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Effect of communicating genetic risk of type 2 diabetes and wearable technologies on wearable device-measured behavioural outcomes in East Asians: protocol of a randomised controlled trial

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ABSTRACT

Introduction The communication of information about the risk of type 2 diabetes (T2D) alone has not been associated with changes in habitual behaviours among individuals of European ancestry. In contrast, the use of wearable devices that monitor physical activity (PA) has been associated with behavioural changes in some studies. It is uncertain whether risk communication might enhance the effects of wearable devices. We aim to assess the effects of communicating genetic risk for T2D alone or in combination with wearable device functions on wearable device-measured PA among overweight or obese East Asians.

Methods and analysis In a parallel group, randomised controlled trial, 355 overweight or obese East Asian individuals aged 40–60 years are allocated into one of three groups: one control and two intervention groups. Blood samples will be used for estimation of T2D genetic risk and analysis of metabolic risk markers. Genetic risk of T2D will be estimated based on 113 single-nucleotide polymorphisms associated with T2D among East Asians. All three groups receive a Fitbit device. Both intervention groups will receive T2D genetic risk estimates along with lifestyle advice, but one of the intervention groups additionally uses Fitbit's step goal setting and prompt functions. Questionnaires and physical measurements are administered at baseline, immediately after intervention delivery, and 6 and 12 months post intervention. The primary outcome is time spent in moderate-to-vigorous PA from the Fitbit, which will be assessed at baseline, immediately post intervention, 12 months post intervention and at 6-month follow-up. Secondary outcomes include other wearable device-measured parameters, sedentary time, and sleep, blood pressure, metabolic risk markers, hand grip strength, self-reported PA, fruit and vegetable consumption, smoking, and psychological variables. Between-group differences in the continuous and categorical variables collected at baseline will be examined using Analysis of Variance (ANOVA) and χ^2 tests, respectively. A series of linear mixed effects models with fixed effects of time, group and interaction between time and group will be performed, with adjustment for potential confounders.

Ethics and dissemination The study protocol has undergone review and received approval from the ethics committee of the University of Hong Kong. Findings from our trial will be disseminated through publication in peer-reviewed research journals and presented at international academic conferences.

Trial registration number ClinicalTrials.gov, NCT05524909. https://register.clinicaltrials.gov/ (11 November 2024).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The protocol employs a multimethod approach by combining genetic risk communication strategies with wearable devices (Fitbit) to motivate behavioural change in overweight or obese East Asians.
⇒ The study incorporates a comprehensive series of assessments including quantification of individuals' genetic risk for type 2 diabetes, device-based measurement of movement behaviours, extensive questionnaires and multiple cardiometabolic risk markers.
⇒ Recruitment conducted in this study is done within local communities in Hong Kong. Since residential addresses of participants were not collected, this presents potential for selection bias.
⇒ This study does not consider possible neighbourhood effects on measured behavioural outcomes.

BACKGROUND

Prevention of type 2 diabetes (T2D) is a major global public health priority.[1] T2D is a multifactorial, heterogeneous, palette of metabolic disorders, caused by both genetic and non-genetic lifestyle traits.[2] The burden of T2D in East Asia, in particular China,[3] has increased dramatically over the past three decades.[4] Recent epidemiological data from Hong Kong suggest that individuals 40–60 years accounted for 40% of incident T2D cases, calling for development and implementation of novel intervention strategies aimed at these middle-aged adults.[5] Compelling epidemiological evidence indicates that favourable levels of lifestyle behaviours, such as physical activity (PA), sedentary behaviour (SB) and diet, are associated with reduced risk of developing T2D.[6] However, motivating individuals to adopt and maintain these risk-reducing behaviours as a prevention strategy for T2D is challenging.

The quantification of genetic risk for common preventable diseases including T2D has been made possible with advances in genomic technologies. Recently, a compelling genome-wide association study established a list of genome-wide significant loci associated with T2D risk specifically for East Asians.[7] East Asia is predicted to become the fastest growing region for direct-to-consumer genetic testing within the next 5 years,[8] which will accelerate the increased demand for genomic services under clinical settings as well as private sectors.[9] This context offers an unprecedented opportunity to evaluate the impact of providing personalised information about polygenic risk of T2D in East Asians.

Currently, however, evidence suggests that communicating genetic risk has limited impact on habitual behaviours. A meta-analysis of 18 previously conducted clinical trials found no impacts of genetic risk communication on six health behaviours,[10] but the studies included had several limitations, as summarised by the authors and subsequent commentaries, including: (1) the communication of risk alone, without support from behavioural change theories, (2) the use of error-prone self-report measures to assess the primary behavioural outcomes, (3) the use of outdated, inaccurate genetic risk prediction methods predominantly involving a single genetic variant and (4) a focus on Western populations, limiting the generalisability to other ethnic groups including East Asians. The lack of a diverse study population in this area of study is particularly concerning. Previous studies[11] have documented substantial differences in awareness, knowledge, attitudes and beliefs towards genetic risk testing between individuals of different ethnic groups, attributable to the differences in cultural backgrounds.[12] It is currently unclear how these differences may affect behavioural responses to genetic risk information.

Emerging wearable devices have opened up new avenues for disease diagnosis and prevention. The US Food and Drug Administration has approved the usage of Apple smartwatches to detect atrial fibrillation via the integrated ECG tool.[13] On the other hand, the built-in accelerometer of Fitbit allow for continuous objective monitoring of personal behavioural indicators including PA and SB over extended periods of time, making it a viable behavioural outcome assessment option in clinical trials. This lends credence to the pre-eminent role that wearable devices could play in disease diagnosis and prevention within clinical settings by offering a balanced compromise between convenience and data accuracy. However, interventions incorporating wearables alone, without theory-based strategies, may not motivate sustained lifestyle behavioural change.[14] Previous intervention research has demonstrated the effects of standard functions of wearable devices (eg, self-monitoring, goal setting, activity prompts) pertaining to behavioural change theories on increasing PA.[15] However, no previous clinical trials have used these prominent wearable functions in conjunction with genetic risk communication.

To our knowledge, this study will be the first randomised controlled trial using the combination of genetic risk communication with standard functions of wearable devices. We aim to address the shortcomings of previous research by combining state-of-the-art genetic risk prediction and communication with wearable devices promoting healthy behaviour through step goals and activity prompts in an East Asian population. The integrated use of individuals' genetic risk information and wearable devices,[16] grounded on theories of behavioural change, has the potential to motivate East Asian individuals to initiate and sustain a more physically active lifestyle for prevention of common non-communicable diseases including T2D. In the era of precision medicine, which aims to provide customised medical care to individuals according to their unique genetic profiles and lifestyle, findings from our study will shed new light on the prevention of T2D through lifestyle modification by providing novel insights into the combined use of personalised genetic risk information and emerging wearable technologies in the context of East Asia.

OBJECTIVES

There are two specific objectives of the study: to determine (1) the effects of communicating genetic risk for T2D and (2) the effects of combining genetic risk communication with step goal setting and prompt functions of a consumer-based wearable device on wearable device-measured moderate-to-vigorous PA (MVPA) in overweight or obese East Asians. It is hypothesised that communicating genetic risk for T2D alone will lead to small changes in wearable device-measured MVPA and that combining genetic risk communication with the theory-based wearable functions will lead to significant increases in wearable device-measured MVPA and that such changes will be more likely to be sustained over 6-month follow-up.

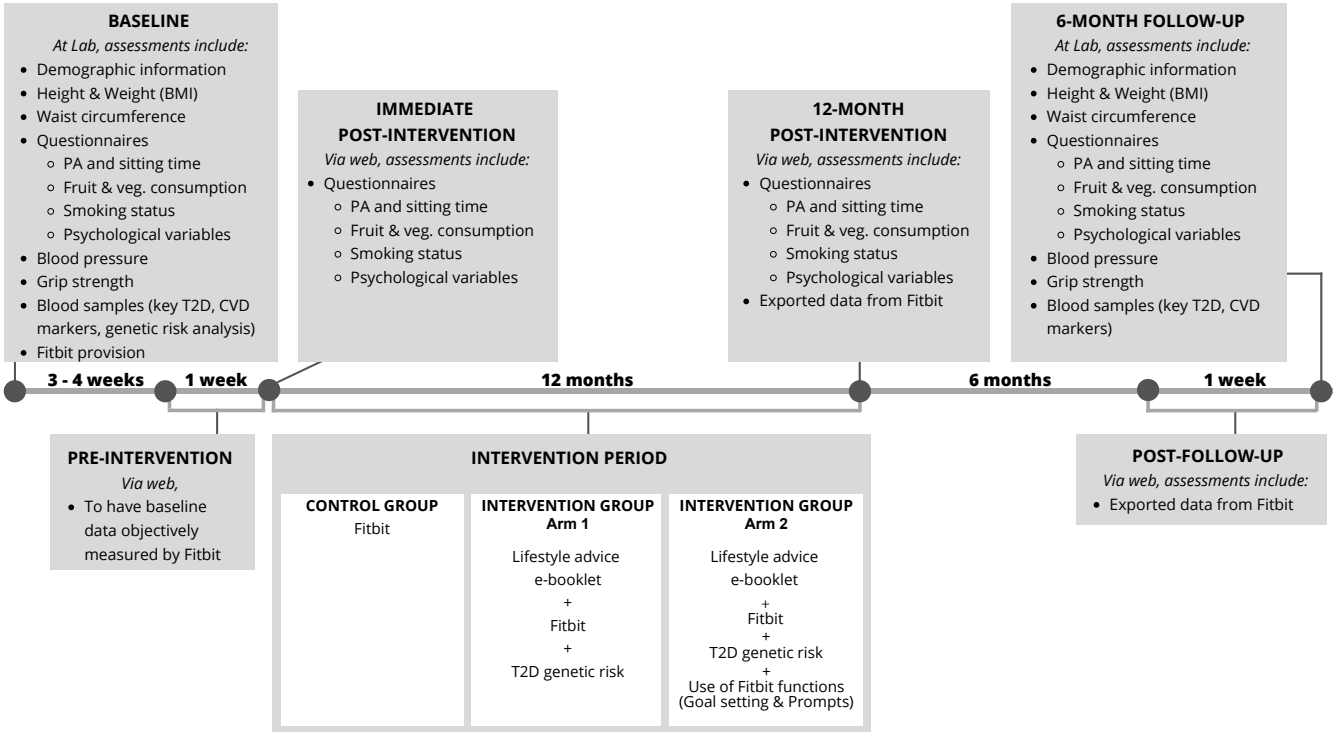

Figure 1 The overall protocol and timeline of the intervention study: genetic risk communication and wearables. Note: A sample of 355 participants are randomly assigned to one of three groups: one control and two intervention groups (arm 1 and arm 2). A control group receives a Fitbit device. Intervention group arm 1 receives an estimated genetic risk of T2D along with a general lifestyle advice e-leaflet (which includes information about the definition and health impacts of T2D and lifestyle advice on four major risk markers of T2D (eg, PA, diet, smoking, weight management) as recommended by the WHO) in addition to the Fitbit device. Intervention group arm 2 also receives a Fitbit device, but has a step goal set 10% higher than their baseline step count and uses its activity prompt functions, in addition to the genetic risk estimate and e-leaflet. BMI, body mass index; CVD, cardiovascular disease; PA, physical activity; T2D, type 2 diabetes.

METHODS

Trial design

Figure 1 shows the overall protocol of the proposed research. The proposed research is a parallel-group randomised controlled trial. A sample of 355 participants are randomly assigned to one of three groups: one control and two intervention groups (arm 1 and arm 2). A control group receives a Fitbit device. Intervention group arm 1 receives an estimated genetic risk of T2D along with a general lifestyle advice e-leaflet (which includes information about the definition and health impacts of T2D and lifestyle advice on four major risk markers of T2D (eg, PA, diet, smoking, weight management) as recommended by the WHO) in addition to the Fitbit device. Intervention group arm 2 also receives a Fitbit device, but has a Fitbit step goal set 10% higher than their baseline step count and uses its activity prompt functions, in addition to the genetic risk estimate and e-leaflet.

Study setting

This study is conducted in Hong Kong. Eligible participants are asked to visit the Exercise Physiology Laboratory at The University of Hong Kong (HKU), a sole study site of the study, for baseline and follow-up assessments. This protocol has been reported according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.[17] Study findings will be reported according to the Consolidated Standards of Reporting Trials statement.

Eligibility criteria

This trial includes individuals of East Asian ancestry aged 40–60 years who are overweight or obese (ie, measured body mass index (BMI)≥23 kg/m^2 according to the WHO BMI-defined cut-offs for Asians), and capable of performing daily-living PA, using English/Chinese and a smartphone in Hong Kong. Individuals are excluded if they 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 (https://hkuhk-my.sharepoint.com/:b:/g/personal/youngwon_hku_hk/EcSHKlEEn8hJupY3LtB8uQABvTDIC8bz3KSALNfHSVGmag?e=WBglcv), are participating in another research study or exercise programme, had experience of genetic testing and/or cannot comprehend English/Chinese (ie, sole language medium for the study).

Interventions

Genetic risk estimate

Using the EDTA blood sample collected from each participant at baseline, 420 µL of whole blood are aliquoted to

extract 10–20 ng/µL of DNA samples by the Centre for PanorOmic Sciences (CPOS) of HKU. Single-nucleotide polymorphism (SNP) genotyping is carried out by the CPOS of HKU (http://www.med.hku.hk/en/research/facilities-and-services/cpos) using the iPLEX Gold reagents on the MassARRAY System (Agena Bioscience, San Diego, California, USA).[18] We estimate remaining lifetime genetic risk and 10-year genetic risk of developing T2D for each participant by employing a series of procedures used in our previous genetic risk communication trial of Europeans[19] and similar to those used by a typical direct-to-consumer genetic testing company.[20] Briefly, each participant's remaining lifetime genetic risk of developing T2D is estimated as the product of their total genetic risk for T2D (according to their genotypes) and remaining lifetime T2D absolute risk (according to their age and sex). For example, each individual's unique total genetic risk for T2D is estimated based on the recently published SNP list (genome-wide significant at p values<5×10^{-8}) associated with T2D risk specifically for East Asians[7] as shown in online supplemental appendix 1. After consulting the CPOS, 113 SNPs (out of the list of the SNPs identified from the recent GWAS[7]) can be analysed by the MassARRAY System. Using the presented OR and allele frequency values[7] and assuming a multiplicative model, we quantify ORs and frequencies for each of three possible genotypes across all 113 SNPs. We then calculate average population risk relative to the no-risk genotype by adding the products of genotype-specific ORs and frequencies for each SNP. Genotype-specific risk in relation to the average population risk at each locus is estimated by dividing the calculated genotype-specific OR for that locus by the corresponding average population risk. Total genetic risk relative to the population for each participant is calculated as the product of 113 genotype-specific risk estimates (ie, 113 loci) according to their own genotypes at each locus. More detailed descriptions about this estimation procedure are illustrated in the supplement of our previous report.[21] The same procedure is performed to calculate 10-year genetic risk of T2D using age-specific and sex-specific 10-year T2D absolute risk (instead of remaining lifetime absolute risk). Estimation of remaining lifetime absolute risk and 10-year absolute risk for T2D is performed using competing risk models[22] based on age-specific and sex-specific diabetes incidence and non-diabetes mortality rates estimated using East Asian data from Global Burden of Disease 2019.

Individuals in both intervention groups receive a total of 52–53 weekly WhatsApp messages and 12 monthly emails containing their own T2D genetic risk estimates along with the lifestyle e-leaflet (See the examples of T2D genetic risk estimates and lifestyle e-leaflet in supplemental appendix 3 and 4). Evidence indicates that regular, repeated risk communication (once a week as opposed to one-off during the 12-month intervention period) can facilitate optimal health behavioural change and reduced common chronic disease risk.[23 24] The genetic risk report also includes a dichotomised genetic risk category: 'increased genetic risk' (if their genetic risk is higher than the average population risk) or 'no increased genetic risk' (if their genetic risk is not higher than the average population risk). The content and design of the T2D genetic risk information are presented in a manner similar to that of a typical direct-to-consumer genetic testing company which is developed by incorporating scientific literature and opinions from users, researchers and diabetes care providers regarding the most effective methods for communicating disease risk estimates.[25]

The lifestyle advice e-leaflet contains information on the definition and health impacts of T2D as well as four lifestyle-modification measures: (1) to achieve and maintain a healthy body weight, (2) to engage in at least 150 min/week of moderate-intensity aerobic PA, at least 75 min/week of vigorous-intensity aerobic PA, or an equivalent combination of both, (3) to eat at least two servings of fruit and three servings of vegetables a day and (4) to abstain from smoking. Genetic risk estimation of T2D will also be provided to participants in the control group on completion of the study.

Step goal setting and prompts

Intervention group arm 2 uses two unique Fitbit features (step goal setting and activity prompts; two of the most important theory-driven components of behavioural change within the Coventry, Aberdeen, and London—Refined framework, and most widely used psychological constructs in interventions using wearables[15 26] in addition to receipt of genetic risk estimation. Individualised daily step goals are set to be 10% higher than participants' own baseline Fitbit step counts (to be calculated as the average of the 7-day preintervention data); setting a 10% higher step goal is determined following the intervention literature using goal setting as an intervention component.[15] The 'Reminder To Move' function of Fitbit is used as a prompt to remind participants to reduce sedentary time and walk at least 250 steps/hour within a specified timeframe (ie, from 9:00 to 22:00 in the proposed research). If the user has not accumulated at least 250 steps/hour, a reminder (for example, '150 steps to go') appears on the Fitbit screen at 10 min before the hour (eg, at 10:50) and causes the device to vibrate. To ensure valid delivery of the intervention, research staff set the daily step goal for participants, and activate the 'Reminders To Move' prompt function through each participant's Fitbit Dashboard. Participants are provided information about the two Fitbit functions via WhatsApp messages. Research staff use the Fitbit Dashboard to monitor the battery life of Fitbit trackers. Reminders to charge and wear the Fitbit are sent to participants every 7 days via WhatsApp to ensure study compliance. Participants are informed that they will own the Fitbit device if they complete the full study protocol. All participation is voluntary. Participants have the right to withdraw from participation under any circumstances for any reason.

Outcomes

Primary outcomes

MVPA (sum of 'fairly active minutes' and 'very active minutes') to be measured by the Fitbit tracker serves as the primary outcome of this research. The primary outcome is assessed at baseline, immediately post intervention, 12 months post intervention and at 6-month follow-up.

Secondary outcomes

An additional five activity indicators (steps, 'sedentary minutes', 'lightly active minutes', calories burn and sleep time) from the Fitbit tracker are used as secondary outcome variables. Measured height and body weight are used to calculate participants' BMI. Systolic and diastolic blood pressure are measured using the OMRON HEM-907 Digital Automatic Blood Pressure Monitor. Hand grip strength is measured using the Jamar Hydraulic Hand Dynamometer, which has good reliability and reproducibility.[27] Blood samples are provided to an accredited medical diagnostic centre on the same day of blood collection and used to assess the five intermediate metabolic risk markers including haemoglobin A1c (HbA1c), total cholesterol, high-density lipoproteins (HDL), low-density lipoproteins (LDL) and triglycerides. The measurements of all secondary outcomes are performed at baseline, immediately post intervention, 12 months post intervention and at 6-month follow-up. We examine changes in these risk markers to gain insights into whether any potential changes in the primary activity outcomes are associated with changes in cardiometabolic risk profiles. The rest of the secondary outcomes, including self-reported PA, fruit and vegetable consumption, smoking status and a list of psychological variables (see online supplemental table 1), are assessed through the questionnaire. We include a set of established psychological variables that serve as key constructs for established behavioural theories (eg, Social Cognitive Theory, Theory of Planned Behavior), to examine not only immediate and longer-term psychological responses to genetic risk information but also the potential associations of changes in psychological constructs with changes in activity levels.

Participant timeline

See figure 2 for the flow of participants and figure 3 for schedule of enrolment, interventions and assessments.

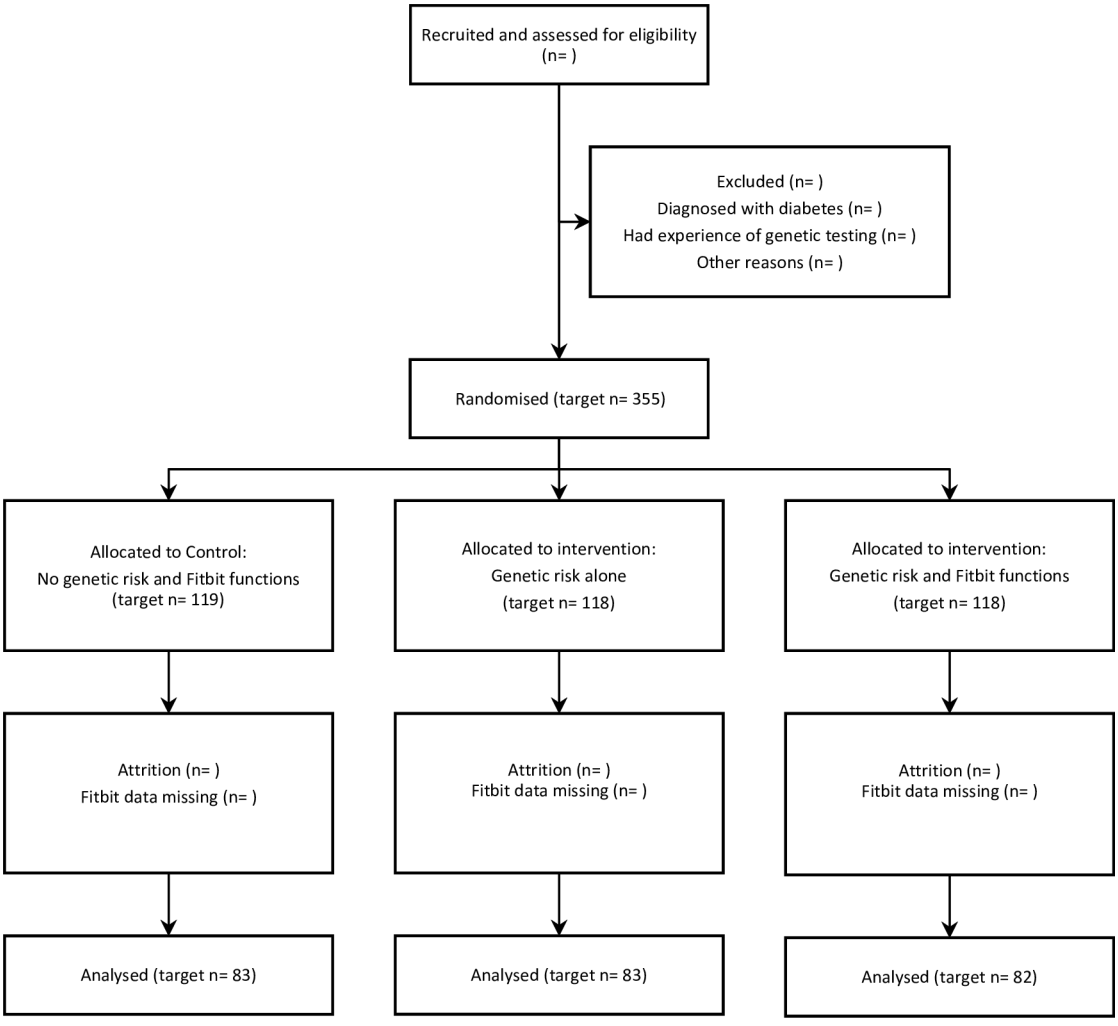

Figure 2 Flowchart of participants. Note: Since the study is ongoing at the time of writing this protocol, an updated flowchart will be published in peer-reviewed research journals once the study has concluded.

TIMEPOINT	Enrolment *Baseline*	Allocation t_0	Post-allocation t_{+12M}	Post-allocation t_{+18M}	Close-out $t_{-Endpoint}$
ENROLMENT					
Eligibility screen	√				
Informed consent	√				
1-week Pre-intervention	√				
Allocation		√			
INTERVENTIONS					
Intervention A			→	→	
Intervention B			→	→	
Control groups			→	→	
ASSESSMENTS					
Demographic information	√			√	
Height	√			√	
Weight	√			√	
Waist circumference	√			√	
Q1- Physical activity and sitting time	√	√	√	√	
Q2- Fruit & veg. consumption	√	√	√	√	
Q3- Smoking status	√	√	√	√	
Q4- Psychological variables	√	√	√	√	
Blood pressure	√			√	
Grip strength	√			√	
Blood sample	√			√	
Fitbit provision	√			√	√

Figure 3 Schedule of enrolment, interventions and assessments. Note: The trial is currently ongoing, and recruitment of participants began in November 2022. Participants will be assessed at baseline, immediately post intervention, 12 months post intervention and at 6-month follow-up. The trial will conclude in February 2025.

Sample size

We recruit a total of 355 overweight or obese East Asians (figure 2). We employ an over-sampling strategy to ensure sufficient statistical power in a subgroup analysis of overweight or obese East Asians with high genetic susceptibility to T2D (n=87; about 35% of the full sample, according to an estimated potential proportion of overweight or obese individuals with high genetic risk for T2D within a given population[28]) as well as in the full sample analysis (n=248; 87/35%). Specifically, the number of participants (n=87) needed for the subsample analysis was determined based on a desired medium effect size F of 0.3086,[29] calculated from a three-group comparison where average wearable device-measured MVPA time would be 80 min/day (along with an SD of 35 min/day per group)[30] in the control group, 85 min/day (ie, minimal changes) in the intervention group receiving genetic risk information alone and 105 min/day (ie, about 23% difference ((105–85)/85×100%) corresponding to a 23% MVPA difference in previous intervention using Fitbit functions[31] in the other intervention group receiving genetic risk information combined with the wearable functions. The sample size calculation is based on an alpha level of 5%, a power level of 80% and a correlation of 0.70 among three repeated measures. A total of 355 participants are recruited to ensure inclusion of an analysis sample of 248 (ie, 248=355–107), taking into account an expected attrition rate of 20% (n=71; 355×20%) and an expected Fitbit data-missing rate of 10% (n=36; 355×10%; eg, data

lost due to insufficient battery life, device lost, device not worn regularly).

Recruitment

Participants are recruited from the local communities of Hong Kong via flyers, word of mouth, posters, local bus advertisements, pull-up banner advertisements and emails. The study title, research question, brief information on the study protocol, participants' benefits, subject inclusion criteria, subject exclusion criteria, contact information of the research team and sign-up methods are included in the recruitment flyers, posters, local bus advertisements and emails. Flyers are distributed and posted on bulletin boards in the local communities. Advertisements will be posted on the back of local bus seats. Email advertisements are also circulated to local organisations and community centres. Interested individuals are asked to complete an online screening form.

Allocation

Sequence generation

A computer-generated list that consists of blocks of six that contain two of each of the three groups per block in a random order is generated. The randomisation list will be incorporated into a computer programme that our staff will use for enrolment and automated randomisation of participants.

Allocation concealment mechanism

Group allocation will be concealed from study staff until the 7-day preintervention period begins (for preparation of corresponding e-leaflets, genetic risk estimates and/or baseline Fitbit step goal calculations) and from participants until the interventions are delivered. Given the nature of the interventions delivered, it will be impossible for participants to be blinded to the specific intervention they receive once the initial interventions are provided; however, study staff analysing participants' deidentified data will remain blinded to participant randomisation assignment.[32]

Implementation

Before recruitment, a staff member without knowledge of participant information will create a computer-generated randomisation list. This staff member will also be responsible for enrolling participants and assigning participants to interventions.

Blinding

Given the nature of the interventions delivered, it will be impossible for participants to be blinded to the specific intervention they receive once the initial interventions are provided. However, study staff analysing participants' deidentified data will remain blinded to participant randomisation assignment. As the design is open label with only outcome assessors being blinded, unblinding will not occur.

Data collection methods

Baseline assessment

Eligible participants are invited to visit our research laboratory for baseline assessments. The baseline assessments include demographic information, standing height, body weight, blood pressure, hand grip strength and questionnaires (administered through Qualtrics). Details about the questionnaires are provided in online supplemental table 1. Three tubes of blood samples (ie, one clotted blood (5 mL per tube) and two EDTA blood (3 mL per tube)) are collected from each participant (after 8-hour fasting) by a registered nurse. The clotted blood and one of the two EDTA samples are used to derive five key biochemical markers of T2D and cardiovascular disease, including HbA1c, total cholesterol, HDL, LDL and triglycerides, by an accredited medical diagnostic centre (PHC Medical Diagnostic Centre, Hong Kong). The other EDTA blood sample is used for genomic DNA extraction by the CPOS of HKU. A Fitbit Inspire V.3 tracker is used as an objective monitoring device to assess primary activity outcomes, and given to all participants at their baseline laboratory visit with detailed instructions on proper use of the device. The Fitbit Inspire V.3 is a waterproof (to 50 m), wristband activity tracker which is equipped with a triaxial accelerometer, altimeter and optical heart rate sensor among others. It can provide various activity parameters including steps taken, minutes spent at four intensity categories (eg, sedentary, lightly active, fairly active, very active (sum of fairly active and very active minutes)), calories burn, heart rate and sleep time, and last approximately 10 days. Previous research has demonstrated acceptable validity and reliability of the device.[33] Participants are asked to record any activities performed while not wearing the device (along with the date/time and reason) on a log sheet provided. Research staff activate each Fitbit device using pairs of emails and passwords generated for each participant and have access to each participant's Fitbit web account (ie, Fitbit Dashboard) from which to extract participants' Fitbit data and activate the two Fitbit functions. Research staff also use the Fitbit Dashboard to monitor the battery life and synchronisation status of Fitbit trackers on a regular basis. Procedures on performing manual synchronisation have also been provided alongside basic instructions during baseline assessment, participants are also welcome to contact staff should any issues arise. Reminders to charge and wear the Fitbit are sent to participants every 7 days via WhatsApp to ensure study compliance. Participants are asked to wear their Fitbit for full 24 hours (including sleep and aquatic activities (except showering)) throughout the entire study period including the 7-day preintervention period; Fitbit data collected during the 7-day preintervention period serve as their baseline PA and SB data. Baseline PA and SB are determined as the average of their daily PA and SB levels, respectively, accumulated over the 7-day preintervention period. Information about the five key biochemical markers of T2D and cardiovascular disease

is sent to all participants on completion of the full study protocol.

Immediate postintervention assessment

On intervention delivery, a link to an online questionnaire (equivalent to the baseline questionnaire) is sent to participants via WhatsApp. Participants in the intervention groups are asked to complete the assessment questionnaire immediately after reading the e-leaflet materials thoroughly. A reminder message, along with the questionnaire link, is sent via WhatsApp if no response is received within 3 hours of intervention delivery.

12-month postintervention assessment

12 months post intervention, Fitbit data collected over the 12-month intervention period are extracted by research staff from each participant's Fitbit Dashboard, and participants are notified of the end of the intervention. A link to the online questionnaire (equivalent to the baseline questionnaire) is sent to participants via WhatsApp. A reminder message, along with the questionnaire link, is sent via WhatsApp if no response is received within 3 hours of questionnaire link provision.

6-month follow-up assessment

6 months post intervention, participants are invited to visit the research laboratory for a follow-up assessment (ie, same as baseline, except with two blood samples instead of three). The blood samples collected are used for analysis of the five markers of diabetes and cardiovascular disease. No genetic risk estimation is performed. Participants are reminded 7 days prior to their lab visit via WhatsApp to continue to wear the Fitbit device. Fitbit data collected over the 7-day period are used as participants' 6-month follow-up activity data. Figure 3 presents the general schedule of the intervention and assessment.

Participants are encouraged to complete the full study protocol as they can receive a series of test results, not only at baseline but also at the follow-up assessment. The tests include key diabetes and cardiovascular disease biochemical markers, grip strength, blood pressure and BMI which all help them make an informed decision of lifestyle changes. In addition, on completion of the full study protocol, participants will own the Fitbit tracker as an incentive.

Data management

Each participant is assigned a unique participant identifier number at baseline so they can be tracked without reference to personal information. All electronic records of participants' information are stored within the network drives of HKU. Hard copies of study materials are stored in locking filing cabinets in the HKU research laboratory. Only staff members of the research team have access to all study materials and data. The datasets analysed during the current study and statistical code are available from the corresponding author on reasonable request, as is the full protocol.

Statistical methods

To ensure fair randomisation between the three groups, between-group differences in the continuous and categorical variables collected at baseline will be examined using ANOVA and χ^2 tests, respectively. Primary outcome analyses will be carried out in accordance with the intention-to-treat principles, which involves analysing all participants based on their allocated treatment groups regardless of adherence or protocol deviations. A series of linear mixed effects models with fixed effects of time, group and interaction between time and group[34] will be performed, with adjustment for potential confounders including age, sex and BMI. Adjusted marginal means along with 95% CIs will be presented for comparison of differences between groups at measurement time points; results for the interaction term will also be presented, which allows for examining different patterns of differences over time between the three groups. Pairwise between-group comparisons will be performed with Bonferroni adjustment. To examine effect modification by genetic risk level, we will create two groups of genetic risk (post hoc) according to the average genetic risk estimate of the sample, and examine the intervention effects within each group of genetic risk, including those with high genetic susceptibility to T2D. Effect modification by education level (ie, colleague graduates and non-colleague graduates) will also be examined, given that the understanding and perception of genetic risk tend to vary by education level.[35] Two sets of sensitivity analyses will be performed (1) with no adjustment for confounders and (2) using an iterative Markov chain Monte Carlo multiple imputation procedure ('mice' package in R) for missing data 12 months post intervention and at follow-up (assuming missing at random) within each group; five imputations to be carried out for each missing value using sex, age, education level, body mass index, blood pressure and hand grip strength at baseline. Differences in categorical variables will be assessed using χ^2 tests. Statistical significance will be set at an alpha level of 5%. All statistical analyses will be performed using R Studio and Stata/SE V.16 (StataCorp LP, College Station, Texas, USA).

Data monitoring

We have no stopping guidelines as this trial is a low-touch, low-risk intervention involving communication of genetic risk and use of wearables.

Harms

This study does not pose any major harms to the health of the participants, given that it only examines the impacts of genetic risk communication and Fitbit functions on behavioural outcomes. However, it may be possible that some participants express discomfort, distress and/or psychological concerns on knowing about their genetic risk for T2D. To assess how psychological responses to genetic risk communication change over the course of the study, assessment questionnaires collecting information about psychological variables are administered at

all four measurement time points. Information obtained from the questionnaires will also be used to understand how changes in psychological states affect changes in PA. All participants are informed of the full scope and content of the study prior to participation, and told that they can withdraw from the study at any phase of the study without providing any reason.

Protocol amendments

The research team would inform the institutional review board of the HKU/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) regarding any modifications to the protocol that may impact the conduct of the study and potential benefits or harms of the participants. Such amendments would be approved by the HKU/HA HKW IRB prior to implementation.

Confidentiality

All study materials and records are stored securely at the study site. All electronic participant records and responses are stored within the network drives of HKU research laboratory. Hard copies of study materials are stored in locking filing cabinets in the HKU research laboratory. Only staff of this project have access to study materials and data collected and be responsible for protection of personal data during and after the study. All study materials and data will be shredded and destroyed 5 years after the completion of the study.

Ancillary and post-trial care

There is no anticipated harm for trial participation. No further ancillary and post-trial care will be provided.

Dissemination policy

We will publish findings of our trial in peer-reviewed research journals, as well as present findings at international academic conferences.

Auditing

Routine audits by the HKU/HA HKW IRB may occur to ensure compliance with the protocol of the project at our study site. The IRB may perform routine audits by a risk-based approach.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this study.

DISCUSSION

We will examine whether genetic risk communication combined with prominent wearable device functions motivates healthy behaviour more than either genetic risk communication alone in East Asians. Using a recently published list of T2D genetic variants specific for East Asians,[7] we will be able to quantify each individual's unique genetic risk of developing T2D. We will also use a widely used wearable device, Fitbit, and its functions to motivate favourable changes in PA as well as other behavioural and cardiometabolic risk markers pertaining to risk of T2D. In addition, we will examine whether or not the intervention effects are maintained over a longer-term period by including measurement at 6-month follow-up. It is possible that communicating genetic risk in combination with wearable device functions will lead to favourable changes in wearable device-measured PA and a series of secondary outcomes not only 12 months post intervention but also at 6-month follow-up.

To our knowledge, this study is the first randomised controlled trial using the combination of genetic risk communication with standard functions of wearable devices in any population. Our study employs state-of-the-art genetic risk prediction and communication with wearable devices promoting healthy behaviour through step goals and activity prompts in an East Asian population. The integrated use of individuals' own genetic makeup and wearable devices,[16] grounded on theories of behavioural change, has the potential to motivate East Asian individuals to initiate and sustain a more physically active lifestyle for prevention of T2D. In the era of precision medicine which aims to provide customised medical care to individuals according to their unique genetic profiles and lifestyle, findings from our study will shed new light on the prevention of T2D through lifestyle modification by providing novel insights into the combined use of personalised genetic risk information and emerging wearable technologies in the context of East Asia.

TRIAL STATUS

The trial is currently ongoing, and recruitment of participants began in November 2022.

DECLARATIONS

Ethics and dissemination

This study has been reviewed and approved on 4 January 2022 by the HKU/HA HKW IRB on (8 December 2022) (Ref. No.: UW 22-007).

This is a low-risk trial and will not pose any major adverse effects on participants' health. No adverse events would arise from following any one of the interventions; as such there should be no formal monitoring of adverse events. However, it may be possible for participants to exhibit some degree of discomfort, distress and/or psychological concerns regarding their genetic risk for T2D. To accommodate for this potential issue, we aim to assess participants' psychological responses to genetic risk communication via web-based questionnaires, which will be administered at all four measurement time points.

A subject information sheet and a written informed consent form will be provided to each study participant before any assessment or data collection (see online supplemental appendix 2). Our study staff will collect signed written informed consent. Participants will be provided with sufficient time to read through

both documents, and the opportunity to ask questions. In the consent form, participants will be asked whether they agree to share the data obtained by this study for any further ancillary research. Participants are informed that they can withdraw from the study at any phase of the study without providing any reason.

We plan to submit our study findings at international academic conferences and submit manuscripts of study findings to refereed research journals in the fields of epidemiology and public health.

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Contributors YK conceived the study and is responsible for the overall content as guarantor. JGG provided assistance with the conceptualisation of the study protocol. All authors contributed to establishing the design of the trial and developed the interventions and measures. YK and FLTC created the study materials. YK is responsible for implementing the protocol. MM, SLRAY and SL assisted with the statistical analysis plan. YK and FLTC drafted the manuscript. All authors contributed to the refinement of the study protocol and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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