ISRCTN96256106 https://doi.org/10.1186/ISRCTN96256106

The effect of nidotherapy on antisocial behaviour and attitudes to intervention

Submission date	Recruitment status
15/10/2006	No longer recruiting
Registration date	**Overall study status**
06/02/2007	Completed
Last Edited	**Condition category**
03/05/2011	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Tyrer

Contact details
Department of Psychological Medicine
Imperial College
St Dunstan's Road
London
United Kingdom
W6 8RP
+44 (0)20 7386 1237
p.tyrer@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0007161104

Study information

Scientific Title

Acronym
NIDO-ASPD

Study objectives
The qualitative component of the study will explore the relationship between the process of nidotherapy and the outcome measures assessed in the main project. A researcher independent of the main trial will complete a series of key informant interviews aimed at identifying themes. This will be followed by in depth interviews with patients and key workers. Eight study participants will be purposely selected ensuring that a range of demographic and clinical factors are covered (e.g. male and female service users, white and Black and Minority Ethnic [BME] service users and those who were initially treatment seeking and treatment resistant). Questioning will be structured by the researcher to ensure coverage of key themes but will also be responsive to issues that emerge from respondents accounts.

We will also collect data from non-participant observation of therapy sessions. This will help the researcher to be aware of differing views, interests and perspectives of the participants and help elucidate accounts of the process given in interviews. All interviews will be tape-recorded and verbatim transcripts made. When patients decline to give consent for interviews consent will be sought form verbatim note taking. Data will be downloaded for analysis using the NVivo computer package.

The hypotheses of this trial are:
1. To determine if nidotherapy is an acceptable form of treatment in forensic settings for both patients and therapists
2. To test whether there are changes in aggressive behaviour, engagement and functioning after nidotherapy and the time scale of such changes
3. To determine if resistance to change in personality is reduced by nidotherapy (as measured by change from Type R to Type S personalities)
4. To determine whether nidotherapy is an appropriate treatment to test in a large randomised controlled trial in forensic patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brent Medical Ethics Committee on the 28/02/2005 (ref: 05/Q0408)

Study design
Observational study with assessments at baseline and up to six months together with qualitative analysis

Primary study design
Observational

Secondary study design

Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Antisocial personality disorder in conjunction with any major mental illness

Interventions
Up to 12 sessions of nidotherapy over a six month period given by a trained nidotherapist.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Change in scores on Modified Overt Aggression Scale (MOAS) after six months from baseline.

The primary objectives of the analysis will be:
1. To describe the processes involved in nidotherapy and which aspects of strategy and approach are most often used
2. To assess from the perspective of service users about the benefits and dis-benefits of this complex intervention and the factors that may promote successful therapy

Secondary outcome measures
To measure changes in personality treatment seeking, engagement, severe episodes of aggression and social functioning after six months.

Overall study start date
01/04/2005

Completion date
31/03/2007

Eligibility

Key inclusion criteria
All patients attending a range of local secure and assertive outreach services in the London Boroughs of Brent and Hammersmith and Fulham are considered for intervention with nidotherapy if they satisfy the following inclusion criteria:
1. Written informed consent for treatment, assessment and examination of case records
2. A diagnosis of any mental state (Axis 1) psychiatric disorder and a personality disorder after assessment using the OPCRIT system (mental state diagnosis) and personality disorder (after

assessment with the Personality Assessment Schedule (PAS)
3. Evidence they are likely to stay in the relevant area for a period of at least six months (i.e. are not likely to have a major forced environmental change such as imprisonment)
4. Agreement for at least some nidotherapy treatment sessions to be audio-taped

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
None if all above satisfied.

Date of first enrolment
01/04/2005

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Psychological Medicine
London
United Kingdom
W6 8RP

Sponsor information

Organisation
National Programme on Forensic Mental Health Research and Development (UK)

Sponsor details

University of Liverpool
C/O HaCCRU
Thompson Yates Building
Quadrangle
Brownlow Hill
Liverpool
United Kingdom
L69 3GB
+44 (0)151 794 5251
k.harney@liverpool.ac.uk

Sponsor type
Research organisation

Website
http://www.nfmhp.org.uk/

Funder(s)

Funder type
Research organisation

Funder Name
National Programme on Forensic Mental Health Research and Development (UK) (ref: M0007161104)

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	01/01/2010		Yes	No