

PARTICIPANT INFORMATION

IsoFIT-BP Study – Isometric exercise for people with raised blood pressure

Full Title of Project: Feasibility study to assess the delivery of a novel isometric exercise intervention for people with Stage 1 hypertension in the NHS

A team of researchers at the University of Kent, Canterbury Christ Church University and East Kent Hospitals University NHS Foundation Trust (EKHUFT) are working with GP practices in your area, to find out if a type of exercise called static (isometric) exercise can be given to you by your local GP surgery or other NHS setting, to reduce your blood pressure.

This information sheet explains why this study is being done and why we would like you to take part.

Please do contact us if you have any questions. Your local research team member contact details are at the end of this sheet.

Purpose of the study

High blood pressure affects many people in the UK. People with raised blood pressure (140-159/90-99 mmHg) are recommended to make changes in their lifestyle (e.g. smoking / drinking / alcohol / diet / exercise) and/or medication in order to reduce their blood pressure.

Current knowledge suggests that a particular type of exercise - isometric exercise - can lower blood pressure. Isometric exercise involves holding a fixed body position for a short period of time (see picture below).



Figure 1. Isometric wall squat exercise

As most of the information to date about the benefits of this type of exercise has come from laboratory-based studies, we want to find out if it is possible for GP practices, hospitals, pharmacies or other NHS settings, to offer NHS patients an isometric exercise plan to do at home and how it might affect a person's blood pressure over 6 months. We will also find out the experiences of doing this type of exercise and whether it can be done consistently at home over time.

This study was designed in consultation with patients and members of the public who are not researchers. This study will help us find out if isometric exercise training is a good option for helping people with raised blood pressure and can be delivered by the NHS for patient benefit.

Why have I been invited?

Your GP practice or hospital care records show that you might be eligible to take part because you have raised blood pressure and you are not yet taking medication for this. To take part you **must not** have any of the conditions listed below and no current injuries or medical problems that would prevent you from being able to do the exercise at home. You must be able to provide written consent to take part in the study.

List of conditions that would make you unsuitable for the study:

- Currently taking blood pressure medication
- If female, be pregnant or currently breast feeding
- Diabetes – Type 1 or Type 2
- Uncorrected congenital or inherited heart condition
- Previous history of any of the following:
 - o Heart attack
 - o Significant heart or blood vessel disease
 - o Stroke or mini-stroke
 - o Aneurysm
 - o Angina
 - o Kidney problems
- You are taking part in another clinical trial

How do I take part?

If you do not have any of the above conditions and decide you would like to take part, please contact us using the details at the end of this information sheet. A member of the research team will then contact you for a quick chat to confirm if you are suitable for the study and book a screening assessment telephone call with a practitioner at your local research site. .

What will happen?

During the study, you might be asked to visit your GP surgery or Kent and Canterbury Hospital research clinic on 1 occasion and will have 4 assessment calls (telephone or video) with the research team. You will be asked to adhere to the following before each of the study assessments (and the potential one-off visit):

- No caffeine (tea, coffee, fizzy drinks, chocolate) within 4 hours of the assessments.

- No alcohol within 12 hours of the assessments.
- No exercise you are unaccustomed to or that would be exhausting, within 24 hours of the assessments. If you feel fatigued prior to an assessment (or the one-off visit) please do not hesitate to inform us straight away and we will rearrange this.
- No food within 2 hours of the assessments.

Adherence to these instructions will be confirmed verbally at the start of each assessment.

What will happen at each of the assessments and the visit to the clinic is described below.

Remote screening assessment:

At this first assessment, a member of the research team will run through your medical information and confirm you are eligible to take part. They will be able to answer any questions you may have and will discuss the study with you. If you are still happy to take part, you will then be asked to complete a consent form which is an online form accessible to complete electronically on a device (such as your smart phone or tablet) so you can complete it whilst on the phone. If you are unable to complete the form electronically there will be a hard copy available for completion by prepaid return postage back to your surgery. The research team will record your medical history and ask about any medications you are currently taking.

If you are female and of child-bearing age, you may be asked to take a pregnancy test and given advice on using contraception during the study.

You will be asked to try a moderate wall squat for 60 seconds to see if you are able to do the exercise. If you are unable to do this, you will not be able to continue in the study. If you are able to, you will then be sent a blood pressure monitor and instructions on how to take your own blood pressure at home for 5 consecutive days. Once we are sure you have all the information you need and can take your blood pressure at home, we will ask you to complete your 5 days consecutive blood pressure readings the following week. You will be asked to record these blood pressure readings in a diary which will be provided. If you get allocated (using randomisation software) to complete the exercise then you will be asked to bring the diary and the blood pressure monitor along to your exercise plan visit.

Baseline Assessment:

This assessment will be held 14 days after the remote screening assessment. The healthcare professional will check if there have been any changes to your medication since the screening assessment. Further to this, you will be asked to complete three questionnaires which consider your general health, diet and exercise. Your home blood pressure measurements will be collected and reviewed to check your values are within eligible range. If these are no longer in range, you may be asked to complete another 5 days of consecutive readings. If they are still no longer in range, then you will not be able to participate in the study and you will be referred back to your GP for standard care treatment. If the values are within eligible range, you will be asked to carry out an observed blood pressure measurement. This will involve measuring your blood pressure following previous guidance given during the remote screening assessment, but with the researcher observing whilst on the video call and recording the measurements. This will enable them to give you any further guidance needed for taking your blood pressure at home. If you are unable to access or use

technology for a video call, you will be asked to attend for an extra visit to your GP surgery to complete the observed blood pressure.

Once the above has been successfully completed you will be randomly allocated to receive one of the following:

- Standard care / lifestyle advice alone for 6 months
- Standard care / lifestyle advice and an isometric exercise programme for 6 months.

If you are allocated to follow the standard care / lifestyle advice alone during the baseline Assessment you will be given verbal and written information about healthy lifestyle choices and we will continue to monitor you for the next 6 months. At the end of the 6 months you will be offered an isometric exercise programme if you would like one.

If you are allocated to receive standard care advice and complete the isometric exercise programme, you will be asked to do an exercise programme for the next 6 months. We will arrange for you to attend a local delivery site, either a local GP surgery or Kent and Canterbury Hospital within the following 7 days for an exercise plan visit for which your travel expenses will be reimbursed (travel costs should be agreed with the study team before claiming). During the visit you will be asked to complete an incremental isometric exercise test, further details are outlined below. Using the results of this test, you will then be given a personalised isometric exercise programme to do at home over the next 6 months. The exercise programme will involve doing the instructed wall squat exercise training session on 3 days each week at home. Each training session will consist of 4 bouts of wall squat for 2 minutes separated by 2 minutes of rest in between each round and should take you approximately 15 minutes to complete in total. If you think that you cannot commit to this, please do not volunteer for the study. Full instructions will be given to you in a training pack to take home. You will also be provided with a blood pressure monitor and a heart rate monitor with full instructions so that you can take readings at home and record them in the study diary provided.

Once the baseline assessment has been completed, you will start receiving reminder messages in text and/or email form, these will be sent to you for the following 6 months. If you are allocated to the standard care / lifestyle advice you will receive messages to remind you to stick to the lifestyle advice given and to remind you to take your blood pressure when necessary. If you are allocated to the standard care / lifestyle advice and isometric exercise plan, you will receive the standard care advice reminders, blood pressure reminders and additional reminders to prompt you to do your isometric exercise training on your training days.

For either of the allocated care options, if the information collected indicates you are not suitable for the study, e.g. your blood pressure has dropped, you will not be able to take part and no further study activity will be conducted. You will return to the care of your GP and where applicable the healthcare professional overseeing your care at the hospital.

Exercise Plan Visit:

At this visit, you will be asked to arrive in comfortable clothing, a t-shirt and loose-fitting shorts or leggings, (exercise type leggings or similar ones that are tight enough to prevent them moving on the leg) and trainers or flat shoes. This is because we may need to use specific monitoring equipment that we will put around your thigh and lower leg. The research team will confirm your medical history and check there have been no changes to your medication in the last week. (Please note: if you have experienced any symptoms of COVID-19, such as a high temperature, a continuous cough or a loss of taste/smell within the ten days prior to this visit, then you will not be able to attend on the arranged day and the appointment will need to be postponed until you have completed your self-isolation period).

You will be asked to do a continuous incremental isometric test, which will last approximately 10 minutes. This test will be used to determine how hard you have to work during the exercise to get the most benefit. The test is split into 2-minute continuous stages and over time the exercise will get harder. You will begin the test at an easy exercise position, see figure 2A below. This position will be held for 2 minutes. After this, the exercise will gradually get harder by asking you to squat lower against the wall every 2 minutes until you reach the last stage (see Figure 2) or until you feel you cannot hold the exercise position any longer. It is a continuous test so there will be no rest between stages. Heart rate and blood pressure will be recorded at time points during the exercise to see how hard your body is having to work. The results of this test are used to determine how deep your wall squat should be during your home-based exercise sessions. Most people are able to complete at least 3 of the 5 (Figure 2 A-E) test stages, which is necessary to provide a valid personalised isometric exercise prescription. If, for any reason, you are unable to do this, you will not be able to continue in the study after the exercise plan visit. However, if you are able to do the 3 stages you will be given an exercise programme to start the next day.

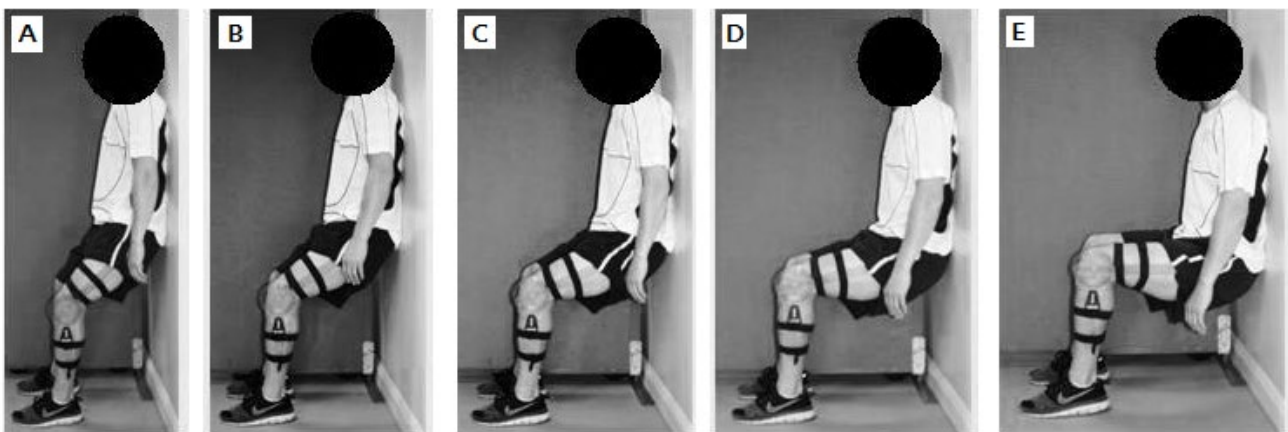


Figure 2. Different isometric wall squat exercise intensities:

Follow up telephone call – Day 7:

If you are randomly selected to receive a wall squat exercise programme, a member of the research team will phone you one week after your exercise plan visit to check how you are doing with your exercise programme. They will check if you have had any problems and also collect your blood pressure and heart rate readings (as logged in your training record) so we can make sure the exercise given is at the right intensity level for you.

Follow up Assessments – Day 28, Month 3 and Month 6:

Following your exercise plan visit, you will be asked to attend 3 follow up assessments through video call with the research team (alternative arrangements will be made for those unable to do this); these will be held at Day 28, 3 months and 6 months.

At each of these remote assessments, you will be asked to take your blood pressure 3 times at home, 15 minutes before the assessment. This will be collected during your visit in addition to your observed blood pressure and heart rate. The research team will check there have been no problems with your health or changes to your medication since the previous assessment. You will be asked to complete the same questionnaires as before about your diet, your general health and any exercise you do. In addition, you will be asked to complete a questionnaire about any health care services you may have used since your last visit.

If you are doing the wall squat exercise programme, at the Month 3 appointment you will be given information about taking part in an optional focus group. The focus group will be an opportunity to talk about your experience of the exercise programme in more detail. If you are interested in taking part in the focus group, you will be asked to complete and return a registration of interest form and you will be contacted with more details about the focus group if you are selected to take part. Those taking part will be given a £15 shopping voucher for their contribution to the focus group.

If you are doing the wall squat exercise programme, at Month 6 you will also be asked to complete a questionnaire about your experience of the exercise.

The study flowchart outlines the described assessments and the table overleaf gives a summary of what will happen at each assessment.

How will you use information about me?

We will need to use information from you and from your medical records for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. Your contact details will also be used to send reminder messages via text or email, you will be asked in which form you would prefer to receive the messages. You might also be contacted by the research team following any alterations to the exercise, to make sure the new intensity is suitable for you.

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.

It will be stored on a password protected network at Canterbury Christ Church University and the University of Kent. It will only ever be accessed by the research team.

Once we have finished the study, all information linking the data to you will be removed (i.e. all personal information associated with the data). 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.

For further information on the East Kent Hospitals University NHS Foundation Trust's research privacy notice please refer to: <https://www.ekhuft.nhs.uk/patients-and-visitors/information-for-patients/patient-information-leaflets/?entryid103=477702&q=0%7edata%7e>. Please inform your health care professional if you would rather have a printed copy of this document.

What are my choices about how my information is used?

We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

Do I have to take part?

It is entirely up to you whether or not you take part. If you decide to take part but change your mind, you are free to withdraw by contacting the research team on the contact details below.

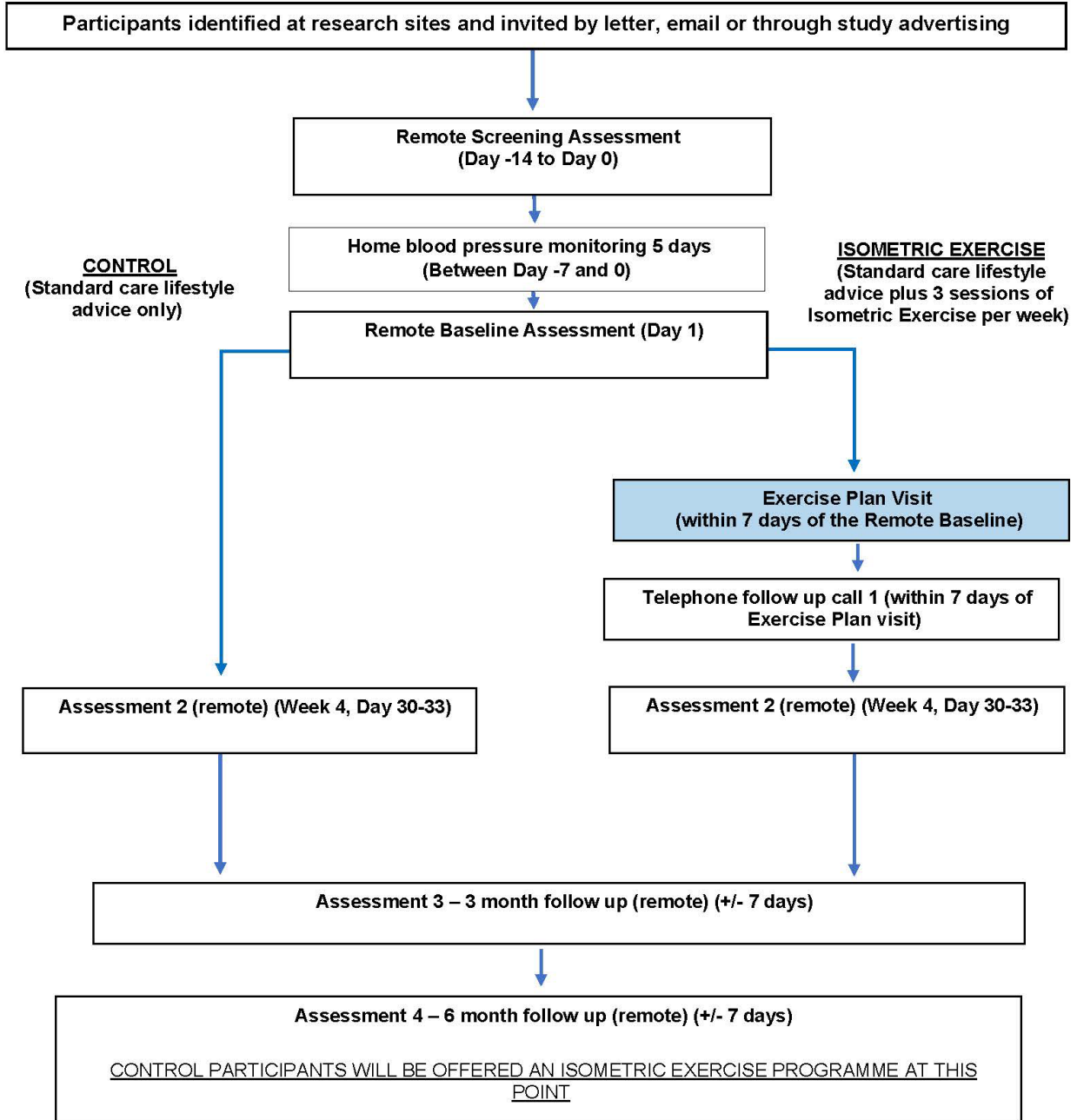
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. Taking part or not taking part in the study will have no effect on the care you receive. The research team will keep your data up to the point at which you withdraw, unless you tell us otherwise. If you have any questions or concerns about taking part do not hesitate to contact us on the details provided at the end of this sheet.

Study flowchart

Key:

Remote assessment
via video call or
telephone

Visit to clinic



Schedule of events

Centre for Health Services Studies

Assessment	Remote Screening Assessment Day -14	Study time point					
		Baseline Assessment Day 1 (remotely)	Exercise Plan visit (within 7 days of Baseline)	Follow up Telephone call – IE arm only (within 7 days of exercise plan visit)	Assessment 2 Day 28-33 (Remotely)	Assessment 3 Month 3 (+/- 7 days) (Remotely)	Assessment 4 Month 6 (+/- 7 days) (Remotely)
Medical history	X	X					
Concomitant Medication	X	X		X	X	X	X
Consent	X						
Observed blood pressure and heart rate		X			X	X	X
Isometric Exercise ability test	X						
Incremental Isometric Exercise test and Isometric Exercise programme provided (for those randomised to intervention arm only)			X				
Adverse Events review				X	X	X	X
Diet questionnaire		X			X	X	X
Exercise questionnaire		X			X	X	X
Quality of life questionnaire		X			X	X	X
Collection of Isometric Exercise diary (for those randomised to intervention arm only)				X	X	X	X
Collection of home blood pressure and heart rate readings	X (between Day -7 and Day 1)	X		X	X	X	X
Health resource use questionnaire					X	X	X
Isometric Exercise experience questionnaire					X		

What are the benefits and risks of taking part?

Since this is a training study you will receive a personal isometric training plan along with regular support and checks throughout the study. You may benefit from improvements in leg strength and fitness over the training period which will benefit your long-term health. You may also experience an improvement in your blood pressure measurements too.

We will ensure that all risks to you as a result of taking part in the study are minimal. This includes all provisions for reducing risk of contracting COVID-19 starting with a minimal number of visits to your local research site (either a local GP surgery or Kent and Canterbury Hospital) (either 0 or 1). If/when you do have to visit, the necessary personal protective equipment will be worn by the research staff and any social distancing procedures in place at your surgery will be followed.

Whilst getting used to doing the exercise, you may feel unbalanced when doing the isometric wall squats. You may experience a burning sensation in your legs and your heart beating faster too. This is your body's normal reaction to performing the exercise and this should lessen as you get used to the exercise plan. You may experience slight muscle aching in the following 48-hour period when you first start to do the exercise programme. This is perfectly normal and will have no long-lasting effects. To help with this, we suggest you rest in between your isometric exercise training sessions and not do any physical activity you would not normally do.

Isometric exercise is known to raise blood pressure and heart rate during exercise, but there is currently no evidence to suggest that this presents any risk to individuals with already elevated blood pressure. The risks of sudden heart problems (like a heart attack) during or after doing isometric exercise are very low. Your training instructions will provide you with details of when to contact the study team or your GP if you record unusually high heart rates or blood pressures in your home diary during or after exercise. This will be explained to you when you are given your exercise plan. You will receive a phone call after the first week of your exercise to check you are happy with your exercise plan and to collect your first week's heart rate and blood pressure information to check the exercise plan intensity level is correct for you. You will be asked to inform us straight away if you experience any problems whilst participating in the study. If the study team are concerned for your safety from the information we collect throughout the study we will let your GP know.

What will happen to the results of the study?

After your involvement in the study is complete, you will receive feedback on your personal results from study assessments. You will also receive a summary of the project findings at the end of the project. Any information you give us will be completely confidential and anonymous. The results of the study may help to improve the care provided to patients in the future. The results will be published in journals and discussed at conferences to share the learning from the study with others.

Who can I contact if I have any further questions or if I want to take part?

If you would like to take part or if you have any further questions, please do not hesitate to contact:

Ellie Santer - Study Coordinator

Canterbury Christ Church University
North Holmes Rd
Canterbury
Kent
CT1 QU

Phone: 01227 923357

Email: IsoFIT-BP@canterbury.ac.uk

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

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- at <http://www.hra.nhs.uk/patientdataandresearch>
- by asking one of the research team
- by sending an email to ekhft.researchandinnovation@nhs.net or caroline.cowley@nhs.net or
- by ringing East Kent Hospitals NHS Foundation Trust Research department on 01227 766877 and asking for the research department.

Who can I contact if I want to make a complaint about the study?

If you are unhappy about any aspects of the study and wish to make a formal complaint, you can do this by contacting the study Chief Investigator:

Professor Chris Farmer

Phone: 07734 180792

Email: c.farmer-357@kent.ac.uk

Thank you for your time, we hope you decide to take part.