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Complete List of Authors:	Hui, Stanley Sai-chuen; The Chinese University of Hong Kong, Xie, Yao Jie; The Hong Kong Polytechnic University, School of Nursing Mak, Winnie ; Chinese University of Hong Kong Mo, Phoenix; The Chinese University of Hong Kong, School of Public Health
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Follow Your Virtual Trainer (FYVT): a randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

Stanley Sai-chuen Hui [1*], Yao Jie Xie [2], Winnie Wing Sze Mak [3], Phoenix Kit-han Mo [4]

1. Department of Sports Science and Physical Education, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
2. School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR
3. Department of Psychology, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
4. The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR

Email address:

Stanley Sai-chuen Hui: stanleyhui1234@gmail.com

Yao Jie Xie: yaojie.xie@gmail.com

Winnie Wing Sze Mak: wwsmak@psy.cuhk.edu.hk

Phoenix Kit-han Mo: phoenix.mo@cuhk.edu.hk

*** Corresponding Author:**

G10, Kwok Sports Building, Department of Sports Science and Physical Education,

The Chinese University of Hong Kong, Shatin, Hong Kong

Tel: (852) 3943-6081; Fax: (852) 2603-5781; Email: stanleyhui1234@gmail.com

ABSTRACT

Introduction: Hong Kong is a highly urbanized city that many people work long hours. The limited time and lack of professional instruction are the typical barriers for them to do exercise. The purpose of this study is to test the effectiveness of an information technology (IT) - based lifestyle intervention program on improving physical activity (PA) level and health status in a sample of middle-aged Hong Kong adults.

Methods and analysis: A two-arm parallel randomized controlled trial named "Follow Your Virtual Trainer (FYVT)" will be conducted among 200 physically inactive Chinese adults aged from 40 to 65 years. Those randomly allocated into intervention group will under the instruction of a web-based computer software termed "Virtual Trainer", to conduct a 3-month self-planned PA program. A serious of online seminars with healthy lifestyle information will be released to the participants biweekly among 3 months. After that, 6 months observation will be followed. Those in control group will only receive a written advice of standard PA recommendation, and the textual content of the seminars. The assessments will be implemented at baseline, 3rd, 6th, and 9th month. Primary outcome is PA measured by accelerometer and International Physical Activity Questionnaire; the second outcomes include cardio-respiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, behavior mediators, and maintenance of PA. The main effectiveness of the intervention will be assessed by linear mixed model that test the random effect of treatment on outcomes at 3rd, 6th, and 9th month.

Ethics and dissemination: This trial has been approved by the Joint Chinese University of

Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235). The study results will be presented at scientific conferences and published in peer-reviewed journals.

Trial registration: ClinicalTrials.gov; NCT02553980, September 17, 2015

Key words: Physical activity; Lifestyle; Intervention; Information technology; Randomized controlled trial; Middle-aged

Strengths and limitations of this study

- This is the first study using an online virtual training system for participants to plan and implement their own PA program for healthy lifestyle improvement.
- The IT- based lifestyle intervention is fast, inexpensive, and convenient for adults, especially those with busy work life.
- The results will provide evidences for the feasibility and effectiveness of implementing the self-planned personalized PA program through human-computer interactive system.
- The major limitation is from the self-management of IT- based training. No one monitors the participants' PA in real time, the compliance depends on the participants' willingness to some extent.

INTRODUCTION

The benefits of regular physical activity (PA) on health have been well documented. The guidelines of practicing proper amount exercise in daily life also have been released to the general public [1-4]. However, 31% of the world's population is still not physically active enough to meet the recommended minimum level of PA [5]. The pandemic of physical inactivity thereby should be a public health priority [6 7]. In Hong Kong, recent cross-sectional surveys reported as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community Fitness Survey 2012) of Hong Kong adults were not active enough to reach the guidelines [8 9]. Although the importance of PA has been widely publicized, more effort is needed to encourage regular PA participation in Hong Kong population.

Middle-aged adults, which are typically ranged from 40 to 65 years of age [10], increased dramatically in Hong Kong in recent years. The 2013 population statistics by the Census and Statistics Department of Hong Kong government reported that due to the baby boom in the 1950-60s and an influx of young immigrants during the 1970-80s, the amount of people whose age from 45 to 64 years significantly increased in recent 10 years, the proportion almost jumped by 10% from 2001 (22.0%) to 2012 (31.4%) [11]. Many health problems may occur when the middle-aged adults step into older age. The increasing health care cost and aggravating disease burden are the important challenges to an aging society.

Hong Kong is a highly urbanized city that many people work long hours daily and over the week, especially for those middle-aged adults. The limited time and lack of professional exercise instruction are always the barriers for them to participate in PA. They may be too busy to seek professional advice on how to exercise. Although it is common that exercisers

seek personal advice and instruction from personal trainers, the lack of channels and time become excuses for non-exercisers to stay in sedentary lifestyles. The question is raised accordingly that how feasible PA recommendation and constant reminding and encouragement can be easily accessible at anytime and at anywhere? With the advances in information technology (IT), the knowledge of PA can be rapidly disseminated through the Internet [12 13]. The role of "personal trainer" can also be replaced by a computer program in which guidelines and instructions for PA can be programmed into interactive software and disseminated to users via the World Wide Web. Electronic format of PA guidelines, exercise reminders, motivators, as well as immediate feedback and evaluation can be easily provided through IT. Once users obtain instant feedback of their progress and knowing their health and fitness improvement, their motivation and willingness to keep participating in PA would be strengthened. Based on these ideas and understanding, we developed a web-based computer software named "Virtual Trainer (VT)" (www.vt.hk), which several cartoon characters of trainers were designed to help the users to implement their personal PA training plans. We then designed a lifestyle intervention program named "Follow Your Virtual Trainer (FYVT)" according to the VT system, with the purpose to improve PA level and health status for middle-aged Hong Kong adults.

Aims and hypotheses

The aim of this study is to evaluate the effectiveness of an IT-based lifestyle intervention program on improving PA level and health status in a sample of middle-aged Hong Kong Chinese adults. The specific objectives include:

1) To determine the effectiveness of the FYVT program for increasing PA participation and PA level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on cardio-respiratory fitness, resting energy expenditure, body composition, blood pressure, health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role of behavior mediators in predicting behavior changes during FYVT program and their associations with outcomes; 4) To evaluate the maintenance of PA for six months during FYVT program.

Specifically, the following hypothesis will be tested:

Chinese middle-aged adults who participate in the lifestyle intervention group will have greater increase in PA and better health status at the end of the 3-month intervention and 6-month follow up than participants in the control group.

METHODS

Study design

A two-arm parallel individual level randomized controlled trial (RCT) is designed according to the CONsolidated Standards Of Reporting Trials (CONSORT) statement [14]. Participants will be randomly allocated into IT- based intervention group or control group to carry out a 3-month intensive program, with additional 6 months follow up, to see the effects of the intervention on improving PA and health status.

Ethics consideration

This study has been approved by The Joint Chinese University of Hong Kong – New

Territories East Cluster Clinical Research Ethics Committee. All participants need providing written informed consent.

Participants

The target study population will be sedentary Chinese adults who use computers and mobile apps frequently. The inclusion criteria include: 1) aged 40 to 65 years; 2) able to understand Cantonese and read Chinese; 3) self-reported inactivity (no habitual exercise experience for at least 6 months); 4) the baseline resting energy expenditure (REE) is less than 1.05 kcal·min^{-1} for men and 0.85 kcal·min^{-1} for women; 5) reachable by telephone; 6) have basic computer skills; 7) have smartphone and always surf internet (at least 4 times per week); and 8) will not leave Hong Kong for a long time (longer than 2 months) during the study period. The exclusion criteria are: 1) self-reported history of cardiovascular and pulmonary diseases, neurological disorder, musculo-skeletal disorder, and osteoarthritis; 2) receiving medically prescribed diet or PA intervention; 3) blood pressure ≥ 160/100 mmHg; 4) using of medication that may influence exercise performance; 5) for women, currently pregnant or plan to become pregnant in the next 1 years, and those receiving hormonal therapy.

We will collaborate with local NGOs in health and family service field to recruit participants via advertisements in flyers, surface mails, and bulletin boards. The interested subjects are required to fill in an assessing form for preliminary screening eligibility before baseline measurement and randomization.

Sample size and power analysis

From the behavioral risk factor survey conducted by the Department of Health of Hong Kong SAR in 2014 [15], only 37.4% of the Hong Kong adults (18-64 years) reached the PA level by WHO recommendations [16]. Bases on this proportion, a sample size of 87 is needed in each group to detect a 15% between-group difference (odds ratio: 1.83) in the proportion of participants reporting the PA that meets the WHO recommendations after 3-month intervention (control group rate 40%, intervention group rate 55%, power=80%, α=5%; with a 2 repeated measurements design). This sample size also has 85% power to detect a difference of 15% in the proportion of participants reporting an increase in high level of PA (control group rate 25%, intervention group rate 40%, power=80%, α=5%). The proportion of high level of PA estimated in the calculation is also drawn from the government survey [17]. With the consideration of 10% dropouts, the final sample size is determined as 100 for each group (87 + 87*10% = 96 ≈ 100).

Randomization, concealment and blinding

The randomization will be done on the individual level after baseline assessment. Eligible participants will be randomly assigned to lifestyle intervention group or control group with the allocation ratio of 1:1. To ensure allocation concealment, an independent statistician that not involved in recruitment and baseline assessment will conduct the randomization by computer-generated allocation sequence. Another researcher will be responsible for arranging participants to undertake their corresponding treatments, they will not be told which group is the “true” intervention group, in both group they receive some “treatments”.

Intervention

Theoretical model for behavior change

The Theory of Planned Behavior [18 19] is adopted as the theoretical basis for the behavioral intervention in the FYVY program. According to this theory model, three types of considerations guide the human behaviors: behavioral beliefs, normative beliefs, and control beliefs. The first type is beliefs on the likely consequences of the behavior, the second type is believes about the normative expectations of others, and the third one is those beliefs on the factors that may facilitate or hinder performance of the behavior [18 20]. These considerations emphasize the importance of an individual's intention to regulate their own PA and healthy lifestyle by cultivating positive attitude, subjective norms of thinking they should perform it, and believe it to be within their own control [21]. Several measures associated with this model are obtained as a matter of course in the study, including fatigue, sleep quality, quality of life, and behavior mediators.

The Virtual Trainer (VT) system

The "Virtual Trainer" (www.vt.hk), an interactive web-based computer software with the integration of the telecommunication instrument (mobile phone messages and apps), was developed by our research team in 2006 (1st version), had undergone major modification in 2010 (2nd version), and under construction of an enhanced version at present (3rd version). The VT system provides professional guidelines as well as multi-level electronic motivators for improving PA participation. It likes a traditional personal trainer, but no real physical form of trainer nor instructor is needed, which implies "Virtual Trainer". We have designed 16 cartoon characters of trainer. Users may select any one of them as their personal trainer,

they will have their own personalized web page which simulates an exercise training room (Figure 1).

The VT system can provide preliminary on-line health screening and health-related fitness assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions will be automatically generated by the VT system (Prescription Module). Moreover, to cater for individual preferences on exercise type, frequency and intensity within the context of personalize exercise prescriptions, the VT system will adopt an interactive approach to retrieve preferences from the users by a series of questions (Scheduler). The system will automatically arrange the preferences of the users, such as date and time of exercise, type and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep tracking the progress of the actual implementation of the users' exercise. Then feedback about the progress, recommendations for changes, reinforcements and other incentive messages will be generated by VT (Progress Evaluation Module). Each recommended exercise program will usually last for 2 to 4 months, then users will be asked to perform the on-line health-fitness evaluation again in order to assess the improvement on personal health and fitness. The VT system also includes the frequent and daily dissemination of short messages to participants via e-mail and sms to their mobile phone. These messages include reminder messages for exercise, incentives messages, positive reinforcement messages, as well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT system, by allowing accurate PA tracking with the integration of automatic detection and transmission of heart rate and pedometer. All these information will be updated in time through new-designed mobile Apps that transfer to online system.

Intervention procedures

Participants in intervention group will receive 3 months of intensive intervention and 6 months follow-up observation. A briefing session will be conducted at first to introduce the conception of the FYVT program, the usage of online VT system, the common types of moderate and vigorous PA, the standard duration and frequency of exercise during intervention, the measurement indicators, and other related issues to the participants. After this session, participants are required to design their own 3-month PA plan through VT system, the basic requirement is no less than twice per week, accumulated at least 150 min/week of moderate PA, or 75 min/week of vigorous PA. During these 3 months, six online seminars will be released to the participants in turn and biweekly, the private web-link of these seminars will be sent to their email box and mobile phone. We develop these psychological theme-based seminars that collaborate with clinical psychologist, public health and exercise experts, to help the participants to tackle lifestyle risk factors. The contents include introductions of what are healthy lifestyles and how to live healthier, the professional advices on how the appropriate physical activities are benefit for health, how to integrate appropriate physical activities into daily life, and the strategies for improving exercise compliance and maintenance. The seminar topics include: 1) Eat a healthy diet; 2) Keep your weight, waist, and blood pressure in check; 3) Stop smoking and cut back alcohol drinking; 4) Positive psychology on self-management; 5) Know your physical fitness; 6) More exercise, better life.

Participants randomized to the control group will only receive a written advice of the WHO recommendation of PA at baseline; and receive the text version of six seminars by email,

under the same intervals as intervention group.

Outcomes

The primary outcome is PA and the second outcomes are cardio-respiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The role of behavior mediators draw from the Theory of Planned Behavior will also be examined.

Primary outcome

PA will be measured through two ways:

1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The accelerometer can measure the frequency, duration, and intensity of PA. It records movement on the vertical and horizontal axis, and allows classification of sedentary, light, moderate, and vigorous activity levels [22]. Participants are told to wear the monitor on their right hip by an elastic belt during waking hours for 7 consecutive days, except the time when swimming or bathing. Sleep time will be recorded by a log sheet. During their wearing time, daily SMS messages will be sent to them to remind the compliance of wearing. The data contain a minimum of 10 h/day wear time and for five of the 7 days are included for analysis. Non-wear time was defined as sixty consecutive zeros (intervals of at least 60 minutes).

2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The Chinese short-form version of IPAQ [23] is used for participants to report their PA during last 7 days, across all domains of transportation, work, household tasks, and leisure time. The duration (in minutes) and frequency (days) of walking, moderate-intensity and

vigorous-intensity activity are recorded. The total metabolic equivalents (METS) by the total minutes per week in each activity are calculated, resulting in a PA estimation in MET-minutes/week, together with the evaluation for duration and frequency of activities, three levels of PA (low, moderate and high) can be classified [23].

Secondary outcomes

Cardio-respiratory fitness The maximal oxygen intake (VO_2 max in $ml \cdot min^{-1} \cdot kg^{-1}$) is used as indicator of cardio-respiratory fitness in our study. VO_2 max refers to the greatest amount of oxygen that an individual can take in from inspired air during intense or maximal exercise [24]. It is considered the best measure of cardiovascular fitness and aerobic endurance [25]. The VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a sports performance lab. Under a strict exercise protocol, participants begin the test wearing masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen intake is computed each minute as the test proceeds toward maximal effort. The highest level of oxygen consumed is recorded subsequently.

Resting energy expenditure The measurement of resting energy expenditure (REE) includes resting Oxygen consumption (VO_2 in $ml \cdot min^{-1} \cdot kg^{-1}$), kilocalorie expenditure (KCal in $KCal \cdot min^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer (Cosmed K4b2, Italy). Participants are asked to wear the anlyzer and lie on a bed for 20 min, the temperature and humidity of the lab will be adjuested to a comfortable situation. VO_2 and kilocalorie expenditure are measured breath-by-breath, the lowest continuous 10 min of metabolic values are recorded. The heart rate is meaured after 20 min rest.

Anthropometrics and body composition The measurements include weight, height, waist

circumference, hip circumference, percentage of body fat, and body mass. A trained research assistant will conduct all the measurements bases on the standard protocol [26]. All measures will be conducted twice and the mean value of two measurements is calculated. The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where appropriate. Body mass index (BMI) is calculated as weight divided by the square of height (BMI = kg/m^2). Obesity is defined as BMI ≥ 25 kg/m^2 according to the World Health Organization standard for Asian populations [27]. A bioelectrical impedance analysis [28] (Tanita, BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are calculated subsequently.

Blood pressure Blood pressure will be measured through mercury sphygmomanometer by a clinical professional staff under the guideline of standard protocol [29]. After at least five minutes sitting, measurement is taken on the right arm of the participant, an appropriately sized cuff is used. Every participant will be measured twice, and the mean of two measurements is computed.

Health related quality of life (HR-QOL) Chinese (HK) version [30] of the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is a widely used instrument to assess HR-QOL in eight dimensions [31 32]: physical functioning (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental health (MH), vitality (VT) and general health perception (GH). The eight dimension scores can be summarized into two summary scores, named, physical health summary (PCS) and mental health summary (MCS). It is an overall assessment of quality of life regarding to physical and mental health, respectively. The PCS and MCS have been identified valid and

equivalent in the Chinese population in Hong Kong [33].

Sleep quality and quantity Sleep quality will be measured by the Chinese version of the Pittsburgh Sleep Quality Index (PSQI) [34].The 19-item PSQI assesses seven dimensions of sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep disturbances, habitual sleep efficiency, use of sleep medication and daytime dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be calculated by adding the seven dimensions scores. Higher scores indicate poorer sleep quality [35]. Sleep quantity will be measured by a 7-day Daily Sleep Log [34]. Participants are asked to record their sleep status for consecutive 7 days when they wake up in the mornings. The sleep log collects information on time to go to bed, sleep onset latency, waking time in the morning, and frequency of awakenings by the corresponding four questions: 1) I went to bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night ____ times [34]. The total sleep time can thus be calculated as the interval time (minutes) between going to bed and waking up in the morning minus the time spent in falling asleep.

Fatigue The Numeric Rating Scale (NRS)-fatigue [36] is used to evaluate fatigue level. It is a scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10, which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. Higher score indicate heavier fatigue is experienced.

Maintenance of physical activity To examine the adherence of PA after the cessation of the 3-month intensive program, a self-administered questionnaire will be given to the participants at 3 and 6 months during the follow-up period. We will determine the activity

maitemnance mainly in two aspects: 1) What percentage of the participnats in the intervention group keep using online VT system to design their personal exercise plans for at least one month in the 6-month follow up period; 2) what percentage of the 24 weeks in the 6-month follow up period the participants in two groups are regularly active at a moderate intensity.

Behavior mediators The possible behavior mediators will be examined by a self-designed questionnaire that bases on Ajzen's guideline for developing a Theory of Planned Behavior questionnaire [20]. We will structure these mediator variables according to attitude, subjective norms and perceived behavioral control, to understand their intention to active participation in physical activities. A seven-point scale is used for each item in the questionnaire. Higher score indicates the higher influence of the mediator on behavioral change.

Procedure of screening eligibility, assessment, and follow up

The subjects' demographics, medical history, exercise habits, exercise eligibility (assessed by modified items from Physical Activity Readiness Questionnaire [37]), and other personal information will be collected through an assessing form during recruitment. The preliminary eligible subjects will be further invited to take the REE test and blood pressure measurement. Those fulfill our study requirements and provide the signed informed consent forms are qualified as eligible participants. They then take the baseline measurement. Since the accelerometer needs 7 days wear time, we ask the participants to wear the monitor for 7 days first, and then come to our lab again for other baseline measures. Randomization is

taken subsequently. Figure 2 demonstrates the overview of protocol procedure. The follow-up assessments will be conducted at the end of 3rd, 6th, and 9th month since the trial begins. Table 1 shows the schedule of each outcome measurement. Participants are required to wear accelerometer 7 days prior to answer the IPAQ, to ensure the time interval of PA measured by accelerometer is in accordance with the measured by IPAQ (recall last 7 days' PA).

Statistical analysis

Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who have valid baseline assessments, regardless drop out later) and the completed cases analysis (only those who participate in program for full period are involved). If the results from two analytical approaches are similar, and the dropout rate is less than 10% in two groups, ITT results will be adopted. One-way ANOVA and Pearson chi-square test are used to compare baseline differences between two groups for continuous and categorical variables, respectively. The effectiveness of the intervention will be assessed by linear mixed model that test the random effect of treatment on outcomes at 3rd, 6th, and 9th month when measured as mean, as well as testing the trend of changes by taking four measurement time points (baseline, 3rd, 6th, 9th month) as random effect in the model. Logistical regression will be used and Odds ratio (OR) is calculated to examine the effect of intervention on categorical variables. The associations between behavior mediators and changes in outcomes will be examined by multiple linear regression analysis.

DISCUSSION

Middle-aged adults often show visible signs of aging such as loss of skin elasticity and graying of the hair. The reduction in aerobic performance and decrease in maximal heart rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle age. Many health problems may occur when the middle-aged adults step into older age. As the age composition of worldwide population will alter as median ages rise and greater increase in elders [38], the increases of diseases burden and extra heavy cost for health care become a big challenge to modern society [39]. Thus, Keep an optimal health status and effectively prevent diseases in middle age are critical for healthy aging and health policy-making in an aging society, which help the population aging to be accompanied by maintaining positive social engagement and productivity, result in the sustained sense of well-being and extended period of good health for most elderly.

Most people agreed that PA is good for health but need constant reminding and encouragement. For Hong Kong middle-aged adults, the busy work and heavy burden of life make them spending less leisure time for exercise. To tackle these concerns, the FYVT program will improve the PA engagement among middle-aged adults, and constantly remind them the need and benefits of PA, as well as providing professional advice on exercise prescription and healthy lifestyle. The services provided by FYVT program have no time and venue limitations, which greatly enhances the efficiency of dissemination.

The VT system provides knowledge, skills, and online demonstration on how to perform PA effectively, and also include online health-fitness assessment and diet analysis. The VT system enable users to plan and design their individualized PA program, and be fit into a

personalized scheduler, then the system will automatically send reminding message and PA implementation to the users through smartphone apps and email. This is how the telecommunication and internet come into play. The cost is relatively low. This module enables users to plan their own physical activity program, which is a typical example of employing the Theory of Planned Behaviour [18 19].

Although there are many advantages of using an online human-computer interactive system to conduct a lifestyle intervention, our study also has inevitable limitation. Since it is a self-managed virtual training program, no one monitor the participants' PA in real time, it is a challenge to quality control, which may depend on the participants' willingness of compliance to some extent. Also, the frequency, duration and intensity of PA may be varied among participants in intervention group. But our major concern is to see whether the IT-based online system can inspire the individuals' interests in PA, and improve their positive behavior. If the effectiveness of this approach is affirmative, this virtual training model can be widely utilized and benefit more people. Thus we suggest that the rigor dosage of intervention is not a main problem, as long as the participants achieve the basic intensity of PA required in the study.

In summary, it would be an inexpensive, convenient, fast, and sustainable approach for adults, especially those with busy work life, to use an online virtual training system to plan and implement their own PA program, and comply with a healthy lifestyle. If the intervention proves to be effective it will provide scientific rationale for the implementation of the self-planned personalized PA program through human-computer interactive system.

Contributors

Study concept and design: SSH, YJX; Obtained funding: SSH, WWSM, PKM, YJX; Administrative, technical, or material support: SSH, WWSM, PKM; Drafting of the manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests

Ethics approval

The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee

Figure legends

Figure 1. Screenshots of two virtual trainer “rooms”

Figure 2. Procedure of screening eligibility, assessment, and follow up

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Table 1. Procedures of recruitment screening and outcomes measurements

Measures	Recruitment screening	Baseline	Month 3	Month 6	Month 9
Demographics	✓				
Medical history	✓				
Exercise habits	✓				
Exercise eligibility (Physical Activity Readiness Questionnaire)	✓				
Physical activity, measured by accelerometer		✓	✓		
Physical activity, measured by IPAQ		✓	✓	✓	✓
Cardio-respiratory fitness		✓	✓		
Resting energy expenditure	✓	✓	✓		
Anthropometrics		✓	✓	✓	✓
Body fat percentage		✓	✓		
Body mass		✓	✓		
Blood pressure	✓	✓	✓	✓	✓
SF-36		✓	✓	✓	✓
Sleep quality and quantity		✓	✓	✓	✓
Fatigue		✓	✓	✓	✓
Behavior mediators		✓	✓	✓	✓
Maintenance of Physical activity				✓	✓

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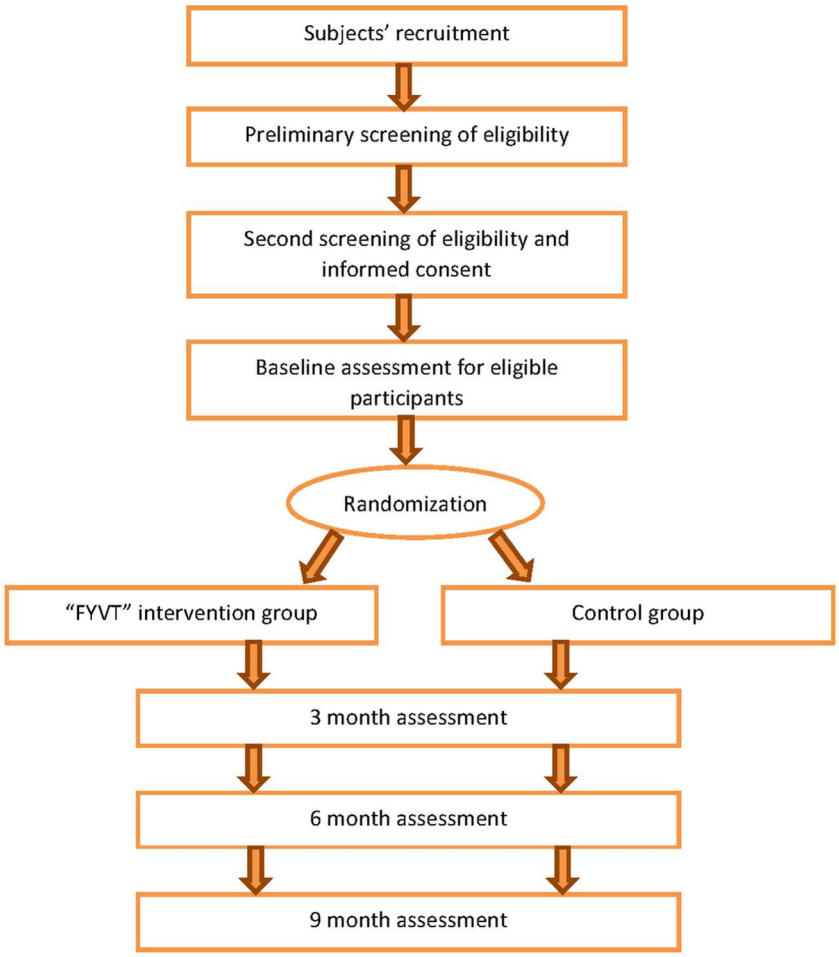
71x106mm (300 x 300 DPI)



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Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

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Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

Stanley Sai-chuen Hui [1*], Yao Jie Xie [2], Ron Chi-wai Kwok [3], Eric Wing-cheung TAM [4], Winnie Wing Sze Mak [5], Phoenix Kit-han Mo [6]

1. Department of Sports Science and Physical Education, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
2. School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR
3. Department of Information Systems, City University of Hong Kong, Kowloon, Hong Kong SAR
4. Department of Health Technology and Informatics, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR
5. Department of Psychology, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
6. The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR

Email address:

Stanley Sai-chuen Hui: stanleyhui1234@gmail.com

Yao Jie Xie: yaojie.xie@polyu.edu.hk

Ron Chi-wai Kwok： isron@cityu.edu.hk

Eric Wing-cheung TAM: hteric@polyu.edu.hk

Winnie Wing Sze Mak: wwsmak@psy.cuhk.edu.hk

Phoenix Kit-han Mo: phoenix.mo@cuhk.edu.hk

*** Corresponding Author:**

G10, Kwok Sports Building, Department of Sports Science and Physical Education,
The Chinese University of Hong Kong, Shatin, Hong Kong
Tel: (852) 3943-6081; Fax: (852) 2603-5781; Email: stanleyhui1234@gmail.com

ABSTRACT

Introduction: Hong Kong is a highly urbanized city where many people work long hours. The limited time and lack of professional instruction are the typical barriers to exercise. The purpose of this study is to test the effectiveness of an information technology (IT)-based lifestyle intervention program on improving physical activity (PA) level and health status in a sample of middle-aged Hong Kong adults.

Methods and analysis: A two-arm parallel randomized controlled trial named "Follow Your Virtual Trainer (FYVT)" will be conducted among 200 physically inactive Chinese adults aged from 40 to 65 years. Those randomly allocated to an intervention group will be under the instruction of a web-based computer software termed "Virtual Trainer" to conduct a 3-month self-planned PA program. A series of online seminars with healthy lifestyle information will be released to the participants biweekly for 3 months. After that, 6 months observation will follow. Those in the control group will only receive a written advice of standard PA recommendation and the textual content of the seminars. The assessments will be implemented at baseline, the 3rd, 6th, and 9th months. The primary outcome is PA measured by accelerometer and International Physical Activity Questionnaire. The secondary outcomes include cardiorespiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, behavior mediators, and maintenance of PA. The main effectiveness of the intervention will be assessed by a linear mixed model that tests the random effect of treatment on outcomes at the 3rd, 6th, and 9th months.

Ethics and dissemination: This trial has been approved by the Joint Chinese University of

Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235). The study results will be presented at scientific conferences and published in peer-reviewed journals.

Trial registration: Virtual Trainer System (3rd Version) for Physical Activity Promotion in Middle-aged Hong Kong Adults. ClinicalTrials.gov; NCT02553980, September 17, 2015

Key words: Physical activity; Lifestyle; Intervention; Information technology; Randomized controlled trial; Middle-aged

Strengths and limitations of this study

- This is the first study using an online virtual training system for participants to plan and implement their own PA program for healthy lifestyle improvement.
- The IT- based lifestyle intervention is fast, inexpensive, and convenient for adults, especially those with a busy work life.
- The results will provide evidence for the feasibility and effectiveness of implementing the self-planned personalized PA program through a human-computer interactive system.
- The major limitation is from the self-management of IT-based training. No one monitors the participants' PA in real time, and compliance depends on the participants' willingness to some extent.

INTRODUCTION

The benefits of regular physical activity (PA) on health are well documented. The guidelines for practicing the proper amount of exercise in daily life have also been released to the general public [1-4]. However, 31% of the world's population is still not physically active enough to meet the recommended minimum level of PA [5]. The pandemic of physical inactivity thereby should be a public health priority [6 7]. In Hong Kong, recent cross-sectional surveys reported that as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community Fitness Survey 2012) of Hong Kong adults were not active enough to reach the guidelines [8 9]. Although the importance of PA has been widely publicized, more effort is needed to encourage regular PA participation in the Hong Kong population.

Middle-aged adults, which are typically ranged from 40 to 65 years of age [10], increased dramatically in Hong Kong in recent years. The 2013 population statistics by the Census and Statistics Department of the Hong Kong government reported that due to the baby boom in the 1950s and 1960s and an influx of young immigrants during the 1970 and 1980s, a number of people whose age range from 45 to 64 years significantly increased in the recent 10 years. The proportion almost jumped by 10% from 2001 (22.0%) to 2012 (31.4%) [11]. Many health problems may occur when the middle-aged adults step into older age. The increasing health care cost and aggravating disease burden are serious challenges to an aging society. Hong Kong is a highly urbanized city where many people work long hours daily and over the week, especially these middle-aged adults. The limited time and lack of professional exercise instruction are always barriers to their participation in PA. They may be too busy to seek professional advice on how to exercise. Although it is common that exercisers seek personal

advice and instruction from personal trainers, the lack of channels and time become excuses for non-exercisers to continue their sedentary lifestyle. The question is then asked as to how feasible PA recommendation and constant reminding and encouragement can be easily accessible at any time and at anywhere. With the advances in information technology (IT), the knowledge of PA can be rapidly disseminated through the Internet [12 13]. The role of "personal trainer" can also be replaced by a computer program in which guidelines and instructions for PA can be programmed into interactive software and disseminated to users via the World Wide Web. The electronic format of PA guidelines, exercise reminders, motivators, as well as immediate feedback and evaluation can be easily provided through IT. Once users obtain instant feedback on their progress and know their health and fitness improvement, their motivation and willingness to keep participating in PA would be strengthened. Based on these ideas and understanding, we developed a web-based computer software named "Virtual Trainer (VT)" (www.vt.hk), with several cartoon characters of trainers designed to help the users to implement their personal PA training plans. We then designed a lifestyle intervention program named "Follow Your Virtual Trainer (FYVT)" according to the VT system, with the purpose of improving PA level and health status for middle-aged Hong Kong adults.

Aims and hypotheses

The aim of this study is to evaluate the effectiveness of an IT-based lifestyle intervention program on improving the PA level and health status in a sample of middle-aged Hong Kong Chinese adults. The specific objectives include:

1) To determine the effectiveness of the FYVT program for increasing PA participation and PA level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure, health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role of behavior mediators in predicting behavior changes during FYVT program and their associations with outcomes; 4) To evaluate the maintenance of PA for six months during FYVT program.

Specifically, the following hypotheses will be tested.

1) Chinese middle-aged adults who participate in the lifestyle intervention group will have a greater increase in PA than participants in the control group at the end of the 3-month intervention. 2) The participants in the intervention group will also have a higher PA level than those in the control group at the end of 6-month follow up. 3) The participants in the intervention group will have a better health status than those in the control group in terms of cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure, health-related quality of life, sleep quantity and quality, and fatigue at the end of the 3-month intervention and 6-month follow-up. 4) At least, 60% of the participants in the intervention group will keep using online VT system to design their personal exercise plans in the 6-month follow-up period.

METHODS

Study design

A two-arm parallel individual level randomized controlled trial (RCT) is designed according to

the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement [14] . Participants will be randomly allocated into IT-based intervention group or control group to carry out a 3-month intensive program, with additional 6 months follow up, to see the effects of the intervention on improving PA and health status.

Ethics consideration

This study has been approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee. All participants shall provide written informed consent to the investigators before the baseline assessment. All the data are confidential and only used for research purpose. Only the researchers who get the permission from the principal investigator have the right to access the data.

Participants

The target study population will be sedentary Chinese adults who use computers and mobile apps frequently. The inclusion criteria include: 1) aged 40 to 65 years; 2) able to understand Cantonese and read Chinese; 3) self-reported inactivity (no habitual exercise experience for at least 6 months); 4) the baseline resting energy expenditure (REE) is less than 1.05 kcal·min^{-1} for men and 0.85 kcal·min^{-1} for women; 5) reachable by telephone; 6) has basic computer skills; 7) has a smartphone and always surfs internet (at least 4 times per week); and 8) will not leave Hong Kong for a long time (longer than 2 months) during the study period. The exclusion criteria are: 1) self-reported history of cardiovascular and pulmonary diseases, neurological disorder, musculoskeletal disorder, and osteoarthritis; 2)

receiving medically prescribed diet or PA intervention; 3) blood pressure ≥ 160/100 mmHg; 4) using of medication that may influence exercise performance; 5) for women, currently pregnant or plan to become pregnant in the next 1 year, and those receiving hormonal therapy.

We will collaborate with local Non-Governmental Organizations in the health and family service fields to recruit participants via advertisements in flyers, surface mails, and bulletin boards. The interested subjects are required to fill in an assessment form for preliminary screening eligibility before baseline measurement. The form includes subjects' demographics, medical history, exercise habits, exercise eligibility (assessed by modified items from Physical Activity Readiness Questionnaire [15]), and other personal information. The preliminary eligible subjects will be further invited to take the REE test and blood pressure measurement. Those that fulfill our study requirements and provide the signed informed consent forms are qualified as eligible participants.

Sample size and power analysis

From the behavioral risk factor survey conducted by the Department of Health of Hong Kong SAR in 2014 [16], only 37.4% of Hong Kong adults (18-64 years) reached the PA level by World Health Organization (WHO) recommendations [17]. Based on this proportion, a sample size of 87 is needed in each group to detect a 15% between-group difference (odds ratio: 1.83) in the proportion of participants reporting the PA that meets the WHO recommendations after a 3-month intervention (control group rate 40%, intervention group rate 55%, power=80%, α=5%; with a 2 repeated measurements design). This sample size also has 85% power to

detect a difference of 15% in the proportion of participants reporting an increase in the high level of PA (control group rate 25%, intervention group rate 40%, power=80%, α=5%). The proportion of high level of PA estimated in the calculation is also drawn from the government survey [18]. With the consideration of 10% dropout, the final sample size is determined as 100 for each group (87 + 87*10% = 96 ≈ 100).

Randomization, concealment and blinding

The randomization will be done on the individual level after baseline assessment. Eligible participants will be randomly assigned to lifestyle intervention group or control group with the allocation ratio of 1:1. To ensure allocation concealment, an independent statistician who is not involved in recruitment and baseline assessment will conduct the randomization by computer-generated allocation sequence. Another researcher will be responsible for arranging the participants to undertake their corresponding treatments; they will not be told which group is the "true" intervention group, and in both groups they will receive some "treatments".

Intervention

Theoretical model for behavior change

The Theory of Planned Behavior [19 20] is adopted as the theoretical basis for the behavioral intervention in the FYVY program. According to this theory model, three types of considerations guide the human behaviors: behavioral beliefs, normative beliefs, and control beliefs. The first type is belief in the likely consequences of the behavior; the second type is

beliefs about the normative expectations of others, and the third one is those beliefs on the factors that may facilitate or hinder the performance of the behavior [19 21]. These considerations emphasize the importance of an individual's intention to regulate their own PA and healthy lifestyle by cultivating a positive attitude and believing it to be within their own control [22]. Several measures associated with this model are obtained as a matter of course in the study, including fatigue, sleep quality, quality of life, and behavior mediators.

The Virtual Trainer (VT) system

The "Virtual Trainer" (www.vt.hk), an interactive web-based computer software with the integration of the telecommunication instrument (mobile phone messages and apps), was developed by our research team in 2006 (1st version). It had undergone a major modification in 2010 (2nd version) and is under reconstruction for an enhanced version at present (3rd version). The VT system provides professional guidelines as well as multi-level electronic motivators for improving PA participation. It likes a traditional personal trainer, but no real physical form of trainer or instructor is needed, which implies a "Virtual Trainer". We have designed 16 cartoon characters of the trainer. Users may select any one of them as their personal trainer; they will have their own personalized web page, which simulates an exercise training room (Figure 1).

The VT system can provide preliminary online health screening and health-related fitness assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions will be automatically generated by the VT system (Prescription Module). Moreover, to cater for individual preferences on exercise type, frequency and intensity within the context of personalized exercise prescriptions, the VT system will adopt an interactive approach to

retrieve preferences from the users by a series of questions (Scheduler). The system will automatically arrange the preferences of the users, such as date and time of exercise, type and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep tracking the progress of the actual implementation of the users' exercise. Then feedback about the progress, recommendations for changes, reinforcements and other incentive messages will be generated by VT (Progress Evaluation Module). Each recommended exercise program will usually last for 2 to 4 months, then users will be asked to perform the online health-fitness evaluation again in order to assess their improvement in personal health and fitness. The VT system also includes the frequent and daily dissemination of short messages to participants via e-mail and sms to their mobile phone. These messages include reminder messages for exercise, incentive messages, positive reinforcement messages, as well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT system to allow accurate PA tracking with the integration of automatic detection and transmission of heart rate and pedometer. All this information will be updated in time through newly designed mobile Apps and transferred to an online system.

Intervention procedures

Participants in the intervention group will receive 3 months of intensive intervention and 6 months follow-up observation. A briefing session will be conducted at first to introduce the conception of the FYVT program, the usage of online VT system, the common types of moderate and vigorous PA, the standard duration and frequency of exercise during the intervention, the measurement indicators and other related issues to the participants. After this session, participants are required to design their own 3-month PA plan through a VT

system; the basic requirement is no less than twice a week, accumulated through at least 150 min/week of moderate PA or 75 min/week of vigorous PA. During these 3 months, six online seminars will be released to the participants in turn and biweekly; the private web-link of these seminars will be sent to their email box and mobile phone. We develop these psychological theme-based seminars that collaborate with a clinical psychologist as well as public health and exercise experts to help the participants to tackle lifestyle risk factors. The contents include introductions of what are healthy lifestyles and how to live healthier, the professional advice on how the appropriate physical activities are beneficial for health, how to integrate appropriate physical activities into daily life, and the strategies for improving exercise compliance and maintenance. The seminar topics include: 1) Eating a healthy diet; 2) Keeping your weight, waist, and blood pressure in check; 3) Stopping smoking and cutting back on alcohol consumption; 4) Positive psychology on self-management; 5) Knowing your physical fitness; 6) More exercise, better life. Participants randomized to the control group will only receive a written advice of the WHO recommendation of PA at baseline and receive the text version of six seminars by email, under the same intervals as the intervention group.

Outcomes

The primary outcome is PA and the secondary outcomes are cardiorespiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The role of behavior mediators draw from the Theory of Planned Behavior will also be examined.

Primary outcome

PA will be measured through two ways:

1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The accelerometer can measure the frequency, duration, and intensity of PA. It records movement on the vertical and horizontal axis and allows classification of sedentary, light, moderate, and vigorous activity levels [23]. Participants are told to wear the monitor on their right hip by an elastic belt during their waking hours for 7 consecutive days, except when swimming or bathing. Sleep time will be recorded on a log sheet. During their wearing time, daily Short Message Service (SMS) messages will be sent to them to remind them of compliance in wearing. The data contain a minimum of 10 h/day wear time and five of the 7 days are included for analysis. Non-wear time was defined as sixty consecutive zeros (intervals of at least 60 minutes).

2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The Chinese short-form version of IPAQ [24] is used for participants to report their PA during the last 7 days, across all domains of transportation, work, household tasks, and leisure time. The duration (in minutes) and frequency (days) of walking, moderate-intensity and vigorous-intensity activity are recorded. The total metabolic equivalents (METS) by the total minutes per week of each activity are calculated, resulting in a PA estimation in MET-minutes/week, together with the evaluation for duration and frequency of activities, and three levels of PA (low, moderate and high) can be classified [24].

Secondary outcomes

Cardio-respiratory fitness The maximal oxygen intake (VO_2 max in $ml \cdot min^{-1} \cdot kg^{-1}$) is used as an

indicator of cardiorespiratory fitness in our study. VO_2 max refers to the greatest amount of oxygen that an individual can take in from the inspired air during intense or maximal exercise [25]. It is considered the best measure of cardiovascular fitness and aerobic endurance [26]. The VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a sports performance lab. Under a strict exercise protocol, participants begin the test wearing masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen intake is computed each minute as the test proceeds toward the maximal effort. The highest level of oxygen consumed is recorded subsequently.

Resting energy expenditure The measurement of resting energy expenditure (REE) includes resting oxygen consumption (VO_2 in $ml \cdot min^{-1} \cdot kg^{-1}$), kilocalorie expenditure (KCal in $KCal \cdot min^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer (Cosmed K4b2, Italy). Participants are asked to wear the analyzer and lie on a bed for 20 min, the temperature and humidity of the lab will be adjusted to a comfortable situation. VO_2 and kilocalorie expenditure are measured breath-by-breath, and the lowest continuous 10 min of metabolic values are recorded. The heart rate is measured after 20 min rest.

Anthropometrics and body composition The measurements include weight, height, waist circumference, hip circumference, percentage of body fat, and body mass. A trained research assistant will conduct all the measurement bases on the standard protocol [27]. All measures will be conducted twice and the mean value of two measurements is calculated. The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where appropriate. Body mass index (BMI) is calculated as weight divided by the square of height ($BMI = kg/m^2$). Obesity is defined as BMI ≥ 25 kg/m^2 according to the World Health

Organization standard for Asian populations [28]. A bioelectrical impedance analysis [29] (Tanita, BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are calculated subsequently.

Blood pressure Blood pressure will be measured through mercury sphygmomanometer by a clinical professional staff under the guideline of standard protocol [30]. After at least five minutes sitting, measurement is taken on the right arm of the participant; an appropriately sized cuff is used. Every participant will be measured twice, and the mean of two measurements is computed.

Health related quality of life (HR-QOL) A Chinese (HK) version [31] of the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is a widely used instrument to assess HR-QOL in eight dimensions [32 33]: physical functioning (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental health (MH), vitality (VT) and general health perception (GH). The eight dimension scores can be summarized into two summary scores, namely, physical health summary (PCS) and mental health summary (MCS). It is an overall assessment of the quality of life regarding physical and mental health, respectively. The PCS and MCS have been identified as valid and equivalent in the Chinese population in Hong Kong [34].

Sleep quality and quantity Sleep quality will be measured by the Chinese version of the Pittsburgh Sleep Quality Index (PSQI) [35]. The 19-item PSQI assesses seven dimensions of sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep disturbances, habitual sleep efficiency, use of sleep medication and daytime dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be

calculated by adding the seven dimensions' scores. Higher scores indicate poorer sleep quality [36]. Sleep quantity will be measured by a 7-day Daily Sleep Log [35]. Participants are asked to record their sleep status for 7 consecutive days when they wake up in the mornings. The sleep log collects information on time to go to bed, sleep onset latency, waking time in the morning, and frequency of awakenings by the corresponding four questions: 1) I went to bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night ____ times [35]. The total sleep time can thus be calculated as the interval time (minutes) between going to bed and waking up in the morning minus the time spent in falling asleep.

Fatigue The Numeric Rating Scale (NRS)-fatigue [37] is used to evaluate fatigue level. It is a scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10, in which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. A higher score indicates that heavier fatigue is experienced.

Maintenance of physical activity To examine the maintenance of PA after the cessation of the 3-month intensive program, a self-administered questionnaire that includes IPAQ will be given to the participants at 6 and 9 months during the follow-up period. We will determine the maintenance mainly in two aspects. 1) What percentage of the participants in the intervention group keeps using online VT system to design their personal exercise plans for at least one month in the 6-month follow up period. 2) In what percentage of the 24 weeks in the 6-month follow-up period are the participants in the two groups regularly active at a moderate intensity?

Behavior mediators The possible behavior mediators will be examined by a self-designed

questionnaire (Appendix I) that is based on Ajzen's guideline for developing a Theory of Planned Behavior questionnaire [21]. We will structure these mediator variables according to attitude, subjective norms and perceived behavioral control, to understand their intention towards active participation in physical activities. A seven-point scale is used for each item in the questionnaire. A Higher score indicates the higher influence of the mediator on behavioral change.

Procedure of assessment and follow-up

After screening for eligibility, the eligible participants are required to take the baseline measurement. Since the accelerometer needs 7 days wear time, we ask the participants to wear the monitor for 7 days first, and then come to our lab again for other baseline measures. Randomization is taken subsequently. Figure 2 demonstrates the overview of protocol procedure. The follow-up assessments will be conducted at the end of the 3rd, 6th, and 9th month after the trial begins. The research assistant will regularly monitor the progress of PA of each participant through the VT system. If there is a delay or missing of PA training during the intervention period, he will send reminders to the corresponding participants through the VT system and help them to catch up on the progress. An event report sheet will be used to record the adverse events by the research assistant every two weeks. Table 1 shows the schedule of each outcome measurement. Participants are required to wear an accelerometer 7 days prior to answering the IPAQ, to ensure the time interval of PA measured by the accelerometer is in accordance with that measured by the IPAQ (recall last 7 days' PA).

Statistical analysis

Double data entry will be adopted. Multiple imputations will be used for the missing data. Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who have valid baseline assessments, regardless of whether they drop out later) and the completed case analysis (only those who participate in the program for the full period are involved). If the results from two analytical approaches are similar and the dropout rate is less than 10% in two groups, ITT results will be adopted. One-way ANOVA and Pearson chi-square test are used to compare baseline differences between two groups for continuous variables (age, METS, VO_2 max, REE, anthropometrics and body composition, blood pressure, HR-QoL, sleep quality and quantity, fatigue, and behavior mediators) and categorical variables (PA level, obesity, and categorical demographic variables), respectively. The effectiveness of the intervention will be assessed by the linear mixed model, which tests the random effect of treatment on outcomes at the 3^{rd}, 6^{th}, and 9^{th} months when measured as mean, as well as tests the trend of changes by taking four measurement time points (baseline, 3^{rd}, 6^{th}, 9^{th} months) as a random effect in the model. Logistical regression will be used and Odds ratio (OR) is calculated to examine the effect of the intervention on categorical variables. The associations between behavior mediators and changes in outcomes will be examined by multiple linear regression analysis.

DISCUSSION

Middle-aged adults often show visible signs of aging such as loss of skin elasticity and graying of the hair. The reduction in aerobic performance and decrease in maximal heart

rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle age. Many health problems may occur when the middle-aged adults step into older age. As the age composition of the worldwide population is altering as median ages rise with an increase in the number of elders [38], the increase of disease burden and extra heavy cost for health care is becoming a big challenge to modern society [39]. Thus, keeping an optimal health status and effectively preventing diseases in middle age are critical for healthy aging and health policymaking in an aging society to help the aging population to maintain positive social engagement and productivity, resulting in a sustained sense of well-being and an extended period of good health for most elderly.

Most people agree that PA is good for health but need constant reminding and encouragement. For Hong Kong middle-aged adults, the busy work schedule and heavy burden of everyday life make them have less leisure time to devote to exercise. To tackle these concerns, the FYVT program will improve the PA engagement among middle-aged adults and constantly remind them of the need and benefits of PA as well as provide professional advice on exercise prescription and healthy lifestyle. The services provided by the FYVT program has no time and venue limitations, which greatly enhances the efficiency of dissemination.

The VT system provides knowledge, skills, and online demonstration on how to perform PA effectively; it also includes online health-fitness assessment and diet analysis. The VT system enables users to plan and design their individualized PA program and fit it into a personalized scheduler; then the system will automatically send a reminder message and PA implementation to the users through smartphone apps and email. This is how

telecommunication and the internet come into play. The cost is relatively low. This module enables users to plan their own physical activity program, which is a typical example of employing the Theory of Planned Behavior [19 20].

Although there are many advantages of using an online human-computer interactive system to conduct a lifestyle intervention, our study also has inevitable limitations. Since it is a self-managed virtual training program, no one monitors the participants' PA in real time, it is a challenge to quality control, which may depend on the participants' willingness of compliance to some extent. Also, the frequency, duration and intensity of PA may be varied among participants in the intervention group. But our major concern is to see whether the IT- based online system can inspire the individuals' interests in PA and improve their positive behavior. If the effectiveness of this approach is affirmative, this virtual training model can be widely utilized and benefit more people. Thus, we suggest that the rigor dosage of intervention is not a major problem as long as the participants achieve the basic intensity of PA required in the study. Another limitation is that there might be measurement bias of some self-reporting outcomes, such as fatigue and sleep quality. But we do not think it will overturn the study results because the self-reporting biases are random in both groups.

In summary, it would be an inexpensive, convenient, fast, and sustainable approach for adults, especially those with a busy work life, to use an online virtual training system to plan and implement their own PA program and comply with a healthy lifestyle. If the intervention proves to be effective, it will provide a scientific rationale for the implementation of the self-planned personalized PA program through a human-computer interactive system.

Contributors

Study concept and design: SSH, YJX, RCK; Obtained funding: SSH, WWSM, PKM, YJX; Administrative, technical, or material support: SSH, EWT, WWSM, PKM; Drafting of the manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests

Ethics approval

The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee

Figure legends

Figure 1. Screenshots of two virtual trainer “rooms”

Figure 2. Procedure of screening eligibility, assessment, and follow up

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Table 1. Procedures of recruitment screening and outcome measurements

Measures	Recruitment screening	Baseline	Month 3	Month 6	Month 9
Demographics	✓				
Medical history	✓				
Exercise habits	✓				
Exercise eligibility (Physical Activity Readiness Questionnaire)	✓				
Physical activity, measured by accelerometer		✓	✓		
Physical activity, measured by IPAQ		✓	✓	✓	✓
Cardio-respiratory fitness		✓	✓		
Resting energy expenditure	✓	✓	✓		
Anthropometrics		✓	✓	✓	✓
Body fat percentage		✓	✓		
Body mass		✓	✓		
Blood pressure	✓	✓	✓	✓	✓
SF-36		✓	✓	✓	✓
Sleep quality and quantity		✓	✓	✓	✓
Fatigue		✓	✓	✓	✓
Behavior mediators		✓	✓	✓	✓
Maintenance of Physical activity				✓	✓

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Figure 1. Screenshots of two virtual trainer "rooms"

71x106mm (300 x 300 DPI)

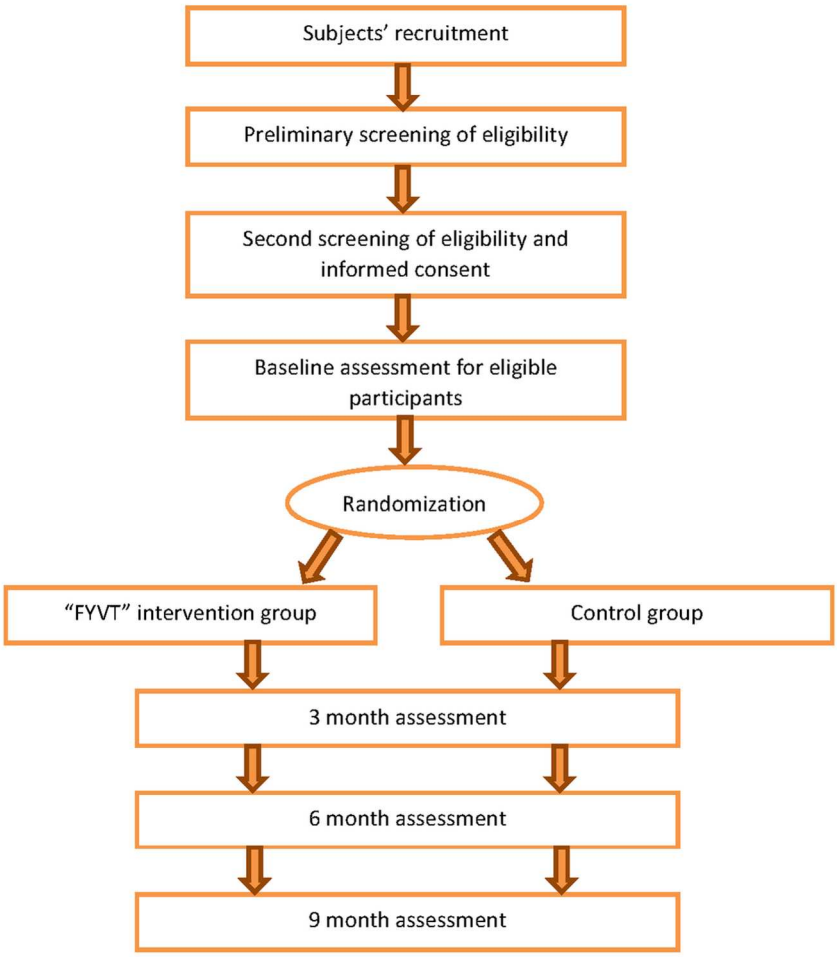

Figure 2. Procedure of screening eligibility, assessment, and follow up

111x143mm (300 x 300 DPI)

Appendix I

Behavior Mediators Questionnaire

Definition of exercise behavior: "Exercising no less than twice per week for the next three months; accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Attitude: Instrumental and experiential aspects

1. My exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity would be:

Bad 1——2——3——4—— 5——6——7 good

Perceived norm: Injunctive and descriptive aspects

2. Most people who are important to me approve of my exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Agree 1——2——3——4—— 5——6——7 disagree

3. Most people like me exercising no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Unlikely 1——2——3——4—— 5——6——7 likely

Perceived behavioral control: Capacity and autonomy aspects

4. I am confident that I can exercise no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

true 1——2——3——4—— 5——6——7 false

5. My exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity is up to me:

disagree 1——2——3——4—— 5——6——7 agree

Intention

I intend to exercise for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity

likely 1——2——3——4—— 5——6——7 unlikely

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	3	Date and version identifier	3
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 22
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8

Methods: Participants, interventions, and outcomes			Page
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12, 18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	18, 27
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9-10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA

Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	8
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix II

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

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Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

Stanley Sai-chuen Hui [1*], Yao Jie Xie [2], Ron Chi-wai Kwok [3], Eric Wing-cheung TAM [4], Winnie Wing Sze Mak [5], Phoenix Kit-han Mo [6]

1. Department of Sports Science and Physical Education, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
2. School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR
3. Department of Information Systems, City University of Hong Kong, Kowloon, Hong Kong SAR
4. Department of Health Technology and Informatics, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR
5. Department of Psychology, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR
6. The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong, Shatin, N.T., Hong Kong SAR

Email address:

Stanley Sai-chuen Hui: stanleyhui1234@gmail.com

Yao Jie Xie: yaojie.xie@polyu.edu.hk

Ron Chi-wai Kwok： isron@cityu.edu.hk

Eric Wing-cheung TAM: hteric@polyu.edu.hk

Winnie Wing Sze Mak: wwsmak@psy.cuhk.edu.hk

Phoenix Kit-han Mo: phoenix.mo@cuhk.edu.hk

*** Corresponding Author:**

G10, Kwok Sports Building, Department of Sports Science and Physical Education,
The Chinese University of Hong Kong, Shatin, Hong Kong
Tel: (852) 3943-6081; Fax: (852) 2603-5781; Email: stanleyhui1234@gmail.com

ABSTRACT

Introduction: Hong Kong is a highly urbanized city where many people work long hours. The limited time and lack of professional instruction are the typical barriers to exercise. The purpose of this study is to test the effectiveness of an information technology (IT)-based lifestyle intervention program on improving physical activity (PA) level and health status in a sample of middle-aged Hong Kong adults.

Methods and analysis: A two-arm parallel randomized controlled trial named "Follow Your Virtual Trainer (FYVT)" will be conducted among 200 physically inactive Chinese adults aged from 40 to 65 years. Those randomly allocated to an intervention group will be under the instruction of a web-based computer software termed "Virtual Trainer" to conduct a 3-month self-planned PA program. A series of online seminars with healthy lifestyle information will be released to the participants biweekly for 3 months. After that, 6 months observation will follow. Those in the control group will only receive a written advice of standard PA recommendation and the textual content of the seminars. The assessments will be implemented at baseline, the 3rd, 6th, and 9th months. The primary outcome is PA measured by accelerometer and International Physical Activity Questionnaire. The secondary outcomes include cardiorespiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, behavior mediators, and maintenance of PA. The main effectiveness of the intervention will be assessed by a linear mixed model that tests the random effect of treatment on outcomes at the 3rd, 6th, and 9th months.

Ethics and dissemination: This trial has been approved by the Joint Chinese University of

Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235). The study results will be presented at scientific conferences and published in peer-reviewed journals.

Trial registration: Virtual Trainer System (3rd Version) for Physical Activity Promotion in Middle-aged Hong Kong Adults. ClinicalTrials.gov; NCT02553980, September 17, 2015

Key words: Physical activity; Lifestyle; Intervention; Information technology; Randomized controlled trial; Middle-aged

Strengths and limitations of this study

- This is the first study using an online virtual training system for participants to plan and implement their own physical activity (PA) program for healthy lifestyle improvement.This trial will implement the self-planned personalized PA program through a human-computer interactive system. The IT- based lifestyle intervention is fast, inexpensive, flexible, and convenient for adults, especially those with a busy work life.
- The major limitation is from the self-management of IT-based training. No one monitors the participants' PA in real time. The practice compliance depends on the participants' willingness to some extent.

INTRODUCTION

The benefits of regular physical activity (PA) on health are well-documented. The guidelines for practicing the proper amount of exercise in daily life have also been released to the general public [1-4]. However, 31% of the world's population is still not physically active enough to meet the recommended minimum level of PA [5]. The pandemic of physical inactivity thereby should be a public health priority [6 7]. In Hong Kong, recent cross-sectional surveys reported that as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community Fitness Survey 2012) of Hong Kong adults were not active enough to reach the guidelines [8 9]. Although the importance of PA has been widely publicized, more effort is needed to encourage regular PA participation in the Hong Kong population.

The number of middle-aged adults, who are typically ranged from 40 to 65 years of age [10], increased dramatically in Hong Kong in recent years. The 2013 population statistics by the Census and Statistics Department of the Hong Kong Government reported that due to the baby boom in the 1950s and 1960s and an influx of young immigrants during the 1970 and 1980s, the number of people whose ages range from 45 to 64 years significantly increased in the recent 10 years. The proportion almost jumped by 10% from 2001 (22.0%) to 2012 (31.4%) [11]. Many health problems may occur when the middle-aged adults step into older age. The increasing health care cost and aggravating disease burden are serious challenges to an aging society.

Hong Kong is a highly urbanized city where many people work long hours daily and over the week, especially these middle-aged adults. The limited time and lack of professional exercise instruction are always barriers to their participation in PA. They may be too busy to seek

professional advice on how to exercise. Although it is common that exercisers seek personal advice and instruction from personal trainers, the lack of channels and time become excuses for non-exercisers to continue their sedentary lifestyle. The question is then asked as to how feasible PA recommendation and constant reminding and encouragement can be easily accessible at any time and at anywhere. With the advances in information technology (IT), the knowledge of PA can be rapidly disseminated through the Internet [12 13]. The role of "personal trainer" can also be replaced by a computer program in which guidelines and instructions for PA can be programmed into interactive software and disseminated to users via the World Wide Web. The electronic format of PA guidelines, exercise reminders, motivators, as well as immediate feedback and evaluation can be easily provided through IT. Once users obtain instant feedback on their progress and know their health and fitness improvement, their motivation and willingness to keep participating in PA would be strengthened. Based on these ideas and understanding, we developed a web-based computer software named "Virtual Trainer (VT)" (www.vt.hk), with several cartoon characters of trainers designed to help the users to implement their personal PA training plans. We then designed a lifestyle intervention program named "Follow Your Virtual Trainer (FYVT)" according to the VT system, with the purpose of improving PA level and health status for middle-aged Hong Kong adults.

Aims and hypotheses

The aim of this study is to evaluate the effectiveness of an IT-based lifestyle intervention program on improving the PA level and health status in a sample of middle-aged Hong Kong

Chinese adults. The specific objectives include:

1) To determine the effectiveness of the FYVT program for increasing PA participation and PA level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure, health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role of behavior mediators in predicting behavior changes during FYVT program and their associations with outcomes; 4) To evaluate the maintenance of PA for six months during FYVT program.

Specifically, the following hypotheses will be tested.

1) Chinese middle-aged adults who participate in the lifestyle intervention group will have a greater increase in PA than participants in the control group at the end of the 3-month intervention. 2) The participants in the intervention group will also have a higher PA level than those in the control group at the end of 6-month follow up. 3) The participants in the intervention group will have a better health status than those in the control group in terms of cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure, health-related quality of life, sleep quantity and quality, and fatigue at the end of the 3-month intervention and 6-month follow-up. 4) At least, 60% of the participants in the intervention group will keep using online VT system to design their personal exercise plans in the 6-month follow-up period.

METHODS

Study design

A two-arm parallel individual level randomized controlled trial (RCT) is designed according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement [14] . Participants will be randomly allocated into IT-based intervention group or control group to carry out a 3-month intensive program, with additional 6 months follow up, to see the effects of the intervention on improving PA and health status. **Participants**

The target study population will be sedentary Chinese adults who use computers and mobile apps frequently. The inclusion criteria include: 1) aged 40 to 65 years; 2) able to understand Cantonese and read Chinese; 3) self-reported inactivity (no habitual exercise experience for at least 6 months); 4) the baseline resting energy expenditure (REE) is less than 1.05 kcal·min^{-1} for men and 0.85 kcal·min^{-1} for women; 5) reachable by telephone; 6) has basic computer skills; 7) has a smartphone and always surfs internet (at least 4 times per week); and 8) will not leave Hong Kong for a long time (longer than 2 months) during the study period. The exclusion criteria are: 1) self-reported history of cardiovascular and pulmonary diseases, neurological disorder, musculoskeletal disorder, and osteoarthritis; 2) receiving medically prescribed diet or PA intervention; 3) blood pressure ≥ 160/100 mmHg; 4) using of medication that may influence exercise performance; 5) for women, currently pregnant or plan to become pregnant in the next 1 year, and those receiving hormonal therapy.

We will collaborate with local Non-Governmental Organizations in the health and family service fields to recruit participants via advertisements in flyers, surface mails, and bulletin boards. The interested subjects are required to fill out an assessment form for preliminary screening eligibility before baseline measurement. The form includes demographics, medical

history, exercise habits, exercise eligibility (assessed by modified items from Physical Activity Readiness Questionnaire [15]), and other personal information. The preliminary eligible subjects will be further invited to take the REE test and blood pressure measurement. Those that fulfill our study requirements and provide the signed informed consent forms are qualified as eligible participants.

Sample size and power analysis

From the behavioral risk factor survey conducted by the Department of Health of Hong Kong SAR in 2014 [16], only 37.4% of Hong Kong adults (18-64 years) reached the PA level by World Health Organization (WHO) recommendations [17]. Based on this proportion, a sample size of 87 is needed in each group to detect a 15% between-group difference (odds ratio: 1.83) in the proportion of participants reporting the PA that meets the WHO recommendations after a 3-month intervention (control group rate 40%, intervention group rate 55%, power=80%, α=5%; with a 2 repeated measurements design). This sample size also has 85% power to detect a difference of 15% in the proportion of participants reporting an increase in the high level of PA (control group rate 25%, intervention group rate 40%, power=80%, α=5%). The proportion of high level of PA estimated in the calculation is also drawn from the government survey [18]. With the consideration of 10% dropout, the final sample size is determined as 100 for each group (87 + 87*10% = 96 ≈ 100).

Randomization, concealment and blinding

The randomization will be done on the individual level after baseline assessment. Eligible

participants will be randomly assigned to lifestyle intervention group or control group with the allocation ratio of 1:1. To ensure allocation concealment, an independent statistician who is not involved in recruitment and baseline assessment will conduct the randomization by computer-generated allocation sequence. Another researcher will be responsible for arranging the participants to undertake their corresponding treatments; they will not be told which group is the "true" intervention group, and in both groups they will receive some "treatments".

Intervention

Theoretical model for behavior change

The Theory of Planned Behavior [19 20] is adopted as the theoretical basis for the behavioral intervention in the FYVY program. According to this theory model, three types of considerations guide the human behaviors: behavioral beliefs, normative beliefs, and control beliefs. The first type is belief in the likely consequences of the behavior; the second type is beliefs about the normative expectations of others, and the third one is those beliefs on the factors that may facilitate or hinder the performance of the behavior [19 21]. These considerations emphasize the importance of an individual's intention to regulate their own PA and healthy lifestyle by cultivating a positive attitude and believing it to be within their own control [22]. Several measures associated with this model are obtained as a matter of course in the study, including fatigue, sleep quality, quality of life, and behavior mediators.

The Virtual Trainer (VT) system

The "Virtual Trainer" (www.vt.hk), an interactive web-based computer software with the integration of the telecommunication instrument (mobile phone messages and apps), was developed by our research team in 2006 (1st version). It had undergone a major modification in 2010 (2nd version) and is under reconstruction for an enhanced version at present (3rd version). The VT system provides professional guidelines as well as multi-level electronic motivators for improving PA participation. It likes a traditional personal trainer, but no real physical form of trainer or instructor is needed, which implies a "Virtual Trainer". We have designed 16 cartoon characters of the trainer. Users may select any one of them as their personal trainer, and they will have their own personalized web page that simulates an exercise training room (Figure 1).

The VT system can provide preliminary online health screening and health-related fitness assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions will be automatically generated by the VT system (Prescription Module). Moreover, to cater for individual preferences on exercise type, frequency and intensity within the context of personalized exercise prescriptions, the VT system will adopt an interactive approach to retrieve preferences from the users by a series of questions (Scheduler). The system will automatically arrange the preferences of the users, such as date and time of exercise, type and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep tracking the progress of the actual implementation of the users' exercise. Then feedback about the progress, recommendations for changes, reinforcements and other incentive messages will be generated by VT (Progress Evaluation Module). Each recommended exercise program will usually last for 2 to 4 months, then users will be asked to perform the

online health-fitness evaluation again in order to assess their improvement in personal health and fitness. The VT system also includes the frequent and daily dissemination of short messages to participants via e-mail and sms to their mobile phone. These messages include reminder messages for exercise, incentive messages, positive reinforcement messages, as well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT system to allow accurate PA tracking with the integration of automatic detection and transmission of heart rate and pedometer. All this information will be updated in time through newly designed mobile Apps and transferred to an online system.

Intervention procedures

Participants in the intervention group will receive 3 months of intensive intervention and 6 months follow-up observation. A briefing session will be conducted at first to introduce the conception of the FYVT program, the usage of online VT system, the common types of moderate and vigorous PA, the standard duration and frequency of exercise during the intervention, the measurement indicators and other related issues to the participants. After this session, participants are required to design their own 3-month PA plan through a VT system; the basic requirement is no less than twice a week, accumulated through at least 150 min/week of moderate PA or 75 min/week of vigorous PA. During these 3 months, six online seminars will be released to the participants in turn and biweekly; the private web-link of these seminars will be sent to their email box and mobile phone. We develop these psychological theme-based seminars that collaborate with a clinical psychologist as well as public health and exercise experts to help the participants to tackle lifestyle risk factors. The contents include introductions of what healthy lifestyles are and how to live

healthier, the professional advice on how the appropriate physical activities are beneficial for health, how to integrate appropriate physical activities into daily life, and the strategies for improving exercise compliance and maintenance. The seminar topics include: 1) Eating a healthy diet; 2) Keeping your weight, waist, and blood pressure in check; 3) Stopping smoking and cutting back on alcohol consumption; 4) Positive psychology on self-management; 5) Knowing your physical fitness; 6) More exercise, better life. Participants randomized to the control group will only receive a written advice of the WHO recommendation of PA at baseline and receive the text version of six seminars by email, under the same intervals as the intervention group.

Outcomes

The primary outcome is PA and the secondary outcomes are cardiorespiratory fitness, resting energy expenditure, anthropometrics, body composition, blood pressure, health-related quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The role of behavior mediators draw from the Theory of Planned Behavior will also be examined.

Primary outcome

PA will be measured through two ways:

1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The accelerometer can measure the frequency, duration, and intensity of PA. It records movement on the vertical and horizontal axis and allows classification of sedentary, light, moderate, and vigorous activity levels [23]. Participants are told to wear the monitor on their right hip by an elastic belt during their waking hours for 7 consecutive days, except when

swimming or showering. Sleep time will be recorded on a log sheet. During their wearing time, daily Short Message Service (SMS) messages will be sent to them to remind them of compliance in wearing. The data contain a minimum of 10 h/day wear time and five of the 7 days are included for analysis. Non-wear time was defined as sixty consecutive zeros (intervals of at least 60 minutes).

2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The Chinese short-form version of IPAQ [24] is used for participants to report their PA during the last 7 days, across all domains of transportation, work, household tasks, and leisure time. The duration (in minutes) and frequency (days) of walking, moderate-intensity and vigorous-intensity activity are recorded. The total metabolic equivalents (METS) by the total minutes per week of each activity are calculated, resulting in a PA estimation in MET-minutes/week, together with the evaluation for duration and frequency of activities, and three levels of PA (low, moderate and high) can be classified [24].

Secondary outcomes

Cardio-respiratory fitness The maximal oxygen intake (VO_2 max in $ml \cdot min^{-1} \cdot kg^{-1}$) is used as an indicator of cardiorespiratory fitness in our study. VO_2 max refers to the greatest amount of oxygen that an individual can take in from the inspired air during intense or maximal exercise [25]. It is considered the best measure of cardiovascular fitness and aerobic endurance [26]. The VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a sports performance lab. Under a strict exercise protocol, participants begin the test wearing masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen intake is computed each minute as the test proceeds toward the maximal effort. The highest

level of oxygen consumed is recorded subsequently.

Resting energy expenditure The measurement of resting energy expenditure (REE) includes resting oxygen consumption (VO_2 in $ml \cdot min^{-1} \cdot kg^{-1}$), kilocalorie expenditure (KCal in $KCal \cdot min^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer (Cosmed K4b2, Italy). Participants are asked to wear the analyzer and lie on a bed for 20 min, the temperature and humidity of the lab will be adjusted to a comfortable situation. VO_2 and kilocalorie expenditure are measured breath-by-breath, and the lowest continuous 10 min of metabolic values are recorded. The heart rate is measured after 20 min rest.

Anthropometrics and body composition The measurements include weight, height, waist circumference, hip circumference, percentage of body fat, and body mass. A trained research assistant will conduct all the measurement bases on the standard protocol [27]. All measures will be conducted twice and the mean value of two measurements is calculated. The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where appropriate. Body mass index (BMI) is calculated as weight divided by the square of height ($BMI = kg/m^2$). Obesity is defined as $BMI \geq 25\ kg/m^2$ according to the World Health Organization standard for Asian populations [28]. A bioelectrical impedance analysis [29] (Tanita, BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are calculated subsequently.

Blood pressure Blood pressure will be measured through mercury sphygmomanometer by a clinical professional staff under the guideline of standard protocol [30]. After at least five minutes sitting, measurement is taken on the right arm of the participant; an appropriately sized cuff is used. Every participant will be measured twice, and the mean of the two

measurements is computed.

Health related quality of life (HR-QOL) A Chinese (HK) version [31] of the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is a widely used instrument to assess HR-QOL in eight dimensions [32 33]: physical functioning (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental health (MH), vitality (VT) and general health perception (GH). Two summary scores, namely, the physical health summary (PCS) and mental health summary (MCS), can be calculated from the eight dimension scores. It is an overall assessment of the quality of life in terms of physical and mental health status. The PCS and MCS have been identified as valid and equivalent in the Chinese population in Hong Kong [34].

Sleep quality and quantity Sleep quality will be measured by the Chinese version of the Pittsburgh Sleep Quality Index (PSQI) [35]. The 19-item PSQI assesses seven dimensions of sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep disturbances, habitual sleep efficiency, use of sleep medication, and daytime dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be calculated by adding the seven dimensions' scores. Higher scores indicate poorer sleep quality [36]. Sleep quantity will be measured by a 7-day Daily Sleep Log [35]. Participants are asked to record their sleep status for 7 consecutive days when they wake up in the mornings. The sleep log collects information on time to go to bed, sleep onset latency, waking time in the morning, and frequency of awakenings by the corresponding four questions: 1) I went to bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night

____ times [35]. The total sleep time can thus be calculated as the interval time (minutes) between going to bed and waking up in the morning minus the time spent in falling asleep.

Fatigue The Numeric Rating Scale (NRS)-fatigue [37] is used to evaluate fatigue level. It is a scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10, in which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. A higher score indicates that heavier fatigue is experienced.

Maintenance of physical activity To examine the maintenance of PA after the cessation of the 3-month intensive program, a self-administered questionnaire that includes IPAQ will be given to the participants at 6 and 9 months during the follow-up period. We will determine the maintenance mainly in two aspects. (1) What percentage of the participants in the intervention group keeps using online VT system to design their personal exercise plans for at least one month in the 6-month follow up period, and (2) in what percentage of the 24 weeks in the 6-month follow-up period are the participants in the two groups regularly active at a moderate intensity?

Behavior mediators The possible behavior mediators will be examined by a self-designed questionnaire (Appendix I) that is based on Ajzen's guideline for developing a Theory of Planned Behavior questionnaire [21]. We will structure these mediator variables according to attitude, subjective norms and perceived behavioral control, to understand their intention towards active participation in physical activities. A seven-point scale is used for each item in the questionnaire. A Higher score indicates the higher influence of the mediator on behavioral change.

Procedure of assessment and follow-up

After screening for eligibility, the eligible participants are required to take the baseline measurement. Since the accelerometer needs 7 days wear time, we ask the participants to wear the monitor for 7 days first, and then come to our lab again for other baseline measures. Randomization is taken subsequently. Figure 2 demonstrates the overview of protocol procedure. The follow-up assessments will be conducted at the end of the 3rd, 6th, and 9th month after the trial begins. The research assistant will regularly monitor the progress of PA of each participant through the VT system. If there is a delay or missing of PA training during the intervention period, he will send reminders to the corresponding participants through the VT system and help them to catch up on the progress. An event report sheet will be used to record the adverse events by the research assistant every two weeks. Table 1 shows the schedule of each outcome measurement. Participants are required to wear an accelerometer 7 days prior to answering the IPAQ, to ensure the time interval of PA measured by the accelerometer is in accordance with that measured by the IPAQ (recall last 7 days' PA).

Statistical analysis

Double data entry will be adopted. Multiple imputations will be used for the missing data. Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who have valid baseline assessments, regardless of whether they drop out later) and the completed case analysis (only those who participate in the program for the full period are involved). If the results from two analytical approaches are similar and the dropout rate is

less than 10% in two groups, ITT results will be adopted. One-way ANOVA and Pearson chi-square test are used to compare baseline differences between two groups for continuous variables (age, METS, VO_2 max, REE, anthropometrics and body composition, blood pressure, HR-QoL, sleep quality and quantity, fatigue, and behavior mediators) and categorical variables (PA level, obesity, and categorical demographic variables), respectively. The effectiveness of the intervention will be assessed by the linear mixed model, which tests the random effect of treatment on outcomes at the 3rd, 6th, and 9th months when measured as mean, as well as tests the trend of changes by taking four measurement time points (baseline, 3rd, 6th, 9th months) as a random effect in the model. Logistical regression will be used and Odds ratio (OR) is calculated to examine the effect of the intervention on categorical variables. The associations between behavior mediators and changes in outcomes will be examined by multiple linear regression analysis.

Ethics and dissemination

This study has been approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee. All participants shall provide written informed consent (Appendix II) to the investigators before the baseline assessment. All the data are confidential and only used for research purpose. Only the researchers who get the permission from the principal investigator have the right to access to the data. The trial was registered at http://www.clinicaltrials.gov with identification no. NCT02553980.

We will disseminate the study results by peer-reviewed publications and conference presentations according to the CONSORT statement recommendations.

DISCUSSION

Middle-aged adults often show visible signs of aging such as loss of skin elasticity and graying of the hair. The reduction in aerobic performance and decrease in maximal heart rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle age. Many health problems may occur when the middle-aged adults step into older age. As the age composition of the worldwide population is altering as median ages rise with an increase in the number of elders [38], the increase of disease burden and extra heavy cost for health care is becoming a big challenge to modern societies [39]. Thus, keeping an optimal health status and effectively preventing diseases in middle age are critical for healthy aging and health policymaking in an aging society to help the aging population to maintain positive social engagement and productivity, resulting in a sustained sense of well-being and an extended period of good health for most elderly.

Most people agree that PA is good for health but need constant reminding and encouragement. For the Hong Kong middle-aged adults, the busy work schedule and heavy burden of everyday life make them have less leisure time to devote to exercise. To tackle these concerns, the FYVT program will improve the PA engagement among middle-aged adults and constantly remind them of the need and benefits of PA as well as provide professional advice on exercise prescription and healthy lifestyle. The services provided by the FYVT program has no time and venue limitations, which greatly enhances the efficiency of dissemination.

The VT system provides knowledge, skills, and online demonstration on how to perform PA

effectively; it also includes online health-fitness assessment and diet analysis. The VT system enables users to plan and design their individualized PA program and fit it into a personalized scheduler; then the system will automatically send a reminder message and PA implementation to the users through smartphone apps and email. This is how telecommunication and the internet come into play. The cost is relatively low. This module enables users to plan their own physical activity program, which is a typical example of employing the Theory of Planned Behavior [19 20].

Although there are many advantages of using an online human-computer interactive system to conduct a lifestyle intervention, our study also has inevitable limitations. Since it is a self-managed virtual training program, no one monitors the participants' PA in real time. It is a challenge to quality control, which may depend on the participants' willingness of compliance to some extent. Also, the frequency, duration and intensity of PA may be varied among participants in the intervention group. But our major concern is to see whether the IT- based online system can inspire the individuals' interests in PA and improve their positive behavior. If the effectiveness of this approach is affirmative, this virtual training model can be widely utilized and benefit more people. Thus, we suggest that the rigor dosage of intervention is not a major problem as long as the participants achieve the basic intensity of PA required in the study. Another limitation is that there might be measurement bias of some self-reporting outcomes, such as fatigue and sleep quality. But we do not think it will overturn the study results because the self-reporting biases are random in both groups.

In summary, it would be an inexpensive, convenient, fast, and sustainable approach for adults, especially those with a busy work life, to use an online virtual training system to plan

and implement their own PA program and comply with a healthy lifestyle. If the intervention proves to be effective, it will provide a scientific rationale for the implementation of the self-planned personalized PA program through a human-computer interactive system.

Contributors

Study concept and design: SSH, YJX, RCK; Obtained funding: SSH, WWSM, PKM, YJX; Administrative, technical, or material support: SSH, EWT, WWSM, PKM; Drafting of the manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests

Ethics approval

The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee

Figure legends

Figure 1. Screenshots of two virtual trainer “rooms”

Figure 2. Procedure of screening eligibility, assessment, and follow up

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Table 1. Procedures of recruitment screening and outcome measurements

Measures	Recruitment screening	Baseline	Month 3	Month 6	Month 9
Demographics	✓				
Medical history	✓				
Exercise habits	✓				
Exercise eligibility (Physical Activity Readiness Questionnaire)	✓				
Physical activity, measured by accelerometer		✓	✓		
Physical activity, measured by IPAQ		✓	✓	✓	✓
Cardio-respiratory fitness		✓	✓		
Resting energy expenditure	✓	✓	✓		
Anthropometrics		✓	✓	✓	✓
Body fat percentage		✓	✓		
Body mass		✓	✓		
Blood pressure	✓	✓	✓	✓	✓
SF-36		✓	✓	✓	✓
Sleep quality and quantity		✓	✓	✓	✓
Fatigue		✓	✓	✓	✓
Behavior mediators		✓	✓	✓	✓
Maintenance of Physical activity				✓	✓

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Figure 1. Screenshots of two virtual trainer "rooms"

71x106mm (300 x 300 DPI)

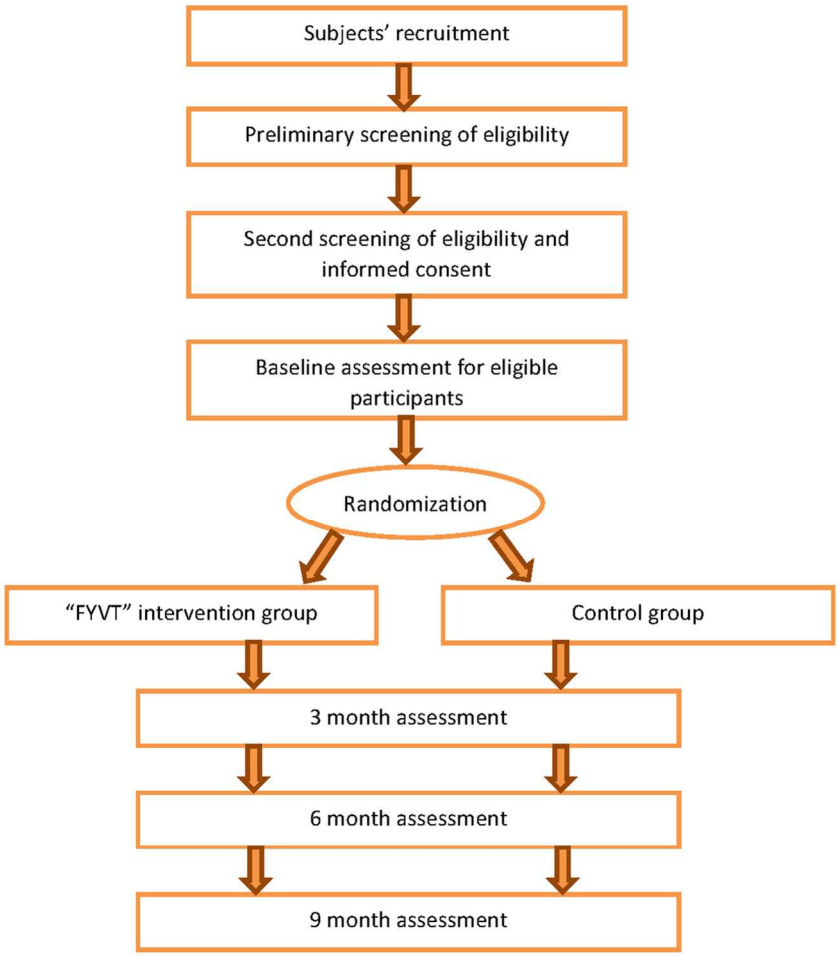

Figure 2. Procedure of screening eligibility, assessment, and follow up

111x143mm (300 x 300 DPI)

Appendix I

Behavior Mediators Questionnaire

Definition of exercise behavior: "Exercising no less than twice per week for the next three months; accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Attitude: Instrumental and experiential aspects

1. My exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity would be:

Bad 1——2——3——4—— 5——6——7 good

Perceived norm: Injunctive and descriptive aspects

2. Most people who are important to me approve of my exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Disagree 1——2——3——4—— 5——6——7 Agree

3. Most people like me exercising no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

Unlikely 1——2——3——4—— 5——6——7 Likely

Perceived behavioral control: Capacity and autonomy aspects

4. I am confident that I can exercise no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity.

True 1——2——3——4—— 5——6——7 False

5. My exercising for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity is up to me:

Disagree 1——2——3——4—— 5——6——7 Agree

Intention

I intend to exercise for no less than twice per week for the next three months, and accumulated at least 150 min/week of moderate physical activity, or 75 min/week of vigorous physical activity

Unlikely 1——2——3——4—— 5——6——7 Likely

Consent Form - FYVT

INFORM CONSENT

Research project title: Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based lifestyle intervention program to promote physical activity and health among middle-aged Hong Kong Chinese

The proposed study is a two-arm randomized controlled trial to help participants planning and implementing their own physical activity (PA) program for healthy lifestyle improvement. The participants will be randomly allocated to two groups. One group will be under the instruction of a web-based computer software to conduct a 3-month self-planned PA program. Another group will receive a written advice of standard PA recommendations, to plan their own PA program. A series of seminars with healthy lifestyle information will be released to the participants biweekly for 3 months. After that, 6 months observation will follow. The assessments will be implemented before the PA programme start, and the 3rd, 6th, and 9th months thereafter. All the measurements are non-invasive and should not result in any undue discomfort. All collected personal information will remain confidential and will be identifiable by codes only known to the researcher. The data are only used for research purpose.

I _____ hereby consent to participate in the captioned research conducted by Prof. Stanley Sai-chuen Hui.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure, contact MS. Wyinga IP about any research related questions (Tel: 39434486); and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of researcher _____

Signature of researcher _____

Date _____

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	3	Date and version identifier	3
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 22
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6
	6b	Explanation for choice of comparators	NA
Objectives	7	Specific objectives or hypotheses	6-7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8

Methods: Participants, interventions, and outcomes			Page
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	12, 18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	18, 27
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9-10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA

Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	8
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	8
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	8
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix II

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.