

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

<b>Submission date</b> 31/05/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/03/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**  
Ms Amy Claringbold

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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

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Westminster  
London  
United Kingdom  
W9 3XZ

## Sponsor information

### Organisation

Central and North West London NHS Foundation Trust

### Sponsor details

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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?
<a href="#">Protocol article</a>	protocol	10/10/2018		Yes	No
<a href="#">Results article</a>	results	02/03/2020	05/03/2021	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No