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## Mobile health–based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

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**Title Page**

Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

**The corresponding author:**

Feng Li, PhD, School of Nursing, Jilin University, No 965, Xin Jiang Avenue, 130000, Changchun, Jilin Province, China.

**Tel.:** 17790089009, **Fax:** (86)431-85619580, **E-mail:** [fli@jlu.edu.cn](mailto:fli@jlu.edu.cn)

Qian Tong, MD, First Hospital of Jilin University, No 71, Xin Min Avenue, 130000, Changchun, China.

**Tel.:** 13074337289, **Fax:** (86)431-58997910, **E-mail:** [tongqian187@aliyun.com](mailto:tongqian187@aliyun.com)

**The name(s) of all authors:**

Linqi Xu<sup>1</sup>, Jinwei Li<sup>1</sup>, Xin Zhang<sup>1</sup>, Yue Pang<sup>1</sup>, Tianzhuo Yu<sup>1</sup>, Xiaoqian Lian<sup>1</sup>, Tianyue Yu<sup>1</sup>, Lanyu Zhu<sup>1,2</sup>, Qian Tong<sup>3\*</sup>, Feng Li<sup>1\*</sup>.

<sup>1</sup>School of Nursing, Jilin University, Changchun, Jilin Province, China.

<sup>2</sup> Changchun University of Chinese Medicine, Changchun, Jilin Province, China

<sup>3</sup>The First Hospital of Jilin University, No 71, Xin Min Avenue, Changchun, Jilin Province, China.

\*These authors contributed equally to this work and should be considered co-corresponding authors

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## Abstract

**Introduction:** Despite proven benefit, physical activity participation remains low in patients with coronary heart disease. There is scientific evidence suggesting that mobile health-based gamification interventions have potential to increase physical activity levels. However, several systematic reviews have found that most gamification intervention designs do not appropriately leverage theories from health behavior models, and empirical evidence on the effectiveness of such interventions among patients with coronary heart disease is still emerging. In the present study, we embed the principles of behavioral economics into a gamification intervention based on a smartphone app (Wechat Applet), the objective of this study is to explore whether a mobile health (mHealth)-based gamification intervention can improve participation in physical activity and other related physical and psychological outcomes in patients with coronary heart disease.

**Methods:** We propose a double-blinded three-arm randomized controlled trial with 108 patients with coronary heart disease. Patients will be randomly divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat applet + step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification + collaboration). The interventions will last for 12 weeks and follow-up for 12 weeks. All patients will receive only WeChat applet-based step goal setting in the follow-up period. The primary outcome is the change in daily step count and the proportions of patient-days that step goals were achieved, which will be measured using the smartphone accelerometer. The secondary outcomes include exercise capacity, biomedical and lifestyle-related risk factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support and mental health and patients' perceptions, and intervention experience.

**Ethics and dissemination:** This study has been approved by the Human Research Ethics Committee of the School of Nursing, Jilin University (HREC 2020122401). The results will be published in peer-reviewed journals and at conferences.

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4 **Trial registration number:** ChiCTR2100044879; Pre-results.  
5

6 **Keywords:** physical activity, behavioral intervention, mobile health, gamification, randomized controlled trial  
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11 **Strength and Limitations of this study**  
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- 13  
14 1. Our WeChat applet-based gamification intervention is technology-based and may improve physical activity  
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16 (PA) adherence in patients with coronary heart disease (CHD).  
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20 2. This study is based on a theoretical framework and will provide insights into how to use mobile health and  
21  
22 game elements to promote patients' intrinsic motivation, thereby improve the adherence.  
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25 3. This study will evaluate patients' psychological needs, intrinsic motivations, perceptions and experience,  
26  
27 which allowing us to understand the internal psychological mechanisms of gamification intervention to  
28  
29 promote physical activity.  
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32  
33 4. The study period was 24 weeks; thus, we could not evaluate and maintain the intervention in 12 months.  
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36 5. The gamification interventions are comprehensive and it would be difficult to analyze the component that  
37  
38 worked.  
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44 **1. Background**  
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46 Coronary heart disease (CHD) is the leading cause of mortality in China. Statistically, around 11 million  
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48 people were affected with CHD in 2017 [1,2]. Exercise-based cardiac rehabilitation and secondary prevention  
49  
50 (CR/SP) plays a crucial role in preventing the recurrence of CHD[3] and has been listed as a Class I  
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52 recommendation for CHD treatment by the American Heart Association (AHA), the American Society of  
53  
54 Cardiology (ACC), and the European Society of Cardiology (ESC)[4-7]. The relevant guidelines recommend that  
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56 patients with CHD should perform, at least, 500-MET-min/week physical activity (PA) every week[8]. Although  
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4 CR/SP have proven benefits, it is often challenging for patients to attain lifestyle changes needed for SP, especially  
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6 with increasing PA levels<sup>[9]</sup>. For example, owing to the poor accessibility of cardiac rehabilitation programs (CRP),  
7  
8 > 80% of patients did not participate in the CRP recommended by the guidelines<sup>[10]</sup>. Moreover, patients with CHD  
9  
10 typically fail to attain their daily PA goals<sup>[11]</sup>.  
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14 mHealth, defined by AHA's scientific statement, "is the use of mobile computing and communication  
15  
16 technologies (e.g. mobile phones, wearable devices) for health services and information"<sup>[12]</sup>, has become an  
17  
18 essential medium to deliver behavioral change interventions and demonstrated promising ability to improve PA  
19  
20 levels<sup>[12-14]</sup>. In China, WeChat is a top-rated multipurpose social media app, with >1.151 billion active users<sup>[15]</sup>.  
21  
22 WeChat applets are lightweight apps that form part of the WeChat ecosystem, which could be used independently  
23  
24 and do not need installation. Compared with mobile apps, WeChat applets are easier to be accepted and applied  
25  
26 by people in China. The third quarter of 2019 recorded >300 million active WeChat applet users every day, thereby  
27  
28 making it well suited to disseminate mHealth interventions in China<sup>[16]</sup>.  
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35 Gamification is the use of game design elements (such as points, leaderboards, progress bars, and badges) in  
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37 non-game contexts (such as management, education, marketing, and healthcare) to increase motivation and  
38  
39 engagement<sup>[17]</sup>. There is growing interest in the application of gamification in mHealth with the view of promoting  
40  
41 healthy behavioral changes<sup>[18-21]</sup>, especially in promoting PA levels<sup>[22]</sup>. Previous studies indicated that  
42  
43 gamification was used in 64% of the top 50 most popular smartphone apps<sup>[23]</sup>. However, several systematic  
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45 reviews reported that most gamification intervention designs did not appropriately leverage theories from health  
46  
47 behavior models<sup>[18,24,25]</sup>. Moreover, as the concept of gamification is relatively new<sup>[17]</sup>, empirical evidence on the  
48  
49 efficacy of gamification PA behavioral change interventions among patients with CHD is still emerging.  
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56 Gamification interventions are rarely based on a sound theoretical framework<sup>[19,21]</sup>. Behavioral economics  
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58 (BE) principles combine conventional economic principles with psychology to elucidate how individuals behave  
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4 and make decisions<sup>[26]</sup>. BE principles can be embedded with a gamification intervention via mobile devices to aid  
5  
6 people to attain their PA goals. For example, based on the loss aversion, which implies that the loss framework is  
7  
8 more effective in stimulating behavioral change than the gain framework, Patel et al. designed an intervention  
9  
10 wherein participants lost points if they did not accomplish their step goals<sup>[27]</sup>. Several previous studies have used  
11  
12 BE principles to help patients lose weight, quit smoking, and adhere to medications<sup>[28-30]</sup>. However, limited data  
13  
14 are available on applying these concepts to improve PA participation in patients with CHD.  
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20 In this study, we have used BE principles to develop a gamification WeChat applet named “Tahnee Weh” to  
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22 resolve this research gap. This study aims to investigate the effects of the mHealth-based gamification intervention  
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24 on participation in PA and evaluate the effects on exercise capacity, biomedical and lifestyle-related risk factors,  
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26 intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support and  
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28 mental health. In addition, a semi-structured interview will be conducted after the intervention to comprehend  
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30 patients’ perceptions and their experience on the intervention.  
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## 35 **2. Methods**

### 36 **2.1 Study design**

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40 This is a double-blind, three-arm randomized controlled trial to evaluate the effects of gamified joint financial  
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42 incentive behavior intervention on participation in PA, exercise capacity, biomedical and lifestyle-related risk  
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44 factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social  
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46 support, and mental health. Patients with CHD will be recruited in a CR center of a tertiary-grade A class hospital  
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48 in Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants will be  
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50 randomly divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat  
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52 applet + step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification +  
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54 collaboration). Patients in the control group will only receive daily step goal setting. The Individual and Team  
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4 groups will receive gamified behavior intervention based on BE principles. The Team group will also receive  
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6 social incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12  
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8 weeks. All patients will just receive WeChat applet-based step goal setting in the follow-up period. Figure 1 shows  
9  
10 a flowchart of the study design. The protocol conforms to the Standard Protocol Items: Recommendations for  
11  
12 Interventional Trials (SPIRIT) reporting guidelines, and the intervention is described per the CONSORT-  
13  
14 EHEALTH checklist<sup>[31-33]</sup>. The study is registered at Clinical Trials.gov: ChiCTR2100044879.

## 19 **2.2 Eligibility and Recruitment**

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23 Patients fulfilling the inclusion and exclusion criteria will be invited to participate in the trial. The inclusion  
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25 criteria are as follows: (i) aged 18–70 years; (ii) patients diagnosed with CHD (including acute myocardial  
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27 infarction and unstable angina), and received percutaneous coronary intervention (PCI) treatment during  
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29 admission; (iii) patients evaluated by cardiologists and rehabilitation therapists if they are suitable for  
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31 participating in our program; (iv) patients willing to provide written informed consent; (v) patients with a  
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33 smartphone and an active WeChat account; and (vi) patients with proficiency in Chinese.

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38 The exclusion criteria include the following: (i) contraindications for exercise rehabilitation (e.g., untreated  
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40 ventricular tachycardia, severe heart failure, uncontrollable hypertension or hypotension, notable exercise  
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42 restriction); (ii) patients unable to use WeChat applet after instruction; (iii) no Internet access in the place of  
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44 residence; (iv) patients requiring a walking aid to move; and (v) patients participating in other clinical trials.

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48 Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting  
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50 participants. Researchers will inform the patients about the details of the study. If they agree to participate in the  
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52 study, they will have to sign the written consent form. After that, we will teach patients to register and log in to  
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54 our WeChat applet “Tahnee Weh”; this is required to get their step data for the past 2 weeks, which will be  
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56 recorded by smartphone accelerometers (as done in many prior studies<sup>[34-37]</sup>) and has been proven accurate for  
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4 tracking step counts<sup>[38]</sup>. Furthermore, a baseline step count will be estimated using the mean step count of the  
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6 previous 2 weeks.  
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### 8 9 **2.3 Sample size calculation**

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11 The main outcome indicator daily step count is selected as the calculation standard. Based on a previous  
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13 study, we will ensure, at least, 90% power to detect an 800-step difference between each intervention arm and  
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15 control, a standard deviation of 2000 steps, and a two-sided  $\alpha$  of 0.05<sup>[39]</sup>. In addition, we will use one-way analysis  
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17 of variance *F*-tests in PASS15.0.5 software and calculate that a total of 84 participants across three arms would  
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19 be recruited. By allowing for an estimated 20% dropout rate, a sample size of 108 will be used in this study.  
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### 24 25 **2.4 Randomization, blinding, and concealed allocation**

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27 Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step  
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29 count (<5000, 5001–7500, or >7500 steps/day). Participants and data collector will be unaware of patient  
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31 assignments at the baseline, 12 weeks, and 24 weeks of the study. Researchers could see the assignments in  
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33 backstage of the WeChat applet, and the interfaces of the WeChat applet for patients in different groups are  
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35 different.  
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### 40 41 **2.5 Control**

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43 All patients will receive step goal setting and could see their progress on the WeChat applet during the 12–  
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45 week intervention and 12–week follow-up. Personalized daily step goals will be set in the WeChat applet  
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47 backstage based on patients' baseline daily step counts, and the goals will increase gradually from the baseline by  
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49 15% each week during the first 6 weeks, and then remained fixed during the last 6 weeks, as described  
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51 elsewhere<sup>[40]</sup>. Moreover, patients could see their daily progress toward their goals using a circular dial on the  
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53 WeChat applet. Of note, patients in the control group will receive no other interventions. If the patient has not  
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55 logged in to the WeChat applet for more than a week, a text message reminder will be sent to the patient.  
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## 2.6 Intervention

Patients in the Individual and Team groups will receive the gamification intervention based on BE principles via the WeChat Applet. Six BE principles (precommitment, fresh start effect, goal gradients, loss aversion, anticipated regret, and social norms) will be embedded within the gamification intervention. The gamification intervention in the Individual group will apply to four game elements—feedback, points, levels, and rewards. In the Team group, collaboration is added besides the abovementioned four game elements. Table 1 provides a summary of game elements, gamification intervention components, and BE principles.

### 2.6.1 Individual group

First, patients will electronically sign a precommitment pledge to try their best to attain their step goal. Precommitment is known to motivate behavioral change<sup>[41,42]</sup>. Second, every Monday, patients will receive 140 points (20 for each day), which leverage the fresh start effect<sup>[43]</sup>. Patients tend to be more driven for aspirational behavior around temporal landmarks like the beginning of the week. Third, if patients reach the target step count, no points will be deducted; if not, 20 points will be deducted. This leverages loss aversion, which has demonstrated that loss framing is more effective at motivating behavioral change than gain framing<sup>[44,45]</sup>. Fourth, a total of five levels will be set, from low to high—bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, patients will be set to the gold level. If a patient has a total score of <80 points in the week, the level will drop, and if the total scores are  $\geq 80$  points, the level will increase; this is done such that the patients would feel their level dropping to silver if they did not attain sufficient points in the first week. At the end of the intervention, if the level of a patient is diamond, he/she will be rewarded with a small prize. Fifth, patients in the two intervention groups will receive feedback weekly based on their progress.

### 2.6.2 Team group

Team group will also receive social incentives based on the Individual group. Patients are assigned to a team

of 3 people, who do not know each other before the intervention. Every Monday, the patients will receive 140 points (20 for each day, 10 for themselves, 10 for their team). If the patient achieves the step goals and the other 2 people in his/her team also achieve the step goals, no points will be deducted. If the patient achieves the step goals, but other 2 people in his/her team do not, 10 points for their team will be deducted. If neither the patient nor the other two people in his/her team achieve the step goal, 20 points will be deducted. Figure 2 presents the WeChat applet interface, and Figure 3 shows the backstage management system of the WeChat applet.

Table 1 A summary of game elements, intervention components, and BE principles

Game elements	Gamification intervention components	BE principles
	Patients will electronically sign a precommitment pledge to try their best to achieve their step goal.	Precommitment
<b>Points</b>	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
<b>Points</b>	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
<b>Collaboration</b>	If the patient achieve the step goals and the other 2 people in her team also achieve the step goals, no points will be deducted; if the patient achieve the step goals but other 2 people in her team do not, 10 points for her team will be deducted; if neither the patient nor the other two people in her team does not achieve the step goal, 20 points will be deducted.	Social norms; Loss aversion; Anticipated Regret
<b>Levels</b>	We set 5 levels, from low to high is bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, the patient is set to the gold level. If the patient has a total score of less than 80 points in a week, the level will drop,	the Fresh Start Effect; Goal Gradients; Loss aversion

	and if the total score is greater than or equal to 80 points, the level will rise.	
<b>Rewards</b>	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
<b>Feedback</b>	Patients in the two intervention groups will receive feedback according to their progress weekly.	

BE, behavioral economics

## 2.7 Outcome measures and data collection

Table 2 shows the summary of the outcome measures for the study. The primary outcome is PA participation, which includes change in daily steps from the baseline to 12 and 24 weeks and the proportion of patient-days that step goals achieved in 12 and 24 weeks. The daily step counts are measured and recorded by smartphone accelerometers, which have been proven accurate for tracking step counts<sup>[38]</sup>.

The secondary outcomes include self-reported PA level using the International Physical Activity Questionnaire (IPAQ)<sup>[46]</sup>, biomedical risk factors which include the body weight (kg), waist circumference (cm), body mass index (BMI), systolic blood pressure (mmHg), diastolic blood pressure (mmHg), resting heart rate (bpm/min), serum total cholesterol (TC, mg%), fasting plasma glucose (mg%), lifestyle-related risk factors, including smoking, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support, anxiety symptom, and depressive symptoms. The IPAQ is filled out online at the baseline, 4 weeks, 8 weeks, 12 weeks, and 24 weeks through the WeChat applet, while the other measurements are taken in the hospital (at the baseline, 12 weeks, and 24 weeks). In addition, usability will be tested at the end of the intervention (at 12 weeks) in the two intervention groups. Furthermore, we will conduct a semi-structured interview to understand patients' perceptions and experience in the two intervention groups.


All adverse events that occur will be reported to the Ethics Committee as required during the 24 weeks study

period. Adverse events are defined as medical occurrences resulting in hospitalization, disability, or deaths.

Table 2 Assessment time-points for primary and secondary outcomes

Outcome	Assessment	Baseline	12 weeks	24 weeks
<b>Primary outcomes</b>				
<b>Physical activity</b>	Change in daily steps	√	√	√
	The proportion of patient-days that step goals were achieved		√	√
	International Physical Activity Questionnaire (IPAQ) <sup>46</sup>	√	√	√
<b>Secondary outcomes</b>				
<b>Exercise capacity</b>	Change in VO <sub>2 peak</sub>	√	√	√
<b>Biomedical risk factors</b>	Body weight, waist circumference, BMI, SBP, DBP, RHR, TC, FPG	√	√	√
<b>Lifestyle-related risk factors</b>	Self-reported smoking	√	√	√
<b>Perceived competence, autonomy, and relatedness</b>	Psychological Needs Satisfaction in Exercise Scale(PNSE) <sup>47</sup>	√	√	√
<b>Intrinsic motivation</b>	Behavioral Regulation in Exercise Questionnaire(BREQ-2) <sup>48</sup>	√	√	√
<b>Perceived enjoyment</b>	Physical Activity Enjoyment Scale (PACES) <sup>49</sup>	√	√	√
<b>Social support</b>	Social Support Rating Scale (SSRS) <sup>50</sup>	√	√	√
<b>Anxiety symptoms</b>	Generalised Anxiety Disorder 7-item Scale (GAD-7) <sup>51</sup>	√	√	√
<b>Depressive symptoms</b>	Patient Health Questionnaire (PHQ-9) <sup>52</sup>	√	√	√
<b>Usability</b>	System Usability Scale(SUS) <sup>53</sup>		√	
<b>Satisfaction</b>			√	
<b>Patients' experience</b>	Semi-structured interview		√	

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<b>Adverse event reporting</b>	Medical occurrences resulting in hospitalization, disability or deaths	
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BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; RHR, resting heart rate; TC, serum total cholesterol; FBG, fasting plasma glucose

## 2.8 Statistical analysis and data management

All continuous variables will be reported as mean and SD, and categorical variables will be described as frequencies and percentages. Within the group changes in daily step counts, the proportion of patient-days that step goals attained, exercise capacity, biomedical and lifestyle-related risk factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support and mental health will be compared using a paired *t*-test or Wilcoxon test depending on the data distribution. Besides, one-way analysis of variance will be used to compare the inter-group differences between the baseline and post-intervention among the outcomes. Main analysis and secondary analysis will be conducted of all the outcomes. In the main analysis, the analysis of outcomes will be conducted per the intention-to-treat principle. In addition, multiple imputations for data were used that were missing and step values <1000 because evidence indicates that these values are unlikely to represent the capture of actual activity<sup>[36,54]</sup>. In the secondary analysis, data analysis will be conducted without multiple imputations, both with and without step values <1000. Furthermore, adjusted analyses include sex, age, BMI, severity of disease, and baseline variables. All statistical analyses will be two-sided, and  $P < 0.05$  will be considered statistically significant. We will use SPSS V.20.0 for data analysis.

In this study, well-trained clinical researchers will record all patients' data using standardized case report forms (CRF). The original data will be recorded timely and accurately, and a copy of the report will be kept in the laboratory. All CRFs are stored in a locked file cabinet to prevent data leakage. All laboratory data will be identified with a code number to ensure the confidentiality of subjects' data. The clinical research data management platform of the School of Nursing of Jilin University is accountable for data monitoring. The chief

investigator can directly access the dataset, and the data scattered to the project team members cannot identify any participant identity information.

## 2.9 Patient and public involvement

Patient and public involvement (PPI) played a vital role in this study. Before designing the WeChat applet, the authors conducted a survey among CHD patients and found that the patients lacked PA and they were willing to be supervised and motivated via their smartphones to promote participation in PA. During the development of WeChat applet, patients with CHD were invited to participate in our discussion, which allowed the authors to consider the thoughts and needs of patients in developing the WeChat applet. In the pilot study, patients were invited to give reasonable recommendations for study design, questionnaire selection, and outcome measurements while considering the burden of intervention. The results of this study will be disseminated to PPI representatives and study participants who wish to be notified.

## 2.10 Validity and reliability

This study uses a rigorous research design (randomized controlled design) and a block random method to assign groups. The grouping results are numbered and placed in a sealed envelope. Participants and data collector will be blinded to the assignments. All questionnaires are completed by the researcher's guidance or ghostwriting. The questionnaires are distributed and collected on the spot to avoid data bias caused by different researchers. Two researchers entered all the data to avoid objective typing errors.

## 3. Ethics considerations

This study will comply with the ethical principles of the Declaration of Helsinki, and the Human Research Ethics has been approved by the School of Nursing, Jilin University (HREC 2020122401). This study has been registered at ClinicalTrials.gov (ChiCTR2100044879).

## 4. Discussion

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4 The authors aim to develop a WeChat applet in this study. Based on the WeChat applet and under the  
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6 guidance of BE principles, the authors will develop a gamification intervention using five game elements,  
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8 including points, levels, feedback, rewards, and collaboration. This study will evaluate the role of mHealth-based  
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10 gamification intervention on PA participation and the effects on exercise capacity, biomedical and lifestyle-related  
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12 risk factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social  
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14 support, and mental health. Moreover, the authors will conduct a semi-structured interview after the intervention  
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16 to elucidate patients' perceptions and experience of the intervention.  
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22 Despite proven benefits, patients with CHD do not often attain their PA goals on their own [11]. Behavioral  
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24 interventions are needed to help them increase PA participation. With the technological advancement, numerous  
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26 smartphone apps have appeared, and gamification was used in most of these apps, which had the potential to  
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28 increase PA motivation and promote behavioral change. However, most gamification intervention designs did not  
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30 appropriately leverage theories from health behavior models and empirical evidence on their efficacy is still  
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32 emerging. A previous study established that BE principles could be embedded with a gamification intervention to  
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34 significantly increase PA among overweight and obese adults<sup>[27]</sup>. However, thus far, there is limited evidence of  
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36 interventions that use these methods to effectively improve PA participation among high-risk patients, such as  
37  
38 patients with CHD<sup>[55]</sup>. Thus, this study will develop a gamification intervention based on a WeChat applet that  
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40 has been specifically developed for this study. Personalized goal setting and progress tracking on WeChat applet  
41  
42 allowed patients to exercise at home. The gamification intervention motivated patients to walk more; this could  
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44 become a new way to promote the implementation of home and exercise-based CR.  
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52  
53 The key of gamification interventions is to organically combine game elements to form a resultant force to  
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55 improve PA, and the key of the resultant force is to comprehend the driving force or motivation behind the  
56  
57 incentive mechanism. Research indicates links between self-determination theory (SDT) and gamification  
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4 concepts. SDT suggests that satisfying three innate psychological needs of competence, autonomy, and relatedness  
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6 could promote autonomous motivation and well-being. Studies reported that individuals with autonomous  
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8 motivation had higher PA participation and better PA adherence than those primarily driven by external factors<sup>[56]</sup>.  
9  
10 Furthermore, the fact that gamification could make interventions more enjoyable aligns with SDT, which assumes  
11  
12 that a key aspect of intrinsic motivation is enjoyment<sup>[17]</sup>. We planned to investigate the internal psychological  
13  
14 mechanism of gamification to promote PA; thus, we evaluated perceived competence, autonomy, relatedness,  
15  
16 enjoyment, and intrinsic motivation. We assumed that gamification intervention promoted the transformation of  
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18 controlled motivation into autonomous motivation by satisfying perceived competence, autonomy, relatedness,  
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20 enjoyment, and ultimately promote PA participation. [Figure 4](#) shows the hypothesized model of PA behavior  
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22 regulation. Moreover, because our intervention platform provides information support for patients, we also  
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24 evaluated the variable social support. Furthermore, we conducted a semi-structured interview after the  
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26 intervention to comprehend patients' experience and capture information on communications among patients in  
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28 the collaboration group, which could explore the internal psychological mechanism of gamification to promote  
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30 exercise motivation.

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40 In China, access to CR is often limited. Patients with CHD often lack PA at home. Our intervention could  
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42 help increase PA participation and bring more health benefits.

#### 43 44 45 **Limitations**

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48 This study has several limitations. First, we will not measure the intensity of PA via the smartphone  
49  
50 accelerometer. In future, we plan to use wearable devices to evaluate the intensity of PA. Second, the study period  
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52 is 24 weeks; thus, we will not be able to evaluate and maintain the intervention in 12 months. Third, the study is  
53  
54 limited to patients with smartphones and a WeChat account, which could lead to a selective bias. Fourth, the  
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56 gamification interventions are comprehensive and it would be difficult to analyze the component that worked.  
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4 Fifth, the reward of this study is money, and points can be directly exchanged for cash. Hence, we will not be able  
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6 to analyze the impact of gamification or the impact of financial incentives.  
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## 8 9 **5. Conclusions**

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11 This study will test the usage of a smartphone and WeChat applet-based gamification intervention to increase  
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13 PA at home. If the intervention increases patients' PA, this is likely to translate into improved patient outcomes  
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15 and reduce the financial burden of CVD on health systems. Overall, the model of the gamification intervention  
16  
17 via smartphone could also be used for other chronic diseases.  
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24  
25 **Acknowledgements** The authors would like to thank the valuable contribution made by the patients and public  
26  
27 representatives during the study design and intervention development.  
28  
29

30  
31 **Contributors** LX, QT and FL conceived the original concept of the study and wrote the first draft of the protocol  
32  
33 manuscript. LX, JL, XZ, YP, TY, XL, TY and LZ contributed to the design of the study. All authors read and  
34  
35 approved the final manuscript.  
36  
37

38  
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40  
41 Community Health Nursing Engineering Laboratory in Jilin Province (Study code: 2020C038-8) awarded to Dr.  
42  
43 Feng Li.  
44  
45

46  
47 **Competing interests** None declared.

48  
49 **Provenance and peer review** Not commissioned; externally peer reviewed.

50  
51 **Data sharing statement** For patient confidentiality concerns and the access possibilities of the data source, the  
52  
53 clinical data collected will not be shared with the public. However, non-clinical data, such as educational materials,  
54  
55 will be shared with the public and other researchers.  
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4 Figure legends  
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6 Figure 1: Study flowchart.  
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8 Figure 2: WeChat applet “Tahnee Weh” interface. (A) Daily step progress using a circular dial; (B) weekly step  
9 progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac  
10 rehabilitation and secondary prevention; (F) International Physical Activity Questionnaire (IPAQ) filling interface.  
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16 Figure 3: The backstage management system of the WeChat applet “Tahnee Weh”.  
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19 Figure 4: The hypothesized model of physical activity (PA) behavior regulation.  
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For peer review only

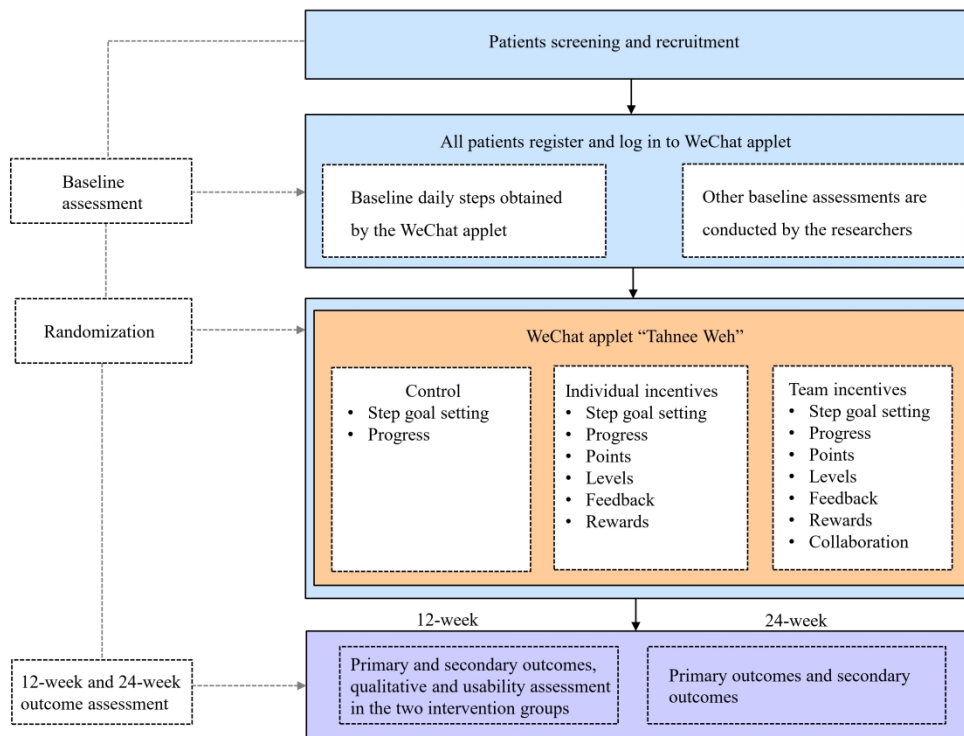


Figure 1: Study flowchart.

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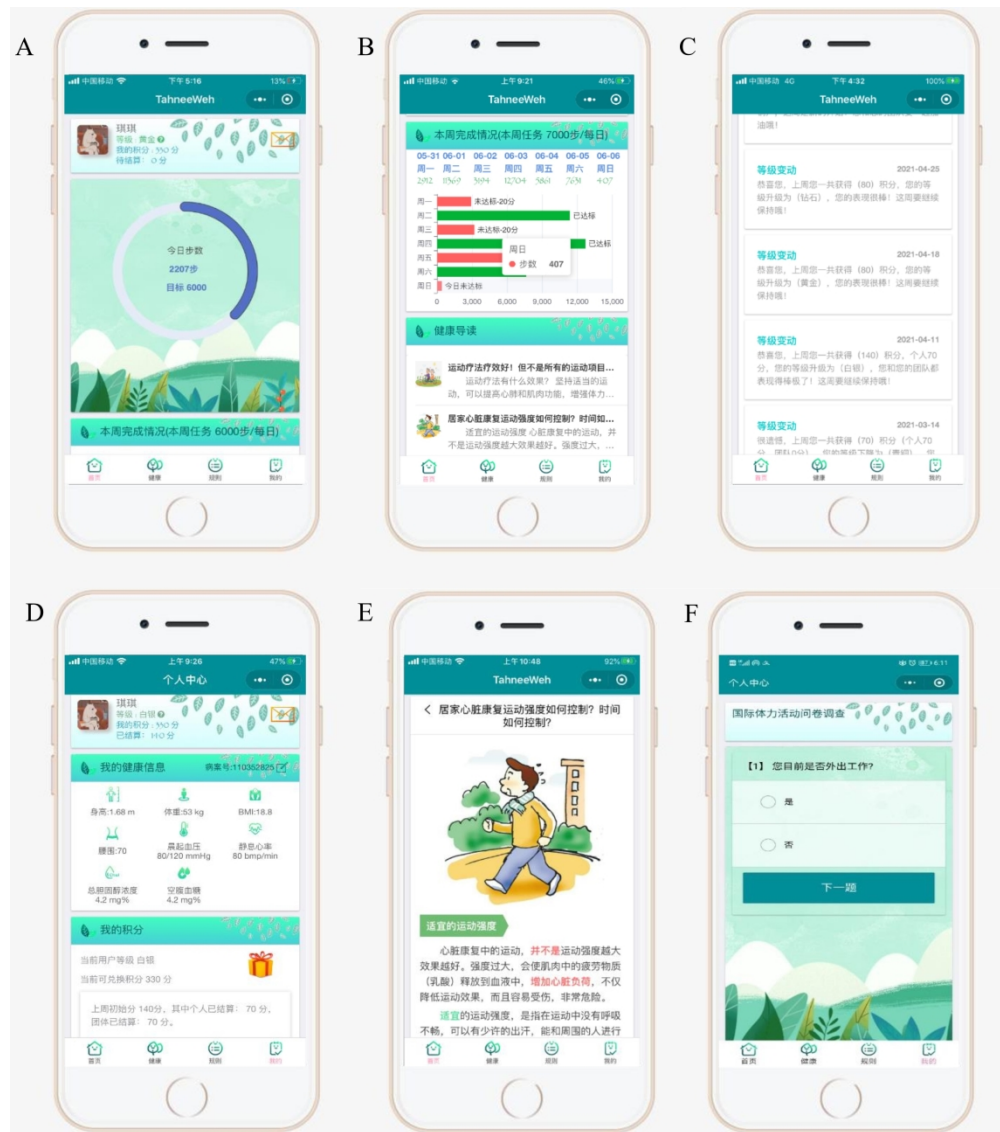


Figure 2: WeChat applet "Tahnee Weh" interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F) International Physical Activity Questionnaire (IPAQ) filling interface.

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Figure 3: The backstage management system of the WeChat applet "Tahnee Weh".

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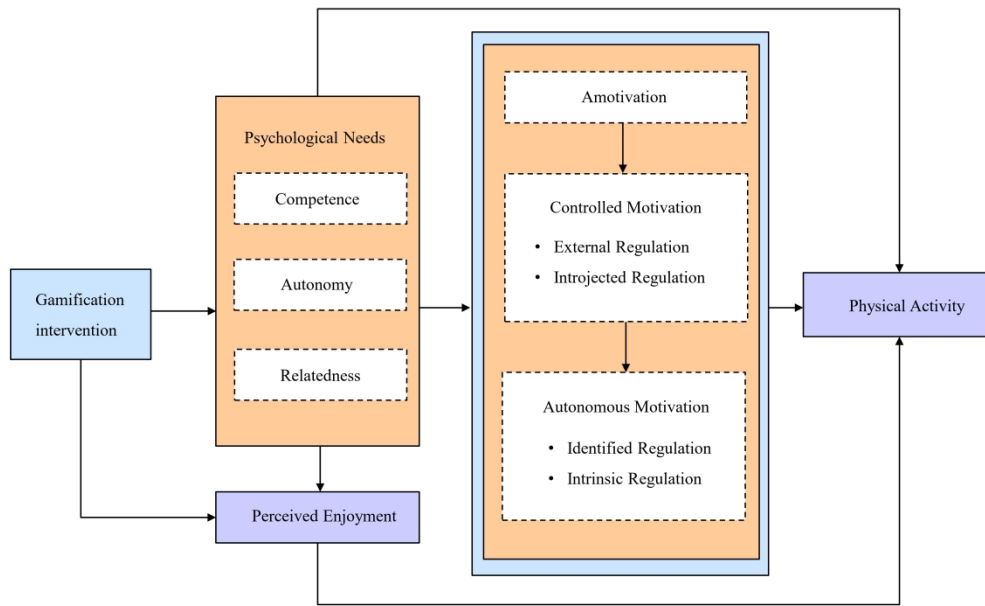


Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

1044x654mm (144 x 144 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

Reporting Item

Page Number

### Administrative

#### information

Title	<a href="#">#1</a>	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
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1	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet	P6
2			registered, name of intended registry	
3				
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6	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	P6
7			Registration Data Set	
8	data set			
9				
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11				
12	Protocol version	<a href="#">#3</a>	Date and version identifier	n/a
13				
14				
15	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	P16
16			support	
17				
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19				
20	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol	P16
21			contributors	
22	responsibilities:			
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24	contributorship			
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28	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	P16
29				
30	responsibilities:			
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32	sponsor contact			
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34	information			
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38	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	P16
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
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52	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	P12
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
55				
56	committees			
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and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

## Introduction

Background and rationale	<a href="#">#6a</a>	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	P3-5
Background and rationale: choice of comparators	<a href="#">#6b</a>	Explanation for choice of comparators	P3-5
Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	P5
Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	P5-6

## Methods:

### Participants, interventions, and outcomes

Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	P5
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academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

1		academic hospital) and list of countries where data	
2		will be collected. Reference to where list of study	
3		sites can be obtained	
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8	Eligibility criteria	<a href="#">#10</a> Inclusion and exclusion criteria for participants. If	P6
9		applicable, eligibility criteria for study centres and	
10		individuals who will perform the interventions (eg,	
11		surgeons, psychotherapists)	
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18	Interventions:	<a href="#">#11a</a> Interventions for each group with sufficient detail to	P7-9
19		allow replication, including how and when they will	
20	description	be administered	
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26	Interventions:	<a href="#">#11b</a> Criteria for discontinuing or modifying allocated	n/a, intervention
27		interventions for a given trial participant (eg, drug	did not involve
28	modifications	dose change in response to harms, participant	harms or others
29		request, or improving / worsening disease)	
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36	Interventions:	<a href="#">#11c</a> Strategies to improve adherence to intervention	P7
37		protocols, and any procedures for monitoring	
38	adherence	adherence (eg, drug tablet return; laboratory tests)	
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43	Interventions:	<a href="#">#11d</a> Relevant concomitant care and interventions that	P8-9
44		are permitted or prohibited during the trial	
45	concomitant care		
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49	Outcomes	<a href="#">#12</a> Primary, secondary, and other outcomes, including	P10-11
50		the specific measurement variable (eg, systolic	
51		blood pressure), analysis metric (eg, change from	
52		baseline, final value, time to event), method of	
53		aggregation (eg, median, proportion), and time	
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point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	<a href="#">#14</a>	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P7	
Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant enrolment to reach target sample size	P7-8	
<b>Methods:</b>				
<b>Assignment of interventions (for controlled trials)</b>				
Allocation: sequence generation	<a href="#">#16a</a>	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	P8	



provided in a separate document that is  
 unavailable to those who enrol participants or  
 assign interventions

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8	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation
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10	concealment		sequence (eg, central telephone; sequentially
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12	mechanism		numbered, opaque, sealed envelopes), describing
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15			any steps to conceal the sequence until
16			
17			interventions are assigned
18			
19			
20	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who
21			
22	implementation		will enrol participants, and who will assign
23			
24			participants to interventions
25			
26			
27			
28	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to
29			
30			interventions (eg, trial participants, care providers,
31			
32			outcome assessors, data analysts), and how
33			
34			
35	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is
36			
37	emergency		permissible, and procedure for revealing a
38			
39	unblinding		participant's allocated intervention during the trial
40			
41			
42			
43	<b>Methods: Data</b>		
44			
45	<b>collection,</b>		
46			
47	<b>management, and</b>		
48			
49	<b>analysis</b>		
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51			
52			
53	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome,
54			
55			baseline, and other trial data, including any related
56			
57			processes to promote data quality (eg, duplicate
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1 measurements, training of assessors) and a  
 2 description of study instruments (eg,  
 3 questionnaires, laboratory tests) along with their  
 4 reliability and validity, if known. Reference to  
 5 where data collection forms can be found, if not in  
 6 the protocol  
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14			
15	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and P10-11
16			
17	retention		complete follow-up, including list of any outcome
18			data to be collected for participants who
19			discontinue or deviate from intervention protocols
20			
21			
22			
23			
24			
25	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage, P12
26			
27			including any related processes to promote data
28			quality (eg, double data entry; range checks for
29			data values). Reference to where details of data
30			management procedures can be found, if not in
31			the protocol
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39	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and P12
40			
41			secondary outcomes. Reference to where other
42			details of the statistical analysis plan can be found,
43			
44			if not in the protocol
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49	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup P12
50			
51	analyses		and adjusted analyses)
52			
53			
54	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to P12
55			
56	population and		protocol non-adherence (eg, as randomised
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1 missing data analysis), and any statistical methods to handle  
 2  
 3 missing data (eg, multiple imputation)  
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## 6 **Methods: Monitoring**

9 Data monitoring: 10 formal committee	<a href="#">#21a</a>	Composition of data monitoring committee (DMC); 11 summary of its role and reporting structure; 12 13 statement of whether it is independent from the 14 15 sponsor and competing interests; and reference to 16 17 where further details about its charter can be 18 19 found, if not in the protocol. Alternatively, an 20 21 explanation of why a DMC is not needed 22 23	P12
25 Data monitoring: 26 interim analysis	<a href="#">#21b</a>	Description of any interim analyses and stopping 27 guidelines, including who will have access to these 28 interim results and make the final decision to 29 terminate the trial 30 31 32 33	n/a, not apply DMC in this trail
35 Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and 37 managing solicited and spontaneously reported 38 adverse events and other unintended effects of 39 trial interventions or trial conduct 40 41 42 43 44	P10
45 Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial 47 conduct, if any, and whether the process will be 48 independent from investigators and the sponsor 49 50 51 52	n/a

## 53 **Ethics and** 54 55 **dissemination** 56 57 58 59 60

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Research ethics approval	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P13
19 20 21 22 23 24 25 26 27 28 29 30 31 32 33	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
34 35 36 37 38 39 40 41 42 43	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P6-7
44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a, not needed in this study
	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P13
	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	P16
	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a, not needed in this study

1	Ancillary and post	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care,	n/a, not needed in
2				
3	trial care		and for compensation to those who suffer harm	this study
4				
5			from trial participation	
6				
7				
8	Dissemination	<a href="#">#31a</a>	Plans for investigators and sponsor to	P16
9				
10	policy: trial results		communicate trial results to participants,	
11				
12			healthcare professionals, the public, and other	
13				
14			relevant groups (eg, via publication, reporting in	
15				
16			results databases, or other data sharing	
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18			arrangements), including any publication	
19				
20			restrictions	
21				
22				
23				
24				
25	Dissemination	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended	P16
26				
27	policy: authorship		use of professional writers	
28				
29				
30				
31	Dissemination	<a href="#">#31c</a>	Plans, if any, for granting public access to the full	P16
32				
33	policy: reproducible		protocol, participant-level dataset, and statistical	
34				
35	research		code	
36				
37				
38	<b>Appendices</b>			
39				
40				
41	Informed consent	<a href="#">#32</a>	Model consent form and other related	Supplementary
42				
43	materials		documentation given to participants and	materials
44				
45			authorised surrogates	
46				
47				
48				
49	Biological	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and	n/a, not needed in
50				
51	specimens		storage of biological specimens for genetic or	this study
52				
53				
54			molecular analysis in the current trial and for future	
55				
56			use in ancillary studies, if applicable	
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2  
3 License CC-BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a  
4  
5 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

## Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

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**Title Page**

Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

**The corresponding author:**

Feng Li, PhD, School of Nursing, Jilin University, No 965, Xin Jiang Avenue, 130000, Changchun, Jilin Province, China.

**Tel.:** 17790089009, **Fax:** (86)431-85619580, **E-mail:** [fli@jlu.edu.cn](mailto:fli@jlu.edu.cn)

Qian Tong, MD, First Hospital of Jilin University, No 71, Xin Min Avenue, 130000, Changchun, China.

**Tel.:** 13074337289, **Fax:** (86)431-58997910, **E-mail:** [tongqian187@aliyun.com](mailto:tongqian187@aliyun.com)

**The name(s) of all authors:**

Linqi Xu<sup>1</sup>, Jinwei Li<sup>1</sup>, Xin Zhang<sup>1</sup>, Yue Pang<sup>1</sup>, Tianzhuo Yu<sup>1</sup>, Xiaoqian Lian<sup>1</sup>, Tianyue Yu<sup>1</sup>, Lanyu Zhu<sup>1,2</sup>, Qian Tong<sup>3\*</sup>, Feng Li<sup>1\*</sup>.

<sup>1</sup>School of Nursing, Jilin University, Changchun, Jilin Province, China.

<sup>2</sup>Changchun University of Chinese Medicine, Changchun, Jilin Province, China

<sup>3</sup>The First Hospital of Jilin University, No 71, Xin Min Avenue, Changchun, Jilin Province, China.

\*These authors contributed equally to this work and should be considered co-corresponding authors

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## Abstract

**Introduction:** Despite proven benefits, physical activity participation remains low in patients with coronary heart disease (CHD). Scientific evidence suggests that mobile health (mHealth)–based gamification interventions could increase physical activity levels. However, several systematic reviews demonstrated that most gamification intervention designs do not appropriately leverage theories from health behavior models, and empirical evidence on the efficacy of such interventions among patients with CHD is still emerging. This study embeds the principles of behavioral economics into a gamification intervention based on a smartphone app (WeChat applet) to explore whether a mHealth-based gamification intervention can improve participation in physical activity and other related physical and psychological outcomes in patients with CHD.

**Methods:** We propose a single-blinded three-arm randomized controlled trial with 108 patients with CHD, who will be randomly divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat applet + step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification + collaboration). The interventions will last for 12 weeks and follow-up for 12 weeks. All patients will receive only WeChat applet-based step goal setting in the follow-up period. The primary outcome is physical activity participation, which includes a change in daily steps and self-reported physical activity from the baseline to 12 and 24 weeks, and the proportion of patient-days that step goals achieved in 12 and 24 weeks. The secondary outcomes include biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support and mental health and patients' perceptions, and intervention experience.

**Ethics and dissemination:** The Human Research Ethics Committee of the School of Nursing, Jilin University (HREC 2020122401) approved this. The results will be published in peer-reviewed journals and presented at conferences.

**Trial registration number:** ChiCTR2100044879; Pre-results.

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**Keywords:** physical activity, behavioral intervention, mobile health, gamification, randomized controlled trial

### **Strength and Limitations of this study**

1. Our WeChat applet-based gamification intervention is technology-based and could improve physical activity adherence in patients with coronary heart disease.
2. This study is based on a theoretical framework and will provide insights into how to use mobile health and game elements to promote patients' intrinsic motivation, thereby increase adherence.
3. This study will examine patients' psychological needs, intrinsic motivations, perceptions, and experience, which will allow us to understand the internal psychological mechanisms of gamification intervention to promote physical activity.
4. The study is limited to patients with smartphones and a WeChat account, which could lead to a selective bias.
5. The gamification interventions are comprehensive and it would be challenging to analyze the component that worked.

### **1. Background**

Coronary heart disease (CHD) is the leading cause of mortality in China. Statistically, around 11 million people were affected with CHD in 2017<sup>[1,2]</sup>. Exercise-based cardiac rehabilitation and secondary prevention (CR/SP) plays a crucial role in preventing the recurrence of CHD<sup>[3]</sup> and has been listed as a Class I recommendation for CHD treatment by the American Heart Association, the American Society of Cardiology, and the European Society of Cardiology<sup>[4-7]</sup>. The relevant guidelines recommend that patients with CHD should perform at least 500-MET-min/week physical activity every week<sup>[8]</sup>. Although CR/SP have proven benefits, it is often challenging for patients to attain lifestyle changes needed for SP, especially with increasing physical activity

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4 levels<sup>[9]</sup>. For example, owing to the poor accessibility of cardiac rehabilitation programs, > 80% of patients did  
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6 not participate in the cardiac rehabilitation programs recommended by the guidelines<sup>[10]</sup>. Moreover, patients with  
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8 CHD typically fail to attain their daily physical activity goals<sup>[11]</sup>.

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11 Mobile health (mHealth), defined by American Heart Association's scientific statement, "is the use of mobile  
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13 computing and communication technologies (e.g. mobile phones, wearable devices) for health services and  
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15 information"<sup>[12]</sup>, has become an essential medium to deliver behavioral change interventions and demonstrated  
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17 promising ability to improve physical activity levels<sup>[12-14]</sup>. For example, the CONNECT trial examined the impact  
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19 of digital health interventions on health behaviors and established the correlation between intervention and  
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21 increased attainment of physical activity targets<sup>[15]</sup>. In China, WeChat is a top-rated multipurpose social media  
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23 app, with >1.151 billion active users<sup>[16]</sup>. WeChat applets are lightweight apps that form part of the WeChat  
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25 ecosystem, which could be used independently and do not need installation. Compared with mobile apps, WeChat  
26  
27 applets are easier to be accepted and applied by people in China. The third quarter of 2019 recorded >300 million  
28  
29 active WeChat applet users every day, thereby making it well suited to disseminate mHealth interventions in  
30  
31 China<sup>[17]</sup>.

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33  
34 Gamification is the use of game design elements (such as points, leaderboards, progress bars, and badges) in  
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36 non-game contexts (such as management, education, marketing, and healthcare) to increase motivation and  
37  
38 engagement<sup>[18]</sup>. There is growing interest in the application of gamification in mHealth with the view of promoting  
39  
40 healthy behavioral changes<sup>[19-22]</sup>, especially in promoting physical activity levels<sup>[23]</sup>. Previous studies indicated  
41  
42 that gamification was used in 64% of the top 50 most popular smartphone apps<sup>[24]</sup>. However, several systematic  
43  
44 reviews reported that most gamification intervention designs did not appropriately leverage theories from health  
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46 behavior models<sup>[19,25,26]</sup>. Moreover, as the concept of gamification is relatively new<sup>[18]</sup>, empirical evidence on the  
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48 efficacy of gamification physical activity behavioral change interventions among patients with CHD is still  
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4 emerging.

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6 Gamification interventions are rarely based on a sound theoretical framework<sup>[20,22]</sup>. Behavioral economics  
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8 principles combine conventional economic principles with psychology to elucidate how individuals behave and  
9  
10 make decisions<sup>[27]</sup>. Behavioral economics principles can be embedded with a gamification intervention via mobile  
11  
12 devices to aid people to attain their physical activity goals. For example, based on the loss aversion, which implies  
13  
14 that the loss framework is more effective in stimulating behavioral change than the gain framework, Patel et al.  
15  
16 designed an intervention wherein participants lost points if they did not accomplish their step goals<sup>[28]</sup>. Several  
17  
18 previous studies have used behavioral economics principles to help patients lose weight, quit smoking, and adhere  
19  
20 to medications<sup>[29–31]</sup>. However, limited data are available on applying these concepts to improve physical activity  
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22 participation in patients with CHD.  
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30 This study will use behavioral economics principles to develop a gamification WeChat applet named  
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32 “TahneeWeh” to resolve the research gap mentioned above. This study aims to investigate the effects of the  
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34 mHealth-based gamification intervention on participation in physical activity and evaluate the effects on  
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36 biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and  
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38 relatedness, social support, and mental health. In addition, a semi-structured interview will be conducted after the  
39  
40 intervention to comprehend patients’ perceptions and their experience on the intervention.  
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## 45 **2. Methods**

### 46 **2.1 Study design**

47  
48 This is a single-blind, three-arm randomized controlled trial to evaluate the effects of the mHealth-based  
49  
50 gamification intervention on participation in physical activity, biomedical and lifestyle-related risk factors,  
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52 intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health.  
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56 Patients with CHD will be recruited in a cardiac rehabilitation center of a tertiary-grade A class hospital in  
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4 Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants will be randomly  
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6 divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat applet +  
7  
8 step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification + collaboration).  
9  
10 Patients in the control group will only receive daily step goal setting. The Individual and Team groups will receive  
11  
12 gamified behavior intervention based on behavioral economics principles. The Team group will also receive social  
13  
14 incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12 weeks. All  
15  
16 patients will just receive WeChat applet-based step goal setting in the follow-up period. The study duration will  
17  
18 be between July 1, 2021 and November 30, 2022. Figure 1 shows a flowchart of the study design. The protocol  
19  
20 conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting  
21  
22 guidelines, and the intervention is described per the CONSORT-EHEALTH checklist<sup>[32–34]</sup>. The study is registered  
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24 at Clinical Trials.gov: ChiCTR2100044879.  
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## 32 **2.2 Eligibility and Recruitment**

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35 Patients fulfilling the inclusion and exclusion criteria will be invited to participate in the trial. The inclusion  
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37 criteria are as follows: (i) aged 18–70 years; (ii) patients diagnosed with CHD(including acute myocardial  
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39 infarction and unstable angina), and received percutaneous coronary intervention (PCI) treatment during  
40  
41 admission; (iii) patients evaluated by cardiologists and rehabilitation therapists if they are suitable for participating  
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43 in our program; (iv) patients willing to provide written informed consent; (v) patients with a smartphone and an  
44  
45 active WeChat account; and (vi) patients with proficiency in Chinese.  
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51 The exclusion criteria include the following: (i) contraindications for exercise rehabilitation (e.g., untreated  
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53 ventricular tachycardia, severe heart failure, uncontrollable hypertension or hypotension, notable exercise  
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55 restriction); (ii) patients unable to use WeChat applet after instruction; (iii) no Internet access in the place of  
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57 residence; (iv) patients requiring a walking aid to move; and (v) patients participating in other clinical trials.  
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4 Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting  
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6 participants. Researchers will inform the patients about the details of the study. If they agree to participate in the  
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8 study, they will have to sign the written consent form. After that, we will teach patients to register and log in to  
9  
10 our WeChat applet “TahneeWeh”; this is required to get their step data for the past 2 weeks, which will be recorded  
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12 by smartphone accelerometers (as done in many prior studies<sup>[35–38]</sup>) and has been proven accurate for tracking step  
13  
14 counts<sup>[39]</sup>. Furthermore, a baseline step count will be estimated using the mean step count of the previous 2 weeks.

### 19 **2.3 Sample size calculation**

21  
22 The main outcome indicator, daily step count, is selected as the calculation standard. Based on a previous  
23  
24 study, we will ensure, at least, 90% power to detect an 800-step difference between each intervention arm and  
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26 control, a standard deviation of 2000 steps, and a two-sided  $\alpha$  of 0.05<sup>[40]</sup>. In addition, we will use one-way analysis  
27  
28 of variance *F*-tests in PASS15.0.5 software and calculate that a total of 84 participants across three arms would  
29  
30 be recruited. By allowing for an estimated 20% dropout rate, a sample size of 108 will be used in this study.

### 34 **2.4 Randomization, blinding, and concealed allocation**

35  
36 Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step  
37  
38 count (<5000, 5001–7500, or >7500 steps/day). The data collector will be unaware of patient assignments at the  
39  
40 baseline, 12 weeks, and 24 weeks of the study. Researchers could see the assignments in the backstage of the  
41  
42 WeChat applet, and the interfaces of the WeChat applet for patients in different groups are different.

### 47 **2.5 Control**

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49 All patients will receive step goal setting and could see their progress on the WeChat applet during the 12–  
50  
51 week intervention and 12-week follow-up. Personalized daily step goals will be set in the WeChat applet  
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53 backstage based on patients’ baseline daily step counts, and the goals will increase gradually from the baseline by  
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55 15% each week during the first 6 weeks and then remained fixed during the last 6 weeks, as described elsewhere<sup>[41]</sup>.

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4 To ensure the increase in physical activity is not harmful to participants, the rehabilitation therapists in our  
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6 research group will assess the condition of each patient and make appropriate adjustments of the step goals.  
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9 Participants could contact us at any time to make an adjustment if it is due to physical conditions. Moreover,  
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11 patients could see their daily progress toward their goals using a circular dial on the WeChat applet. Of note,  
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13 patients in the control group will receive no other interventions. If a patient does not log in to the WeChat applet  
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15 for over a week, a text message reminder will be sent to the patient.  
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## 19 **2.6 Intervention**

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22 Patients in the Individual and Team groups will receive the gamification intervention based on behavioral  
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24 economics principles via the WeChat applet. Six behavioral economics principles (precommitment, fresh start  
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26 effect, goal gradients, loss aversion, anticipated regret, and social norms) will be embedded within the  
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28 gamification intervention. The gamification intervention in the Individual group will apply to four game  
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30 elements—feedback, points, levels, and rewards. In the Team group, collaboration is added besides the four game  
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32 elements mentioned above. Table 1 provides a summary of game elements, gamification intervention components,  
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34 and behavioral economics principles.  
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### 39 **2.6.1 Individual group**

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41  
42 First, patients will electronically sign a precommitment pledge to try their best to attain their step goal.  
43  
44 Precommitment is known to motivate behavioral change<sup>[42,43]</sup>. Second, every Monday, patients will receive 140  
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46 points (20 for each day), which leverage the fresh start effect<sup>[44]</sup>. Patients tend to be more driven for aspirational  
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48 behavior around temporal landmarks like the beginning of the week. Third, if patients reach the target step count,  
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50 no points will be deducted; if not, 20 points will be deducted. This leverages loss aversion, demonstrating that  
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52 loss framing is more effective at motivating behavioral change than gain framing<sup>[45,46]</sup>. Fourth, a total of five levels  
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54 will be set, from low to high—bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, patients  
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will be set to the gold level. If a patient has a total score of <80 points in the week, the level will drop, and if the total scores are  $\geq 80$  points, the level will increase; this is done such that the patients would feel their level dropping to silver if they did not attain sufficient points in the first week. At the end of the intervention, if the level of a patient is diamond, he/she will be rewarded with a small prize. Fifth, patients in the two intervention groups will receive feedback weekly based on their progress.

### 2.6.2 Team group

The Team group will also receive social incentives based on the Individual group. Patients are assigned to a team of 3 people, who do not know each other before the intervention. Every Monday, the patients will receive 140 points (20 for each day, 10 for themselves, 10 for their team). If the patient achieves the step goals and the other 2 people in his/her team also achieve the step goals, no points will be deducted. If the patient achieves the step goals, but other 2 people in his/her team do not, 10 points for their team will be deducted. If neither the patient nor the other two people in his/her team achieve the step goal, 20 points will be deducted. Figure 2 presents the WeChat applet interface, and Figure 3 shows the backstage management system of the WeChat applet.

Table 1 A summary of game elements, intervention components, and behavioral economics (BE) principles

Game elements	Gamification intervention components	BE principles
	Patients will electronically sign a precommitment pledge to try their best to achieve their step goal.	Precommitment
<b>Points</b>	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
<b>Points</b>	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
<b>Collaboration</b>	If the patient achieve the step goals and the other 2 people in her team also achieve the step goals, no points will be deducted; if the patient achieve the step goals but	Social norms; Loss aversion; Anticipated Regret



	other 2 people in her team do not, 10 points for her team will be deducted; if neither the patient nor the other two people in her team does not achieve the step goal, 20 points will be deducted.	
<b>Levels</b>	We set 5 levels, from low to high is bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, the patient is set to the gold level. If the patient has a total score of less than 80 points in a week, the level will drop, and if the total score is greater than or equal to 80 points, the level will rise.	the Fresh Start Effect; Goal Gradients; Loss aversion
<b>Rewards</b>	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
<b>Feedback</b>	Patients in the two intervention groups will receive feedback according to their progress weekly.	

## 2.7 Outcome measures and data collection

Table 2 shows the summary of the outcome measures for the study. The primary outcome is physical activity participation, which includes a change in daily steps and self-reported physical activity from the baseline to 12 and 24 weeks, and the proportion of patient-days that step goals achieved in 12 and 24 weeks. The daily step counts will be measured and recorded by smartphone accelerometers, which have been proven accurate for tracking step counts<sup>[39]</sup>. Self-reported physical activity level will be measured by the International Physical Activity Questionnaire (IPAQ)<sup>[47]</sup>.

The secondary outcomes include biomedical risk factors, which include the body weight(kg), waist circumference (cm), body mass index (BMI), systolic blood pressure (mmHg), diastolic blood pressure (mmHg), resting heart rate (bpm/min), serum total cholesterol (TC, mg%), fasting plasma glucose(mg%), lifestyle-related risk factors, including smoking, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social

support, anxiety symptom, and depressive symptoms. The IPAQ will be filled out online at the baseline, 12 weeks, and 24 weeks through the WeChat applet, while the other measurements will be taken in the hospital (at the baseline, 12 weeks, and 24 weeks). In addition, usability will be tested at the end of the intervention (at 12 weeks) in the two intervention groups using the System Usability Scale (SUS)<sup>48</sup>. Furthermore, we will conduct a semi-structured interview to understand patients' perceptions and experiences in the two intervention groups.

All adverse events will be reported to the Ethics Committee as required during the 24 weeks study period.

Adverse events are defined as medical occurrences resulting in hospitalization, disability, or death.

Table 2 Assessment time-points for primary and secondary outcomes

Outcome	Assessment	Baseline	12 weeks	24 weeks
<b>Primary outcomes</b>				
<b>Physical activity</b>	Change in daily steps	√	√	√
	The proportion of patient-days that step goals were achieved		√	√
	International Physical Activity Questionnaire (IPAQ) <sup>47</sup>	√	√	√
<b>Secondary outcomes</b>				
<b>Biomedical risk factors</b>	Body weight, waist circumference, BMI, SBP, DBP, RHR, TC, FPG	√	√	√
<b>Lifestyle-related risk factors</b>	Self-reported smoking	√	√	√
<b>Competence, autonomy, and relatedness</b>	Psychological Needs Satisfaction in Exercise Scale(PNSE) <sup>49</sup>	√	√	√
<b>Intrinsic motivation</b>	Behavioral Regulation in Exercise Questionnaire(BREQ-2) <sup>50</sup>	√	√	√
<b>Enjoyment</b>	Physical Activity Enjoyment Scale (PACES) <sup>51</sup>	√	√	√

<b>Social support</b>	Social Support Rating Scale (SSRS) <sup>52</sup>	√	√	√
<b>Anxiety symptoms</b>	Generalised Anxiety Disorder 7-item Scale (GAD-7) <sup>53</sup>	√	√	√
<b>Depressive symptoms</b>	Patient Health Questionnaire (PHQ-9) <sup>54</sup>	√	√	√
<b>Usability</b>	System Usability Scale (SUS) <sup>48</sup>		√	
<b>Satisfaction</b>			√	
<b>Patients' experience</b>	Semi-structured interview		√	
<b>Adverse event reporting</b>	Medical occurrences resulting in hospitalization, disability or deaths	←—————→		

BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; RHR, resting heart rate; TC, serum total cholesterol; FBG, fasting plasma glucose

## 2.8 Statistical analysis and data management

All continuous variables will be reported as mean and SD, and categorical variables will be described as frequencies and percentages. Within-group changes in daily step counts, the proportion of patient-days that step goals attained, self-reported physical activity, biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health will be compared using a paired *t*-test or Wilcoxon test depending on the data distribution. Besides, a one-way analysis of variance will be used to compare the intergroup differences between the baseline and postintervention among the outcomes. Main analysis and secondary analysis will be conducted of all the outcomes. In the main analysis, the analysis of outcomes will be conducted per the intention-to-treat principle. In addition, multiple imputations for data will be used that are missing and with step values <1000 because evidence indicates that these values are unlikely to represent the capture of actual activity<sup>[37,55]</sup>. In the secondary analysis, data analysis will be conducted without multiple imputations, both with and without step values <1000. Furthermore, adjusted analyses include sex, age, BMI, severity of disease, and baseline variables. All statistical analyses will be two-sided, and  $P < 0.05$  will be considered statistically significant. We will use SPSS V.20.0 for data analysis.

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4 In this study, well-trained clinical researchers will record all patients' data using standardized case report  
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6 forms (CRF). The original data will be recorded timely and accurately, and a copy of the report will be kept in the  
7  
8 laboratory. All CRFs will be stored in a locked file cabinet to prevent data leakage. All laboratory data will be  
9  
10 identified with a code number to ensure the confidentiality of subjects' data. The clinical research data  
11  
12 management platform of the School of Nursing of Jilin University will be accountable for data monitoring. The  
13  
14 chief investigator can directly access the dataset, and the data scattered to the project team members cannot  
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16 identify any participant identity information.  
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## 22 **2.9 Patient and public involvement**

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24 Patient and public involvement (PPI) played a vital role in this study. Before designing the WeChat applet,  
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26 the authors conducted a survey among patients with CHD and found that patients lacked physical activity and  
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28 were willing to be supervised and motivated via their smartphones to promote participation in physical activity.  
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30 During the development of WeChat applet, patients with CHD will be invited to participate in our discussion,  
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32 allowing the authors to consider the thoughts and needs of patients in developing the WeChat applet. In the pilot  
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34 study, patients will be invited to give reasonable recommendations for study design, questionnaire selection, and  
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36 outcome measurements while considering the burden of intervention. The results of this study will be disseminated  
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38 to PPI representatives and study participants who wish to be notified.  
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## 45 **2.10 Validity and reliability**

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47 This study will use a rigorous research design (randomized controlled design) and a block random method  
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49 to assign groups. The grouping results will be numbered and placed in a sealed envelope. Participants and data  
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51 collector will be blinded to the assignments. All questionnaires will be completed by the researcher's guidance or  
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53 ghostwriting. The questionnaires will be distributed and collected on the spot to avoid data bias caused by different  
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55 researchers. Two researchers will enter all the data to avoid objective typing errors.  
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### 3. Ethics and dissemination

This study will comply with the ethical principles of the Declaration of Helsinki, and the Human Research Ethics has been approved by the School of Nursing, Jilin University (HREC 2020122401). This study is registered at Clinical Trials.gov (ChiCTR2100044879). All participants will be required to provide written informed consent. Research reports will be disseminated through scientific forums, including peer-reviewed publications and presentations at national and international conferences.

### 4. Discussion

The authors aim to develop a WeChat applet in this study. Based on the WeChat applet and under the guidance of behavioral economics principles, the authors will develop a gamification intervention using five game elements, including points, levels, feedback, rewards, and collaboration. This study will evaluate the role of mHealth-based gamification intervention on physical activity participation and the effects on biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health. Moreover, the authors will conduct a semi-structured interview after the intervention to elucidate patients' perceptions and experience of the intervention.

Despite proven benefits, patients with CHD do not often attain their physical activity goals on their own<sup>[11]</sup>. Behavioral interventions are needed to help them increase physical activity participation. With technological advancement, numerous smartphone apps have appeared, and gamification was used in most of these apps, which had the potential to increase physical activity motivation and promote behavioral change. However, most gamification intervention designs did not appropriately leverage theories from health behavior models and empirical evidence on their efficacy is still emerging. A previous study established that behavioral economics principles could be embedded with a gamification intervention to significantly increase physical activity among overweight and obese adults<sup>[28]</sup>. However, thus far, there is limited evidence of interventions that use these

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4 methods to effectively improve physical activity participation among high-risk patients, such as patients with  
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6 CHD<sup>[56]</sup>. Thus, this study will develop a gamification intervention based on a WeChat applet that has been  
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8 specifically developed for this study. Personalized goal setting and progress tracking on the WeChat applet will  
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10 allow patients to exercise under supervision. The gamification intervention motivated patients to walk more; this  
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12 could become a new way to promote the implementation of home and exercise-based cardiac rehabilitation.  
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17 The key of gamification interventions is to organically combine game elements to form a resultant force to  
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19 improve physical activity, and the key of the resultant force is to comprehend the driving force or motivation  
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21 behind the incentive mechanism. Research indicates links between self-determination theory and gamification  
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23 concepts. Self-determination theory suggests that satisfying three innate psychological needs of competence,  
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25 autonomy, and relatedness could promote autonomous motivation and well-being. Reportedly, individuals with  
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27 autonomous motivation had higher physical activity participation and better physical activity adherence than those  
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29 primarily driven by external factors<sup>[57]</sup>. Furthermore, the fact that gamification could make interventions more  
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31 enjoyable aligns with self-determination theory, which assumes that a key aspect of intrinsic motivation is  
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33 enjoyment<sup>[18]</sup>. We plan to investigate the internal psychological mechanism of gamification to promote physical  
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35 activity; thus, we will evaluate the competence, autonomy, relatedness, enjoyment, and intrinsic motivation. We  
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37 assume that gamification intervention promotes the transformation of controlled motivation into autonomous  
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39 motivation by satisfying competence, autonomy, relatedness, enjoyment, and ultimately promote physical activity  
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41 participation. Figure 4 shows the hypothesized model of physical activity behavior regulation. Moreover, because  
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43 our intervention platform will provide information support for patients, we will also evaluate the variable social  
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45 support. Furthermore, we will conduct a semi-structured interview after the intervention to comprehend patients'  
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47 experiences and capture information on communications among patients in the collaboration group, which could  
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49 explore the internal psychological mechanism of gamification to promote exercise motivation.  
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4 In China, access to cardiac rehabilitation is often limited. Patients with CHD often lack physical activity. Our  
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6 intervention could help increase physical activity participation and bring more health benefits.  
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### 8 9 **Limitations**

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11 This study has several limitations. First, we will not measure the intensity of physical activity via the  
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13 smartphone accelerometer. In future, we plan to use wearable devices to evaluate the intensity of physical activity.  
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15 Second, the study is limited to patients with smartphones and a WeChat account, which could lead to a selective  
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17 bias. Third, the gamification interventions are comprehensive, and it would be difficult to analyze the component  
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19 that worked. Fourth, it is a multilayered and complex intervention, and the projected sample size will make it  
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21 challenging to say that the results will be much more than a pilot study given there will be three groups.  
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32  
33 representatives during the study design and intervention development.  
34

35  
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37  
38 manuscript. LX, JL, XZ, YP, TY, XL, TY and LZ contributed to the design of the study. All authors read and  
39  
40 approved the final manuscript.  
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43  
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47  
48 Feng Li.  
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51 **Competing interests:** None declared.  
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54 **Provenance and peer review:** Not commissioned; externally peer reviewed.  
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57 **Data sharing statement:** For patient confidentiality concerns and the access possibilities of the data source, the  
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59 clinical data collected will not be shared with the public. However, non-clinical data, such as educational materials,  
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will be shared with the public and other researchers.

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For peer review only

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4 Figure legends

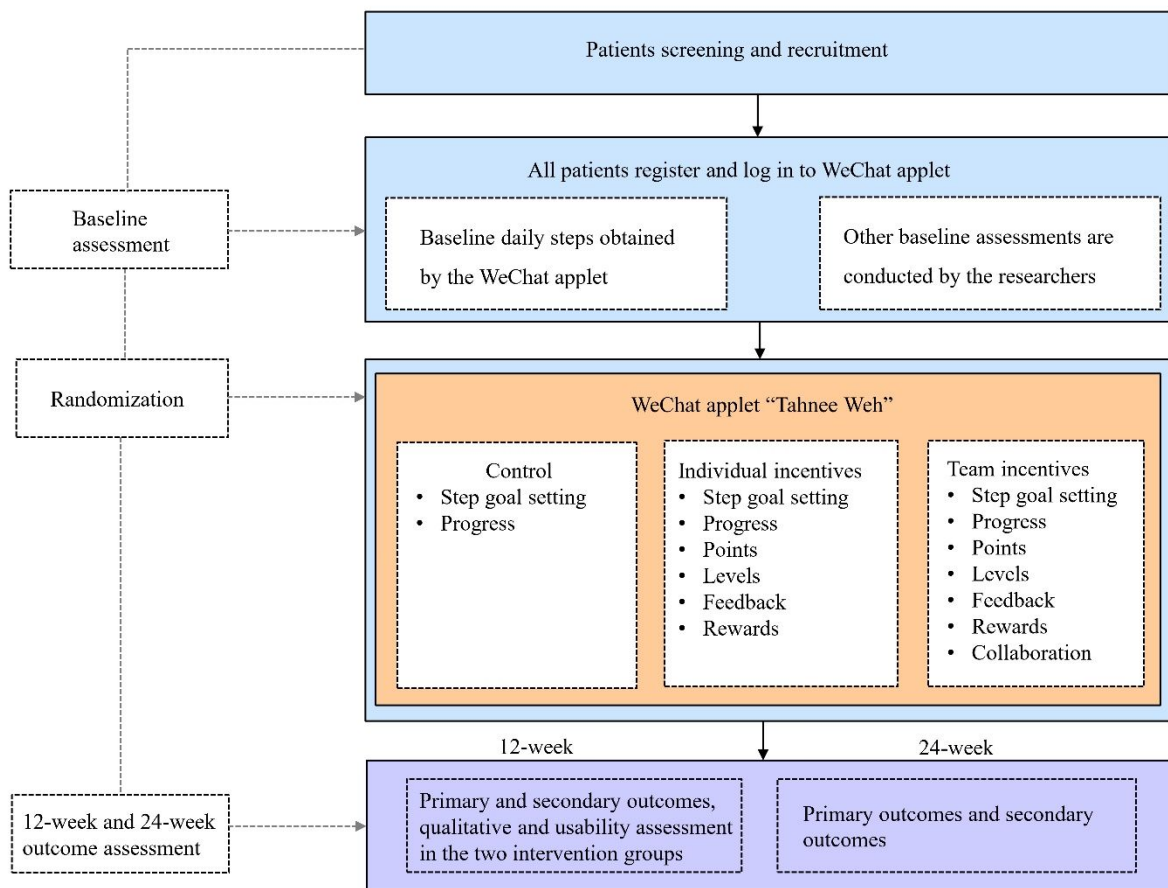
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6 Figure 1: Study flowchart.

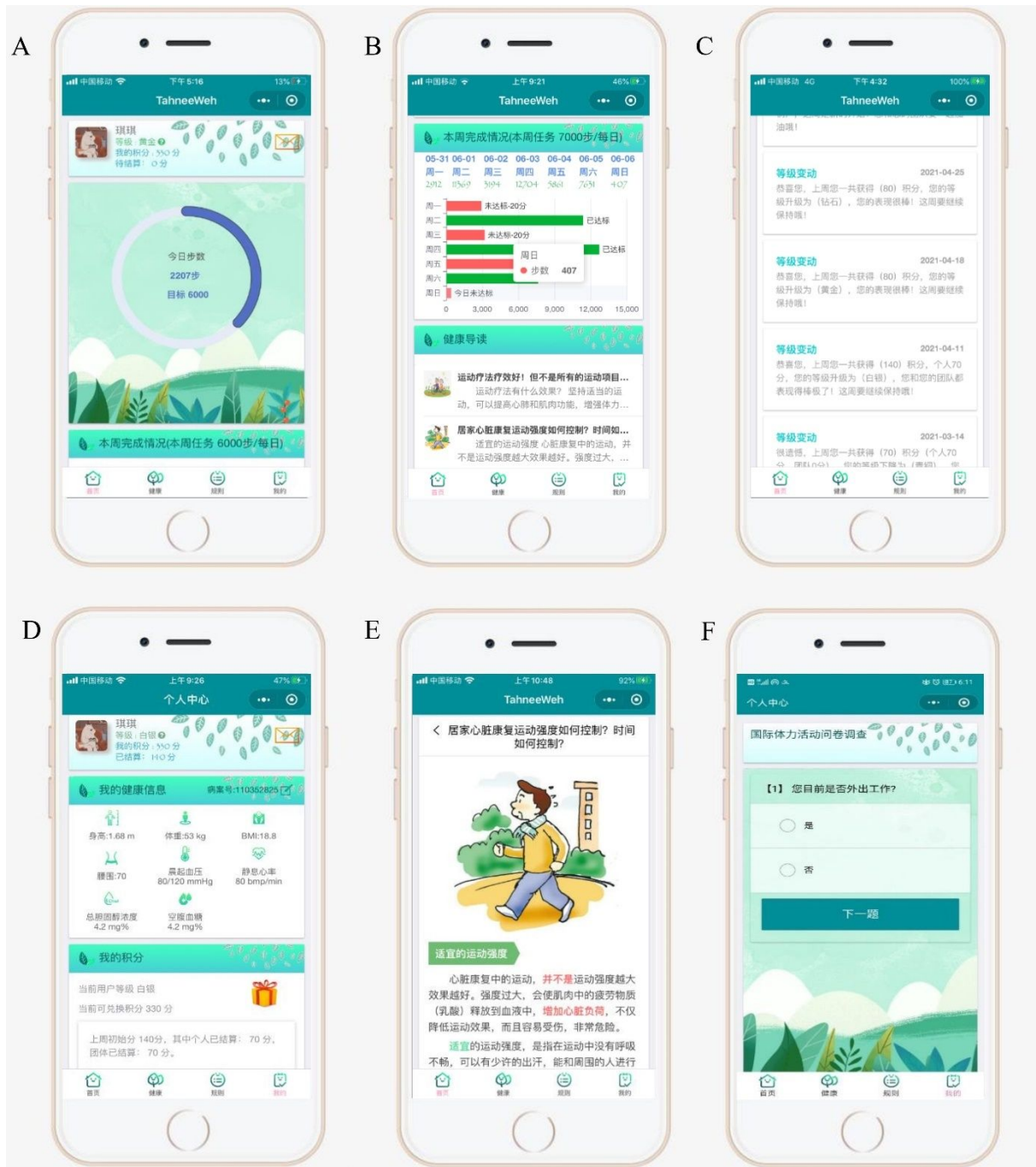
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8 Figure 2: WeChat applet “TahneeWeh” interface. (A) Daily step progress using a circular dial; (B) weekly step  
9 progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac  
10 rehabilitation and secondary prevention; (F)International Physical Activity Questionnaire (IPAQ) filling interface.  
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16 Figure 3: The backstage management system of the WeChat applet “TahneeWeh.”

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19 Figure 4: The hypothesized model of physical activity (PA) behavior regulation.  
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Tahnee Weh

Admin 在线

控制台 hot 常规管理 new 权限管理 积分兑换管理 问答问题 资讯管理 健康资讯管理 在线命令管理 会员管理

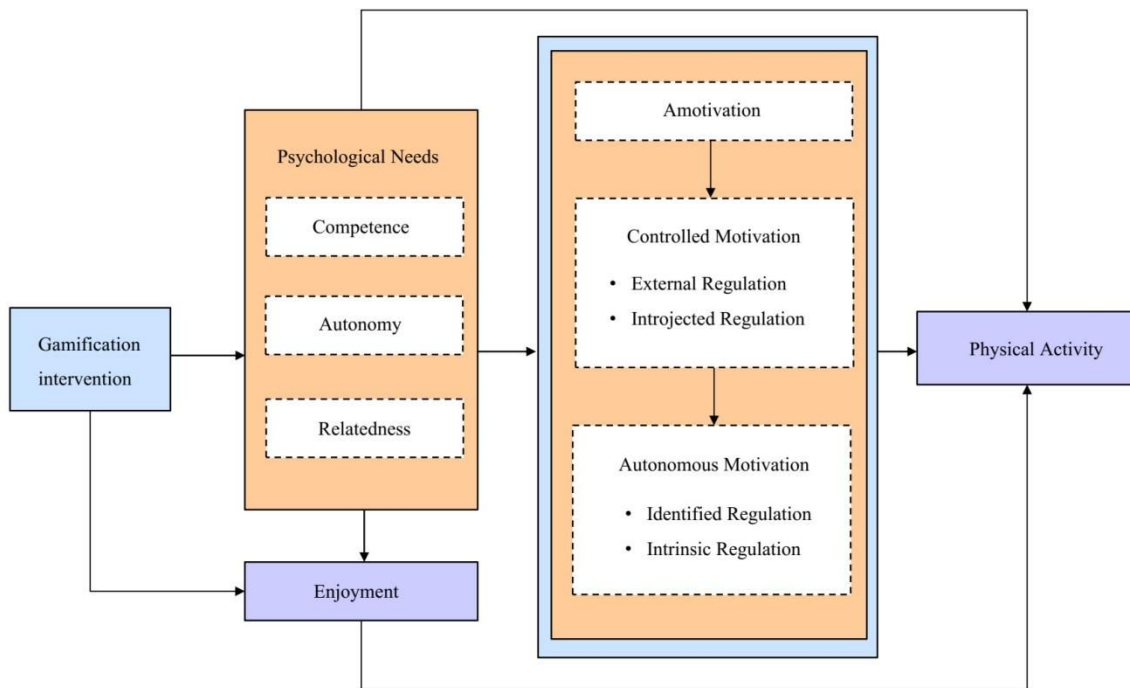
控制台 微信运动步数 会员列表 健康信息 健康资讯管理 会员规则

添加 编辑 删除 更多

主键	资讯标题	是否置顶	来源	权重	添加时间	操作
46	什么性格容易得心脏病?	1	健康导读	46	2021-05-27 19:42:57	+
45	压力!!!是心肌梗死的诱因!	0	健康导读	45	2021-05-27 18:37:07	+
44	心脏病发作的处置方法!	1	健康导读	44	2021-05-27 17:12:21	+
43	心脏病患者可以进行性生活吗?	0	健康导读	43	2021-05-27 16:58:24	+
42	注意防寒防暑!驾车时的注意事项~	0	健康导读	42	2021-05-27 16:43:38	+
41	洗澡时,如厕时应该注意什么?	0	健康导读	41	2021-05-26 21:27:49	+
40	适量饮酒!不要过多食用甜品!	1	健康导读	40	2021-05-26 21:03:20	+
39	多吃食物纤维!多吃水果!	0	健康导读	39	2021-05-26 20:40:33	+
38	低盐饮食!盐分多的食物有哪些?	1	健康导读	38	2021-05-26 16:40:27	+
37	富含胆固醇的食物有哪些?合理摄入!	1	健康导读	37	2021-05-26 15:56:02	+

显示第 1 到第 10 条记录, 总共 25 条记录 每页显示 10 条记录

上一页 1 2 3 下一页 跳转



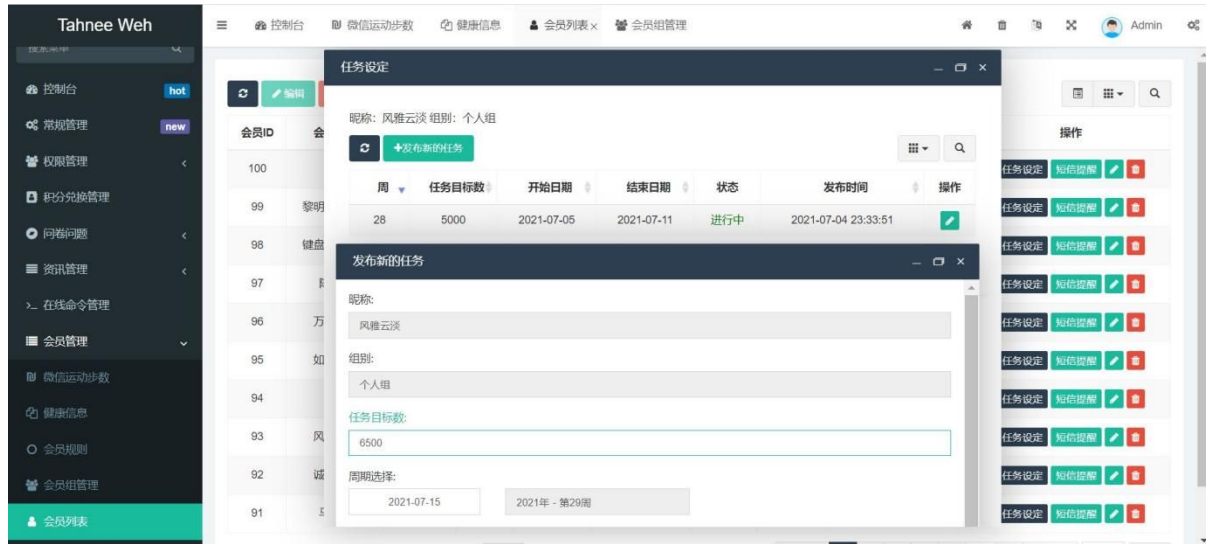
Some other backstage interface of the WeChat applet “TahneeWeh”



The screenshot shows the 'Tahnee Weh' backend interface with the '会员列表' (Member List) tab selected. The table displays the following data:

会员ID	会员昵称	会员头像	姓名	病案号	会员电话	组别	是否分组	添加时间	操作
171	译曦		刘伟	02296770	15843255896	团体组10	是	2021-07-24 12:09:46	任务设定 短信提醒
170	姚		姚淑凡	02297810	15804413021	对照组	是	2021-07-24 12:03:24	任务设定 短信提醒
169	二运		王洪运	02297525	15714448555	对照组	是	2021-07-24 11:51:34	任务设定 短信提醒
168	唐万山		唐万山	02297877	15861562323	对照组	是	2021-07-24 11:41:55	任务设定 短信提醒
167	崔久英		崔久英	02298040	18616585677	个人组	是	2021-07-24 11:22:03	任务设定 短信提醒
166	徐爱军		徐爱军	02297096	13009108370	团体组10	是	2021-07-24 10:32:18	任务设定 短信提醒
165	自然 李希民		李希民	02297100	15694319871	个人组	是	2021-07-24 10:20:36	任务设定 短信提醒
164	L		陈国民	02298020	13298887152	对照组	是	2021-07-24 10:06:34	任务设定 短信提醒
163	肖国贤		肖国贤	02296589	18548237408	个人组	是	2021-07-23 16:26:10	任务设定 短信提醒
162	李国华		李国华	00967693	13756104388	对照组	是	2021-07-23 14:28:51	任务设定 短信提醒





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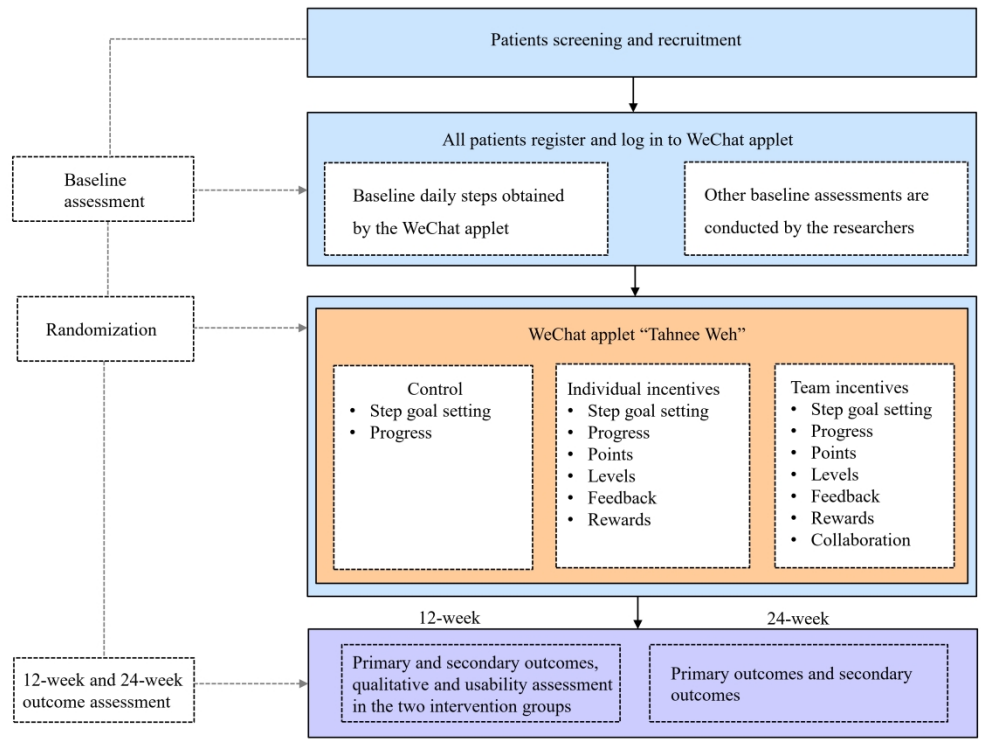


Figure 1: Study flowchart.

971x735mm (144 x 144 DPI)

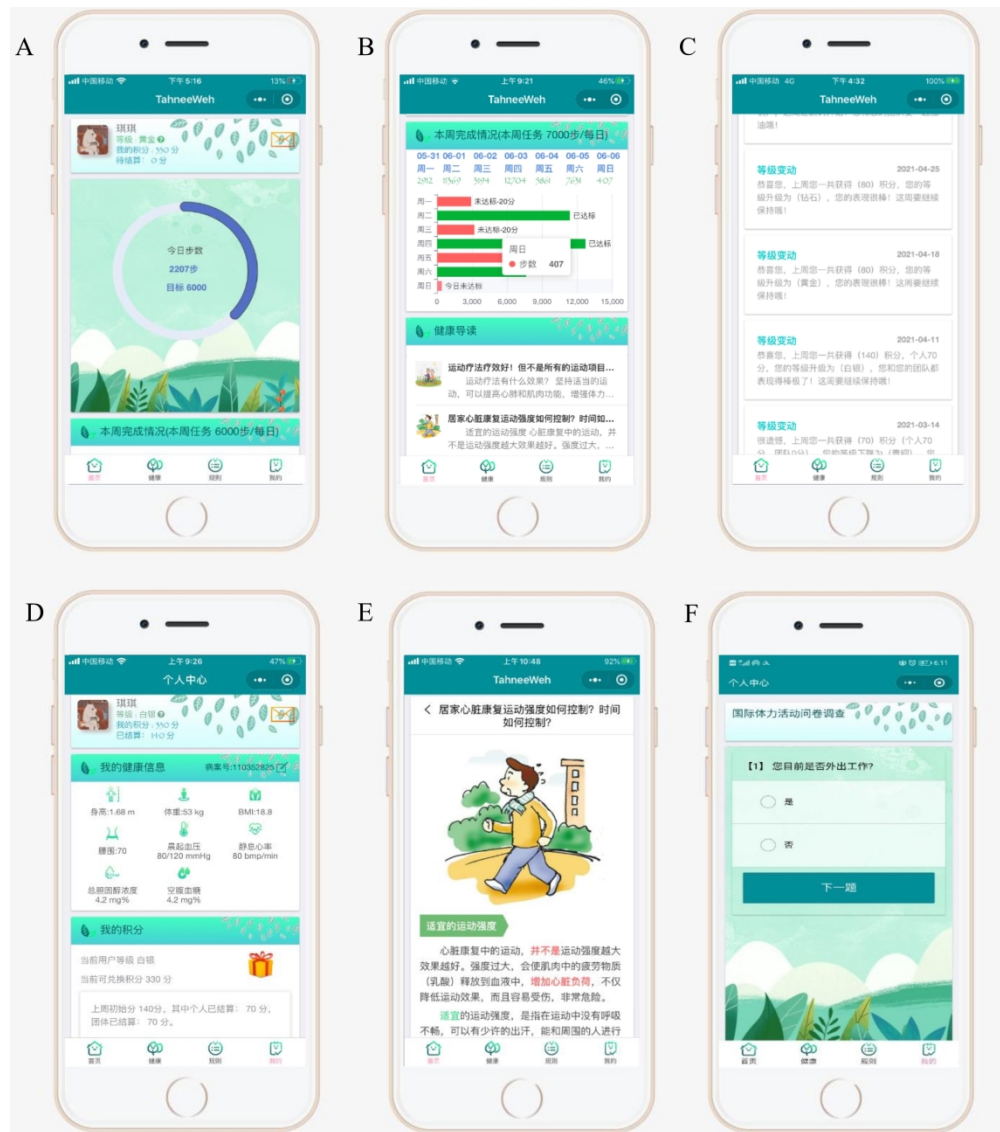


Figure 2: WeChat applet "Tahnee Weh" interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F) International Physical Activity Questionnaire (IPAQ) filling interface.

674x761mm (144 x 144 DPI)

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Figure 3: The backstage management system of the WeChat applet "Tahnee Weh".

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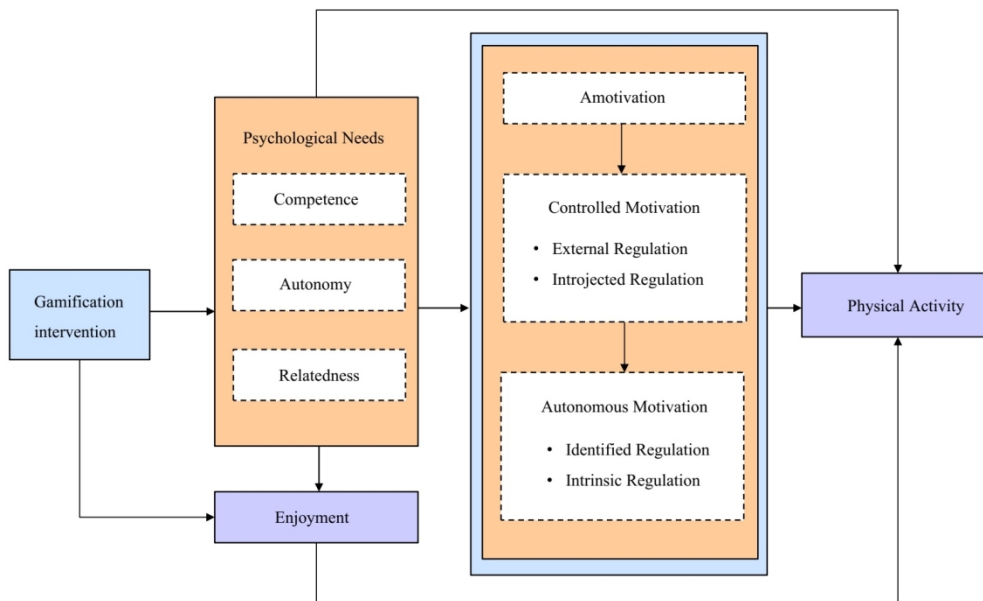


Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

299x184mm (144 x 144 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

Reporting Item

Page Number

### Administrative

#### information

Reporting Item	Page Number
<b>Title</b>	<b>P1</b>
<b>#1</b> Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	

1	Trial registration	<a href="#">#2a</a>	Trial identifier and registry name. If not yet	P6
2			registered, name of intended registry	
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6	Trial registration:	<a href="#">#2b</a>	All items from the World Health Organization Trial	P6
7			Registration Data Set	
8	data set			
9				
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11				
12	Protocol version	<a href="#">#3</a>	Date and version identifier	n/a
13				
14				
15	Funding	<a href="#">#4</a>	Sources and types of financial, material, and other	P16
16			support	
17				
18				
19				
20	Roles and	<a href="#">#5a</a>	Names, affiliations, and roles of protocol	P16
21			contributors	
22	responsibilities:			
23				
24	contributorship			
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28	Roles and	<a href="#">#5b</a>	Name and contact information for the trial sponsor	P16
29				
30	responsibilities:			
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32	sponsor contact			
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34	information			
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38	Roles and	<a href="#">#5c</a>	Role of study sponsor and funders, if any, in study	P16
39			design; collection, management, analysis, and	
40	responsibilities:		interpretation of data; writing of the report; and the	
41			decision to submit the report for publication,	
42	sponsor and funder		including whether they will have ultimate authority	
43			over any of these activities	
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52	Roles and	<a href="#">#5d</a>	Composition, roles, and responsibilities of the	P12
53			coordinating centre, steering committee, endpoint	
54	responsibilities:		adjudication committee, data management team,	
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56	committees			
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and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

## Introduction

Background and rationale	<a href="#">#6a</a>	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	P3-5
Background and rationale: choice of comparators	<a href="#">#6b</a>	Explanation for choice of comparators	P3-5
Objectives	<a href="#">#7</a>	Specific objectives or hypotheses	P5
Trial design	<a href="#">#8</a>	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	P5-6

## Methods:

### Participants, interventions, and outcomes

Study setting	<a href="#">#9</a>	Description of study settings (eg, community clinic,	P5
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academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

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8	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If P6
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10			applicable, eligibility criteria for study centres and
11			individuals who will perform the interventions (eg,
12			surgeons, psychotherapists)
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18	Interventions:	<a href="#">#11a</a>	Interventions for each group with sufficient detail to P7-9
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20	description		allow replication, including how and when they will
21			be administered
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25	Interventions:	<a href="#">#11b</a>	Criteria for discontinuing or modifying allocated n/a, intervention
26			
27	modifications		interventions for a given trial participant (eg, drug did not involve
28			dose change in response to harms, participant harms or others
29			request, or improving / worsening disease)
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35	Interventions:	<a href="#">#11c</a>	Strategies to improve adherence to intervention P7
36			
37	adherence		protocols, and any procedures for monitoring
38			adherence (eg, drug tablet return; laboratory tests)
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43	Interventions:	<a href="#">#11d</a>	Relevant concomitant care and interventions that P8-9
44			
45	concomitant care		are permitted or prohibited during the trial
46			
47			
48	Outcomes	<a href="#">#12</a>	Primary, secondary, and other outcomes, including P10-11
49			
50			the specific measurement variable (eg, systolic
51			blood pressure), analysis metric (eg, change from
52			baseline, final value, time to event), method of
53			aggregation (eg, median, proportion), and time
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point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

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8	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions
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10			(including any run-ins and washouts),
11			assessments, and visits for participants. A
12			schematic diagram is highly recommended (see
13			Figure)
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20	Sample size	<a href="#">#14</a>	Estimated number of participants needed to
21			achieve study objectives and how it was
22			determined, including clinical and statistical
23			assumptions supporting any sample size
24			calculations
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32	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant
33			enrolment to reach target sample size
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38	<b>Methods:</b>		
39			
40	<b>Assignment of</b>		
41	<b>interventions (for</b>		
42	<b>controlled trials)</b>		
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47	Allocation:	<a href="#">#16a</a>	Method of generating the allocation sequence (eg,
48	sequence		computer-generated random numbers), and list of
49			any factors for stratification. To reduce
50	generation		predictability of a random sequence, details of any
51			planned restriction (eg, blocking) should be
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provided in a separate document that is  
 unavailable to those who enrol participants or  
 assign interventions

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8	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation
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10	concealment		sequence (eg, central telephone; sequentially
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12	mechanism		numbered, opaque, sealed envelopes), describing
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15			any steps to conceal the sequence until
16			
17			interventions are assigned
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20	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who
21			
22	implementation		will enrol participants, and who will assign
23			
24			participants to interventions
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28	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to
29			
30			interventions (eg, trial participants, care providers,
31			
32			outcome assessors, data analysts), and how
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35	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding is
36			
37	emergency		permissible, and procedure for revealing a
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39	unblinding		participant's allocated intervention during the trial
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43	<b>Methods: Data</b>		
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45	<b>collection,</b>		
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47	<b>management, and</b>		
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49	<b>analysis</b>		
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53	Data collection plan	<a href="#">#18a</a>	Plans for assessment and collection of outcome,
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55			baseline, and other trial data, including any related
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57			processes to promote data quality (eg, duplicate
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1 measurements, training of assessors) and a  
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 3 description of study instruments (eg,  
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 5 questionnaires, laboratory tests) along with their  
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 7 reliability and validity, if known. Reference to  
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 9 where data collection forms can be found, if not in  
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 11 the protocol  
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15	Data collection plan:	<a href="#">#18b</a>	Plans to promote participant retention and	P10-11
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17	retention		complete follow-up, including list of any outcome	
18			data to be collected for participants who	
19			discontinue or deviate from intervention protocols	
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24	Data management	<a href="#">#19</a>	Plans for data entry, coding, security, and storage,	P12
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26			including any related processes to promote data	
27			quality (eg, double data entry; range checks for	
28			data values). Reference to where details of data	
29			management procedures can be found, if not in	
30			the protocol	
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39	Statistics: outcomes	<a href="#">#20a</a>	Statistical methods for analysing primary and	P12
40			secondary outcomes. Reference to where other	
41			details of the statistical analysis plan can be found,	
42			if not in the protocol	
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49	Statistics: additional	<a href="#">#20b</a>	Methods for any additional analyses (eg, subgroup	P12
50			and adjusted analyses)	
51	analyses			
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54	Statistics: analysis	<a href="#">#20c</a>	Definition of analysis population relating to	P12
55			protocol non-adherence (eg, as randomised	
56	population and			
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1 missing data analysis), and any statistical methods to handle  
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 3 missing data (eg, multiple imputation)  
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## 6 **Methods: Monitoring**

9 Data monitoring: 10 formal committee	<a href="#">#21a</a>	11 Composition of data monitoring committee (DMC); 12 summary of its role and reporting structure; 13 statement of whether it is independent from the 14 sponsor and competing interests; and reference to 15 where further details about its charter can be 16 found, if not in the protocol. Alternatively, an 17 explanation of why a DMC is not needed 18 19 20 21 22 23	P12
25 Data monitoring: 26 interim analysis	<a href="#">#21b</a>	27 Description of any interim analyses and stopping 28 guidelines, including who will have access to these 29 interim results and make the final decision to 30 terminate the trial 31 32 33	n/a, not apply DMC in this trail
35 Harms	<a href="#">#22</a>	36 Plans for collecting, assessing, reporting, and 37 managing solicited and spontaneously reported 38 adverse events and other unintended effects of 39 trial interventions or trial conduct 40 41 42 43 44	P10
45 Auditing	<a href="#">#23</a>	46 Frequency and procedures for auditing trial 47 conduct, if any, and whether the process will be 48 independent from investigators and the sponsor 49 50 51 52	n/a

## 53 **Ethics and** 54 55 **dissemination** 56 57 58 59 60

1	Research ethics	<a href="#">#24</a>	Plans for seeking research ethics committee /	P13
2				
3	approval		institutional review board (REC / IRB) approval	
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6	Protocol	<a href="#">#25</a>	Plans for communicating important protocol	n/a
7				
8	amendments		modifications (eg, changes to eligibility criteria,	
9			outcomes, analyses) to relevant parties (eg,	
10			investigators, REC / IRBs, trial participants, trial	
11			registries, journals, regulators)	
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18	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from	P6-7
19			potential trial participants or authorised surrogates,	
20			and how (see Item 32)	
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26	Consent or assent:	<a href="#">#26b</a>	Additional consent provisions for collection and	n/a, not needed in
27			use of participant data and biological specimens in	
28	ancillary studies		ancillary studies, if applicable	this study
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34	Confidentiality	<a href="#">#27</a>	How personal information about potential and	P13
35			enrolled participants will be collected, shared, and	
36			maintained in order to protect confidentiality	
37			before, during, and after the trial	
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44	Declaration of	<a href="#">#28</a>	Financial and other competing interests for	P16
45			principal investigators for the overall trial and each	
46	interests		study site	
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51	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial	n/a, not needed in
52			dataset, and disclosure of contractual agreements	
53			that limit such access for investigators	this study
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1 2 3 4 5 6 7	Ancillary and post trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a, not needed in this study
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Dissemination policy: trial results	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P16
25 26 27 28 29 30	Dissemination policy: authorship	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of professional writers	P16
31 32 33 34 35 36 37	Dissemination policy: reproducible research	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P16
38	<b>Appendices</b>			
39 40 41 42 43 44 45 46 47 48	Informed consent materials	<a href="#">#32</a>	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
49 50 51 52 53 54 55 56 57 58 59 60	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a, not needed in this study

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4  
5 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

## Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-054623.R2
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Complete List of Authors:	Xu, Linqi; Jilin University Li, Jinwei; Jilin University, School of Nursing Zhang, Xin; Jilin University, School of Nursing Pang, Yue; Jilin University, School of Nursing Yu, Tianzhuo; Jilin University Lian, Xiaoqian; Jilin University Yu, Tianyue; Jilin University Zhu, Lanyu; Jilin University; Changchun University of Chinese Medicine Tong, Qian; First Hospital of Jilin University Li, Feng; Jilin University
<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Nursing, Rehabilitation medicine
Keywords:	Coronary heart disease < CARDIOLOGY, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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**Title Page**

Mobile health-based gamification intervention to increase physical activity participation among patients with coronary heart disease: Study protocol of a randomized controlled trial

**The corresponding author:**

Feng Li, PhD, School of Nursing, Jilin University, No 965, Xin Jiang Avenue, 130000, Changchun, Jilin Province, China.

**Tel.:** 17790089009, **Fax:** (86)431-85619580, **E-mail:** [fli@jlu.edu.cn](mailto:fli@jlu.edu.cn)

Qian Tong, MD, First Hospital of Jilin University, No 71, Xin Min Avenue, 130000, Changchun, China.

**Tel.:** 13074337289, **Fax:** (86)431-58997910, **E-mail:** [tongqian187@aliyun.com](mailto:tongqian187@aliyun.com)

**The name(s) of all authors:**

Linqi Xu<sup>1</sup>, Jinwei Li<sup>1</sup>, Xin Zhang<sup>1</sup>, Yue Pang<sup>1</sup>, Tianzhuo Yu<sup>1</sup>, Xiaoqian Lian<sup>1</sup>, Tianyue Yu<sup>1</sup>, Lanyu Zhu<sup>1,2</sup>, Qian Tong<sup>3\*</sup>, Feng Li<sup>1\*</sup>.

<sup>1</sup>School of Nursing, Jilin University, Changchun, Jilin Province, China.

<sup>2</sup>Changchun University of Chinese Medicine, Changchun, Jilin Province, China

<sup>3</sup>The First Hospital of Jilin University, No 71, Xin Min Avenue, Changchun, Jilin Province, China.

\*These authors contributed equally to this work and should be considered co-corresponding authors

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## Abstract

**Introduction:** Despite proven benefits, physical activity participation remains low in patients with coronary heart disease (CHD). Scientific evidence suggests that mobile health (mHealth)-based gamification interventions could increase physical activity levels. However, several systematic reviews demonstrated that most gamification intervention designs do not appropriately leverage theories from health behavior models, and empirical evidence on the efficacy of such interventions among patients with CHD is still emerging. This study embeds the principles of behavioral economics into a gamification intervention based on a smartphone app (WeChat applet) to explore whether a mHealth-based gamification intervention can improve participation in physical activity and other related physical and psychological outcomes in patients with CHD.

**Methods:** We propose a single-blinded three-arm randomized controlled trial with 108 patients with CHD, who will be randomly divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat applet + step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification + collaboration). The interventions will last for 12 weeks and follow-up for 12 weeks. All patients will receive only WeChat applet-based step goal setting in the follow-up period. The primary outcome is physical activity participation, which includes a change in daily steps and self-reported physical activity from the baseline to 12 and 24 weeks, and the proportion of patient-days that step goals achieved in 12 and 24 weeks. The secondary outcomes include biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support and mental health and patients' satisfaction, perceptions, and intervention experience.

**Ethics and dissemination:** The Human Research Ethics Committee of the School of Nursing, Jilin University (HREC 2020122401) approved this. The results will be published in peer-reviewed journals and presented at conferences.

**Trial registration number:** ChiCTR2100044879; Pre-results.

**Keywords:** physical activity, behavioral intervention, mobile health, gamification, randomized controlled trial

### **Strength and Limitations of this study**

1. Our WeChat applet-based gamification intervention is technology-based and could improve physical activity adherence in patients with coronary heart disease.
2. This study is based on a theoretical framework and will provide insights into how to use mobile health and game elements to promote patients' intrinsic motivation, thereby increase adherence.
3. This study will examine patients' psychological needs, intrinsic motivations, perceptions, and experience, which will allow us to understand the internal psychological mechanisms of gamification intervention to promote physical activity.
4. The study is limited to patients with smartphones and a WeChat account, which could lead to a selective bias.
5. The gamification interventions are comprehensive and it would be challenging to analyze the component that worked.

### **1. Background**

Coronary heart disease (CHD) is the leading cause of mortality in China. Statistically, around 11 million people were affected with CHD in 2017<sup>[1,2]</sup>. Exercise-based cardiac rehabilitation and secondary prevention (CR/SP) plays a crucial role in preventing the recurrence of CHD<sup>[3]</sup> and has been listed as a Class I recommendation for CHD treatment by the American Heart Association, the American Society of Cardiology, and the European Society of Cardiology<sup>[4-7]</sup>. The relevant guidelines recommend that patients with CHD should perform at least 500-MET-min/week physical activity every week<sup>[8]</sup>. Although CR/SP have proven benefits, it is

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4 often challenging for patients to attain lifestyle changes needed for SP, especially with increasing physical activity  
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6 levels<sup>[9]</sup>. For example, owing to the poor accessibility of cardiac rehabilitation programs, > 80% of patients did  
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8 not participate in the cardiac rehabilitation programs recommended by the guidelines<sup>[10]</sup>. Moreover, patients with  
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10 CHD typically fail to attain their daily physical activity goals<sup>[11]</sup>.  
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14 Mobile health (mHealth), defined by American Heart Association's scientific statement, "is the use of mobile  
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16 computing and communication technologies (e.g. mobile phones, wearable devices) for health services and  
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18 information"<sup>[12]</sup>, has become an essential medium to deliver behavioral change interventions and demonstrated  
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20 promising ability to improve physical activity levels<sup>[12-14]</sup>. For example, the CONNECT trial examined the impact  
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22 of digital health interventions on health behaviors and established the correlation between intervention and  
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24 increased attainment of physical activity targets<sup>[15]</sup>. In China, WeChat is a top-rated multipurpose social media  
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26 app, with >1.151 billion active users<sup>[16]</sup>. WeChat applets are lightweight apps that form part of the WeChat  
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28 ecosystem, which could be used independently and do not need installation. Compared with mobile apps, WeChat  
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30 applets are easier to be accepted and applied by people in China. The third quarter of 2019 recorded >300 million  
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32 active WeChat applet users every day, thereby making it well suited to disseminate mHealth interventions in  
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34 China<sup>[17]</sup>.  
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43 Gamification is the use of game design elements (such as points, leaderboards, progress bars, and badges) in  
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45 non-game contexts (such as management, education, marketing, and healthcare) to increase motivation and  
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47 engagement<sup>[18]</sup>. There is growing interest in the application of gamification in mHealth with the view of promoting  
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49 healthy behavioral changes<sup>[19-22]</sup>, especially in promoting physical activity levels<sup>[23]</sup>. Previous studies indicated  
50  
51 that gamification was used in 64% of the top 50 most popular smartphone apps<sup>[24]</sup>. However, several systematic  
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53 reviews reported that most gamification intervention designs did not appropriately leverage theories from health  
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55 behavior models<sup>[19,25,26]</sup>. Moreover, as the concept of gamification is relatively new<sup>[18]</sup>, empirical evidence on the  
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4 efficacy of gamification physical activity behavioral change interventions among patients with CHD is still  
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6 emerging.

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9 Gamification interventions are rarely based on a sound theoretical framework<sup>[20,22]</sup>. Behavioral economics  
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11 principles combine conventional economic principles with psychology to elucidate how individuals behave and  
12  
13 make decisions<sup>[27]</sup>. Behavioral economics principles can be embedded with a gamification intervention via mobile  
14  
15 devices to aid people to attain their physical activity goals. For example, based on the loss aversion, which implies  
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17 that the loss framework is more effective in stimulating behavioral change than the gain framework, Patel et al.  
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19 designed an intervention wherein participants lost points if they did not accomplish their step goals<sup>[28]</sup>. Several  
20  
21 previous studies have used behavioral economics principles to help patients lose weight, quit smoking, and adhere  
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23 to medications<sup>[29–31]</sup>. However, limited data are available on applying these concepts to improve physical activity  
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25 participation in patients with CHD.  
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33 This study will use behavioral economics principles to develop a gamification WeChat applet named  
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35 “TahneeWeh” to resolve the research gap mentioned above. This study aims to investigate the effects of the  
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37 mHealth-based gamification intervention on participation in physical activity and evaluate the effects on  
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39 biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and  
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41 relatedness, social support, and mental health. In addition, a semi-structured interview will be conducted after the  
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43 intervention to comprehend patients’ satisfaction, perceptions and their experience on the intervention.  
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## 48 **2. Methods**

### 49 **2.1 Study design**

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52 This is a single-blind, three-arm randomized controlled trial to evaluate the effects of the mHealth-based  
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54 gamification intervention on participation in physical activity, biomedical and lifestyle-related risk factors,  
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56 intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health.  
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4 Patients with CHD will be recruited in a cardiac rehabilitation center of a tertiary-grade A class hospital in  
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6 Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants will be randomly  
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8 divided into three groups (Control group: WeChat applet + step goal setting; Individual group: WeChat applet +  
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10 step goal setting + gamification; Team group: WeChat applet + step goal setting + gamification + collaboration).  
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12 Patients in the control group will only receive daily step goal setting. The Individual and Team groups will receive  
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14 gamified behavior intervention based on behavioral economics principles. The Team group will also receive social  
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16 incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12 weeks. All  
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18 patients will just receive WeChat applet-based step goal setting in the follow-up period. The study duration will  
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20 be between July 1, 2021 and November 30, 2022. Figure 1 shows a flowchart of the study design. The protocol  
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22 conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting  
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24 guidelines, and the intervention is described per the CONSORT-EHEALTH checklist<sup>[32-34]</sup>. The study is registered  
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26 at Clinical Trials.gov: ChiCTR2100044879.  
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## 34 35 **2.2 Eligibility and Recruitment**

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38 Patients fulfilling the inclusion and exclusion criteria will be invited to participate in the trial. The inclusion  
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40 criteria are as follows: (i) aged 18–70 years; (ii) patients diagnosed with CHD(including acute myocardial  
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42 infarction and unstable angina), and received percutaneous coronary intervention (PCI) treatment during  
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44 admission; (iii)patients evaluated by cardiologists and rehabilitation therapists if they are suitable for participating  
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46 in our program; (iv) patients willing to provide written informed consent; (v) patients with a smartphone and an  
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48 active WeChat account; and (vi) patients with proficiency in Chinese.  
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54 The exclusion criteria include the following: (i) contraindications for exercise rehabilitation (e.g., untreated  
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56 ventricular tachycardia, severe heart failure, uncontrollable hypertension or hypotension, notable exercise  
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58 restriction); (ii) patients unable to use WeChat applet after instruction; (iii) no Internet access in the place of  
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4 residence; (iv) patients requiring a walking aid to move; and (v) patients participating in other clinical trials.  
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6 Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting  
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8 participants. Patients undergoing PCI will be referred to the cardiac rehabilitation center, which is adjacent to the  
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10 wards to receive physical activity counseling and obtain the follow-up booklet before discharge. The follow-up  
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12 booklet will remind patients to return for review in 4 weeks, 12 weeks, 24 weeks, and 12 months after discharge,  
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14 which is very helpful to avoid patients' loss to follow-up. In the rehabilitation center, researchers will screen the  
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16 eligible patients and then inform the patients about the details of the study. If they agree to participate in the study,  
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18 they will have to sign the written consent form and complete the questionnaires using a traditional pen and paper  
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20 method. We will mark the specific date of 12 and 24 weeks of his returning to complete the outcome measurement  
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22 on his follow-up booklet and tell him if he is not available on that day; he could contact us to change the date  
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24 accordingly. After that, we will teach patients to register and log in to our WeChat applet "TahneeWeh"; this is  
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26 required to get their step data for the past 2 weeks, which will be recorded by smartphone accelerometers (as done  
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28 in many prior studies<sup>[35-38]</sup>) and has been proven accurate for tracking step counts<sup>[39]</sup>. Furthermore, a baseline step  
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30 count will be estimated using the mean step count of the previous 2 weeks.  
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### 40 **2.3 Sample size calculation**

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42 The main outcome indicator, daily step count, is selected as the calculation standard. Based on a previous  
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44 study, we will ensure, at least, 90% power to detect an 800-step difference between each intervention arm and  
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46 control, a standard deviation of 2000 steps, and a two-sided  $\alpha$  of 0.05<sup>[40]</sup>. In addition, we will use one-way analysis  
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48 of variance *F*-tests in PASS15.0.5 software and calculate that a total of 84 participants across three arms would  
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50 be recruited. By allowing for an estimated 20% dropout rate, a sample size of 108 will be used in this study.  
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### 56 **2.4 Randomization, blinding, and concealed allocation**

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58 Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step  
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count (<5000, 5001–7500, or >7500 steps/day). The data collector will be unaware of patient assignments at the baseline, 12 weeks, and 24 weeks of the study. Researchers could see the assignments in the backstage of the WeChat applet, and the interfaces of the WeChat applet for patients in different groups are different.

## 2.5 Control

All patients will receive step goal setting and could see their progress on the WeChat applet during the 12-week intervention and 12-week follow-up. Personalized daily step goals will be set in the WeChat applet backstage based on patients' baseline daily step counts, and the goals will increase gradually from the baseline by 15% each week during the first 6 weeks and then remain fixed during the last 6 weeks, as described elsewhere<sup>[41]</sup>. To ensure the increase in physical activity is not harmful to participants, the rehabilitation therapists in our research group will assess the condition of each patient and make appropriate adjustments to the step goals. Participants could contact us at any time to make an adjustment if it is due to physical conditions. Moreover, patients could see their daily progress toward their goals using a circular dial on the WeChat applet. Of note, patients in the control group will receive no other interventions. If a patient does not log in to the WeChat applet for over a week, a text message reminder will be sent.

## 2.6 Intervention

Patients in the Individual and Team groups will receive the gamification intervention based on behavioral economics principles via the WeChat applet. Six behavioral economics principles (precommitment, fresh start effect, goal gradients, loss aversion, anticipated regret, and social norms) will be embedded within the gamification intervention. The gamification intervention in the Individual group will apply to four game elements—feedback, points, levels, and rewards. In the Team group, collaboration is added besides the four game elements mentioned above. Table 1 provides a summary of game elements, gamification intervention components, and behavioral economics principles.

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### 2.6.1 Individual group

First, patients will electronically sign a precommitment pledge to try their best to attain their step goal. Precommitment is known to motivate behavioral change<sup>[42,43]</sup>. Second, every Monday, patients will receive 140 points (20 for each day), which leverage the fresh start effect<sup>[44]</sup>. Patients tend to be more driven for aspirational behavior around temporal landmarks like the beginning of the week. Third, if patients reach the target step count, no points will be deducted; if not, 20 points will be deducted. This leverages loss aversion, demonstrating that loss framing is more effective at motivating behavioral change than gain framing<sup>[45,46]</sup>. Fourth, a total of five levels will be set, from low to high—bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, patients will be set to the gold level. If a patient has a total score of <80 points in the week, the level will drop, and if the total scores are  $\geq 80$  points, the level will increase; this is done such that the patients would feel their level dropping to silver if they did not attain sufficient points in the first week. At the end of the intervention, if the level of a patient is diamond, he/she will be rewarded with a small prize. Fifth, patients in the two intervention groups will receive feedback weekly based on their progress.

### 2.6.2 Team group

The Team group will also receive social incentives based on the Individual group. Patients are assigned to a team of 3 people, who do not know each other before the intervention. Every Monday, the patients will receive 140 points (20 for each day, 10 for themselves, 10 for their team). If the patient achieves the step goals and the other 2 people in his/her team also achieve the step goals, no points will be deducted. If the patient achieves the step goals, but other 2 people in his/her team do not, 10 points for their team will be deducted. If neither the patient nor the other two people in his/her team achieve the step goal, 20 points will be deducted. Figure 2 presents the WeChat applet interface, and Figure 3 shows the backstage management system of the WeChat applet.

Table 1 A summary of game elements, intervention components, and behavioral economics (BE) principles

Game elements	Gamification intervention components	BE principles
	Patients will electronically sign a precommitment pledge to try their best to achieve their step goal.	Precommitment
<b>Points</b>	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
<b>Points</b>	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
<b>Collaboration</b>	If the patient achieve the step goals and the other 2 people in her team also achieve the step goals, no points will be deducted; if the patient achieve the step goals but other 2 people in her team do not, 10 points for her team will be deducted; if neither the patient nor the other two people in her team does not achieve the step goal, 20 points will be deducted.	Social norms; Loss aversion; Anticipated Regret
<b>Levels</b>	We set 5 levels, from low to high is bronze, silver, gold, platinum, and diamonds. At the beginning of the trial, the patient is set to the gold level. If the patient has a total score of less than 80 points in a week, the level will drop, and if the total score is greater than or equal to 80 points, the level will rise.	the Fresh Start Effect; Goal Gradients; Loss aversion
<b>Rewards</b>	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
<b>Feedback</b>	Patients in the two intervention groups will receive feedback according to their progress weekly.	

## 2.7 Outcome measures and data collection

Patients recruited in the trial will be asked to complete the questionnaires and outcome measurements in the cardiac rehabilitation clinic when they return to hospital for a review. The WeChat applet will automatically remind patients to complete the outcome measurements in 12 and 24 weeks. If the patient does not return on time,

researchers will telephonically inquire about the reasons. We will also report the numbers and reasons of patients lost to follow-up.

Table 2 shows the summary of the outcome measures for the study. The primary outcome is physical activity participation, which includes a change in daily steps and self-reported physical activity from the baseline to 12 and 24 weeks, and the proportion of patient-days that step goals achieved in 12 and 24 weeks. The daily step counts will be measured and recorded by smartphone accelerometers, proven accurate for tracking step counts<sup>[39]</sup>. Self-reported physical activity level will be measured by the International Physical Activity Questionnaire (IPAQ)<sup>[47]</sup>.

The secondary outcomes include biomedical risk factors, which include the body weight(kg), waist circumference (cm), body mass index (BMI), systolic blood pressure (mmHg), diastolic blood pressure (mmHg), resting heart rate (bpm/min), lifestyle-related risk factors, including smoking, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, anxiety symptom, and depressive symptoms. The IPAQ will be filled out online at the baseline, 12 weeks, and 24 weeks through the WeChat applet, while the other measurements will be taken in the hospital (at the baseline, 12 weeks, and 24 weeks). In addition, usability will be tested at the end of the intervention (at 12 weeks) in the two intervention groups using the System Usability Scale (SUS)<sup>[48]</sup>. Furthermore, we will conduct a semi-structured interview to understand patients' satisfaction, perceptions and experiences in the two intervention groups.

All adverse events will be reported to the Ethics Committee as required during the 24 weeks study period. Adverse events are defined as medical occurrences resulting in hospitalization, disability, or death.

Table 2 Assessment time-points for primary and secondary outcomes

Outcome	Assessment	Baseline	12 weeks	24 weeks
<b>Primary outcomes</b>				
<b>Physical activity</b>	Change in daily steps	√	√	√

	The proportion of patient-days that step goals were achieved	√	√	√
	International Physical Activity Questionnaire (IPAQ) <sup>47</sup>	√	√	√
<b>Secondary outcomes</b>				
<b>Biomedical risk factors</b>	Body weight, waist circumference, BMI, SBP, DBP, RHR	√	√	√
<b>Lifestyle-related risk factors</b>	Self-reported smoking	√	√	√
<b>Competence, autonomy, and relatedness</b>	Psychological Needs Satisfaction in Exercise Scale(PNSE) <sup>49</sup>	√	√	√
<b>Intrinsic motivation</b>	Behavioral Regulation in Exercise Questionnaire(BREQ-2) <sup>50</sup>	√	√	√
<b>Enjoyment</b>	Physical Activity Enjoyment Scale (PACES) <sup>51</sup>	√	√	√
<b>Social support</b>	Social Support Rating Scale (SSRS) <sup>52</sup>	√	√	√
<b>Anxiety symptoms</b>	Generalised Anxiety Disorder 7-item Scale (GAD-7) <sup>53</sup>	√	√	√
<b>Depressive symptoms</b>	Patient Health Questionnaire (PHQ-9) <sup>54</sup>	√	√	√
<b>Usability</b>	System Usability Scale (SUS) <sup>48</sup>		√	
<b>Satisfaction</b>	Semi-structured interview		√	
<b>Patients' experience</b>	Semi-structured interview		√	
<b>Adverse event reporting</b>	Medical occurrences resulting in hospitalization, disability or deaths	←—————→		

BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; RHR, resting heart rate

## 2.8 Statistical analysis and data management

All continuous variables will be reported as mean and SD, and categorical variables will be described as frequencies and percentages. Within-group changes in daily step counts, the proportion of patient-days that step

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4 goals attained, self-reported physical activity, biomedical and lifestyle-related risk factors, intrinsic motivation,  
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6 enjoyment, competence, autonomy, and relatedness, social support, and mental health will be compared using a  
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8 paired *t*-test or Wilcoxon test depending on the data distribution. Besides, a one-way analysis of variance will be  
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10 used to compare the intergroup differences between the baseline and postintervention among the outcomes. Main  
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12 analysis and secondary analysis will be conducted of all the outcomes. In the main analysis, the analysis of  
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14 outcomes will be conducted per the intention-to-treat principle. In addition, multiple imputations for data will be  
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16 used that are missing and with step values <1000 because evidence indicates that these values are unlikely to  
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18 represent the capture of actual activity<sup>[37,55]</sup>. In the secondary analysis, data analysis will be conducted without  
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20 multiple imputations, both with and without step values <1000. Furthermore, adjusted analyses include sex, age,  
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22 BMI, severity of disease, and baseline variables. Moreover, we will compare the baseline differences between  
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24 patients lost to follow up and patients who adhere to follow-up. All statistical analyses will be two-sided, and *P* <  
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26 0.05 will be considered statistically significant. We will use SPSS V.20.0 for data analysis.  
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35 In this study, well-trained clinical researchers will record all patients' data using standardized case report  
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37 forms (CRF). The original data will be recorded timely and accurately, and a copy of the report will be kept in the  
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39 laboratory. All CRFs will be stored in a locked file cabinet to prevent data leakage. All laboratory data will be  
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41 identified with a code number to ensure the confidentiality of subjects' data. The clinical research data  
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43 management platform of the School of Nursing of Jilin University will be accountable for data monitoring. The  
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45 chief investigator can directly access the dataset, and the data scattered to the project team members cannot  
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47 identify any participant identity information.  
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## 53 **2.9 Patient and public involvement**

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55 Patient and public involvement (PPI) played a vital role in this study. Before designing the WeChat applet,  
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57 the authors conducted a survey among patients with CHD and found that patients lacked physical activity and  
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4 were willing to be supervised and motivated via their smartphones to promote participation in physical activity.  
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6 During the development of WeChat applet, patients with CHD will be invited to participate in our discussion,  
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8 allowing the authors to consider the thoughts and needs of patients in developing the WeChat applet. In the pilot  
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10 study, patients will be invited to give reasonable recommendations for study design, questionnaire selection, and  
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12 outcome measurements while considering the burden of intervention. The results of this study will be disseminated  
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14 to PPI representatives and study participants who wish to be notified.  
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### 18 19 **2.10 Validity and reliability**

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22 This study will use a rigorous research design (randomized controlled design) and a block random method  
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24 to assign groups. The grouping results will be numbered and placed in a sealed envelope. Participants and data  
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26 collectors will be blinded to the assignments. All questionnaires will be completed by the researcher's guidance  
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28 or ghostwriting. The questionnaires will be distributed and collected on the spot to avoid data bias caused by  
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30 different researchers. Two researchers will enter all the data to avoid objective typing errors.  
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### 34 35 **3. Ethics and dissemination**

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37 This study will comply with the ethical principles of the Declaration of Helsinki, and the Human Research  
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39 Ethics has been approved by the School of Nursing, Jilin University (HREC 2020122401). This study is registered  
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41 at Clinical Trials.gov (ChiCTR2100044879). All participants will be required to provide written informed consent.  
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43 Research reports will be disseminated through scientific forums, including peer-reviewed publications and  
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45 presentations at national and international conferences.  
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### 50 51 **4. Discussion**

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53 The authors aim to develop a WeChat applet in this study. Based on the WeChat applet and under the  
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55 guidance of behavioral economics principles, the authors will develop a gamification intervention using five game  
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57 elements, including points, levels, feedback, rewards, and collaboration. This study will evaluate the role of  
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4 mHealth-based gamification intervention on physical activity participation and the effects on biomedical and  
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6 lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social  
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8 support, and mental health. Moreover, the authors will conduct a semi-structured interview after the intervention  
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10 to elucidate patients' satisfaction, perceptions and experience of the intervention.  
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14 Despite proven benefits, patients with CHD do not often attain their physical activity goals on their own<sup>[11]</sup>.  
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16 Behavioral interventions are needed to help them increase physical activity participation. With technological  
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18 advancement, numerous smartphone apps have appeared, and gamification was used in most of these apps, which  
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20 could increase physical activity motivation and promote behavioral change. However, most gamification  
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22 intervention designs did not appropriately leverage theories from health behavior models, and empirical evidence  
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24 on their efficacy is still emerging. A previous study established that behavioral economics principles could be  
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26 embedded with a gamification intervention to significantly increase physical activity among overweight and obese  
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28 adults<sup>[28]</sup>. However, thus far, there is limited evidence of interventions that use these methods to effectively  
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30 improve physical activity participation among high-risk patients, such as patients with CHD<sup>[56]</sup>. Thus, this study  
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32 will develop a gamification intervention based on a WeChat applet that has been specifically developed for this  
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34 study. Personalized goal setting and progress tracking on the WeChat applet will allow patients to exercise under  
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36 supervision. The gamification intervention motivated patients to walk more; this could become a new way to  
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38 promote the implementation of home and exercise-based cardiac rehabilitation.  
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48 The key of gamification interventions is to organically combine game elements to form a resultant force to  
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50 improve physical activity, and the key of the resultant force is to comprehend the driving force or motivation  
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52 behind the incentive mechanism. Research indicates links between self-determination theory and gamification  
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54 concepts. Self-determination theory suggests that satisfying three innate psychological needs of competence,  
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56 autonomy, and relatedness could promote autonomous motivation and well-being. Reportedly, individuals with  
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4 autonomous motivation had higher physical activity participation and better physical activity adherence than those  
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6 primarily driven by external factors<sup>[57]</sup>. Furthermore, the fact that gamification could make interventions more  
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8 enjoyable aligns with self-determination theory, which assumes that a key aspect of intrinsic motivation is  
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10 enjoyment<sup>[18]</sup>. We plan to investigate the internal psychological mechanism of gamification to promote physical  
11  
12 activity; thus, we will evaluate competence, autonomy, relatedness, enjoyment, and intrinsic motivation. We  
13  
14 assume that gamification intervention promotes the transformation of controlled motivation into autonomous  
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16 motivation by satisfying competence, autonomy, relatedness, enjoyment, and ultimately promote physical activity  
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18 participation. Figure 4 shows the hypothesized model of physical activity behavior regulation. Moreover, because  
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20 our intervention platform will provide information support for patients, we will also evaluate the variable social  
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22 support. Furthermore, we will conduct a semi-structured interview after the intervention to comprehend patients'  
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24 experiences and capture information on communications among patients in the collaboration group, which could  
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26 explore the internal psychological mechanism of gamification to promote exercise motivation.  
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35 In China, access to cardiac rehabilitation is often limited. Patients with CHD often lack physical activity. Our  
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37 intervention could help increase physical activity participation and bring more health benefits.  
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#### 40 **Limitations**

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42 This study has several limitations. First, we will not measure the intensity of physical activity via the  
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44 smartphone accelerometer. In future, we plan to use wearable devices to evaluate the intensity of physical activity.  
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46 Second, the study is limited to patients with smartphones and a WeChat account, which could lead to a selective  
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48 bias. Third, the gamification interventions are comprehensive, and it would be difficult to analyze the component  
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50 that worked. Fourth, it is a multilayered and complex intervention, and the projected sample size will make it  
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52 challenging to say that the results will be much more than a pilot study given there will be three groups.  
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**Competing interests:** None declared.

**Provenance and peer review:** Not commissioned; externally peer-reviewed.

**Data sharing statement:** For patient confidentiality concerns and the access possibilities of the data source, the clinical data collected will not be shared with the public. However, non-clinical data, such as educational materials, will be shared with the public and other researchers.

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4 Figure legends

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6 Figure 1: Study flowchart.

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8 Figure 2: WeChat applet “TahneeWeh” interface. (A) Daily step progress using a circular dial; (B) weekly step  
9 progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac  
10 rehabilitation and secondary prevention; (F)International Physical Activity Questionnaire (IPAQ) filling interface.

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16 Figure 3: The backstage management system of the WeChat applet “TahneeWeh.”

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19 Figure 4: The hypothesized model of physical activity (PA) behavior regulation.  
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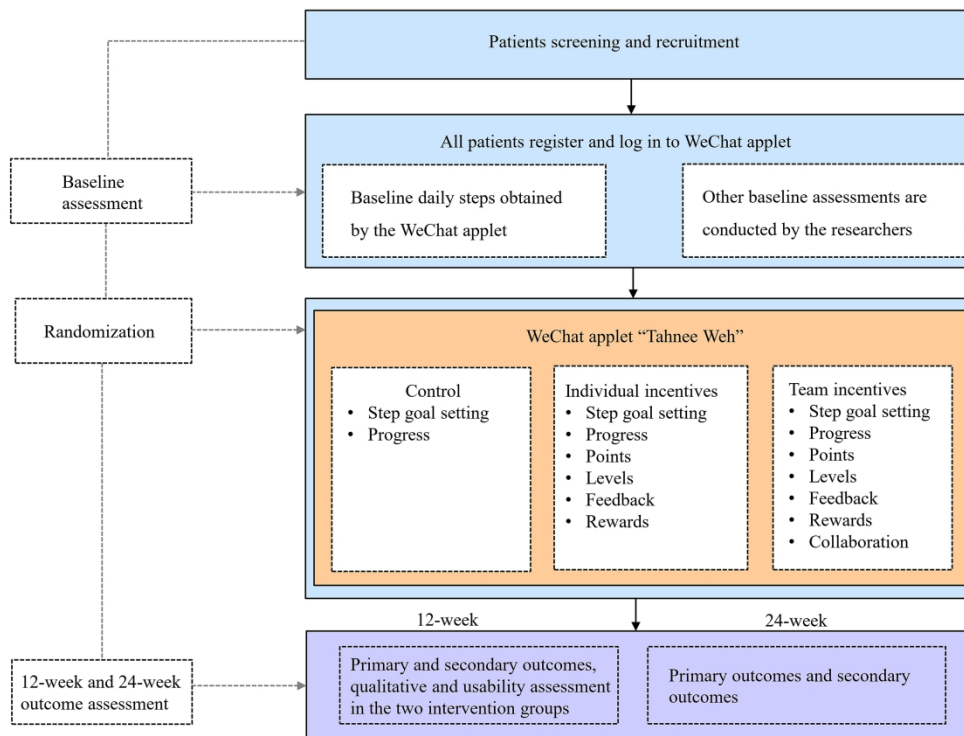


Figure 1: Study flowchart.

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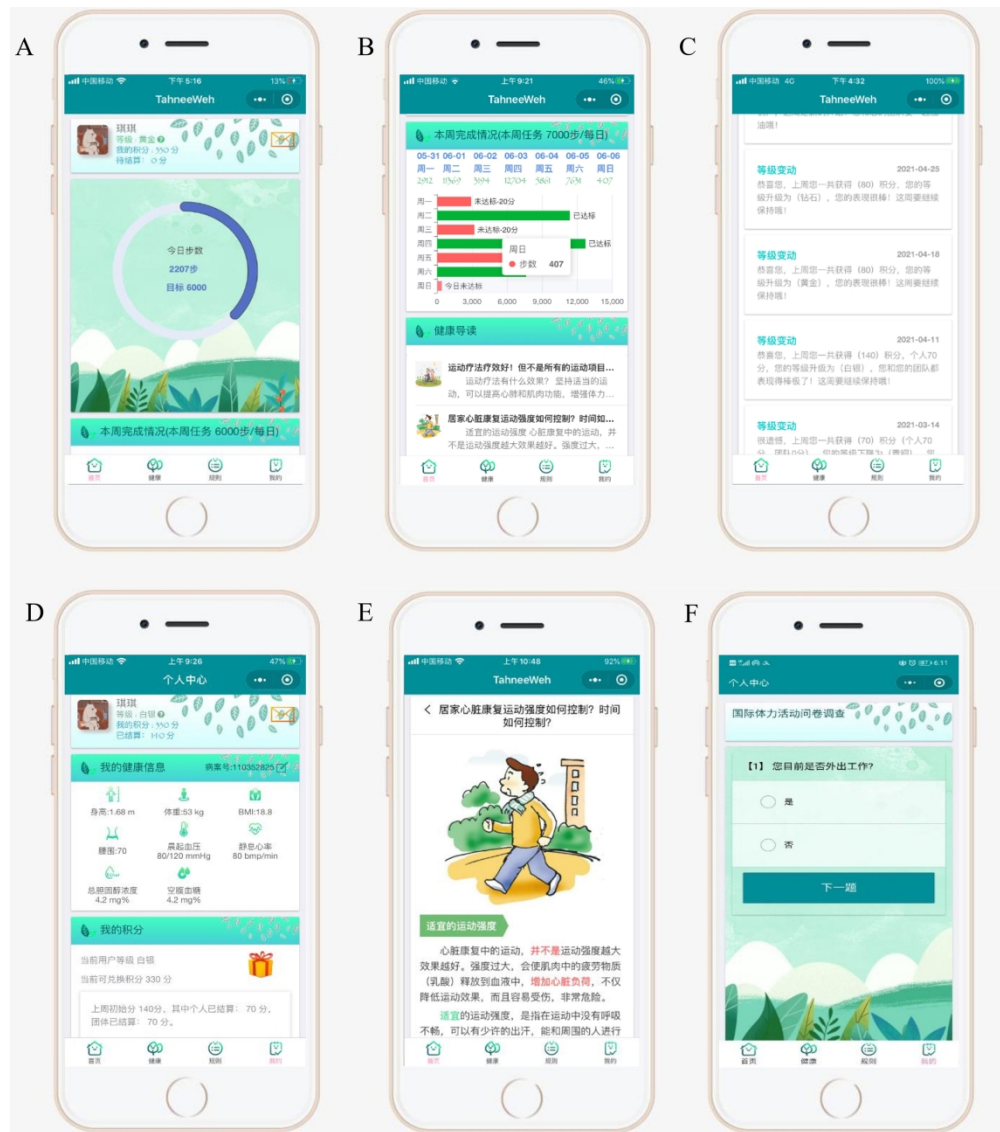


Figure 2: WeChat applet "TahneeWeh" interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F) International Physical Activity Questionnaire (IPAQ) filling interface.

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Figure 3: The backstage management system of the WeChat applet "TahneeWeh."

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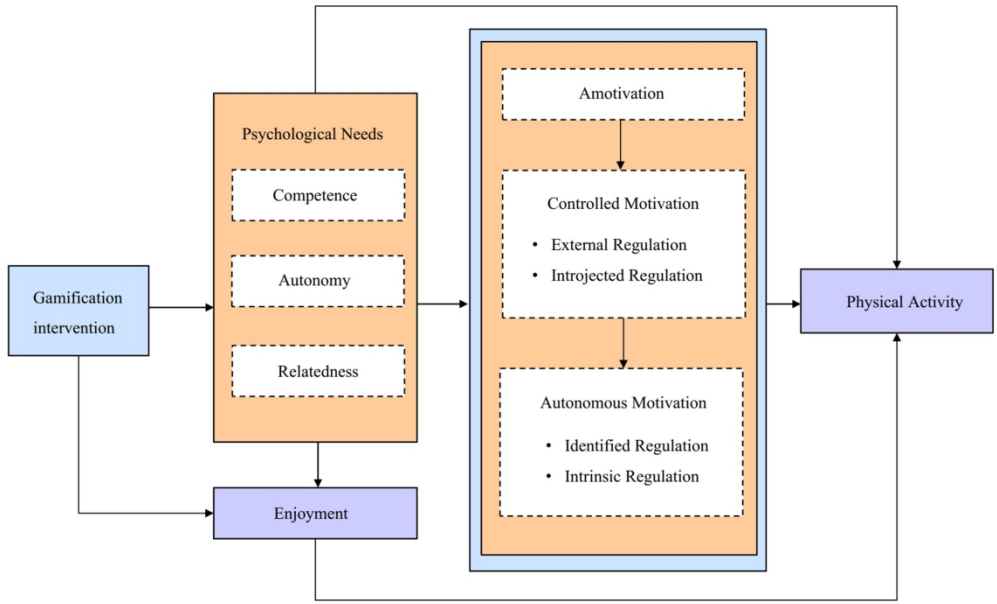


Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

299x184mm (300 x 300 DPI)

# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

	Reporting Item	Page Number
<b>Administrative information</b>		
Title	<a href="#">#1</a> Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	<a href="#">#2a</a> Trial identifier and registry name. If not yet registered, name of intended registry	P6, P14
Trial registration: data set	<a href="#">#2b</a> All items from the World Health Organization Trial Registration Data Set	P6
Protocol version	<a href="#">#3</a> Date and version identifier	n/a
Funding	<a href="#">#4</a> Sources and types of financial, material, and other support	P17
Roles and responsibilities:	<a href="#">#5a</a> Names, affiliations, and roles of protocol contributors	P17

contributorship

Roles and responsibilities: sponsor contact information [#5b](#) Name and contact information for the trial sponsor P17

Roles and responsibilities: sponsor and funder [#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 P17

Roles and responsibilities: committees [#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) P13

## 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 P3-5

Background and rationale: choice of comparators [#6b](#) Explanation for choice of comparators P3-5

Objectives [#7](#) Specific objectives or hypotheses P5

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, non-inferiority, exploratory) P5-6

## Methods: Participants, interventions, and

**outcomes**

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3	Study setting	<a href="#">#9</a>	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
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9	Eligibility criteria	<a href="#">#10</a>	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
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16	Interventions: description	<a href="#">#11a</a>	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
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21	Interventions: modifications	<a href="#">#11b</a>	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)
22			n/a, intervention did not involve harms or others
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28	Interventions: adherence	<a href="#">#11c</a>	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)
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35	Interventions: concomitant care	<a href="#">#11d</a>	Relevant concomitant care and interventions that are permitted or prohibited during the trial
36			P8-10
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39	Outcomes	<a href="#">#12</a>	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
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51	Participant timeline	<a href="#">#13</a>	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
52			Figure 1
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1	Sample size	<a href="#">#14</a>	Estimated number of participants needed to	P7
2			achieve study objectives and how it was	
3			determined, including clinical and statistical	
4			assumptions supporting any sample size	
5			calculations	
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9	Recruitment	<a href="#">#15</a>	Strategies for achieving adequate participant	P6-7
10			enrolment to reach target sample size	
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13	<b>Methods:</b>			
14	<b>Assignment of</b>			
15	<b>interventions (for</b>			
16	<b>controlled trials)</b>			
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20	Allocation: sequence	<a href="#">#16a</a>	Method of generating the allocation sequence	P8
21	generation		(eg, computer-generated random numbers), and	
22			list of any factors for stratification. To reduce	
23			predictability of a random sequence, details of	
24			any planned restriction (eg, blocking) should be	
25			provided in a separate document that is	
26			unavailable to those who enrol participants or	
27			assign interventions	
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33	Allocation	<a href="#">#16b</a>	Mechanism of implementing the allocation	P8
34	concealment		sequence (eg, central telephone; sequentially	
35	mechanism		numbered, opaque, sealed envelopes), describing	
36			any steps to conceal the sequence until	
37			interventions are assigned	
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41	Allocation:	<a href="#">#16c</a>	Who will generate the allocation sequence, who	P8
42	implementation		will enrol participants, and who will assign	
43			participants to interventions	
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46	Blinding (masking)	<a href="#">#17a</a>	Who will be blinded after assignment to	P8
47			interventions (eg, trial participants, care providers,	
48			outcome assessors, data analysts), and how	
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52	Blinding (masking):	<a href="#">#17b</a>	If blinded, circumstances under which unblinding	n/a, not blind to
53	emergency		is permissible, and procedure for revealing a	researchers
54	unblinding		participant's allocated intervention during the trial	
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57	<b>Methods: Data</b>			
58	<b>collection,</b>			
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1 **management, and**  
2 **analysis**

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4 Data collection plan [#18a](#) Plans for assessment and collection of outcome, Table 2  
5 baseline, and other trial data, including any  
6 related processes to promote data quality (eg,  
7 duplicate measurements, training of assessors)  
8 and a description of study instruments (eg,  
9 questionnaires, laboratory tests) along with their  
10 reliability and validity, if known. Reference to  
11 where data collection forms can be found, if not in  
12 the protocol  
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18 Data collection plan: [#18b](#) Plans to promote participant retention and P10-12  
19 retention complete follow-up, including list of any outcome  
20 data to be collected for participants who  
21 discontinue or deviate from intervention protocols  
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25 Data management [#19](#) Plans for data entry, coding, security, and P13  
26 storage, including any related processes to  
27 promote data quality (eg, double data entry; range  
28 checks for data values). Reference to where  
29 details of data management procedures can be  
30 found, if not in the protocol  
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35 Statistics: outcomes [#20a](#) Statistical methods for analysing primary and P13  
36 secondary outcomes. Reference to where other  
37 details of the statistical analysis plan can be  
38 found, if not in the protocol  
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42 Statistics: additional [#20b](#) Methods for any additional analyses (eg, P13  
43 analyses subgroup and adjusted analyses)  
44

45 Statistics: analysis [#20c](#) Definition of analysis population relating to P13  
46 population and protocol non-adherence (eg, as randomised  
47 missing data analysis), and any statistical methods to handle  
48 missing data (eg, multiple imputation)  
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52 **Methods:**  
53 **Monitoring**

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56 Data monitoring: [#21a](#) Composition of data monitoring committee P13  
57 formal committee (DMC); summary of its role and reporting  
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structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

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9	Data monitoring:	<a href="#">#21b</a>	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
10	interim analysis		n/a, not apply DMC in this trail
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15	Harms	<a href="#">#22</a>	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
16			P11
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22	Auditing	<a href="#">#23</a>	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
23			n/a
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27	<b>Ethics and dissemination</b>		
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31	Research ethics approval	<a href="#">#24</a>	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval
32			P13
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35	Protocol amendments	<a href="#">#25</a>	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)
36			n/a
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43	Consent or assent	<a href="#">#26a</a>	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
44			P6-7
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49	Consent or assent: ancillary studies	<a href="#">#26b</a>	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
50			n/a, not needed in this study
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54	Confidentiality	<a href="#">#27</a>	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
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1 2 3 4 5	Declaration of interests	<a href="#">#28</a>	Financial and other competing interests for principal investigators for the overall trial and each study site	P17
6 7 8 9 10	Data access	<a href="#">#29</a>	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a, not needed in this study
11 12 13 14 15	Ancillary and post trial care	<a href="#">#30</a>	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a, not needed in this study
16 17 18 19 20 21 22 23 24 25 26 27	Dissemination policy: trial results	<a href="#">#31a</a>	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P14,17
28 29 30 31	Dissemination policy: authorship	<a href="#">#31b</a>	Authorship eligibility guidelines and any intended use of professional writers	P14,17
32 33 34 35 36	Dissemination policy: reproducible research	<a href="#">#31c</a>	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P14,17
37	<b>Appendices</b>			
38 39 40 41 42 43 44	Informed consent materials	<a href="#">#32</a>	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
45 46 47 48 49 50	Biological specimens	<a href="#">#33</a>	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a, not needed in this study

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