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ORIGINAL ARTICLE

A Mobile App-based Approach in Cardiovascular Disease Prevention: A Prospective Randomized Study

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Abstract
Cardiovascular risk factors are prevalent in the Italian population, and cardiovascular diseases remain a leading cause of mortality in the Western world. As the incidence of risk factors and cardiovascular diseases increases with age, effective and early prevention and management strategies are crucial. This study aims to evaluate the feasibility and potential benefits of using the Heartaway® mobile application as an additional intervention to standard clinical care for patients with hypertension. The study will explore improvements in blood pressure control, medication adherence, cardiovascular risk factors, lifestyle habits, and cardiovascular outcomes. The results of this study may contribute to a broader integration of telemedicine into cardiovascular disease prevention in the clinical practice.

Keywords Cardiovascular prevention · Telemedicine · Cardiovascular risk · Hypertension · Adherence

1 Introduction

Cardiovascular risk factors are highly prevalent in Italy, with a significant portion of the population affected by conditions such as hypertension, hypercholesterolemia, diabetes, cigarette smoking and obesity [1–3]. Cardiovascular diseases continue to be the leading cause of death in the Western world [4, 5]. The aging population further exacerbates the burden of cardiovascular diseases, as elderly patients often have multiple comorbidities and require close and intensive monitoring and management [6–8]. Effective prevention and management strategies are essential to mitigate the impact of cardiovascular diseases, especially in the context of a healthcare system facing new challenges such as the recent pandemic [9–12].

In the recent years, there has been a gradual but slow adoption of new approaches to more effectively managing chronic cardiovascular diseases. These approaches aim to provide more timely and integrated healthcare services, facilitated by advancements in telecommunication technologies [13–21].

The key objectives of these approaches include:

- Enabling remote patient management, reducing the need for in-person healthcare visits.
- Providing continuous remote monitoring of patients to detect emerging conditions, prevent clinical deterioration, and assess medication adherence.
- Identifying patients in the need of urgent medical attention in order to minimize hospital overcrowding.
- Offering educational feedback to patients and their caregivers on managing chronic diseases.

Telemedicine, with its ability to cover geographic distances, use widely available information and communication technologies, and involve healthcare professionals in direct patient care or consultation, aligns with these objectives. However, it still requires further refinement in terms of usability, data security, patient-friendliness, and data collection [13–17].

Moreover, data are missing about the efficacy of a telehealth approach in managing cardiovascular risk factors and related clinical outcomes.

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1.1 Hypothesis of the Study

Our project aims to test the effectiveness of adding a remote medical approach using an App (Heartaway®) developed for smartphones, compared to standard in-person visit alone in the management of patients with hypertension. The scope of the pilot study will be to verify the feasibility of the App (Heartaway®), specifically designed for smartphones.

1.2 Primary Endpoint

- Evaluation of blood pressure reduction.

1.3 Secondary Endpoints

- Assessment of medication adherence.
- Assessment of individual cardiovascular risk factors, including total cholesterol, HDL, LDL, fasting glucose, HbA1c, body mass index (BMI) and waist circumference.
- Evaluation of lifestyle factors, including physical activity, smoking habits, and alcohol consumption.
- Assessment of the incidence of cardiovascular diseases.
- Evaluation of the number of outpatients requiring unplanned cardiology visits, emergency room admissions due to cardiovascular events, and planned cardiovascular hospitalizations.

2 Materials and Methods

This study will be a non-profit, prospective, 1:1 randomized, single-center intervention study, conducted at the Department of Clinical and Molecular Medicine at the University of Rome Sapienza in collaboration with the Excellence European Hypertension Center of the Cardiology Division at the University Hospital Sant'Andrea in Rome [22]. The study is promoted and supported supported by the Italian Society of Cardiovascular Prevention (SIPREC) and has been submitted to the Ethic Committee "Territoriale Area Lazio 1".

The study will be conducted over a 36-month period (Fig 1). During the first three months of the project, the Heartaway® App, developed by the Department of Clinical and Molecular Medicine at the University of Rome Sapienza, will be internally tested by the investigators.

In the subsequent 6 months, consecutive patients with hypertension attending the Hypertension Center at the University Hospital Sant'Andrea will be enrolled. Inclusion criteria include age > 18 years, the ability to provide informed consent, possession of a smartphone with iOS or Android operating systems, a diagnosis of hypertension, and at least one other cardiovascular risk factor, evidence of subclinical target organ damage, or previous cardiovascular disease.

Exclusion criteria include NYHA class III-IV heart failure, ongoing hemodialysis, poor prognosis due to cancer, pregnancy, unavailability of laboratory tests required for a

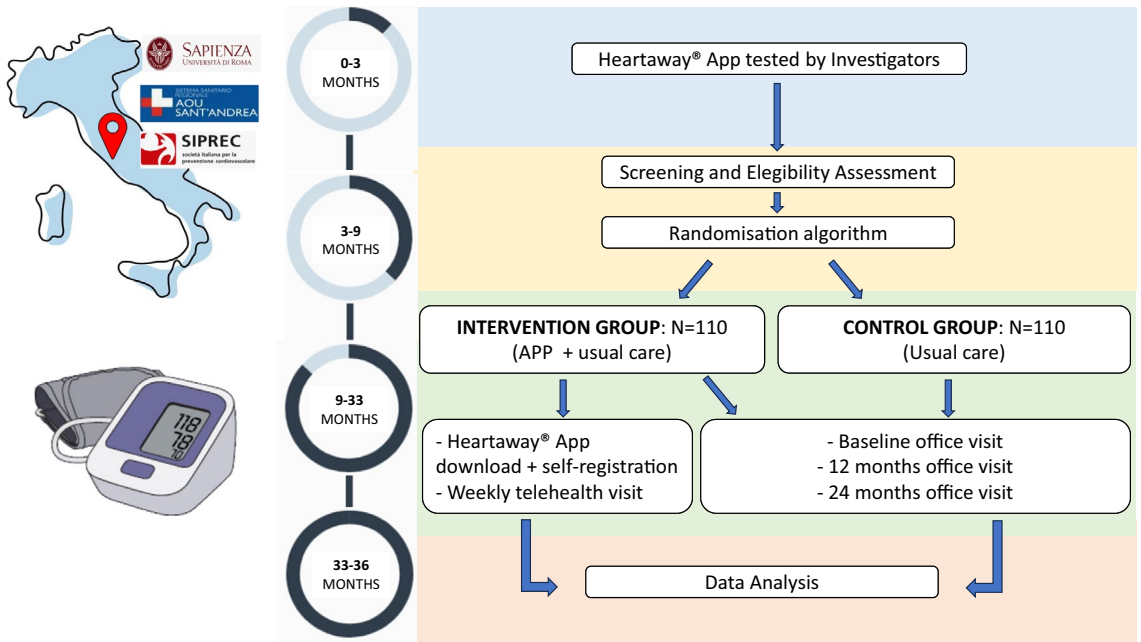

Fig. 1 Study design

comprehensive cardiovascular risk assessment, and contraindications to telemedicine.

After obtaining written informed consent, enrolled patients will be randomly assigned to either the Heartaway® App group (intervention group) or the standard clinical care group (control group) in a 1:1 ratio using the Biased Coin method (estimated sample size 220 patients, 110 per group). The randomization process will be performed by a research support unit.

All patients will receive standard clinical care according to the European Society of Cardiology guidelines, including at least yearly clinical assessment, anthropometric measurements, physical examination, vital signs measurements, laboratory tests, and electrocardiograms. The follow-up of these patients will continue for the following 24 months.

The Heartaway® app, is an application developed for use on a smartphone (iOS or Android). With a self-registration, each subject of the intervention group should provide information about anthropometric data, cardiovascular risk factors, cardiovascular diseases and other comorbidities, current drug therapy and laboratory data. Based on these information, the Heartaway® app will calculate the SCORE-2/SCORE-2 OP, a new algorithm to estimate 10-year risk of CV disease in apparently healthy people, described in 2021 by European Society of Cardiology guidelines [6]].

The most interesting app functionality is the weekly telehealth visit consisting in questions about vital parameters, fluid intake, body weight, onset or deterioration of chest pain, dyspnea, palpitation and peripheral swelling. The App, based on an algorithm capable to integrate subject answers, will provide automatically to the medical staff a report on each patient cardiovascular health. At each annual study visit, a structured patient interview will be administered face-to-face by a study coordinator to assess app usability and collect recommendations for app improvement.

3 Expected Results

In recent years, communication and interaction with others have increasingly relied on remote communication tools such as personal computers, smartphones, and smartwatches [23]. Therefore, the validation of new technological tools and telemedicine approaches is essential. This project aims to test the effectiveness of remote medical management of cardiovascular prevention using a simple smartphone app (Heartaway®) compared to standard care in a population of hypertensive patients.

Thanks to the expected added value of the App in the clinical management of hypertensive outpatients, we hypothesize a better control of blood pressure levels and a better adherence to treatments in cases vs controls.

Expected results include better control of BP, improved awareness of cardiovascular risk factors, better control of cardiovascular risk factors, enhanced medication adherence, reduced emergency department visits, decreased unplanned outpatient visits, and fewer hospitalizations. Such outcomes, if achieved, may translate in. reduced healthcare burdens and costs for the national healthcare system.

4 Conclusions

This study is planned to evaluate the feasibility and potential benefits of incorporating telemedicine, specifically the Heartaway® App, into cardiovascular disease prevention and management. If the first single-center phase of our pilot study will achieve the designated goals, the study will be extended to a much larger nationwide study, with a multicenter approach, to provide reliable data about the efficacy of a telehealth approach in reducing the global cardiovascular risk and related clinical outcomes, trying to fill the current gap in telemedicine scientific validation.

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Data availability Not applicable.

Declarations

Conflict of Interest The authors have nothing to disclose.

Ethical Approval The study has been submitted to the Ethic Committee "Territoriale Area Lazio 1".

Informed Consent Informed consent was obtained from all individual participants included in the study

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