

# Participant Information Sheet

## The Families Reporting Every Step to Health (FRESH) Study

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### Summary

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It's great you are interested in finding out more about the FRESH research study. This leaflet provides more information about the study itself, and how you and your family can be involved. Please take time to read this information and talk it through with your family.

Families Reporting Every Step to Health (FRESH) is a research study to find out how active you are and what activities you enjoy doing as a family. We are also interested in testing how effective the intervention website we have created is at increasing family activity levels.

To do this we will compare data from families with access to the intervention website with data from families who do not have access to the intervention website. The active intervention length of the study is 8 weeks, but we would also like to come back after a year to see how your family activity levels may have changed.

For further details about the study please read the following leaflet. We hope this will give you a clear understanding of the study, what your family participation will involve and answer any questions or concerns you might have.

Please do not hesitate to contact us if you require any further information or clarification. We would be happy to hear from you.

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### How to contact us

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If you have any questions about this study please speak to:

**Justin Guagliano or Beth Haines**

MRC Epidemiology Unit and Centre for Diet and Activity Research  
University of Cambridge

Email: [fresh@mrc-epid.cam.ac.uk](mailto:fresh@mrc-epid.cam.ac.uk)  
Freephone: 0800 783 3009

Website including a video about the study: [www.cedar.iph.cam.ac.uk/research/directory/fresh](http://www.cedar.iph.cam.ac.uk/research/directory/fresh)

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## 1 Why we are doing this study?

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To find out more about family activity levels and what sort of activities families enjoy doing together. We would also like families to help us test a new intervention website. We want to see if the intervention website can support families to be more active together.

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## 2 Who can take part?

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Your family can take part in FRESH, if you:

- Have a child in Year 3 – 6 at primary school.
- Have at least one adult (living in the child's main household) willing to participate in the project. Wider family participation is encouraged, but not required.
- Can at least do light physical activity (e.g., walking).
- Have sufficient understanding of the English language.
- Have access to the internet at home

We are aiming to recruit a total of 60 families across Norfolk and Suffolk to take part in the study.

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## 3 What will happen to me if I take part?

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### Giving Consent

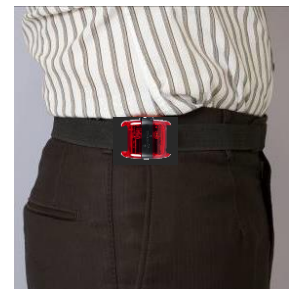
Before any measurements are taken we will ask the adult members of your household who would like to take part in the project to sign a consent form. We will also ask the main parent/carer to sign a parental consent form for all participating children. All children in your household who would like to take part will also be asked to give their assent to participate.

### Taking Measurements

We will take some measurements from all participating family members on three occasions, once at the beginning, once approximately 10 weeks later, and once at the end of the project, week 52. Measurements will occur at a location convenient for you. If you are uncomfortable with some measures, you may opt out of that measure.

At each measurement visit we will ask to collect the following information:

- Height, weight, waist circumference, and blood pressure.
- Fitness with a short step test (about 10 minutes).
- A short questionnaire about you and your family.
- Children only will be asked to complete memory and attention tasks.
- A short video-recorded activity where you will plan a holiday as a family.
- Some families will also be asked to take part in a family discussion with a researcher to talk about your experiences with being involved in the project.
- Physical activity for 7 days using GPS and an activity monitor. These are small devices that are worn on your hip (see pictures below).



In addition, for those families with access to the website, we will monitor their use to enable us to assess website engagement.

### How do we find out if the intervention website works?

We want to see if it makes a difference if everyone in the family is tracking their steps using the website compared to tracking their steps without access to the website and receiving no tracking equipment. **To do this we randomly allocate (like flipping a coin) families to one of three groups:**

- Group 1) These families will get a pedometer (a monitor that allows you to track your step counts) and access to the intervention website; or
- Group 2) These families will get a pedometer but no access to the intervention website; or

- Group 3) These families will not receive a pedometer and have no access to the intervention website.

While we recognise that you may feel that you have “missed-out” if your family is allocated to Group 3, families in this group are extremely important to helping us figure out if the intervention works.

### When will I find out which Group my family is in?

Approximately one week after the first measurement visit.

If you are in Group 1 or 2 we will arrange another visit to set you up with the pedometers. In addition, families in Group 1 will also be shown how to use the intervention website.

If you have any difficulties with the website, you can contact us for help. The pedometers provided will enable you to log your steps on the website. For the next 8 weeks, your family will have full access to engage with the website. You will be asked to log your step counts on the intervention website at least once per week, but we’d like you to wear the pedometer as much as possible throughout the week, so that you know how many steps you took daily.

That’s it! You will continue to have access to the website after the 8 week intervention period, so your family can continue to complete step challenges.

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## 4 Possible benefits and disadvantages of taking part

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### What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks with taking part in the FRESH study. This study has been designed with families, for families. It promotes inclusivity of all family members, and focuses on enhancing quality family time through physical activity. All measures in this study have been used before in both adults and children and we will follow established procedures.

### What are the possible benefits of taking part?

The FRESH study encourages families to spend time and achieve activity goals together. Therefore, by participating in this project you may feel more connected as a family and may also experience some health improvements.

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## 5 More information about taking part

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### Do I have to take part?

No, it is up to you and your family to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign the consent forms. If you do not want to participate, but other family members do, your family will be eligible if a minimum of one adult (living in the household) and one child (in Year 3-6) participate.

You can stop taking part in some parts of this study, or all of it, at any time and without giving a reason. If one member of your family decides to stop taking part in the project, this does not necessarily mean your whole family must withdraw also. As long as there is one adult (living in the household) or one child (in school years 3-6) willing to continue they will be allowed to.

### Will I receive any payment for taking part?

Upon the return of your GPS and activity monitor, at all measurement periods, we will give out £5 vouchers to each participating family member. Also, the pedometers we hand out are yours to keep. At the end of the study each participating family member will receive a physical activity summary.

### Will my taking part be kept confidential?

Your family’s participation will be kept strictly confidential. However, as with anyone else who works with children, we have a responsibility in relation to safeguarding children, which includes a duty to disclose to the relevant authorities any instance of reasonable evidence of non-accidental child suffering. This would not occur

without prior consultation with our trained clinical staff.

### What will happen to information about me collected during the study?

If you agree to take part in this project, any information we collect from you will be kept confidential and stored anonymously on secure computers. Paper records of data (e.g. consent forms) will be stored either in locked filing cabinets within lockable offices within an access restricted building, or will be sent off site to a secure storage facility that complies with our security requirements. All data handling, processing, transfer and storage procedures comply with our obligations under the Data Protection Act, 1998, and comply with our local data handling and security policies and procedures. Personal data will only be accessed and used by those who have been granted permission. For those with access to the FRESH website we will ask your permission to hold your email address in the web-based system to enable automatic messages to be sent to support your participation.

### What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the research team who will do their best to answer your questions. Contact details are listed in Section 6.

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

When the project is completed, we will publish/present the results in academic journals/conferences (or similar), so that other researchers or interested parties can see them. Your identity and any personal details will be kept confidential. No named information about you will be published in any works stemming from this project. We will also provide you with a summary of your physical activity measurements.

### Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder is the National Institute

for Health Research Public Health Research Programme (project number 15/01/19).

### Who has reviewed the study?

This trial has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by the University of Cambridge Humanities and Social Sciences Research Ethics Committee.

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## 6 Contact for further information

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If you have any questions regarding the study please do not hesitate to contact us.

### Local researcher

Dr. Justin Guagliano  
Research Associate  
MRC Epidemiology Unit and Centre for Diet and Activity Research  
University of Cambridge

### Study Support

Beth Haines  
Study Coordinator  
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### Principal Investigator

Dr. Esther van Sluijs  
Group Leader  
MRC Epidemiology Unit and Centre for Diet and Activity Research  
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Thank you for taking the time to consider taking part in this study!