a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Motivate T2D

PARTICIPANT INFORMATION & CONSENT FORM

Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes

Principal investigator: Prof. Ali McManus, School of Health & Exercise Sciences, University of British Columbia

Collaborators from The University of British Columbia (UBC), Canada: Prof. Ali McManus, Dr. Jonathan Little, Dr. Mary Jung, Dr. Charlotte Jones (Medical Doctor), Prof. Joel Singer, Mr. Jonathan Low, Mrs. Audrey Kirby

UK Investigators: Dr. Matthew Cocks (UK Chief Investigator, Liverpool John Moores University, UK), Dr. Robert Andrews (Medical Doctor, University of Exeter), Prof. Helen Jones (Liverpool John Moores University, UK), Dr. Tori Sprung (Liverpool John Moores University, UK), Prof. Ceu Mateus (University of Lancaster), Dr. Katie Hesketh (Liverpool John Moores University, UK)

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STUDY INVITATION

We are contacting you because you have been identified as a person who is potentially eligible for a research study we are conducting at the University of British Columbia. We are aware that you have recently (within the last 2 years) been diagnosed with Type 2 diabetes. We are inviting you to participate in a study that aims to help people with Type 2 diabetes exercise enough to benefit their health and increase their everyday physical activity levels.

The study is described in more detail in the following sections, but briefly the study involves you participating in a 6-month home-based exercise intervention that you will co-design with an exercise specialist. Throughout the 6-month exercise intervention you will have consultations with your exercise specialist. You will also complete three detailed health checks in your own home,1) before the intervention, 2) immediately following the intervention (6-months) and 3) 6-months after the intervention finishes (12-months).

If you wish to participate in this study, you will be asked to digitally sign this consent form. Please take time to read the following information carefully – this tells you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. Feel free to discuss this with your family, friends, and doctor before you decide.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

If you have any questions please do not hesitate to contact Dr. Ali McManus or Jonathan Low at motivate.T2D@ubc.ca or call Ali McManus at 250-864-3513.

DO I HAVE TO TAKE PART IN THIS STUDY?

No. Taking part in this study is entirely voluntary. You can refuse to participate in this study and even if you decide to participate, you can still withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled to or are presently receiving. The researchers have a duty of care to all subjects and will inform you of any information that may affect your willingness to remain in the study.

WHO IS DOING THE STUDY?

This study is being conducted by a team of researchers from the University of British Columbia: Dr's Ali McManus, Jonathan Little, Mary Jung, Charlotte Jones and Joel Singer. They are assisted by Mr. Jonathan Low, a PhD student and Mrs. Audrey Kirby, a research manager. We are working with a research team in the UK led by Dr. Matthew Cocks who are conducting the same study in people who live in Liverpool, UK. Our research in Canada is sponsored by the Canadian Institute of Health Research (CIHR).

PURPOSE OF THE STUDY

Being physically active and exercising is really important for the treatment of Type 2 diabetes, as it helps control your blood sugar and improve physical function. Lots of people find it hard to be physically active and sticking with exercise is very difficult for a lot of people. Research is needed to help create new ways that will help people to exercise regularly. This will benefit their diabetes management, particularly in the early stages after diagnosis.

We would like to test whether adding mobile technology to a home-based exercise counselling program makes it easier for T2D patients to begin and maintain regular exercise. Everyone who joins the study will receive regular exercise counselling from an exercise specialist, but half of all participants will also receive mobile technology - a fitness watch - that links to a mobile phone application (App). The mobile App allows our exercise specialist to provide more personalized feedback throughout the program via the fitness watch and we are interested in finding out whether having the fitness watch and mobile App (or mHealth) will make it easier for people with Type 2 diabetes to achieve their exercise goals.

AM I ELIGIBLE FOR THIS STUDY?

You are likely to be eligible for this study if you fulfil the following criteria:

- Diagnosed with T2D within the previous 5–24 months
- Male or Female
- Aged 40-75
- Treat your diabetes with only Metformin or lifestyle modifications (diet and exercise)
- For those prescribed Metformin: have used a stable dose for 3-months or more

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Meeting any of the following criteria will prevent you from participating in the study:

- Aged under 40 or over 75
- HbA1c more than 10%
- Blood pressure higher than 160/110 mmHg
- Treat your diabetes with an antidiabetic drug other than Metformin
- Unstable angina (frequent chest pain)
- Atrial Fibrillation
- Myocardial infarction (heart attack) within the previous 3 months
- Transient ischemic attack (TIA) within the previous 6 months
- Heart failure ≥class 2
- Inability to increase activity
- Pregnancy or planning to become pregnant
- Less than 6 months post childbirth or stopped breastfeeding less than 1 month ago
- Not owning a smartphone/ or having no data plan or access to Wi-Fi
- Currently meeting the recommended exercise guidelines (150 min of moderate intensity exercise per week).

If you are unsure on any of these, then please talk to your family doctor or contact the research team and we can help too.

WHAT DO I HAVE TO DO?

All aspects of the study will be remote and can be done from the comfort of your own home. If you agree to take part, you will

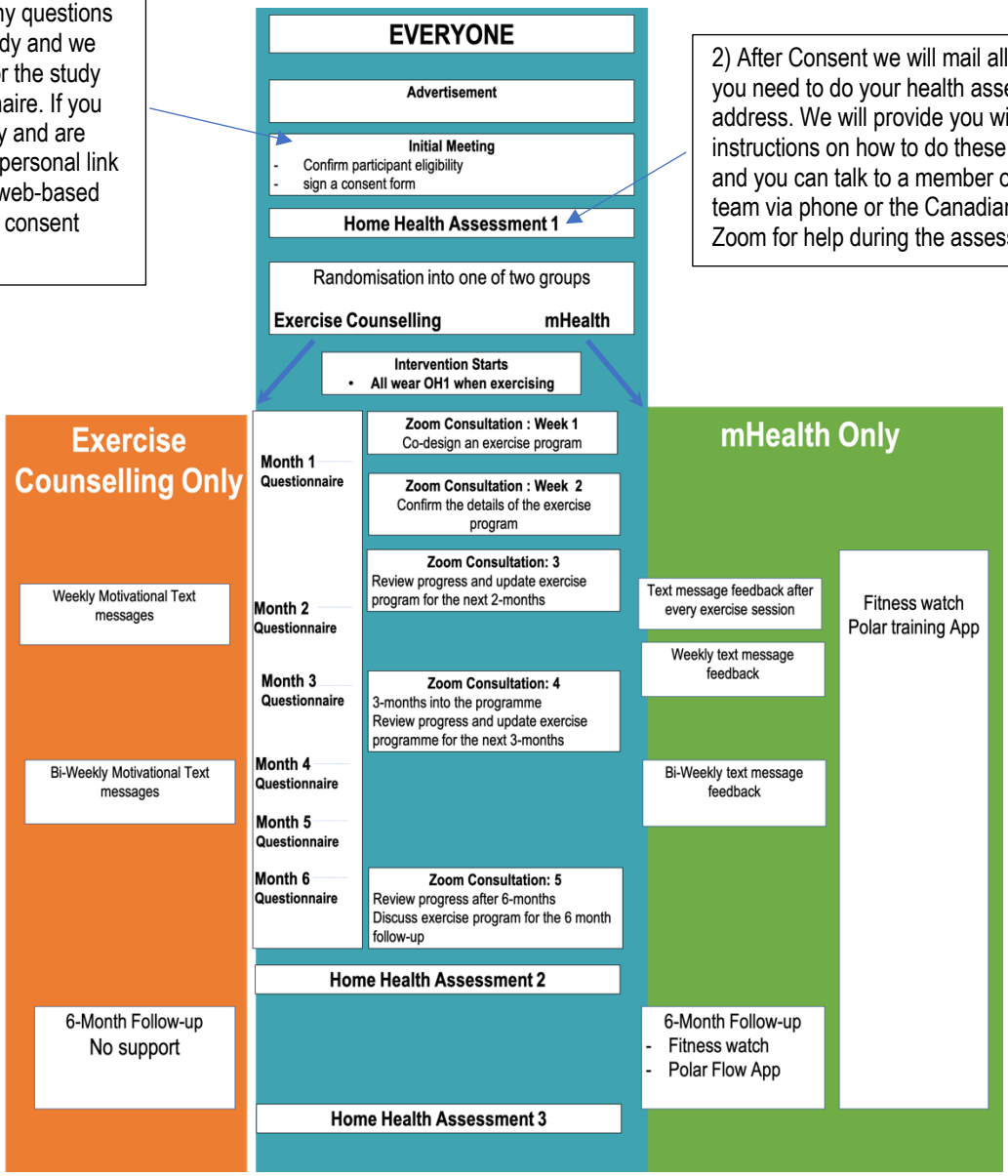
- Complete a 6-month exercise programme
- Have three health assessments (each taking approximately 1 hour with breaks):
    - before the start of the exercise program (Home Health Assessment 1),
    - immediately after the exercise program (Home Health Assessment 2)
    - 6-months after you finished the exercise program (Home Health Assessment 3).
- Complete a questionnaire pack at these same time points (taking about 45 minutes with breaks).

We have provided an overview of all the aspects of the study in Figure 1.

Figure 1. Overview of the study.

1)The first step is an initial meeting, via telephone or a Zoom video call (your preference). You can ask any questions you may have about the study and we can assess your eligibility for the study using a screening questionnaire. If you wish to take part in the study and are eligible, we will email you a personal link to UBC REDCap, a secure web-based site where you can sign this consent document digitally.

2) After Consent we will mail all the equipment you need to do your health assessment to your address. We will provide you with detailed written instructions on how to do these assessments, and you can talk to a member of the research team via phone or the Canadian video-call App Zoom for help during the assessments.



3) After the assessments you will be randomly assigned to either the Exercise Counselling Only group or mHealth group. Everyone will receive the same 6-month exercise counselling program, supported by an exercise specialist, but the mHealth group also receives a fitness watch that links to a mobile training App. Groups are chosen randomly, the same as tossing a coin, so that it is as fair as possible and you have a 50/50 chance of being in the Exercise Counselling Only or mHealth group.

After Randomization the 6-month Exercise Intervention Begins.

Everyone will download the Canadian Zoom video call App for the exercise counselling. No personal information or sign-up is required for the Canadian Zoom App to work. During the exercise consultations, if you are comfortable, we will audio record (not video), your interactions with your exercise specialist will be recorded. You are free to decline to be audio recorded in this manner and you are free to stop the recording at any time.

Table 1. Details of the Exercise Intervention.

<table>
<tr><th>All Participants</th><th>Exercise Counselling Only</th><th>mHealth</th></tr>
<tr><td>The aim of the program is to slowly increase the amount you exercise until you reach the guidelines for weekly exercise (150 minutes of moderate-to-vigorous exercise per week).

You will work with your exercise specialist to co-design an exercise program that works for you, choosing from a wide selection of exercise types e.g., walking, cycling, swimming, online exercise classes, walking soccer and specific to where you like to exercise – for example in your house, outdoors, while commuting to work or the store or walking the dog.

To support you through the 6-month program you will have 5 consultations with your exercise specialist. The sessions will be conducted using the Canadian Zoom App.

Everyone will complete a monthly questionnaire using the UBC Qualtrics website. The questionnaire records your exercise participation and will be completed monthly for the duration of the study (12 months). If the questionnaire is not completed within 3 or 7 days of receipt email or text (patient preference) reminder will be sent.</td><td>To support your exercise program, you will receive weekly text messages for the first 3-months. These messages will be motivational statements encouraging you to exercise.

After the first 3 months these text messages will be sent every other week.

You will be able to contact your exercise specialist at any time (via email or Zoom) or reply to the weekly/bi-weekly text messages and ask any questions you may have.

You will be given an arm-band device that records your heart rate, but does not provide any feedback. You will wear this device whenever you exercise and you will mail it back to us at the end of the 6-month intervention. We will mail you another to wear during the follow-up.</td><td rowspan="2">You will be given a fitness watch (Polar Ignite) and access to a free online training App (Polar Flow). The fitness watch will act as a personal training on your wrist, giving you feedback during every exercise session. You will download the Polar Flow App to use with the watch and we will give you the account details and log-in user ID and password that we have created for you using your study code. The fitness watch syncs to the Polar Flow App, which connects to Polar cloud storage. When syncing, the App may use your cellular data if you are not connected to WIFI and we will not reimburse this cost. We will remind you to use WIFI!

We will ask for your permission to access the information stored by your Polar Flow App. This allows your exercise specialist to track your progress and provide personalized feedback throughout the program. The data that syncs to the Polar cloud storage is owned by Polar and not UBC. When you use Polar services, Polar may collect some of your data. Because we have created your account from your personal study number, no personal identifying information such as name or date of birth or personal email is available to Polar. However, they may use your exercise data and be able to track your IP address. The data Polar do access is used only to offer you the service in question, nothing else. Polar does not disclose, give or sell your data to anyone unless they are required to do so pursuant to a mandatory provision of law. They may use some of the data in research and development work to improve their services, but for such purposes they always use the data in a fully anonymized form, and no personal identifiers are left in the data.

Polar is a globally operating company with customers all over the world. For this reason, in most cases your data is transferred out of your home country. Your data is stored on Polar ecosystem servers which are located in the European Union (EU/EEA) area. The user ID you have been provided may be transferred outside the EU/EEA to the servers of Polar's service providers for automatic notification purposes or for error reporting purposes. Even in those cases, service providers do not have access to your data.

When data is transferred it is done only for the purpose of providing the service. Your data is not disclosed or given to any third parties; it is still under Polar's control and under your ownership. The privacy policies of Polar are available here and these are also provided by email: https://www.polar.com/ca-en/legal/privacy-notice</td></tr>
<tr><td colspan="2">Consultation 1: The week after you complete home health assessment 1.

You and your exercise specialist will talk about your current beliefs on exercise, the benefits of exercise and your concerns about exercising. This will help the exercise specialist plan for your exercise program.

Consultation 2: The week after consultation 1, your exercise specialist will develop an initial exercise program for you. Together you will discuss the program and how to achieve it.

Consultation 3: 2-4 weeks into the exercise program your exercise specialist will review your progress with you and make any changes to the exercise program if required.

Consultation 4: 3 months into the exercise program your exercise specialist will review your progress with you and make any changes to the exercise program if required.

Consultation 5: at the end of the 6-month exercise program your exercise specialist will review your progress and discuss how you can continue to exercise now the structured program has finished.</td></tr>
</table>

	You will also be given an arm-band device that records your heart rate, but does not provide any feedback. You will wear this device whenever you exercise and you will mail it back to us at the end of the 6-month intervention. We will mail you another to wear during the follow-up. After Consultation 2, you will be asked to provide feedback after every exercise session via the Polar Flow App. Your exercise specialist will send a text message based on what you did in the session and your feedback and if needed, your exercise program will be modified. After one month you will receive weekly text messages from the exercise specialist. These will be based on the training you have done. After the first 3-months, these text messages will be sent every other week. Data from the fitness watch and your feedback will be used to monitor and personalize the program during consultations 3, 4 and 5.

Home Health Assessments

You will complete the health assessments in the morning having completed an overnight fast (nothing to eat or drink except water for at least 10 hours). Try to avoid alcohol, caffeine and vigorous exercise the day before testing. Before completing the measurements, you will need to drink a glass of water. The measurements should take about 1 hour to complete.

1. Body Composition: You will measure your height, weight and waist circumference. We will send you a tape measure and a digital scale to do this.

2. Blood Pressure: You will measure your blood pressure with a home use blood pressure monitor that we will send to you.

3. Blood Sample: Using a commercially available home testing kit (www.MonitorMyHealth.org.uk) you will collect a small blood sample from your finger. After washing your hands with warm water for 2 minutes (to get the blood flowing to your fingers), you will use a lancet (like a small pin) to make a small cut on your finger (you will feel a small scratch). You will then fill a small tube with 500ul of blood. It helps the blood to flow if you remain standing when you are collecting the drops of blood. You might need to repeat the process on more than one finger to get enough blood. You will then mail the sample back to the lab for analysis in the pre-paid/pre-addressed envelope on the day you took the blood sample. It is really important that it is put in the mailbox on the same day of collection.

4. 14-Day Flash Glucose Monitoring & **Physical Activity**:

You will wear two separate devices:

1. A physical activity watch, worn continuously on your wrist (similar to a digital watch).

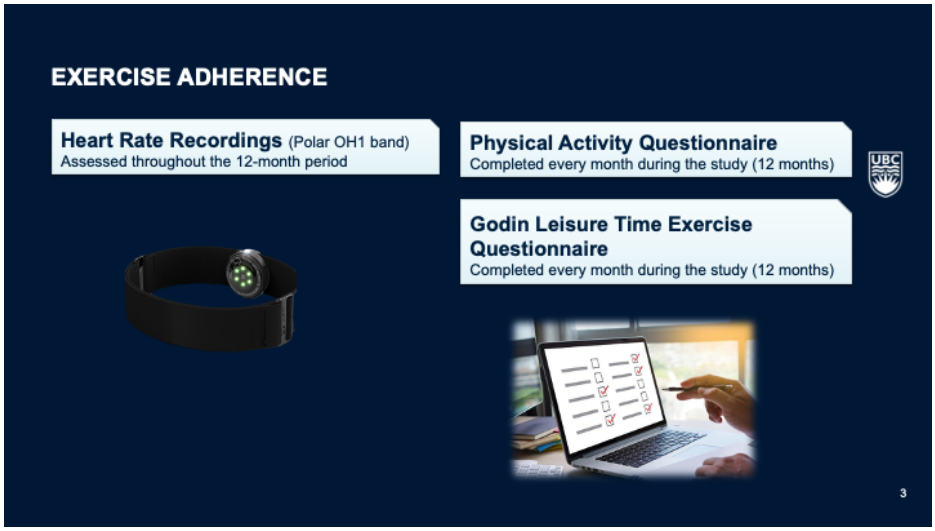
2. A flash glucose sensor. This device is inserted under the skin on your upper arm to check blood sugar levels throughout the 14-day period. You will insert this yourself. Like the blood sample described above, you will feel a small scratch when the sensor is inserted. To start the sensor, we will ask you to scan it with a reader device that we will have sent you. After 14-days, we will ask you to scan the sensor and then remove it.

You are asked to return the physical activity watch, the flash glucose sensor and the reader by mail, using the pre-paid/pre-addressed envelope.

5. Questionnaires: As part of the health assessment, you will complete 6 online questionnaires using a link that we email or text to you. This link takes you to UBC Qualtrics – a secure online system for completing questionnaires. You can decide not to complete a questionnaire or any specific questions. The questionnaires will ask about: 1) the impact of your health status on your everyday life, 2) your use of healthcare over the previous 12 weeks, 3) your satisfaction with your diabetes treatment, 4) your typical exercise levels over the past week, and 5) your motivation for regular exercise.

During post-intervention and follow-up testing two additional questionnaires will be used to assess 1) how your satisfaction with your diabetes treatment has changed and 2) your rapport with your exercise specialist.

Assessments during the exercise program



Interviews: A small group of participants from both groups will be asked to take part in a phone/zoom video call (as preferred) interview to talk about their experience of the research project and you might be chosen. You are free to decline this invitation. The interviews will occur three times: 1) following the baseline health assessment, 2) post-intervention or 3) at follow-up.

We will select a diverse range of participants to take part in the interviews. These discussions will be audio recorded, but your name is removed from any quotations used, so that no one can be identified from them. Immediately after the interview, the audio files that are transferred from the computer to a secure UBC network storage platform Workspace. They are then deleted from the computer.

WHAT ARE MY RESPONSIBILITIES?

1. Complete the tests at the beginning, post-intervention and at follow-up as instructed;
2. Return the monitors and blood samples using the pre-paid postal as instructed;
3. Answer questionnaires;
4. Complete the exercise programme;
5. Report any issues with the assessments;
6. Report any issues with the exercise program;
7. Let us know any noticeable changes in your health status (e.g., sickness, cold) during the trial.

Your total time in the study, from the initial recruitment meeting to finishing the last follow-up home assessments, is about **one year and 1 month**. The home assessments you complete at the beginning, post-intervention and at follow-up take about **1 hour each time to complete, with breaks**. The questionnaires you complete at the beginning, post-intervention and at follow-up, take about **45 minutes each time, with breaks**. We estimate that the time commitment during the 6-month exercise intervention (text messages, consultations, synching App etc.) is about **20 minutes a day, four days a week.**

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

- Blood Sampling: You will collect a finger prick blood sample at three time points during the 12-month study (baseline, post-intervention and follow-up). You may experience some sensitivity or bruising on your finger where the blood sample is taken, but this will be short-lived and normally only lasts ~24 hours. You will be

given guidance on how to do this and can also have a meeting (phone or Zoom as preferred) where you can discuss this test.

- Exercise: You may experience fatigue during the exercise sessions. This is normal and will be short-lived and you should fully recover within hours of the process. However, during exercise there is a very minimal risk of unforeseen heart failure. Although specific figures are not available for people with Type 2 diabetes, the risk of a cardiac event or complication in adults without existing heart disease ranges from 1 in 400,000 – 800,000 hours of exercise. Even in patients with heart disease, who are recognised as high risk, the risk equates to 1 death every 176,000 hours of exercise. As such, the risk is deemed extremely small. You are also free to stop exercising at any point if you feel uncomfortable.
- Polar Mobile App use: If you use the Polar mobile App, Polar may collect some of your data. Because we have created your account from your personal study number, no personal identifying information such as name or date of birth is available to Polar. However, they may use your exercise data and be able to track your IP address.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

All participants will co-design their own 6-month personalized exercise and physical activity program with an exercise specialist and have 5 exercise consultations with an exercise specialist, spread across the initial 6-month program. You will also complete three basic health assessments. To do these assessments you will be given, to keep, a tape measure, digital scale and a blood pressure monitor.

Participants in the mHealth group will keep the fitness watch (Polar Ignite) and have access to a free online training App (Polar Flow). The fitness watch acts like a personal trainer on your wrist providing live feedback on how to exercise. The Polar Flow App will help you track your exercise and enable your exercise specialist to follow your progression and provide regular personalized feedback.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information about you and your samples already collected. You have the right to request the destruction of your information and samples collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the data and samples will not be able to be withdrawn because the data and sample is no longer identifiable (meaning it cannot be linked in any way back to your identity).

CAN I BE ASKED TO LEAVE THE STUDY?

If you are not able to follow the requirements of the study, you may be asked to withdraw from the study. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

WHAT HAPPENS TO MY INFORMATION AND HOW IS IT KEPT CONFIDENTIAL?

Your confidentiality will be respected throughout the study. You will be assigned a unique study number as a participant e.g., AA-001. This number will not include any personal information that could identify you. Only this number will be used on any information collected about you during the course of this study, so that your identity will be kept confidential. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law. However, research

records and health or other source records identifying you may be inspected in the presence of the Investigator and the University of British Columbia Clinical Research Ethics Board for the purpose of monitoring the research.

No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

By signing this consent form, you are consenting to the transfer of blood samples to the United Kingdom. The samples will be securely transferred to Dr. Rob Andrews, a member of the UK research time based at the Royal Devon and Exeter Hospital in Exeter, UK. This allows us to make sure we are assessing the blood samples in the same way in the two countries. Your unique study number will be used to identify the blood samples and maintain confidentiality. Samples will be strictly used for research and data obtained will be kept under secure files. After the sample has been analyzed, any remaining blood will be disposed of immediately.

During the exercise consultations, if you are willing, we will audio record your interactions with your exercise specialist. Similarly, if you are chosen to be interviewed during the intervention period (only some participants), these interviews are audio recorded. The audio recordings are saved on a UBC password protected computer and then transferred to the UBC Workspace – a secure UBC cloud storage site. Audio recordings are deleted from the recording computer as soon as the transfer to UBC Workspace is complete.

All the analyzed information from the project is stored using UBC REDCap account for the study – this is a UBC hosted cloud-based platform. The information will be retained in this secure storage for 5 years, after which it will be destroyed.

Your rights to privacy are legally protected by Canadian federal and provincial laws. You also have the legal right of access to the information about you that has been provided to the sponsor (CIHR) and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

After we publish our findings all the information is de-identified and may be deposited into a publicly accessible repository held by UBC library or by Liverpool John Moores University library in the UK and with the UBC Library UBC Dataverse. This information could include information related to the tests you completed or the exercise intervention. At no time will any identifying information, such as your name or birth date be included in such data. This means that other researchers may analyze the data for different reasons other than those described in this consent form. Once the data is made publicly available, you will not be able to withdraw your data.

WHAT HAPPENS IF SOMETHING GOES WRONG?

If you have any problems, at any time during the study, please contact Dr. Ali McManus or Jonathan Low at motivate.T2D@ubc.ca or call Ali McManus at 250-864-3513. In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following person can then be contacted for further information: Dr. Ali McManus at 250-807-8192 (office) or 250-864-3513 (24 hr mobile).

WHAT WILL THE STUDY COST ME?

All of the costs associated with this study will be covered by the research team, including any equipment or postage costs. You will receive a $10 Amazon voucher each time you complete the study questionnaires. You will be asked to complete the questionnaires 3 times in total (total $30).

SIGNING THE CONSENT FORM AND MY RIGHTS AS A PARTICIPANT

By signing the digital consent form on the UBC Qualtrics website site, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by the provincial medical plan.

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office

of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at (Toll Free) 00 1 877 822 8598. Please reference the study number (H20-01936) when calling so the Complaint Line staff can better assist you.

Study Title: Mobile Health Biometrics to Enhance Exercise and Physical Activity Adherence in Type 2 Diabetes (Motivate T2D)

My signature on this consent form means:

1. I have read and understood the information in this consent form.
2. I have had sufficient time to consider the information provided and to ask for advice if necessary.
3. I understand that I am not waiving any of my legal rights as a result of signing this consent form.
4. I have been able to ask questions and have had satisfactory responses to my questions.
5. I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
6. I understand that participation in this study is entirely voluntary and I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
7. I will receive a signed and dated copy of the consent form by email.

Signatures

I consent to participate in this study

_____ _____ _____

Name of Participant Signature Date

_____

Participant Contact telephone

_____ _____ _____

Consent obtained by Signature Study Role Date