mental Wellbeing Scale which indexes wellbeing across 5 domains, collected at baseline, weeks 4, 8, 12, 16 and at follow-up
  - 2.7. ICEpop CAPability measure for adults measuring capability in the general adult population and is commonly used as part of economic evaluation to index facets of wellbeing, collected at baseline, week 16 and at follow-up
  - 2.8. Social functioning is measured by the Work and Social Adjustment Scale which indexes the impact of mental illness on social functioning, collected at baseline, weeks 4, 8, 12, 16 and at follow-up
  - 2.9. European Quality of Life-Five Dimensions is a health-related quality of life scale (collected at baseline, weeks 4, 8, 12, 16 and at follow-up)
  - 2.10. Christo Inventory for Substance Misuse used to measure the impact of substance abuse on a person's daily functioning (collected at baseline)

2.11. Support in Employment Questionnaire (developed for this study) indexes the amount of time a participant reports receiving help with employment related activity, collected at baseline, week 16 and at follow-up  
3. The use of physical health, mental health, criminal justice and social services is measured by a Service Receipt Inventory (developed for this study) and is collected at baseline, week 16 and at follow-up interview

**Overall study start date**

18/05/2016

**Completion date**

30/08/2016

## **Eligibility**

**Key inclusion criteria**

DBT-SE Attendees:

1. Probable Personality disorder (PD) based on the Standardized Assessment of Personality – Abbreviated Scale (SAPAS)
2. Currently unemployed
3. Eligible for employment in the UK
4. Available for employment
5. Functional literacy
6. Aged 18-65 years

DBT-SE Supporters:

≥18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 96; UK Sample Size: 96

**Key exclusion criteria**

DBT-SE Attendees:

1. In receipt of a pension
2. Current florid psychosis

3. Personality disorder (PD) due to head injury
4. Unable to communicate in English
5. Suicide attempt in past 3 months
6. Self-harm in the past month
7. Formal diagnosis of Bipolar Disorder
8. Substance use at a level that would affect functioning at work
9. Currently in receipt of standard or modified DBT

**Date of first enrolment**

18/05/2016

**Date of final enrolment**

30/09/2016

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Goodmayes Hospital**

Barley Lane

Ilford

United Kingdom

IG3 8XJ

**Study participating centre**

**Larkwood Centre**

Thorpe Coombe Hospital

714 Forest Road

Walthamstow

United Kingdom

E17 3HP

**Study participating centre**

**Mind City, Hackney and Waltham Forest**

8-10 Tudor Road

London

United Kingdom

E9 7SN

**Study participating centre**  
**Wood Lane Baptist Church**  
118 Wood Lane  
Dagenham  
United Kingdom  
RM9 5SL

## Sponsor information

### Organisation

North East London NHS Foundation Trust

### Sponsor details

Tantallon House  
Goodmayes Hospital Site  
Barley Lane  
Ilford  
England  
United Kingdom  
IG3 8XJ

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/023e5m798>

## 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

1. The Feasibility Study Protocol will be submitted for peer-review before the end of 2016 to the open access 'Journal of Pilot and Feasibility Studies'.
2. Plans to conduct a qualitative appraisal of referrer behaviour over the course of the feasibility study, exploring the barriers and enablers to referring clients into this study and into programmes of research more generally. Planned submission of this manuscript for publication in the first quarter of 2017.
3. Plans to conduct a psychometric validation of the 'Carer Burden Questionnaire' included in the Feasibility Study. Data from the Feasibility Study will be used as a pilot study and then expanded as part of an undergraduate thesis over the course of the next academic year (commencement September 2016). Planned submission of this manuscript for publication Summer 2017.
4. Plans to conduct a psychometric validation of the 'Support in Employment Seeking Activity' questionnaire included in the Feasibility Study. Data from the Feasibility Study will be used as a pilot study and then expanded as part of an undergraduate thesis over the course of the next academic year (commencement September 2016). Planned submission of this manuscript for publication in the second quarter of 2017.

## Intention to publish date

31/12/2017

## Individual participant data (IPD) sharing plan

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No