

The effect of nidothrapy on antisocial behaviour and attitudes to intervention

Submission date 15/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/05/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 nidothrapy 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

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Sponsor information

Organisation

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

Sponsor details

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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