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Reducing health inequalities: a place-based approach to supporting the wellbeing of vascular patients

Submission date
08/10/2024

Recruitment status
Recruiting

Registration date
15/11/2024

Overall study status
Ongoing

Last Edited
22/01/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to test the feasibility and acceptability of a secondary care place-based intervention focused on four dimensions linked to the Labonte model: physiological impacts, health behaviours, psycho-social factors, and wider determinants of health. This pilot study targets individuals diagnosed with vascular conditions to explore effective methods for addressing health inequalities and improving health behaviours

Who can participate?
Patients aged between 18 and 100 years with a history of ischemic stroke or transient ischemic attack

What does the study involve?
The study includes health checks (e.g., blood pressure, height, weight) and health coaching based on cognitive-behavioural therapy principles. Participants will receive home visits from Equality Health Advisors, who will support them in addressing physiological and psycho-social factors and help them navigate public and community services.

What are the possible benefits and risks of participating?
Possible benefits include improved physical health and mental well-being, better health behaviours and increased social connectedness, and enhanced self-efficacy in managing personal health and improved health literacy. There are limited risks associated with participating in home visits, but participants have the right to withdraw at any time without affecting their care

Where is the study run from?
The study will be conducted within the Aneurin Bevan University Health Board (UK), specifically at multiple hospital sites where valid informed consent and case report form A will be completed. The intervention is place-based and will be undertaken in the participant's own home (video link and telephone calls may be used as an alternative on the participant's request)

When is the study starting and how long is it expected to run for?
October 2024 to October 2025

Who is funding the study?
Welsh Stroke Implementation Group

Who is the main contact?
1. Anna Pennington, Anna.Pennington@wales.nhs.uk
2. Dr Jonathan Hewitt, HewittJ2@cardiff.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342682

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPON1991-24, CPMS 62219

Study information

Scientific Title
Targeted pilot study to ascertain the feasibility and acceptability of the Equality Health-CVD intervention for patients with vascular conditions

Acronym
Equality Health-CVD

Study objectives
To test the feasibility and acceptability of a secondary care place-based intervention using a pilot study. The intervention focuses on four dimensions linked to the Labonte model:
1. Physiological impacts – health check
2. Health behaviours – health coaching
3. Psycho-social factors – community and public service assets
4. Wider determinants of health – community and public service assets

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 11/09/2024, South East Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, Edinburgh, EH1 3EG, United Kingdom; +44 (0)7814 764 241; Sandra.Wyllie@nhs.scot), ref: 24/SS/0067

Study design
Single-centre pilot study, utilising a mixed-methods approach that includes both qualitative interviews and quantitative data collection via validated questionnaires

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Home

Study type(s)
Prevention, Quality of life

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Transient ischaemic attack, minor stroke, peripheral arterial disease

Interventions
The intervention, delivered by Equality Health Advisors over a 12-week period, is based on the Labonte model and targets four key dimensions of health.

Intervention focus:
1. Physiological impacts: regular health checks, including measurements like blood pressure and BMI.
2. Health behaviours: coaching sessions aimed at improving lifestyle and health-related habits.
3. Psycho-social factors: leveraging community resources and public services to address social determinants of health.

4. Wider determinants of health: tackling broader issues such as income, housing, and education that influence health outcomes.

The pilot study will recruit 20 participants and follow them for 12 weeks. During this time, participants will be offered 4 home visits 4 weeks apart (video link or telephone call optional)

The participants will receive personalised health and wellbeing checks, coaching, and social and public asset support. Data will be collected to track participants' health outcomes and social factors, helping refine the intervention before a larger-scale trial.

Data will be analysed descriptively, focusing on response and completion rates from questionnaires. Additionally, thematic analysis will be conducted on qualitative interviews to explore both participants' and Equality Health Advisors' experiences and any necessary adjustments.

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 22/01/2025:

The feasibility of the Equality Health-CVD intervention will be ascertained through the following activities:
1. Recruitment and retention recorded during the following timepoints: baseline and 1, 4, 8, and 12 weeks post-baseline
2. The number and duration of contact visits, completion of the four intervention components, completion of data collection, the number of community and public service resources provided, and detailed descriptions of participants' social background, collected at various timepoints at 1, 4, 8, and 12 weeks post-baseline

The researchers will also evaluate whether the following criteria progression have been met prior to planning a future large-scale trial:
1. Recruitment -% of target number of participants recruited (target: 20; 9 -month recruitment period)
2.Retention - % of patients who participate in 12-week follow-up (of those who complete min. 1 intervention session)
3.Feasibility of intervention implementation - The intervention is implemented with fidelity (i.e., 4 home visits conducted with data collected recorded at each visit and signposting to community and public assets.

Previous primary outcome measure:

The feasibility of the Equality Health-CVD intervention will be ascertained through the following activities:
1. Recruitment and attrition recorded during the following timepoints: baseline and 1, 4, 8, and 12 weeks post-baseline
2. The number and duration of contact visits, completion of the four intervention components, completion of data collection, the number of community and public service resources provided, and detailed descriptions of participants' social background, collected at various timepoints at 1, 4, 8, and 12 weeks post-baseline

The researchers will also evaluate whether the following criteria progression have been met prior to planning a future large-scale trial:
1. Number of participants offered the intervention and declined uptake during the consent process (≤20%)
2. Recruitment rate (≥80% of the target number of participants recruited within the first 5 months)
3. Follow-up completion (90-100% of participants complete the scheduled number of contact visits and 90-100% of participants complete the scheduled number of contact visits)
4. Attrition rate at the end of the study (25% drop out consider progression to RCT)
5. Completion of data collection (≥95% of required data points collected)

Secondary outcome measures
1. The participants' acceptability and perception of the Equality Health-CVD Intervention, evaluated through qualitative semi-structured interviews at the end of the study
2. The deliverers' (Equality Health Advisors) acceptability of the intervention, including barriers and facilitators to delivery and perceived impacts of the intervention, evaluated using qualitative semi-structured interviews at the end of the study

Participants will complete the following questionnaires baseline and 12 weeks post-baseline to support the evaluation within this feasibility study:
1. Self-reported physical, mental and social health measured using PROMIS 10
2. Social wellbeing measured using the South Wales Social Wellbeing Scale (SWSWBS)
3. Quality of life measured using EuroQol-5D

The quantitative PROMS will be used in conjunction with qualitative semi-structured interviews as data descriptors. The aim is to assess whether the participants are willing and able to complete these measures, in addition to capturing subjective health and social wellbeing outcomes that may enhance data richness.

Overall study start date
24/10/2024

Completion date
31/10/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/01/2025:

1. Male or female
2. ≥18–100 years of age
3. History of ischemic stroke National Institutes of Health Stroke Scale (NIHSS) score of less than 5
and/or
4. History of transient ischaemic attack
and/or
5. Referral to Peripheral Vascular Clinic
6. Capacity to consent
7. Willingness to partake in a qualitative interview at the end of the intervention

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Previous inclusion criteria:

1. (Identified as) male and female
2. ≥18–100 years of age
3. History of ischemic stroke National Institutes of Health Stroke Scale (NIHSS) score of less than 5
and/or
4. History of transient ischaemic attack
and/or
5. Referral to Peripheral Vascular Clinic
6. Capacity to consent
7. Willingness to partake in a qualitative interview at the end of the intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Less than 18 years of age
2. Patients receiving or eligible for palliative care
3. Unwillingness or inability (e.g. physical or cognitive) to comply with study procedures
4. Any person already participating in a clinical rehabilitation home intervention
5. Unwillingness to take part in a qualitative interview at the end of the intervention

Date of first enrolment
13/11/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Aneurin Bevan University Lhb
Headquarters - St Cadoc's Hospital
Lodge Road
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Sponsor information

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ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Other

Funder Name
Welsh Stroke Implementation Group

Results and Publications

Publication and dissemination plan
The researchers intend to publish the protocol in October 2024 and the full study results on completion of the implementation phase between January and March 2026

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Anna Pennington (Anna.Pennington@wales.nhs.uk).

Ownership of the data arising from this study resides with the Sponsoring Organisation, Cardiff University. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared. The authors will acknowledge that the study was funded by the Stroke Implementation Group and other contributors will be acknowledged.

The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

The study will be portfolio adopted. Summaries of results will also be made available to the Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

Only anonymised data will be shared, both quantitative and qualitative, after 31/10/2026. Consent from participants will be required before the implementation phase of the study. All data will be anonymised, and recordings of transcribed data will be kept no longer than necessary. Research data will be kept securely and separately from any personal data collected as part of the study.

The study will be conducted in compliance with the principles of the Declaration of Helsinki (2013) and the principles of GCP and in accordance with all applicable regulatory guidance, including but not limited to the UK Policy Framework for Health and Social Care 2017. This protocol and related documents (and any subsequent amendments) will be submitted for review to the relevant parties (HRA/HCRW and REC).

Annual progress reports and a final report at the conclusion of the study will be submitted to the relevant parties within the timelines defined if required.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	04/09/2024	08/10/2024	No	No