BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-054623
Article Type:	Protocol
Date Submitted by the Author:	19-Jun-2021
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Keywords:	Coronary heart disease < CARDIOLOGY, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

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Word count: 3684

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.

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 may improve physical activity (PA) adherence in patients with coronary heart disease (CHD).
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 improve the adherence.
3. This study will evaluate patients' psychological needs, intrinsic motivations, perceptions and experience, which allowing us to understand the internal psychological mechanisms of gamification intervention to promote physical activity.
4. The study period was 24 weeks; thus, we could not evaluate and maintain the intervention in 12 months.
5. The gamification interventions are comprehensive and it would be difficult 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 [1,2]. Exercise-based cardiac rehabilitation and secondary prevention (CR/SP) plays a crucial role in preventing the recurrence of CHD[3] and has been listed as a Class I recommendation for CHD treatment by the American Heart Association (AHA), the American Society of Cardiology (ACC), and the European Society of Cardiology (ESC)[4–7]. The relevant guidelines recommend that patients with CHD should perform, at least, 500-MET-min/week physical activity (PA) every week[8]. Although

CR/SP have proven benefits, it is often challenging for patients to attain lifestyle changes needed for SP, especially with increasing PA levels[9]. For example, owing to the poor accessibility of cardiac rehabilitation programs (CRP), > 80% of patients did not participate in the CRP recommended by the guidelines[10]. Moreover, patients with CHD typically fail to attain their daily PA goals[11].

mHealth, defined by AHA's scientific statement, "is the use of mobile computing and communication technologies (e.g. mobile phones, wearable devices) for health services and information"[12], has become an essential medium to deliver behavioral change interventions and demonstrated promising ability to improve PA levels[12-14]. In China, WeChat is a top-rated multipurpose social media app, with >1.151 billion active users[15]. WeChat applets are lightweight apps that form part of the WeChat ecosystem, which could be used independently and do not need installation. Compared with mobile apps, WeChat applets are easier to be accepted and applied by people in China. The third quarter of 2019 recorded >300 million active WeChat applet users every day, thereby making it well suited to disseminate mHealth interventions in China[16].

Gamification is the use of game design elements (such as points, leaderboards, progress bars, and badges) in non-game contexts (such as management, education, marketing, and healthcare) to increase motivation and engagement[17]. There is growing interest in the application of gamification in mHealth with the view of promoting healthy behavioral changes[18-21], especially in promoting PA levels[22]. Previous studies indicated that gamification was used in 64% of the top 50 most popular smartphone apps[23]. However, several systematic reviews reported that most gamification intervention designs did not appropriately leverage theories from health behavior models[18,24,25]. Moreover, as the concept of gamification is relatively new[17], empirical evidence on the efficacy of gamification PA behavioral change interventions among patients with CHD is still emerging.

Gamification interventions are rarely based on a sound theoretical framework[19,21]. Behavioral economics (BE) principles combine conventional economic principles with psychology to elucidate how individuals behave

and make decisions[26]. BE principles can be embedded with a gamification intervention via mobile devices to aid people to attain their PA goals. For example, based on the loss aversion, which implies that the loss framework is more effective in stimulating behavioral change than the gain framework, Patel et al. designed an intervention wherein participants lost points if they did not accomplish their step goals[27]. Several previous studies have used BE principles to help patients lose weight, quit smoking, and adhere to medications[28-30]. However, limited data are available on applying these concepts to improve PA participation in patients with CHD.

In this study, we have used BE principles to develop a gamification WeChat applet named "Tahnee Weh" to resolve this research gap. This study aims to investigate the effects of the mHealth-based gamification intervention on participation in PA and evaluate the effects on exercise capacity, biomedical and lifestyle-related risk factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support and mental health. In addition, a semi-structured interview will be conducted after the intervention to comprehend patients' perceptions and their experience on the intervention.

2. Methods

2.1 Study design

This is a double-blind, three-arm randomized controlled trial to evaluate the effects of gamified joint financial incentive behavior intervention on participation in PA, exercise capacity, biomedical and lifestyle-related risk factors, intrinsic motivation, perceived enjoyment, perceived competence, autonomy, and relatedness, social support, and mental health. Patients with CHD will be recruited in a CR center of a tertiary-grade A class hospital in Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants 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). Patients in the control group will only receive daily step goal setting. The Individual and Team

groups will receive gamified behavior intervention based on BE principles. The Team group will also receive social incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12 weeks. All patients will just receive WeChat applet-based step goal setting in the follow-up period. Figure 1 shows a flowchart of the study design. The protocol conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines, and the intervention is described per the CONSORT-EHEALTH checklist[31-33]. The study is registered at Clinical Trials.gov: ChiCTR2100044879.

2.2 Eligibility and Recruitment

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

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

Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting participants. Researchers will inform the patients about the details of the study. If they agree to participate in the study, they will have to sign the written consent form. After that, we will teach patients to register and log in to our WeChat applet “Tahnee Weh”; this is required to get their step data for the past 2 weeks, which will be recorded by smartphone accelerometers (as done in many prior studies[34–37]) and has been proven accurate for

tracking step counts[38]. Furthermore, a baseline step count will be estimated using the mean step count of the previous 2 weeks.

2.3 Sample size calculation

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

2.4 Randomization, blinding, and concealed allocation

Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step count (<5000, 5001–7500, or >7500 steps/day). Participants and 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 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 remained fixed during the last 6 weeks, as described elsewhere[40]. 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 the patient has not logged in to the WeChat applet for more than a week, a text message reminder will be sent to the patient.

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[41,42]. Second, every Monday, patients will receive 140 points (20 for each day), which leverage the fresh start effect[43]. 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[44,45]. 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 ≥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
Points	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
Points	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
Collaboration	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
Levels	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.	
Rewards	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
Feedback	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[38].

The secondary outcomes include self-reported PA level using the International Physical Activity Questionnaire (IPAQ)[46], 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
Primary outcomes				
Physical activity	Change in daily steps	√	√	√
	The propotion of patient-days that step goals were achieved		√	√
	International Physical Activity Questionnaire (IPAQ)[46]	√	√	√
Secondary outcomes				
Exercise capacity	Change in $VO_{2\ peak}$	√	√	√
Biomedical risk factors	Body weight, waist circumference, BMI, SBP, DBP, RHR, TC, FPG	√	√	√
Lifstyle-related risk factors	Self-reported smoking	√	√	√
Perceived competence, autonomy, and relatedness	Psychological Needs Satisfaction in Exercise Scale(PNSE)[47]	√	√	√
Intrinsic motivation	Behavioral Regulation in Exercise Questionnaire(BREQ-2)[48]	√	√	√
Perceived enjoyment	Physical Activity Enjoyment Scale (PACES)[49]	√	√	√
Social support	Social Support Rating Scale (SSRS)[50]	√	√	√
Anxiety symptoms	Generalised Anxiety Disorder 7-item Scale (GAD-7) [51]	√	√	√
Depressive symptoms	Patient Health Questionnaire (PHQ-9)[52]	√	√	√
Usability	System Usability Scale(SUS)[53]		√	
Satisfaction			√	
Patients' experience	Semi-structured interview		√	

Adverse event reporting	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 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[36,54]. 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.

2.10Validity 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 ClinicalTrails.gov (ChiCTR2100044879).

4. Discussion

The authors aim to develop a WeChat applet in this study. Based on the WeChat applet and under the guidance of BE 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 PA participation and the effects on exercise capacity, biomedical and lifestyle-related risk factors, intrinsic motivation, perceived enjoyment, perceived 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 PA goals on their own [11]. Behavioral interventions are needed to help them increase PA participation. With the technological advancement, numerous smartphone apps have appeared, and gamification was used in most of these apps, which had the potential to increase PA 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 BE principles could be embedded with a gamification intervention to significantly increase PA among overweight and obese adults[27]. However, thus far, there is limited evidence of interventions that use these methods to effectively improve PA participation among high-risk patients, such as patients with CHD[55]. Thus, this study will develop a gamification intervention based on a WeChat applet that has been specifically developed for this study. Personalized goal setting and progress tracking on WeChat applet allowed patients to exercise at home. The gamification intervention motivated patients to walk more; this could become a new way to promote the implementation of home and exercise-based CR.

The key of gamification interventions is to organically combine game elements to form a resultant force to improve PA, and the key of the resultant force is to comprehend the driving force or motivation behind the incentive mechanism. Research indicates links between self-determination theory (SDT) and gamification

concepts. SDT suggests that satisfying three innate psychological needs of competence, autonomy, and relatedness could promote autonomous motivation and well-being. Studies reported that individuals with autonomous motivation had higher PA participation and better PA adherence than those primarily driven by external factors[56]. Furthermore, the fact that gamification could make interventions more enjoyable aligns with SDT, which assumes that a key aspect of intrinsic motivation is enjoyment[17]. We planned to investigate the internal psychological mechanism of gamification to promote PA; thus, we evaluated perceived competence, autonomy, relatedness, enjoyment, and intrinsic motivation. We assumed that gamification intervention promoted the transformation of controlled motivation into autonomous motivation by satisfying perceived competence, autonomy, relatedness, enjoyment, and ultimately promote PA participation. Figure 4 shows the hypothesized model of PA behavior regulation. Moreover, because our intervention platform provides information support for patients, we also evaluated the variable social support. Furthermore, we conducted a semi-structured interview after the intervention to comprehend patients' experience and capture information on communications among patients in the collaboration group, which could explore the internal psychological mechanism of gamification to promote exercise motivation.

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

Limitations

This study has several limitations. First, we will not measure the intensity of PA via the smartphone accelerometer. In future, we plan to use wearable devices to evaluate the intensity of PA. Second, the study period is 24 weeks; thus, we will not be able to evaluate and maintain the intervention in 12 months. Third, the study is limited to patients with smartphones and a WeChat account, which could lead to a selective bias. Fourth, the gamification interventions are comprehensive and it would be difficult to analyze the component that worked.

Fifth, the reward of this study is money, and points can be directly exchanged for cash. Hence, we will not be able to analyze the impact of gamification or the impact of financial incentives.

5. Conclusions

This study will test the usage of a smartphone and WeChat applet-based gamification intervention to increase PA at home. If the intervention increases patients' PA, this is likely to translate into improved patient outcomes and reduce the financial burden of CVD on health systems. Overall, the model of the gamification intervention via smartphone could also be used for other chronic diseases.

Acknowledgements The authors would like to thank the valuable contribution made by the patients and public representatives during the study design and intervention development.

Contributors LX, QT and FL conceived the original concept of the study and wrote the first draft of the protocol manuscript. LX, JL, XZ, YP, TY, XL, TY and LZ contributed to the design of the study. All authors read and approved the final manuscript.

Funding This work is financially supported by a Construction Program of Independent Innovation Ability of Community Health Nursing Engineering Laboratory in Jilin Province (Study code: 2020C038-8) awarded to Dr. Feng Li.

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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Figure legends

Figure 1: Study flowchart.

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.

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

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

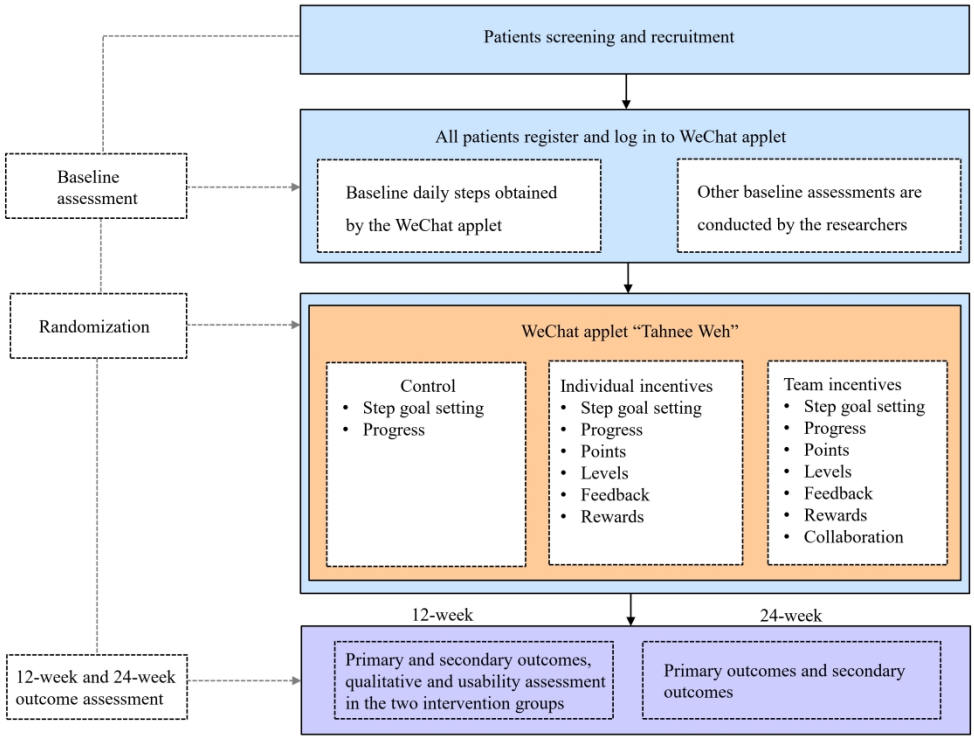

Figure 1: Study flowchart.

971x735mm (144 x 144 DPI)

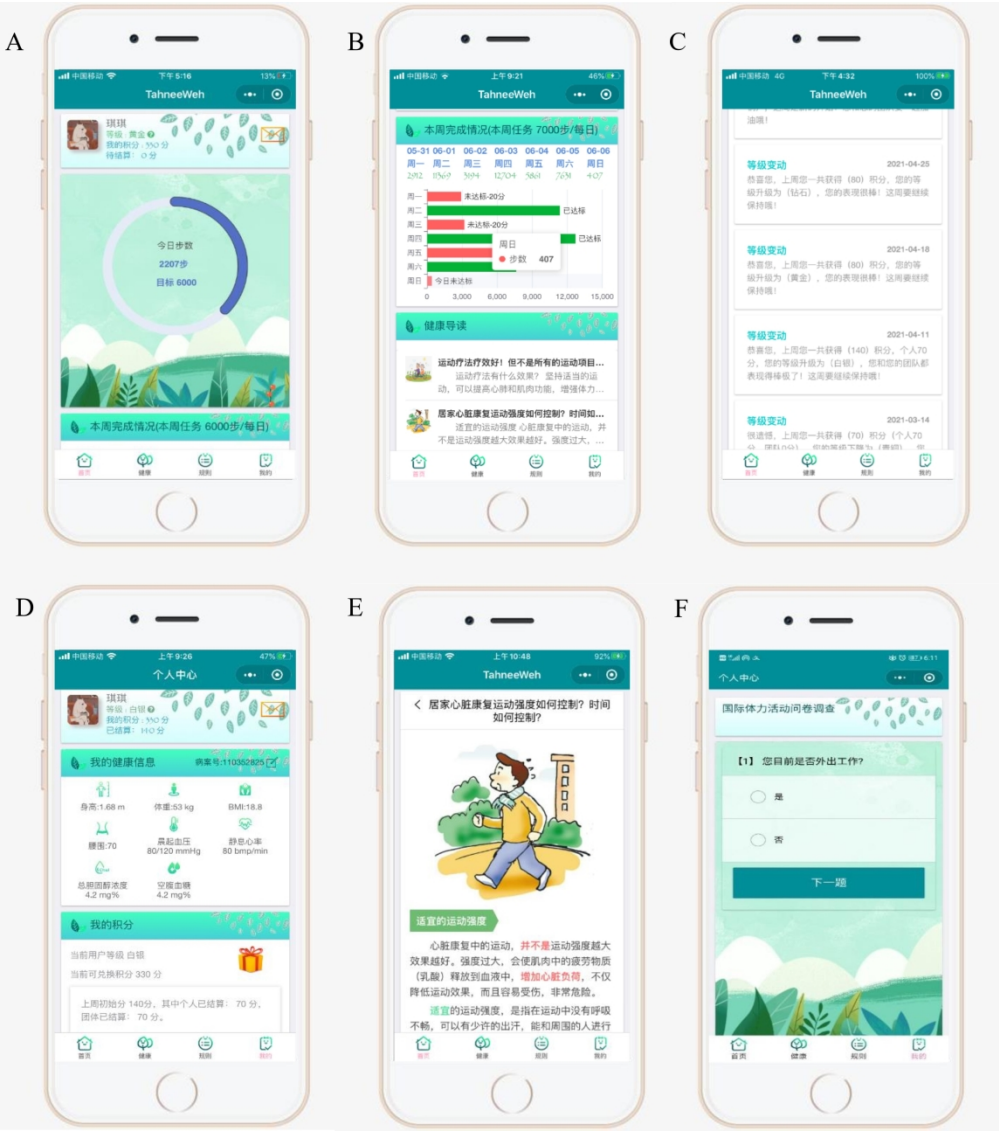

Figure 2: WeChat applet "Tahnee Weh" interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F) International Physical Activity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

674x761mm (144 x 144 DPI)

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

338x146mm (144 x 144 DPI)

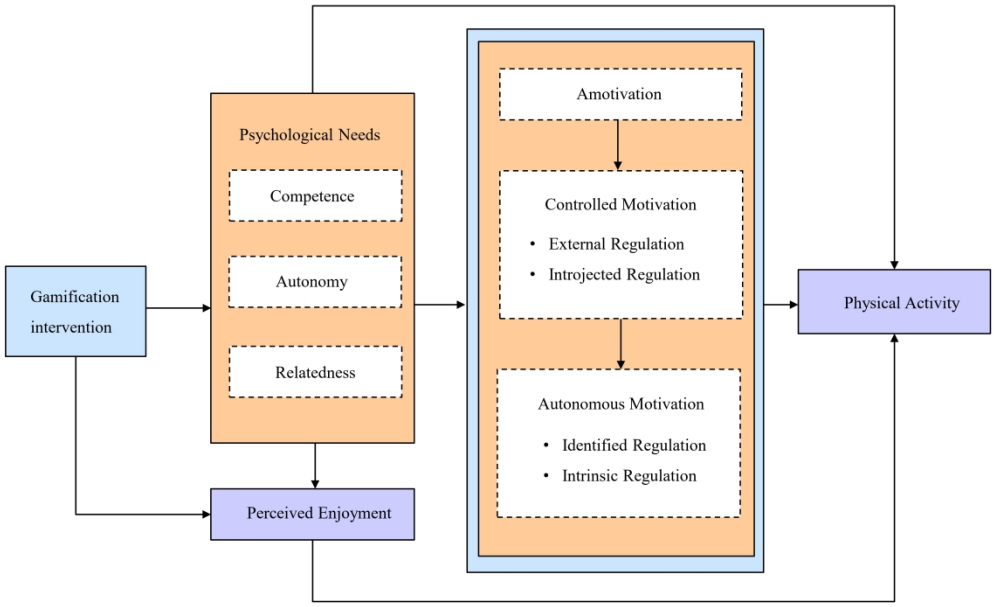

Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

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.

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

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P6
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	P6
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	P16
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	P16
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	P16
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	P16
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	P12

		and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
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			
Study setting	#9	Description of study settings (eg, community clinic,	P5

		academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P7-9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a, intervention did not involve harms or others
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8-9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time	P10-11

		point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P7-8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	P8

		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P8-
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a, not blind to researchers
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate	Table 2

		measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P10-11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P12
Statistics: analysis population and	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised	P12

missing data		analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P12
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a, not apply DMC in this trail
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P10
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			

Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P6-7
Consent or assent: ancillary studies	#26b	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	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	P16
Data access	#29	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

Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a, not needed in this study
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	P16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a, not needed in this study

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:	*BMJ Open*
Manuscript ID	bmjopen-2021-054623.R1
Article Type:	Protocol
Date Submitted by the Author:	23-Nov-2021
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
Primary Subject Heading:	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

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

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Word count: 3798

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.

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 [1,2]. Exercise-based cardiac rehabilitation and secondary prevention (CR/SP) plays a crucial role in preventing the recurrence of CHD[3] 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[4–7]. The relevant guidelines recommend that patients with CHD should perform at least 500-MET-min/week physical activity every week[8]. Although CR/SP have proven benefits, it is often challenging for patients to attain lifestyle changes needed for SP, especially with increasing physical activity

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

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

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

emerging.

Gamification interventions are rarely based on a sound theoretical framework[20,22]. Behavioral economics principles combine conventional economic principles with psychology to elucidate how individuals behave and make decisions[27]. Behavioral economics principles can be embedded with a gamification intervention via mobile devices to aid people to attain their physical activity goals. For example, based on the loss aversion, which implies that the loss framework is more effective in stimulating behavioral change than the gain framework, Patel et al. designed an intervention wherein participants lost points if they did not accomplish their step goals[28]. Several previous studies have used behavioral economics principles to help patients lose weight, quit smoking, and adhere to medications[29–31]. However, limited data are available on applying these concepts to improve physical activity participation in patients with CHD.

This study will use behavioral economics principles to develop a gamification WeChat applet named "TahneeWeh" to resolve the research gap mentioned above. This study aims to investigate the effects of the mHealth-based gamification intervention on participation in physical activity and evaluate the effects on biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health. In addition, a semi-structured interview will be conducted after the intervention to comprehend patients' perceptions and their experience on the intervention.

2. Methods

2.1 Study design

This is a single-blind, three-arm randomized controlled trial to evaluate the effects of the mHealth-based gamification intervention on participation in physical activity, biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health. Patients with CHD will be recruited in a cardiac rehabilitation center of a tertiary-grade A class hospital in

Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants 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). Patients in the control group will only receive daily step goal setting. The Individual and Team groups will receive gamified behavior intervention based on behavioral economics principles. The Team group will also receive social incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12 weeks. All patients will just receive WeChat applet-based step goal setting in the follow-up period. The study duration will be between July 1, 2021 and November 30, 2022. Figure 1 shows a flowchart of the study design. The protocol conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines, and the intervention is described per the CONSORT-EHEALTH checklist[32–34]. The study is registered at Clinical Trials.gov: ChiCTR2100044879.

2.2 Eligibility and Recruitment

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

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

Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting participants. Researchers will inform the patients about the details of the study. If they agree to participate in the study, they will have to sign the written consent form. After that, we will teach patients to register and log in to our WeChat applet "TahneeWeh"; this is required to get their step data for the past 2 weeks, which will be recorded by smartphone accelerometers (as done in many prior studies[35–38]) and has been proven accurate for tracking step counts[39]. Furthermore, a baseline step count will be estimated using the mean step count of the previous 2 weeks.

2.3 Sample size calculation

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

2.4 Randomization, blinding, and concealed allocation

Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step 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 remained fixed during the last 6 weeks, as described elsewhere[41].

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 of 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 to the patient.

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.

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[42,43]. Second, every Monday, patients will receive 140 points (20 for each day), which leverage the fresh start effect[44]. 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[45,46]. 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 ≥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
Points	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
Points	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
Collaboration	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.	
Levels	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
Rewards	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
Feedback	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[39]. Self-reported physical activity level will be measured by the International Physical Activity Questionnaire (IPAQ)[47].

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)[48]. 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
Primary outcomes				
Physical activity	Change in daily steps	√	√	√
	The proportion of patient-days that step goals were achieved		√	√
	International Physical Activity Questionnaire (IPAQ)[47]	√	√	√
Secondary outcomes				
Biomedical risk factors	Body weight, waist circumference, BMI, SBP, DBP, RHR, TC, FPG	√	√	√
Lifestyle-related risk factors	Self-reported smoking	√	√	√
Competence, autonomy, and relatedness	Psychological Needs Satisfaction in Exercise Scale(PNSE)[49]	√	√	√
Intrinsic motivation	Behavioral Regulation in Exercise Questionnaire(BREQ-2)[50]	√	√	√
Enjoyment	Physical Activity Enjoyment Scale (PACES)[51]	√	√	√

Social support	Social Support Rating Scale (SSRS)[52]	√	√	√
Anxiety symptoms	Generalised Anxiety Disorder 7-item Scale (GAD-7) [53]	√	√	√
Depressive symptoms	Patient Health Questionnaire (PHQ-9)[54]	√	√	√
Usability	System Usability Scale (SUS)[48]		√	
Satisfaction			√	
Patients' experience	Semi-structured interview		√	
Adverse event reporting	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[37,55]. 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 will be 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 will be 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 patients with CHD and found that patients lacked physical activity and were willing to be supervised and motivated via their smartphones to promote participation in physical activity. During the development of WeChat applet, patients with CHD will be invited to participate in our discussion, allowing the authors to consider the thoughts and needs of patients in developing the WeChat applet. In the pilot study, patients will be 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 will use a rigorous research design (randomized controlled design) and a block random method to assign groups. The grouping results will be numbered and placed in a sealed envelope. Participants and data collector will be blinded to the assignments. All questionnaires will be completed by the researcher's guidance or ghostwriting. The questionnaires will be distributed and collected on the spot to avoid data bias caused by different researchers. Two researchers will enter all the data to avoid objective typing errors.

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 [11]. 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[28]. However, thus far, there is limited evidence of interventions that use these

methods to effectively improve physical activity participation among high-risk patients, such as patients with CHD[56]. Thus, this study will develop a gamification intervention based on a WeChat applet that has been specifically developed for this study. Personalized goal setting and progress tracking on the WeChat applet will allow patients to exercise under supervision. The gamification intervention motivated patients to walk more; this could become a new way to promote the implementation of home and exercise-based cardiac rehabilitation.

The key of gamification interventions is to organically combine game elements to form a resultant force to improve physical activity, and the key of the resultant force is to comprehend the driving force or motivation behind the incentive mechanism. Research indicates links between self-determination theory and gamification concepts. Self-determination theory suggests that satisfying three innate psychological needs of competence, autonomy, and relatedness could promote autonomous motivation and well-being. Reportedly, individuals with autonomous motivation had higher physical activity participation and better physical activity adherence than those primarily driven by external factors[57]. Furthermore, the fact that gamification could make interventions more enjoyable aligns with self-determination theory, which assumes that a key aspect of intrinsic motivation is enjoyment[18]. We plan to investigate the internal psychological mechanism of gamification to promote physical activity; thus, we will evaluate the competence, autonomy, relatedness, enjoyment, and intrinsic motivation. We assume that gamification intervention promotes the transformation of controlled motivation into autonomous motivation by satisfying competence, autonomy, relatedness, enjoyment, and ultimately promote physical activity participation. Figure 4 shows the hypothesized model of physical activity behavior regulation. Moreover, because our intervention platform will provide information support for patients, we will also evaluate the variable social support. Furthermore, we will conduct a semi-structured interview after the intervention to comprehend patients' experiences and capture information on communications among patients in the collaboration group, which could explore the internal psychological mechanism of gamification to promote exercise motivation.

In China, access to cardiac rehabilitation is often limited. Patients with CHD often lack physical activity. Our intervention could help increase physical activity participation and bring more health benefits.

Limitations

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

Acknowledgements: The authors would like to thank the valuable contribution made by the patients and public representatives during the study design and intervention development.

Contributors: LX, QT and FL conceived the original concept of the study and wrote the first draft of the protocol manuscript. LX, JL, XZ, YP, TY, XL, TY and LZ contributed to the design of the study. All authors read and approved the final manuscript.

Funding: This work is financially supported by a Construction Program of Independent Innovation Ability of Community Health Nursing Engineering Laboratory in Jilin Province (Study code: 2020C038-8) awarded to Dr. Feng Li.

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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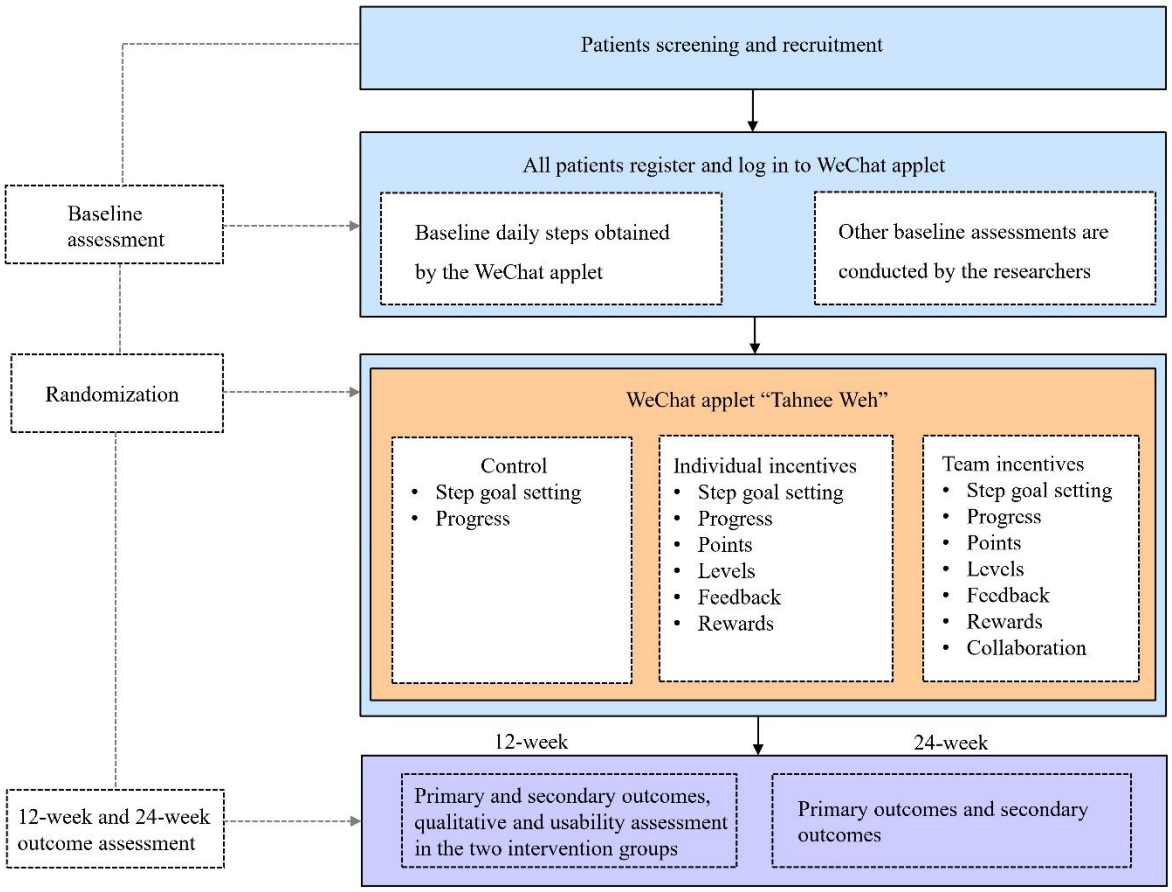
Figure legends

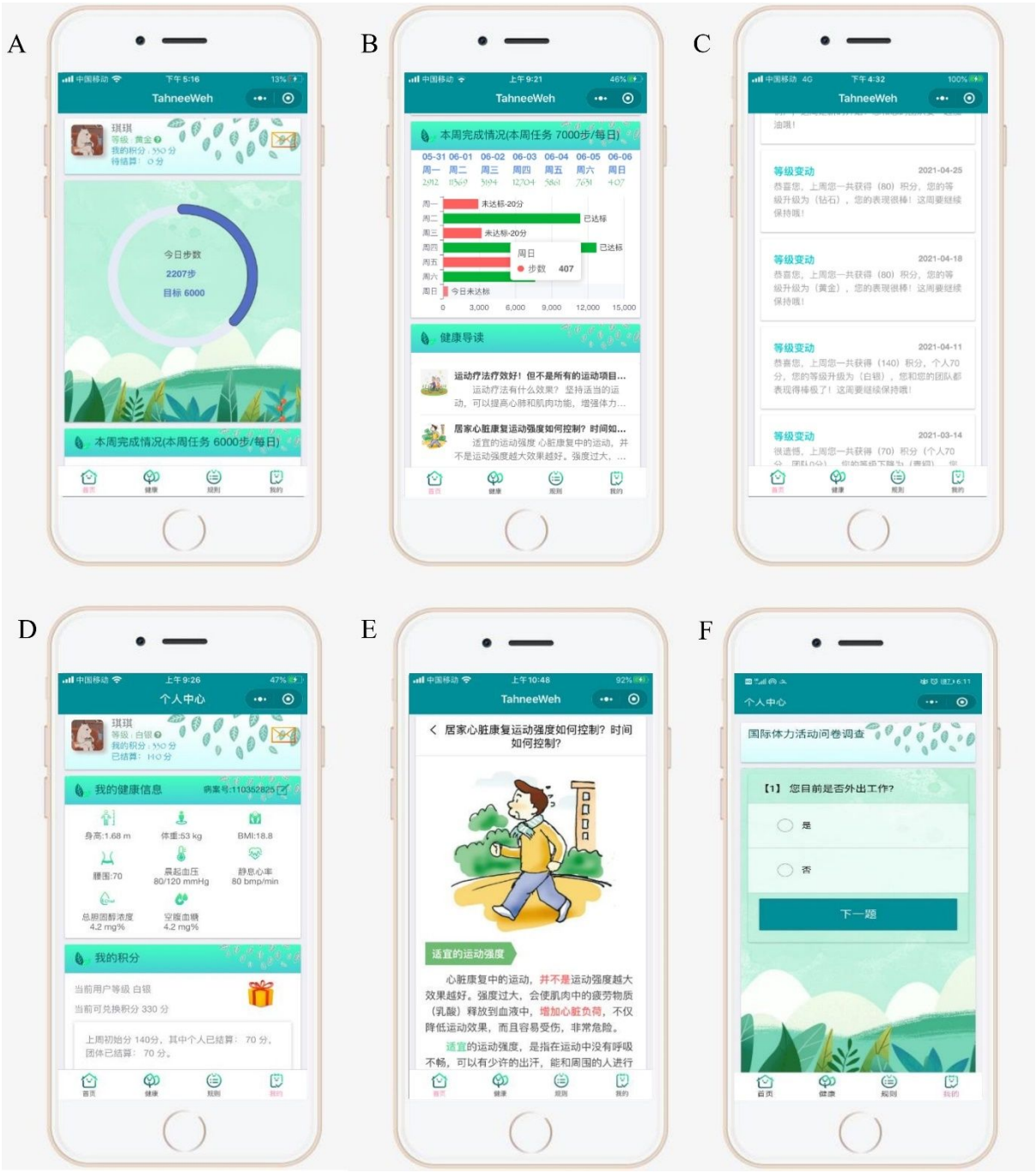
Figure 1: Study flowchart.

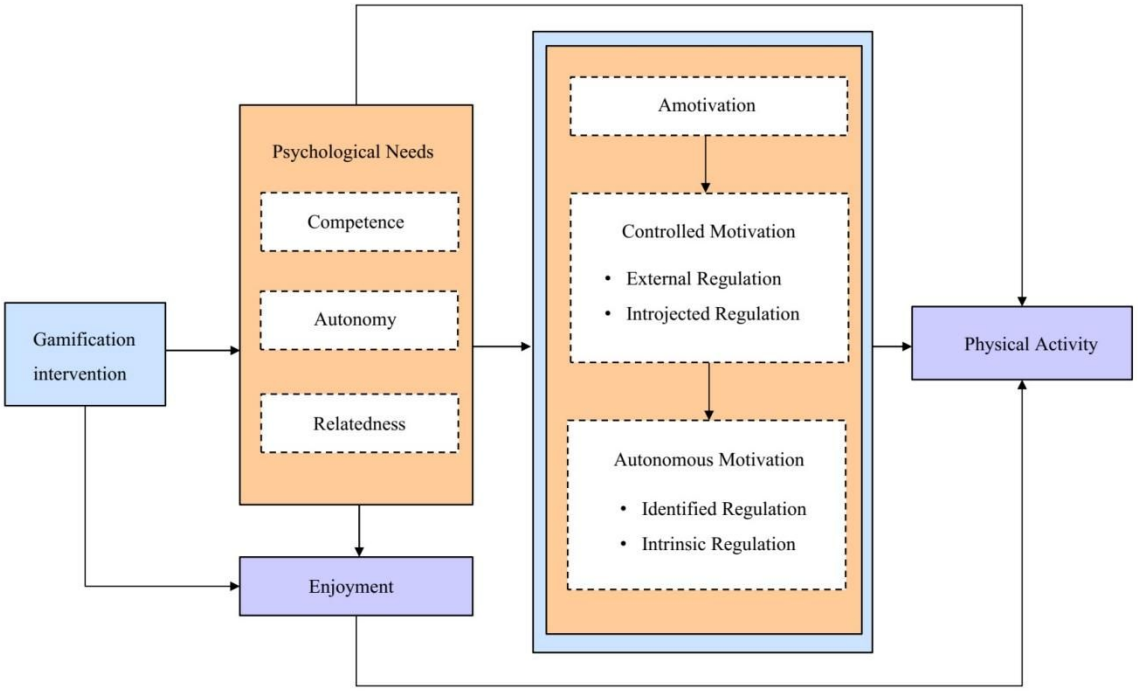
Figure 2: WeChat applet “TahneeWeh” interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F)International Physical Activity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

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

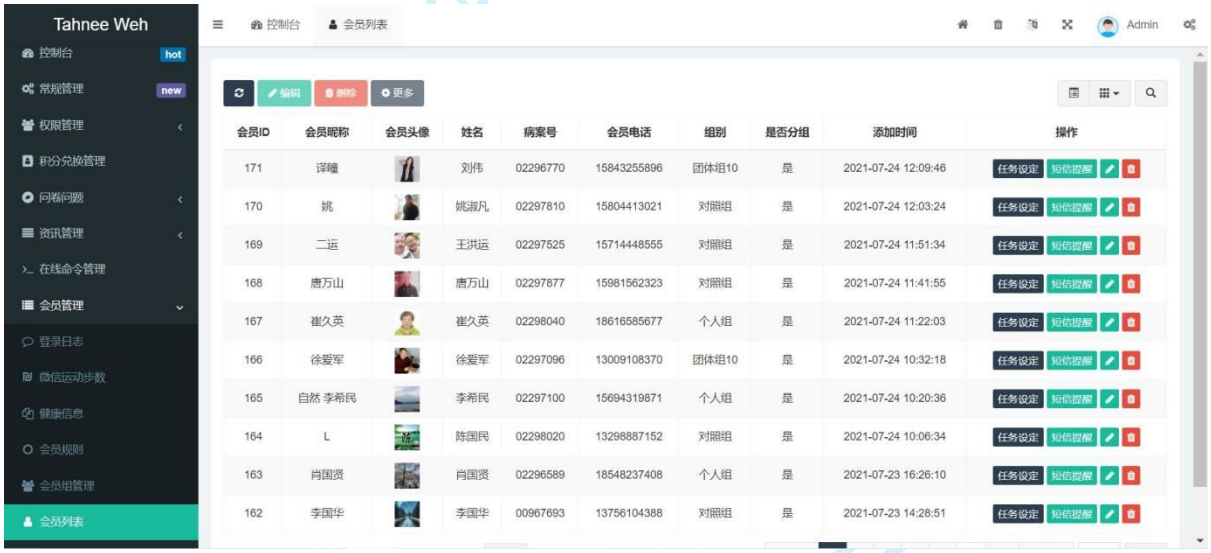
Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

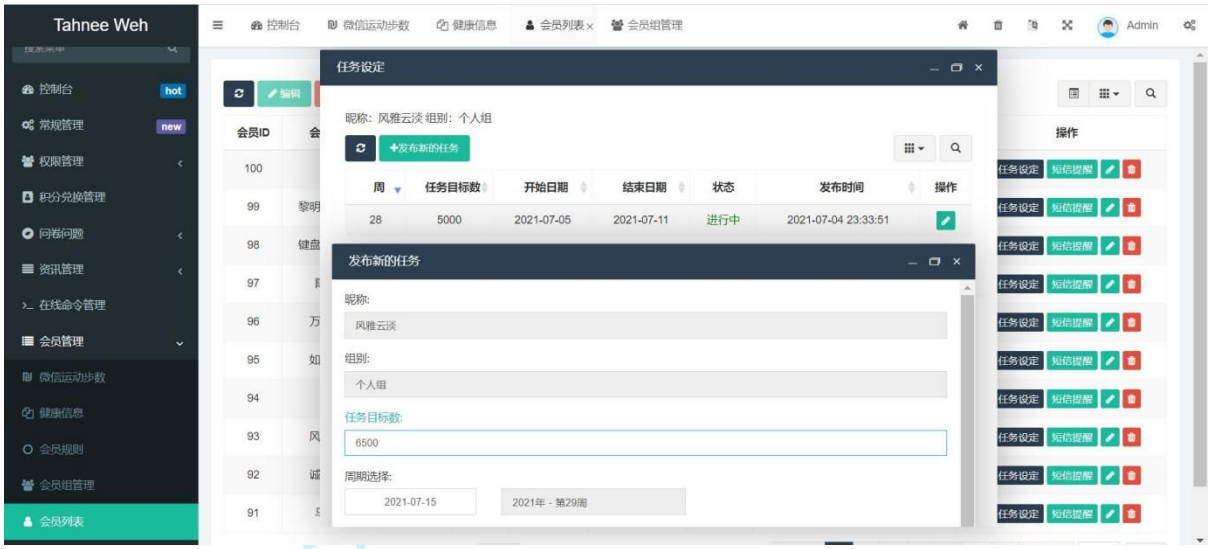






Some other backstage interface of the WeChat applet “TahneeWeh”





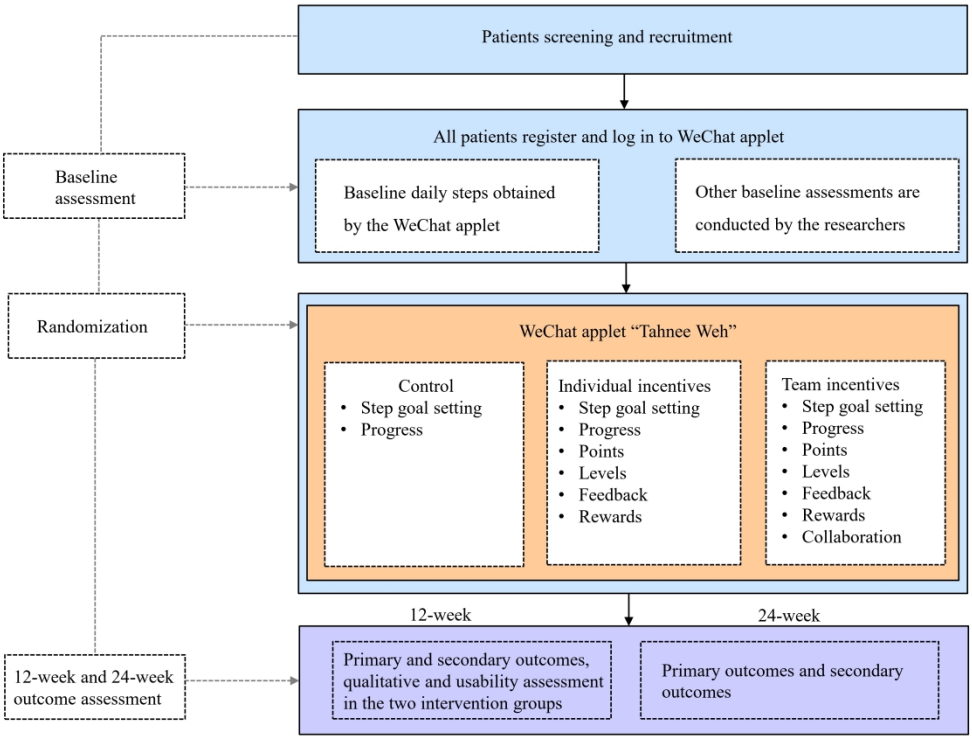


Figure 1: Study flowchart.

971x735mm (144 x 144 DPI)

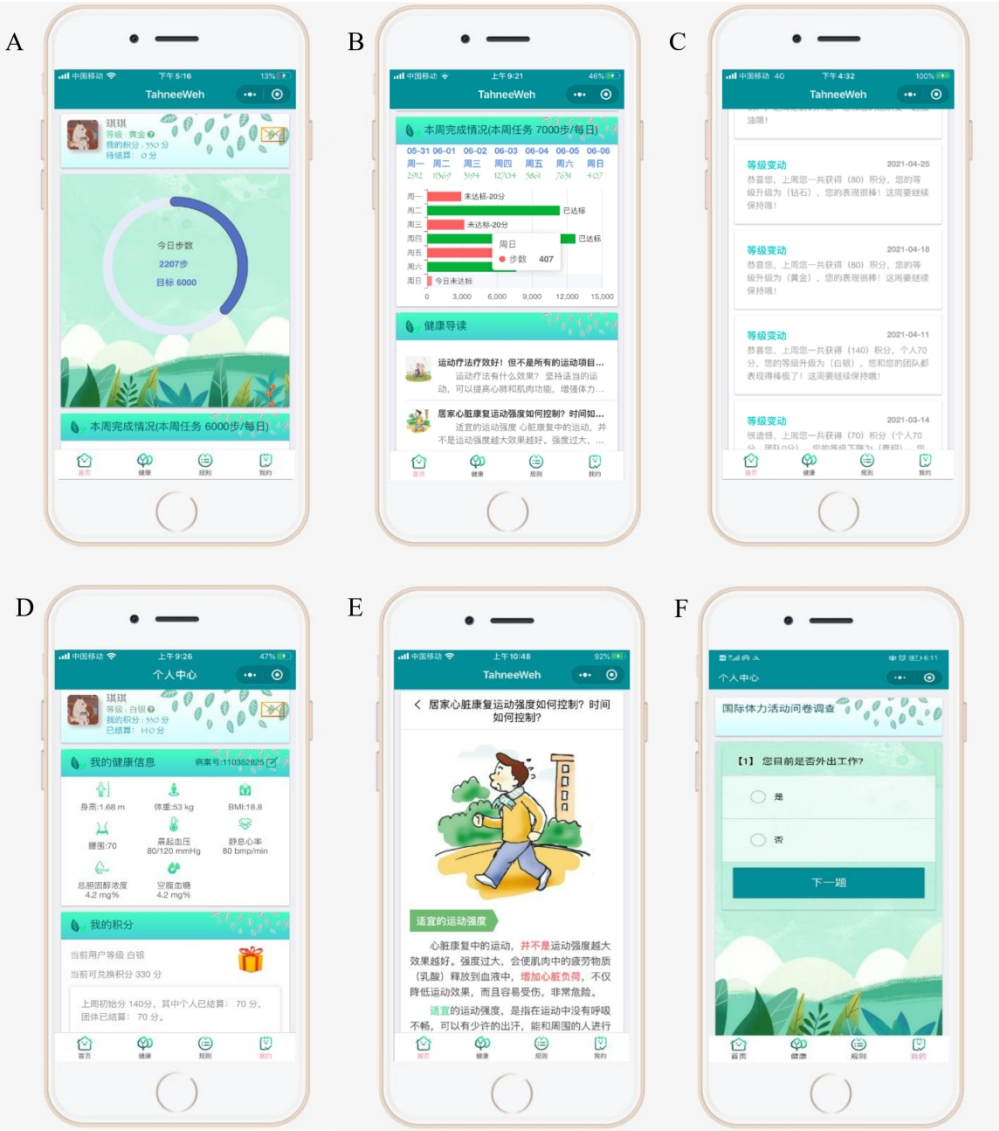


Figure 2: WeChat applet "Tahnee Weh" interface. (A) Daily step progress using a circular dial; (B) weekly step progress; (C) feedback on weekly level changes; (D) points and level in this week; (E) health education on cardiac rehabilitation and secondary prevention; (F) International Physical Activity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

674x761mm (144 x 144 DPI)

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

338x146mm (144 x 144 DPI)

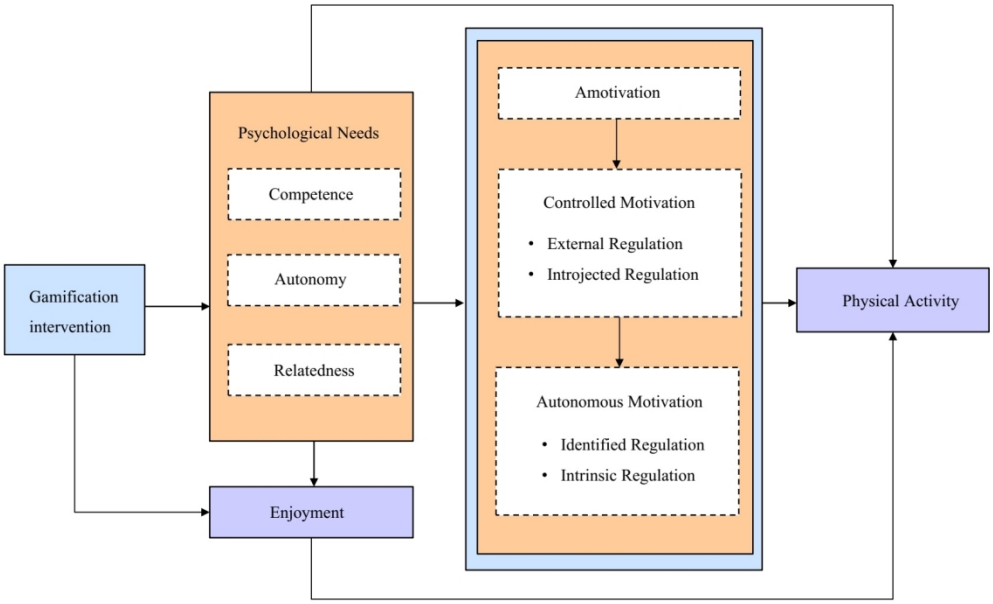


Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

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 SPIRITreporting 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	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P6
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	P6
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	P16
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	P16
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	P16
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	P16
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team,	P12

		and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
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			
Study setting	#9	Description of study settings (eg, community clinic,	P5

		academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P7-9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a, intervention did not involve harms or others
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8-9
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time	P10-11

		point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P7-8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	P8

		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P8-
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a, not blind to researchers
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate	Table 2

		measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P10-11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P12
Statistics: analysis population and	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised	P12

missing data		analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P12
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a, not apply DMC in this trail
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P10
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			

Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P6-7
Consent or assent: ancillary studies	#26b	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	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P13
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	P16
Data access	#29	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

Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a, not needed in this study
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P16
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	P16
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P16
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a, not needed in this study

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:	*BMJ Open*
Manuscript ID	bmjopen-2021-054623.R2
Article Type:	Protocol
Date Submitted by the Author:	29-Dec-2021
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
Primary Subject Heading:	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

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

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Word count: 3846

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 [1,2]. Exercise-based cardiac rehabilitation and secondary prevention (CR/SP) plays a crucial role in preventing the recurrence of CHD[3] 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[4–7]. The relevant guidelines recommend that patients with CHD should perform at least 500-MET-min/week physical activity every week[8]. Although CR/SP have proven benefits, it is

often challenging for patients to attain lifestyle changes needed for SP, especially with increasing physical activity levels[9]. For example, owing to the poor accessibility of cardiac rehabilitation programs, > 80% of patients did not participate in the cardiac rehabilitation programs recommended by the guidelines[10]. Moreover, patients with CHD typically fail to attain their daily physical activity goals[11].

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

Gamification is the use of game design elements (such as points, leaderboards, progress bars, and badges) in non-game contexts (such as management, education, marketing, and healthcare) to increase motivation and engagement[18]. There is growing interest in the application of gamification in mHealth with the view of promoting healthy behavioral changes[19–22], especially in promoting physical activity levels[23]. Previous studies indicated that gamification was used in 64% of the top 50 most popular smartphone apps[24]. However, several systematic reviews reported that most gamification intervention designs did not appropriately leverage theories from health behavior models[19,25,26]. Moreover, as the concept of gamification is relatively new[18], empirical evidence on the

efficacy of gamification physical activity behavioral change interventions among patients with CHD is still emerging.

Gamification interventions are rarely based on a sound theoretical framework[20,22]. Behavioral economics principles combine conventional economic principles with psychology to elucidate how individuals behave and make decisions[27]. Behavioral economics principles can be embedded with a gamification intervention via mobile devices to aid people to attain their physical activity goals. For example, based on the loss aversion, which implies that the loss framework is more effective in stimulating behavioral change than the gain framework, Patel et al. designed an intervention wherein participants lost points if they did not accomplish their step goals[28]. Several previous studies have used behavioral economics principles to help patients lose weight, quit smoking, and adhere to medications[29–31]. However, limited data are available on applying these concepts to improve physical activity participation in patients with CHD.

This study will use behavioral economics principles to develop a gamification WeChat applet named "TahneeWeh" to resolve the research gap mentioned above. This study aims to investigate the effects of the mHealth-based gamification intervention on participation in physical activity and evaluate the effects on biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health. In addition, a semi-structured interview will be conducted after the intervention to comprehend patients' satisfaction, perceptions and their experience on the intervention.

2. Methods

2.1 Study design

This is a single-blind, three-arm randomized controlled trial to evaluate the effects of the mHealth-based gamification intervention on participation in physical activity, biomedical and lifestyle-related risk factors, intrinsic motivation, enjoyment, competence, autonomy, and relatedness, social support, and mental health.

Patients with CHD will be recruited in a cardiac rehabilitation center of a tertiary-grade A class hospital in Changchun (China) through posters and e-mail of discharged patients. A total of 108 participants 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). Patients in the control group will only receive daily step goal setting. The Individual and Team groups will receive gamified behavior intervention based on behavioral economics principles. The Team group will also receive social incentives based on the Individual group. The intervention will last for 12 weeks and follow-up for 12 weeks. All patients will just receive WeChat applet-based step goal setting in the follow-up period. The study duration will be between July 1, 2021 and November 30, 2022. Figure 1 shows a flowchart of the study design. The protocol conforms to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines, and the intervention is described per the CONSORT-EHEALTH checklist[32–34]. The study is registered at Clinical Trials.gov: ChiCTR2100044879.

2.2 Eligibility and Recruitment

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

The exclusion criteria include the following: (i) contraindications for exercise rehabilitation (e.g., untreated ventricular tachycardia, severe heart failure, uncontrollable hypertension or hypotension, notable exercise restriction); (ii) patients unable to use WeChat applet after instruction; (iii) no Internet access in the place of

residence; (iv) patients requiring a walking aid to move; and (v) patients participating in other clinical trials.

Experienced clinical nurses, rehabilitation therapists, and researchers will be responsible for recruiting participants. Patients undergoing PCI will be referred to the cardiac rehabilitation center, which is adjacent to the wards to receive physical activity counseling and obtain the follow-up booklet before discharge. The follow-up booklet will remind patients to return for review in 4 weeks, 12 weeks, 24 weeks, and 12 months after discharge, which is very helpful to avoid patients' loss to follow-up. In the rehabilitation center, researchers will screen the eligible patients and then inform the patients about the details of the study. If they agree to participate in the study, they will have to sign the written consent form and complete the questionnaires using a traditional pen and paper method. We will mark the specific date of 12 and 24 weeks of his returning to complete the outcome measurement on his follow-up booklet and tell him if he is not available on that day; he could contact us to change the date accordingly. After that, we will teach patients to register and log in to our WeChat applet "TahneeWeh"; this is required to get their step data for the past 2 weeks, which will be recorded by smartphone accelerometers (as done in many prior studies[35–38]) and has been proven accurate for tracking step counts[39]. Furthermore, a baseline step count will be estimated using the mean step count of the previous 2 weeks.

2.3 Sample size calculation

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

2.4 Randomization, blinding, and concealed allocation

Patients will be randomized to a study arm using block sizes of 6, stratified by the participant baseline step

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[41]. 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.

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[42,43]. Second, every Monday, patients will receive 140 points (20 for each day), which leverage the fresh start effect[44]. 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[45,46]. 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 ≥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
Points	Every Monday the patients will receive 140 points (20 for each day).	the Fresh Start Effect
Points	If the patients reach the target step count, no points will be deducted; if not, 20 points will be deducted.	Loss aversion; Anticipated Regret
Collaboration	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
Levels	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
Rewards	At the end of the intervention, if the patients' level is diamond, they will be rewarded with a small prize.	
Feedback	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[39]. Self-reported physical activity level will be measured by the International Physical Activity Questionnaire (IPAQ)[47].

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)[48]. 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
Primary outcomes				
Physical activity	Change in daily steps	√	√	√

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

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[37,55]. 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. Moreover, we will compare the baseline differences between patients lost to follow up and patients who adhere to follow-up. 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 will be 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 will be 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 patients with CHD and found that patients lacked physical activity and

were willing to be supervised and motivated via their smartphones to promote participation in physical activity. During the development of WeChat applet, patients with CHD will be invited to participate in our discussion, allowing the authors to consider the thoughts and needs of patients in developing the WeChat applet. In the pilot study, patients will be 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 will use a rigorous research design (randomized controlled design) and a block random method to assign groups. The grouping results will be numbered and placed in a sealed envelope. Participants and data collectors will be blinded to the assignments. All questionnaires will be completed by the researcher's guidance or ghostwriting. The questionnaires will be distributed and collected on the spot to avoid data bias caused by different researchers. Two researchers will enter all the data to avoid objective typing errors.

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' satisfaction, perceptions and experience of the intervention.

Despite proven benefits, patients with CHD do not often attain their physical activity goals on their own [11]. 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 could 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[28]. However, thus far, there is limited evidence of interventions that use these methods to effectively improve physical activity participation among high-risk patients, such as patients with CHD[56]. Thus, this study will develop a gamification intervention based on a WeChat applet that has been specifically developed for this study. Personalized goal setting and progress tracking on the WeChat applet will allow patients to exercise under supervision. The gamification intervention motivated patients to walk more; this could become a new way to promote the implementation of home and exercise-based cardiac rehabilitation.

The key of gamification interventions is to organically combine game elements to form a resultant force to improve physical activity, and the key of the resultant force is to comprehend the driving force or motivation behind the incentive mechanism. Research indicates links between self-determination theory and gamification concepts. Self-determination theory suggests that satisfying three innate psychological needs of competence, autonomy, and relatedness could promote autonomous motivation and well-being. Reportedly, individuals with

autonomous motivation had higher physical activity participation and better physical activity adherence than those primarily driven by external factors[57]. Furthermore, the fact that gamification could make interventions more enjoyable aligns with self-determination theory, which assumes that a key aspect of intrinsic motivation is enjoyment[18]. We plan to investigate the internal psychological mechanism of gamification to promote physical activity; thus, we will evaluate competence, autonomy, relatedness, enjoyment, and intrinsic motivation. We assume that gamification intervention promotes the transformation of controlled motivation into autonomous motivation by satisfying competence, autonomy, relatedness, enjoyment, and ultimately promote physical activity participation. Figure 4 shows the hypothesized model of physical activity behavior regulation. Moreover, because our intervention platform will provide information support for patients, we will also evaluate the variable social support. Furthermore, we will conduct a semi-structured interview after the intervention to comprehend patients' experiences and capture information on communications among patients in the collaboration group, which could explore the internal psychological mechanism of gamification to promote exercise motivation.

In China, access to cardiac rehabilitation is often limited. Patients with CHD often lack physical activity. Our intervention could help increase physical activity participation and bring more health benefits.

Limitations

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

Acknowledgements: The authors would like to thank the valuable contribution made by the patients and public representatives during the study design and intervention development.

Contributors: LX, QT and FL conceived the original concept of the study and wrote the first draft of the protocol manuscript. LX, JL, XZ, YP, TY, XL, TY and LZ contributed to the design of the study. All authors read and approved the final manuscript.

Funding: This work is financially supported by a Construction Program of Independent Innovation Ability of Community Health Nursing Engineering Laboratory in Jilin Province (Study code: 2020C038-8) awarded to Dr. Feng Li.

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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Figure legends

Figure 1: Study flowchart.

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.

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

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

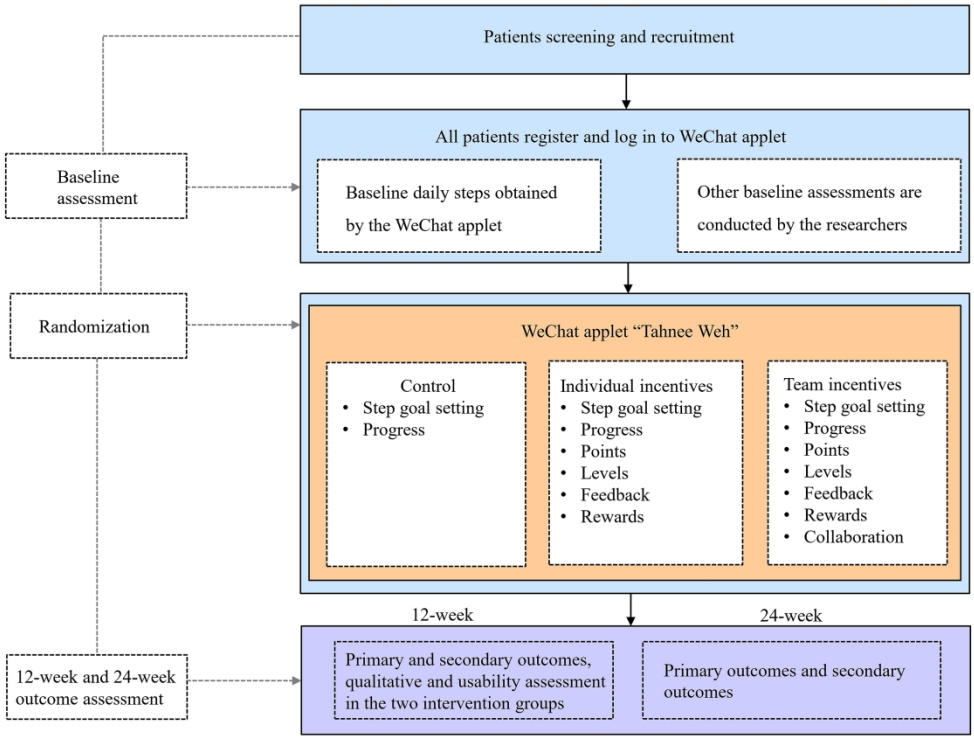

Figure 1: Study flowchart.

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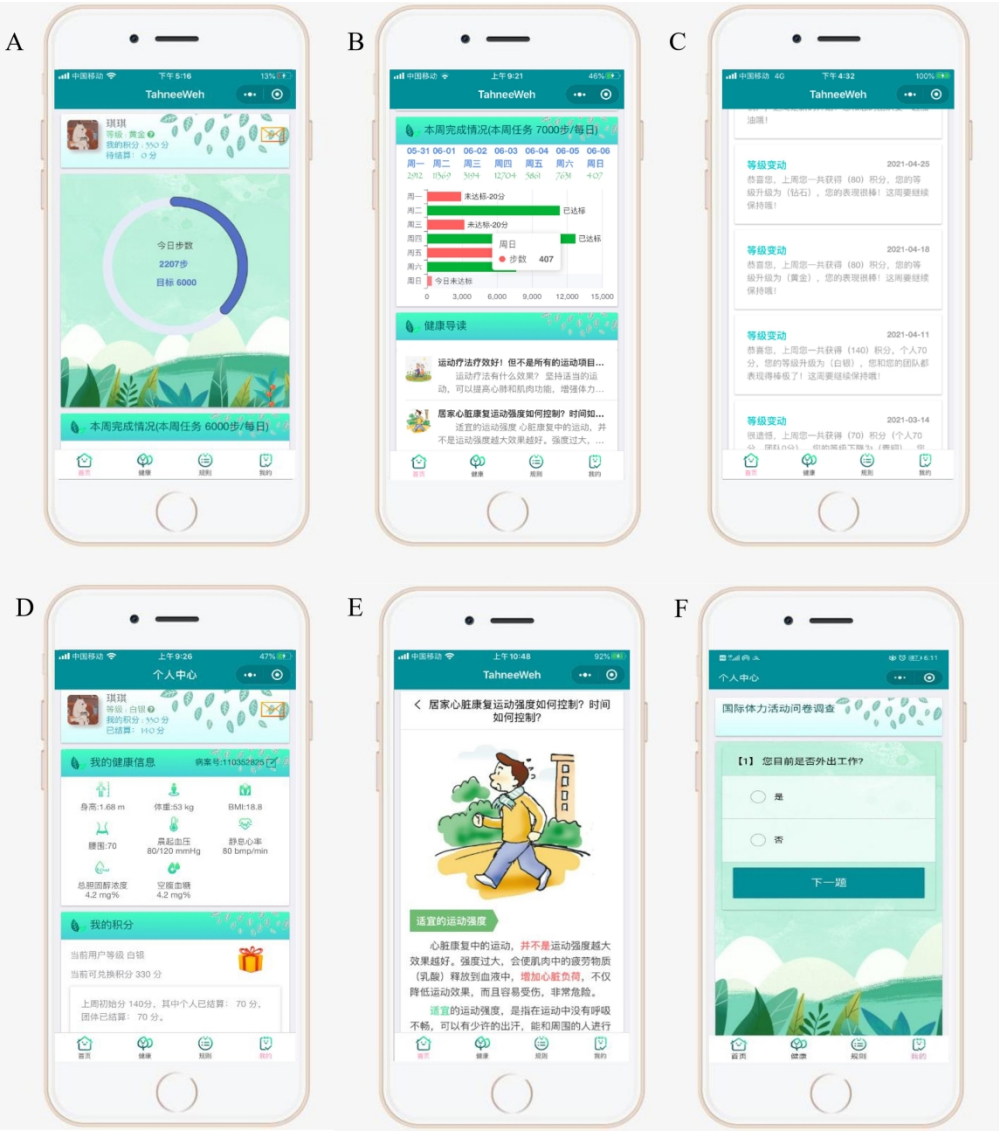

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254x286mm (300 x 300 DPI)

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

338x146mm (300 x 300 DPI)

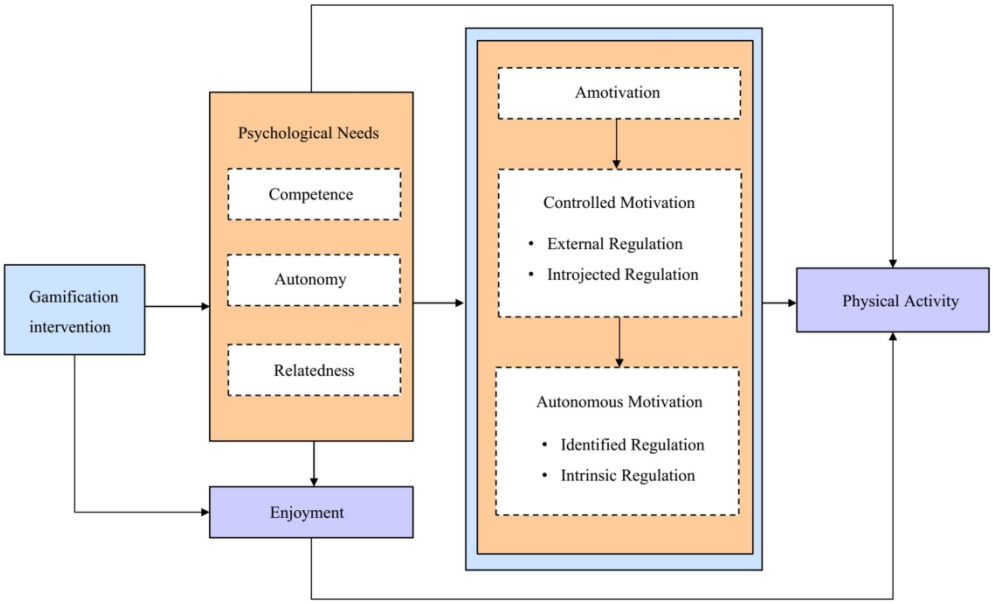

Figure 4: The hypothesized model of physical activity (PA) behavior regulation.

299x184mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

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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.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	P6, P14
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	P6
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	P17
Roles and responsibilities:	#5a	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			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P6-7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P8-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a, intervention did not involve harms or others
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	P7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P8-10
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P10-12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1

Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P7
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	P6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	P8
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	P8
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	P8
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	P8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a, not blind to researchers
Methods: Data collection,			

management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Table 2
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P10-12
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	P13
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P13
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P13
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	P13
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting	P13

		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	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a, not apply DMC in this trail
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	P11
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	P13
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P6-7
Consent or assent: ancillary studies	#26b	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	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	P14

Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	P17
Data access	#29	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
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a, not needed in this study
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	P14,17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	P14,17
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P14,17
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a, not needed in this study