# Systematic Intervention to Transform Environment: a randomised controlled trial of nidotherapy in an assertive outreach team

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
15/10/2006	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/02/2007	Completed	[X] Results		
<b>Last Edited</b> 08/06/2011	Condition category	Individual participant data		
U8/U0/ZU11	Mental and Behavioural Disorders			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

Prof Peter Tyrer

#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

#### Scientific Title

#### Acronym

SITE

#### **Study objectives**

To test the feasibility and likely effectiveness of nidotherapy, a new treatment for personality disorder and chronic mental illness, in a group that is most difficult to treat - those cared for by an assertive outreach team, in an exploratory randomised controlled trial.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

St Marys Hospital Research Ethics Committee on 16/07/2003 (ref: R&D03/X008E).

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Co-morbid personality disorder and severe mental illness (schizophrenia, bipolar disorder or severe depressive illness)

#### **Interventions**

Nidotherapy (a new treatment designed to change the environment to suit the needs of the peson with the chronic disorder) versus assertive treatment as usual in the team.

#### **Intervention Type**

Other

#### **Phase**

#### Primary outcome measure

Reduction of usage of psychiatric beds one year after treatment

### Secondary outcome measures

- 1. Reduction in number of admissions
- 2. Social function (using the Social Functioning Questionnaire)
- 3. Psychiatric symptomatology (using Brief Psychiatric Rating Scale [BPRS])
- 4. Patient satisfaction (Consultation Satisfaction Questionnaire [CSQ])
- 5. Engagement with services (Engagement and Acceptance Scale [EAS])

#### Overall study start date

01/10/2003

#### Completion date

31/12/2006

## **Eligibility**

#### Key inclusion criteria

Randomisation of all eligible patients who give consent currently under the care of an assertive outreach team.

#### Participant type(s)

Patient

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

### Target number of participants

52

#### Key exclusion criteria

Those who refuse to take part.

#### Date of first enrolment

01/10/2003

#### Date of final enrolment

31/12/2006

## Locations

### Countries of recruitment

England

#### **United Kingdom**

Study participating centre
Department of Psychological Medicine
London
United Kingdom
W8 8RP

## Sponsor information

#### Organisation

Central North West London Mental Health NHS Trust (UK)

#### Sponsor details

30 Eastbourne Terrace London England United Kingdom W2 6LA +44 (0)20 8237 2000 david.slater@nhs.net

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.cnwl.org/index.html

## Funder(s)

#### Funder type

Charity

#### **Funder Name**

Nicola Pigott Memorial Fund (UK) (ref: CNWL019070)

## **Results and Publications**

### Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2009		Yes	No