***Participant Information***

**ACTIVATE study to help people to be more physically active**

We are inviting you to take part in a study that is testing a mobile health app (EXI), wearable physical activity tracker (Apple Watch) and financial incentives to help people become more physically active.

Before you decide if you would like to take part, please read this information sheet carefully–it explains why the research is being done and what it means for you if you take part. If you have any questions, please contact the study team (details below).

**What is the ACTIVATE study about?**

Many people with type 2 diabetes can improve their health and reduce their blood sugar levels through being more active. So, it is particularly important to understand ways patients with diabetes can be encouraged and supported to do this. This study will explore if an activity reward programme, which combines a phone-based app (EXI), wearable movement tracker (Apple Watch) and financial rewards can help people to be more active. The programme is called the Milton Keynes Activity Reward Programme.

EXI is a health app which creates a personalised physical activity programme to encourage you to do and move more. It has been designed by experts to encourage movement and activity safely and slowly, depending on your starting levels. It will encourage and inspire you to carefully increase your activity goals over time and offers rewards in the form of vouchers if you meet these goals.

This study is aimed at everyone with type 2 diabetes regardless of their current fitness level or ability. However, there are certain criteria to meet in order to take part:

**Who can take part?**

You can take part in the study if:

* Aged 18 years or older.
* Diagnosis of type 2 diabetes confirmed by your GP practice.
* You have had your diabetes blood test check (HbA1c) within the last 3 months
* Own and use an Apple smartphone that can run the EXI app (i.e., Apple iOS 15.0 or above which are usually iPhones purchased after 2014 – iphone 6 and above)
* Agree that the study team can notify your GP of your involvement in the study (if applicable).
* Physically mobile and be able to increase your physical activity
* You live in Milton Keynes and are registered with a GP in Milton Keynes

You cannot take part in the study if you:

* are pregnant and/or breastfeeding.
* You only own a non-Apple or Android phone
* Have a significant health condition that affects your ability to be active or is likely to do so in the next 24 months
* are already active, i.e. meet the present government guidance to do. 150 minutes of moderate to vigorous physical activity each week

You can also only take part if you give your consent to take part, having read and understood the information about the study.

**What will happen if I agree to take part?**

You have been sent this participant information sheet as you have your annual diabetes review coming up. If you agree to take part in the study there will be a few things that need completing before your appointment.

*At baseline*

* You will be asked to complete an expression of interest form and some questions about your physical activity. Based on your answers, you may be eligible to take part and the study team will contact you to confirm if you are eligible to take part.
* If you are eligible, a consent form will be sent to you either in the post or via email. Once you have read and checked yes to each of the consent statements, you will be asked to sign a consent form to check that you understand and agree to take part.
* Upon completion of the consent form, you will be sent a short online questionnaire to complete which will ask you about your lifestyle and how active you are, your health and wellbeing, as well as how you use your phone. This questionnaire should take no longer than 20 minutes to complete.
* We will then allocate you to one of two groups at random (like tossing a coin):
  + **Activity Reward Programme group**: If you are in this group, you will be given the intervention. You will be asked to use the EXI mobile phone app, the wearable physical activity monitor (Apple watch), and have the opportunity to earn financial rewards (up to £365 in vouchers per year, or £7 per week) by meeting your activity goals for a 24-month period. The watch is only for your personal use. You will be asked to wear the Apple watch each day throughout the day so that it can accurately track your physical activity. The watch will send information to your Apple phone about the duration and intensity of your physical activity so that the EXI App can work out if you are meeting your physical activity prescription or goals. The App will give you feedback to tell you if you are meeting your physical activity goals. It is recommended that participants take part in a 6-minute walk test weekly to track progress, although this is not compulsory.

Vouchers will be earned each week, but can only be claimed at three monthly intervals (with the option to accumulate vouchers and collect at a future date). Vouchers will be claimed through the EXI App. Vouchers will have an expiry date, which will vary by retailer, typically the expiry date will be six months from the issue date.

* + **Comparison group**: If you are in this group, you will receive some general written information about how to increase your physical activity. You will be given the intervention (the activity reward programme) after 12 months, and continue using the intervention for the final 12 months of the study.

Once you have been allocated to the EXI group or the comparison group, you will start the study either with a telephone appointment with a member of the research team or a research nurse from Milton Keynes University Hospital. With your permission, the research nurse or researcher will audio record your conversation about increasing your physical activity *(optional).*

*At 12 months*

* We will also arrange for you to complete the same questionnaire as at the start of the study (with some additional questions around your use of the healthcare services in the past 12 months to determine if any changes have occurred. This questionnaire should take no longer than 30 minutes to complete.
* You may be invited to take part in an individual interview or group discussion (‘focus group’) about your experiences of the study *(optional).* The interviews and discussions will be recorded.
* You will have your normal routine diabetes annual review; we will use some of the information collected (blood test results, weight, blood pressure) from this to understand whether the intervention has worked.
* After 12 months, the comparison group will be given access the EXI app, wearable activity monitor and the opportunity to earn the financial incentives (vouchers).

*At 24 months*

* We will also arrange for you to complete the same questionnaire as at 12 months to determine if any changes have occurred.
* You will have your normal routine diabetes annual review; we will use some of the information collected from this to understand whether the intervention has worked.

**What data will be collected?**

We will collect data on your physical activity and heart rate from the Apple watch, which will include your steps, and minutes of physical activity, heart rate during resting and exercise. We will also collect the amount of time that you spend using the EXI app. We will also collect the percentage compliance to the physical activity prescription which you are set by the EXI app.

Furthermore, to determine whether the intervention has influenced your health, we will also collect the health data from your annual diabetes check. This will include height, weight, blood pressure, and the result of your blood test including HbA1c. To do this, we will use your first and last name, date of birth and address to find your NHS number, which will be used to collect the data from the diabetes health check (e.g. weight, blood pressure, HbA1c) as well as whether there have been any changes to your diabetes medications or increase use of NHS services.

**How long will the study take?**

You will be involved in the study for around 24 months (2 years) in total.

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

We hope the study will help you to be more physically active and it may improve your health and your diabetes.

By agreeing to participate you will provide researchers with information that may help others to become more physically active to improve their health.

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

We do not expect any risks or disadvantages from taking part in this study. Participants will need to give up some of their time to fill out the study documents and take part in the study. The intervention is aimed at encouraging you to be more active and to do this in a gradual way. However sometimes there are risks when increasing your physical activity too quickly, such as feeling tired or developing muscle or joint stiffness or pain; these symptoms are normally minor and should not last long.

**How do I take part?**

If you are interested in taking part you can complete the enclosed expression of interest form and physical activity questionnaire and return them to Milton Keynes University Hospital using the freepost envelope provided **or** contact the research team on: **Email: DiabetesTrial@mkuh.nhs.uk** or **Telephone: 01908 996652**

**What if I do not want to take part?**

It is up to you to decide if you want to take part. Your medical care and rights will not be affected whatever your decision.

**What if I do not want to carry on with the study?**

You can stop taking part in the study at any time. You do not have to give a reason for this. It will not affect your medical care or rights in any way. If you decide to withdraw, we will keep all the other information that we have already collected about you. If you decide to withdraw from the study, we do request that you return your Apple Watch to the study team.

**Who is organising and funding the research?**

The trial is a partnership between Milton Keynes University Hospital, Milton Keynes City Council and primary care in Milton Keynes. Loughborough University are providing support with the evaluation of the trial. The study is sponsored by Milton Keynes University Hospital (MKUH) NHS Foundation Trust and coordinated by the MKUH R&D department.The trial is being funded by Milton Keynes City Council.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the Black Country Research Ethics Committee.

**Will my taking part in this study be kept confidential?**

If you agree to take part in the study, we will inform your GP of your participation. In the unlikely event of any adverse events relating to the study, your GP will inform the study team so we can keep accurate records of events which might be related to the study.

If you decide to take part in this study, all information collected about you will be kept strictly confidential. It will be securely handled and stored at MKUH in accordance with your consent and the provisions of the General Data Protection Regulation (GDPR). With your permission, and where relevant to your involvement in the study, your data may be looked at by researchers at Loughborough University, the study Sponsor (Milton Keynes University Hospital) or the regulatory authorities. Your anonymised research data (this means data that you cannot be identified from) may also be looked at by wider members of the research team from other collaborating universities. Your GP/health professional will be informed of your participation in the study.

All the personal information you provide will be processed in accordance with data protection legislation on the public task basis (the processing of your data is necessary for us to perform the study and it is in the public benefit) and will be treated in strict confidence unless (under legal obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participants or others or requested by the audit regulatory authorities.

If you would like further information please contact ACTIVATE study, Milton Keynes University Hospital, Milton Keynes, MK6 5LD**: Email: DiabetesTrial@mkuh.nhs.uk** or **Telephone**: 01908 866652

Chief Investigator for the study is Dr Oliver Mytton Milton Keynes Council/Milton Keynes University Hospital, Milton Keynes, UK [oliver.mytton@milton-keynes.gov.uk](mailto:oliver.mytton@milton-keynes.gov.uk).

**Additional Information and Data Privacy Notice**

**What happens if I have a complaint about the study?**

If you have a concern about any aspect of this study, you should ask to speak to the study team at the MKUH R&D department who will do their best to answer your questions. The contact details for the study team are at the bottom of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting normal National Health Service complaints mechanisms, this is usually the Patient Advisory and Liaison Service (PALS). NHS PALS Service at MKUH NHS Trust: Email: [*pals@mkuh.nhs.uk*](mailto:pals@mkuh.nhs.uk) or Telephone: 01908660033 (reception)

**What if something goes wrong during my participation in the study?**

In the event that something does go wrong and you are harmed during the study, and this is due to someone's negligence then you may have grounds for legal action for compensation against MKUH NHS Foundation 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 will happen to the results of the research study?**

Once the study has finished, we may publish the findings in an academic journal including direct quotations from your interviews, if you participate in one. No individual patients will be identified in any publications and all quotations will be anonymous.

The study team will be using information/data collected from you to undertake this study. MKUH are responsible for looking after your information and using it properly. The MKUH R&D and Loughborough University will process personal data. From time to time SMS text messages will be sent to you using the phone number you provide us with. If you are randomised to EXI intervention, your daily physical activity data will be collected from the app and stored to help us understand your physical activity patterns. The EXI App securely collects data and ensures its safe transfer using end-to-end encryption to the EXI Customer Database. The database is stored in an AWS cloud environment, located on servers based in the United Kingdom (UK), and encrypted at rest

**What personal information will be collected from me and how will it be used?**

Your name, date of birth, gender, home address, ethnicity, marital status, employment status, household income and healthcare professional’s contact details will be collected during your participation and will only be used in relation to the study and for no other purpose. If you are randomised to EXI, your first name, last name, email address and unique trial number will be preloaded onto the app by the research team. This information and details will be used to validate your participation in the study and provide access to the EXI app, and to an Apple Watch. All data will be stored centrally in a secure database.

We will also use some routinely collected NHS data (healthcare use, prescribed diabetes medication, blood tests relating to diabetes, and body weight) to help understand the effects of the intervention. We will use your name, date of birth, home address and GP practice to retrieve this information from your NHS records.

**What is the legal basis for processing my personal information?**

Under the GDPR, some of the personal data which will be collected from you is categorised as “sensitive data” (e.g. your name and contact details). The processing of these data is necessary for scientific research in accordance with safeguards. This means that the study has been through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data. Personal data will be processed on the public task basis. Individuals’ rights to erasure and data portability do not apply if data is processed on the basis of public task. However, individuals do have a right to object.

**What are my choices about how my 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. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your NHS records. If you do not want this to happen, tell us and we will stop.

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.

**How long will identifiable personal information be retained?**

Your contact details will be retained by the study team until after the end of the study. This is so we can maintain contact with you during the study and to send you the results once the study has finished.

Personal data including date of birth, ethnicity and employment status will be anonymised and stored with research data for at least 10 years in line with the MKUH policy.

**How long will anonymised data/results be retained?**

Your anonymised data will be retained by the study team for at least 10 years after the completion of the research in line with the study office and Loughborough University’s Policy. The research team will seek approval from the MKUH NHS Foundation Trust as the sponsor of the study before the deletion of data.

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

* at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* our leaflet is available from <https://www.hra.nhs.uk/patientdataandresearch>
* by asking one of the research team
* or by contacting the Data Protection Officer of the study Sponsor on DiabetesTrial@mkuh.nhs.uk

**Thank you for reading this information sheet and for considering taking part in this study.**