ISRCTN12178260 https://doi.org/10.1186/ISRCTN12178260

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	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2024	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

Study website
https//:www.nidotherapy.co.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Peter Tyrer

ORCID ID
http://orcid.org/0000-0002-0358-1459

Contact details
The Nead House, Cotham
Newark
United Kingdom
NG23 5JS
+44 (0)7714765885
p.tyrer@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Built environment/local authority, Community

Study type(s)
Diagnostic, Quality of life, Efficacy

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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)

Overall study start date
18/03/2024

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
300

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
England

United Kingdom

Study participating centre
Nidotherapy Advice and Training Centre
Cotham
Newark
United Kingdom
NG23 5JU

Sponsor information

Organisation
Nottingham Trent University

Sponsor details
Dean of School of Architecture, Design & the Built Environment, Nottingham Trent University, Maudslay, Goldsmith Street
Nottingham
England
United Kingdom
NG1 5JS
+44 (0)115 848 4796
andrew.knight@ntu.ac.uk

Sponsor type
University/education

Website
https://www.ntu.ac.uk/study-and-courses/academic-schools/architecture-design-built-environment

ROR
https://ror.org/04xyxjd90

Funder(s)

Funder type
Charity

Funder Name
NIDUS-UK

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

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
Protocol file		25/03/2024	25/03/2024	No	No