Journal of
VASCULAR SOCIETIES
GREAT BRITAIN & IRELAND

J.Vasc.Soc.G.B.Irel. 2025;5(1):15-22
http://doi.org/10.54522/jvsgbi.2025.201

www.jvsgbi.com

PROTOCOL

# Protocol for the Physical Activity after Cardiovascular Screening (PACS) study in women aged 60–69 years: a prospective observational cohort study

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**Received:** 23rd May 2025
**Accepted:** 29th September 2025
**Online:** 24th November 2025

**Plain English Summary**

Why we are undertaking this work: Women are more likely than men to be misdiagnosed or receive poorer treatment for cardiovascular disease. Two key conditions – elevated blood pressure (BP) and peripheral artery disease (PAD) – are often missed in women. Both conditions are serious risk factors for heart disease and stroke. Screening and lifestyle advice, especially around exercise, can help reduce risk. This study was launched to find out if screening women for PAD and BP, and giving them tailored advice, could improve physical activity and health outcomes.

What we will do: We will invite women aged 60–69 years from Leicestershire to attend screening for PAD and high BP. Two hundred of these women will be invited to wear an activity tracker for 7 days at the time of screening and again 6 months later. One hundred women who are not being screened will be invited as a comparison. The goal is to track changes in physical activity levels and examine any lifestyle improvements after screening and receiving health advice.

What we expect to find: We expect to find that women who are diagnosed with PAD or high BP will increase their physical activity levels the most. This is compared with women who screen negative or who are not screened. We are also collecting information such as smoking and alcohol use and weight to see if the screening helps encourage broader health changes.

What this means: If our findings support the idea that screening leads to increased activity and healthier behaviours, it could justify rolling out targeted screening for women across the UK. This may help close the gender gap in cardiovascular care, promote healthier lifestyles and reduce the risk of heart attacks and strokes in women.

## Abstract

Introduction: Women with cardiovascular disease receive a poorer standard of care than men; they are more likely to be misdiagnosed and undertreated. Individuals with peripheral artery disease (PAD) and/or elevated blood pressure (BP) have a similar cardiovascular risk as those with established ischaemic heart disease. As part of a National Institute for Health and Care Research (NIHR) programme, we are screening women for PAD and elevated BP. The primary objective is to determine key performance metrics for a screening programme: attendance and disease prevalence. There is, however, an opportunity to undertake a more detailed process evaluation of PAD+BP screening in women to help address this sex-based health inequality. We aim to assess whether screening and/or the identification of PAD/elevated BP, along with patient education in the form of leaflets and face-to-face advice, results in positive changes in physical activity.

Methods and analysis: The Physical Activity after Cardiovascular Screening (PACS) study is funded by the British Heart Foundation (FS/CRTF/23/24452) and is a sub-study of the NIHR PHAST-F study, an observational cross-sectional multicentre feasibility study (NIHR200601; UK's Clinical Study Registry Registration ISRCTN17320335). Women in Leicestershire aged 60–69 years will be invited to attend for PAD+BP screening. Two hundred consenting participants (100 positive for PAD/or elevated BP and 100 negative) will undergo assessment of physical activity using accelerometers and complete the International Physical Activity Questionnaire Short Form, the EQ-5D-5L, Generalised Anxiety Disorder Questionnaire and the

Edinburgh Claudication Questionnaire. Follow-up assessments will include accelerometers, questionnaires and GP data obtained at 6 months. An unscreened cohort of 100 women will also be recruited to evaluate the broader impact of screening.

Ethics and dissemination: The study has received ethical approval from the Sub-Committee of the North of Scotland Research Ethics Committee (reference 21/NS/0147). The results will be disseminated through research presentations, papers and social media.

**Key words:** peripheral artery disease; hypertension; screening; physical activity; health inequalities

## Introduction

Women with cardiovascular disease receive a poorer standard of care than men; they are more likely to be misdiagnosed and undertreated.[1] Contributing factors include failure to recognise the importance of secondary prevention, sex-related differences in clinical presentation, delays in seeking care and misperceptions about cardiovascular disease in women.[1] These issues also contribute to elevated blood pressure (BP) and peripheral artery disease (PAD) being underdiagnosed and understudied in women.[2]

The pathophysiology of PAD is similar to coronary artery disease.[3,4] Studies of asymptomatic individuals with PAD demonstrate a 5-year cardiovascular risk of around 20%.[5,6] UK primary care data records the prevalence of diagnosed PAD at around 3%;[7] however, large empirical population studies estimate the true prevalence to be between 13% and 18%.[8–10] A lack of public awareness contributes to this under-diagnosis. In a recent small study of population screening for PAD, Davies *et al*.[11] found that most individuals with PAD do not recognise their symptoms or present to health services.

Elevated BP is also often underdiagnosed due to its asymptomatic nature. It is estimated that up to 6–8 million adults within the UK could have undiagnosed or uncontrolled elevated BP.[12] This is significant as it is one of the most important risk factors for cardiovascular disease and death. In fact, a linear relationship between BP and mortality from both ischaemic heart disease and stroke exists. Mortality from ischaemic heart disease and stroke doubles for every 20 mmHg systolic or 10 mmHg diastolic increase in BP.[13]

Physical activity is an important modifiable risk factor for both PAD and elevated BP, improving pain-free walking distance as well as overall cardiorespiratory fitness.[2,14,15] Higher levels of physical activity are also associated with a lower risk of cardiovascular disease and reduction in all-cause mortality over the medium and long term.[15] Exercise is a subset of physical activity that is planned, structured and repetitive with the aim of improving or maintaining physical fitness.[16] In individuals with hypertension, exercise is as effective as antihypertensive medication in reducing systolic BP.[17] A supervised exercise programme is the primary clinical management strategy for individuals with PAD.[13,14,18] However, a recent audit[19] showed that only 36% of UK vascular centres were able to offer supervised exercise therapy for PAD. Additionally, of those that did, only 6.8% were fully compliant with current National Institute for Health and Care Excellence (NICE) guidelines.[14]

### Existing evidence

The Viborg vascular trial (VIVA),[20] a Danish study that assessed the efficacy and cost-effectiveness of combined screening for PAD, BP and abdominal aortic aneurysm (AAA) in men aged 65–74 years, showed a significant reduction in all-cause mortality compared with no screening. The trial, however, did not assess objective physical activity levels and was unable to assess the impact that screening and clinical management had on physical exercise. A small population screening study from South Wales[11] invited men aged 45 and women over 55 with cardiovascular risk factors for PAD screening. Similar to VIVA, this study did not assess the impact on physical activity levels.

Currently within the UK individuals aged 40–74 years with no pre-existing cardiovascular disease are invited for a free NHS Health Check every five years. During this appointment, individuals receive an assessment for BP, hypercholesterolaemia and body mass index as well as general cardiovascular advice focused on smoking cessation, physical activity and maintaining a healthy lifestyle. In 2023, only 40% of individuals invited for an NHS Health Check attended.[21] In recent years there has been a trend towards lower rates of attendance, therefore more needs to be done to maximise cardiovascular health screening at every clinical encounter.

### PHAST-F Study

The Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial (PHAST) is a multicentre £2.4 million NIHR-funded programme examining the feasibility and effectiveness of screening men for PAD and elevated BP at the same time as screening for AAA (NIHR200601, Chief Investigator: Bown). As there is no AAA screening programme for women, the overall PHAST approach potentially exacerbates the sex-based inequality in preventative cardiovascular medicine highlighted above. To directly address this inequality, the PHAST programme includes a limited feasibility study of isolated BP and PAD screening for women (PHAST-F). This feasibility study is focused on determining attendance for screening and disease prevalence but is a good opportunity to undertake a more detailed evaluation of responses to PAD+BP screening in this population. The European Society for Vascular Surgery guidelines recommend the consideration of screening for PAD in individuals aged ≥70 years or 45–69 years with cardiovascular risk factors.[22] The current National AAA Screening Programme invites men on the year of their 65th birthday. Therefore, women aged 60–69 years are invited to take part in this feasibility study to align closely with these two considerations.

### Ongoing studies

A search of the clinicaltrials.gov, International Standard Randomised Controlled Trials Number and EU Clinical Trials registries identified no ongoing population screening trials in this area (PAD or elevated BP). We have not identified any ongoing trials of population screening for PAD or elevated BP funded by the NIHR or other UK institutions.

## Why is this research needed now?

The PACS study supports the 10 Year Health Plan for England[23] by preventing heart attacks and strokes, and aligns with the Department of Health and Social Care's prioritisation[24] for prevention medicine. In 2019 the National Cardiovascular Disease Prevention System Leadership Forum launched its cardiovascular disease prevention programme. Additionally, the *Lancet* has commissioned a global report on cardiovascular disease in women to tackle the inequality in cardiovascular health by 2030.[25] This research is therefore timely as well as relevant. This study aims to assess if PAD+BP screening and providing women with information on disease pathology and treatment will ultimately increase physical activity levels and overall cardiovascular health.

## Research hypothesis

Women who screen negative for PAD/elevated BP will have a greater level of physical activity at initial screening than women who screen positive. Women who screen positive for PAD/elevated BP will have a greater increase in physical activity levels from initial screening to 6 months than women who screen negative.

## Outcomes

### Primary outcome

Change in average daily milligravities (m*g*) of physical activity (measured using GENEActiv accelerometer (acceleration/steps)) and MVPA (defined as time accumulated above an average acceleration of 100 m*g* in bouts of at least 1 minute)[26] from screening to 6 months.

### Secondary outcomes

- Average daily m*g* of physical activity and moderate to vigorous physical activity (MVPA) in women aged 60–69 years
- Comparison of physical activity and MVPA at screening of women who screen negative for PAD/and or elevated BP and women who screen positive
- Comparison of average daily m*g* of physical activity and MVPA at screening for women who screen negative for PAD/and or elevated BP and women who screen positive
- Change in smoking, alcohol consumption, weight and subjectively documented physical activity levels in individuals who screen positive for elevated BP/and or PAD
- Time spent in 24 hours of physical behaviour intensities (inactive time, light physical activity, moderate physical activity and sleep) amongst all groups

## Objectives

### Primary objectives

To assess the average change in accelerometer-assessed physical activity/steps immediately after initial PAD+BP screening to 6 months in women.

### Secondary objectives

- To determine the 'normal' physical activity levels of women aged 60–69 years
- To determine whether women who screen positive for elevated BP/PAD have lower baseline levels of physical activity than those who screen negative
- To determine whether women who screen positive for elevated BP/and or PAD have a greater increase in physical activity levels at 6 months than women who screen negative
- To determine whether elevated BP/and or PAD at screening results in a positive change in health behaviour

## Methods and analysis

### Study design

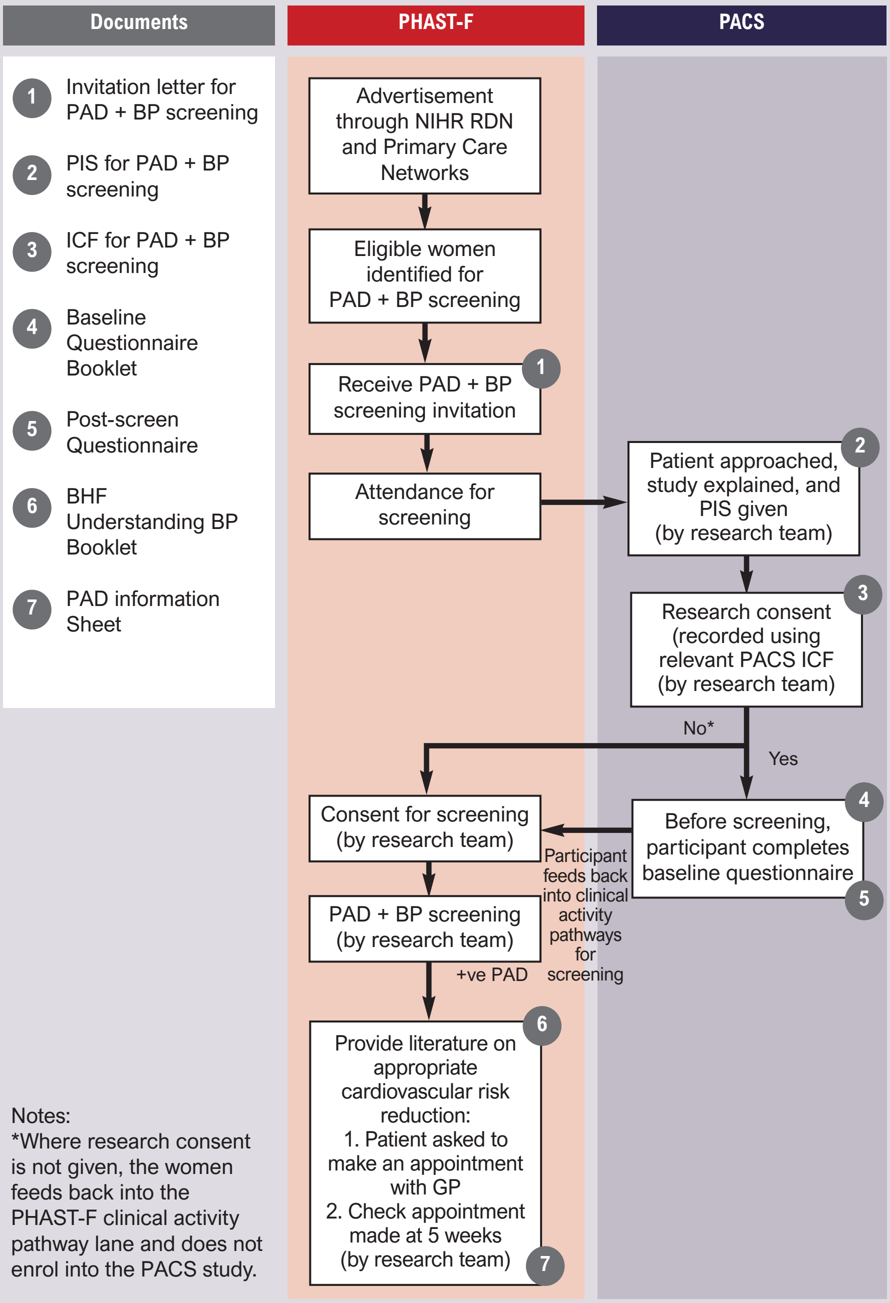
The Standard Protocol Items: Recommendations for Intervention Trials[27] and the Strengthening the Reporting of Observational Studies in Epidemiology[28] statements were followed in the development of this study. The Physical Activity after Cardiovascular Screening (PACS) study is a prospective observational cohort study to determine if screening for hypertension and PAD results in an increase in physical activity levels from baseline to 6 months after screening. PACS is funded by the British Heart Foundation (FS/CRTF/23/24452). It is a sub-study of the PHAST-F study, which is an observational cross-sectional multicentre feasibility study funded by the NIHR Programme Grants for Applied Research scheme (NIHR200601) (Figure 1).

### Study setting

Women attending for PAD+BP screening as part of the PHAST-F study will be invited to participate in PACS. The NIHR Research Delivery Network will support the recruitment of Leicestershire general practices to take part in PHAST-F. In addition, individual general practices based in Leicestershire will be directly approached by members of the trial team.

Women aged 60–69 years registered with participating general

**Figure 1** Flow of participant recruitment into the PACS study



Notes:
*Where research consent is not given, the women feeds back into the PHAST-F clinical activity pathway lane and does not enrol into the PACS study.

Key: PAD = peripheral artery disease; BP = blood pressure; PIS = participant information sheet; ICF = informed consent; BHF = British Heart Foundation; GP = General Practice

**Table 1** Inclusion and exclusion criteria.

| Inclusion criteria | Exclusion criteria |
|---|---|
| Willing and able to provide informed consent | Women unable to provide consent |
| Women aged 60–69 years and registered at a Leicestershire General Practice | Co-morbidity that the research team consider to be a contraindication to the study |
| An ability to understand verbal and written English | Serious illness with life expectancy <6 months |

practices will then be invited to attend for PAD+BP screening. Letters of invitation will be sent via post with patients asked to contact the department, either by telephone or email, to book a screening appointment at a convenient time for them. All letters will also include a PAD screening information leaflet (see Appendix 1 Supplementary file online at www.jvsgbi.com) and a local map.

Leicestershire has been chosen as the study location because it is a ‘plural city’ with no single ethnic majority. The wider Leicestershire area serves individuals from diverse socioeconomic and ethnic backgrounds across rural and urban areas.

## Eligibility criteria

The target population for this study are women aged 60–69 years registered with a Leicestershire General Practice and attending the PHAST-F programme for PAD+BP screening. Patients will be eligible for the study if they fulfil the inclusion and exclusion criteria shown in Table 1.

## Recruitment

Upon arrival at the screening clinic, women attending for PAD+BP screening will receive a participant information sheet (see Appendix 1 Supplementary file online at www.jvsgbi.com). Patients will be pre-screened by a member of the clinical team and approached to ask if they wish to speak to a member of the research team. It will be emphasised that declining participation in PACS will not affect their clinical care, and screening will proceed as planned. Patients who express interest will be directed to a member of the research team, who will confirm eligibility and obtain informed consent prior to screening.

## Data collection

The following data will be collected at baseline and at 6 months:

- Demographics: age, sex, ethnicity, height, weight, smoking and alcohol use, occupation status (or previous occupation where retired)

- Cardiovascular history: hypertension, PAD, diabetes, hypercholesterolaemia, angina, myocardial infarction, stroke/transient ischaemia attack, cardiac arrhythmia, operation for coronary arteriosclerosis
- Medication history
- Patient-reported outcomes: European Quality of Life 5 Dimensions 5-level (EQ-5D-5L), Generalised Anxiety Disorder Questionnaire (GAD-7), Edinburgh Claudication Questionnaire (ECQ) and International Physical Activity Questionnaire Short Form (IPAQ-SF)
- Health utilisation (for health economics analysis): Accident and Emergency attendance, hospital admissions, hospital outpatient appointments, primary care services accessed

### Intervention: PAD+BP screening

A systematic review of the diagnostic accuracy of automated and semi-automated ankle-brachial pressure index (ABPI)/toe pressure devices and a consensus conference to determine real-world usability was previously undertaken to determine the most suitable device for PHAST-F.[29] Trained healthcare professionals will perform the ABPI using the MESI-ABPI-MD device.[30] Measurements will be obtained after a period of rest in the supine position. Systolic BP will be measured simultaneously in one arm (brachial artery) and both ankles (posterior tibial arteries). The test is then repeated using the alternate arm. The ABPI is automatically calculated by the MESI-ABPI-MD device and the reading will be verified by healthcare professionals. The ABPI reading will be the lowest of the two readings. All results obtained during screening will be sent to the patients' general practitioner.

Elevated BP will be defined as either a systolic BP of >140 mmHg or a diastolic BP of >90 mmHg and individuals will receive a British Heart Foundation (BHF) 'Understanding Blood Pressure' booklet.[31] The BHF booklet provides advice on physical activity with suggested guidance on how to increase levels. PAD will be defined as an ABPI of <0.9, as per NICE Guidelines.[14] Individuals diagnosed with PAD will receive a PAD Information Sheet (see Appendix 1 Supplementary file online at www.jvsgbi.com). The PAD Information Sheet also provides advice on physical activity. All patients diagnosed with elevated BP and/or PAD will be asked to make an appointment with their GP to discuss their results further and undergo further investigations, if required. For all individuals who screen positive, the research team will make a follow-up telephone call appointment at 5 weeks to discuss what health behaviour changes (cessation of smoking, reduction in alcohol consumption, maintenance of a healthy weight and increase in subjectively documented physical activity levels), if any, have been adopted.

### Follow-up

Follow-up will be conducted remotely and will take place at 6 months. The data collection mentioned above will be collected via post. Participants who do not return 6-month GENEActiv results will be contacted by telephone. GP data and routinely collected data will also be obtained throughout the follow-up period. Data collected will include: date of GP appointment, BP at GP attendance, result of home BP diary, changes in medication, diagnosis of other cardiovascular-related risk factors (hypercholesterolaemia, stroke/transient ischaemic attack, angina, myocardial infarction, diabetes, major limb amputation, intervention for PAD), referral to secondary care services and associated outcomes. These data will be obtained to examine uptake and adherence to cardiovascular risk management following self-made GP appointments for those who screen positive for PAD/and or elevated BP.

#### *Accelerometer*

The accelerometer used will be the GENEActiv device. This device has been used in a wide range of clinical trials and is a well-recognised validated device for research in physical activity. Participants will provide consent to wear a GENEActiv accelerometer on their non-dominant wrist (defined as their non-writing wrist) 24 hours a day for 7 days. The GENEActiv will be initialised to begin recording at 00:01 hours at 100 Hz. Participants will be encouraged to go to bed wearing the device the evening of their screening appointment. They will also complete a self-reported diary stating the time they went to bed, estimated time they went to sleep, when they woke up in the morning and when they physically got out of bed. These results will be analysed in conjunction with the accelerometer results. Follow-up GENEActiv devices will be sent out to participants at 6 months via postal services along with the above questionnaires.

#### *Unscreened group*

We recognise that recruiting women for PACS who are attending for PAD+BP screening may influence baseline physical activity levels. We will invite women from the same population and age range as those invited for PAD+BP screening. To facilitate this, participants will be recruited through the Extended Cohort for E-health, Environment, and DNA (EXCEED) study. The EXCEED protocol has been described previously.[32] Briefly, EXCEED is a longitudinal health study assessing the impact of genetics and lifestyle on long-term health conditions. The EXCEED study team were approached to help with recruitment into the unscreened 'control' group. A data access proposal form was approved by the core group in EXCEED with changes approved by the Sub-Committee of the North of Scotland Research Ethics Committee (Reference 21/NS/0147). Participants enrolled in the EXCEED study who have agreed to be contacted for future research will be invited to participate in PACS. Email invitations will be sent out from the EXCEED team until 100 women aged 60–69 years living in Leicestershire have enrolled into the PACS study. Consent will be obtained using one of the following methods, depending on participant preference and logistical feasibility: e-signature, email response, email attachment, postal consent, verbal consent (documented by the researcher), or written in-person consent. The unscreened group will wear a GENEActiv accelerometer and complete questionnaires, as described above.

### Statistical analysis and plan

*Sample size*

We know that an increase of 1000 steps or 10 minutes of brisk walking corresponds to an increase of roughly 2 m*g* of average acceleration.[33] Previous data regarding accelerometers corresponds to initial activity levels rather than degree of change. Therefore, our power calculation is based on the outcome of m*g* at 6 months. A sample size of 200 participants (100 positive for PAD/or elevated BP and 100 negative) would provide >80% power to detect a difference of 4 m*g* (roughly 2000 steps or 20 minutes of brisk walking). This would be at the 5% significance level, providing more than 61% of participants reached the 6-month time point (based on a standard deviation of ±7.8 m*g*). PAD and elevated BP outcomes will be analysed together as exercise is the primary treatment for both cardiovascular diseases. We will also undertake a sub-group analysis between women who are positive for PAD and women who are positive for elevated BP.

*Unscreened group*

We will aim for an attendance of 100 participants as a baseline convenience sample to compare physical activity levels of women who undergo PAD+BP screening with those who do not receive PAD+BP screening.

*Accelerometer processing*

The GENEActiv data will be uploaded using GENEActiv PC software version 3.3 and analysed using the latest version of the R-package GGIR version in R (http://cran.r-project.org). The approach for GENEActiv analysis has been described previously.[34–37] Briefly, local gravity will be used as a reference for autocalibration,[35] sustained abnormally high values will be detected and the average magnitude of dynamic acceleration will be calculated (corrected for gravity and expressed as Euclidean Norm Minus One (ENMO) in m*g* averaged over 5 s epochs). Participants will be excluded if their accelerometer files show a post-calibration error of >0.01 *g* (10 m*g*), <3 days of valid wear (defined as >16 hours per day), or wear data are not present for each 15 min period of the 24 hour cycle.[36] The default non-wear setting in GGIR will be used, which imputes invalid data by the average at similar timepoints on different days of the week.[36]

The following measures will be generated and averaged across all valid days:

1. Average acceleration – used as a proxy measure of overall volume of physical activity (24-hour day). Higher levels of average acceleration correspond to higher levels of physical activity. The minimum clinically important difference is an increase in average acceleration by 1 m*g* a day[38] (equivalent to a 5-minute brisk walk; 15-minute slow walk; or 500 daily steps).[33]
2. The intensity gradient – used to describe the distribution of physical activity intensity across the day.[37] The intensity gradient is helpful to describe an individual's activity profile. The steeper the gradient, the less time spent at higher levels of acceleration. Thus, the intensity gradient is always negative.
3. MVPA – defined as the time accumulated above an average acceleration of 100 m*g* in bouts of at least 1 minute (ie, moderate physical activity as described below).[26]
4. Time spent in different physical behaviour intensities across 24 hours:[39]
    - Inactive time (defined as time accumulated below 40 m*g*)[39]
    - Light physical activity (defined as time accumulated 40–99 m*g*)
    - Moderate physical activity (defined as time accumulated 100–399 m*g*)
    - Vigorous physical activity (defined as time accumulated >400 m*g*)

### Data analysis

Categorical data will be presented as absolute values and proportions (%) with a $\chi^2$ test used to compare proportions between groups. Where data are paired, McNemar's test will be used (ie, baseline to 6 months) or Fisher's exact test if the sample size is less than five. Where more than two categories are present (never smoker; previous smoker; current smoker), then a $\chi^2$ test will be used.

Continuous variables will be examined for normality using histograms, skewness and kurtosis. Normally distributed variables will be reported as mean (± standard deviation) with a t-test (independent, ie, screen negative vs screen positive group) or a paired t-test (paired, ie, baseline to 6 months) used to compare within or between groups. For non-normally distributed variables, median (interquartile range) with a Wilcoxon rank-sum test (independent) or a Wilcoxon signed-rank test (paired) will be used to compare differences between groups. Where comparisons are undertaken across more than two groups (ie, control vs screen negative vs screen positive), ANOVA (normally distributed) or a Kruskal–Wallis test (non-normally distributed) will be used.
All analyses will be performed using R Core Team (Version 4.4.1; 2024; R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: https://www.R-project.org/).

### Data management

Data will be recorded directly into the paper case report form (source data) and then transcribed into the electronic case report form. Original copies of the participant consent form and information sheet will be filed in the Investigator Site with copies placed in the participant's hospital notes. Data entry will be conducted by the site research team and the Leicester Clinical Trials Unit (LCTU). Participant contact details will be securely collected and retained to enable send out of follow-up questionnaires by post. Data management will be through MACRO, a validated web-based data entry system and database.

## KEY MESSAGES

- This is a multicentre study recruiting women from primary care services across rural and urban areas, increasing the representativeness of the study population.
- Recruitment will include women from varied socioeconomic and ethnic backgrounds, enhancing the generalisability of the findings.
- The study uses both objective (accelerometery) and subjective (validated questionnaires) methods to assess physical activity, health status and symptoms.
- The study will determine whether PAD+BP screening alone is sufficient for improving the overall physical activity level and thus overall cardiovascular health in women.
- The outcome of the study will inform the future NIHR Health Technology Assessment Programme to see if physical activity monitoring can be used as an outcome for cardiovascular screening.
- As a feasibility sub-study with a relatively small sample size and short follow-up, the study may not capture longer-term or less pronounced behavioural changes.

### Study management

The management of PACS will be undertaken by SJM, a British Heart Foundation Clinical Training Fellow. The management of PHAST-F will be undertaken by the LCTU, a fully registered UK Clinical Research Collaboration Clinical Trials Unit (UKCRC no.43) in collaboration with the Investigators and the Trial Management Group. The LCTU will be responsible for site set-up, project management, statistical expertise and provision of MACRO databases. Serious adverse events are not expected. The study intervention consists of PAD and BP screening, which are known to be safe with no long-term physical consequences.

## Dissemination

We will disseminate and present our results at national UK conferences such as the Vascular Societies' Annual Scientific Meeting. The results of this will be published in a peer-reviewed academic journal as it will be relevant for other researchers in cardiovascular medicine, psychology, epidemiology, public health and vascular surgery. It will inform these future researchers if physical activity levels could be used as a measurable outcome in screening. It will also inform the design of our future NIHR Health Technology Assessment Programme to see if physical activity monitoring can be used as an outcome for cardiovascular screening.

We will also publish outputs on social media in lay format and use existing PAD and diabetes patient groups to involve patients in dissemination, as well as our PPI group. This will improve patient education and ultimately cardiovascular health. For those involved in PACS, it represents an opportunity to discuss cardiovascular risk factor modification. The encouragement of a healthy lifestyle and exercise will lead to improved cardiovascular risk management and be of direct benefit to patients.

**Conflict of Interest:** AS has received consultancy and lecture fees/honoraria from Shockwave Ltd, Abbott Ltd, BD Medical, General Electric Healthcare and Medyria GmBH. He has also received research funding from Shockwave Ltd, Abbott Ltd, Boston Scientific Ltd and educational fees from Cook Medical.

**Funding:** The funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results. PACS is funded by the BHF (FS/CRTF/23/24452). PHAST-F is funded by the NIHR Programme Grants for Applied Research scheme (NIHR200601). EXCEED is funded by the University of Leicester, the NIHR Leicester Respiratory Biomedical Research Centre, the NIHR Clinical Research Network East Midlands, the Medical Research Council (Grant G0902313) and the Wellcome Trust (Grant 202849). SJM is funded by a BHF Clinical Research Training Fellowship (FS/CRTF/23/24452). MJB and SEB are funded by the BHF (CH/F/22/90014).

**Patient and public involvement statement:** A *de novo* patient and public involvement (PPI) group was established for the broader NIHR PHAST programme, of which PHAST-F is the second work package and PACS is a sub-study. This group contributed to the development of participant-facing materials and study procedures, including those related to accelerometer use. A PPI co-applicant is a member of the PACS Trial Management Group (TMG) and an independent PPI representative sits on the Programme Steering Committee, contributing to oversight and dissemination planning.

**Author contributions:** SJM, MJB and AS were involved in conception and design of the PACS study. SEB obtained ethics approval. SB and AVR provided statistical expertise in clinical trial design and SJM is conducting the primary statistical analysis. All authors edited, revised, and approved the final manuscript. MJB is the Chief Investigator for PHAST-F and SJM is the NIHR Associate Principal Investigator.

**Ethics approval:** PACS has received ethical approval as part of a substantial amendment to the PHAST-F Programme (Sub-Committee of the North of Scotland Research Ethics Committee; Reference 21/NS/0147). PHAST-F is registered on The UK's Clinical Study Registry (Registration ISRCTN17320335). The study protocol v.2.0 dated 8 August 2023 has been reviewed by the Sub-Committee of the North of Scotland Research Ethics Committee (Reference 21/NS/0147) and was approved on 18 October 2023.

**Acknowledgements:** The authors would like to thank the PHAST-F Programme Steering Committee and Data Monitoring Committee, the EXCEED group, the Leicester Clinical Trials Unit, the Leicester Diabetes Centre, the Sponsor (University of Leicester) and the NIHR Leicester Biomedical Research Centre for their support in the PACS study. The views expressed are those of the authors and are not necessarily those of the British Heart Foundation, NIHR or the Department of Health and Social Care.

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**Reviewer acknowledgement:** *JVSGBI* thanks Akhtar Nasim, Consultant Vascular Surgeon & Clinical Director for Vascular Services, Sheffield Teaching Hospitals Foundation for their contribution to the peer review of this work.

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**Appendix 1** Legend....

| | | Reporting Item | Page Number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2 |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | 2 |
| Protocol version | #3 | Date and version identifier | 15 |
| Funding | #4 | Sources and types of financial, material, and other support | 16 |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | 15 |
| Roles and responsibilities: sponsor contact information | #5b | Name and contact information for the trial sponsor | 16 |
| Roles and responsibilities: sponsor and funder | #5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 16 |

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|---|---|---|---|
| Roles and responsibilities: committees | #5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | 15 & 16 |
| **Introduction** | | | |
| Background and rationale | #6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 4 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 5 |
| Objectives | #7 | Specific objectives or hypotheses | 7 |
| Trial design | #8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) | 7 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | #9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will | 9 |

| | | | |
|---|---|---|---|
| | | be collected. Reference to where list of study sites can be obtained | |
| Eligibility criteria | #10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10 |
| Interventions: modifications | #11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease) | NA |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | NA |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 9 |
| Outcomes | #12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), | 6 |

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|  |  | and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended |  |
| Participant timeline | #13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 8 |
| Sample size | #14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 12 & 13 |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 9 |
| **Methods: Assignment of interventions (for controlled trials)** |  |  |  |
| Allocation: sequence generation | #16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | NA |

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| Allocation concealment mechanism | #16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | NA |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | NA |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | NA |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | NA |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection plan | #18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. | 10 |

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| | | Reference to where data collection forms can be found, if not in the protocol | |
| Data collection plan: retention | #18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 11 |
| Data management | #19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 14 |
| Statistics: outcomes | #20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 13 & 14 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 13 & 14 |
| Statistics: analysis population and missing data | #20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 13 |
| **Methods: Monitoring** | | | |

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| Data monitoring: formal committee | #21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 16 |
| Data monitoring: interim analysis | #21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | NA |
| Harms | #22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 14 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | NA |
| **Ethics and dissemination** | | | |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 15 |
| Protocol amendments | #25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, | 15 |

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|  |  | analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators) |  |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 10 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | NA |
| Confidentiality | #27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 14 |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 16 |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 15 |
| Ancillary and post trial care | #30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy: trial results | #31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other | 15 |

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| | | relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 15 |
| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 15 |
| **Appendices** | | | |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | Supplementary |
| Biological specimens | #33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | NA |

NHS
University Hospitals
of Leicester
NHS Trust

# Peripheral arterial disease (PAD) screening

A free NHS cardiovascular health check

# Overview

This leaflet provides information on screening for peripheral arterial disease, also referred to as PAD.

It explains what peripheral arterial disease (PAD) is and what happens when you go for screening. It should help you decide if you want to be screened.

The PAD screening check is a simple free measure of the blood pressure in your arms and legs. It is similar to having a regular blood pressure check.

# Who we screen

You have been invited because you are between 60 and 69, the age at which people are most likely to benefit from PAD screening.

This screening programme is being run by the University Hospitals of Leicester. This is a local pilot programme of PAD screening to find out if this is something the NHS should offer across the country.

# Peripheral arterial disease

Peripheral arterial disease is a condition that occurs when the blood vessels that carry blood from your heart to your legs become narrowed or blocked. This is usually due to a build-up of fatty material in the wall of the blood vessel. If this becomes severe the amount of blood getting to the legs can become critical, causing pain and putting people at risk of amputation.

Most people don't know that they have PAD until it becomes very bad. If PAD is detected before it causes problems there are ways to prevent it getting worse.

Peripheral arterial disease is mainly caused by age. As we get older natural wear and tear on our blood vessels damages them over time and causes them to narrow. Smoking, high blood pressure, poor diet and diabetes can all makes this process happen faster.

# Potential risks of PAD

Peripheral arterial disease is important for two reasons:

- If PAD is diagnosed and treated before it gets too bad, complications related to poor circulation in the legs can be prevented.
- PAD is an indicator of the overall health of all the blood vessels in your body. If you have furred up arteries in your legs then you are more likely to have the same problem in other places such as the blood vessels to your heart or brain. People with PAD are more likely to suffer from conditions such as heart attacks or strokes. The same treatments that can prevent PAD getting worse also reduce the risk of these other conditions.

## Benefits of screening

PAD often does not cause any symptoms. People who do have symptoms from PAD, such as pain when walking, often don't realise this is caused by PAD. This means there are a lot of people with PAD who don't know that they have it.

Screening can find PAD early, before it causes any problems. There are several simple ways to treat PAD to reduce the chance of serious problems occurring from PAD or related diseases.

## Risk factors

Between **1 in 5** and **1 in 10** people have PAD, many of whom have no symptoms. Testing people for PAD also includes checking the blood pressure in the arm. This means the test can also pick up high blood pressure. Up to **1 in 3** people have high blood pressure.

Your risk of PAD can increase because of:

- **smoking**
- **high blood pressure**
- **diabetes**
- **not being physically active**
- **high cholesterol**
- **high body weight, obesity (body mass index over 30)**
- **family history of PAD, stroke, or heart disease**

## PAD screening test

We use a simple blood pressure test but do this on the legs and the arms at the same time. This is very quick and usually lasts less than 10 minutes.

At the clinic we will check your personal details, explain the screen and give you the chance to ask any questions. We will ask you to lie down. You will not need to undress but it will help if you wear clothes that allow us easy access to your arms and legs. We will put blood pressure cuffs on your arms and legs. The blood pressure cuffs will then squeeze your arms and legs very tightly to measure your blood pressure.

We will tell you your result straight away and also send a copy to your GP practice.

# Possible screening results:

**Normal**
In most people the test will be normal. In this case nothing further needs to be done and you will not need any further tests or treatment.

**Peripheral arterial disease**
If the blood pressure in your legs is lower than the blood pressure in your arms this indicates peripheral arterial disease (PAD).

**High blood pressure**
The PAD screening test also measures the blood pressure in your arm. This is not done in the same way as a standard blood pressure measurement and sometimes people's blood pressure can be raised just because they are being tested. If the PAD screening test finds high blood pressure this will need to be checked again to make sure the reading is correct.

# What happens if I am found to have PAD and/or high blood pressure?

The main reason for offering screening for PAD and high blood pressure is that people with PAD and/or high blood pressure are at higher than normal risk of developing circulatory problems, or dying from these circulatory problems over time. Doctors usually refer to your personal risk of developing circulatory problems as your 'cardiovascular risk'.

If you are found to have PAD and/or high blood pressure we will ask you to book an appointment to see your GP for assessment. We will also inform your GP directly. We will provide you with additional information about what you can do to help reduce your cardiovascular risk.

When you go to your appointment at your GP's surgery you will be assessed. The appointment at your GP practice will focus on what you can do to reduce this risk, as well as double-checking your blood pressure if necessary.

The main things that will be checked are:

- **Whether you smoke**
- **How physically active you are**
- **Your weight**
- **How much alcohol you drink**
- **Whether you have, or are at risk of diabetes**
- **What your blood pressure is (this may need to be checked more than once)**
- **What your blood cholesterol (fat) levels are**

- The information obtained from these checks will be used to work out the best way for you to help reduce your cardiovascular risk. Further information will be provided depending on your particular requirements.

# What happens if I am found to have PAD and/or high blood pressure? (continued...)

Most people will benefit from increasing their levels of physical activity, improving their diet and making sure they don't drink too much alcohol. People who smoke should stop smoking if possible and the NHS can provide help with this. New medication may be recommended to treat high blood pressure or diabetes. If you have PAD and/or high blood pressure you will probably benefit from medication such as aspirin to thin the blood slightly. Statin tablets are usually prescribed for people who have PAD.

# Risks from screening

There is very minimal risk from the screen itself. Some people find that the blood pressure cuffs used can be uncomfortable. If this affects you then the screening test can be stopped at any time.

There are two main risks of being screened for PAD and high blood pressure:

Receiving an invitation for screening or attending for screening can cause people to worry about what the screening test might show. Some people who are found to have PAD or high blood pressure at screening worry about what this might mean for them. Some people get depressed if they are found to have a condition they didn't know about.

People diagnosed with PAD or high blood pressure at screening will be offered help to reduce their cardiovascular risk. This mostly involves making changes to your lifestyle such as improving diet and doing more exercise, which does not put you at any risk. Many people will be offered new medication if they are diagnosed with PAD or high blood pressure however. Whilst most people will benefit from such treatment, all medications carry a risk of side effects. A few people who would never have started these medications had they not been for screening will develop or be harmed from these side effects. In rare cases these can be serious. The benefits and risks of starting new medications will be discussed with you before they are started and it is up to you if you want to receive these treatments.

# Other conditions

Screening is just to see if you have PAD and/or high blood pressure. It does not look for other conditions. If you are worried about any medical problem you should speak to your GP practice.

# Accuracy of screening test

The test used to diagnose PAD is very reliable. No screening test can be completely effective. A few people who have PAD will be missed by the screening test so it is important to look out for symptoms related to PAD.

# More information

- The Circulation Foundation supports people with diseases of the veins and arteries, known as vascular diseases, including peripheral arterial disease: www.circulationfoundation.org.uk

- The British Heart Foundation also provides information about vascular disease: www.bhf.org.uk

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# Participant Information Sheet

# Physical Activity before Cardiovascular Screening (PACS)

**Chief Investigator:** Professor Matthew Bown

## Introduction

We are inviting you to join a research study looking at physical activity levels.

## Why have we asked you to take part in this research?

We are asking you to participate in this research because you are a woman aged 60-69 years old.

## What will be involved if you take part in this research?

If you decide to participate in this research, we will ask you to complete a questionnaire and wear a device that measures your physical activity levels. We will also collect information about what happens to you afterwards.

## Do I have to take part in the research?

No - participation in this research is entirely voluntary. Your decision will not affect the care you receive from the NHS today or at any time in the future.

## How will my personal data be used?

- In this research study, we will use information from you, your medical records and/or GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
- Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
- At the end of the study we will save some of the data in case we need to check it and/or for future research.
- We will make sure no-one can work out who you are from the reports we write.

**This information pack tells you more about this**

FUNDED BY NIHR | National Institute for Health and Care Research

## Deciding whether or not to take part in the research study

- It is important for you to understand why the research is being done and what your participation would involve, so please take your time to read this information sheet.
- A member of the research team will go through this with you and answer any questions you may have.
- If you decide you do not want to take part, then you do not have to do anything else.

## What is the purpose of this study?

The research is being done because we don't know what the normal physical activity levels are in women aged between 60-69 years. This information is helpful when comparing physical activity levels in people with specific diseases. This may help to improve NHS services.

## If I do decide to take part in the research, what will I have to do?

- We would like to collect some information from you by asking you to fill in a questionnaire. (Approx. 15 minutes).
- We will ask you to wear a watch-like device called a GENEActiv on your non-dominant, non-handwriting wrist. This will collect information about your activity levels. (Wearing for 7 days). It is better for the research study to wear the device on your non-handwriting wrist, but it you can't wear it on this wrist, you may still take part. You will need to tell us you are wearing it on your dominant, handwriting wrist if you decide to take part. This is because we use our dominant hand more often day-to-day.
- You will need to wear the device on the same wrist, i.e. don't swap from one wrist to the other.
- We will ask you to complete a diary of when you wake up, go to bed, etc.
- Please note:
    - ⇒ You will not be paid or reimbursed for any part of the research; you will be reimbursed for any reasonable transport/parking costs. You will be asked to provide original receipts for our records.

## If I do decide to take part in the research, how will I receive the device and questionnaire?

The device, questionnaire, diary and related instructions will be sent to you in the post.

## What will happen as part of:

### … the questionnaires?

- We will ask for your name, date of birth NHS/CHI number, and contact details such as your postal address, email address, and phone landline/mobile number.
- We will ask you your sex, height and weight, as well as your date of birth, ethnicity, and most recent occupational status.

- We will also ask you to provide a brief medical history and ask questions about smoking habits, alcohol use, quality of life, psychological wellbeing, and any use of health services.

**…assessing physical activity?**

We will ask you to wear a GENEActiv device. A GENEActiv is a lightweight, waterproof, wrist-worn device, designed for 24-hour wear. You will be shown how to use this device and first asked to wear it for 7 days. After this, it will then need to be returned using the pre-paid envelope provided. We recommend that you obtain a certificate of posting.

## Will any of my electronic health records be used as part of the study?

Yes… and all participants in the study will be followed up electronically for up to five years.

- The PACS research team (including the University of Leicester, study investigators, and the Department of Cardiovascular Sciences, University of Leicester) are therefore asking for your permission to use your personal information to obtain information about you from the electronic medical records held by central NHS and UK Government organisations [(NHS Digital (England and Wales)] or your GP.
- Your personal information (name, date of birth, and NHS number) and a code number will be securely provided to these NHS organisations. These groups will then use this personal information to extract information about you from their databases (e.g. visits to your GP, visits or admissions to hospital, etc.). Using the same secure process, these organisations will send this information (i.e. your electronic health records linked to your code number and not your name) back to the research team.
- If we need to obtain this information via your GP, we will need to first contact your GP to notify them about your participation in the study.

## How will we use information about you?

- The University of Leicester research team will need to use information from you, your medical records and/or your GP for this research project.
- This information will include your: name/initials, date of birth, contact details, GP records, NHS number, signed consent forms (if applicable), and recordings/written transcripts and video/call/email correspondence (if consent is provided this way), and chosen method of consent. People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the data so we can check the results.
- We will write our reports in a way that no-one can work out that you took part in the study.

- The data collected as part of this study may be used for the writing of educational projects such as a Master's degree or a PhD. If you would like to know more about this, please contact the PACS coordinating team via gpacs@leicester.ac.uk

## What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health via routinely collected health data or contacting your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, the data collected from this study may be used in future research for the NHS.
- If you agree to take part in this study, you will have the option to be contacted about potentially taking part in other future, ethically approved research for the NHS.

## Where can I find out more about how my information is used?

- at https://www.hra.nhs.uk/information-about-patients/
- by reading the 'Patient Data and Research leaflet' available at: https://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dpo@le.ac.uk
- by visiting the following website: https://www2.le.ac.uk/offices/ias
- by ringing us on 0116 229 7945
- Sponsor's Data Protection Officer: Parmjit Gill, Information Assurance Services Manager, Information Assurance Services, University of Leicester, University Road, Leicester, LE1 7RH.

## What are the possible disadvantages/advantages of taking part?

You will need to give up some of your time to complete the questionnaires. We cannot guarantee any direct benefit from participating, but you will be helping to make a significant contribution to NHS research.

## Who is organising and coordinating the research?

- The study is led by the Chief Investigator, Professor Matthew Bown, a Professor of Vascular Surgery. Professor Bown is part of the University of Leicester, Department of Cardiovascular Sciences. More information about the department and Professor Bown can be found here: https://www2.le.ac.uk/departments/cardiovascular-sciences/people/bown
- The PACS study is organised and coordinated by the Department of Cardiovascular Sciences, University of Leicester and sponsored by the University of Leicester.

- Please note: none of the research team receive financial reward if you decide to participate.

## Contacting the research team

Local site team: Sarah Jane Messeder, Vascular Research Office, Cardiovascular Sciences Wing, University of Leicester, Glenfield Hospital, Groby Road, Leicester, LE3 9QP. Tel: 0116 250 2381
PACS co-ordinating team: gpacs@leicester.ac.uk

## What will happen to the results of the research study?

The information collected during the study will be entered into a computer database, analysed, and interpreted. The results of the research study will be presented to medical researchers at scientific meetings and published in medical journals. Once the study has finished, we can provide you with the research highlights detailing what we have learned, as well as direct you towards the full results of the study.

## Who is funding the research?

The study is funded by a grant from the National Institute for Health Research Programme Grants for Applied Research (NIHR PGfAR): https://fundingawards.nihr.ac.uk/award/NIHR200601.

## What if I am harmed or wish to complain about the study?

It is very unlikely that you will be harmed in this type of research study, but should you wish to complain, you can first ask to speak to the local site team (see page 5). If you wish to further address your concerns on a formal basis, you should contact the Patient Information and Liaison Service or local complaints service via 08081 788337. If you are harmed during the research due to someone's negligence, then you may have grounds for legal action against the University of Leicester, but you may have to pay your own legal costs. The normal NHS complaints service will still be available to you.

## Who has reviewed the study?

All research that involves NHS patients or staff is reviewed by an independent group of people called a Research Ethics Committee (REC) to protect your safety, rights, wellbeing and dignity. This study has been reviewed by North of Scotland (2) Research Ethics Committee and has received a favourable ethical opinion.

## I've read this information sheet, asked the research team my questions, and have decided I want to take part in the research, what now?

You will be given this information sheet to keep and be asked to provide your consent to participate in the research. Consent can be done in a variety of ways and the method is your choice. **Please carefully read all options.**

- **By responding to an email from the research team**
  - ⇒ You may only do this if no one else has access to your email address mailbox. This is so we know it is you providing consent. You will need to confirm that no one else has access to the mailbox you are providing consent from.
  - ⇒ The research team will send you the consent form wording in an email and ask you to add your initials next to each statement.
  - ⇒ You will NOT provide your written signature via this method but correspondence will be kept.
  - ⇒ You will be given a copy of your consent form to keep via email after the research team have completed their parts of the consent form.

- **By Adobe Sign e-signature software**
  - ⇒ The research team will provide you with a link sent to your email address by Adobe Sign e-signature software (https://www.adobe.com/uk/sign.html)
  - ⇒ The software will guide you on which parts of the consent form to complete.
  - ⇒ You have the choice whether or not to provide an image of your written signature and the electronic record will be kept.
  - ⇒ You will automatically receive a copy of your consent form from Adobe Sign when the research team have completed their parts of the consent form.

- **By post**
  - ⇒ You will need to complete the consent form in wet ink and provide your written signature
  - ⇒ You will need to post us your completed consent form to the address in the section ‘Contacting the research team’. We recommend that you let us know when you have posted it.
  - ⇒ You will be given a copy of your consent form to keep after the research team have completed their parts of the consent form, either via email or by post.

- **Verbally, by phone/video call**
  - ⇒ The research team will arrange a time to speak to you to go through each item on the consent form and complete the consent form on your behalf.
  - ⇒ You will NOT provide your written signature and recordings/written transcripts/correspondence of your verbal consent will be kept.
  - ⇒ You will be given a copy of your consent form to keep via email after the research team have completed their parts of the consent form.

- **By scanned email attachment**
  - ⇒ You will need to complete the consent form in wet ink and provide your written signature
  - ⇒ You will need to scan and add your completed consent form as an email attachment and send it in an email to the address in the section ‘Contacting the research team’.

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    - ⇒ You will be given a copy of your consent form to keep via email after the research team have completed their parts of the consent form.

- **By visiting a member of the research team in person**
    - ⇒ The research team will arrange a time for you to come to Glenfield Hospital so you can provide written consent with a member of the team.
    - ⇒ You will need to provide your written signature via this method.
    - ⇒ You will be given a copy of your consent form to keep after the research team have completed their parts of the consent form, either via email or in person.

**Thank you for reading this information pack**

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