

Online Supplemental file 2. SPIRIT Item 2b: All items from the World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT05339841
Date of registration in primary registry	21 April, 2022
Secondary identifying numbers	R1256/20-CCM 1319; RCR-2019-23669116_001
Source(s) of monetary or material support	Italian Ministry of Health
Primary sponsor	Monzino Cardiology Center IRCCS
Secondary sponsor(s)	none
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Contact for scientific queries	Principal Investigators: Giulio Pompilio, Centro Cardiologico Monzino IRCCS (giulio.pompilio@cardiologicomonzino.it); Gianfranco Parati, Istituto Auxologico Italiano IRCCS (parati@auxologico.it) Scientific contact: studiocvprevital@retecardiologica.it
Public title	Italian Digital Primary Cardiovascular Prevention Study (CV-PREVITAL)
Scientific title	Digital Strategies in Primary Cardiovascular Prevention in the Italian Population
Countries of recruitment	Italy
Health condition(s) or problem(s) studied	Subjects in primary cardiovascular prevention
Intervention(s)	Intervention group: subjects assigned to a mobile health application (mHealth) app that delivers a personalized digital health support program based on periodic messages with advice, motivational reminders and support to improve lifestyle habits and risk factor control
	Control group: subjects assigned to usual care
Key inclusion and exclusion criteria	Ages eligible for study: ≥ 45 years; Sexes eligible for study: both; Accepts healthy volunteers: yes
	Inclusion criteria: adult subjects (≥ 45 years) consenting to participate in the study and using a smartphone
	Exclusion criteria: current or previous cardiovascular disease (personal history of myocardial infarction, angina pectoris, arterial revascularization procedures, stroke, transient ischemic attack, peripheral artery disease); Psychiatric disorders; Participation in other clinical trials
Study type	Interventional (mobile health application vs usual care)
	Allocation: randomized;
	Intervention model: parallel assignment; Masking: none (Open Label);

	Primary purpose: cardiovascular disease prevention
	Phase: not applicable
Date of first enrolment	June 10, 2022
Target sample size	82,800
Recruitment status	Recruiting
Primary outcome(s)	<ul style="list-style-type: none"> • Short term (month 12): change in cardiovascular risk • Long term (year 7): between groups difference in the incidence of vascular events
Key secondary outcomes	<ul style="list-style-type: none"> • Change of a combined endpoint including hypertension, diabetes, hypercholesterolemia [month 12] • Systolic and diastolic blood pressure (mmHg) [month 12] • HDL-C, LDL-C, and triglycerides (mg/dL) [month 12] • HbA1c (%) [month 12] • Body weight (kg) [month 12] • Physical activity (IPAQ questionnaire) [month 12] • Mediterranean diet adherence (PREDIMED questionnaire) [month 12] • Mediterranean diet adherence (Moli-Sani questionnaire) [month 12] • Smoking status [month 12] • Alcohol intake [month 12] • Salt intake (MiniSal questionnaire) [month 12] • Stress (Perceived Stress Scale; PSS) [month 12] • Psychological distress (PHQ 4 questionnaire) [month 12] • Anxiety (PHQ 4 questionnaire) [month 12] • Depression (PHQ 4 questionnaire) [month 12] • Multidimensional Health Locus of Control Scale (MHLCS) - Internality [month 12] • Multidimensional Health Locus of Control Scale (MHLCS) - Powerful Others Externality [month 12] • Multidimensional Health Locus of Control Scale (MHLCS) - Chance Externality [month 12] • General Self Efficacy (GSE Scale) [month 12] • Risk propensity (RPS Scale) [month 12] • Sleep quality (Pittsburgh Sleep Quality Index) [month 12] • Subjects' adherence to data recording [month 12] • Interruptions in the use of the mHealth App [month 12] • Adherence to recommended therapies [month 12] • Cost/effectiveness of intervention [year 7] • House ownership as socioeconomic status indicator [year 7]

	<ul style="list-style-type: none">• Type of residence as socioeconomic status indicator [year 7]• Education as socioeconomic status indicator [year 7]• Employment status as socioeconomic status indicator [year 7]• Type of profession as socioeconomic status indicator [year 7]• Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - history of hospitalization (questionnaire) [year 7]• Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - history of symptoms (questionnaire) [year 7]• Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - history of asymptomatic disease (questionnaire) [year 7]• Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - history of vaccination (questionnaire) [year 7]
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