

Nottinghamshire Environmental Village Project

Submission date	Recruitment status	[X] Prospectively registered
17/03/2024	No longer recruiting	[X] Protocol
Registration date	Overall study status	[] Statistical analysis plan
11/06/2024	Completed	[] Results
Last Edited	Condition category	[] Individual participant data
03/12/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Nidotherapy is the systematic and collaborative manipulation of the environment in all its forms to create a better fit for a person and improve mental health. It has shown beneficial effects in individuals but not yet in whole communities. This study introduces nidotherapy to the whole communities of six villages in Nottinghamshire in a systematic stepped-wedge design and measures several outcomes, the main one being the improvement in social function.

Who can participate?

Adults aged from 18 to 100 years old who have mental capacity, can give consent and who do not have life-threatening physical illnesses

What does the study involve?

The assessment of personality strengths and function, self-rated mood symptoms, quality of life and social function on four occasions over one year together with a three-month programme of nidotherapy advice at a randomly chosen three-month period.

What are the possible benefits and risks of participating?

The benefits could include improved social function, better village integration, reduced loneliness, and symptomatic improvement. The risks include errors from inappropriate environmental interventions or unexpected conflict if environmental wishes create opposition.

Where is the study run from?

The Nidotherapy Advice and Training Centre at Cotham in Nottinghamshire (UK). Nottingham Trent University and Imperial College London are the main academic partners.

When is the study starting and how long is it expected to run for?

March 2024 to December 2025

Who is funding the study?

NIDUS-UK (a registered charity)

Who is the main contact?

Professor Peter Tyrer, p.tyrer@imperial.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Nottinghamshire nidotherapy project

Acronym

NEVP

Study objectives

Current study hypothesis as of 24/06/2024:

Nidotherapy, environmental advice given by a trained facilitator, is superior or inferior to an explanation of nidotherapy principles in improving social function and life satisfaction in whole communities

Previous study hypothesis:

Nidotherapy, environmental advice given by a trained facilitator, is superior to an explanation of nidotherapy principles in improving social function and life satisfaction in whole communities

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 20/08/2024, Schools of Business, Law and Social Sciences Research Ethics Committee (AADHREC) (Nottingham Trent University, Nottingham, NG1 4FQ, United Kingdom; +44 (0) 1158488157; annabel.cali@ntu.ac.uk), ref: 1900275

Study design

Interventional cluster-randomized stepped-wedge trial and linked qualitative study

Primary study design

Interventional

Study type(s)

Diagnostic, Efficacy, Quality of life

Health condition(s) or problem(s) studied

Improving social function and life satisfaction in whole communities

Interventions

A cluster-randomised step-wedged trial is planned in six village communities in Nottinghamshire, England covering an adult population of 622. The population in all six villages will be offered a full nidotherapy assessment followed by agreed environmental change in different three-month periods over one year. All six villages have populations between 51 and 120 residents and are similar demographically.

All adults in the six villages (total 442) will be approached to take part in the study. They will be asked to complete assessments of mental health, personality status, social function, quality of life and an environmental satisfaction form on three occasions. The primary outcome will change in social function, secondary outcomes include health-related quality of life, anxiety and depressive symptoms, personality status, costs of nidotherapy and life satisfaction. Adverse events will also be recorded.

The analysis will be carried out using the intention to treat with imputation of missing data. The analysis will be separated into three components: (i) the change in scores of the primary outcome (social function), (ii) the change in scores of all secondary outcomes, including costs, and (iii) changes in environmental satisfaction.

The procedure described for all villages will be followed but in the active nidotherapy villages further assessments before any changes will include an environmental analysis involving social, physical and personal aspects, matching of personality characteristics with the development of an environmental intervention using a formal procedure (or if no intervention is required a plan for a future change) and a timetable (nidopathway) with subsequent monitoring of progress. Because the choice of environmental change is made by the patient, the course cannot be predicted in advance but in most cases, the main components are completed within two months, and for the trial, all interventions will be completed in three months.

Nidotherapy will be administered by therapists, or, more accurately, trained environmental facilitators, who have completed training in the subject by a combination of theoretical learning and practice under supervision. This enables a full assessment of personality strengths and motivations and allows the right choice of intervention to follow. Some of the practical aspects of achieving environmental change may also require nidotherapy volunteers who have also been

trained in the principles of nidotherapy. A significant proportion of these will come from undergraduates and postgraduates of Nottingham Trent University.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 24/06/2024:

Impaired functioning measured using the Short Social Functioning Questionnaire (SSFQ) at baseline and 3, 6, 9 and 12 months

Previous primary outcome measure:

Impaired functioning measured using the Work and Social Adjustment Scale (WSAS) at baseline and 3, 6, 9 and 12 months

Key secondary outcome(s)

Current secondary outcome measures as of 24/06/2024:

The following secondary outcome measures are assessed at baseline and 12 months,

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
2. Personality strengths measured using the Abbreviated Personality Strengths Scale (APSS)
3. Quality of life measured using the Recovering Quality of Life (ReQoL) scale
4. Personality status measured using the Structured Assessment of Personality Abbreviated Scale (SAPAS)
5. Social cohesion measured using the PROMIS-SF (a four-item scale)
6. Personality disorder measured using the Personality Assessment Schedule for ICD-11 (PAS-ICD-11)
7. Personality traits measured using the Personality Assessment Questionnaire for ICD-11 (PAQ-11)

The following scales will also be administered at 3, 6 and 9 months:

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
2. Impaired functioning measured using the Short Social Functioning Questionnaire

An Environmental Checklist will be given before all other assessments at baseline, 3, 6, 9 and 12 months

A community satisfaction scale will be given at 12 months

Previous secondary outcome measure:

The following secondary outcome measures are assessed at baseline and 3, 6, 9 and 12 months, except satisfaction which is assessed at 12 months:

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) scoring
2. Changes in personality strengths measured using the Abbreviated Personality Strengths Scale (APSS)
3. Changes in quality of life measured using the Recovering Quality of Life (ReQoL) scale
4. Change in costs of nidotherapy measured using a record of total individual and community costs developed by Professor Barbara Brett (King's Health Economics)
5. Satisfaction with care measured using the Client Satisfaction Scale (CSQ-8)
6. Personality disorder measured using the Structured Assessment of Personality Abbreviated Scale (SAPAS)

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Adult with full mental capacity
2. Able to give informed consent

Participant type(s)

Resident

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

117

Key exclusion criteria

1. Serious life-threatening physical illness
2. Lack of mental capacity

Date of first enrolment

20/08/2024

Date of final enrolment

21/11/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Nidotherapy Advice and Training Centre

Cotham
Newark
England
NG23 5JU

Sponsor information

Organisation

Nottingham Trent University

ROR

<https://ror.org/04xyxjd90>

Funder(s)

Funder type

Charity

Funder Name

NIDUS-UK

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the study will be stored in a non-publicly available repository at Imperial College, London

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		25/03/2024	No	Yes	
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		25/03/2024	25/03/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes