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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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Manuscripts

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4 1 **Follow Your Virtual Trainer (FYVT): a randomized controlled trial protocol of IT- based**
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6 2 **lifestyle intervention program to promote physical activity and health among middle-aged**
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8 3 **Hong Kong Chinese**

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29 **ABSTRACT**

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

35 **Methods and analysis:** A two-arm parallel randomized controlled trial named “Follow Your
36 Virtual Trainer (FYVT)” will be conducted among 200 physically inactive Chinese adults aged
37 from 40 to 65 years. Those randomly allocated into intervention group will under the
38 instruction of a web-based computer software termed “Virtual Trainer”, to conduct a
39 3-month self-planned PA program. A series of online seminars with healthy lifestyle
40 information will be released to the participants biweekly among 3 months. After that, 6
41 months observation will be followed. Those in control group will only receive a written
42 advice of standard PA recommendation, and the textual content of the seminars. The
43 assessments will be implemented at baseline, 3rd, 6th, and 9th month. Primary outcome is PA
44 measured by accelerometer and International Physical Activity Questionnaire; the second
45 outcomes include cardio-respiratory fitness, resting energy expenditure, anthropometrics,
46 body composition, blood pressure, health-related quality of life, sleep quality and quantity,
47 fatigue, behavior mediators, and maintenance of PA. The main effectiveness of the
48 intervention will be assessed by linear mixed model that test the random effect of treatment
49 on outcomes at 3rd, 6th, and 9th month.

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

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4 51 Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235).

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6 52 The study results will be presented at scientific conferences and published in peer-reviewed
7
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9 53 journals.

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11 54 **Trial registration:** ClinicalTrials.gov; NCT02553980, September 17, 2015
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16 56 **Key words:** Physical activity; Lifestyle; Intervention; Information technology; Randomized
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19 57 controlled trial; Middle-aged
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4 73 **Strengths and limitations of this study**
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- 6 74 • This is the first study using an online virtual training system for participants to plan
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9 75 and implement their own PA program for healthy lifestyle improvement.
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11 76 • The IT- based lifestyle intervention is fast, inexpensive, and convenient for adults,
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14 77 especially those with busy work life.
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16 78 • The results will provide evidences for the feasibility and effectiveness of
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19 79 implementing the self-planned personalized PA program through human-computer
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21 80 interactive system.
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24 81 • The major limitation is from the self-management of IT- based training. No one
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26 82 monitors the participants' PA in real time, the compliance depends on the
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29 83 participants' willingness to some extent.
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95 INTRODUCTION

96 The benefits of regular physical activity (PA) on health have been well documented. The
97 guidelines of practicing proper amount exercise in daily life also have been released to the
98 general public ¹⁻⁴. However, 31% of the world's population is still not physically active
99 enough to meet the recommended minimum level of PA ⁵. The pandemic of physical
100 inactivity thereby should be a public health priority ^{6,7}. In Hong Kong, recent cross-sectional
101 surveys reported as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community Fitness
102 Survey 2012) of Hong Kong adults were not active enough to reach the guidelines ^{8,9}.
103 Although the importance of PA has been widely publicized, more effort is needed to
104 encourage regular PA participation in Hong Kong population.
105 Middle-aged adults, which are typically ranged from 40 to 65 years of age ¹⁰, increased
106 dramatically in Hong Kong in recent years. The 2013 population statistics by the Census and
107 Statistics Department of Hong Kong government reported that due to the baby boom in the
108 1950-60s and an influx of young immigrants during the 1970-80s, the amount of people
109 whose age from 45 to 64 years significantly increased in recent 10 years, the proportion
110 almost jumped by 10% from 2001 (22.0%) to 2012 (31.4%) ¹¹. Many health problems may
111 occur when the middle-aged adults step into older age. The increasing health care cost and
112 aggravating disease burden are the important challenges to an aging society.
113 Hong Kong is a highly urbanized city that many people work long hours daily and over the
114 week, especially for those middle-aged adults. The limited time and lack of professional
115 exercise instruction are always the barriers for them to participate in PA. They may be too
116 busy to seek professional advice on how to exercise. Although it is common that exercisers

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4 117 seek personal advice and instruction from personal trainers, the lack of channels and time
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6 118 become excuses for non-exercisers to stay in sedentary lifestyles. The question is raised
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9 119 accordingly that how feasible PA recommendation and constant reminding and
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11 120 encouragement can be easily accessible at anytime and at anywhere? With the advances in
12
13 121 information technology (IT), the knowledge of PA can be rapidly disseminated through the
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15 122 Internet^{12 13}. The role of “personal trainer” can also be replaced by a computer program in
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17 123 which guidelines and instructions for PA can be programmed into interactive software and
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19 124 disseminated to users via the World Wide Web. Electronic format of PA guidelines, exercise
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21 125 reminders, motivators, as well as immediate feedback and evaluation can be easily provided
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23 126 through IT. Once users obtain instant feedback of their progress and knowing their health
24
25 127 and fitness improvement, their motivation and willingness to keep participating in PA would
26
27 128 be strengthened. Based on these ideas and understanding, we developed a web-based
28
29 129 computer software named “Virtual Trainer (VT)” (www.vt.hk), which several cartoon
30
31 130 characters of trainers were designed to help the users to implement their personal PA
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33 131 training plans. We then designed a lifestyle intervention program named “Follow Your
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35 132 Virtual Trainer (FYVT)” according to the VT system, with the purpose to improve PA level and
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37 133 health status for middle-aged Hong Kong adults.
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135 **Aims and hypotheses**

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

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4 139 1) To determine the effectiveness of the FYVT program for increasing PA participation and PA
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6 140 level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on
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8 141 cardio-respiratory fitness, resting energy expenditure, body composition, blood pressure,
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10 142 health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role
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12 143 of behavior mediators in predicting behavior changes during FYVT program and their
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14 144 associations with outcomes; 4) To evaluate the maintenance of PA for six months during
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16 145 FYVT program.

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21 146 Specifically, the following hypothesis will be tested:

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24 147 Chinese middle-aged adults who participate in the lifestyle intervention group will have
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26 148 greater increase in PA and better health status at the end of the 3-month intervention and
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28 149 6-month follow up than participants in the control group.
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32 33 34 151 **METHODS**

35 36 152 **Study design**

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39 153 A two-arm parallel individual level randomized controlled trial (RCT) is designed according to
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41 154 the CONSolidated Standards Of Reporting Trials (CONSORT) statement¹⁴. Participants will be
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43 155 randomly allocated into IT- based intervention group or control group to carry out a 3-month
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45 156 intensive program, with additional 6 months follow up, to see the effects of the intervention
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47 157 on improving PA and health status.
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51 52 53 54 159 **Ethics consideration**

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56 160 This study has been approved by The Joint Chinese University of Hong Kong – New
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4 161 Territories East Cluster Clinical Research Ethics Committee. All participants need providing
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6 162 written informed consent.
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9 163 **Participants**

10 164 The target study population will be sedentary Chinese adults who use computers and
11
12 165 mobile apps frequently. The inclusion criteria include: 1) aged 40 to 65 years; 2) able to
13
14 166 understand Cantonese and read Chinese; 3) self-reported inactivity (no habitual exercise
15
16 167 experience for at least 6 months); 4) the baseline resting energy expenditure (REE) is less
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18 168 than 1.05 kcal·min⁻¹ for men and 0.85 kcal·min⁻¹ for women; 5) reachable by telephone; 6)
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20 169 have basic computer skills; 7) have smartphone and always surf internet (at least 4 times per
21
22 170 week); and 8) will not leave Hong Kong for a long time (longer than 2 months) during the
23
24 171 study period. The exclusion criteria are: 1) self-reported history of cardiovascular and
25
26 172 pulmonary diseases, neurological disorder, musculo-skeletal disorder, and osteoarthritis; 2)
27
28 173 receiving medically prescribed diet or PA intervention; 3) blood pressure ≥ 160/100 mmHg; 4)
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30 174 using of medication that may influence exercise performance; 5) for women, currently
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32 175 pregnant or plan to become pregnant in the next 1 years, and those receiving hormonal
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34 176 therapy.
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44 177 We will collaborate with local NGOs in health and family service field to recruit participants
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46 178 via advertisements in flyers, surface mails, and bulletin boards. The interested subjects are
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48 179 required to fill in an assessing form for preliminary screening eligibility before baseline
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50 180 measurement and randomization.
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56 182 **Sample size and power analysis**

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4 183 From the behavioral risk factor survey conducted by the Department of Health of Hong Kong
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6 184 SAR in 2014¹⁵, only 37.4% of the Hong Kong adults (18-64 years) reached the PA level by
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8 185 WHO recommendations¹⁶. Bases on this proportion, a sample size of 87 is needed in each
9
10 186 group to detect a 15% between-group difference (odds ratio: 1.83) in the proportion of
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12 187 participants reporting the PA that meets the WHO recommendations after 3-month
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14 188 intervention (control group rate 40%, intervention group rate 55%, power=80%, $\alpha=5\%$; with
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16 189 a 2 repeated measurements design). This sample size also has 85% power to detect a
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18 190 difference of 15% in the proportion of participants reporting an increase in high level of PA
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20 191 (control group rate 25%, intervention group rate 40%, power=80%, $\alpha=5\%$). The proportion
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22 192 of high level of PA estimated in the calculation is also drawn from the government survey¹⁷.
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24 193 With the consideration of 10% dropouts, the final sample size is determined as 100 for each
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26 194 group ($87 + 87*10\% = 96 \approx 100$).
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36 196 **Randomization, concealment and blinding**

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38 197 The randomization will be done on the individual level after baseline assessment. Eligible
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40 198 participants will be randomly assigned to lifestyle intervention group or control group with
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42 199 the allocation ratio of 1:1. To ensure allocation concealment, an independent statistician
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44 200 that not involved in recruitment and baseline assessment will conduct the randomization by
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46 201 computer-generated allocation sequence. Another researcher will be responsible for
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48 202 arranging participants to undertake their corresponding treatments, they will not be told
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50 203 which group is the “true” intervention group, in both group they receive some “treatments”.
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4 205 **Intervention**

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6 206 ***Theoretical model for behavior change***

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8 207 The Theory of Planned Behavior^{18 19} is adopted as the theoretical basis for the behavioral
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10 208 intervention in the FYVY program. According to this theory model, three types of
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12 209 considerations guide the human behaviors: behavioral beliefs, normative beliefs, and control
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14 210 beliefs. The first type is beliefs on the likely consequences of the behavior, the second type is
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16 211 believes about the normative expectations of others, and the third one is those beliefs on
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18 212 the factors that may facilitate or hinder performance of the behavior^{18 20}. These
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20 213 considerations emphasize the importance of an individual's intention to regulate their own
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22 214 PA and healthy lifestyle by cultivating positive attitude, subjective norms of thinking they
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24 215 should perform it, and believe it to be within their own control²¹. Several measures
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26 216 associated with this model are obtained as a matter of course in the study, including fatigue,
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28 217 sleep quality, quality of life, and behavior mediators.

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36 218 ***The Virtual Trainer (VT) system***

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38 219 The "Virtual Trainer" (www.vt.hk), an interactive web-based computer software with the
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40 220 integration of the telecommunication instrument (mobile phone messages and apps), was
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42 221 developed by our research team in 2006 (1st version), had undergone major modification in
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44 222 2010 (2nd version), and under construction of an enhanced version at present (3rd version).
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46 223 The VT system provides professional guidelines as well as multi-level electronic motivators
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48 224 for improving PA participation. It likes a traditional personal trainer, but no real physical form
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50 225 of trainer nor instructor is needed, which implies "Virtual Trainer". We have designed 16
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52 226 cartoon characters of trainer. Users may select any one of them as their personal trainer,
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4 227 they will have their own personalized web page which simulates an exercise training room
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6 228 (Figure 1).
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9 229 The VT system can provide preliminary on-line health screening and health-related fitness
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11 230 assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions
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13 231 will be automatically generated by the VT system (Prescription Module). Moreover, to cater
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15 232 for individual preferences on exercise type, frequency and intensity within the context of
16
17 233 personalize exercise prescriptions, the VT system will adopt an interactive approach to
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19 234 retrieve preferences from the users by a series of questions (Scheduler). The system will
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21 235 automatically arrange the preferences of the users, such as date and time of exercise, type
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23 236 and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep
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25 237 tracking the progress of the actual implementation of the users' exercise. Then feedback
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27 238 about the progress, recommendations for changes, reinforcements and other incentive
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29 239 messages will be generated by VT (Progress Evaluation Module). Each recommended
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31 240 exercise program will usually last for 2 to 4 months, then users will be asked to perform the
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33 241 on-line health-fitness evaluation again in order to assess the improvement on personal
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35 242 health and fitness. The VT system also includes the frequent and daily dissemination of short
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37 243 messages to participants via e-mail and sms to their mobile phone. These messages include
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39 244 reminder messages for exercise, incentives messages, positive reinforcement messages, as
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41 245 well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT
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43 246 system, by allowing accurate PA tracking with the integration of automatic detection and
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45 247 transmission of heart rate and pedometer. All these information will be updated in time
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47 248 through new-designed mobile Apps that transfer to online system.
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4 249 ***Intervention procedures***
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6 250 Participants in intervention group will receive 3 months of intensive intervention and 6
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8 251 months follow-up observation. A briefing session will be conducted at first to introduce the
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10 252 conception of the FYVT program, the usage of online VT system, the common types of
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12 253 moderate and vigorous PA, the standard duration and frequency of exercise during
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14 254 intervention, the measurement indicators, and other related issues to the participants. After
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16 255 this session, participants are required to design their own 3-month PA plan through VT
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18 256 system, the basic requirement is no less than twice per week, accumulated at least
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20 257 150 min/week of moderate PA, or 75 min/week of vigorous PA. During these 3 months, six
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22 258 online seminars will be released to the participants in turn and biweekly, the private
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24 259 web-link of these seminars will be sent to their email box and mobile phone. We develop
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26 260 these psychological theme-based seminars that collaborate with clinical psychologist, public
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28 261 health and exercise experts, to help the participants to tackle lifestyle risk factors. The
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30 262 contents include introductions of what are healthy lifestyles and how to live healthier, the
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32 263 professional advices on how the appropriate physical activities are benefit for health, how to
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34 264 integrate appropriate physical activities into daily life, and the strategies for improving
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36 265 exercise compliance and maintenance. The seminar topics include: 1) Eat a healthy diet; 2)
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38 266 Keep your weight, waist, and blood pressure in check; 3) Stop smoking and cut back alcohol
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40 267 drinking; 4) Positive psychology on self-management; 5) Know your physical fitness; 6) More
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42 268 exercise, better life.
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53 269 Participants randomized to the control group will only receive a written advice of the WHO
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55 270 recommendation of PA at baseline; and receive the text version of six seminars by email,
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4 271 under the same intervals as intervention group.

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9 273 **Outcomes**

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11 274 The primary outcome is PA and the second outcomes are cardio-respiratory fitness, resting

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13 275 energy expenditure, anthropometrics, body composition, blood pressure, health-related

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15 276 quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The role of

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17 277 behavior mediators draw from the Theory of Planned Behavior will also be examined.

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21 278 **Primary outcome**

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24 279 PA will be measured through two ways:

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26 280 1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The

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28 281 accelerometer can measure the frequency, duration, and intensity of PA. It records

29
30 282 movement on the vertical and horizontal axis, and allows classification of sedentary, light,

31
32 283 moderate, and vigorous activity levels²². Participants are told to wear the monitor on their

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34 284 right hip by an elastic belt during waking hours for 7 consecutive days, except the time when

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36 285 swimming or bathing. Sleep time will be recorded by a log sheet. During their wearing time,

37
38 286 daily SMS messages will be sent to them to remind the compliance of wearing. The data

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40 287 contain a minimum of 10 h/day wear time and for five of the 7 days are included for analysis.

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42 288 Non-wear time was defined as sixty consecutive zeros (intervals of at least 60 minutes).

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44 289 2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The

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46 290 Chinese short-form version of IPAQ²³ is used for participants to report their PA during last 7

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48 291 days, across all domains of transportation, work, household tasks, and leisure time. The

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50 292 duration (in minutes) and frequency (days) of walking, moderate-intensity and

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4 293 vigorous-intensity activity are recorded. The total metabolic equivalents (METS) by the total
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6 294 minutes per week in each activity are calculated, resulting in a PA estimation in
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8 295 MET-minutes/week, together with the evaluation for duration and frequency of activities,
9
10 296 three levels of PA (low, moderate and high) can be classified²³.

14 297 **Secondary outcomes**

16 298 **Cardio-respiratory fitness** The maximal oxygen intake (VO_2 max in $ml \cdot min^{-1} \cdot kg^{-1}$) is used as
17
18 299 indicator of cardio-respiratory fitness in our study. VO_2 max refers to the greatest amount of
19
20 300 oxygen that an individual can take in from inspired air during intense or maximal exercise
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22 301²⁴. It is considered the best measure of cardiovascular fitness and aerobic endurance²⁵. The
23
24 302 VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a
25
26 303 sports performance lab. Under a strict exercise protocol, participants begin the test wearing
27
28 304 masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen
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30 305 intake is computed each minute as the test proceeds toward maximal effort. The highest
31
32 306 level of oxygen consumed is recorded subsequently.

33
34 307 **Resting energy expenditure** The measurement of resting energy expenditure (REE) includes
35
36 308 resting Oxygen consumption (VO_2 in $ml \cdot min^{-1} \cdot kg^{-1}$), kilocalorie expenditure (KCal in
37
38 309 KCal $\cdot min^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer
39
40 310 (Cosmed K4b2, Italy). Participants are asked to wear the analyzer and lie on a bed for 20 min,
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42 311 the temperature and humidity of the lab will be adjusted to a comfortable situation. VO_2
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44 312 and kilocalorie expenditure are measured breath-by-breath, the lowest continuous
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46 313 10 min of metabolic values are recorded. The heart rate is measured after 20 min rest.

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48 314 **Anthropometrics and body composition** The measurements include weight, height, waist
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4 315 circumference, hip circumference, percentage of body fat, and body mass. A trained
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6 316 research assistant will conduct all the measurements bases on the standard protocol ²⁶. All
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9 317 measures will be conducted twice and the mean value of two measurements is calculated.
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11 318 The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where
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13 319 appropriate. Body mass index (BMI) is calculated as weight divided by the square of height
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15 320 (BMI = kg/m²). Obesity is defined as BMI ≥ 25 kg/m² according to the World Health
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18 321 Organization standard for Asian populations ²⁷. A bioelectrical impedance analysis ²⁸ (Tanita,
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21 322 BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are
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24 323 calculated subsequently.
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26 324 **Blood pressure** Blood pressure will be measured through mercury sphygmomanometer by a
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29 325 clinical professional staff under the guideline of standard protocol ²⁹. After at least five
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31 326 minutes sitting, measurement is taken on the right arm of the participant, an appropriately
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34 327 sized cuff is used. Every participant will be measured twice, and the mean of two
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37 328 measurements is computed.
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39 329 **Health related quality of life (HR-QOL)** Chinese (HK) version ³⁰ of the Medical Outcomes
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41 330 Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is
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44 331 a widely used instrument to assess HR-QOL in eight dimensions ^{31 32}: physical functioning
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46 332 (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental
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49 333 health (MH), vitality (VT) and general health perception (GH). The eight dimension scores
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52 334 can be summarized into two summary scores, named, physical health summary (PCS) and
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55 335 mental health summary (MCS). It is an overall assessment of quality of life regarding to
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58 336 physical and mental health, respectively. The PCS and MCS have been identified valid and
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337 equivalent in the Chinese population in Hong Kong³³.

338 **Sleep quality and quantity** Sleep quality will be measured by the Chinese version of the

339 Pittsburgh Sleep Quality Index (PSQI)³⁴. The 19-item PSQI assesses seven dimensions of

340 sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep

341 disturbances, habitual sleep efficiency, use of sleep medication and daytime

342 dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be

343 calculated by adding the seven dimensions scores. Higher scores indicate poorer sleep

344 quality³⁵. Sleep quantity will be measured by a 7-day Daily Sleep Log³⁴. Participants are

345 asked to record their sleep status for consecutive 7 days when they wake up in the mornings.

346 The sleep log collects information on time to go to bed, sleep onset latency, waking time in

347 the morning, and frequency of awakenings by the corresponding four questions: 1) I went to

348 bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday

349 evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night

350 ____ times³⁴. The total sleep time can thus be calculated as the interval time (minutes)

351 between going to bed and waking up in the morning minus the time spent in falling asleep.

352 **Fatigue** The Numeric Rating Scale (NRS)-fatigue³⁶ is used to evaluate fatigue level. It is a

353 scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10,

354 which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. Higher

355 score indicate heavier fatigue is experienced.

356 **Maintenance of physical activity** To examine the adherence of PA after the cessation of the

357 3-month intensive program, a self-administered questionnaire will be given to the

358 participants at 3 and 6 months during the follow-up period. We will determine the activity

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4 359 maintenance mainly in two aspects: 1) What percentage of the participants in the
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6 360 intervention group keep using online VT system to design their personal exercise plans for at
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8 361 least one month in the 6-month follow up period; 2) what percentage of the 24 weeks in the
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10 362 6-month follow up period the participants in two groups are regularly active at a moderate
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12 363 intensity.

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16 364 **Behavior mediators** The possible behavior mediators will be examined by a self-designed
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18 365 questionnaire that bases on Ajzen's guideline for developing a Theory of Planned Behavior
19
20 366 questionnaire²⁰. We will structure these mediator variables according to attitude,
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22 367 subjective norms and perceived behavioral control, to understand their intention to active
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24 368 participation in physical activities. A seven-point scale is used for each item in the
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26 369 questionnaire. Higher score indicates the higher influence of the mediator on behavioral
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28 370 change.

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35 36 372 **Procedure of screening eligibility, assessment, and follow up**

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38 373 The subjects' demographics, medical history, exercise habits, exercise eligibility (assessed by
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40 374 modified items from Physical Activity Readiness Questionnaire³⁷), and other personal
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42 375 information will be collected through an assessing form during recruitment. The preliminary
43
44 376 eligible subjects will be further invited to take the REE test and blood pressure measurement.
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46 377 Those fulfill our study requirements and provide the signed informed consent forms are
47
48 378 qualified as eligible participants. They then take the baseline measurement. Since the
49
50 379 accelerometer needs 7 days wear time, we ask the participants to wear the monitor for 7
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52 380 days first, and then come to our lab again for other baseline measures. Randomization is
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4 381 taken subsequently. Figure 2 demonstrates the overview of protocol procedure. The
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6 382 follow-up assessments will be conducted at the end of 3rd, 6th, and 9th month since the trial
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9 383 begins. Table 1 shows the schedule of each outcome measurement. Participants are
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11 384 required to wear accelerometer 7 days prior to answer the IPAQ, to ensure the time interval
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13 385 of PA measured by accelerometer is in accordance with the measured by IPAQ (recall last 7
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15 386 days' PA).
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20 21 388 **Statistical analysis**

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24 389 Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who
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26 390 have valid baseline assessments, regardless drop out later) and the completed cases analysis
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29 391 (only those who participate in program for full period are involved). If the results from two
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31 392 analytical approaches are similar, and the dropout rate is less than 10% in two groups, ITT
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33 393 results will be adopted. One-way ANOVA and Pearson chi-square test are used to compare
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35 394 baseline differences between two groups for continuous and categorical variables,
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37 395 respectively. The effectiveness of the intervention will be assessed by linear mixed model
38
39 396 that test the random effect of treatment on outcomes at 3rd, 6th, and 9th month when
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41 397 measured as mean, as well as testing the trend of changes by taking four measurement time
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43 398 points (baseline, 3rd, 6th, 9th month) as random effect in the model. Logistical regression will
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45 399 be used and Odds ratio (OR) is calculated to examine the effect of intervention on
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47 400 categorical variables. The associations between behavior mediators and changes in
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49 401 outcomes will be examined by multiple linear regression analysis.
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403 **DISCUSSION**

404 Middle-aged adults often show visible signs of aging such as loss of skin elasticity
405 and graying of the hair. The reduction in aerobic performance and decrease in maximal heart
406 rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle
407 age. Many health problems may occur when the middle-aged adults step into older age. As
408 the age composition of worldwide population will alter as median ages rise and greater
409 increase in elders³⁸, the increases of diseases burden and extra heavy cost for health care
410 become a big challenge to modern society³⁹. Thus, Keep an optimal health status and
411 effectively prevent diseases in middle age are critical for healthy aging and health
412 policy-making in an aging society, which help the population aging to be accompanied by
413 maintaining positive social engagement and productivity, result in the sustained sense of
414 well-being and extended period of good health for most elderly.

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

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

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4 425 personalized scheduler, then the system will automatically send reminding message and PA
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6 426 implementation to the users through smartphone apps and email. This is how the
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9 427 telecommunication and internet come into play. The cost is relatively low. This module
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11 428 enables users to plan their own physical activity program, which is a typical example of
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13 429 employing the Theory of Planned Behaviour^{18 19}.

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16 430 Although there are many advantages of using an online human-computer interactive system
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18 431 to conduct a lifestyle intervention, our study also has inevitable limitation. Since it is a
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21 432 self-managed virtual training program, no one monitor the participants' PA in real time, it is
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23 433 a challenge to quality control, which may depend on the participants' willingness of
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26 434 compliance to some extent. Also, the frequency, duration and intensity of PA may be varied
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29 435 among participants in intervention group. But our major concern is to see whether the IT-
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31 436 based online system can inspire the individuals' interests in PA, and improve their positive
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34 437 behavior. If the effectiveness of this approach is affirmative, this virtual training model can
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37 438 be widely utilized and benefit more people. Thus we suggest that the rigor dosage of
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39 439 intervention is not a main problem, as long as the participants achieve the basic intensity of
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41 440 PA required in the study.

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44 441 In summary, it would be an inexpensive, convenient, fast, and sustainable approach for
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46 442 adults, especially those with busy work life, to use an online virtual training system to plan
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49 443 and implement their own PA program, and comply with a healthy lifestyle. If the
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51 444 intervention proves to be effective it will provide scientific rationale for the implementation
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53 445 of the self-planned personalized PA program through human-computer interactive system.

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9 449 **Contributors**10
11 450 Study concept and design: SSH, YJX; Obtained funding: SSH, WWSM, PKM, YJX;12
13 451 Administrative, technical, or material support: SSH, WWSM, PKM; Drafting of the14
15 452 manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and16
17 453 approved the final manuscript.18
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28
29 457 **Competing interests**30
31 458 The authors declare that they have no competing interests32
33
34 459 **Ethics approval**35
36 460 The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research37
38 461 Ethics Committee39
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4 469 **Figure legends**

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6 470 Figure 1. Screenshots of two virtual trainer “rooms”

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9 471 Figure 2. Procedure of screening eligibility, assessment, and follow up

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Table 1. Procedures of recruitment screening and outcomes measurements

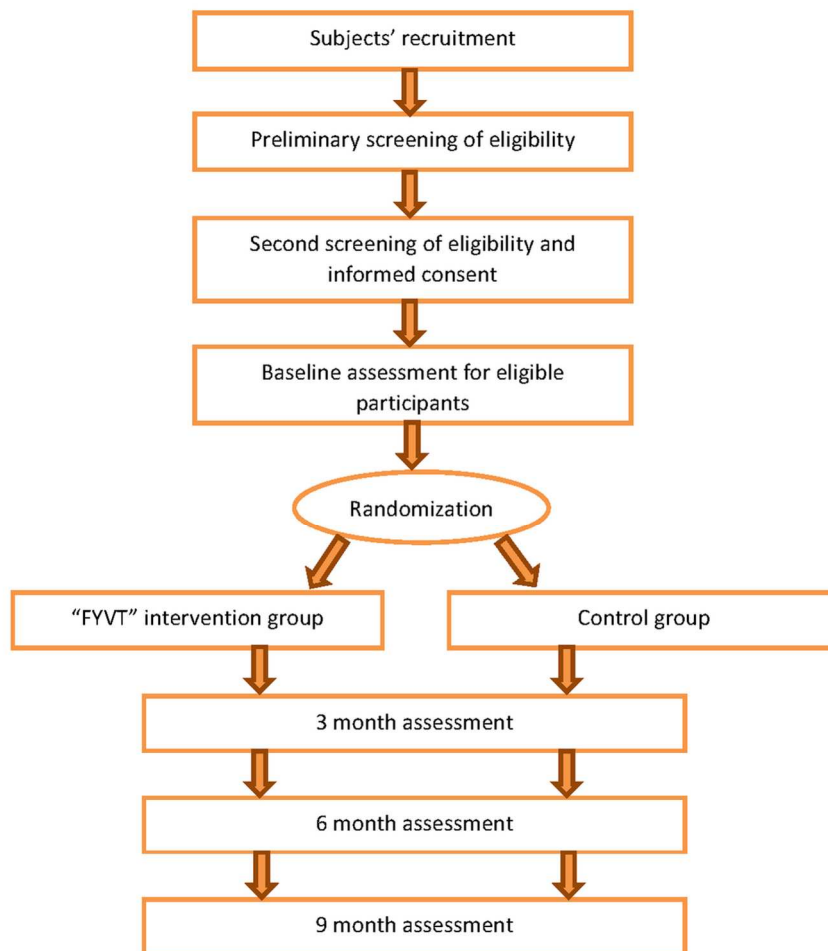
| Measures | Recruitment screening | Baseline | Month 3 | Month 6 | Month 9 |
|--|-----------------------|----------|---------|---------|---------|
| Demographics | ✓ | | | | |
| Medical history | ✓ | | | | |
| Exercise habits | ✓ | | | | |
| Exercise eligibility (Physical Activity Readiness Questionnaire) | ✓ | | | | |
| 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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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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| Secondary Subject Heading: | Sports and exercise medicine |
| Keywords: | Physical activity, Lifestyle, Intervention, Information technology < BIOTECHNOLOGY & BIOINFORMATICS, Randomized controlled trial, Middle-aged |
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1 **Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based**
2 **lifestyle intervention program to promote physical activity and health among middle-aged**
3 **Hong Kong Chinese**

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30 ABSTRACT

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

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

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

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4 52 Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235).

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6 53 The study results will be presented at scientific conferences and published in peer-reviewed
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9 54 journals.

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14 56 **Trial registration:** Virtual Trainer System (3rd Version) for Physical Activity Promotion in

15
16 57 Middle-aged Hong Kong Adults. ClinicalTrials.gov; NCT02553980, September 17, 2015

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20
21 59 **Key words:** Physical activity; Lifestyle; Intervention; Information technology; Randomized

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24 60 controlled trial; Middle-aged

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4 74 **Strengths and limitations of this study**
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9 76 • This is the first study using an online virtual training system for participants to plan
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14 77 and implement their own PA program for healthy lifestyle improvement.
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18 78 • The IT- based lifestyle intervention is fast, inexpensive, and convenient for adults,
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22 79 especially those with a busy work life.
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26 80 • The results will provide evidence for the feasibility and effectiveness of
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29 81 implementing the self-planned personalized PA program through a human-computer
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33 82 interactive system.
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37 83 • The major limitation is from the self-management of IT-based training. No one
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41 84 monitors the participants' PA in real time, and compliance depends on the
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45 85 participants' willingness to some extent.
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4 96 **INTRODUCTION**
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6 97 The benefits of regular physical activity (PA) on health are well documented. The guidelines
7
8 98 for practicing the proper amount of exercise in daily life have also been released to the
9
10 99 general public ¹⁻⁴. However, 31% of the world's population is still not physically active
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12 100 enough to meet the recommended minimum level of PA ⁵. The pandemic of physical
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14 101 inactivity thereby should be a public health priority ^{6,7}. In Hong Kong, recent cross-sectional
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16 102 surveys reported that as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community
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18 103 Fitness Survey 2012) of Hong Kong adults were not active enough to reach the guidelines ^{8,9}.
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20 104 Although the importance of PA has been widely publicized, more effort is needed to
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22 105 encourage regular PA participation in the Hong Kong population.
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28 106 Middle-aged adults, which are typically ranged from 40 to 65 years of age ¹⁰, increased
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30 107 dramatically in Hong Kong in recent years. The 2013 population statistics by the Census and
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32 108 Statistics Department of the Hong Kong government reported that due to the baby boom in
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34 109 the 1950s and 1960s and an influx of young immigrants during the 1970 and 1980s, a
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36 110 number of people whose age range from 45 to 64 years significantly increased in the recent
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38 111 10 years. The proportion almost jumped by 10% from 2001 (22.0%) to 2012 (31.4%) ¹¹. Many
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40 112 health problems may occur when the middle-aged adults step into older age. The increasing
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42 113 health care cost and aggravating disease burden are serious challenges to an aging society.
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44 114 Hong Kong is a highly urbanized city where many people work long hours daily and over the
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46 115 week, especially these middle-aged adults. The limited time and lack of professional exercise
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48 116 instruction are always barriers to their participation in PA. They may be too busy to seek
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50 117 professional advice on how to exercise. Although it is common that exercisers seek personal
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4 118 advice and instruction from personal trainers, the lack of channels and time become excuses
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6 119 for non-exercisers to continue their sedentary lifestyle. The question is then asked as to how
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9 120 feasible PA recommendation and constant reminding and encouragement can be easily
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11 121 accessible at any time and at anywhere. With the advances in information technology (IT),
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13 122 the knowledge of PA can be rapidly disseminated through the Internet^{12 13}. The role of
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15 123 “personal trainer” can also be replaced by a computer program in which guidelines and
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18 124 instructions for PA can be programmed into interactive software and disseminated to users
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21 125 via the World Wide Web. The electronic format of PA guidelines, exercise reminders,
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23 126 motivators, as well as immediate feedback and evaluation can be easily provided through IT.
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26 127 Once users obtain instant feedback on their progress and know their health and fitness
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29 128 improvement, their motivation and willingness to keep participating in PA would be
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31 129 strengthened. Based on these ideas and understanding, we developed a web-based
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34 130 computer software named “Virtual Trainer (VT)” (www.vt.hk), with several cartoon
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37 131 characters of trainers designed to help the users to implement their personal PA training
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39 132 plans. We then designed a lifestyle intervention program named “Follow Your Virtual Trainer
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41 133 (FYVT)” according to the VT system, with the purpose of improving PA level and health status
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44 134 for middle-aged Hong Kong adults.
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136 **Aims and hypotheses**

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

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4 140 1) To determine the effectiveness of the FYVT program for increasing PA participation and PA
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6 141 level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on
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8 142 cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure,
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10 143 health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role
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12 144 of behavior mediators in predicting behavior changes during FYVT program and their
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14 145 associations with outcomes; 4) To evaluate the maintenance of PA for six months during
15
16 146 FYVT program.

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21 147 Specifically, the following hypotheses will be tested.

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24 148 1) Chinese middle-aged adults who participate in the lifestyle intervention group will have a
25
26 149 greater increase in PA than participants in the control group at the end of the 3-month
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28 150 intervention. 2) The participants in the intervention group will also have a higher PA level
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30 151 than those in the control group at the end of 6-month follow up. 3) The participants in the
31
32 152 intervention group will have a better health status than those in the control group in terms
33
34 153 of cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure,
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36 154 health-related quality of life, sleep quantity and quality, and fatigue at the end of the
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38 155 3-month intervention and 6-month follow-up. 4) At least, 60% of the participants in the
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40 156 intervention group will keep using online VT system to design their personal exercise plans in
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42 157 the 6-month follow-up period.

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159 **METHODS**

160 **Study design**

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

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4 162 the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement
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6 163 ¹⁴. Participants will be randomly allocated into IT-based intervention group or control group
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9 164 to carry out a 3-month intensive program, with additional 6 months follow up, to see the
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11 165 effects of the intervention on improving PA and health status.
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167 **Ethics consideration**

168 This study has been approved by the Joint Chinese University of Hong Kong – New Territories
169 East Cluster Clinical Research Ethics Committee. All participants shall provide written
170 informed consent to the investigators before the baseline assessment. All the data are
171 confidential and only used for research purpose. Only the researchers who get the
172 permission from the principal investigator have the right to access the data.
173

174 **Participants**

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

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4 184 receiving medically prescribed diet or PA intervention; 3) blood pressure \geq 160/100 mmHg; 4)
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6 185 using of medication that may influence exercise performance; 5) for women, currently
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9 186 pregnant or plan to become pregnant in the next 1 year, and those receiving hormonal
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11 187 therapy.

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14 188 We will collaborate with local Non-Governmental Organizations in the health and family
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16 189 service fields to recruit participants via advertisements in flyers, surface mails, and bulletin
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18 190 boards. The interested subjects are required to fill in an assessment form for preliminary
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20 191 screening eligibility before baseline measurement. The form includes subjects'
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22 192 demographics, medical history, exercise habits, exercise eligibility (assessed by modified
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24 193 items from Physical Activity Readiness Questionnaire ¹⁵), and other personal information.
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26 194 The preliminary eligible subjects will be further invited to take the REE test and blood
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28 195 pressure measurement. Those that fulfill our study requirements and provide the signed
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30 196 informed consent forms are qualified as eligible participants.
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37 38 39 198 **Sample size and power analysis**

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41 199 From the behavioral risk factor survey conducted by the Department of Health of Hong Kong
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43 200 SAR in 2014 ¹⁶, only 37.4% of Hong Kong adults (18-64 years) reached the PA level by World
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45 201 Health Organization (WHO) recommendations ¹⁷. Based on this proportion, a sample size of
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47 202 87 is needed in each group to detect a 15% between-group difference (odds ratio: 1.83) in
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49 203 the proportion of participants reporting the PA that meets the WHO recommendations after
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51 204 a 3-month intervention (control group rate 40%, intervention group rate 55%, power=80%,
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53 205 $\alpha=5\%$; with a 2 repeated measurements design). This sample size also has 85% power to
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4 206 detect a difference of 15% in the proportion of participants reporting an increase in the high
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6 207 level of PA (control group rate 25%, intervention group rate 40%, power=80%, $\alpha=5\%$). The
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8 208 proportion of high level of PA estimated in the calculation is also drawn from the
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11 209 government survey¹⁸. With the consideration of 10% dropout, the final sample size is
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14 210 determined as 100 for each group ($87 + 87*10\% = 96 \approx 100$).
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212 **Randomization, concealment and blinding**

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

223 ***Theoretical model for behavior change***

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

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4 228 beliefs about the normative expectations of others, and the third one is those beliefs on the
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6 229 factors that may facilitate or hinder the performance of the behavior^{19 21}. These
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9 230 considerations emphasize the importance of an individual's intention to regulate their own
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11 231 PA and healthy lifestyle by cultivating a positive attitude and believing it to be within their
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13 232 own control²². Several measures associated with this model are obtained as a matter of
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16 233 course in the study, including fatigue, sleep quality, quality of life, and behavior mediators.
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18 234 ***The Virtual Trainer (VT) system***

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21 235 The "Virtual Trainer" (www.vt.hk), an interactive web-based computer software with the
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23 236 integration of the telecommunication instrument (mobile phone messages and apps), was
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26 237 developed by our research team in 2006 (1st version). It had undergone a major modification
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29 238 in 2010 (2nd version) and is under reconstruction for an enhanced version at present (3rd
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31 239 version). The VT system provides professional guidelines as well as multi-level electronic
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34 240 motivators for improving PA participation. It likes a traditional personal trainer, but no real
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36 241 physical form of trainer or instructor is needed, which implies a "Virtual Trainer". We have
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39 242 designed 16 cartoon characters of the trainer. Users may select any one of them as their
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41 243 personal trainer; they will have their own personalized web page, which simulates an
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44 244 exercise training room (Figure 1).

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46 245 The VT system can provide preliminary online health screening and health-related fitness
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49 246 assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions
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51 247 will be automatically generated by the VT system (Prescription Module). Moreover, to cater
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54 248 for individual preferences on exercise type, frequency and intensity within the context of
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56 249 personalized exercise prescriptions, the VT system will adopt an interactive approach to
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4 250 retrieve preferences from the users by a series of questions (Scheduler). The system will
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6 251 automatically arrange the preferences of the users, such as date and time of exercise, type
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8 252 and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep
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10 253 tracking the progress of the actual implementation of the users' exercise. Then feedback
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12 254 about the progress, recommendations for changes, reinforcements and other incentive
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14 255 messages will be generated by VT (Progress Evaluation Module). Each recommended
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16 256 exercise program will usually last for 2 to 4 months, then users will be asked to perform the
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18 257 online health-fitness evaluation again in order to assess their improvement in personal
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20 258 health and fitness. The VT system also includes the frequent and daily dissemination of short
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22 259 messages to participants via e-mail and sms to their mobile phone. These messages include
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24 260 reminder messages for exercise, incentive messages, positive reinforcement messages, as
25
26 261 well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT
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28 262 system to allow accurate PA tracking with the integration of automatic detection and
29
30 263 transmission of heart rate and pedometer. All this information will be updated in time
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32 264 through newly designed mobile Apps and transferred to an online system.

265 ***Intervention procedures***

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

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4 272 system; the basic requirement is no less than twice a week, accumulated through at least
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6 273 150 min/week of moderate PA or 75 min/week of vigorous PA. During these 3 months, six
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8 274 online seminars will be released to the participants in turn and biweekly; the private
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10 275 web-link of these seminars will be sent to their email box and mobile phone. We develop
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12 276 these psychological theme-based seminars that collaborate with a clinical psychologist as
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14 277 well as public health and exercise experts to help the participants to tackle lifestyle risk
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16 278 factors. The contents include introductions of what are healthy lifestyles and how to live
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18 279 healthier, the professional advice on how the appropriate physical activities are beneficial
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20 280 for health, how to integrate appropriate physical activities into daily life, and the strategies
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22 281 for improving exercise compliance and maintenance. The seminar topics include: 1) Eating
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24 282 a healthy diet; 2) Keeping your weight, waist, and blood pressure in check; 3) Stopping
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26 283 smoking and cutting back on alcohol consumption; 4) Positive psychology on
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28 284 self-management; 5) Knowing your physical fitness; 6) More exercise, better life.
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30 285 Participants randomized to the control group will only receive a written advice of the WHO
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32 286 recommendation of PA at baseline and receive the text version of six seminars by email,
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34 287 under the same intervals as the intervention group.
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46 289 **Outcomes**

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48 290 The primary outcome is PA and the secondary outcomes are cardiorespiratory fitness,
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50 291 resting energy expenditure, anthropometrics, body composition, blood pressure,
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52 292 health-related quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The
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54 293 role of behavior mediators draw from the Theory of Planned Behavior will also be examined.
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294 **Primary outcome**

295 PA will be measured through two ways:

296 1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The
297 accelerometer can measure the frequency, duration, and intensity of PA. It records
298 movement on the vertical and horizontal axis and allows classification of sedentary, light,
299 moderate, and vigorous activity levels²³. Participants are told to wear the monitor on their
300 right hip by an elastic belt during their waking hours for 7 consecutive days, except when
301 swimming or bathing. Sleep time will be recorded on a log sheet. During their wearing time,
302 daily Short Message Service (SMS) messages will be sent to them to remind them of
303 compliance in wearing. The data contain a minimum of 10 h/day wear time and five of the 7
304 days are included for analysis. Non-wear time was defined as sixty consecutive zeros
305 (intervals of at least 60 minutes).

306 2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The
307 Chinese short-form version of IPAQ²⁴ is used for participants to report their PA during the
308 last 7 days, across all domains of transportation, work, household tasks, and leisure time.
309 The duration (in minutes) and frequency (days) of walking, moderate-intensity and
310 vigorous-intensity activity are recorded. The total metabolic equivalents (METs) by the total
311 minutes per week of each activity are calculated, resulting in a PA estimation in
312 MET-minutes/week, together with the evaluation for duration and frequency of activities,
313 and three levels of PA (low, moderate and high) can be classified²⁴.

314 **Secondary outcomes**

315 **Cardio-respiratory fitness** The maximal oxygen intake ($\text{VO}_2 \text{ max}$ in $\text{ml}\cdot\text{min}^{-1}\cdot\text{kg}^{-1}$) is used as an

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4 316 indicator of cardiorespiratory fitness in our study. VO_2 max refers to the greatest amount of
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6 317 oxygen that an individual can take in from the inspired air during intense or maximal exercise
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8 318 ²⁵. It is considered the best measure of cardiovascular fitness and aerobic endurance ²⁶. The
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11 319 VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a
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14 320 sports performance lab. Under a strict exercise protocol, participants begin the test wearing
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16 321 masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen
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18 322 intake is computed each minute as the test proceeds toward the maximal effort. The highest
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21 323 level of oxygen consumed is recorded subsequently.

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24 324 **Resting energy expenditure** The measurement of resting energy expenditure (REE) includes
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26 325 resting oxygen consumption (VO_2 in $ml \cdot min^{-1} \cdot kg^{-1}$), kilocalorie expenditure (KCal in
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28 326 KCal $\cdot min^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer
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31 327 (Cosmed K4b2, Italy). Participants are asked to wear the analyzer and lie on a bed for 20 min,
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34 328 the temperature and humidity of the lab will be adjusted to a comfortable situation. VO_2 and
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36 329 kilocalorie expenditure are measured breath-by-breath, and the lowest continuous
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39 330 10 min of metabolic values are recorded. The heart rate is measured after 20 min rest.

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41 331 **Anthropometrics and body composition** The measurements include weight, height, waist
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43 332 circumference, hip circumference, percentage of body fat, and body mass. A trained
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46 333 research assistant will conduct all the measurement bases on the standard protocol ²⁷. All
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49 334 measures will be conducted twice and the mean value of two measurements is calculated.
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52 335 The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where
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54 336 appropriate. Body mass index (BMI) is calculated as weight divided by the square of height
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56 337 ($BMI = kg/m^2$). Obesity is defined as $BMI \geq 25 kg/m^2$ according to the World Health

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4 338 Organization standard for Asian populations²⁸. A bioelectrical impedance analysis²⁹ (Tanita,
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6 339 BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are
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9 340 calculated subsequently.

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11 341 **Blood pressure** Blood pressure will be measured through mercury sphygmomanometer by a
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13 342 clinical professional staff under the guideline of standard protocol³⁰. After at least five
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15 343 minutes sitting, measurement is taken on the right arm of the participant; an appropriately
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17 344 sized cuff is used. Every participant will be measured twice, and the mean of two
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21 345 measurements is computed.

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23 346 **Health related quality of life (HR-QOL)** A Chinese (HK) version³¹ of the Medical Outcomes
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25 347 Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is
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27 348 a widely used instrument to assess HR-QOL in eight dimensions^{32 33}: physical functioning
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29 349 (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental
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31 350 health (MH), vitality (VT) and general health perception (GH). The eight dimension scores
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33 351 can be summarized into two summary scores, namely, physical health summary (PCS) and
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35 352 mental health summary (MCS). It is an overall assessment of the quality of life regarding
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37 353 physical and mental health, respectively. The PCS and MCS have been identified as valid and
38
39 354 equivalent in the Chinese population in Hong Kong³⁴.

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41 355 **Sleep quality and quantity** Sleep quality will be measured by the Chinese version of the
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43 356 Pittsburgh Sleep Quality Index (PSQI)³⁵. The 19-item PSQI assesses seven dimensions of
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45 357 sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep
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47 358 disturbances, habitual sleep efficiency, use of sleep medication and daytime
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51 359 dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be
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4 360 calculated by adding the seven dimensions' scores. Higher scores indicate poorer sleep
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6 361 quality³⁶. Sleep quantity will be measured by a 7-day Daily Sleep Log³⁵. Participants are
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9 362 asked to record their sleep status for 7 consecutive days when they wake up in the mornings.
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11 363 The sleep log collects information on time to go to bed, sleep onset latency, waking time in
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13 364 the morning, and frequency of awakenings by the corresponding four questions: 1) I went to
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15 365 bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday
16
17 366 evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night
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19 367 ____ times³⁵. The total sleep time can thus be calculated as the interval time (minutes)
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21 368 between going to bed and waking up in the morning minus the time spent in falling asleep.
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26 369 **Fatigue** The Numeric Rating Scale (NRS)-fatigue³⁷ is used to evaluate fatigue level. It is a
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28 370 scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10,
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30 371 in which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. A
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32 372 higher score indicates that heavier fatigue is experienced.
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36 373 **Maintenance of physical activity** To examine the maintenance of PA after the cessation of
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38 374 the 3-month intensive program, a self-administered questionnaire that includes IPAQ will be
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40 375 given to the participants at 6 and 9 months during the follow-up period. We will determine
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42 376 the maintenance mainly in two aspects. 1) What percentage of the participants in the
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44 377 intervention group keeps using online VT system to design their personal exercise plans for
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46 378 at least one month in the 6-month follow up period. 2) In what percentage of the 24 weeks
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48 379 in the 6-month follow-up period are the participants in the two groups regularly active at a
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50 380 moderate intensity?
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55 381 **Behavior mediators** The possible behavior mediators will be examined by a self-designed
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4 382 questionnaire (Appendix I) that is based on Ajzen's guideline for developing a Theory of
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6 383 Planned Behavior questionnaire²¹. We will structure these mediator variables according to
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8 384 attitude, subjective norms and perceived behavioral control, to understand their intention
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10 385 towards active participation in physical activities. A seven-point scale is used for each item
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12 386 in the questionnaire. A Higher score indicates the higher influence of the mediator on
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14 387 behavioral change.
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20 21 389 **Procedure of assessment and follow-up**

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23 390 After screening for eligibility, the eligible participants are required to take the baseline
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25 391 measurement. Since the accelerometer needs 7 days wear time, we ask the participants to
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27 392 wear the monitor for 7 days first, and then come to our lab again for other baseline
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29 393 measures. Randomization is taken subsequently. Figure 2 demonstrates the overview of
30
31 394 protocol procedure. The follow-up assessments will be conducted at the end of the 3rd, 6th,
32
33 395 and 9th month after the trial begins. The research assistant will regularly monitor the
34
35 396 progress of PA of each participant through the VT system. If there is a delay or missing of PA
36
37 397 training during the intervention period, he will send reminders to the corresponding
38
39 398 participants through the VT system and help them to catch up on the progress. An event
40
41 399 report sheet will be used to record the adverse events by the research assistant every two
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43 400 weeks. Table 1 shows the schedule of each outcome measurement. Participants are required
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45 401 to wear an accelerometer 7 days prior to answering the IPAQ, to ensure the time interval of
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47 402 PA measured by the accelerometer is in accordance with that measured by the IPAQ (recall
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49 403 last 7 days' PA).
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4 404 **Statistical analysis**

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6 405 Double data entry will be adopted. Multiple imputations will be used for the missing data.
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9 406 Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who
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11 407 have valid baseline assessments, regardless of whether they drop out later) and the
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13 408 completed case analysis (only those who participate in the program for the full period are
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15 409 involved). If the results from two analytical approaches are similar and the dropout rate is
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17 410 less than 10% in two groups, ITT results will be adopted. One-way ANOVA and Pearson
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19 411 chi-square test are used to compare baseline differences between two groups for
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21 412 continuous variables (age, METS, VO₂ max, REE, anthropometrics and body composition,
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23 413 blood pressure, HR-QoL, sleep quality and quantity, fatigue, and behavior mediators) and
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25 414 categorical variables (PA level, obesity, and categorical demographic variables), respectively.
26
27 415 The effectiveness of the intervention will be assessed by the linear mixed model, which tests
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29 416 the random effect of treatment on outcomes at the 3rd, 6th, and 9th months when measured
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31 417 as mean, as well as tests the trend of changes by taking four measurement time points
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33 418 (baseline, 3rd, 6th, 9th months) as a random effect in the model. Logistical regression will be
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35 419 used and Odds ratio (OR) is calculated to examine the effect of the intervention on
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37 420 categorical variables. The associations between behavior mediators and changes in
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39 421 outcomes will be examined by multiple linear regression analysis.
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423 **DISCUSSION**

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

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4 426 rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle
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6 427 age. Many health problems may occur when the middle-aged adults step into older age. As
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9 428 the age composition of the worldwide population is altering as median ages rise with an
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11 429 increase in the number of elders³⁸, the increase of disease burden and extra heavy cost for
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14 430 health care is becoming a big challenge to modern society³⁹. Thus, keeping an optimal
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16 431 health status and effectively preventing diseases in middle age are critical for healthy aging
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19 432 and health policymaking in an aging society to help the aging population to maintain
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21 433 positive social engagement and productivity, resulting in a sustained sense of well-being and
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24 434 an extended period of good health for most elderly.

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26 435 Most people agree that PA is good for health but need constant reminding and
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29 436 encouragement. For Hong Kong middle-aged adults, the busy work schedule and heavy
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31 437 burden of everyday life make them have less leisure time to devote to exercise. To tackle
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34 438 these concerns, the FYVT program will improve the PA engagement among middle-aged
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36 439 adults and constantly remind them of the need and benefits of PA as well as provide
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39 440 professional advice on exercise prescription and healthy lifestyle. The services provided by
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41 441 the FYVT program has no time and venue limitations, which greatly enhances the efficiency
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44 442 of dissemination.

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46 443 The VT system provides knowledge, skills, and online demonstration on how to perform PA
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49 444 effectively; it also includes online health-fitness assessment and diet analysis. The VT system
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51 445 enables users to plan and design their individualized PA program and fit it into a
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54 446 personalized scheduler; then the system will automatically send a reminder message and PA
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57 447 implementation to the users through smartphone apps and email. This is how
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4 448 telecommunication and the internet come into play. The cost is relatively low. This module
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6 449 enables users to plan their own physical activity program, which is a typical example of
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8 450 employing the Theory of Planned Behavior^{19 20}.
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11 451 Although there are many advantages of using an online human-computer interactive system
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13 452 to conduct a lifestyle intervention, our study also has inevitable limitations. Since it is a
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15 453 self-managed virtual training program, no one monitors the participants' PA in real time, it is
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17 454 a challenge to quality control, which may depend on the participants' willingness of
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19 455 compliance to some extent. Also, the frequency, duration and intensity of PA may be varied
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21 456 among participants in the intervention group. But our major concern is to see whether the
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23 457 IT- based online system can inspire the individuals' interests in PA and improve their positive
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25 458 behavior. If the effectiveness of this approach is affirmative, this virtual training model can
26
27 459 be widely utilized and benefit more people. Thus, we suggest that the rigor dosage of
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29 460 intervention is not a major problem as long as the participants achieve the basic intensity of
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31 461 PA required in the study. Another limitation is that there might be measurement bias of
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33 462 some self-reporting outcomes, such as fatigue and sleep quality. But we do not think it will
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35 463 overturn the study results because the self-reporting biases are random in both groups.
36
37 464 In summary, it would be an inexpensive, convenient, fast, and sustainable approach for
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39 465 adults, especially those with a busy work life, to use an online virtual training system to plan
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41 466 and implement their own PA program and comply with a healthy lifestyle. If the intervention
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43 467 proves to be effective, it will provide a scientific rationale for the implementation of the
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45 468 self-planned personalized PA program through a human-computer interactive system.
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4 470 **Contributors**

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6 471 Study concept and design: SSH, YJX, RCK; Obtained funding: SSH, WWSM, PKM, YJX;

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8 472 Administrative, technical, or material support: SSH, EWT, WWSM, PKM; Drafting of the

9
10 473 manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and

11
12 474 approved the final manuscript.

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15
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17
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19
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23 478 **Competing interests**

24
25 479 The authors declare that they have no competing interests

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28 480 **Ethics approval**

29
30 481 The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research

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32 482 Ethics Committee

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492 **Figure legends**

493 Figure 1. Screenshots of two virtual trainer “rooms”

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

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For peer review only

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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)

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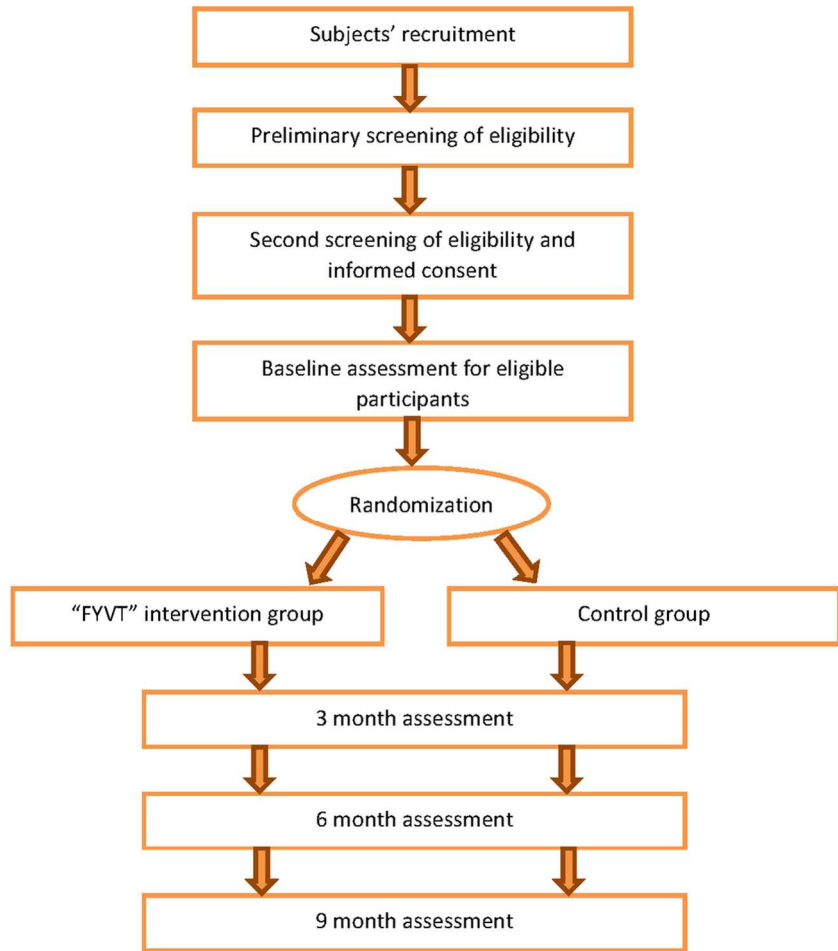


Figure 2. Procedure of screening eligibility, assessment, and follow up

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



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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 |
|---------------------|-----|--|----|

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| 2 | Allocation | 16b | Mechanism of implementing the allocation sequence (eg, central | 10 |
| 3 | concealment | | telephone; sequentially numbered, opaque, sealed envelopes), describing | |
| 4 | mechanism | | any steps to conceal the sequence until interventions are assigned | |
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| 6 | Implementati | 16c | Who will generate the allocation sequence, who will enrol participants, and | 10 |
| 7 | on | | who will assign participants to interventions | |
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| 10 | Blinding | 17a | Who will be blinded after assignment to interventions (eg, trial participants, | 10 |
| 11 | (masking) | | care providers, outcome assessors, data analysts), and how | |
| 12 | | | | |
| 13 | | 17b | If blinded, circumstances under which unblinding is permissible, and | 10 |
| 14 | | | procedure for revealing a participant's allocated intervention during the | |
| 15 | | | trial | |
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| 18 | Methods: Data collection, management, and analysis | | | |
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| 20 | Data collection | 18a | Plans for assessment and collection of outcome, baseline, and other trial | 14-18 |
| 21 | methods | | data, including any related processes to promote data quality (eg, | |
| 22 | | | duplicate measurements, training of assessors) and a description of study | |
| 23 | | | instruments (eg, questionnaires, laboratory tests) along with their reliability | |
| 24 | | | and validity, if known. Reference to where data collection forms can be | |
| 25 | | | found, if not in the protocol | |
| 26 | | | | |
| 27 | | | | |
| 28 | | 18b | Plans to promote participant retention and complete follow-up, including | 18 |
| 29 | | | list of any outcome data to be collected for participants who discontinue or | |
| 30 | | | deviate from intervention protocols | |
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| 33 | Data | 19 | Plans for data entry, coding, security, and storage, including any related | 19 |
| 34 | management | | processes to promote data quality (eg, double data entry; range checks for | |
| 35 | | | data values). Reference to where details of data management procedures | |
| 36 | | | can be found, if not in the protocol | |
| 37 | | | | |
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| 39 | Statistical | 20a | Statistical methods for analysing primary and secondary outcomes. | 19 |
| 40 | methods | | Reference to where other details of the statistical analysis plan can be | |
| 41 | | | found, if not in the protocol | |
| 42 | | | | |
| 43 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 19 |
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| 45 | | 20c | Definition of analysis population relating to protocol non-adherence (eg, as | 19 |
| 46 | | | randomised analysis), and any statistical methods to handle missing data | |
| 47 | | | (eg, multiple imputation) | |
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| 50 | Methods: Monitoring | | | |
| 51 | | | | |
| 52 | Data | 21a | Composition of data monitoring committee (DMC); summary of its role and | NA |
| 53 | monitoring | | reporting structure; statement of whether it is independent from the | |
| 54 | | | sponsor and competing interests; and reference to where further details | |
| 55 | | | about its charter can be found, if not in the protocol. Alternatively, an | |
| 56 | | | explanation of why a DMC is not needed | |
| 57 | | | | |
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| 59 | | 21b | Description of any interim analyses and stopping guidelines, including who | NA |
| 60 | | | will have access to these interim results and make the final decision to | |
| | | | terminate the trial | |

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|----|---------------------------------|-----|--|--------|
| 1 | | | | |
| 2 | Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and | 18 |
| 3 | | | spontaneously reported adverse events and other unintended effects of | |
| 4 | | | trial interventions or trial conduct | |
| 5 | | | | |
| 6 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether | NA |
| 7 | | | the process will be independent from investigators and the sponsor | |
| 8 | | | | |
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| 10 | Ethics and dissemination | | | |
| 11 | | | | |
| 12 | Research | 24 | Plans for seeking research ethics committee/institutional review board | 8 |
| 13 | ethics approval | | (REC/IRB) approval | |
| 14 | | | | |
| 15 | Protocol | 25 | Plans for communicating important protocol modifications (eg, changes to | NA |
| 16 | amendments | | eligibility criteria, outcomes, analyses) to relevant parties (eg, | |
| 17 | | | investigators, REC/IRBs, trial participants, trial registries, journals, | |
| 18 | | | regulators) | |
| 19 | | | | |
| 20 | | | | |
| 21 | Consent or | 26a | Who will obtain informed consent or assent from potential trial participants | 8 |
| 22 | assent | | or authorised surrogates, and how (see Item 32) | |
| 23 | | | | |
| 24 | | 26b | Additional consent provisions for collection and use of participant data and | NA |
| 25 | | | biological specimens in ancillary studies, if applicable | |
| 26 | | | | |
| 27 | | | | |
| 28 | Confidentiality | 27 | How personal information about potential and enrolled participants will be | 8 |
| 29 | | | collected, shared, and maintained in order to protect confidentiality before, | |
| 30 | | | during, and after the trial | |
| 31 | | | | |
| 32 | Declaration of | 28 | Financial and other competing interests for principal investigators for the | 22 |
| 33 | interests | | overall trial and each study site | |
| 34 | | | | |
| 35 | Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure | 8 |
| 36 | | | of contractual agreements that limit such access for investigators | |
| 37 | | | | |
| 38 | | | | |
| 39 | Ancillary and | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to | NA |
| 40 | post-trial care | | those who suffer harm from trial participation | |
| 41 | | | | |
| 42 | Dissemination | 31a | Plans for investigators and sponsor to communicate trial results to | 3 |
| 43 | policy | | participants, healthcare professionals, the public, and other relevant | |
| 44 | | | groups (eg, via publication, reporting in results databases, or other data | |
| 45 | | | sharing arrangements), including any publication restrictions | |
| 46 | | | | |
| 47 | | 31b | Authorship eligibility guidelines and any intended use of professional | NA |
| 48 | | | writers | |
| 49 | | | | |
| 50 | | 31c | Plans, if any, for granting public access to the full protocol, participant- | NA |
| 51 | | | level dataset, and statistical code | |
| 52 | | | | |
| 53 | | | | |
| 54 | | | | |
| 55 | Appendices | | | |
| 56 | | | | |
| 57 | Informed | 32 | Model consent form and other related documentation given to participants | Appen |
| 58 | consent | | and authorised surrogates | dix II |
| 59 | materials | | | |
| 60 | | | | |

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|---|------------|----|--|----|
| 1 | | | | |
| 2 | Biological | 33 | Plans for collection, laboratory evaluation, and storage of biological | NA |
| 3 | specimens | | specimens for genetic or molecular analysis in the current trial and for | |
| 4 | | | future use in ancillary studies, if applicable | |
| 5 | | | | |

6 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
7 Explanation & Elaboration for important clarification on the items. Amendments to the
8 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
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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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1 **Follow Your Virtual Trainer (FYVT): A randomized controlled trial protocol of IT- based**
2 **lifestyle intervention program to promote physical activity and health among middle-aged**
3 **Hong Kong Chinese**

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30 **ABSTRACT**

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

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

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

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4 52 Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CRE 2015235).

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6 53 The study results will be presented at scientific conferences and published in peer-reviewed
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9 54 journals.

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14 56 **Trial registration:** Virtual Trainer System (3rd Version) for Physical Activity Promotion in

15
16 57 Middle-aged Hong Kong Adults. ClinicalTrials.gov; NCT02553980, September 17, 2015

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20
21 59 **Key words:** Physical activity; Lifestyle; Intervention; Information technology; Randomized

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24 60 controlled trial; Middle-aged

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4 74 **Strengths and limitations of this study**
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9 76 and implement their own physical activity (PA) program for healthy lifestyle
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11 77 improvement. This trial will implement the self-planned personalized PA program
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13 78 through a human-computer interactive system. The IT-based lifestyle intervention is
14
15 79 fast, inexpensive, flexible, and convenient for adults, especially those with a busy
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17 80 work life.
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21 81 • The major limitation is from the self-management of IT-based training. No one
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23 82 monitors the participants' PA in real time. The practice compliance depends on the
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25 83 participants' willingness to some extent.
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4 96 **INTRODUCTION**

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6 97 The benefits of regular physical activity (PA) on health are well-documented. The guidelines
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8 98 for practicing the proper amount of exercise in daily life have also been released to the
9
10 99 general public ¹⁻⁴. However, 31% of the world's population is still not physically active
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12 100 enough to meet the recommended minimum level of PA ⁵. The pandemic of physical
13
14 101 inactivity thereby should be a public health priority ^{6,7}. In Hong Kong, recent cross-sectional
15
16 102 surveys reported that as many as 70.9% (Sport-for-All Survey 2009) to 71.4% (Community
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18 103 Fitness Survey 2012) of Hong Kong adults were not active enough to reach the guidelines ^{8,9}.
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20 104 Although the importance of PA has been widely publicized, more effort is needed to
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22 105 encourage regular PA participation in the Hong Kong population.
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29 106 The number of middle-aged adults, who are typically ranged from 40 to 65 years of age ¹⁰,
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31 107 increased dramatically in Hong Kong in recent years. The 2013 population statistics by the
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33 108 Census and Statistics Department of the Hong Kong Government reported that due to the
34
35 109 baby boom in the 1950s and 1960s and an influx of young immigrants during the 1970 and
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37 110 1980s, the number of people whose ages range from 45 to 64 years significantly increased in
38
39 111 the recent 10 years. The proportion almost jumped by 10% from 2001 (22.0%) to 2012
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41 112 (31.4%) ¹¹. Many health problems may occur when the middle-aged adults step into older
42
43 113 age. The increasing health care cost and aggravating disease burden are serious challenges
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45 114 to an aging society.
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50 115 Hong Kong is a highly urbanized city where many people work long hours daily and over the
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52 116 week, especially these middle-aged adults. The limited time and lack of professional exercise
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54 117 instruction are always barriers to their participation in PA. They may be too busy to seek
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4 118 professional advice on how to exercise. Although it is common that exercisers seek personal
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6 119 advice and instruction from personal trainers, the lack of channels and time become excuses
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9 120 for non-exercisers to continue their sedentary lifestyle. The question is then asked as to how
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11 121 feasible PA recommendation and constant reminding and encouragement can be easily
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13 122 accessible at any time and at anywhere. With the advances in information technology (IT),
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15 123 the knowledge of PA can be rapidly disseminated through the Internet^{12 13}. The role of
16
17 124 “personal trainer” can also be replaced by a computer program in which guidelines and
18
19 125 instructions for PA can be programmed into interactive software and disseminated to users
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21 126 via the World Wide Web. The electronic format of PA guidelines, exercise reminders,
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23 127 motivators, as well as immediate feedback and evaluation can be easily provided through IT.
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25 128 Once users obtain instant feedback on their progress and know their health and fitness
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27 129 improvement, their motivation and willingness to keep participating in PA would be
28
29 130 strengthened. Based on these ideas and understanding, we developed a web-based
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31 131 computer software named “Virtual Trainer (VT)” (www.vt.hk), with several cartoon
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33 132 characters of trainers designed to help the users to implement their personal PA training
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35 133 plans. We then designed a lifestyle intervention program named “Follow Your Virtual Trainer
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37 134 (FYVT)” according to the VT system, with the purpose of improving PA level and health status
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39 135 for middle-aged Hong Kong adults.
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51 **Aims and hypotheses**

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53 138 The aim of this study is to evaluate the effectiveness of an IT-based lifestyle intervention
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55 139 program on improving the PA level and health status in a sample of middle-aged Hong Kong
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4 140 Chinese adults. The specific objectives include:
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6 141 1) To determine the effectiveness of the FYVT program for increasing PA participation and PA
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8 142 level in Chinese adults; 2) To determine the health benefits of PA promotion by FYVT on
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10 143 cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure,
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12 144 health-related quality of life, sleep quantity and quality, and fatigue; 3) To examine the role
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14 145 of behavior mediators in predicting behavior changes during FYVT program and their
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16 146 associations with outcomes; 4) To evaluate the maintenance of PA for six months during
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18 147 FYVT program.

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21 148 Specifically, the following hypotheses will be tested.

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24 149 1) Chinese middle-aged adults who participate in the lifestyle intervention group will have a
25
26 150 greater increase in PA than participants in the control group at the end of the 3-month
27
28 151 intervention. 2) The participants in the intervention group will also have a higher PA level
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30 152 than those in the control group at the end of 6-month follow up. 3) The participants in the
31
32 153 intervention group will have a better health status than those in the control group in terms
33
34 154 of cardiorespiratory fitness, resting energy expenditure, body composition, blood pressure,
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36 155 health-related quality of life, sleep quantity and quality, and fatigue at the end of the
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38 156 3-month intervention and 6-month follow-up. 4) At least, 60% of the participants in the
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40 157 intervention group will keep using online VT system to design their personal exercise plans in
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42 158 the 6-month follow-up period.
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52 53 54 160 **METHODS**

55 56 161 **Study design** 57 58 59 60

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4 162 A two-arm parallel individual level randomized controlled trial (RCT) is designed according to
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6 163 the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement
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9 164 ¹⁴. Participants will be randomly allocated into IT-based intervention group or control group
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11 165 to carry out a 3-month intensive program, with additional 6 months follow up, to see the
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14 166 effects of the intervention on improving PA and health status. **Participants**
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16 167 The target study population will be sedentary Chinese adults who use computers and
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18 168 mobile apps frequently. The inclusion criteria include: 1) aged 40 to 65 years; 2) able to
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21 169 understand Cantonese and read Chinese; 3) self-reported inactivity (no habitual exercise
22
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24 170 experience for at least 6 months); 4) the baseline resting energy expenditure (REE) is less
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26 171 than 1.05 kcal·min⁻¹ for men and 0.85 kcal·min⁻¹ for women; 5) reachable by telephone; 6)
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29 172 has basic computer skills; 7) has a smartphone and always surfs internet (at least 4 times per
30
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32 173 week); and 8) will not leave Hong Kong for a long time (longer than 2 months) during the
33
34 174 study period. The exclusion criteria are: 1) self-reported history of cardiovascular and
35
36 175 pulmonary diseases, neurological disorder, musculoskeletal disorder, and osteoarthritis; 2)
37
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39 176 receiving medically prescribed diet or PA intervention; 3) blood pressure ≥ 160/100 mmHg; 4)
40
41 177 using of medication that may influence exercise performance; 5) for women, currently
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44 178 pregnant or plan to become pregnant in the next 1 year, and those receiving hormonal
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46 179 therapy.
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49 180 We will collaborate with local Non-Governmental Organizations in the health and family
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51 181 service fields to recruit participants via advertisements in flyers, surface mails, and bulletin
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54 182 boards. The interested subjects are required to fill out an assessment form for preliminary
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57 183 screening eligibility before baseline measurement. The form includes demographics, medical
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4 184 history, exercise habits, exercise eligibility (assessed by modified items from Physical Activity
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6 185 Readiness Questionnaire ¹⁵), and other personal information. The preliminary eligible
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9 186 subjects will be further invited to take the REE test and blood pressure measurement. Those
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11 187 that fulfill our study requirements and provide the signed informed consent forms are
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13 188 qualified as eligible participants.
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19 **Sample size and power analysis**

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21 191 From the behavioral risk factor survey conducted by the Department of Health of Hong Kong
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23 192 SAR in 2014 ¹⁶, only 37.4% of Hong Kong adults (18-64 years) reached the PA level by World
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25 193 Health Organization (WHO) recommendations ¹⁷. Based on this proportion, a sample size of
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27 194 87 is needed in each group to detect a 15% between-group difference (odds ratio: 1.83) in
28
29 195 the proportion of participants reporting the PA that meets the WHO recommendations after
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31 196 a 3-month intervention (control group rate 40%, intervention group rate 55%, power=80%,
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33 197 $\alpha=5\%$; with a 2 repeated measurements design). This sample size also has 85% power to
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35 198 detect a difference of 15% in the proportion of participants reporting an increase in the high
36
37 199 level of PA (control group rate 25%, intervention group rate 40%, power=80%, $\alpha=5\%$). The
38
39 200 proportion of high level of PA estimated in the calculation is also drawn from the
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41 201 government survey ¹⁸. With the consideration of 10% dropout, the final sample size is
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43 202 determined as 100 for each group ($87 + 87*10\% = 96 \approx 100$).
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49 **Randomization, concealment and blinding**

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51 204 The randomization will be done on the individual level after baseline assessment. Eligible
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4 206 participants will be randomly assigned to lifestyle intervention group or control group with
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6 207 the allocation ratio of 1:1. To ensure allocation concealment, an independent statistician
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8 208 who is not involved in recruitment and baseline assessment will conduct the randomization
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10 209 by computer-generated allocation sequence. Another researcher will be responsible for
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12 210 arranging the participants to undertake their corresponding treatments; they will not be told
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14 211 which group is the “true” intervention group, and in both groups they will receive some
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16 212 “treatments”.
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214 **Intervention**

215 ***Theoretical model for behavior change***

216 The Theory of Planned Behavior^{19 20} is adopted as the theoretical basis for the behavioral
217 intervention in the FYVY program. According to this theory model, three types of
218 considerations guide the human behaviors: behavioral beliefs, normative beliefs, and control
219 beliefs. The first type is belief in the likely consequences of the behavior; the second type is
220 beliefs about the normative expectations of others, and the third one is those beliefs on the
221 factors that may facilitate or hinder the performance of the behavior^{19 21}. These
222 considerations emphasize the importance of an individual’s intention to regulate their own
223 PA and healthy lifestyle by cultivating a positive attitude and believing it to be within their
224 own control²². Several measures associated with this model are obtained as a matter of
225 course in the study, including fatigue, sleep quality, quality of life, and behavior mediators.

226 ***The Virtual Trainer (VT) system***

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4 227 The “Virtual Trainer” (www.vt.hk), an interactive web-based computer software with the
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6 228 integration of the telecommunication instrument (mobile phone messages and apps), was
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9 229 developed by our research team in 2006 (1st version). It had undergone a major modification
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11 230 in 2010 (2nd version) and is under reconstruction for an enhanced version at present (3rd
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14 231 version). The VT system provides professional guidelines as well as multi-level electronic
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16 232 motivators for improving PA participation. It likes a traditional personal trainer, but no real
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19 233 physical form of trainer or instructor is needed, which implies a “Virtual Trainer”. We have
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21 234 designed 16 cartoon characters of the trainer. Users may select any one of them as their
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24 235 personal trainer, and they will have their own personalized web page that simulates an
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26 236 exercise training room (Figure 1).

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29 237 The VT system can provide preliminary online health screening and health-related fitness
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31 238 assessments (Health-fitness Evaluation Module). Then, suggestions of exercise prescriptions
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34 239 will be automatically generated by the VT system (Prescription Module). Moreover, to cater
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36 240 for individual preferences on exercise type, frequency and intensity within the context of
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39 241 personalized exercise prescriptions, the VT system will adopt an interactive approach to
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41 242 retrieve preferences from the users by a series of questions (Scheduler). The system will
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44 243 automatically arrange the preferences of the users, such as date and time of exercise, type
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46 244 and intensity of exercise, etc., into a Scheduler program. The Scheduler program will keep
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49 245 tracking the progress of the actual implementation of the users’ exercise. Then feedback
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51 246 about the progress, recommendations for changes, reinforcements and other incentive
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54 247 messages will be generated by VT (Progress Evaluation Module). Each recommended
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56 248 exercise program will usually last for 2 to 4 months, then users will be asked to perform the
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4 249 online health-fitness evaluation again in order to assess their improvement in personal
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6 250 health and fitness. The VT system also includes the frequent and daily dissemination of short
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9 251 messages to participants via e-mail and sms to their mobile phone. These messages include
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11 252 reminder messages for exercise, incentive messages, positive reinforcement messages, as
12
13 253 well as helpful tips on exercise and diet. We are now developing the 3rd version of the VT
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15 254 system to allow accurate PA tracking with the integration of automatic detection and
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17 255 transmission of heart rate and pedometer. All this information will be updated in time
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19 256 through newly designed mobile Apps and transferred to an online system.
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23 257 ***Intervention procedures***

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26 258 Participants in the intervention group will receive 3 months of intensive intervention and 6
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28 259 months follow-up observation. A briefing session will be conducted at first to introduce the
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30 260 conception of the FYVT program, the usage of online VT system, the common types of
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32 261 moderate and vigorous PA, the standard duration and frequency of exercise during the
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34 262 intervention, the measurement indicators and other related issues to the participants. After
35
36 263 this session, participants are required to design their own 3-month PA plan through a VT
37
38 264 system; the basic requirement is no less than twice a week, accumulated through at least
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40 265 150 min/week of moderate PA or 75 min/week of vigorous PA. During these 3 months, six
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42 266 online seminars will be released to the participants in turn and biweekly; the private
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44 267 web-link of these seminars will be sent to their email box and mobile phone. We develop
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46 268 these psychological theme-based seminars that collaborate with a clinical psychologist as
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48 269 well as public health and exercise experts to help the participants to tackle lifestyle risk
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50 270 factors. The contents include introductions of what healthy lifestyles are and how to live
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4 271 healthier, the professional advice on how the appropriate physical activities are beneficial
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6 272 for health, how to integrate appropriate physical activities into daily life, and the strategies
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9 273 for improving exercise compliance and maintenance. The seminar topics include: 1) Eating
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11 274 a healthy diet; 2) Keeping your weight, waist, and blood pressure in check; 3) Stopping
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13 275 smoking and cutting back on alcohol consumption; 4) Positive psychology on
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15 276 self-management; 5) Knowing your physical fitness; 6) More exercise, better life.
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18 277 Participants randomized to the control group will only receive a written advice of the WHO
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20 278 recommendation of PA at baseline and receive the text version of six seminars by email,
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22 279 under the same intervals as the intervention group.
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29 **Outcomes**

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31 282 The primary outcome is PA and the secondary outcomes are cardiorespiratory fitness,
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33 283 resting energy expenditure, anthropometrics, body composition, blood pressure,
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35 284 health-related quality of life, sleep quality and quantity, fatigue, and maintenance of PA. The
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37 285 role of behavior mediators draw from the Theory of Planned Behavior will also be examined.
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40 **Primary outcome**

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42 287 PA will be measured through two ways:

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44 288 1) Accelerometer (Actigraph GT3X, Florida, USA) for objective PA measurement. The
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46 289 accelerometer can measure the frequency, duration, and intensity of PA. It records
47
48 290 movement on the vertical and horizontal axis and allows classification of sedentary, light,
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50 291 moderate, and vigorous activity levels²³. Participants are told to wear the monitor on their
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52 292 right hip by an elastic belt during their waking hours for 7 consecutive days, except when
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4 293 swimming or showering. Sleep time will be recorded on a log sheet. During their wearing
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6 294 time, daily Short Message Service (SMS) messages will be sent to them to remind them of
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9 295 compliance in wearing. The data contain a minimum of 10 h/day wear time and five of the 7
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11 296 days are included for analysis. Non-wear time was defined as sixty consecutive zeros
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14 297 (intervals of at least 60 minutes).

15
16 298 2) International Physical Activity Questionnaire (IPAQ) for subjective PA measurement. The
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18 299 Chinese short-form version of IPAQ²⁴ is used for participants to report their PA during the
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21 300 last 7 days, across all domains of transportation, work, household tasks, and leisure time.
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24 301 The duration (in minutes) and frequency (days) of walking, moderate-intensity and
25
26 302 vigorous-intensity activity are recorded. The total metabolic equivalents (METs) by the total
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28 303 minutes per week of each activity are calculated, resulting in a PA estimation in
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31 304 MET-minutes/week, together with the evaluation for duration and frequency of activities,
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34 305 and three levels of PA (low, moderate and high) can be classified²⁴.

36 306 **Secondary outcomes**

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39 307 **Cardio-respiratory fitness** The maximal oxygen intake (VO_2 max in $ml \cdot min^{-1} \cdot kg^{-1}$) is used as an
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41 308 indicator of cardiorespiratory fitness in our study. VO_2 max refers to the greatest amount of
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44 309 oxygen that an individual can take in from the inspired air during intense or maximal exercise
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46 310²⁵. It is considered the best measure of cardiovascular fitness and aerobic endurance²⁶. The
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48
49 311 VO_2 max will be measured using a symptom limited maximal treadmill exercise test in a
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51 312 sports performance lab. Under a strict exercise protocol, participants begin the test wearing
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54 313 masks to direct the air into a portable metabolic analyzer (Cosmed K4b2, Italy); oxygen
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56 314 intake is computed each minute as the test proceeds toward the maximal effort. The highest
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4 315 level of oxygen consumed is recorded subsequently.

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6 316 **Resting energy expenditure** The measurement of resting energy expenditure (REE) includes
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8 317 resting oxygen consumption (VO_2 in $\text{ml}\cdot\text{min}^{-1}\cdot\text{kg}^{-1}$), kilocalorie expenditure (KCal in
9
10 318 KCal $\cdot\text{min}^{-1}$), and resting heart rate. These will also be measured by the metabolic analyzer
11
12 319 (Cosmed K4b2, Italy). Participants are asked to wear the analyzer and lie on a bed for 20 min,
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14 320 the temperature and humidity of the lab will be adjusted to a comfortable situation. VO_2 and
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16 321 kilocalorie expenditure are measured breath-by-breath, and the lowest continuous
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18 322 10 min of metabolic values are recorded. The heart rate is measured after 20 min rest.

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20 323 **Anthropometrics and body composition** The measurements include weight, height, waist
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22 324 circumference, hip circumference, percentage of body fat, and body mass. A trained
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24 325 research assistant will conduct all the measurement bases on the standard protocol²⁷. All
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26 326 measures will be conducted twice and the mean value of two measurements is calculated.
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28 327 The anthropometrics are measured to the nearest 0.1 kilogram or centimeter where
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30 328 appropriate. Body mass index (BMI) is calculated as weight divided by the square of height
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32 329 ($\text{BMI} = \text{kg}/\text{m}^2$). Obesity is defined as $\text{BMI} \geq 25 \text{ kg}/\text{m}^2$ according to the World Health
33
34 330 Organization standard for Asian populations²⁸. A bioelectrical impedance analysis²⁹ (Tanita,
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36 331 BC 581, Japan) will be used to test body fat percentage. Fat mass and lean mass are
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38 332 calculated subsequently.

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40 333 **Blood pressure** Blood pressure will be measured through mercury sphygmomanometer by a
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42 334 clinical professional staff under the guideline of standard protocol³⁰. After at least five
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44 335 minutes sitting, measurement is taken on the right arm of the participant; an appropriately
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46 336 sized cuff is used. Every participant will be measured twice, and the mean of the two
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4 337 measurements is computed.

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6 338 **Health related quality of life (HR-QOL)** A Chinese (HK) version³¹ of the Medical Outcomes
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8 339 Study 36-item Short-Form Health Survey (SF-36) is used for HR-QOL assessment. The SF-36 is
9
10 340 a widely used instrument to assess HR-QOL in eight dimensions^{32 33}: physical functioning
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12 341 (PF), role physical (RP), bodily pain (BP), role emotional (RE), social functioning (SF), mental
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14 342 health (MH), vitality (VT) and general health perception (GH). Two summary scores, namely,
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16 343 the physical health summary (PCS) and mental health summary (MCS), can be calculated
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18 344 from the eight dimension scores. It is an overall assessment of the quality of life in terms of
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20 345 physical and mental health status. The PCS and MCS have been identified as valid and
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22 346 equivalent in the Chinese population in Hong Kong³⁴.

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28 347 **Sleep quality and quantity** Sleep quality will be measured by the Chinese version of the
29
30 348 Pittsburgh Sleep Quality Index (PSQI)³⁵. The 19-item PSQI assesses seven dimensions of
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32 349 sleep quality over the past month: sleep latency and duration, subjective sleep quality, sleep
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34 350 disturbances, habitual sleep efficiency, use of sleep medication, and daytime
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36 351 dysfunction. Score 0 to 3 is used for each dimension, and a cumulative score (0–21) can be
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38 352 calculated by adding the seven dimensions' scores. Higher scores indicate poorer sleep
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40 353 quality³⁶. Sleep quantity will be measured by a 7-day Daily Sleep Log³⁵. Participants are
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42 354 asked to record their sleep status for 7 consecutive days when they wake up in the mornings.
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44 355 The sleep log collects information on time to go to bed, sleep onset latency, waking time in
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46 356 the morning, and frequency of awakenings by the corresponding four questions: 1) I went to
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48 357 bed at ____ (clock time) yesterday evening; 2) I fell asleep in ____ (minutes) yesterday
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50 358 evening; 3) I got out of bed at ____ (clock time) this morning; 4) I woke up during the night
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4 359 ____ times³⁵. The total sleep time can thus be calculated as the interval time (minutes)
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6 360 between going to bed and waking up in the morning minus the time spent in falling asleep.
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9 361 **Fatigue** The Numeric Rating Scale (NRS)-fatigue³⁷ is used to evaluate fatigue level. It is a
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11 362 scale with numbers from 0 to 10 for participants' self-rating. The score ranges from 0 to 10,
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13 363 in which 0 presents no fatigue at all and 10 presents the highest experience of fatigue. A
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15 364 higher score indicates that heavier fatigue is experienced.
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19 365 **Maintenance of physical activity** To examine the maintenance of PA after the cessation of
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21 366 the 3-month intensive program, a self-administered questionnaire that includes IPAQ will be
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23 367 given to the participants at 6 and 9 months during the follow-up period. We will determine
24
25 368 the maintenance mainly in two aspects. (1) What percentage of the participants in the
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27 369 intervention group keeps using online VT system to design their personal exercise plans for
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29 370 at least one month in the 6-month follow up period, and (2) in what percentage of the 24
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31 371 weeks in the 6-month follow-up period are the participants in the two groups regularly
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33 372 active at a moderate intensity?
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39 373 **Behavior mediators** The possible behavior mediators will be examined by a self-designed
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41 374 questionnaire (Appendix I) that is based on Ajzen's guideline for developing a Theory of
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43 375 Planned Behavior questionnaire²¹. We will structure these mediator variables according to
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45 376 attitude, subjective norms and perceived behavioral control, to understand their intention
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47 377 towards active participation in physical activities. A seven-point scale is used for each item
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49 378 in the questionnaire. A Higher score indicates the higher influence of the mediator on
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51 379 behavioral change.
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4 381 **Procedure of assessment and follow-up**

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6 382 After screening for eligibility, the eligible participants are required to take the baseline
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9 383 measurement. Since the accelerometer needs 7 days wear time, we ask the participants to
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11 384 wear the monitor for 7 days first, and then come to our lab again for other baseline
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13 385 measures. Randomization is taken subsequently. Figure 2 demonstrates the overview of
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15 386 protocol procedure. The follow-up assessments will be conducted at the end of the 3rd, 6th,
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17 387 and 9th month after the trial begins. The research assistant will regularly monitor the
18
19 388 progress of PA of each participant through the VT system. If there is a delay or missing of PA
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21 389 training during the intervention period, he will send reminders to the corresponding
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23 390 participants through the VT system and help them to catch up on the progress. An event
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25 391 report sheet will be used to record the adverse events by the research assistant every two
26
27 392 weeks. Table 1 shows the schedule of each outcome measurement. Participants are required
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29 393 to wear an accelerometer 7 days prior to answering the IPAQ, to ensure the time interval of
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31 394 PA measured by the accelerometer is in accordance with that measured by the IPAQ (recall
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33 395 last 7 days' PA).

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43 397 **Statistical analysis**

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45 398 Double data entry will be adopted. Multiple imputations will be used for the missing data.
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47 399 Data will be analyzed both by the intention-to-treat (ITT) principle (include participants who
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49 400 have valid baseline assessments, regardless of whether they drop out later) and the
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51 401 completed case analysis (only those who participate in the program for the full period are
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53 402 involved). If the results from two analytical approaches are similar and the dropout rate is
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4 403 less than 10% in two groups, ITT results will be adopted. One-way ANOVA and Pearson
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6 404 chi-square test are used to compare baseline differences between two groups for
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9 405 continuous variables (age, METS, VO₂ max, REE, anthropometrics and body composition,
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11 406 blood pressure, HR-QoL, sleep quality and quantity, fatigue, and behavior mediators) and
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13 407 categorical variables (PA level, obesity, and categorical demographic variables), respectively.
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16 408 The effectiveness of the intervention will be assessed by the linear mixed model, which tests
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18 409 the random effect of treatment on outcomes at the 3rd, 6th, and 9th months when measured
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21 410 as mean, as well as tests the trend of changes by taking four measurement time points
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23 411 (baseline, 3rd, 6th, 9th months) as a random effect in the model. Logistical regression will be
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26 412 used and Odds ratio (OR) is calculated to examine the effect of the intervention on
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29 413 categorical variables. The associations between behavior mediators and changes in
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31 414 outcomes will be examined by multiple linear regression analysis.
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36 416 **Ethics and dissemination**

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39 417 This study has been approved by the Joint Chinese University of Hong Kong – New Territories
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41 418 East Cluster Clinical Research Ethics Committee. All participants shall provide written
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44 419 informed consent (Appendix II) to the investigators before the baseline assessment. All the
45
46 420 data are confidential and only used for research purpose. Only the researchers who get the
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49 421 permission from the principal investigator have the right to access to the data. The trial was
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51 422 registered at <http://www.clinicaltrials.gov> with identification no. NCT02553980.
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54 423 We will disseminate the study results by peer-reviewed publications and conference
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56 424 presentations according to the CONSORT statement recommendations.
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6 426 **DISCUSSION**

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8 427 Middle-aged adults often show visible signs of aging such as loss of skin elasticity
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11 428 and graying of the hair. The reduction in aerobic performance and decrease in maximal heart
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13 429 rate also occur as a sign of aging. Strength and flexibility also decrease throughout middle
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15 430 age. Many health problems may occur when the middle-aged adults step into older age. As
16
17 431 the age composition of the worldwide population is altering as median ages rise with an
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19 432 increase in the number of elders³⁸, the increase of disease burden and extra heavy cost for
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21 433 health care is becoming a big challenge to modern societies³⁹. Thus, keeping an optimal
22
23 434 health status and effectively preventing diseases in middle age are critical for healthy aging
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25 435 and health policymaking in an aging society to help the aging population to maintain
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27 436 positive social engagement and productivity, resulting in a sustained sense of well-being and
28
29 437 an extended period of good health for most elderly.

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31 438 Most people agree that PA is good for health but need constant reminding and
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33 439 encouragement. For the Hong Kong middle-aged adults, the busy work schedule and heavy
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35 440 burden of everyday life make them have less leisure time to devote to exercise. To tackle
36
37 441 these concerns, the FYVT program will improve the PA engagement among middle-aged
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39 442 adults and constantly remind them of the need and benefits of PA as well as provide
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41 443 professional advice on exercise prescription and healthy lifestyle. The services provided by
42
43 444 the FYVT program has no time and venue limitations, which greatly enhances the efficiency
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45 445 of dissemination.

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47 446 The VT system provides knowledge, skills, and online demonstration on how to perform PA
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4 447 effectively; it also includes online health-fitness assessment and diet analysis. The VT system
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6 448 enables users to plan and design their individualized PA program and fit it into a
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9 449 personalized scheduler; then the system will automatically send a reminder message and PA
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11 450 implementation to the users through smartphone apps and email. This is how
12
13 451 telecommunication and the internet come into play. The cost is relatively low. This module
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15 452 enables users to plan their own physical activity program, which is a typical example of
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17 453 employing the Theory of Planned Behavior^{19 20}.
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19 454 Although there are many advantages of using an online human-computer interactive system
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21 455 to conduct a lifestyle intervention, our study also has inevitable limitations. Since it is a
22
23 456 self-managed virtual training program, no one monitors the participants' PA in real time. It is
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25 457 a challenge to quality control, which may depend on the participants' willingness of
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27 458 compliance to some extent. Also, the frequency, duration and intensity of PA may be varied
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29 459 among participants in the intervention group. But our major concern is to see whether the
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31 460 IT- based online system can inspire the individuals' interests in PA and improve their positive
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33 461 behavior. If the effectiveness of this approach is affirmative, this virtual training model can
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35 462 be widely utilized and benefit more people. Thus, we suggest that the rigor dosage of
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37 463 intervention is not a major problem as long as the participants achieve the basic intensity of
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39 464 PA required in the study. Another limitation is that there might be measurement bias of
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41 465 some self-reporting outcomes, such as fatigue and sleep quality. But we do not think it will
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43 466 overturn the study results because the self-reporting biases are random in both groups.
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45 467 In summary, it would be an inexpensive, convenient, fast, and sustainable approach for
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47 468 adults, especially those with a busy work life, to use an online virtual training system to plan
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4 469 and implement their own PA program and comply with a healthy lifestyle. If the intervention
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6 470 proves to be effective, it will provide a scientific rationale for the implementation of the
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9 471 self-planned personalized PA program through a human-computer interactive system.
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56 490 **Contributors**
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4 491 Study concept and design: SSH, YJX, RCK; Obtained funding: SSH, WWSM, PKM, YJX;
5
6 492 Administrative, technical, or material support: SSH, EWT, WWSM, PKM; Drafting of the
7
8 493 manuscript: YJX, SSH; Critical revision of the manuscript: YJX, SSH. All authors read and
9
10
11 494 approved the final manuscript.
12

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17
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19

20 21 498 **Competing interests**

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23
24 499 The authors declare that they have no competing interests
25

26 27 500 **Ethics approval**

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29 501 The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research
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31 502 Ethics Committee
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51 52 53 54 55 56 512 **Figure legends** 57 58 59 60

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4 513 Figure 1. Screenshots of two virtual trainer “rooms”
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6 514 Figure 2. Procedure of screening eligibility, assessment, and follow up
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56 **Table 1. Procedures of recruitment screening and outcome measurements**
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| Measures | Recruitment | | Month | Month | Month |
|--|-------------|----------|-------|-------|-------|
| | screening | Baseline | 3 | 6 | 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)

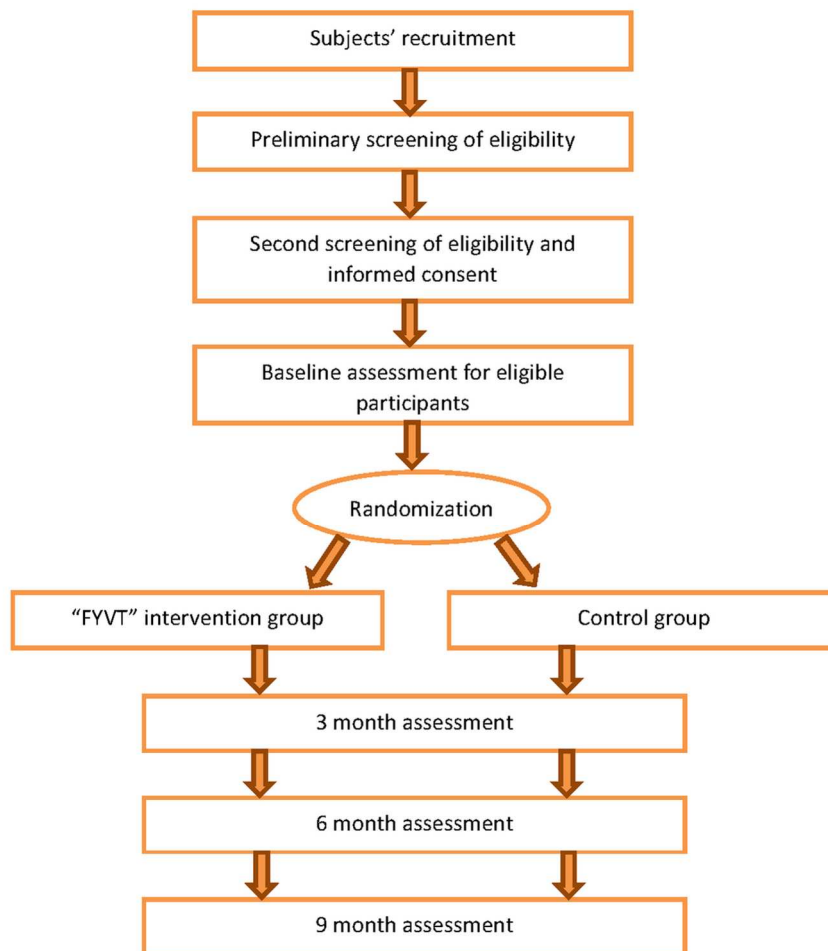


Figure 2. Procedure of screening eligibility, assessment, and follow up

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 _____



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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 |
|---------------------|-----|--|----|

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|----|---|-----|---|-------|
| 1 | | | | |
| 2 | Allocation | 16b | Mechanism of implementing the allocation sequence (eg, central | 10 |
| 3 | concealment | | telephone; sequentially numbered, opaque, sealed envelopes), describing | |
| 4 | mechanism | | any steps to conceal the sequence until interventions are assigned | |
| 5 | | | | |
| 6 | Implementati | 16c | Who will generate the allocation sequence, who will enrol participants, and | 10 |
| 7 | on | | who will assign participants to interventions | |
| 8 | | | | |
| 9 | | | | |
| 10 | Blinding | 17a | Who will be blinded after assignment to interventions (eg, trial participants, | 10 |
| 11 | (masking) | | care providers, outcome assessors, data analysts), and how | |
| 12 | | | | |
| 13 | | 17b | If blinded, circumstances under which unblinding is permissible, and | 10 |
| 14 | | | procedure for revealing a participant's allocated intervention during the | |
| 15 | | | trial | |
| 16 | | | | |
| 17 | | | | |
| 18 | Methods: Data collection, management, and analysis | | | |
| 19 | | | | |
| 20 | Data collection | 18a | Plans for assessment and collection of outcome, baseline, and other trial | 14-18 |
| 21 | methods | | data, including any related processes to promote data quality (eg, | |
| 22 | | | duplicate measurements, training of assessors) and a description of study | |
| 23 | | | instruments (eg, questionnaires, laboratory tests) along with their reliability | |
| 24 | | | and validity, if known. Reference to where data collection forms can be | |
| 25 | | | found, if not in the protocol | |
| 26 | | | | |
| 27 | | | | |
| 28 | | 18b | Plans to promote participant retention and complete follow-up, including | 18 |
| 29 | | | list of any outcome data to be collected for participants who discontinue or | |
| 30 | | | deviate from intervention protocols | |
| 31 | | | | |
| 32 | | | | |
| 33 | Data | 19 | Plans for data entry, coding, security, and storage, including any related | 19 |
| 34 | management | | processes to promote data quality (eg, double data entry; range checks for | |
| 35 | | | data values). Reference to where details of data management procedures | |
| 36 | | | can be found, if not in the protocol | |
| 37 | | | | |
| 38 | | | | |
| 39 | Statistical | 20a | Statistical methods for analysing primary and secondary outcomes. | 19 |
| 40 | methods | | Reference to where other details of the statistical analysis plan can be | |
| 41 | | | found, if not in the protocol | |
| 42 | | | | |
| 43 | | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 19 |
| 44 | | | | |
| 45 | | 20c | Definition of analysis population relating to protocol non-adherence (eg, as | 19 |
| 46 | | | randomised analysis), and any statistical methods to handle missing data | |
| 47 | | | (eg, multiple imputation) | |
| 48 | | | | |
| 49 | | | | |
| 50 | Methods: Monitoring | | | |
| 51 | | | | |
| 52 | Data | 21a | Composition of data monitoring committee (DMC); summary of its role and | NA |
| 53 | monitoring | | reporting structure; statement of whether it is independent from the | |
| 54 | | | sponsor and competing interests; and reference to where further details | |
| 55 | | | about its charter can be found, if not in the protocol. Alternatively, an | |
| 56 | | | explanation of why a DMC is not needed | |
| 57 | | | | |
| 58 | | | | |
| 59 | | 21b | Description of any interim analyses and stopping guidelines, including who | NA |
| 60 | | | will have access to these interim results and make the final decision to | |
| | | | terminate the trial | |

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|----|---------------------------------|-----|--|--------|
| 1 | | | | |
| 2 | Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and | 18 |
| 3 | | | spontaneously reported adverse events and other unintended effects of | |
| 4 | | | trial interventions or trial conduct | |
| 5 | | | | |
| 6 | Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether | NA |
| 7 | | | the process will be independent from investigators and the sponsor | |
| 8 | | | | |
| 9 | | | | |
| 10 | Ethics and dissemination | | | |
| 11 | | | | |
| 12 | Research | 24 | Plans for seeking research ethics committee/institutional review board | 8 |
| 13 | ethics approval | | (REC/IRB) approval | |
| 14 | | | | |
| 15 | Protocol | 25 | Plans for communicating important protocol modifications (eg, changes to | NA |
| 16 | amendments | | eligibility criteria, outcomes, analyses) to relevant parties (eg, | |
| 17 | | | investigators, REC/IRBs, trial participants, trial registries, journals, | |
| 18 | | | regulators) | |
| 19 | | | | |
| 20 | | | | |
| 21 | Consent or | 26a | Who will obtain informed consent or assent from potential trial participants | 8 |
| 22 | assent | | or authorised surrogates, and how (see Item 32) | |
| 23 | | | | |
| 24 | | 26b | Additional consent provisions for collection and use of participant data and | NA |
| 25 | | | biological specimens in ancillary studies, if applicable | |
| 26 | | | | |
| 27 | | | | |
| 28 | Confidentiality | 27 | How personal information about potential and enrolled participants will be | 8 |
| 29 | | | collected, shared, and maintained in order to protect confidentiality before, | |
| 30 | | | during, and after the trial | |
| 31 | | | | |
| 32 | Declaration of | 28 | Financial and other competing interests for principal investigators for the | 22 |
| 33 | interests | | overall trial and each study site | |
| 34 | | | | |
| 35 | Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure | 8 |
| 36 | | | of contractual agreements that limit such access for investigators | |
| 37 | | | | |
| 38 | | | | |
| 39 | Ancillary and | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to | NA |
| 40 | post-trial care | | those who suffer harm from trial participation | |
| 41 | | | | |
| 42 | Dissemination | 31a | Plans for investigators and sponsor to communicate trial results to | 3 |
| 43 | policy | | participants, healthcare professionals, the public, and other relevant | |
| 44 | | | groups (eg, via publication, reporting in results databases, or other data | |
| 45 | | | sharing arrangements), including any publication restrictions | |
| 46 | | | | |
| 47 | | 31b | Authorship eligibility guidelines and any intended use of professional | NA |
| 48 | | | writers | |
| 49 | | | | |
| 50 | | 31c | Plans, if any, for granting public access to the full protocol, participant- | NA |
| 51 | | | level dataset, and statistical code | |
| 52 | | | | |
| 53 | | | | |
| 54 | | | | |
| 55 | Appendices | | | |
| 56 | | | | |
| 57 | Informed | 32 | Model consent form and other related documentation given to participants | Appen |
| 58 | consent | | and authorised surrogates | dix II |
| 59 | materials | | | |
| 60 | | | | |

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|---|------------|----|--|----|
| 1 | | | | |
| 2 | Biological | 33 | Plans for collection, laboratory evaluation, and storage of biological | NA |
| 3 | specimens | | specimens for genetic or molecular analysis in the current trial and for | |
| 4 | | | future use in ancillary studies, if applicable | |
| 5 | | | | |

6 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
7 Explanation & Elaboration for important clarification on the items. Amendments to the
8 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
9 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
10 license.
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For peer review only