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Effects of a community-based heart-healthy lifestyle promoting program

Submission date	**Recruitment status**	[X] Prospectively registered
26/08/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2025	Circulatory System	

Plain English summary of protocol

Background and study aims

There is little information on the effects of offline and online behavioral strategies on heart-healthy behaviors in cardiovascular prevention, compared to an online-only strategy. In this context, we designed an Heart-Healthy Lifestyle Promoting Program (i.e., HeartHELP program) using a hybrid behavioral strategy. The hybrid behavioral strategy comprises a combined intervention of both mobile-app and motivational interviewing. The mobile-app use is an intervention mode as an online strategy, while motivational interviewing is an intervention mode as an offline strategy in the present study. We have two aims: First, a hybrid-intervention group would have greater improvements in the indices of heart-healthy behaviors than a control group. Second, a hybrid-intervention group would have greater improvements in the indices of heart-healthy behaviors than a mobile-app group.

Who can participate?

Study participants are 75 adults who are community-dwelling individuals at risk for cardiovascular disease, having at least one component of metabolic syndrome.

What does the study involve?

The study participants will be randomly assigned to control, mobile-app, or hybrid groups. The HeartHELP program is a 12 week intervention comprising of both mobile-app use and motivational interviewing based on a hybrid behavioral strategy. The hybrid group will receive the 12-week HeartHELP program as online and offline strategies, the mobile-app group will receive an intervention of mobile-app use. as online strategies. The mobile-app was developed by the principal investigator and consists of technologies for information, self-monitoring and feedback. The control group will receive paper-based information about cardiovascular prevention.

What are the possible benefits and risks of participating?

Participants of control, mobile-app, and hybrid groups may have knowledge and skills for cardiovascular prevention and promotion through participating in the pre-test of the self-reported questionnaires, anthropometric measures, and blood works and receiving heart-healthy information. Moreover, each group will receive cash incentives according to their participation levels. Participants may have some physical and psychological discomforts through

spending time responding to survey questionnaires, physical measures, and blood work. More specifically, blood works are an invasive procedure with physical pain and problems (i.e., swelling or inflammation). In this case, the blood work will be conducted by skilled nurses who had more than three-year clinical experience. For the measurement of waist circumference, we will protect privacy by providing private space and a skilled-measurement procedure.

Where is the study run from?
College of Nursing, Korea University

When is the study starting and how long is it expected to run for?
August 2022 to August 2023

Who is funding the study?
National Research Foundation of Korea (NRF) grant from the Korean Government (No. NRF-2019R1A2C1004116).

Who is the main contact?
Jina Choo, PhD, DrPH, RN, jinachoo@korea.ac.kr

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NRF-2019R1A2C1004116

Study information

Scientific Title
Effects of a community-based Heart-HEalthy Lifestyle Promoting program: using a hybrid behavioral strategy

Acronym
HeartHELP study

Study objectives
1. A hybrid-intervention group would have greater improments in the indices of heart-healthy behaviors than a control group.
2. A hybrid-intervention group would have greater improvements in the indices of heart-healthy behaviors than a mobile-app group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2022, Korea University Institutional Review Board (145 Anam-ro Seongbuk-gu, Seoul, 02841, Korea, South; +82-2-3290-1137; kuirb@korea.ac.kr), ref: KUIRB-2022-0287-01

Study design
Randomized controlled trial with three groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Cardiovascular health promotion and prevention among community-dwelling individuals who are at risk for cardiovascular disease

Interventions
Current interventions as of 31/03/2025:

The intervention is named as the "Community-based Heart-Healthy Lifestyle Promoting Program (i.e., HeartHELP program)". The HeartHELP program contains of three intervention modes:
1. General information for cardiovascular health
2. Mobile-application use
3. Motivational interveiwing counselling.
The duration of the program is 12 weeks.

The final sample size is

75, which will be randomly allocated into 25 in the control group, 25 in the mobile-app group, or 25 in the hybrid-intervention group. After the completion of participant recruitment (N = 75), we will create a participant list by the recruitment time order.

A random allocation in the present study will be carried out by a principal investigator using age- and gender-stratified randomization. Random code lists will be generated by age- and gender-stratified groups, such as 20-29, 30-39, 40-49, 50-59, and 60-65 years groups by gender. Using the participant list, we will assign participants within a stratified group according to age- and gender – stratified random code lists.

We have three study arms: The hybrid-intervention group, the mobile-app group, and the control group.

The hybrid-intervention group will be received three intervention modes: 1) general information on cardiovascular health; 2) mobile-application use; and 3) motivational interviewing counselling. The mobile-app group will be received two intervention modes: 1) general information on cardiovascular health; and 2) mobile-application use. The control group will be received one intervention mode: 1) general information on cardiovascular health.

The general information indicates the receiving of a brochure including contents of cardiovascular disease, cardiovascular risk factors, and general lifestyle change. The mobile-application use indicates an online intervention mode, i.e., the receiving of text messages, self-monitoring of their lifestyle behaviors, and the receiving of feedback messages based on the outcomes of behavioral practices. The motivational interviewing counselling indicates an offline intervention mode, i.e., customized individual counseling and group-wise counseling based on the principle of motivational interviewing.

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Previous interventions as of 03/11/2022:

The intervention is named as the "Community-based Heart-Healthy Lifestyle Promoting Program (i.e., HeartHELP program)". The HeartHELP program contains of three intervention modes:
1. General information for cardiovascular health
2. Mobile-application use
3. Motivational interveiwing counselling.
The duration of the program is 12 weeks.

The final sample size is 60, which will be randomly allocated into 20 in the control group, 20 in the mobile-app group, or 20 in the hybrid-intervention group. After the completion of participant recruitment (N = 60), we will create a participant list by the recruitment time order.

A random allocation in the present study will be carried out by a principal investigator using age- and gender-stratified randomization. Random code lists will be generated by age- and gender-stratified groups, such as 20-29, 30-39, 40-49, 50-59, and 60-65 years groups by gender. Using the participant list, we will assign participants within a stratified group according to age- and gender – stratified random code lists.

We have three study arms: The hybrid-intervention group, the mobile-app group, and the control group.

The hybrid-intervention group will be received three intervention modes: 1) general information on cardiovascular health; 2) mobile-application use; and 3) motivational interviewing counselling. The mobile-app group will be received two intervention modes: 1) general information on cardiovascular health; and 2) mobile-application use. The control group will be received one intervention mode: 1) general information on cardiovascular health.

The general information indicates the receiving of a brochure including contents of cardiovascular disease, cardiovascular risk factors, and general lifestyle change. The mobile-application use indicates an online intervention mode, i.e., the receiving of text messages, self-monitoring of their lifestyle behaviors, and the receiving of feedback messages based on the outcomes of behavioral practices. The motivational interviewing counselling indicates an offline intervention mode, i.e., customized individual counseling and group-wise counseling based on the principle of motivational interviewing.

Previous interventions:
The intervention is named as the "Community-based Heart-Healthy Lifestyle Promoting Program (i.e., HeartHELP program)". The HeartHELP program contains of three intervention modes:
1. General information for cardiovascular health
2. Mobile-application use
3. Motivational interveiwing counselling.
The duration of the program is 12 weeks.

The final sample size is 75, which will be randomly allocated into 25 in the control group, 25 in the mobile-app group, or 25 in the hybrid-intervention group. After the completion of participant recruitment (N = 75), we will create a participant list by the recruitment time order.

A random allocation in the present study will be carried out by a principal investigator using age- and gender-stratified randomization. Random code lists will be generated by age- and gender-stratified groups, such as 20-29, 30-39, 40-49, 50-59, and 60-65 years groups by gender. Using the participant list, we will assign participants within a stratified group according to age- and gender – stratified random code lists.

We have three study arms: The hybrid-intervention group, the mobile-app group, and the control group.

The hybrid-intervention group will be received three intervention modes: 1) general information on cardiovascular health; 2) mobile-application use; and 3) motivational interviewing counselling. The mobile-app group will be received two intervention modes: 1) general information on cardiovascular health; and 2) mobile-application use. The control group will be received one intervention mode: 1) general information on cardiovascular health.

The general information indicates the receiving of a brochure including contents of cardiovascular disease, cardiovascular risk factors, and general lifestyle change. The mobile-

application use indicates an online intervention mode, i.e., the receiving of text messages, self-monitoring of their lifestyle behaviors, and the receiving of feedback messages based on the outcomes of behavioral practices. The motivational interviewing counselling indicates an offline intervention mode, i.e., customized individual counseling and group-wise counseling based on the principle of motivational interviewing.

Intervention Type
Behavioural

Primary outcome measure
Heart-healthy behaviors, as measured by the Evaluation Tool of the managment behaviors of metabolic syndrome at pre- and post-intervention

Secondary outcome measures
Measured at pre- and post-intervention:
1. Heart-healthy self-efficacy by self-report questionnaire
2. Heart-healthy motivation by self-report questionnaire
3. Heart-healthy biophyscial factors (i.e., body mass index, waist circumference, blood pressure, fasting glucose, total-cholesterol, LDL-cholesterol, and HDL-cholesterol) measured by anthropometric and blood pressure measures, and blood sampling

Overall study start date
01/08/2022

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Community-dwelling adults who are at risk for cardiovascular disease, specifically having at least one component of metabolic syndrome according to the NCEP-ATP III.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
19 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
75

Total final enrolment
75

Key exclusion criteria
Current exclusion criteria as of 31/03/2025:

1. Adults who were medically diagnosed with diabetes mellitus or cardiovascular diseases
2. Adults who were medically diagnosed with psychiatric disease including major depression or anxiety disorder
3. Adults having activity limitations
4. Adults with cognition problems
5. Adults who were not able to respond to self-reported questionnaire
6. Adults who were not able to use mobile application

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Previous exclusion criteria:

1. Adults with antihypertensive, lipid-lowering medications, or hypoglycemics (including insulin injection)
2. Adults who were medically diagnosed with diabetes mellitus or cardiovascular diseases
3. Adults who were medically diagnosed with psychiatric disease including major depression or anxiety disorder
4. Adults having activity limitations
5. Adults with cognition problems
6. Adults who were not able to respond to self-reported questionnaire
7. Adults who were not able to use mobile application

Date of first enrolment
17/10/2022

Date of final enrolment
03/02/2023

Locations

Countries of recruitment
Korea, South

Study participating centre
College of Nursing, Korea University
145 Anam-ro
Seongbuk-gu
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Sponsor information

Organisation
Korea University

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Sponsor type
University/education

Website
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ROR
https://ror.org/047dqcg40

Funder(s)

Funder type
Government

Funder Name
National Research Foundation of Korea (NRF) grant from the Korean Government (No. NRF-2019R1A2C1004116)

Results and Publications

Publication and dissemination plan
Presentation of abstract in 2023 American Heart Association Scientific meeting.
Publication in the Journal of Advanced Nursing

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the principal investigator (PI), Jina Choo, PhD, DrPH, RN (jinachoo@korea.ac.kr) when the PI decides to publicize the data. As of now, it is not possible to specify a specific time

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		01/04/2019	04/10/2022	No	No
Basic results		31/03/2025	31/03/2025	No	No