 



**MISSION-RA**

**Participant Information Sheet**

**M**ov**I**ng to **S**upport **S**ustained **I**mprovement of **O**utcomes i**N** **R**heumatoid **A**rthritis (MISSION-RA)

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1. Invitation and brief summary

Thank you for taking the time to read this information sheet. We would like to invite you to take part in our research study. Taking part is entirely up to you.

Before you decide we would like you to understand why we are doing this research and what it will involve. A member of our research team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have. Please feel free to talk to others about the study too if you wish.

This information sheet tells you the purpose of the study, what will happen if you take part and information about the conduct of the study. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

Your participation in the study is entirely voluntary.

2. What is this research about?

Research tells us that physical activity is good for people living with Rheumatoid Arthritis (RA). However, people living with RA can find physical activity a challenge, due to symptoms like joint pain or fatigue. Better support is needed to help people living with RA do more physical activity, and to stay physically active in the long-term.

We are going to develop an **RA-specific computer programme** that can use data from activity trackers to help people with RA become more physically active. To do this, we will first capture the unique physical activity behaviour of people living with RA using **activity trackers** and an **automated** **wearable camera**. The computer programme will then be developed using this data.

The RA-specific computer programme will be able to recognise types of physical activity, such as walking, gardening, stair-climbing and swimming from activity tracker data. This computer programme will then be used to help explore if certain activities are better than others for improving health in RA (e.g. walking vs. stair-climbing).

The computer programme will then be built into a mobile phone app which links to a popular activity tracker - **the Fitbit**. This **MISSION-RA app and Fitbit activity tracker** will give personalised feedback on physical activity behaviour and suggest changes to help people with RA increase their physical activity and improve their health.

In total, at least 248 people living with RA will be involved in developing the RA-specific computer programme and the MISSION-RA app. The National Rheumatoid Arthritis Society (NRAS) are supporting the MISSION-RA study, and will also help develop the MISSION-RA app. This will help to make sure that the computer programme and the MISSION-RA app are specifically tailored for the needs of people with RA to give them more personalised support to increase their physical activity, if they want and need to.

3. Why have I been chosen?

We are asking you to take part in this study because you have a diagnosis of RA, are over 18 years old and can walk either independently or with the assistance of a walking aid.

4. What would taking part involve?

If you agree to take part in this study, you will be provided with a copy of this information leaflet. Once you have read through and have had the opportunity to discuss the study with a member of the research team, you will be asked to sign a consent form if you still wish to take part.

You do not need to agree to take part in the study immediately, and can have some time to think about whether or not you would like to participate. If you would like to take part in the study at a later date, you can do so by contacting the research team using the contact details at the end of the information sheet.

**If you decide to take part:** Before you can take part in the study, we will check your eligibility. If you are able to take part, we will ask you to have a morning visit at the hospital where you receive your usual medical care. The procedures undertaken at the visit are described below.

**Hospital visit:**

You will be part of the study for 8 days. During your hospital visit, we will complete some assessments, and give you the activity trackers and automated wearable camera to wear. You will be asked to wear the activity trackers for the next 8 days, and the wearable camera for the next 2 days. These devices will let us collect information on your activity.

The assessments we will complete are similar to those that you normally have as part of your Rheumatology appointments. In these assessments you will:

* Have your height and weight measured.
* Have your blood pressure taken, after you have rested for 5 minutes.
* Have your RA disease activity assessed. This will be using the Disease Activity Score-28, which is done by counting the number of swollen and tender joints in your hands, elbows, shoulders and knees, and taking a blood sample. More details about the blood sample is below.
* Complete some questionnaires about your daily activities, your health, and your use of smartphones and activity trackers. This will help us understand how your activity patterns relate to some of these factors.

**Blood samples:** When you provide your initial consent to take part in the study, you will be asked to agree for 2 blood samples to be taken. These samples will be used to determine your Disease Activity Score-28, and to measure things in your blood associated with your RA disease activity. In addition, we will also ask for your consent to collect **2 optional blood samples**, which we will analyse to look at levels of inflammation in your blood. **You will be asked to provide your consent for these separately to the procedures described above**. The optional samples will be stored at the University of Birmingham, so that we can analyse it in the future to answer new research questions which might emerge. All blood samples will be taken by someone trained in taking blood.

**Activity trackers and wearable camera:** After the assessments, you will be fitted with the activity trackers and wearable camera, which are shown below.

**The Autographer**

An automated wearable camera. This will be worn attached to your clothes at the level of your chest.

**Size = 8.5 (h) x 2.9 (w) x 2.0 (d) cm**

**The Fitbit Versa 3**

This will be worn on your non-dominant wrist

**Size = 3.4 (h) x 3.4 (w) x 0.8 (d) cm**





**The Axivity accelerometer**

You will wear one of these on your dominant wrist, and the other will be attached to the outside of your ankle using a waterproof dressing.

**Size = 2.3 (h) x 3.3 (w) x 0.8 (d) cm**

You will be asked to wear the activity trackers for the next 8 days, including overnight whilst you sleep. The activity trackers will be used to measure how your body moves when you do different types of activity during the 8 days. The Fitbit device will send data to your smartphone regarding your movement. If you do not have a smartphone, we will provide you with one to use whilst you are taking part in the study.

You will only be asked to wear the camera for the first 2 full days you are taking part in the study. The wearable camera will record images every 20-30 seconds, and does not record sound or conversations. These images will depict what you do and for how long, e.g. walking to work, sitting at home), and will be matched with the activity tracker data. This matching means we can eventually “teach” the activity trackers how to recognise specific types of activity, without needing a camera. You will also be given instructions to take home, to remind you how to wear the devices, and a paper log to record any times you removed or replaced the devices. At the end of the 8 days, you will receive a text message or email, depending on what you prefer, asking you to send the devices back to the hospital, using the freepost envelope provided.

During the 8 days you are wearing the devices, we will also ask you to use an app to respond to questions about your current symptoms (e.g., pain and fatigue), and how you are feeling (wellbeing and mood). The app will prompt you to respond to questions at set time intervals throughout the day. The questions you will be asked, and the frequency has been decided in consultation with people living with RA. You will not be asked to respond to questions more than 4 times per day. To use the app, the research team will give you will be a unique log in code, so you can download it onto your own smartphone, or one which you borrow whilst you are taking part in the study.

Whilst you are taking part in the study, we will ask you to continue with your normal activities of daily life – we will not ask you to change your behaviour in any way, and you will receive your usual medical care. If the days you are taking part in the study are not a “typical” or an “average” day for you, this is ok. We are interested in capturing the variety of activities people with RA do, rather than trying to see how active a particular person is.

If you decide to take part in the study, you would not be liable for any loss or damage to any of the devices (accelerometers, Fitbit, wearable camera, smartphone (if borrowed), that may occur.

5. What are the possible benefits of taking part?

We will be able to give feedback on some aspects of your general health (e.g. blood pressure) and information relating to your physical activity levels. The information you help us collect will be used to develop an intervention (the MISSION-RA app) which may be made available through the NHS, with the aim of improving the longer-term care for people with RA.

6. What are the possible disadvantages and risks of taking part?

This study should not have any effects on your everyday life.

**COVID-19:**  All wearable devices will be thoroughly cleaned using alcohol-based wipes. If you need to clean the devices, please use an isopropyl alcohol-based wipe (70% concentration). Current government guidelines and local safety procedures in relation to the ongoing pandemic will be followed in order to minimise any risk of exposure to the virus.

**Activity trackers:**  The activity trackers cannot harm you. They do not give out radiation, electrical current, vibration, or heat. Very rarely, people can experience mild skin irritation. If this occurs, please remove the device causing the irritation and let the research team know by reporting the information in your Device, Sleep and Symptom Diary. The activity trackers have no GPS technology and cannot track your whereabouts.

**Wearable camera:** We recognise that your privacy and/or the privacy of others (e.g. family members, cohabitants, friends, co-workers) may be a concern when wearing the camera. Therefore, the following measures have been put in place to help alleviate these concerns:

*Your privacy:*

* The camera captures images automatically every 20-30 seconds but **does not record sound or conversations**.
* You can **use the privacy lens to black out recording*,* or remove the cameraat any time** if you are feeling uncomfortable, or if you are in a location where wearing the camera would be inappropriate (e.g. a changing room, swimming pool, school, bank, hospital, airport, or church).
* The camera images are encrypted, so that only the research team can download and view your images. We will also delete all of the camera images from the device as soon as they have been downloaded.
* Although you will not be able to access your images**, you can contact the research team to** **request specific times of the day in which you would like your images to be deleted** in case of sensitive, embarrassing, or private images. For example, you may have forgotten you are wearing the device when you are going to the toilet.

**Privacy of others:**

*Family, friends, co-habitants and co-workers:* if you are spending a significant amount of time with a family member, friend, or co-worker (e.g. going to lunch, having a meeting), we recommend you inform this individual you are wearing the camera. We will provide you with pocket sized “wearable camera information cards” to help explain the purpose of the camera to these individuals. These information cards will explain that; the camera takes pictures, does not record sound or conversations, and how the data is being protected and used for research.

There may be some occupations where wearing a camera in the workplace is not appropriate (e.g. teachers, medical professionals). When we explain the study to you, we will ask you about your occupation, and if we consider it is not appropriate for you to wear a camera whilst at work but you would like to take part, you will be offered the opportunity to take part over 2 days when you are not at work (e.g. the weekend or on your days off). **Please discuss with the research team if you are unsure about whether this study is appropriate for you due to your occupation.**

*Members of the public:* if members of the public ask about the camera, you will be provided with some “wearable camera information cards”, to give to them, which include the above statement along with the research team’s contact details if they have any concerns or want more information (please see tear-off tabs at the bottom of the **“Wearable Camera Instructions**”). An example of what you might say to a member of the public who approaches you is; ***“I am volunteering for a research study about my everyday activities. This is a wearable camera. It records images but not sound or conversations. I would be happy to remove it if you would like me to.”***

**Time and effort:**

We acknowledge that this study may require time commitment and there are multiple different things that you will need to remember to do over the 8 day study period. You can contact the research team at any time if you need any support (their contact details are at the bottom of this document).

7. Who is organising and funding the research?

This research is being funded by the National Institute for Health Research (NIHR) and carried out by Dr Sally Fenton. The University of Birmingham Clinical Trials Unit (BCTU) are helping to organise the study. The Sponsor for the study is the University of Birmingham, which means the University has certain legal and ethical responsibilities for the trial. The data controller is the University of Birmingham. This means that the University is responsible for looking after your information and using it properly.

8. How have patients been involved in this study?

The National Rheumatoid Arthritis Society (NRAS) have worked with the MISSION-RA researchers since 2018 to develop the research questions that MISSION-RA aims to address. NRAS are supporting delivery of the research by making sure the research is acceptable for people living with RA, helping to recruit participants, and analysing the data.

A group of people living with RA have helped to develop this research topic, and to decide on the inclusion and exclusion criteria for people taking part. People living with RA have also helped us to choose the wearable camera, and have reviewed the study procedures and this information sheet to help make sure what we are asking participants to do is acceptable for people with RA. They have also helped us to develop the MISSION-RA app, which we will use to collect data about your symptoms and mood. Finally, people living with RA will also help the research team design the MISSION-RA app that we will produce at the end of this research.

9. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given a favourable opinion by the Queen Square Research Ethics Committee.

10. Involvement of your Healthcare providers

The Rheumatology department at the hospital where you receive your care will know you are participating in this study. Your GP will not be informed that you are participating in this study*.*

How will we use information about you?

We will need to use information collected from you and your medical records for this research project. This information will include your;

* name
* date of birth
* gender
* age
* ethnicity
* post-code
* data from your medical notes (described in part 4 above)
* your e-mail address and/or telephone number

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 unique study ID 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.

11. 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

12. Where can you find out more about how your information is used?

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

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* The Health Research Authority leaflet, available at [**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch)
* by asking one of the research team
* by sending an email to s.a.m.fenton@bham.ac.uk,
* by ringing us on 07964000182
* from the University of Birmingham Data Protection Office: **Email:** dataprotection@contacts.bham.ac.uk. **Telephone:** 0121 414 3916

13. What will happen to the data I give?

Data from the Axivity activity trackers, Fitbits and wearable camera, will be identified using your study ID (not your name) and downloaded onto a secure server at the University of Birmingham where it will be stored.

*Wearable camera images:* camera images will be used to create “codes” for specific types of activities (e.g. walking, stairclimbing). What we are really interested in are the different activities you are doing rather than the images themselves. Whilst we are doing the coding, it will not be possible to anonymise your camera images, but they will be kept in a password-protected folder in a secure system at the University of Birmingham, so that only the research team and collaborators at the University of Oxford can access them. Your camera images will not be shared or published, and will be kept confidential. The only exception to this is that where images provide evidence of wrongdoing or potential harm, the University of Birmingham is under legal and professional obligation to breach confidentiality and pass on image data to appropriate authorities. For example, if any images are found to depict illegal activities, such as taking illicit substances, criminal damage and sexual violence. In such cases the University of Birmingham may be obliged to contact relevant statutory bodies/agencies.

*Fitbit and App data:* Data from the FitBit and self-reported via the app, will be processed by the University of Oxford and a company called Cuttlefish Ltd. Data processed by them will be anonymised (using your study ID) and will not be linked to personal data, such as your name. Whilst they are processing your data it will be held on secure servers, and then transferred directly to the University of Birmingham for analysis. The University of Oxford and Cuttlefish Ltd act on behalf of the University of Birmingham, and must follow our rules about keeping your information safe. We make sure we have appropriate contracts in place with them to protect and safeguard your data.

We may also need to share your anonymised data with collaborators at the University of Loughborough University, so that they can help to analyse the data. We have appropriate agreements in place with them to protect and safeguard your data.

How long will my data be kept? All data will be kept for 10 years after the end of the study. Only members of the research team and Birmingham Clinical Trials Unit staff will have access to this data archive. Camera images will be deleted as soon as possible after analysis (“coding”) of the data.

Blood samples: For the 2 blood samples taken at the stage of initial consent, one will be immediately analysed, and then disposed of. The 2nd blood sample, and the 2 optional blood samples taken with additional consent will be stored and may be analysed in the future to answer new research questions about physical activity and RA. We will ask your consent to use these samples to answer future research questions when we take your consent for this study.

14. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the Chief Investigator, Dr Sally Fenton, who will do her best to answer your questions (E-mail: s.a.m.fenton@bham.ac.uk, Tel: 07964 000182).

If you remain unhappy and wish to complain formally, you can do this by contacting the **Patient Advice and Liaison Service (PALS)** at your hospital (see Contact Information at the end of this information sheet).

15. Will my travel expenses be reimbursed?

Yes, you will receive up to £15 to reimburse your travel expenses. You will also receive £5 to buy some food and drink after your fasted blood sample.

16. What happens when the study stops?

At the end of your participation in the study your Rheumatologist will continue to look after you and your treatment as normal.

17. What will happen to the results of the study?

The results of the study will be published and a final report written. Data may be presented at scientific meetings. An anonymised copy of all the data collected over the course of the study (except the camera images) will be made available for other researchers to use in the future.

18. Do you have any further questions?

If you require further information about the study, then please contact the Chief Investigator (Dr Sally Fenton, contact information on the next page). You can also speak to your Rheumatology consultant if you have questions about whether or not you should participate.

To find more information about the MISSION-RA study on the MISSION-RA website at [www.mission-ra.co.uk](http://www.mission-ra.co.uk) and the twitter account @MISSION\_RA. You can find out more information about how physical activity can help people living with RA, through the National Rheumatoid Arthritis Society at <https://nras.org.uk/resource/exercise-and-rheumatoid-arthritis/>.

**Contact Information**

**Dr Sally Fenton**

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