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Piloting Photoplethysmographic Smartphone-Based Atrial Fibrillation Screening in Austria

App-Development for a Large-Scale Centreless Prospective Controlled Randomised Trial

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Abstract: Atrial fibrillation (AF), the most common sustained arrhythmia, affects over 59 million people worldwide and carries a high risk of serious complications such as stroke. However, AF often goes undiagnosed, leaving many patients untreated. Photoplethysmography (PPG) is a non-invasive method for AF detection, accessible via wearables or smartphone apps. This paper presents two integrated smartphone apps—one for user registration and one for PPG-based AF screening—developed for use in a large-scale, prospective, randomised, centreless clinical trial. The screening app incorporates third-party AF detection Software Development Kits (SDKs) which are certified as class IIa medical devices. A pilot study confirmed the technical feasibility of the approach and identified minor areas for improvement. These insights will guide app refinement ahead of a nationwide AF screening study in Austria, planned for 2026.

Keywords: Digital health, mobile health, mHealth, atrial fibrillation, photoplethysmography

1 Introduction

Atrial fibrillation (AF), the most common sustained arrhythmia, affects over 59 million people globally [1] and often remains undiagnosed due to its asymptomatic and intermittent nature [2]. Despite its strong association with stroke, heart failure, and mortality, nearly 25% of cases are only identified after stroke [3], and undiagnosed prevalence estimates range from 13% to 35% [4, 5]. Current ECG-based screening methods [6-8], while effective, are costly and logistically intensive for large-scale use.

Photoplethysmography (PPG), widely available through smartphone and smartwatch sensors, offers a scalable, low-cost solution by detecting pulse wave irregularities indicative of AF. Large observational studies like the Apple [9], Huawei [10], and Fitbit [11] Heart Studies have demonstrated the feasibility of mass digital engagement, though with low detection rates due to younger, lower-risk cohorts and follow-up limitations. The eBRAVE-AF trial [12] was the first randomised study to show that smartphone-based PPG screening significantly improves detection of treatment-relevant AF compared to usual care, offering a promising path for accessible, digital AF screening at scale. Although this study proved the effectiveness of PPG in detecting AF, the effect of digital screening on clinical outcomes, mainly if they can improve mortality and reduce strokes, remains unclear.

The Austrian Digital Heart Program is a research project funded by the Ludwig Boltzmann Gesellschaft, which aims at evaluating the potential of digital screening on clinical outcomes in a large-scale randomised centreless clinical trial in Austria, aiming to include almost 100,000 patients. The scale, target population (elderly citizens) and centreless nature of the trial introduces challenges that need to be addressed on a technical level to ensure a high registration and adherence of subjects. The present paper describes technical details of the developed alpha versions of a registration and an AF screening mobile application, which will be updated based on an initial

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pilot feasibility and usability study, and thereafter to be in the large-scale randomised trial.

2 Methods

2.1 Photoplethysmography (PPG)

Photoplethysmography (PPG) sensors are widely used in clinical applications and in commercially available medical devices. By optical measurement techniques, the volume change of the blood in the tissue can be determined only with a few components such as a light emitting diode and a detector catching the transmitted light beam from the tissue [10].

In a recent review, Sibomana et al. compared PPG-based AF detection solutions based on smart watches with ECG-chest patches, concluding that both, ECG smart chest patches and PPG smartwatches are highly effective for detecting atrial fibrillation [13].

2.2 PPG-based atrial fibrillation detection on smart phones

PPG measurement can not only be applied with specific wearables like smart watches, but also via specific smartphone apps, as shown in Figure 1. In this case, the smartphone's camera is used to detect changes in specific spectral regions of a video which is recorded while a person puts a finger on the camera. Recently, Gill et al. [14] included 28 studies providing 31 comparisons of smartphone-based PPG vs. ECG-based AF detection approaches, revealing high sensitivity and specificity for PPG-based AF detection, ranging from 81% to 100%, and from 85% to 100%, respectively.

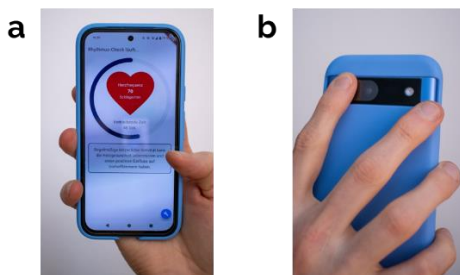


Fig. 1: The smartphone's integrated camera can be used to detect atrial fibrillation based on PPG (a shows user view on the app, b shows the finger placement on the camera)

While many apps analysed by Gill et al. have shown high accuracy for AF detection, most of them are limited

concerning their application in clinical settings due to a lack of certification as a medical device. The Preventicus Heartbeats app [15], which was used in the eBRAVE-AF trial [12], is certified as a medical device class IIa. FibriCheck [16], in addition to being certified as a complete app, also provides two SDKs, which are also certified as class IIa medical devices, and which can be integrated into self-designed software solutions: A Camera SDK for recording the PPG signal and Cloud SDK for classifying the previously recorded signal depending on the respective cardiac rhythm. Due to this flexibility, FibriCheck was identified as a promising candidate for integration in our AF study.

3 Results

We identified that highly diverging requirements need to be met by the trial software in different phases: While self-registration of approx. 100,000 participants requires an extremely simple and user-friendly process, preferably without the need to install any app on the participant's device, PPG measurement needs a dedicated app which incorporates certified software packages. Therefore, we decided to develop two interacting mobile applications supporting AF screening in future large-scale, centreless, randomised controlled clinical trials:

- 1) A **registration web app** for interested and eligible citizens to register for the programme
- 2) A **screening mobile app** for regular PPG-based AF screening using the smartphone's camera

Both applications are described in the following.

3.1 Registration app

The registration app enabled participants to self-register for the study. It was developed as a mobile-first web app in the JavaScript framework Vue.js. Via this registration app, eligibility criteria were checked, basic demographic and individual health data were collected as a FHIR resource (*QuestionnaireResponse*). Information concerning the study was provided both in textual and audiovisual format. Considering the target population of elderly participants, special attention was paid to increase usability (e.g., button size, colour contrast, font size). Health-related questions were aided with tooltips explaining medical information in layman's terms via a digital persona to improve accuracy of participants-generated responses. The registration app concluded with a placeholder screen to the simulated randomisation result and final instructions how to proceed

within the study workflow. Instructions were individualised for used platform (desktop vs. mobile) and operating system (e.g., Android vs. iOS) to simplify the transition to the screening app.

3.2 Screening app

The screening app was developed using the open-source framework Flutter. It is available for Android and iOS.

PPG measurements were implemented by incorporating SDKs provided by FibriCheck. The Camera SDK activates the camera of the mobile phone and checks if a finger is placed on the camera lens. When a finger is detected, the measurement is started, and the PPG signal is calculated from the video stream for 60 seconds. The SDK then provides a JSON object containing the recorded data and additional metadata. This object is sent to the FibriCheck cloud using the Cloud SDK to analyse the PPG signal to detect heart rhythm conditions. The response is a JSON object containing the analysis results. Additionally, a PDF report for the participant is generated which is downloaded and cached. The measurement data, analysis result, and PDF report are attached to a FHIR *DiagnosticReport* and uploaded to the backend service for storage. To show a list of historical measurements, the backend service can provide a FHIR Bundle containing the *DiagnosticReports* of previous measurements.

Figure 2 provides an overview of the architecture of the screening app and the interfaces to the FibriCheck solutions.

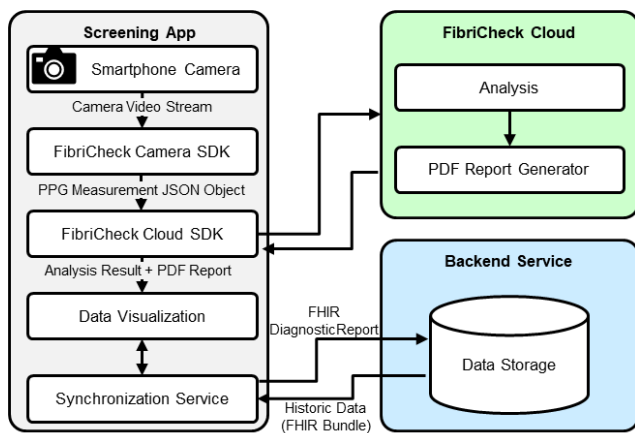


Fig. 2: Overview of the architecture of the screening app and its interconnection with the medical-device-certified FibriCheck SDKs

3.3 Pilot study

Both mobile apps were tested in a small-scale pilot study at two study centres: the University Clinic of Internal Medicine III/ Cardiology and Angiology – Medical University

Innsbruck and the Division of Cardiology, Department of Internal Medicine, Medical University of Graz (MUG). Participants were recruited during 11/2024 – 04/2025. The pilot study was approved by the ethics committee of the MUI (vote nr. 1066/2023) and the ethics committee of the MUG (vote nr. EK 1066/2024). Initial results based on testing with 120 patients aged 65-85 years (33 (28%) female) indicated, that self-registration and PPG self-measurement are feasible. Several suggestions for improvements were identified in terms of a) app design, b) instructions presented in textual, graphical and video-based format, and c) the overall process of registration and self-measurement. Relevant trends can be summarised as follows: Participants preferred breaking up input fields over multiple screens (i.e., max 2-3 inputs per screen), automatically displaying information after a period of inactivity was generally well-perceived and medical wordings must be chosen extremely carefully as low health literacy should be assumed. These suggestions will be considered in the subsequent release of the apps.

4 Discussion

During the design phase of our study, we identified that pre-existing PPG-based AF detection apps are valuable for various application scenarios. However, usage of such an app without any modification is not feasible in a large-scale centre-less study. Further on, we found that separation of the two most important processes of our study – participant self-registration and PPG measurement – into two dedicated apps, developed in different app technologies, seems suitable and feasible. Although this design is related to increased efforts for development and maintenance, we consider the advantages in terms of usability high enough to accept these costs.

Integration of the two FibriCheck SDKs for PPG measurement and for rhythm classification into the AF screening Flutter app was possible with reasonable efforts in terms of development, legal, and ethical aspects. Results from initial pilot testing with 120 cardiac patients revealed minor areas for improvement, but did not identify any major barriers of the overall concept for the next project phases.

So far, the apps have been tested with 120 patients in an in-clinic setting only. No home-based scenarios were tested yet. When there were problems, study-assistants could support the participants to solve the problems and continue with the registration / screening process. During the planned large-scale study, this whole process will need to be conducted without any personal support, except for information provided by the app, videos, etc. While in the large-scale study, the target population will represent citizens with typically no

known cardiac disease, the pilot study focussed on cardiac patients registered at the department of cardiology of the Medical University Innsbruck. All these patients were asked to evaluate the registration and the screening app, without any randomisation in place. This process will need to be adapted for the large-scale study, where randomisation will be implemented after registration, with only the intervention group being equipped with the screening app.

Until Q1/2026, the current versions of the apps will be further developed, considering the outcomes of the results presented here. Subsequent versions of the apps will be validated in further pilot studies. In parallel, we are finalising the study protocol of the planned large-scale centreless controlled randomised study, which is planned to be started in Q2/2026, with the overall aim to evaluate whether PPG-based AF screening via smartphones can reduce strokes in Austria.

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