ISRCTN12097902 https://doi.org/10.1186/ISRCTN12097902

Digital wellness coaching for working-age adults: feasibility, user experiences, effects, and cost-effectiveness

Submission date
06/08/2025

Recruitment status
No longer recruiting

Registration date
06/08/2025

Overall study status
Ongoing

Last Edited
17/09/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the feasibility, user experiences, effects, and cost-effectiveness of a digital wellness coaching programme called Skipper. The study will be conducted by the Finnish Heart Association and the Finnish Institute for Health and Welfare as part of the EU Joint Action on Cardiovascular Diseases and Diabetes (JACARDI, 2023–2027, https://jacardi.eu/). JACARDI supports European countries in implementing evidence-based practices to reduce the burden of cardiovascular diseases and diabetes.

Who can participate?
Adults aged 18 to 65 years who are willing to promote their wellbeing and ready to participate in an independently conducted digital coaching. The participants should have access to the Internet and be able to understand Finnish both by listening and reading.

Participants will be recruited from workplaces and allocated to one of two study groups based on their workplace or working unit. The study groups comprise (1) an intervention group that receives the coaching immediately and (2) a waitlist control group that receives general information on factors that influence wellbeing and that will be offered the opportunity to participate in the coaching after the study.

What does the study involve?
The participants of the intervention group complete the digital wellness coaching programme independently on a web-based platform that can be accessed with a smartphone, tablet, or computer. The programme lasts six months and strives to promote wellbeing, healthy lifestyle habits, physical fitness, and health. The programme consists of five thematic periods, each of which lasts five weeks. These periods build on modules related to physical activity, diet, and sleep. The modules provide varying interactive content, such as factual information, quizzes, practical exercises, and reflective assignments. The modules can be completed self-paced, and the programme supports the completion with features that enable self-monitoring and receiving feedback and reminders.

For all participants, the study lasts 12 months and involves measurements at three time points: at baseline, at the end of the intervention, and at six months after the end of the intervention. The measurements comprise body fitness tests (hand grip-strength, heart rate variability, body composition, waist circumference) and online questionnaires on wellbeing, lifestyle habits, and health. At baseline, the online questionnaire also collects information on the participant's background (e.g., sociodemographics and e-service use). At the end of the intervention, the questionnaire asks the participants of the intervention group to share their experiences of the coaching.

What are the possible benefits and risks of participating?
The digital wellness coaching programme teaches the participants to (1) identify their own strengths, (2) use their strengths appropriately in varying situations, and (3) notice connections between healthy lifestyle habits and wellbeing. The programme also strengthens the participants' competence and sense of responsibility for maintaining their wellbeing and health. Moreover, the participants gain information on their body fitness level.

The study does not involve any direct health risks or harms, but completing the data collection and the coaching will take some time and effort. The study participants will not receive financial or other compensation. The participants have full freedom to choose whether to participate in the study or not, and they can withdraw from the study at any time.

Where is the study run from?
The Finnish Heart Association and the Finnish Institute for Health and Welfare, Helsinki, Finland.

When is the study starting and how long is it expected to run for?
The planning of the study started in January 2024 and the data collection will be completed by the end of January 2027.

Who is funding the study?
The study will be carried out as part of the EU Joint Action on Cardiovascular Diseases and Diabetes (JACARDI) that has received funding from the EU4Health Programme 2021–2027 under the Grant Agreement no. 101126953.

Who is the main contact?
Kirsti Kasila (email: kirsti.kasila@sydanliitto.fi) and Eeva Rantala (email: eeva.rantala@thl.fi)

Contact information

Type(s)
Scientific

Contact name
Prof Jaana Lindström

Contact details
PO Box 30
Helsinki
Finland
00271
+358 (0)29 524 8635
jaana.lindstrom@thl.fi

Type(s)
Scientific

Contact name
Dr Eeva Rantala

ORCID ID
https://orcid.org/0000-0001-8512-6638

Contact details
PO Box 30
Helsinki
Finland
00271
+358 (0)29 524 7224
eeva.rantala@thl.fi

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Kirsti Kasila

ORCID ID
https://orcid.org/0000-0001-5921-9603

Contact details
PO Box 50
Helsinki
Finland
00621
+358 (0)50 342 7234
kirsti.kasila@sydanliitto.fi

Additional identifiers

Study information

Scientific Title
The feasibility, user experiences, effects, and cost-effectiveness of a fully automated digital wellness coaching programme: a cluster randomised pilot trial among working-age adults in Finland

Study objectives
The objective of this study is to develop a fully automated six-month digital wellness coaching programme and evaluate its (1) feasibility, (2) user experiences, (3) effects, and (4) cost-effectiveness among working-age adults.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 22/05/2025, Keski-Suomen hyvinvointialueen alueellinen lääketieteellinen tutkimuseettinen toimikunta (The Regional Medical Research Ethics Committee of the Wellbeing Services County of Central Finland) (Hoitajantie 3, Jyväskylä, 40620, Finland; +358 (0) 14 269 5134; paivi.lampinen@hyvaks.fi), ref: 1U/2025

Primary study design
Interventional

Study design
Interventional two-arm parallel group unblinded cluster randomized controlled trial

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
The promotion of wellbeing, healthy lifestyle habits, and fitness among working-age adults

Interventions
The intervention is a fully automated digital wellness coaching programme, called Skipper. The programme lasts six months and covers three behavioural domains—physical activity, diet, and sleep—with an overarching focus on recovery. The coaching consists of an introductory period (1 week) and five thematic periods (á 5 weeks), which the coachee conducts independently on a web-based platform. The platform can be accessed with a smartphone, tablet, or computer.

Each thematic period of the coaching builds on concise modules related to physical activity, diet, and sleep. The modules dive into specific topics with varying interactive content, including factual information, quizzes, practical exercises, and reflective assignments. During the first four weeks of each period, the coachee receives access to new modules at the beginning of each week. The fifth week of the period serves as a summary and guides the coachee to reflect on the past four weeks and to monitor progress. The fifth and final thematic period of the coaching summarises the key learnings of the programme and provides the coachee a personal plan for maintaining their wellbeing. While the curriculum of the coaching is fixed and scheduled, the modules can be completed self-paced, and the programme provides a personalised experience with content that facilitates introspection and self-assessment and with technical features that enable self-monitoring and receiving feedback and reminders.

The coaching emphasises individual resources and resilience and their use in the pursuit of purposeful, positive changes. The aim is to promote autonomy, self-efficacy, and self-regulatory skills to manage and navigate adaptively through varying situations. The physical activity modules of the coaching include motivational and educational content, and instructions on concrete physical exercises (relaxation, balance, functional, flexibility, strength, and cardiovascular training). The diet-related modules guide to reflect on and enhance personal relationship with food and eating, eating-related traits, meal pattern, ability to sense the needs of the body and mind, healthiness of dietary habits, and the food environment. The seep-related modules include sleep- and relaxation-related information, engaging questions, personalised feedback, tips, and exercises.

Study participants will be recruited from workplaces in Central Finland. The aim is to find 4–8 collaborating workplaces that are medium to large in size and operate in various fields. The workplaces will be randomised into two study arms: (1) intervention workplaces whose participants receive the digital wellness coaching and (2) waitlist control workplaces whose participants receive information on factors that influence wellbeing. The waitlist control participants will be offered the opportunity to participate in the coaching after the study. The randomisation will be conducted at the level of workplace or working unit.

Potential workplaces will be identified through online searches and the research team's networks and contacted in a descending order based on the number of employees. The contacts will primarily be addressed to human resources or other administration. Organisations that express interest in collaboration meet the research team to discuss the study in more detail. For organisations that decide to collaborate with the study, necessary research permits will be obtained. The organisations select one or more members of their staff as coordinators who communicate with the research team, forward information on the study to the employees of the organisation, support in participant recruitment, and help to organise study measurements. The study will be presented to the employees, and those interested in participating can enrol by completing an online registration form.

For each participant, the study will last 12 months and involve measurements at three time points. For the intervention group, the coaching programme runs for the first six months. All participants will participate in body fitness tests and complete an online questionnaire at baseline (month 0), at the end of the intervention (month 6), and at six months after the end of the intervention (month 12). Before the baseline body fitness tests, each participant meets a member of the research team face to face and signs an informed consent form. The body fitness tests will be organised at the participant's workplace and cover hand grip-strength, heart rate variability in rest, body composition (bioelectrical impedance), waist circumference, height, and weight. After the tests, the participants receive personal feedback on their fitness. The online questionnaires collect information on wellbeing, lifestyles (physical activity, diet, and sleep), and health (perceived health status, quality of life, life satisfaction, work ability, and health literacy). At baseline, the questionnaire also collects information on the participant's background (e.g., sociodemographics, prior attempts to change lifestyles, and e-service use). At the end of the intervention, the questionnaire asks the participants of the intervention group to share their experiences of the coaching (acceptability, overall score, likelihood to recommend).

Intervention Type
Behavioural

Primary outcome(s)
Wellbeing is measured with the self-reported WHO-5 Well-Being Index at month 0, 6, and 12.

Key secondary outcome(s)
Effects based on objective outcome measures:
1. Fitness is measured with the Body Fitness Index (computed based on hand grip-strength, heart rate variability, body composition, waist circumference, height, and weight) at month 0, 6, and 12.

Effects based on participant-reported outcome measures:
2. Physical activity is measured with questionnaire items from population-based health surveys at month 0, 6, and 12.
3. Physical literacy is measured with the Perceived Physical Literacy Instrument at month 0, 6,

and 12.
4. Diet quality is measured with the Healthy Diet Index at month 0, 6, and 12.
5. Eating competence is measured with the Satter Eating Competence Inventory 2.0 at month 0, 6, and 12.
6. Sleep is measured with questionnaire items from prior research at month 0, 6, and 12.
7. Perceived health status is measured with a questionnaire item from prior research at month 0, 6, and 12.
8. Health-related quality of life is measured with EQ-5D-5L at month 0, 6, and 12.
9. Overall life satisfaction is measured with a questionnaire item from the World Happiness Report at month 0, 6, and 12.
10. Work ability is measured with the Work Productivity and Activity Impairment Questionnaire at month 0, 6, and 12.
11. Health literacy is measured with the Consumer Health Activation Index at month 0, 6, and 12.
12. Vitality is measured with a questionnaire item from prior research at month 0, 6, and 12.

Implementation and feasibility:
13. Reach/participation is measured as the proportion of invitees who enrol in the study at month 0.
14. Engagement with the coaching programme (e.g., logins, time spent, and activities completed on the digital coaching platform) is measured with usage data collected on the digital coaching platform continuously throughout the 6-month intervention.
15. Dropout (i.e., the proportion of participants who discontinue using the coaching programme) and the timepoint at which the dropout occurs are measured with usage data collected on the digital coaching platform continuously throughout the 6-month intervention.

User experiences:
14. Acceptability of the coaching programme is measured with questionnaire items based on the Theoretical Framework of Acceptability at month 6.
15. Overall score of the coaching programme is measured with a questionnaire item at month 6.
16. Likelihood to recommend the coaching programme to a friend or colleague is measured with the Net Promoter Score at month 6.

Cost-effectiveness:
16. Cost-effectiveness is measured with changes in quality of life (quality-adjusted life years, QALYs) and productivity (productivity-adjusted life years, PALYs), and with an estimate of the minimum participant volume required for the incremental cost-effectiveness ratio to remain below a predefined cost-effectiveness threshold. These estimates build on the implementation costs of the coaching programme, participant outcome measures collected at month 0, 6, and 12 (perceived health status, quality of life, life satisfaction, work ability, health literacy, BMI, and grip strength), participant's postal code measured with a questionnaire at month 0, and the socio-economic characteristics of each postal code area retrieved from the Statistics Finland database.

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Informed consent

3. Willingness to promote own wellbeing
4. Readiness to participate in an independently conducted digital coaching
5. Access to Internet via computer, tablet, or smartphone
6. Proficiency in the Finnish language (listening and reading comprehension)

Participant type(s)
Healthy volunteer, Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Simultaneous participation in another health/wellness/lifestyle intervention
2. Pregnancy
3. A pacemaker or other electronic medical device implanted into the body
4. Any other reason that may prevent participation in (a) coaching related to physical activity, diet, and sleep, or (b) the body fitness tests of the study, which include a handgrip test, a heart rate variability measurement from the wrist, a body composition analysis (bioelectrical impedance), and a waist circumference measurement with a measuring tape.

Date of first enrolment
22/09/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Finland

Study participating centre
The Finnish Heart Association
Oltermannintie 8, P.O. Box 50
Helsinki
Finland
00621

Sponsor information

Organisation
Finnish Heart Association

Organisation
Finnish Institute for Health and Welfare

ROR
https://ror.org/03tf0c761

Funder(s)

Funder type
Government

Funder Name
EU4Health Programme 2021–2027, Grant Agreement no. 101126953

Funder Name
Finnish Heart Association

Funder Name
Finnish Institute for Health and Welfare

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study can be made available upon a reasonable request from Dr Eeva Rantala (eeva.rantala@thl.fi) after the publication of the study results and up to ten years after the end of the study as defined in the following excerpt from the data management plan that was approved by the regional medical research ethics committee of the wellbeing services county of Central Finland:
"If jointly decided by the Finnish Heart Association and the Finnish Institute for Health and Welfare, anonymized research data and its usage rights may be shared with another research

organization operating in Finland for research purposes by drafting a research collaboration agreement with the respective organization... The research data will be stored in anonymized form for 10 years after the end of the study, after which the data will be destroyed."

IPD sharing plan summary

Available on request