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Low intensity psychological support for people with personality disorder: Randomised controlled trial

Submission date
31/05/2017

Recruitment status
No longer recruiting

Registration date
18/07/2017

Overall study status
Completed

Last Edited
05/03/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Personality disorders are long-term mental health conditions which affect 1 in 20 people in the UK. People with personality disorders have severe problems forming and maintaining relationships with others which can lead to poor mental health, social exclusion, and impaired quality of life. No drugs are currently licensed for the treatment of personality disorder; instead NICE guidelines recommend structured psychological (talking) therapies, which are intensive and are delivered over a 12-18 month period. Current guidelines for treating depression and other common mental disorders generally recommend a 'stepped care approach' in which all patients are initially offered low-intensity treatment and only those who do not respond to this are offered longer-term and more intensive therapy. It has been argued that a stepped care approach should also be used to treat people with personality disorder, however little research has been undertaken to develop or test 'low-intensity' therapies for people with personality disorders. In 2014-16 staff working at the Waterview Centre in London developed a low-intensity therapy for people with personality disorder. The aim of this study is to look at whether it would be possible to conduct a study looking at the effectiveness of this therapy.

Who can participate?
Adults aged 18 and older who are diagnosed with a personality disorder

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive psychologically focused advice and support. Those in the intervention group will receive around 6 sessions of advice and support delivered by a trained therapist. These sessions are usually face-to-face but can be delivered by phone and supplemented by texts, emails or other methods in accordance with participant preferences. Participants are also provided with access to written and web-based information and signposted to other services as appropriate. Those in the second group continue to receive treatment as usual. This includes follow-up appointments or other treatments that would have been delivered normally. All participants are assessed at the beginning of the study and followed up at six months to assess quality of life, health and overall mental health.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in emotional health. There are no anticipated risks of participation.

Where is the study run from?
Waterview Centre (UK)

When is study starting and how long is it expected to run for?
January 2017 to December 2018

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

Who is the main contact?
Ms Amy Claringbold
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34705

Study information

Scientific Title
Assessing a Low Intensity Treatment for Enduring personality-related problems

Acronym
ALITE

Study objectives
The aim of this study is to examine the feasibility of conducting a parallel-arm, single-blind, randomised trial of a low-intensity intervention that utilises psychoeducation and psychologically informed support to help people diagnosed with personality disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central-Hampshire A, 13/07/2017, ref: 17/SC/0249

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 Disorders; UKCRC code/ Disease: Mental Health/ Disorders of adult personality and behaviour

Interventions
Participants with a diagnosis of personality disorder are randomised to receive either treatment as usual or low intensity psychological support. The randomisation list is generated by the independent web-based service 'sealed envelope'. Equal numbers of participants are randomised to the two arms of the trial and stratification will occur by gender and study centre.

Intervention group: Participants in this group receive low intensity psychological support is a combination of psychoeducation and psychologically informed support. This intervention is designed to help patients form links between their emotions and actions and promote their ability to care for themselves. Trained therapists will work with participants to understand

relationship difficulties, existing problems and coping strategies. This involves up to 10 60-minute treatment sessions delivered over a 6-month period. Sessions can be delivered face to face or by phone in accordance with patient preferences.

Treatment as usual group: Treatment as usual is delivered in accordance with current NICE guidelines. This comprises of assessment, care planning and review. It may involve pharmacotherapy and referral to other services including access to inpatient care at times of crisis.

All participants are assessed at the beginning of the study and followed up at 6 months to assess quality of life, health and overall mental health.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of the study is measured using the following:
1. Recruitment of at least 80% of the study sample i.e 48 participants from the total of 60 we are aiming to recruit.
2. Uptake of the low intensity intervention by at least 60% of participants in the active arm of the trial i.e. 18 of the 30 who are randomised to the low intensity intervention will have received it according to feedback from the therapist assigned to the participant.
3. Completion of follow-up interviews at six months by 75% of study participants. To determine the feasibility of calculating a cost analysis of health economics, we will record completion rates for the cost data, and analyse them to determine what the cost-drivers are likely to be if proceeding to a full clinical trial.

Secondary outcome measures
1. Impairment of functioning is measured using the Work and Social Adjustment Scale at baseline and six months
2. Mental health is assessed using the participant-completed Warwick and Edinburgh Well-Being Schedule at baseline and six months
3. Suicidal thoughts and behaviour is measured using Four questions on suicidal thoughts and behaviour taken from the national household survey of psychiatric morbidity at baseline and six months
4. Health-related quality of life is measured using the EuroQol Five Dimensions (EQ-5D) at baseline and six months
5. Satisfaction with care is assessed using the participant-completed four-item Client Satisfaction Questionnaire at baseline and six months
6. Resource use and costs are assessed using a modified version of the Adult Service User Schedule (AD-SUS) at baseline and six months
7. Change in overall health is measured using the patient version of the Clinical Global Impression Scale at baseline and six months

Overall study start date
30/01/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Clinical diagnosis of personality disorder
3. Positive screening result using the International Personality Disorder Examination self-administered questionnaire
4. Competent and willing to provide written, informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
63

Key exclusion criteria
1. A current clinical diagnosis of a co-existing organic or psychotic mental disorder (dementia, bipolar affective disorder (type I and II), delusional disorder, schizophrenia, schizoaffective disorder or schizotypal disorder
2. Cognitive or language difficulties that would preclude subjects providing informed consent or compromise participation in study procedures

Date of first enrolment
13/07/2017

Date of final enrolment
11/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Waterview Centre
Central and North West London NHS Foundation Trust

7a Woodfield Road
Westminster
London
United Kingdom
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Sponsor information

Organisation
Central and North West London NHS Foundation Trust

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Stephenson House
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05drfg619

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 a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	10/10/2018		Yes	No
Results article	results	02/03/2020	05/03/2021	Yes	No
HRA research summary			26/07/2023	No	No