Full Title: TARGETED PILOT STUDY TO ASCERTAIN THE FEASIBILITY AND ACCEPTABILITY OF THE EQUALITY HEALTH-CVD INTERVENTION for PATIENTS WITH VASCULAR CONDITIONS

Short Title/Acronym: EQUALITY HEALTH-CVD

Sponsor: Cardiff University, 30-36 Newport Road, Cardiff, Wales, CF24 0DE **Email Address:** resgov@cardiff.ac.uk
Study Coordination Centre: N/A
Funder: Stroke Implementation Group
Chief Investigator: Dr Jonathan Hewitt Clinical Reader, Cardiff University Research Lead for Stroke, HSCRW Stroke Consultant – Aneurin Bevan University Health Board
Investigator (s): Anna Pennington Professional Doctorate Student - Cardiff University Public Health Principal - Aneurin Bevan University Health Board
Sponsor/R&D ref: SPON1991-24
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Protocol version number and date: Version 1.2 04.09.2024

This protocol has been authorised by:			
Name	**Role**	**Signature**	**Date**
			20/08/2024

Jonathan Hewitt	Chief Investigator		
Name	**Role**	**Signature**	**Date**
Anna Pennington	Principal Investigator Cardiff University Student		**20/08/2024**

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1. GENERAL INFORMATION

1.1. Study Summary

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Study Title	TARGETED PILOT STUDY TO ACERTAIN THE FEASIBILITY AND ACCEPTABILITY OF THE EQUALITY HEALTH-CVD INTERVENTION for PATIENTS WITH VASCULAR CONDITIONS
Internal ref. no. / short title	EQUALITY HEALTH-CVD
Study Design	Pilot Study To explore the feasibility and acceptability of a secondary care place-based intervention focusing 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
Planned Sample Size	20 participants
Planned Study Duration	October 2024-October 2025
Primary Objectives	1. To determine effective means of recruiting participants (recruitment and attrition) 2. To assess the feasibility of implementing the intervention (e.g number and duration of contact visits, completion of four intervention components, completion of data collection and number of community and public service assets offered, description of social background)
Secondary Objectives	3. To explore the participants acceptability and perception of the intervention 4. To explore the deliverers acceptability of the intervention, including barriers and facilitators to delivery and perceived impacts.
Statistical Methodology and Analysis	Statistical methodology will be descriptive.

1.2 Funding and Support in kind

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**

Stroke Implementation Group	Financial Support during the implementation phase

1.3 Role of Study Sponsor

The sponsor of this study is Cardiff University (CU). It is the role of the sponsor to confirm that there are proper arrangements to initiate, manage, monitor, and finance a study. The sponsor will not play a role in the study design, conduct, data analysis and interpretation, manuscript writing, or the dissemination of results; this will be the responsibility of the Chief Investigator, Dr Jonathan Hewitt, an employee of the sponsor organisation.

The sponsor has responsibility for overall oversight of the trial. The role of the Sponsor is to ensure the study is run safely and effectively by requiring the following:

- Proportionate peer review
- Provision of all appropriate, valid supporting documentation at the point of application
- Clear definition of roles and responsibilities of organisations and individuals, signed off prior to the study commencing
- Appropriate level of monitoring and audit
- A risk assessment process to identify any potential risks to the organisation or the health, safety, and well-being of researchers and research participants
- Involvement of patients and/or the public in study design, where appropriate
- The Chief Investigator's suitability to fulfil their role, through relevant experience and appropriate training
- Provide guidance in relation to the required ethical and/or other regulatory approvals that may be required
- Provide assurance of adequate indemnity/insurance for design, management and conduct of the study
- Dissemination of study findings in an appropriate manner

The Sponsor, through their Research and Development department, has a veto on overall approval for the study.

The funder's role is to finance the study and to receive a study report.

1.4 Protocol Contributors

The protocol has been written by Professional Doctorate student Anna Pennington and has been reviewed and revised by Dr Kelly Morgan and Dr Jonathan Hewitt, the student's supervisors. Health Professionals employed by Aneurin Bevan University Health Board, groups associated with the Gwent Public Service Board, and Carers

and individuals with lived experience have provided further input through consultation.

KEY WORDS:

Cardiovascular Disease

Equality Health Advisor

Pilot Study

Health Behaviours

Peripheral Vascular Disease

Psycho-social factors

Physiological impacts

Stroke

Transient ischaemic attack

Wider determinants of health

2. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
EHA	Equality Health Advisor
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
ICH	International Conference of Harmonisation
ISF	Investigator Site File
HCRW	Health and Care Research Wales
HRA	Health Research Authority
NHS	National Health Service
PI	Principal Investigator
PIS	Participant Information Sheet
R&D	Research & Development Office
REC	Research Ethics Committee

RN	Research Nurse
SOG	Study Operational Group
SMG	Study Management Group
SPT	Study Project Team
TMF	Trial Master File

3. BACKGROUND AND RATIONALE

Cardiovascular disease and stroke are common causes of mortality and morbidity in the United Kingdom (UK) (Biobank 2023) and carry a high economic burden (Gheorghe et al. 2018; Patel et al. 2019). Cardiovascular disease and stroke can impact people of all backgrounds, but health disparities are more prominent in those of low sociodemographic and ethnic groups (Razieh et al. 2022). These groups tend to experience poorer health outcomes and are more likely to be impacted (Stack et al. 2020; Eastwood et al. 2021; Razieh et al. 2022). Currently, cardiovascular disease and stroke cost the National Health Service (NHS) and wider economy some £55.1 billion per year (Luengo-Fernández et al. 2006; Patel et al. 2019)

Peripheral vascular disease (PVD) is the third leading cause of atherosclerotic morbidity following coronary heart disease and stroke (Criqui et al. 2021). Research suggests those diagnosed with PVD are vulnerable to more severe cardiovascular events (Grenon et al. 2013). Furthermore, PVD shares several risk factors with atrial fibrillation, with a credible link to an increased risk of stroke (O'Neal et al. 2014)

To reduce incidences of cardiovascular disease, stroke and peripheral vascular disease preventative measures such as lifestyle modifications and risk factor management have proven to be effective (Sarikaya et al. 2015; Rippe 2019; King et al. 2022; Ghodeshwar et al. 2023) However, their effectiveness may be limited due to various challenges (Bailey 2016). Evidence shows social gradient and social determinants of health (SDoH) as key denominators of health and wellbeing and has informed policy in recent years (Michael Marmot 2010; Michael Marmot 2020).

However, despite efforts in achieving equitable improvements to health across all social gradients, progress is proving difficult in the current social, economic, and political environment, (Adler and Newman 2002; Carey and Crammond 2015; Solutions 2021). Considering the complexities influencing health inequalities, a one size fits all approach seldom succeeds (Matheson 2020) (NHS-England 2022). Thus, leading to targeted policies addressing social determinants of health exposing bleak deliverable outcomes (Lee et al. 2018).

Public Health Wales (PHW) supports strategies to improve population health advocating that all public bodies pursue a collective response to new ways of working (PHW 2022). This places the NHS in a unique position as an anchor institution to tackle social determinants of health, intently endorsed across the UK's four devolved nations (nhsconfed 2021; NHS-England 2022)

The health burden of cardiovascular disease, stroke and peripheral vascular disease on patients, caregivers, the health system, and the broader economy, is substantial – resulting in markedly reduced ability to perform activities of daily living, poor health-related quality of life, high rates of unplanned hospitalisations, excessive costs, and premature mortality (Roth et al. 2020; Portas et al. 2022)

In contrast to lifestyle modifications and risk factor management therapies provided by primary and secondary care NHS provision (Riley et al. 2015), in the effort to address social determinants of health, there is limited research in evidence-based interventions that captures and acts upon adverse social determinants of health, such as food and housing insecurity, or exposure violence and poverty (Kreuter et al. 2021; Powell-Wiley et al. 2022)

Professor Sir Michael Marmot provides subtle clarity in his book the Health Gap (Marmot 2017) to support modifications to health practice:

"Why treat people and send them back to the conditions that made them sick?" p4

The NHS, in particular Aneurin Bevan University Health Board perhaps can support their local community in the attempt to reduce health inequalities and social determinants of health. The recently published Building a Fairer Gwent: improving health equity and the social determinants report (Michael Marmot 2023) confirms this call for action. Therefore, there is an urgent need for tailored interventions to help people to live the life they wish to live rather than a life dictated to them because of their circumstances. In this study the target population are those diagnosed with a vascular condition. The aim is to explore if a targeted place-based Health and Wellbeing Improvement Intervention using the UK Government endorsed adapted Labonte model is feasible and acceptable to intervention providers and stakeholders.

Why this research is important for the public/patients/healthcare services

National Institute for Health and Care Excellence (NICE) guidance states reducing health inequalities is part of its core principles (NICE 2023). However, scepticism in effective NHS deliverables to address healthcare inaccessibility and poor healthcare quality, wider determinants of health and negative health behaviours is recognisable (Attree et al. 2012; Asaria et al. 2016)

People justification

Research indicates that the largest health disparities are experienced by members of the most socially disadvantaged communities. Evidence suggests, the most socially disadvantaged people live with long-term conditions earlier, accumulate them more quickly, and endure them longer (Michael Marmot 2010; Bambra et al. 2020; Michael Marmot 2020). This establishes a moral requirement for the NHS and wider partners to actively seek novel social and health-related interventions that may alleviate health and wellbeing outcomes.

Business and economic justification

The most socially disadvantaged individuals and localities command a higher expenditure per capita than the wealthiest with longer lifespans, despite living shorter lives and more years spent in poor health. Excessive costs for healthcare can be attributed to the use of pharmacological therapy, hospital emergency room visits, extended hospital stays, postponed discharges, and pressure on elective care (McCabe et al. 2017). How health inequality affects the fall in economic productivity is a further cause for concern. According to a modelling analysis by the Health Foundation, by 2040, one in five people will live with one or more major illnesses (Watt 2023). This establishes a business case to improve outcomes in population health with the aim to potentially reduce and repurpose cost savings for social and economic benefit.

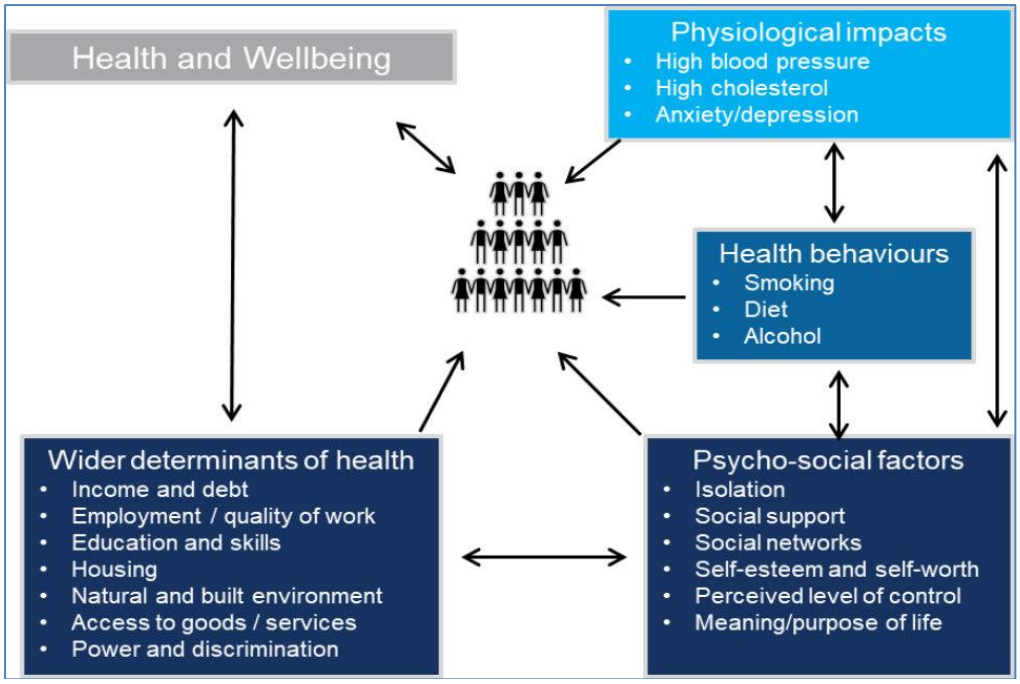
Healthcare quality

There is a clear intersection between patient safety and health inequalities, manifesting itself in communication breakdown, deterring marginalised ethnic groups from seeking timely medical attention (Chauhan et al. 2020). Poorer members of society lack access to digital tools, increasing the likelihood of missed appointments and access to timely treatments. Healthcare services providing a one size fits all pathway, coinciding with unequal risks of harm between different ethnic population groups (Wade et al. 2022). A recent report published by the NHS Race and Health Observatory claims ethnic health inequality is prominent and further work to address inequalities such as improving the quality of ethnicity data and increased investment in community engagement (King'sFund 2021). It is evident, health needs of the UK population are changing (McKee et al. 2021) in terms of prevention and treatment of illness and disabilities. Thus, providing an ethical stance to make improvements to a care model.

Research seems prominent in its commitment to understand what approaches the NHS is taking to address inequalities (Dorling et al. 2016; Brennan et al. 2023). However, there seems a lack of comprehensive research focusing specifically on test and learn interventions that may reduce inequalities for those in the secondary care system, using a place-based approach. In short, knowledge of health inequalities and the benefits of addressing social determinants of health is evident, but evidence of interventions that bring about significant change is limited (McGowan et al. 2021; PublicHealthEngland 2021; Maria Luisa Buzelli and Alderwick 2022).

Faced with a high unmet need for effective interventions to reduce inequalities in outcomes, experience, and access, NICE (NICE 2023) recommends applying place based approaches considering factors identified in the UK government advocated adapted Labonte model.

Figure 1: Adapted Labonte model



Source: Public Health England. Adapted Labonte model Place-based approaches for reducing health inequalities: accessed on 06/12/2023

This model aims to simplify the causes of health inequalities in what is deemed a complex system. The adapted Labonte model considers lifestyle drift, drawing attention to wider determinants that shape health behaviour and influence change (Cohn 2014; Carey et al. 2016).

Building a Fairer Gwent (Michael Marmot 2023) report advocates universal interventions in every area of Gwent with provision developed more intensely where need is higher. The report provides evidence that more targeted interventions are needed.

By focusing on inequalities and inequities of wider determinants of health, improving health behaviours, checking physiological status, and addressing psychosocial factors the EQUALITY HEALTH-CVD pilot study intention is to compliment these priorities as a test and learn project. The study aims to understand if the EQUALITY HEALTH-CVD pilot study is accepted to those diagnosed with a vascular condition. The study has the potential to benefit a larger community by providing a more targeted approach to individuals who require more care. In contrast, this study will be accessible to participants from all social backgrounds and descriptive analysis of social economic factors will be discussed to inform future research.

4. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

RESEARCH QUESTION/AIM(S)

Aim: 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

Questions:

1. Is the Intervention feasible and acceptable in terms of recruitment and attrition?
2. Is it feasible to implement the intervention?
   (e.g., number and duration of contact visits, completion of data collection, completion of four intervention components, and number of community and public service assets offered, description of social background)
3. What are the participants perceived experiences and perceptions of the intervention?
4. What are the deliverers perceived experiences and perceptions of the intervention, including barriers and facilitators to delivery and perceived impacts?

Objectives	**Outcome Measures/Endpoints**
Primary Objective To test the feasibility and acceptability of a secondary care place-based intervention focusing 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	1) To determine effective means of recruiting participants (recruitment and attrition) 2) To assess the feasibility of implementing the intervention (e.g number and duration of contact visits, completion of four intervention components, completion of data collection and number of community and public service assets offered, description of social background) **When, Who and How** *Baseline, RN – CRF A and questionnaires* *1 week EHA-* *Equality Health Home Visit form* *4 weeks EHA* *Equality Health Home Visit form*

	8 weeks EHA *Equality Health Home Visit form* *12 weeks EHA Equality Health Home Visit form, questionnaire*
Secondary Objectives To explore the participants acceptability and perception of the intervention Explore the deliverers acceptability of the intervention, including barriers and facilitators to delivery and perceived impacts.	1. To explore the participants acceptability and perception of the intervention 2. Explore the deliverers acceptability of the intervention, including barriers and facilitators to delivery and perceived impacts. **When, Who and How** *12 weeks researcher - interview CRF B and questionnaires*

5. STUDY DESIGN

The research design is a mixed method pilot study with nested longitudinal qualitative interviews and questionnaires.

The value of undertaking a pilot study is to gain an understanding of interventional suitability without costly and time intensive research activity and probable risk of study failure (Bell et al. 2018) In addition to providing useful information concerning the protocol design and implementation (Hassan et al. 2006).

The mixed method approach used in this study consists of semi structured interviews with participants and deliverers (Equality Health Advisors), including validated questionnaires at baseline and at a 12-week time point.

This is a single centre study recruiting participants registered within the Aneurin Bevan University catchment area in a secondary care setting.

The pilot study identification, screening, and consent will take place in the following Aneurin Bevan University Health Board hospital sites.

- Grange University Hospital (GUH)
- Royal Gwent Hospital (RGH)
- Nevil Hall Hospital
- Ysbyty Ystrad Fawr (YYF)
- Cwmbran PAD Clinic

Identification and screening will be discerned by the participants care team; this includes first contact. Consent will be conducted by the research delivery team, and may include care team, research nurse, CI, or PI.

This is a place-based intervention - Ideally all contact visits within the intervention will be undertaken in the participant's home. However, participants will be offered an alternative option of a video link if this is not applicable.

6. STUDY MANAGEMENT

Study Project Team (SPT) – Weekly Meetings
This team will include CI, PI, co-investigator, members of the participants care team, research nurse and Equality Health Advisors. This team will discuss recruitment, CRFA, participant comments/ participant home visits, protocol queries, participant queries, data queries, CRFB participants comments/ potential study risks/ escalations.

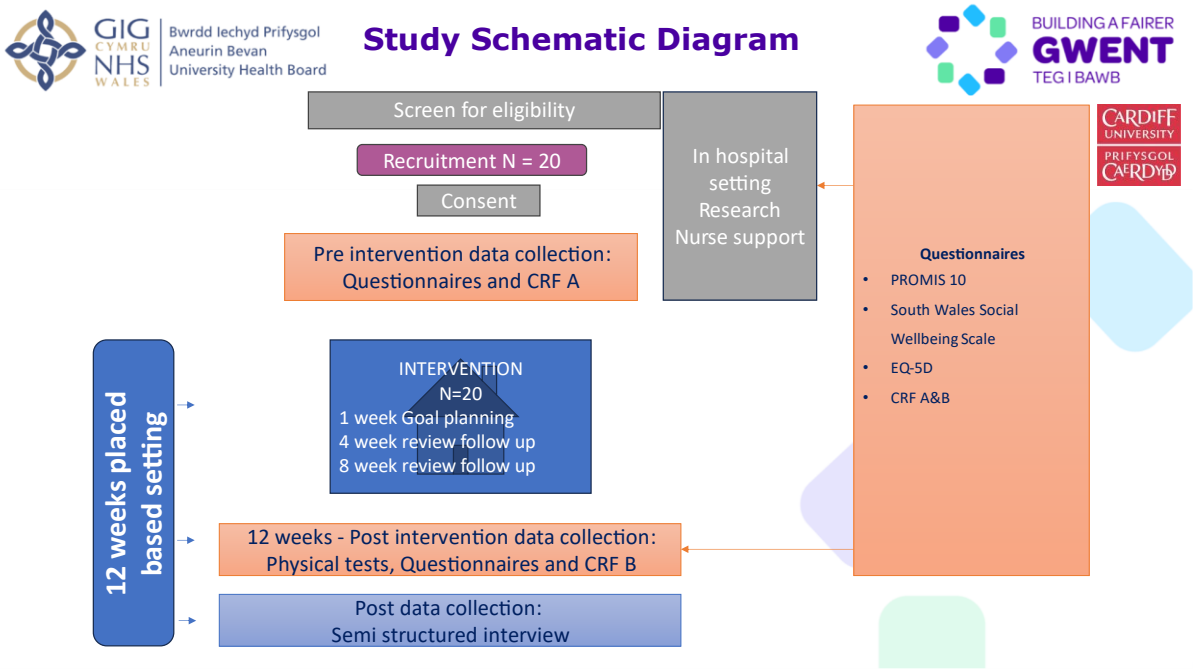
Study Management Group (SMG) – Monthly Meeting
Study management will consist of a monthly supervisory meeting with the researcher and two Cardiff University supervisors. Including, ABUHB Quality Assurance Officer Independent Data Validation Reviewer (Quantitative) Independent Data Validation Reviewer (Qualitative)

Study Operational Group (SOG)
There will be a quarterly SOG meeting which will include health professionals, researchers and patient and public persons during the implementation phase to help inform amendments to the protocol if necessary. This group will receive regular reports from the researcher with details of progress including summary of screening logs, numbers recruited and completed outcome assessments, and study protocol deviations.

Patient and Public Involvement (PPI) Advisory Group
As part of the study two PPI members with lived experience will join the SOG.

7. STUDY FLOW CHART and/or SCHEDULE OF STUDY PROCEDURES

Diagram 1: Equality Health -CVD - Intervention developed by the researcher in conjunction with Professional and PPI consultation



Procedures **Intervention**	**Weeks**				
	Screening **0 weeks**	**Week1**	**Week 4**	**Week 8**	**12 weeks**
Eligibility criteria review	x				
Informed consent	x				
Medical history	x				

Case Report Form A Including audit c	x				
Health Check (Including Weight, HR, BP, BMI, Waist Circumference)		x			x
EQ-5D	x				x
PROMIS 10	X				x
South Wales Social Wellbeing Scale	x				x
Equality Health Home Visit form		x	x	x	x
Case Report Form B Including audit c					x
Semi Structured Interview					x

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

The sample size is 20 participants. In this instance, time and resource constraints make recruiting a larger sample challenging. While 20 participants may be smaller than the typical guideline of 30 suggested by (Billingham et al. 2013) it may still provide valuable insights.

8.2 Inclusion Criteria

To obtain person centred standards a series of professional and public, patient engagement sessions were arranged to develop and finalise the EQUALITY HEALTH-CVD protocol. Dedicated discussion groups' and 'one-to-one consultation meetings' with professionals and those with lived experience helped address any challenges and improved the quality of the protocol research design. The recommendations included narrowing the eligibility criteria to focus only on participants diagnosed with transient ischaemic attack, peripheral vascular disease and ischemic stroke NIHSS score of 5 and below. This will ensure that clinical input

after hospital discharge does not compound intervention results and reduces the burden of excessive healthcare support systems overwhelming the participants.

Patients -

1. (Identified as) Male and Female
2. ≥18–100 years of age
3. History of ischemic stroke NHISS 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

Equality Health Advisors for semi-structured interviews:

Undertaken the role of an Equality Health Advisor

8.3. Exclusion Criteria

Patients

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

Equality Health Advisors for semi-structured interviews:
No exclusion criteria required

9. STUDY PROCEDURES

Schedule of assessments (0 month)

Participants in the study will undergo eligibility screening in three different settings. During emergency admission in GUH, as an inpatient at YYF or during a routine clinic at various sites. The participants care team will provide potential participants with a patient information sheet.

Baseline data

All participants will be consented by a delegated member of the ABUHB research delivery team. After consent the following questionnaires will be completed

- CASE REPORT FORM A
- PROMIS 10
- EQ-5D
- South Wales Social Wellbeing Scale

The questionnaires will be collected either by Microsoft forms if Wi-Fi is available or paper form and then transferred to an excel database.

The initial consultation of the intervention date and time be organised either during baseline data collection by the ABUHB research delivery team, or via telephone or email by the Equality Health Advisor.

(Follow Up 1)
Equality Health- CVD Intervention (week 1) Initial Consultation

Consented Participants will be offered an initial face to face home based appointment where the Equality Health Advisor will provide place-based support focusing on four domains.

1. Physiological impacts
2. Health behaviours
3. Psycho-social factors
4. Wider determinants of health

1.The Equality Health Advisor will conduct the following physical tests:

- Blood Pressure and HR
- Height
- Weight
- BMI
- Waist Circumference

All physical test results will be recorded - if blood pressure is considered high: Hypertension: Systolic 140 mm Hg or higher or diastolic 90 mm Hg or higher the Equality Health Advisor will advise the participant to keep track of their blood pressure at home using an automated blood pressure monitor once a day at a different time of the day for a period of seven days. If blood pressure remains high after this time the participant will be advised to seek medical support at their registered GP surgery. If the participant does not own a blood pressure monitor, a monitor recommended by the British and Irish Hypertension Society blood pressure will be provided to the participant by the study team.

If a blood pressure reading is in the category of hypertensive crisis (180/100) the Equality Health Advisor will advise the participant to seek immediate medical support.

2. The Equality Health Advisor will complete an equality health home visit data collection form with the assistance of the participant. The participant will undertake a coaching session that aims to elicit a goal setting conversation to create a personal goal plan. The aim is to create a person-centred plan. There will also be an opportunity for the equality Health Advisor and participant to discuss health literacy.

3 & 4 Based on the information provided, the Equality Health Advisor will present a range of options to overcome barriers and address needs concerning psycho-social factors and wider determinants of health - which may mean linking the participant to different services within the community. The Equality Health Advisor may need to provide extra support in helping the participant navigate different services such as contacting services on the participants behalf.

The participant will receive assistance and guidance related to the Labonte Model during this meeting, including guidance on health and lifestyle. A four-week follow-up visit will be scheduled when the amount of assistance is documented. Data collection in terms of services contacted and action log for next appointment will be documented.

Follow up 2 - (4 weeks)

The Equality Health Advisor will visit the participant at home after four weeks to follow up on progression and assist in any additional needs. The plan will be adapted if any barriers are encountered. Together, the participant and the Equality Health Advisor will identify a solution. Information about delivery time, mode, application of intervention components, and retention/adherence rate will all be gathered by the Equality Health Advisor using either an electronic device or paper reporting form that will be transferred to an excel sheet.

Follow up 3 - (8 weeks)

The Equality Health Advisor will visit the participant at home after eight weeks to follow up on progression and assist in any additional needs. The plan will be adapted if any barriers are encountered. Together, the participant and the Equality Health Advisor will identify a solution. Information about delivery time, mode, application of intervention components, and retention/adherence rate will all be gathered by the Equality Health Advisor using an electronic device or paper reporting form that will be transferred to an excel sheet.

Follow up 4 - Intervention end of study visit (12 weeks)

The final review at 12 weeks will involve a physical health check and questionnaires conducted at the baseline assessment and initial consultation. There will also be a follow up goal setting conversation to ascertain if the participant requires further

support. Information about delivery time, mode, application of intervention components, and retention/adherence rate will all be gathered by the Equality Health Advisor using either an electronic device or paper reporting form that will be transferred to an excel sheet.

The questionnaires are as follows.

- CASE REPORT FORM B
- PROMIS 10
- EQ-5D
- South Wales Social Wellbeing Scale

The physical tests are as follows:

- Blood Pressure and HR
- Height
- Weight
- BMI
- Waist Circumference

NB: If the participant feels uncomfortable with Equality Health Advisor visiting their home at any point, they will be offered an alternative of a telephone or video call. This will be recorded on the Equality Health home visit form.

Process Evaluation

Participants and Equality Health Advisor semi-structured interviews

As part of the final intervention process evaluation, a small cohort of participants (approximately 8-10) using a non-probability convenience sample as described by (Suen et al. 2014) will undertake a semi structured interview during the 12 week follow up visit. The semi structured interviews will be conducted by the researcher.

A set of standard questions will be asked to ascertain the following:

- The participant's experiences and perceptions of the Equality Health-CVD Intervention.
- The participant's acceptability of the intervention and study design.
- Challenges or opportunities of future research in reducing health inequalities in the community.

In addition, approximately 2-4 Equality Health Advisors will undertake a semi structured interview to explore their views of the EQUALITY HEALTH-CVD study using a similar thematic qualitative process as the participants.

In addition, the Equality Health Advisor will keep a reflective diary.

It should be noted that further interviews may be required if new data is still presenting itself after the final interview. This study aims to achieve theoretical saturation in that sampling will continue until eligible participant pool has been exhausted or interviews are not yielding new information.

NB: Further details in section 10

Logic Model

Context	Intervention	Mechanisms of impact	Intervention outcomes
Setting: Secondary care support service. **Target population:** People diagnosed with either of the following: • History of ischemic stroke NHISS score of less than 5 • History of Transient ischemic attack • Peripheral Vascular Disease **Number of Participants** Total = 20 **Aim:** Improve Health and Wellbeing	Link participants to community-based interventions. Link participants to CIVIC interventions that support (Closeness, Identity, Valued relationships, Involvement, Cared for/accepted) – Civic duty Provide Health and Wellbeing coaching using basis CBT. (Using NHS England health and wellbeing coaches framework)	Accessible pathways into service-based and community-based interventions Participative social functioning Knowing who to contact Participant is Listened to Supporting Participant motivation Flexible role	Improved physical health. Improved mental health and well-being Better Health Behaviours Increased social connectedness. Reduce social isolation. Improved healthcare utilisation outcomes (such as fewer GP visits and lower emergency admission) Increase Self Efficacy in managing personal health Enhance goal achievement.
Age: Male and Female – Age 18 to 100 **Deliverers:** Equality Health Advisors **Number of Visits:** 4 visit in total – approximately 4 week apart	Physiological testing • Blood Pressure and HR • Height • Weight • BMI • Waist Circumference	Trusting interpersonal relationship Person-centred approach Adaptability of intervention Cross pathway referrals	Reduction in risky health behaviours Improve health literacy. Support health awareness through physiological testing.
Length of Visit: Approximately 1 hour	**Act upon wider determinants of health** Fuel poverty -Nest Income – Citizens Advice		Increased engagement in preventive health behaviours

	Poor housing and living conditions. Education Unemployment Health care service		Improve disease management. Greater awareness of social determinants of health Increase access to essential services (e.g., healthcare, transportation)

9.1. Recruitment

20 participants will be recruited over a 4-to-8-month period. The aim is to recruit a conservative 5 participants per month for a total of 4 months to reach a target recruitment of 20 participants. The following routes of recruitment will be used: Potential participants will be identified locally at sites across Aneurin Bevan University Health Board by cardiovascular disease, peripheral artery, and stroke specialists. Including emergency admission, in patient setting or consultant and nurse lead clinics.

9.2. Screening and Eligibility Assessment

Initial identification and eligibility of participants will be confirmed by the clinical team and supported by delegated ABUHB research delivery team.

Potential participants will obtain a Participant Information Sheet (PIS) (via various routes including in hospital setting, at a clinical appointment or posted out with the potential participants outpatient appointment letter.

Electronic screening logs will be kept and will include reason for non-participation. The reason for non-participation will be sought via the ABUHB research delivery team.

9.3. Informed Consent

Informed consent will be sought by delegated ABUHB research delivery team members named on the delegation log. Eligible participants will be provided with verbal information about the study and given a copy of the written Patient Information sheet.

The patient will be given adequate time to review the information sheet and ask questions. Patients may choose to give consent on the same day or take the

information home to consider. In this case patients will be given the contact details of the research nurse to arrange a follow up appointment.

A copy of the PIS and completed consent form will be uploaded onto the participant's CWS file with a record of the discussion. A copy of the consent form will be provided to the participant to keep, and a copy will be also kept in the electronic master trial file. This file will be held on a ABUHB Research and Development computer server during the course of the study.

The participant will always be given the chance to ask questions during the consent process.

For translation delegated staff will use the Wales Interpretation and Translation service. This will support the consent process, provision of information and intervention visits.

9.4. Discontinuation/Withdrawal of Participants from Study

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the study.

In this instance, participants who consent and subsequently withdraw should complete a withdrawal form with the researcher or delegated member of staff to determine and evidence the withdrawal request.

If a participant withdraws from the study, the research team will not attempt to recruit another participant. Once the target recruitment number of 20 participants has been reached, the study will be closed to recruitment.

9.5. Study Amendments

The CI will seek advice from the Sponsor prior to submission of amendments to the relevant bodies. The CI will seek approval for any substantial amendments to the protocol or other study documents from HRA/HCRW and REC (if applicable). The NHS R&D Office(s) will need to confirm capacity and capability prior to implementation. Amendments to the protocol or other study documents will not be implemented prior to these approvals being granted. Non substantial amendments should be notified to the HCRW and REC for information and may also need to be reviewed and accepted by R&D departments before they can be implemented in practice at site(s).

9.6. Definition of End of Study

Study completion will be the date of the last follow up of the last patient.

Discontinuation of the study if required will be decided upon by the Study Management Group.

10. TECHNIQUES AND TOOLS

Intervention

The Equality Health Advisors will undertake various training before implementation including a PCI Accredited Tailored Health Coaching Course. The Equality Health Advisors will access module 1 to support the coaching element of the intervention This course aims to provide tailored health coaching for Health and Social Care Professionals. All training provided will be paid through grant funding

Semi Structured Interviews

The semi structured interviews and qualitative thematic process will follow using (Braun and Clarke 2006) principles to explore both participants' experiences of participation in the intervention. This will be conducted by the researcher, preferably in person. However, there will be a video call option available to the participant. It is intended that audio recordings from the interviews will be transcribed by the researcher or may be sent to a professional transcriber, all information will remain confidential. Following transcription, the transcribed documents will be shared with the participant to ensure they agree with the transcribed information. For analysis, individual transcripts and audio recordings will be read and listened to multiple times for the researcher to fully submerge themselves in the data.

A systematic analysis to generate initial themes will be completed using computer assisted qualitative data analysis software (CAQDAS) and data will be reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al. 2007). A reflexive diary will be used to support separation of researcher opinion and member checks to promote credibility and confirmability. Data collection will cease once subsequent data saturation is achieved.

In addition, descriptive analysis will be made on quantitative data collected which includes validated questionnaires (Promis-10 and South Wales Social Wellbeing Scale) and case report forms, this analysis aims to understand the basic characteristics of the EQUALITY HEALTH – CVD study data, including the social economic demographics of the recruited participants.

Questionnaires

The following questionnaires will be completed at baseline and 12 weeks.

PROMIS 10 - The PROMIS 10 is a comprehensive and accessible set of tools used to measure self-reported physical, mental and social health, including symptoms, function and general perceptions of health and wellbeing.

South Wales Social Wellbeing Scale – The South Wales Social Wellbeing Scale (SWSWBS) is a tool to the quality of respondents' overall experience of social wellbeing via the external social resources they possess, their perceived ability to engage in and enjoy the social world in which they live, and, as a result, their capacity for human functioning and flourishing.

EuroQol-5D - EQ-5D is an instrument which evaluates the generic quality of life developed in Europe and widely used. The EQ-5D descriptive system is a preference-based HRQL measure with one question for each of the five dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression

The quantitative PROMS will be used in conjunction with qualitative semi structured interviews as data descriptors. The aim is to assess if 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.

Physical Testing

The Equality Health Advisor will conduct a series of tests**.** The purpose of the physical tests is to identify participants at risk, set goals and elicit health improvement conversations, monitor progress and establish baseline measures for future testing as part of the intervention.
CE-marked/UKCA calibrated devices and equipment will be used. The Equality Health Advisor will consider the testing environment and physical limitation of participants prior to conducting a test. All tests will be safe, reproducible, validated, reliable, sensitive, acceptable to participant, and practical to undertake.

11. Protocol Compliance

Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator.

Deviations from the protocol which are found to frequently recur are not acceptable and will require immediate action and could potentially be classified as a serious breach.

All delegated staff are ABUHB employed and adhere to ABUHB policies including the ABUHB lone worker policy. All mandatory training and DBS enhancement will be checked. In addition, a training check list will be completed and signed off before intervention implementation.

The Equality Health Advisors and Researcher (Principal Investigator) will meet (weekly/fortnightly). The Equality Health Advisors will be DBS Enhanced checked

and will receive tailored health coaching training. Further training will be undertaken and signed off using a training log prior to study implementation. A Training log is provided in the appendices. All Equality Health Advisors and delegated staff will be supported by the Principal Investigator, Chief Investigator and *S*OG for the duration of the study.

Furthermore, prior to study commencement the researcher will undertake training in interview techniques, in addition to qualitative and quantitative education. The researcher and delegated delivery team holds a valid Informed Consent Certification and will ensure all participants fully understand what is being asked of them in accordance with GCP guidelines.

11.1. Adverse Events and Serious Adverse Event definitions

Adverse Event (AE): Any untoward medical occurrence in a trial participant which does not necessarily have a causal relationship with this intervention. An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory finding), symptom, or disease.

Serious Adverse Event (SAE): Any adverse event that:

• Results in death

• Is life-threatening*

• Required hospitalisation or prolongation of existing hospitalisation**

• Results in persistent or significant disability or incapacity

• Consists of a congenital anomaly or birth defect

• Other medically important condition ***

* Note: The term “life-threatening” in the definition of serious refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure, for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures does not constitute an adverse event.

*** Note: other events that may not result in death are not life-threatening, or do not require hospitalisation may be considered as a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

The AEs and SAEs triggered during the study period are expected to be non-study related due the nature of this study

11.2. Reporting procedures for SAEs

Depending on the nature of the event, the reporting procedures outlined in this protocol should be followed. Any queries concerning adverse event reporting should be directed to the Chief Investigator by phone and then send the completed SAE form to the Chief Investigator within the following 24 hours.

The research team will report all related SAEs as required by their local Research and Development Office.

N.B. When setting up study reporting systems ensure no Patient/Participant Identifiable Information (PID) is e-mailed outside the University.

Contact details for reporting SAEs

Please send SAE forms to:

E-mail: Jonathan.Hewitt@wales.nhs.uk

Tel: 07375 128 973 (Mon to Fri 09.00 – 17.00)

Only reports of Serious Adverse Events (SAEs) that are:

related to the study (i.e. they resulted from administration of any of the research procedures) and

unexpected (i.e. not listed in the protocol as an expected occurrence)

should be submitted to both the REC that gave a favourable opinion of the study and the Sponsor by the Chief Investigator (CI) using the Non-CTIMP safety report to REC form which is available on the HRA website https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/

https://www.hra.nhs.uk/documents/2466/Non_CTIMP_Safety_Report_Form_Accessible_September_2020_AA.odt

These should be sent within 15 days of the Chief Investigator becoming aware of the event.

Unrelated and Expected SAEs do not require reporting to the Sponsor but a copy of the SAE report should be retained in the Investigator Site File for monitoring/audit unless alternative arrangements have been agreed during study set up.

The CI will send the Annual Progress Report to the main REC and to the sponsor using the HRA template.

11.3. Urgent Safety Measures and Serious Breaches of GCP

The CI and PIs may take immediate safety measures to protect research participants against any hazard to their health or safety without prior authorisation from the REC or sponsor. However, they must alert the sponsor as soon as possible of any such urgent measures by contacting the Cardiff University Research Governance Team and CI. The CI will notify the REC of the presenting issue within 3 days of the urgent measure setting out the reasons for the urgent measure and the plan for further action. If a site PI identifies the presenting issue, he or she should also inform their local R&D department.
In the event that a serious breach of GCP is suspected, this will be reported to the sponsor and REC immediately and will be investigated by the sponsor. Any corrective action required will be undertaken by the CI and REC informed. If necessary, a protocol amendment will be submitted for review.

12. STATISTICS AND ANALYSIS

12.1. Description of Statistical Methods

Questionnaires

The researcher will analyse and report response and completion rates to questionnaires, in addition to summarising descriptive variability in questionnaire outcomes.

Participant and Equality Health Advisor Interviews

Analysis of interview data will follow Braun and Clarke's thematic method and will include

- Data collection
- Data Management (using qualitative software)
- Data Analysis (familiarisation, generating codes, searching for theme, defining ad naming themes)
- Illustrative quotes will support findings

Equality Health Advisors Reflective Diaries

Analysis of reflective diaries will help understand the thoughts, feelings and experiences documented by the Equality Health Advisors over the study time period. These accounts will support findings

These points of interest are aimed to identify insights and problems that may occur before considering a full RCT.

Progression criteria

To recognise and acknowledge protocol success the following criteria will be applied using a green light system.

Criteria Progression	**Green Light**	**Amber Light**	**Red Light**
Recruitment and Attrition			
No of participants offered the intervention and declined uptake during the consent process	≤ 20%	≤ 50-74% Investigate reasons for refusal	≤ 75% Use Modify intervention Using 6 SQUID (Six-Step Quality Improvement Design)
Recruitment Rate	≥ 80% of the target number of participants recruited within the first 5 months.	50-79% of the target number recruited within the first 5 months. Implement additional recruitment strategy	49-0% of the target number recruited within the first 5 months. Re-evaluate recruitment strategies and consider protocol modifications
Attrition Rate at the end of the study	25% Drop out Consider progression to RCT	26-60% Drop out Investigate reasons for dropout and implement retention strategies	75-100% Consider not proceeding with RCT funding bid submission
Follow up Completion	90-100% of participants complete the scheduled number of contact visits.	60-89% of participants complete the scheduled number of contact visits. Investigate barriers and enhance follow-up procedures.	< 75% of participants complete the scheduled number of contact visits Re-evaluate follow up strategy and consider protocol adjustments when considering future research.

Feasibility of Implementing the Intervention			
Follow up Completion	90-100% of participants complete the scheduled number of contact visits.	60-89% of participants complete the scheduled number of contact visits. Investigate barriers and enhance follow-up procedures.	< 75% of participants complete the scheduled number of contact visits Re-evaluate follow up strategy and consider protocol adjustments when considering future research.
Duration of visits	Average visit duration aligns with the planned schedule ± 10%	Average visit duration deviates from the planned schedule by 11-20%. Analyse time management and adjust visit plans if necessary.	Average visit duration deviates from the planned schedule by > 20%. Reassess visit structure and content.
Completion of Intervention Components	≥ 90% of participants complete all four components of the intervention.	75-89% completion rate. Identify and address barriers to the Labonte Model implementation	< 75% completion rate. Re-evaluate intervention design and implementation strategies.
Completion of Data Collection	≥ 95% of required data points collected	80-94% of required data points collected. Enhance data collection methods and follow-up.	80% of required data points collected. Implement corrective measures and consider protocol revisions.
Utilisation of Community and Public Service Asset	All planned community and public service assets are utilised as per individual goal plan	75-99% of planned assets are utilized. Identify reasons for underutilisation and adjust as necessary.	< 75% of planned assets are utilised. Conduct a thorough review and consider alternative assets or engagement strategies.
Participants' Acceptability and Perception			
Participant Satisfaction	≥ 80% of participants report	60-79% of participants report	< 60% of participants report

	high satisfaction with the intervention	high satisfaction. Investigate concerns and enhance the intervention based on feedback.	high satisfaction. Conduct a thorough review and consider major modifications to the intervention
Perception of Effectiveness	≥ 80% of participants perceive the intervention as beneficial to their health and well-being.	60-79% of participants perceive the intervention as beneficial. Address specific areas of concern to improve perceived effectiveness.	< 60% of participants perceive the intervention as beneficial. Re-evaluate the intervention's approach and content.
Deliverers' Acceptability and Perceived Impact			
Equality Health Advisor Satisfaction	All Equality Health Advisors report high satisfaction with the implementation process. Use of Equality Advisor Handbook	Half of the Equality Health Advisors report high satisfaction. Identify and address concerns to enhance deliverer experience. Use of Equality Advisor Handbook	Equality Health Advisors do not report high satisfaction. Conduct a detailed review and consider significant modifications to the Equality Advisor Handbook and delivery process.
Identification of Barriers and Facilitators	Comprehensive identification of key barriers and facilitators, with actionable insights.	Partial identification with some actionable insights. Further investigation needed to fully understand and address issues.	Inadequate identification of barriers and facilitators. Implement a focused review and action plan to gather necessary insights.
Perceived Impact	All Equality Health Advisors perceive the intervention as having a positive impact on participants.	Half of the Equality Health Advisors perceive a positive impact. Explore specific areas for improvement.	Equality Health Advisors do not perceive a positive impact. Reassess and potentially redesign aspects of the intervention

13. DATA MANAGEMENT

13.1. Access to Data

All participant identification and referral procedures as well as procedures for data storage, processing and management will comply with Cardiff University policies. Direct access will be granted to authorised representatives from the sponsor and host institution for monitoring and/or audit of the study to ensure compliance with the relevant data protection legislation.

The study may be subject to inspection and audit by Cardiff University under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research 2017.

Direct access will be granted to authorised representatives from the sponsor and host institution for monitoring and/or audit of the study to ensure compliance with the relevant data protection legislation.

13.2. Data Recording and Record Keeping

The researcher and delegated staff will be GDPR compliant, and data collected will be stored on a secure NHS server that only the researcher and delegated research staff are able to access for the duration of the study. The data will be collected using a ABUHB laptop using Microsoft word and an excel database. If a paper based CRF or Equality Health form is utilised a copy of the completed form will be scanned and saved in the Equality Health site file in a Research and Development SharePoint folder.

Equality Health-CVD data validity and data quality will be monitored by a member of the ABUHB Office of Population Health team named on the delegation log.

Anonymisation of data will be conducted throughout study implementation and during the analysis and will include removing direct identifiers between the screening and recruitment log and the Equality Health database. In addition to generalising specific demographics and contextual details. Intervention outcome data will remain anonymised to the public, with only the researcher and delegated staff having access to identifiable personal data.

All information collected during the study will be kept strictly confidential. Personal data will be kept on file for the minimum amount of time as necessary, with the exception of study consent forms which will be retained for a further 15 years in accordance with Cardiff University data retention requirements.

The study master trial file will be transferred to Cardiff University secure servers at the end of the student thesis submission for long term storage.

13.3. Participant Confidentiality and Data Protection

All investigators and study site staff must comply with the requirements of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

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.

Electronic Data –The CI will maintain separate databases with and without participant identifiable data (PID). All data stored electronically will be stored on local NHS IT assets, and access to the data will be restricted to only those delegated to access the data via the delegation log and the CI.

Hard Copy Data – Where data exists in hard copy, the CI and delegated staff are responsible for ensuring safe and secure storage of either identifiable or non-identifiable data. The data will be kept with ABUHB research and development department until the end of the study.

At the end of the study, all data will be transferred to Cardiff University secure servers and locations for long term storage.

The CI and research team is responsible for the data entry, quality of the data and data analysis. The CI will act as the data custodian and data controller for this study.

13.4 Record Storage and Retention

The TMF and ISF containing essential documents will be kept for a minimum of 15 years after completion of study in line with Cardiff University data retention requirements. Documents (paper and electronic) will be retained in a secure location during and after the study has finished. A label stating the required retention time should be placed on the inside front cover of the medical records for study participants. Each PI at any participating site will archive the essential documents generated at the site for the agreed archiving period in accordance with the signed Site agreement and Cardiff University data retention policies.

Essential documents pertaining to the study shall not be destroyed without permission from the sponsor.

14. QUALITY ASSURANCE PROCEDURES

The study may be subject to inspection and audit by Cardiff University under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research 2017.

15. ETHICAL AND REGULATORY CONSIDERATIONS

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.

15.1. Review and Approvals

15.1.1. Ethical Approval and HRA/HCRW approval

- Before the start of the study, approval will be sought from HRA/HCRW and REC for the protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters
- Amendments that require review by HRA/HCRW and REC will not be implemented until approval is granted. The CI (or delegate) should submit any amendments through the IRAS Identity Gateway. This will automatically submit the amendment to both REC and HRA /HCRW.
- The chief investigator (or delegate) also needs to notify the R&D offices and local research teams the amendment(s). The R&D Office(s) will have 35 days from receipt of the amendment to confirm capacity and capability.
- All correspondence with the REC will be retained in the TSF/ISF
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC

15.1.2. Peer Review

This study has been funded by the Stroke Implementation Group. The protocol has been peer reviewed by Educational Supervisors Dr Kelly Morgan and Dr Jonathan Hewitt

15.1.3. Governance Review

The study will be assessed for governance and legal compliance by HCRW. Once all checks are satisfied HCRW will issue HRA/HCRW approval. The study should not

commence at any site until local confirmation of capacity and capability is also received via email by the CI/ PI.

15.2. Reporting

The CI shall submit once a year throughout the study or on request, a progress report to the REC and sponsor (as required). In addition, an end of study notification and final report will be submitted to the relevant parties.

15.3. Expenses and Benefits and PPI consultation

PPI consultation

The acceptability of the study design has been informed through extensive PPI. The protocol was drafted by the researcher then subsequently informed following three focus groups and several one-to-one interviews.

An online focus group was held on Tuesday 6th February 2024 10am – 11.30am. Health Professionals and Professionals from Public Services Board (PBS) organisations attended and helped inform the protocol.

The recruitment of the public, patient involvement group (those with lived experience) derived from the ABUHB Community Neurological Rehabilitation Service, with the ABUHB Head of Community Neurological Conditions Service contacting two established Gwent patient support groups.

The Stroke reference group received an email on 31st January 2024, inviting them to participate in an online focus group via a “teams” online platform on 13th February 2024, starting at 11 a.m. The Community Neurological Rehabilitation team set up another in-person focus group on 13th February 2024, at Cwmbran Stadium at 3:30 p.m.

In accordance with National Institute for Health Care Research recommendations all participants received a £25 expenses voucher for their contribution.

A focus group and one to one interview evaluation report prepared by the researcher was sent out to all focus group workshop members on 26th March 2024 and is available to the REC upon request.

Further PPI consultation was sought between 6th-18th May 2024. In addition, 1/2 PPI members will continue to support the study by attending and contributing to the SOG during the implementation phase. The PPI representatives will be paid a £25 expenses voucher for contributing to meetings, reviewing study materials, or contributing to study dissemination.

Research Participants Expenses

The aim of the study is to ascertain the feasibility of the Equality Health intervention. For this reason, participants recruited into the study will not be reimbursed for participation. However, if during the consent phase participants are asked to attend an additional consent appointment outside of standard of care, the participants will be offered reasonable travel expenses.

16. INDEMNITY AND FINANCE

16.1. Indemnity

Non-negligent harm: This study is an academic, investigator-led and designed study. The CI, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a clinical trial/study and cannot offer any indemnity.

Negligent harm: The Sponsor shall indemnify the site against claims arising negligent acts and/or omissions of the Sponsor or its employees in connection with the clinical trial/study (including the design of the Protocol to the extent that the Protocol was designed solely by the Sponsor and the Site has adhered to the approved version of the Protocol) save to the extent that any such claim is the result of negligence on the part of the Site or its employees.

17. PUBLICATION AND REGISTRATION POLICY

Ownership of the data arising from this study resides with the Sponsoring Organisation. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared. Authors will acknowledge that the study was funded by 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 Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

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APPENDIX A: AMENDMENT HISTORY

Amendment No.	**Protocol Version No.**	**Date issued**	**Author(s) of changes**	**Details of Changes made**