HKU Med LKS Faculty of Medicine School of Public Health 香港大學公共衞生學院

Subject Information Sheet

Study Title:	Combined Effects of Communicating Genetic Risk of Type 2 Diabetes and Wearable Technologies On Objectively Measured Behavioural Outcomes in Overweight or Obese East Asian Individual
Principal Investigator:	Dr. Youngwon Kim Assistant Professor School of Public Health, LKS Faculty of Medicine, The University of Hong Kong

Dear Participant,

I am Dr. Youngwon Kim from the School of Public Health, The University of Hong Kong. I would like to invite you to participate in this research study. It is important for you to understand the specific goal and procedures of our research, before you make the decision. Please take the time to read the following information carefully. Additionally, you can also contact us if anything is not clear or if you would like to know more about the study. Thank you for your consideration and please take the time to decide if you wish to participate in this study.

Purpose of the Study

Our study aims to determine the effects of 1) communication of genetic risk for type 2 diabetes (T2D) on objectively measured physical activity and sedentary behavior in East Asians, and 2) the combination of genetic risk communication with step-goal setting and prompt functions of a consumer-based wearable device on objectively measured physical activity and sedentary behavior in East Asians. .

Why have I been chosen?

Our study involves 355 individuals of East Asian ancestry aged 40-60 years, who are overweight or obese (i.e. measured BMI ≥23 kilograms/meters^2), and can perform daily-living physical activity, use English and use a smartphone in Hong Kong. To minimize bias in the study, we exclude people who have been diagnosed with any type of diabetes, are pregnant or lactating, are unable to perform daily-life physical activities (determined through Physical Activity Readiness Questionnaire [PAR-Q]), are participating in another research stud, or had experience of genetic testing.

Do I have to take part?

It is entirely up to you to decide whether or not you should take part in the study. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form (of which will also have the researcher's signature). It is also important to note that even after signing the consent form, you are still free to withdraw from the study at any time without providing any reason.

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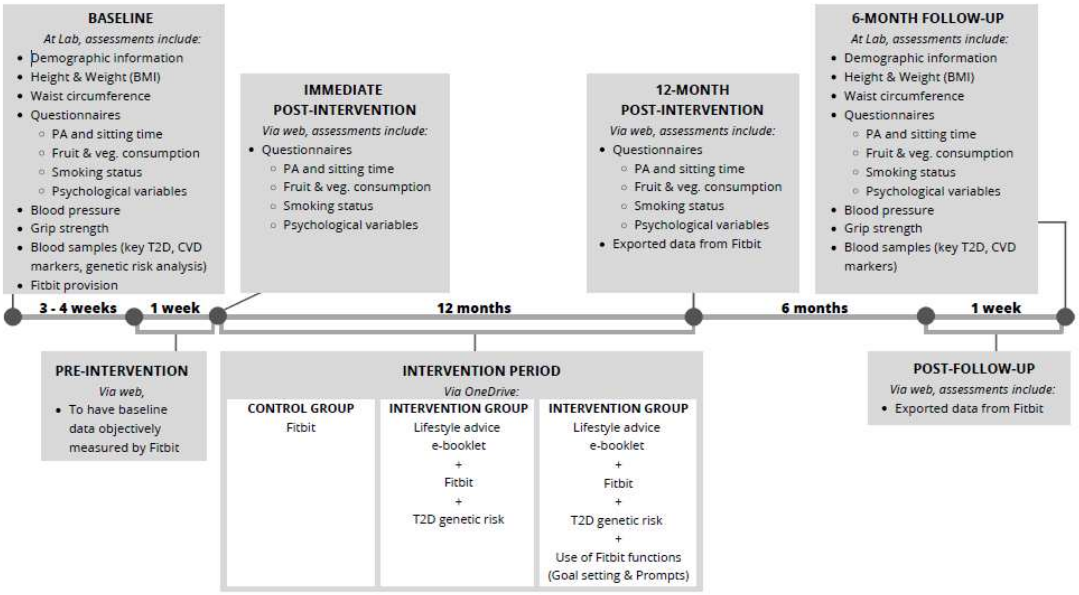
What will happen to me if I take part?



The above figure shows the overall timeline of the study. The full study protocol will take approximately 20 months for you to complete. You will be randomly assigned to one of three groups (1 control and 2 intervention groups). The group allocation will be performed by a computer program completely at random. You will receive a general lifestyle advice e-leaflet (which includes information about T2D and its prevention) and a Fitbit Inspire 3 activity tracker (for objective measurement of physical activity throughout the trial). You are required to wear the Fitbit for full 24 hours throughout the full study period (including 1 week of "Pre-Intervention", 12 months of "Intervention" and the entire "6-Month follow-up"). Depending on your group allocation, you may also receive an estimated genetic risk of T2D alone, or in combination with an individualized Fitbit step goal and use its prompt functions. During the course of the study, you will be invited to visit the research laboratory (located in Pokfulam) twice for an 1-hour assessment (at Baseline and 6-month follow-up). The assessments include collection of demographic information, measurement of body weight, height, blood pressure and hand grip strength, a series of questionnaires and collection of blood samples for analysis of key diabetes and cardiovascular biochemical markers and T2D genetic risk. You will also be asked to complete an online questionnaire twice at home (Immediate post-intervention and 12-month post-intervention). Throughout the study, you will receive text messages via Whatsapp for the purpose of delivering study materials and reminding you to wear and charge your Fitbit during the designated periods.

What do I have to do?

There are no lifestyle restrictions for this study. Please continue to take your regular medication (if any). If you become pregnant during the study, please let me know as soon as possible and you will be required to withdraw from the study.

What are the disadvantages and risks of taking part?

The risk for the present study is minimal. The major intervention component is providing either genetic risk information or Fitbit functions alone, or the combination of both. All participation is voluntary. Additionally, you will have the right to withdraw from participation under any circumstances for any reason. There are no obligations for the study.

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What are the benefits of taking part?
First of all, you will learn not only about the definition, risk factors and health consequences of T2D, but also about how to prevent T2D through lifestyle modifications (i.e. advice on physical activity, diet, weight management, and smoking cessation). Moreover, if you are allocated into one of the 2 intervention groups, you will receive information on your genetic risk of T2D, which could help you make an informed decision of lifestyle changes. In addition, you will receive a series of test results including a blood test report on the key diabetes and cardiovascular disease biochemical markers, grip strength, blood pressure and BMI. Last but not least, upon completion of the full study protocol, you will own the Fitbit tracker.

What if something goes wrong?
If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you can contact our research team (Tel: 52447300 / 28315285, Email: pastudy@hku.hk) or Dr. Youngwon Kim (Tel: 28315252, Email: youngwon.kim@hku.hk).

Will my taking part in this study be kept confidential?
You have the rights of access to personal data and publicly available study results, if and when needed. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or their office (Tel: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured. By consenting to participate in this study, you expressly authorize:

- The principal investigator and his research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process;
  and
- The relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

What will happen to the results of the research study?
In accordance with journal publication guidelines, the raw data of this research study will be kept in a secure location for a maximum of five years after publication of the first paper. Any published paper will not include reference to any personal identifiers. You can also obtain a copy of the published results by contacting me.

Who is organising and funding the research?
The project is funded by the Li Ka Shing Faculty of Medicine of the University of Hong Kong.

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Who has reviewed the study?
This current study has been reviewed and approved by the Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster (Ref. No. : UW 22-007).

Contact for further information
Please complete the reply slip below to indicate whether you would like to participate in this research soon. If you have any questions about the research, please feel free to contact our research team (see the contact information provided above). If you wish to obtain further information about the rights of participants in research, please contact the Institutional Review Board of The University of Hong Kong/ Hospital Authority Hong Kong West Cluster (Tel: 2255 4086).

Your help is very appreciated in our research. You will be given a copy of this information sheet and a signed consent form to keep. Thank you for your kind attention and support.

Yours Faithfully,

Dr. Youngwon Kim
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The University of Hong Kong
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Email: youngwon.kim@hku.hk

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Subject Consent Form

Study Number:
Patient Identification Number for this trial:

Study Title:	Combined Effects of Communicating Genetic Risk of Type 2 Diabetes and Wearable Technologies On Objectively Measured Behavioural Outcomes in Overweight or Obese East Asian Individual
Name of Researcher:	Dr. Youngwon Kim, Assistant Professor in School of Public Health of HKU

		Please ☑ box
1. I confirm that I have read and understood the information sheet dated ___/___/___ for the above study and have had the opportunity to ask questions.		☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without any reason or negative consequences.		☐
3. I understand that the information I provide is confidential and will not be revealed to anyone.		☐
4. I understand that I will be contacted via Whatsapp during the study.		☐
5. I agree to take part in the above study.		☐
6. I agree to share the data collected by this project for further ancillary research.		☐
_____ Name of Participant	_____ Date	_____ Signature
_____ Name of Researcher	_____ Date	_____ Signature

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_____ Name of person taking consent (if different from researcher)	_____ Date	_____ Signature