Maintaining function and participation through tailored 24-hour physical behaviours for people living with multiple cardiorenal metabolic conditions and frailty (The PERSONAL-AGILITY study).

Participant Information Sheet: Feasibility Study

Chief Investigator: Dr Hannah Young

INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand

- why the research is being done
- what it will involve.

Please read this information sheet carefully and discuss with others if you wish. If there is anything you do not understand, or require further information about, please contact us. We will be happy to answer any questions you have.

WHAT IS THIS STUDY ABOUT?

24-hour physical behaviours include all the ways we might move through a typical day, including:

1. Sleep

2. Sitting (also termed sedentary behaviour)
3. Stepping (walking)
4. Sweating (moderate to vigorous physical activity)
5. Strengthening (resistance exercise)

There are many barriers to being active and getting enough sleep. We have developed the PERSONAL-AGILITY intervention which:

- helps people to understand and track their personal health, wellbeing and 24-hour physical behaviours (stepping, sweating, strengthening, sitting and sleeping) with support from a healthcare professional or trained researcher.
- allows people to decide what aspects of the 24-hour physical behaviours matter most to them. The support they receive will then focus on this and be specific to their needs.
- supports people to access activities groups and services that interest them in their local communities.

Having two or more chronic conditions is called multiple long-term conditions. The number of people living with multiple long-term conditions is increasing. Multiple long-term conditions can affect people's:

- ability to 'bounce back' from illness
- independence and the amount of care and support from family and friends.

- quality of life.

Supporting people with multiple long-term conditions to improve their '24-hour physical behaviours' may improve their:

- Mental and physical health and wellbeing
- Resilience
- Independence
- Quality of life.

The aim of this study is to :

1. **Assess participants' satisfaction with the PERSONAL-AGILITY intervention**: Understand how much participants enjoy and value their experience with the program.
2. **Evaluate the feasibility of conducting a larger study**: Determine the practicality and logistical aspects of a full-scale trial of the PERSONAL-AGILITY intervention in the future.

The findings from this study will guide improvements to the PERSONAL-AGILITY program and help design a more effective and participant-friendly larger-scale study.

WHY HAVE I BEEN INVITED TO TAKE PART?

We have been invited you to take part because you:

- Are over 18 years old
- Are living with multiple long-term conditions, one of which is Type 2 Diabetes Mellitus

and

- may experience challenges bouncing back from illness or injury, or health issues **or**
- be finding daily tasks more challenging, feeling more tired, and slowed up.

We may also have invited you to take part because someone you care for is taking part in the study. This is because we want to find out whether PERSONAL-AGILITY is suitable and helpful for carers too.

PERSONAL-AGILITY uses online tools with in-person and phone support from a healthcare professional or researcher. To be able to take part you need to be willing to use the online tools. If you can't access to the internet, we can provide equipment and resources. We will support you if you are not confident online.

WHY ARE WE ASKING CARERS TO BE INVOLVED?

- A carer is someone who provides unpaid help to a friend or family member needing support, perhaps due to illness, older age, disability, a mental health condition or an addiction.
- You might be caring for someone but not 'call' or 'see' yourself as a carer.

- Receiving carers allowance or other benefits and entitlements does not mean you are a 'paid' carer.
- Carer support can improve the 24-hour physical behaviours of those they care for.
- For carers themselves, improving 24-hour physical behaviours can also:
    - positively influence the physical and mental work of caring.
    - reduce the carers risk of developing multiple long-term conditions themselves
    - support the carer to manage existing long-term conditions they live with.
- A carer can take part so that they can support the person they care for **AND** improve their own health and wellbeing.
- If you join the intervention as a 'pair', you will receive some parts of the intervention together and some separately.

DO I HAVE TO TAKE PART?

No, taking part in this study is voluntary. If you don't take part, this will not affect any care that you or your relative/friend receives. If you decide to take part but later change your mind, you are free to withdraw any time. We will keep any information collected with consent up to the point you drop out of the study. We will use this information in the study. If you decide to take part as a 'pair' and one person drops out, the remaining person may continue to take part on their own.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

During the study you will receive results from a range of health and wellbeing assessments. We will be happy to review the results with you after the study is completed.

If you are in the PERSONAL-AGILITY group, the intervention could benefit you in several ways. Our team will discuss your needs with you and support you to improve your 24-hour physical behaviours. These improve many markers of independence and physical and mental health and wellbeing. We will provide personalised care and appointments around your needs and preferences. Your care will focus on what matters to you. We hope this will help people to engage more with their healthcare and support them to manage their health in the best way for them.

Taking part in this research study could help to inform future research. This could benefit other people living with and caring for people with multiple long-term conditions. This is important as there has not been much research in this area. The results could lead to improved medical treatments and care in the future.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There may be an additional time commitment for people in the PERSONAL-AGILITY intervention group. We will arrange appointments at your convenience. You will be able to choose where you would like to have your appointment to make it as easy as possible for you. The interview part of the study is optional. You do not have to take part in this if you don't want to.

The functional tests are not strenuous but can make some people feel uncomfortable or unsteady. If needed, we will conduct these tests in the presence of another person. You can choose not to do the test. You can stop the test whenever you wish. Some people may find the activity monitors uncomfortable. Should this be the case, you will be able to remove the device.

The pin prick blood test may be uncomfortable. Not everyone who takes part will need to do this test. If you do, trained research staff will do the test. You can choose not to do the test. We will make every attempt to make the procedure as comfortable as possible.

There may be some risks associated with becoming more active and sitting less. These include a slightly elevated risk of falls for people who have had a previous fall. Overall, previous research tells us that the benefits of being more physically active far outweigh the risks of active, and that in the long

run sitting more does not make you safer. We will ensure that you are well enough to take part in the programme as part of the screening process, and we will also make sure that you have a programme which takes into account any previous falls you may have had to ensure that it is right for your needs. Some physical activities can be associated with short-term muscle aches which are normal, but can be uncomfortable, particularly if you are not used to being physically active.

There are minimal risks associated with the interventions we will use to support you to improve your sleep, but for some people with severe insomnia they may not be effective and could lead to frustration, or possibly worsening sleep habits. We will track this closely throughout the intervention, and refer you to your GP if we suspect that you may need more in-depth support, or that you might have an underlying condition which requires treatment to improve your sleep.

WILL IT COST ME ANYTHING TO TAKE PART?

No, it will not cost you anything to take part. Your travel and parking for all appointments associated with the study (including the optional interview) can be reimbursed. If you take part in the interview, we will offer you a £20 voucher for your time. We will offer you an additional £5 for online interviews. This is to cover the cost of the hidden costs (electricity and internet use) of an online interview. We will cover caring costs of up to £15

per hour for carers who take part in the interview. This is so they may organise alternative care arrangements without being out of pocket.

WHAT ARE THE NEXT STEPS IF I TAKE PART?

- If you are interested in taking part, our research team will contact you by phone or email.

- We will check that you are eligible to participate by asking you some simple questions.

- We will give you time to consider the information sheet and ask us any questions.

- If you wish to participate, we will ask you to sign a consent form. We will give a copy of this form to keep.

- After you provide your consent, we may do a further screening check (the pin prick blood test described below) to check you are eligible to participate. Carer participants do not need to do this.

- At this stage, if you would like a carer or family member to participate in a pair with you, we will get in touch with them. They will go through the same checks and consent process.

- We will ask you to complete some tests and questionnaires at another appointment. This is explained in more detail below.

- After this appointment, we will put you into one of two groups. You will either continue with your **usual standard care** or receive the **PERSONAL-AGILITY intervention.** If you take part as a 'pair' you will both be put into the same group. Your group is decided randomly, by chance. Neither you, nor your healthcare team, or the research team can decide which group you are in. Once you are put into one of the groups this cannot be changed. Putting into a group by chance (randomly) helps make sure the groups are the same to start with, so we can compare PERSONAL AGILITY with usual care.

- Overall, your involvement will last six months.

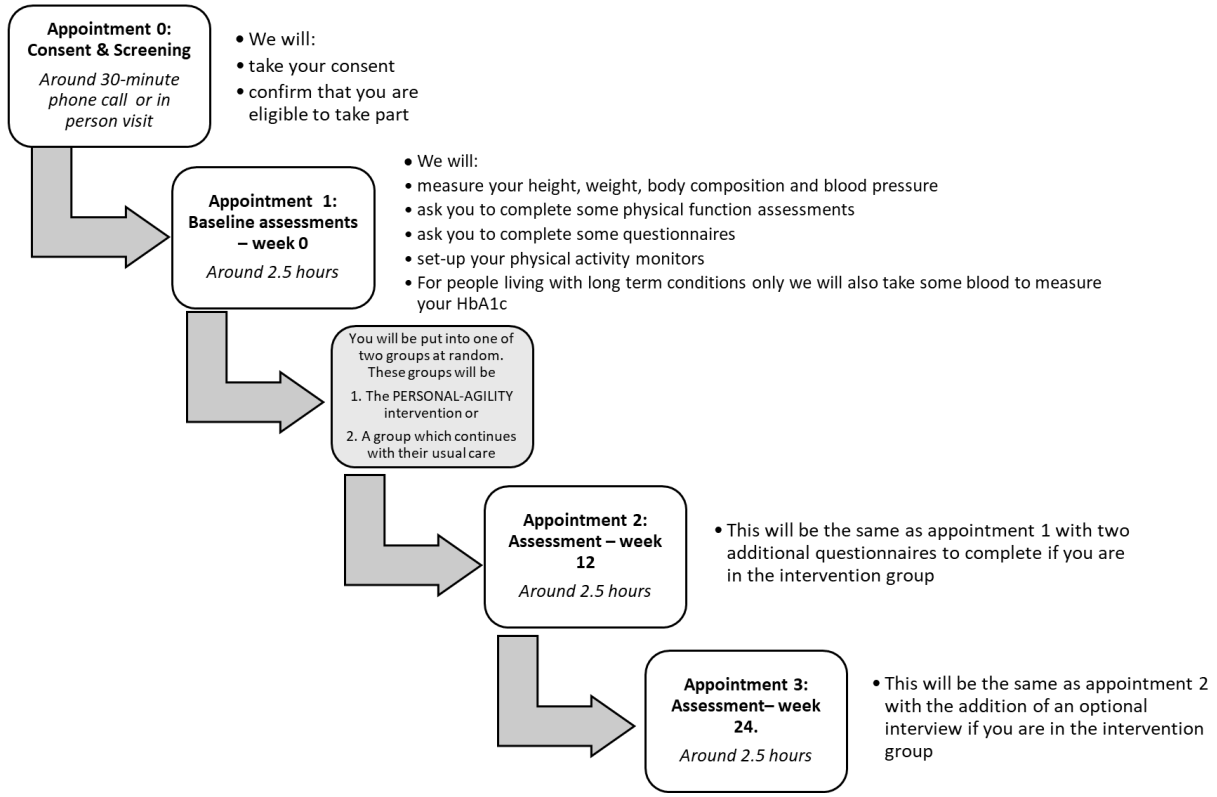
- For both study groups, there will be three study appointments.

- There may be additional appointments for the intervention group.

- You will be able to choose where your appointments take place. The only test that needs to take place at the Leicester General Hospital is the pin-prick blood test.

- Appointments can take place:
  - in your home,
  - at the Leicester General Hospital or
  - at another venue (if appropriate).
- If you take part as a 'pair' you can choose to do these assessments together, or separately.

APPOINTMENT SCHEDULE AND ASSESSMENTS



These appointments can be arranged flexibly, and you can break them down into two or three smaller appointments if this is easier for you.

WHAT IS INVOLVED AS PART OF THE STUDY APPOINTMENTS?

Appointment 1 (baseline)

We will

- collect information about you (e.g. your age, sex, gender and ethnicity, medical history and medications).
- ask you to complete several tests and questionnaires. These are explained later in this document.

- If you are a carer, we will also ask you for some information on your caring relationship and role.

Appointment 2 (follow up, at 12 weeks)

- At this appointment we will conduct all the same assessments in appointment 1.
- If you are in the PERSONAL-AGILITY group, we will ask you to complete two additional questionnaires.

Appointment 3 (follow up, at 24 weeks)

- At this appointment you will repeat all the assessments in appointment 2. If you are in the PERSONAL-AGILITY group, you may be asked to take part in an interview.
- This is optional. It will help us to understand your thoughts and experiences of PERSONAL-AGILITY.
- If you are interested, you will be given another participant information sheet with further information about the interview.

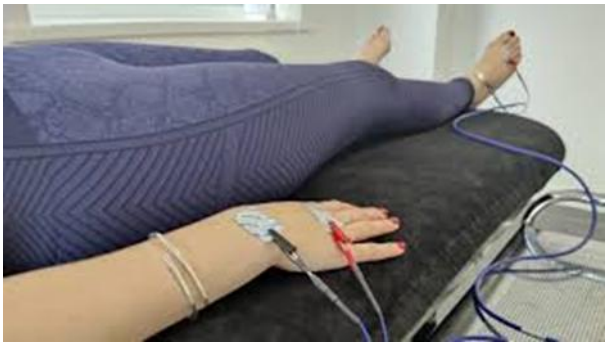
- You will need to provide your consent to be interviewed.
- The interview will be arranged at your convenience.

WHAT WILL YOU MEASURE AT EACH APPOINTMENT?

- You should wear comfortable clothing and flat footwear (such as trainers) for your appointments.
- All participants will be asked to complete the following measures at each study appointment:

1. Body composition

- We will
    - measure the amount of muscle, fat, and water your body is made up of.
    - do this using a non-invasive machine.
    - put four sticky pads on your body (two on your hand and two on your foot).
- The test is simple, safe, and quick.
- The machine passes series of harmless currents through your body.
- The process takes under five minutes and you won't feel anything.



1. The device used to measure body composition

2. Physical measurements

We will measure:

- Your blood pressure three times at each appointment.
- Your height and weight or ask you for these measurements.

3. Strength and physical function

We will measure your

- grip strength. This will involve gripping the device shown below as hard as you can on both hands.

2.. The device used to measure handgrip

- physical function. We will do this in two ways. The first test is called the Short Physical Performance Battery. It includes
  - checking your standing balance
  - measuring your usual walking speed over a short-distance
  - measuring how quickly you can stand from a chair five times.

The second test is called the Berg Balance Test, and this assesses your balance

- sitting down
- standing up
- whilst doing some everyday activities.

Do not worry if you cannot do these tests, we will score you according to your ability.

4. Physical activity monitors

- We will give you a small device, a bit like a watch, to wear on your wrist and another, about the size of a SIM card, to wear on your thigh.
- These devices measure how much time you spend being active and sitting down.
- You will wear these for 9 days. After 9 days we will collect these from you or ask you to post them back to us in a pre-paid envelope.
- They can be worn all day and night; you can sleep and shower in them.
- We will ask you fill in a wake and sleep log whilst wearing the devices.

3. The devices used to measure physical activity levels and sitting time

5. Questionnaires

We will ask you to complete some questionnaires which will measure:

- your quality of life
- the impact symptoms like pain and fatigue have on your everyday life
- your ability to participate everyday life events which are important to you
- goals which are important to you.
- We will ask carers to complete an additional questionnaire. This measures how much physical and emotional caring work they experience.

6. Pin-prick blood test

- We will ask people living with multiple long-term conditions if we can prick their fingertip with a needle.
- We will use a drop of their blood to measure their haemoglobin A1c (HbA1c).

- The HbA1c test measures the amount of blood sugar (glucose) attached to your haemoglobin.
- Haemoglobin is the part of your red blood cells that carries oxygen from your lungs to the rest of your body. The test gives a good indication of how well your diabetes is controlled.
- Carers will not have to do a pin-prick blood test.

7. Other assessments

- If you are in the PERSONAL-AGILITY group, you will be asked if you are happy for a researcher to audio record your intervention appointments.
- This is so we can see if the healthcare professionals are delivering the intervention correctly.
- You will not be the focus of the recording.
- We will copy audio recordings onto a secure, University Hospitals of Leicester NHS Trust drive.
- Members of the study team will complete a written record based on the audio.
- After this, we will then destroy the recording of your appointment.
- We will not include any information which could identify you.

TREATMENT PHASE

As explained above, the two groups in this study are:

- Usual Care or
- PERSONAL-AGILITY.

For this study there is more chance (2:1) of being put into the PERSONAL-AGILITY group. This is to give the research team more opportunity to test the intervention.

Group 1 – Usual care

You will receive your normal, usual care. We will give you general information about the 24-hour physical behaviours.

Group 2 –PERSONAL-AGILITY

- If you are in the PERSONAL-AGILITY group, you will have additional in-person and telephone appointments with a healthcare professional or researcher to discuss your 24-hour physical behaviours.

- We will use
    - online tools
    - activity monitors
    - personalised videos

to help you to understand and keep track of your health and wellbeing.

- You will be supported to use these. You do not need to have access to the internet or an activity monitor to take part.

- Using this information, you can then decide what aspects of the 24-hour physical behaviours matter most to you. You might choose to improve your sleep, your physical activity or to reduce your sitting time.

- This will be done in partnership with a healthcare professional or researcher.
- The intervention will focus on the areas that you have decided are important to you, and not those which aren't. It will be tailored to your needs so might include advice and support on improving your sleep, increasing your physical activity, or reducing your sitting time, or a combination of these.

- We will ask you for more information about your life, needs and circumstances so we can tailor our support to you. The support you receive will be truly personalised to your needs.

- We will also work together with you to make it as easy as possible for you to get the most from the intervention.

- If you are joining the intervention as a 'pair' you will receive some parts of the intervention together and some separately.

- You may also be supported to access activities groups and services that interest you in your community.

- These groups might focus directly on your 24-hour physical behaviours (for example an exercise class in your area), but you may also choose to attend a group or activity which doesn't.

- We hope that by finding enjoyable activities near where you live it will maintain the potential benefits of the intervention for longer.

- If you don't already use an activity monitor to track your activity and sleep, you will be provided with a Fitbit to use. To connect the Fitbit with Steps4Health and MyHealthMapp, you'll need to create a Fitbit account. Don't worry—we'll support you through the process. You'll be asked to provide some basic information, including your name, email address, password, date of birth, gender, height, and weight. Once your account is set up, you'll log in and choose which parts of your Fitbit data you'd like to link with Steps4Health and MyHealthMapp.

- Fitbit can collect location data (from GPS signals, Wi-Fi access points, and IP addresses) for certain features, but you must give permission for this. Sharing your location isn't required to participate in the intervention, and you'll be shown how to disable location tracking through your Fitbit or mobile device settings. Fitbit keeps the data it collects until you choose to delete it or stop using its services. You can view, manage, and delete your Fitbit data through your account settings, or you can delete your account entirely, which will remove all your data from Fitbit's systems.
- We'll inform you of your data rights during the consent process and again at the end of the intervention, so you can decide whether to delete your Fitbit account. This won't affect the data collected via MyHealthMapp and Steps4Health, which will still be retained for the study.

WHAT WILL HAPPEN TO ANY STUDY DATA COLLECTED FROM ME?

We will analyse your results throughout the study. This will happen at the University Hospitals of Leicester NHS Trust. We will also ask for your permission to keep your research data for use in future ethically approved research; this is optional. We will dispose of any samples that we do not have your permission to store or that have not been 'used up'.

We may share research data and samples with other academic, industry and commercial partners. These may be universities, NHS organisations or companies involved in health and care research in this country or abroad.

Your research data and samples will be shared in a coded format, so that no-one can identify you.

We will ask for your permission to share your name, address, contact details and bank details with the PERSONAL-AGILITY study team at the University Hospitals of Leicester NHS Trust. This is so that we can

- make payments to you for attending study appointments
- contact you
- post you any study-related equipment (including physical activity monitors).

Once your involvement in the study is complete, we will destroy these details.

We will also ask for your permission to share your initials, date of birth and sex with Sealed Envelope Ltd. Sealed Envelope is a secure online system which helps us to select your treatment group randomly. You need to agree to this to take part in the study. Once the study has ended, Sealed Envelope Ltd will destroy your data.

WHAT IF I CHANGE MY MIND?

You can stop being part of the study at any time. You don't have to give a reason. Your ongoing care will not be affected. If you are in the PERSONAL-AGILITY group, you will return to your usual care. If you are no longer able

to consent, you will be withdrawn. We will keep research information we have already collected up until you withdraw. You will have the option to take part in future research using data saved from this study. If you decide to take part as a 'pair' and one person drops out of the study, the remaining person may continue on their own.

WILL MY PARTICIPATION BE KEPT CONFIDENTIAL?

While you are taking part in the study, your personal identifiable data and contact details will be accessible to the researchers, so that they can contact you. We will keep all information about you safe and secure. We will write our reports in a way that no-one can work out that you took part. 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.

WILL YOU LET MY GENERAL PRACTITIONER/FAMILY DOCTOR (GP) KNOW ABOUT MY INVOLVEMENT IN THE STUDY?

We will tell your GP you are taking part in the study. Any other medical practitioners who treat you (e.g., if you are admitted to hospital for any reason) will also be informed. During the appointments, it is possible that previously unknown conditions may be revealed. We will let both you, and your GP know about these findings.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you, your medical records and your GP for this study. This information will include your initials,NHS number, name, and contact details and date of birth. 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.
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.

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. We will keep information about you that we already have. -We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about we how we use your information at https://www.hra.nhs.uk/information-about-patients/

- By asking one of the research team
- By contacting us via the e-mail address or phone number at the end of this sheet
- By contacting Mr Saiful Choudhury (Data Protection Officer) at infogov@uhl-tr.nhs.uk

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH PROJECT?

On the consent form, you can choose to be informed about the results of the study. If you consent for this to happen, we will store your contact details securely, separately from your other clinical information, and we will only use them for the purposes you have chosen. The results of the study will be reported and shared at conferences and in scientific journals. We will also share the results with the public through press releases, TV and radio interviews, social media, public lectures, and the internet. You will not be recognised in any report or publication. The data collected as part of this study may be used, in part or in whole, for the writing of educational projects such as a master's degree or a PhD.

WHO IS ORGANISING AND FUNDING THE RESEARCH PROJECT?

The person in overall charge of this study is Dr Hannah Young. This study has been organised by the University of Hospitals of Leicester NHS Trust. The study is funded by the National Institute of Health and Care Research and is being sponsored by the University Hospitals of Leicester NHS Trust. The funders are not directly involved in running the study or analysing the results.

WHO HAS REVIEWED THE RESEARCH PROJECT?

The NHS Research Ethics Committee has reviewed and granted our research a favourable ethical opinion (South Central Oxford B Research Ethics Committee, reference number: 24/SC/0367). This opinion cannot guarantee that no harm will come to the participants. However, it means that the committee members are satisfied that the study will respect your rights. It also means that all risks are as reduced as they can be. They are also satisfied that you have been given enough information to make an informed decision.

WHAT IF SOMETHING GOES WRONG?

If you wish to complain or have any concerns about any aspect of this study, you should ask to speak with a member of the study team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the hospital's Patient Information and Liaison Service (PILS). Contact details for PILS office can be found below.

- Free phone: 08081 788337
- Online contact form: https://www.leicestershospitals.nhs.uk/patients/patient-welfare/patient-information-and-liaison-service/contact-form/
- Email us: **pils.complaints.compliments@uhl-tr.nhs.uk**
- Write to us: Patient Information and Liaison Service, The Firs, C/O Glenfield Hospital, Groby Road, Leicester, LE3 9QP.

It is very unlikely that you would be harmed by taking part in this type of research study. If something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against University Hospitals of Leicester NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

WHAT SHOULD I DO IF I WANT TO TAKE PART?

If you are interested in taking part, please contact Dr Hannah Young or Martha Thomas on 0116 2584323 or email personalagility@uhl-

Thank you for taking the time to read this information and consider taking part in this research.