A systematic environmental intervention, nidotherapy, given to whole communities: protocol for a randomised step-wedge trial

Peter Tyrer, Mike Crawford, Barbara Barrett, Woody Caan, Conor Duggan, Tim Kendall, Andrew Knight, Richard Parish and Min Yang

Abstract

Background
Environmental changes can have positive impact on mental illness. Systematic planned and guided environmental change in all its aspects is called nidotherapy. It has shown benefit in two randomised trials but has not yet been tested in whole communities.

Methods/Design
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 the course of 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 intention to treat together with imputation of missing data. Analysis will be separated into three components: (i) the change in scores of the primary outcome (social function),(ii) change in scores of all secondary outcomes, including costs, (iii) changes in environmental satisfaction.

Conclusions
This will be the first to examine the benefit of systematic collaborative environmental change on mental health in a whole community. (250 words)

Trial registration: Current Controlled Trials: ISRCTN being submitted

Keywords: nidotherapy, community interventions, social function, step-wedge cluster randomised trial, personality

BACKGROUND

There has been considerable interest in the positive effects of environmental change in the management of mental illness and the promotion of well-being. Many of these have involved exposing people to natural surroundings, particularly the green environment, and there is growing evidence that such interventions improve mental health mainly by reducing depression and anxiety symptoms (1-5). These interventions are not usually introduced for specific health problems in the mentally ill apart from life-style elements to improve cardiovascular health (2). Community studies have also shown that greening unsatisfactory waste environments has a positive impact on the mental functioning of communities (6-9).

However, all these interventions are decided by external agencies, not by people or patients themselves. Nidotherapy, a planned personal collaborative environmental change was developed in 2002 (10) and has been in use in the NHS and internationally for 25 years but only in a few limited places. Nidotherapy is an individual therapy but differs from all other psychotherapies in that it focuses entirely on changing the environment, not the person and has been highly praised for its attention to individual needs (11). Although it is superficially similar other environmental interventions such as social prescribing it differs in that patient themselves choose the environmental interventions they would like to be implemented. The task of the nidotherapist is to determine by a full assessment of individual capabilities and motivation if the change is feasible, and then help to facilitate its attainment (12).

Nidotherapy has been tested in two small controlled trials, one in severe mental illness and one in people with intellectual disability. The first of these was carried out in patients with severe mental illness and personality disorder in an inner-city service. This showed evidence of cost-effectiveness by reducing hospital in-patient care and promoting better community placement (13), improving social function in those with comorbid substance use (14), and meriting a Cochrane review (15). The second trial was carried out in patients with intellectual disability who showed challenging behaviour and in view of the limited mental capacity of the patients the training in nidotherapy was carried out with staff. This trial also showed benefit in reducing challenging behaviour compared with the enhanced care programme approach but the benefits did not show immediately (16). There has also been another study

showing problems in providing choice in nidotherapy in forensic patients (17) and a series of case studies showing long-term benefit after treatment (18-19).

The proposed study intends to extend the scope of nidotherapy into a whole population setting where there is more opportunity for individual needs to be matched up with others in the community. For example, one of the main causes of poor mood in elderly people living alone is loneliness. Interventions to improve this have had limited success (20) but in a community setting environmental interventions to improve social involvement could be made easily if fellow neighbours were able to meet lonely individuals in common activities. These could be facilitated by nidotherapy.

Research objectives

The primary objective of the trial is to determine if nidotherapy given in a whole community setting is more effective in improving social function than a mere demonstration of nidotherapy principles in other whole communities. The secondary objectives are to determine if nidotherapy also improves depressive and anxiety symptoms, quality of life, personality functioning, and satisfaction with care to a greater extent than just demonstration of principles. We also wish to determine if nidotherapy is cost-effective by recording all the costs associated with its administration.

Methods

The trial design is a cluster randomised controlled trial using a step-wedge design of nidotherapy to be given to all adult residents (18 or over) in six villages in Nottinghamshire in central England. The plan is to randomise the six villages into three groups each containing two villages, with active nidotherapy being given to each group for a period of 3 months. As the project will explain the principles of nidotherapy from the start of the study, when the people in villages are not receiving active nidotherapy they will represent a passive nidotherapy control population.

Study setting

The six villages are Cotham, Hawton, Kilvington, Alverton, Thorpe and Sibthorpe (total population, 422). Each village has similar demographic characteristics with most residents over the age of 60, with no economically deprived areas, with living in owned properties. Each village has a church but no shops.

Eligibility criteria

The intention is to recruit all who satisfy the eligibility criteria to be involved in the trial.

Inclusion criteria:
Aged 18 or over

Exclusion criteria:
Impaired mental capacity leading to inability to consent
Serious physical illness preventing the possibility of planned environmental change
Inability to speak English sufficiently well to understand all parts of the trial

Statistical design

The trial will be of randomised clustered step-wedge design with two arms. Two randomisations will be carried out at three steps. The trial will proceed in three steps. In the first step two villages will be randomly selected for nidotherapy, with the other four as controls. At step two, another two villages of the remaining four will be randomised to nidotherapy with the other four villages as controls, although there may be carry-over effects of nidotherapy in the first two villages selected. In the third step the remaning two villages will receive nidotherapy. Thus the two villages receiving nidotherapy at first randomisation will have two periods to observe the post-treatment effects, with the second two having one period to observe the post-treatment effects. The last two villages will have nidotherapy completed nine months after the trial starts and a final follow-up will take place after one year.

Mixed effects models are well known to MY and are proposed for the data analysis of this trial design, including the assessment of carry-over effects of nidotherapy in the first four villages randomised.

Interventions

All villages:
The eligible inhabitants of all villages will receive an explanation of nidotherapy and a rounded assessment of their present circumstances, their personal

strengths and motivations, and mental health status. This is presented as a rough mental health assessment but with no further intervention. A good assessment of general functioning and personality is an important part of environmental selection in nidotherapy.

Nidotherapy villages:

The procedure described for all villages will be followed but in the active nidotherapy villages further assessments prior to 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 future change) and a timetable (nidopathway) with subsequent monitoring of progress (21). 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 purposes of the trial all intervention will be completed by 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 many 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.

Examples of the changes achieved in nidotherapy range from community ones to improve social isolation, employment interventions, improving local amenities, help in relationships, and bigger changes such as a change of housing arrangements. The main advantage of community involvement is joint decision making between members of the village, allowing shared benefits to be attained. If nidotherapy is embraced across the village further benefits could be achieved. Equipoise is present to the extent that unsolicited interventions to people who do not ask for them might be perceived negatively and lead to rejection.

Ethical aspects

All subjects taking part in the study will receive a participation information sheet and complete a signed consent form. We will follow the Helsinki Declaration criteria in that participants will have the right to cease involvement in the study and to withdraw from the trial at any time and for any reason, without prejudice to his or her future care. An investigator may also withdraw a participant from the trial at any time in the interests of the participant's health and well-being or for administrative reasons.

Assessments

Baseline (preceded by randomisation):

All subjects will receive a baseline assessment to determine eligibility and agreement to take part in all parts of the trial. This will be preceded by publicity from local news outlets.

Each of the subjects agreeing to take part will complete the following assessments, deliberately chosen to be relatively short and easy to complete in all groups:

1. Work &Social Adjustment Scale (WSA)(22), a well tested measure (23)
2. Structured Assessment of Personality - Abbreviated Scale (SAPAS)(24)
3. Assessment of Personality Strengths Scale (APSS)(25)
4. Hospital Anxiety and Depression Scale (HADS) (26)
5. Personality Assessment Questionnaire for ICD-11 (27)
6. Recovering Quality of Life (ReQoL) (28)
7. Personality Assessment Schedule for ICD-11 (PAS-ICD11)(29)
8. A satisfaction scale (30) and the WSA (22) will be completed at 1 year.

Costs of all approach for costing interventions.

These instruments can take up to one hour to complete but this is much shorter in the absence of pathology. They are needed to achieve a good baseline assessment for good environmental decisions to be made.

Second assessment Three months after baseline assessment, further randomisation if step-wedge design used

The assessments apart from the personality ones will be completed in all subjects.

Third assessment 6 months after baseline

The assessments apart from the personality ones will be completed in all subjects.

Fourth assessment at 9 months.

All the assessments at baseline will be repeated at 9 months.

Follow-up

After one year the WSA scale (22) and satisfaction scale (30) will be completed, and an adverse event scale derived from the work of Klatte et al (31) will be administered to determine any adverse events in either arm of the trial.

Funding: In progress. £50K support from NIDUS-UK obtained to date.

References

1. Adewuyi, FA, Knobel, P, Gogna, P, & Dadvand, P. Health effects of green prescription: A systematic review of randomized controlled trials. Environment Res 2023; 236(Pt 2):116844.
2. Looijmans, A., Jörg, F., Bruggeman, R. *et al.* Design of the lifestyle interventions for severe mentally ill outpatients in the Netherlands (LION) trial; a cluster randomised controlled study of a multidimensional web tool intervention to improve cardiometabolic health in patients with severe mental illness. BMC Psychiatry 2017; 17: 107.
3. Robinson, T, Robertson, N, Curtis, F, Darko, N, & Jones, CR. Examining Psychosocial and Economic Barriers to Green Space Access for Racialised Individuals and Families: A Narrative Literature Review of the Evidence to Date. Int J Environment Res & Pub Health 2022; 20:745.
4. Briggs, R, Morris, PG, & Rees, K. The effectiveness of group-based gardening interventions for improving wellbeing and reducing symptoms of mental ill-health in adults: a systematic review and meta-analysis. J Ment Health 2023; 32 :787-804.

5. Coventry, PA, Brown, JE, Pervin, J, et al. Nature-based outdoor activities for mental and physical health: Systematic review and meta-analysis. SSM Population Health 2021;16:100934.
6. South, EC, Hohl, BC, Kondo, MC, MacDonald, JM, & Branas, CC. Effect of greening vacant land on mental health of community-dwelling adults: A cluster randomized trial. JAMA Network Open 2018; 6: e180298.
7. Moyer, R, MacDonald, JM, Ridgeway, G, & Branas, CC. Effect of remediating blighted vacant land on shootings: A citywide cluster randomized trial. Am J Pub Health 2019; 109: 140-4.
8. Garvin, EC, Cannuscio, CC, & Branas, CC. Greening vacant lots to reduce violent crime: a randomised controlled trial. Inj Prevention 2013 ;19:198.
9. Kolster, A, Heikkinen, M, Pajunen, A, Mickos, A, Wennman, H, & Partonen, T. Targeted health promotion with guided nature walks or group exercise: a controlled trial in primary care. Frontiers in Public Health 2023; 11:1208858.
10. Tyrer, P. Nidotherapy: a new approach to the treatment of personality disorder. Acta Psychiat Scand 2002; 105: 469-471.
11. Pallanti, S. Nidotherapy: harmonising the environment with the patient. Am J Psychiatry 2010; 167: 871.
12. Tyrer, P, Sensky T, & Mitchard S. The principles of nidotherapy in the treatment of persistent mental and personality disorders. *Psychother Psychosom* 2003; 72: 350-6.
13. Ranger, M, Tyrer, P, Milošeska, K, et al. Cost-effectiveness of nidotherapy for comorbid personality disorder and severe mental illness: randomized controlled trial. *Epidemiol Psichiat Sociale* 2009; 18: 128-36.
14. Tyrer, P, Miloseska, K, Whittington, C, et al. Nidotherapy in the treatment of substance misuse, psychosis and personality disorder: secondary analysis of a controlled trial**.** The Psychiatrist 2011; 35: 9 - 14.
15. Chamberlain, IJ, Sampson, S. Nidotherapy for schizophrenia. Schizophr Bull 2013; 39: 17-21.
16. Tyrer, P, Tarabi, SA, Bassett, P, et al. Nidotherapy compared with enhanced care programme approach training for adults with aggressive challenging behaviour and intellectual disability (NIDABID): cluster-randomised controlled trial. *J Int Dis Res* 2017; 61**:** 521-31*.*
17. Spencer, S-J, Rutter, D & Tyrer, P. Integration of nidotherapy into the management of mental illness and antisocial personality: a qualitative study. Int J soc Psychiatry 2010; 56: 50-59.
18. Tyrer, P & Bajaj, P Nidotherapy: making the environment do the therapeutic work. Adv Psychiat Treatment 2005; 11: 232-8.

19. Spears, B, Tyrer, H, & Tyrer, P. Nidotherapy in the successful management of comorbid depressive and personality disorder. Personal Ment Health 2017; 11**:** 344-50.
20. Hsueh, YC, Batchelor, R, Liebmann, M, et al. A systematic review of studies describing the effectiveness, acceptability, and potential harms of place-based interventions to address loneliness and mental health problems. *Int J Environment Res Pub Health* 2022; 19: 4766.
21. Tyrer, P & Tyrer, H. *Nidotherapy: harmonising the environment to the patient.* Cambridge University Press, 2018.
22. Pedersen, G, Kvarstein, EH, & Wilberg, T. The Work and Social Adjustment Scale: Psychometric properties and validity among males and females, and outpatients with and without personality disorders. Personal Ment Health 2017;11:215-28.
23. Moran, P, Leese, M, Lee, T, et al. Standardised Assessment of Personality - Abbreviated Scale (SAPAS): preliminary validation of a brief screen for personality disorder. Br J Psychiatry 2003; 183: 228-32.
24. Yang, M, Tyrer, P, & Tyrer, H. The recording of personality strengths: An analysis of the impact of positive personality features on the long-term outcome of common mental disorders. Personal Ment Health 2022; 16: 120-9.
25. Zigmond, AS, & Snaith, RP. The Hospital Anxiety and Depression Scale. Acta Psychiat Scand 1983; 57: 361–70.
26. Kim, Y-R, Tyrer, P, & Hwang S-T. Personality Assessment Questionnaire for ICD-11 personality trait domains: development and testing. Personal Ment Health 2021; 15: 58-71.
27. Keetharuth, AD, Bjorner, JB, Barkham, M, et al. Exploring the item sets of the Recovering Quality of Life (ReQoL) measures using factor analysis. Qual Life Res 2019; 28: 1005-15.
28. Klatte, R., Strauss, B., Flückiger, C., et al. Defining and assessing adverse events and harmful effects in psychotherapy study protocols: A systematic review. Psychother (Chicago*)* 2023; 60: 130-48.
29. Seivewright, H, Green, J, Salkovskis, P, Barrett, B, Nur, U, & Tyrer, P. Cognitive-behavioural therapy for health anxiety in a genitourinary medicine clinic: Randomised controlled trial. Br J Psychiatr*y* 2008; 193: 332–7.
30. Shipley, K, Hilborn, B, Hansell, A, Tyrer, J & Tyrer, P. Patient satisfaction: a valid measure of quality of care in a psychiatric service. Acta Psychiat Scand 2000; 101**:** 330-333.

Peter Tyrer, Division of Psychiatry, Imperial College, London and Nottingham Trent University; **Mike Crawford,** Division of Psychiatry, Imperial College, London; **Barbara Barrett,** King's Health Economics, London; **Woody Caan**, Royal Society of Public Health, London; **Conor Duggan,** University of Nottingham; **Tim Kendall,** University of Sheffield; **Andrew Knight,** Dept of Architecture, Design and the Built Environment, Nottingham Trent University; **Richard Parish,** Department of Public Health, University of Chester; **Min Yang,** School of Public Health, Sichuan University, Chengdu, China, and Faculty of Health, Art and Design, Swinburne University of Technology, Melbourne, Australia