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#### 1. Invitation

### 1.1. Can I still take part if I have an existing illness?

Yes. All participants who have previously taken part in the Fenland Study are invited to participate in this phase of the study, regardless of any other conditions you may have. If you have any concerns about the clinic visit due to an existing illness, please contact the study team by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours.

### 1.2. Why was I re-contacted?

We would like to invite all participants who attended the first phase of the Fenland Study and who agreed to be re-contacted, to participate in phase 3 of the Fenland Study. The information we collect from you will be used to define how changes in behavioural and environmental factors **over time** determine diabetes, obesity and other related health conditions.

### 1.3. Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide not to take part, we will completely respect your decision and it will not affect the healthcare you receive in any way. Please contact us by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours to tell us you do not wish to take part, so we know not to send you reminder invitations.

If you decide to take part, we will ask you to consent via our electronic consent form.

### 1.4. I have changed my mind/my circumstances have changed and I now want to take part, what should I do?

You can contact us by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours to let us know.

### 1.5. My neighbour was interested when I told him about the study, can he take part as well?

We are only inviting people to Phase 3 of the study who have previously been part of the Fenland Study. Unfortunately, we are not recruiting new participants to the Fenland Study.

#### 1.6. Can a friend or family member download the app too?

Unfortunately, no. This app is for participants of the Fenland Study only and is not for any other use.

### 2. Appointment

#### 2.1. How do I book an appointment for a clinic visit?

On the study timeline, the online booking system will be activated where you can choose a date, time and location that is convenient to you. Clinic visit appointments are displayed 3-4 weeks in advance to allow for the sending out of questionnaires

and the physical activity monitor. Please note that bookings are on a first come, first served basis. In some circumstances, we may contact you to book an appointment.

Please remember to keep a note of your mileage and/or receipts that you incur to attend the clinic visit so we can reimburse you.

Alternatively, you can contact us by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a>, or phone 0800 085 6183 during office hours.

2.2. I need to rebook my clinic visit appointment, what should I do? If you need to rebook your clinic visit appointment please call us on 0800 085 6183 in the first instance. Please note we ideally need to rebook your clinic visit within 6 weeks of your original date. This is because some of the questionnaires and the wearing of the physical activity monitor are related to the clinic visit. If your rebooked clinic visit is more than 6 weeks after your original date, you may need to complete certain questionnaires again prior to your new clinic visit date as well as wear the physical activity monitor again.

### 2.3. I would like to take part but cannot attend a clinic visit, can I still contribute?

Yes, you are still able to take part without attending a clinic visit; however this would mean not receiving any feedback (as outlined below). Instead of using the app, we will send you a link to the web-based version of the questionnaires via email and you can click on the link to complete these.

### 3. App

3.1. How do I know my Smartphone is the right version for the App? Compatible software for iOS (iPhones) is 13.0 or above (<a href="https://support.apple.com/en-gb/HT201685">https://support.apple.com/en-gb/HT201685</a>). Compatible software for Android phones is version 10.0 or above (<a href="https://support.google.com/android/answer/7680439?hl=en-GB">https://support.google.com/android/answer/7680439?hl=en-GB</a>).

If you do not have a compatible device, you will have the option to use an online web platform to answer questionnaires from home.

**3.2.** Does the app use up much storage space on my phone? No. The app takes less than most social media apps – approximately 50MB.

#### 3.3. I do not usually use apps on my phone, is the app difficult to use?

We have designed the app to be as easy to use as possible including for those people who do not regularly use apps. However, if you have any questions or problems using the app, please contact the study team by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours.

### 3.4. I am having difficulty with the app; how can I get help?

If you are having any difficulties, please contact the study team by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours.

### 3.5. How much time does it take to fill in my information into the app?

We have divided the questionnaires into sections so you do not need to complete them all in one go. You can do a section at your convenience and you can return to them to finish questions before you submit. Each questionnaire section will take less than 10 minutes to complete.

#### 3.6. How do I know when to complete questionnaires?

Most of the questionnaire sections will be available for you to complete at your convenience as soon as you have downloaded the app. These are accessed via the study timeline or via the Study tab at the bottom of the screen. We would like you to complete these before your clinic visit. There are certain questions related to your diet and physical activity for example, that we would like you to complete close to your clinic visit. We will send you a notification via the app when to complete these and it will be indicated in the Study Timeline that they are ready to be completed.

### 3.7. What happens if I change my mobile device whilst I'm taking part in the study?

Your progress on questionnaires will only transfer to a new device if it is completed. For those questionnaires that you have started, but not completed, if you switch to a new mobile device at this time, your progress will be lost. To avoid this, ensure the questionnaire you are currently answering is completed before you switch devices.

### 3.8. I do not want to use the app; can I fill in the questions somewhere else?

Yes. If you do not want to, or cannot use the app, you can use a web-based version of the questionnaires. We will send the link to these via email and you can click on the link to complete the questionnaires. Please contact the study team by email on fenlandstudy@mrc-epid.cam.ac.uk or phone 0800 085 6183 during office hours.

### 3.9. I cannot or do not want to fill in the questionnaire online, can I get the questionnaire in a different format?

No. Unfortunately, we can only provide the questionnaires through the app or via a web-based link as we are not providing paper versions of the questionnaires. If you are having problems completing the questionnaires, please contact the study team by email on <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours.

Alternatively, it is possible to complete the questionnaires at the clinic visit with the assistance of one of our researchers.

### 3.10. What has happened to the information I gave in my questionnaires? Will I receive feedback on this?

Your questionnaires will be very valuable in the overall study. We combine all the information from all study participants and study how these relate to the other

measurements, such as the blood measurements from the clinic visit. This will not be undertaken until the end of the study, so we cannot report any results to you at this time. However, we will be updating you on the results of the study as they become available in our newsletters and via the app Discover pages.

#### 4. Clinic Visit

### 4.1. What clothing and footwear do I need to wear?

You should wear light comfortable clothing that (ideally) is free from metallic parts, for example jogging bottoms instead of jeans. Please wear shoes you would be comfortable walking in, for example trainers or flat-bottomed shoes and not high heels (as high heels will damage the belt on the treadmill).

### 4.2. Why do I need to fast from 10pm?

Consumption of food and most drinks can lead to inaccurate blood results. For example, eating something before attending the clinic visit would mean your blood glucose levels would show a higher reading, compared to if the sample was taken fasted. Please drink only water (still or sparkling) to keep yourself hydrated after this time and take any medication/s prescribed to you as well as any over the counter medicines.

4.3. I have an injury/joint problem which means I cannot go on a treadmill There are two test options that can be completed as part of the physical activity testing at the clinic visit, a treadmill, or a self-paced walk test. Ability to complete the treadmill test is assessed in the pre-screening questionnaire that you are asked to complete before your clinic visit. Joint/injury problems are taken into account. If you are concerned about the treadmill, you will have opportunity to discuss this with staff at your visit

### 4.4. I have not received my travel expenses. How long should I have to wait?

We submit your travel claim for payment as soon as we are able. That should mean that you receive reimbursement 6-8 weeks after your visit. If you have waited longer than that and not received your payment, please do contact us on our free-phone 0800 085 6183 or send us an email <a href="mailto:fenlandstudy@mrc-epid.cam.ac.uk">fenlandstudy@mrc-epid.cam.ac.uk</a> and we will check on your payment for you.

### 4.5. How much blood do you take?

The amount of blood taken is very small and equates to 3 tablespoons (54ml).

#### 4.6. What if I do not have any appropriate clothing/footwear?

We can provide scrubs (similar to the ones doctors and nurse wear) you can wear (these are washed after every use). You are able to walk on the treadmill bare foot if you are OK to do so.

### 4.7. Can you tell me if there are any risks with this scan?

Radiation exposure from a DEXA scan is very small. We continually receive X-rays (background radiation) from the atmosphere on a daily basis and the DEXA X-rays

exposure from a whole-body scan is equivalent to up to 8 hours of background radiation. For your reference, a single chest X-ray is equal to approximately 5 days of atmospheric radiation.

### 4.8. What are contrast media and radioisotopes that are used in medical imaging scans?

Contrast media and radioisotopes are substances that are used before medical imaging scans to help produce clear and detailed images of specific areas or tissues. Some common examples used in medical imaging include Barium, Iodine and Technetium-99m (Tc-99m). If you have a scan of this type within the 4 weeks prior to your clinic visit please call the study team on 0800 085 6183 as we will need to rearrange your visit

### 5. Completing the Recent Physical Activity Questionnaire (RPAQ)

### 5.1. Issues entering durations in questionnaire (continually told missing values with pop up message)

Within the questionnaire, most questions require an answer to progress to the next question. Where a question asks for a duration and has boxes for "hours" and "minutes", a value must be entered in each box (even if the answer is 0). E.g., 0hrs 30mins or 1hr 0mins

### 5.2. The activity I do is not listed in the recreation section

Unfortunately, it is not possible to have every activity listed in the questionnaire. If your activity is not listed, please include it under an activity in the list that it is most similar to.

# 6. Physical Activity Monitor - Please remember to bring the device with you to the clinic visit Wearing the Axivity Monitor

#### 6.1. Can I swim with the device?

The monitor is waterproof and robust, so you can wear it all the time, including during showering, bathing, and swimming. However, extremes of temperature may damage the battery so it should be taken off while you have a sauna, for example.

### 6.2. I am not allowed to wear the monitor at work, can I still take part in this aspect of the study?

If you are willing to do so we would ask that you still wear the monitor for all aspects of your daily life that you are able to.

### 6.3. I have a latex allergy, what is the strap made of?

The strap is made of silicone with a stainless-steel buckle and is made from FDA approved material.

### 6.4. I am away in the days leading up to my clinic visit, what shall I do about wearing the monitor?

If you are still happy wearing the monitor during this time, then we would ask you to still wear it. If this is not possible, then we would ask if you could wear it following the clinic visit. If this is the case, please let us know on <a href="mailto:fen1andstudy@mrc-epid.cam.ac.uk">fen1andstudy@mrc-epid.cam.ac.uk</a> or phone 0800 085 6183 during office hours, so we do not send you out a monitor in advance.

### 6.5. Am I able to wear through airport security?

Wearing the device during travel should not affect any security checks. We recommend that you take the accompanying instruction sheet, which provides information about the device with you. The battery of the device is similar to that in a watch so would it need to be removed and placed in a tray if going through airport security. It should not be placed in a suitcase or bag going into the hold of an aircraft as it contains a lithium battery

### 6.6. Will the strap cause irritation?

In very rare instances, individuals may experience minor skin irritation or develop a localised rash from wearing the wrist strap. Leaving the monitor off for one night should alleviate this. However, if the irritation persists, please remove the monitor and still return the monitor to us as per instructions you received. Please do let us know if you have any skin irritation from wearing the monitor.

**6.7.** Can you track where I am going or see where I have been? The monitor has no form of tracker or GPS capability. We cannot see anything regarding location from the data. It is only measuring movement.

### 6.8. But I usually wear my watch on that particular wrist

Is it possible move your watch onto the other wrist or further up your wrist (i.e., closer to the elbow)? It is important that the body location is consistent between participants and across our study. We are asking all participants to wear it on their non-dominant wrist, just above the wrist joint.

#### 6.9. Are the monitors the same as we wore before?

For this phase of the study the monitors are slightly different. You will now only be asked to wear one monitor for the 7-day period. This is a wrist worn device, which measures movement very similar to previous phases, and the attachment is comparable to a watch strap.

**6.10.** Is the monitor safe to wear with a pacemaker or cochlear implant? Yes, the monitor will not interfere with these devices. It does not transmit any signals, data is stored on the device and downloaded when returned.

### 6.11. What do you hope to gain for collecting all this (physical activity) data?

From these data we hope to better understand the interaction between physical activity and other lifestyle and genetic factors that may lead to the development of obesity, type II diabetes and other related metabolic disorders. By taking measurements again in the same volunteers, we are able to look at changes in lifestyle which also may influence the development of these disorders.

### 7. Health Report

### 7.1. What is the Health Report?

The health report is your results from the clinic visit. Here you will find your blood glucose results, blood pressure, height, weight, results from the DEXA scan (if you had one) and an estimate of your fitness level.

7.2. Can I see my results from my previous clinic visits?

Please contact The Fenland Study Team using our free-phone number 0800 085 6183 (during office hours) or send us an email fenlandstudy@mrc-epid.cam.ac.uk.

- **7.3.** Can I have my blood results from my previous clinic visits? Unfortunately, we are not able to provide you with the blood results from your previous clinic visits.
- **7.4.** I am worried about my blood results, whom should I talk to? Your GP will receive your blood results within 4 weeks of your clinic visit (if you provide us with consent to do so) so they are best person to get in touch with if you have any concerns regarding your results. If you did not provide consent for us to forward your results to your GP, you should make an appointment with them to discuss further.

#### 7.5. What do the results mean?

We have provided links to various websites in your health report to provide you with further information about what the results mean. We recommend that you talk to your GP if you have concerns.

### 8. Physical activity measures

8.1. My fitness estimate is much higher/lower than I expected?

The treadmill test has changed in this phase of the study. This could affect the estimate of your fitness, especially if your peak heart rate remained far away from your predicted maximum heart rate when you were exercising.

We currently use predicted maximum heart rate to estimate your fitness level which is based on age and some medications and usually varies +/-20bpm. Your true maximum heart rate could only be measured if we were to exercise you to exhaustion and this is not feasible within this study.

During the treadmill test we aim to raise your heart rate within to a certain range of your maximum heart rate for more accurate fitness estimations. However, it may be that the test was not sufficiently strenuous for you, and this could not be achieved.

Other factors such as requesting to stop early, or unsuitable footwear may have caused the test to be stopped early.

## 8.2. I do not believe my fitness has changed that much since taking part in previous phases of this study, however my fitness results are very different?

The treadmill test has changed in this phase of the study. As a result, the value from this phase of the study is not fully comparable to those of previous phases. In addition to this over the years that the Fenland study has been conducted, methods and protocols have developed (thanks in part to your participation in studies like this). This means the way fitness is calculated across the phases is also not exactly the same. Whilst we have tried to make them as comparable as possible there are inevitably going to be some differences due to the level of detail now collected.

### 9. Ultrasound

### 9.1. Will my GP or I get my results from the liver scan?

You will not get feedback from the ultrasound liver scan. The results of the measurement are not comparable to a clinical test as there is no reference population to compare your measurements against. However, in this study we are hoping to use the results to help understand the range of liver fat levels you typically see in an adult population and how this may relate to health outcomes like blood pressure and metabolic measurements, such as insulin levels.

### 9.2. Is my liver normal?

If necessary, our scans will be reviewed by a specialist and if there is anything to report, we will pass the information to your GP (provided you have given us consent to do so).

#### 10. DEXA

**10.1.** Can you tell if my bones are strong enough / if I have osteoporosis? This DEXA scan is not the same as the scan used to diagnose osteoporosis and osteopenia. Although the scan does measure bone mineral density, it does so across the whole skeleton. Currently, there are no bone mineral density reference values for whole body scans. We use this scan mainly to assess overall body fat distribution.

#### 10.2. Why is my percent body fat high but my BMI is normal?

Body Mass Index (BMI) is used as a screening tool that calculates an individual's weight in proportion to their height. It is a simple measure, which indicates low or healthy weight range, overweight, or obesity. However, BMI has its limitations as it is unable to distinguish between weight that is muscle and body fat (for example elite rugby players with their high level of muscle mass would be considered obese). As a result, some individuals with a healthy BMI range may still have a high percentage body fat, highlighting the importance of additional measures to evaluate body composition accurately.

### 10.3. Why is my percent body fat so different from the value I measured with impedance scale at the gym or using skinfolds?

There are several methods available to measure body composition, such as bioelectrical impedance analysis BIA), skinfold measurements, and DEXA scans. Each method has its advantages and limitations, and the accuracy can differ based on the individual's circumstances and the chosen method. For example, BIA is a quick and convenient method, but it can be affected by factors such as how hydrated you are and results vary according to the quality of the device. Skinfold measurements can be more accurate but the measurements require training to perform. DEXA scans are better for body composition measurements but are more expensive and involve exposure to some radiation so cannot be used frequently.

### 10.4. Will I hear back about research findings?

Yes. In addition to the periodic newsletters we currently send, we will also update all our volunteers on the results of the study as they become available via the app Discover pages.

At the end of Phase 3, we also plan to hold public meetings as we have done in the past. This will give you a chance to get more detailed feedback on the research and so that you can ask questions directly to the researchers.

Please feel free to contact us if you have any more queries regarding The Fenland Study using our free-phone number 0800 085 6183 (during office hours) or send us an email <u>fenlandstudy@mrc-epid.cam.ac.uk</u>