

Hong Kong Baptist University

Informed Consent Statement

Title of study:

[A blended intervention to promote physical activity, health, and work productivity among office employees using intervention mapping: a cluster-randomized controlled trial]

NCT number:

NCT04391270

Document date:

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Principle investigator:

Dr. Gao Yang

Information

You are invited to participate in a research study. The purpose of this study is primarily to implement and evaluate a blended intervention to improve physical activity (PA), health and work productivity among office employees.

The study consists of a 3-month intervention and a 9-month follow-up. A double-blind 3-arm cluster-randomized controlled trial (RCT) will be adopted, and 33 companies will be randomly selected and assigned into three groups. All employees will be invited to participate and screened for eligibility using an online questionnaire (international physical activity questionnaire (IPAQ), short version). Those with insufficient PA (not meeting WHO recommendations: at least 150-300 minutes of moderate-intensity PA per week; or at least 75-150 minutes of vigorous-intensity PA; or a combination of moderate and vigorous intensity PA) will be included in the study. This study adopted effective theory of planned behaviour (TPB) and behavioural change techniques (BCTs) to improve participants' PA level. The primary outcome variable in this study is changes in levels of moderate to vigorous PA (objectively measured using accelerometers); secondary outcomes consist of health-related (including body weight, central adiposity, blood pressure, blood glucose, lipids, depression, anxiety, stress, and quality of life), work-related (including absenteeism and presenteeism), and theory-related variables (including intrinsic motivation, self-efficacy, intention, etc.). All participants will be evaluated and measured a total of 3 times at 1, 4 and 13 months, with the evaluation indicators shown in Table 1. The questionnaire can be completed by scanning the

QR code on the mobile phone, the physical measurement and blood tests will be conducted in your company or adjusted at your convenience (Table 1).

Table 1 Description of outcome measurements

Outcome indicator	Description of measurement	Potential consequences & countermeasures
Non-invasive		
PA	The research-grade physical activity recorder, which records only physical activity levels, does not record personal data or activity tracks. ActiGraph accelerometer, an electronic device. It will be worn on an elastic belt above the right hip of each participant when walking, doing exercise, or sitting, for seven days in a row	None
Height	Portable stadiometer	None
Weight	Tanita Body Composition Analyzer	None
% BF	Tanita Body Composition Analyzer	None
Waist circumference	Flexible meter ribbon	None
Blood pressure	Omron M6 Compact	None
Depression, anxiety, stress	Questionnaire	None
Quality of life	Questionnaire	None
Absenteeism	Records from participating companies	None
Presenteeism	Questionnaire	None
Theory-related determinants	Questionnaire	None
Invasive		
Fasting blood sugar	The four metabolic indicators will be measured using the Cobas Lipid Panel and ACCU-CHEK Performa. After a 10-hour overnight fast, a total of 100 µl fingertip blood will be collected by a registered researcher using a heparinized capillary tube (Microvette®100) for blood glucose, total cholesterol, triglyceride and high-density lipoprotein analyses.	Safe, but can be a little scary and painful. Countermeasures include: communicating in advance, offering a distraction, help them relax, and verbal encourage.
Total cholesterol		
Triglyceride		
High-density lipoprotein		

Benefits

Being physically active can not only reduce the risk of some major non-communicable diseases and death, but also prevent the development of communicable diseases, including COVID-19. It might also play a role to increase productivity at work. More than half of Hong Kong adults lack enough PA to maintain health and prevent disease. Participants have the opportunity to improve PA, health and work productivity by engaging this study. Results from the study would bridge the knowledge gap and help improve their PA levels, as well as serve as a case study for other researchers, policy makers and the public. Participants and companies in this study are likely to reap the following benefits:

Benefits to participants:

- 1) Three health measurements for free and one health tracking report (within 3 months after the third measurement);
- 2) Get HK\$ 50 coupon after each evaluation;

3) Participants who complete all the tests will have a chance to win a grand prize of HK\$1000 coupon (quota: 5 persons)

4) Participants have the opportunity to successfully improve PA, health, work productivity, job satisfaction, self-esteem and well-being by participating in this study, and it is beneficial to maintain long-term physical health.

Benefits to participating companies:

Increase employee morale; enhance employee productivity or performance; recruitment and retention tool; reduce absenteeism and presenteeism; reduce disability days or claims; reduce health care costs; enhance corporate image.

Reasonably foreseeable risks or discomforts

The intervention to the participants is overall safe. However, previous studies reported some rare consequences emerged during interventions, such as sports injury. We will monitor any consequences closely and prevent them via diverse means (e.g., to inform participants of the possible adverse consequences in advance and provide feasible and practical preventive strategies to them).

Emergency medical treatment

In the unlikely event of physical injury resulting from your participation in this study, emergency medical treatment will be provided at no cost to you. If you are injured during the study, please inform the researcher immediately. If you require additional medical treatment, you will be responsible for the cost. No other compensation will be provided if you are injured in this study.

Confidentiality

Personal data collected from this study, including your last name, contact information, company and a unique number assigned to the individual, will be used and retained by the research team until the end of the study and destroyed when no longer needed. The personal data collected will only be used by the project leader to send information related to the study. The research team will ensure that all necessary compliance measures are taken in accordance with the provisions of Hong Kong's Personal Data (Privacy) Ordinance, including access control, protection, retention and deletion of personal data. If you want to withdraw or update your personal data at any time, you can notify Sun Yan (Department of Sport, Physical Education and Health, Hong Kong Baptist University) at 19482302@life.hkbu.edu.hk

Contact

If you have questions at any time about the study or the procedures, you may contact the researcher, Miss. SUN, Yan / Dr. GAO, Yang, at Department of Sport, Physical Education,

and Health, Hong Kong Baptist University, and 5488 3327 / 3411 3082. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in this study have been violated, you may send an email to: hkbu_rec@hkbu.edu.hk or post to: Research Ethics Committee, Hong Kong Baptist University, Kowloon Tong, Hong Kong.

Participation

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you have the right to withdraw from the study at any time without any fines or loss of profit; if you decide to withdraw from the study, you can contact the researcher: Sun Yan / Gao Yang, at Department of Sport, Physical Education, and Health, Hong Kong Baptist University, the contact phone number is 5488 3327 / 3411 3082.

Your participation is important for success of the study. Thank you for your cooperation.

Consent

I have read and understand the above information. I have received a copy of this form. I agree to participate in this study.

Signature of the Subject _____ Date _____

Signature of the Investigator _____ Date _____