

The Acceptability of Wearables for Atrial Fibrillation Screening: Interim Analysis of the SAFER Wearables Study

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Abstract

We report an interim analysis of the SAFER Wearables Study, a study assessing the acceptability of wearables for atrial fibrillation (AF) screening. The aim was to identify factors influencing the acceptability of wearables in older adults. The study enrolled community-dwelling adults aged 65 and over, who were asked to wear three wearable rhythm monitoring devices for one week: two wrist-worn devices similar to a smartwatch and a fitness tracker, and a chest patch. Feedback on device acceptability was collected via a questionnaire and informal telephone discussions. 95% of the 21 participants reported being happy to wear any of the devices for one week. However, 24% of participants removed the chest patch early due to skin irritation, and 38% reported that it caused skin irritation. Several strategies to improve acceptability were identified from the feedback. The findings provide insight into factors influencing the acceptability of wearables in older adults, a target population for AF screening.

1. Introduction

Systematic screening for atrial fibrillation (AF) holds promise for improving diagnosis rates and reducing stroke risk through subsequent anticoagulation. Wearable devices could enhance or complement existing approaches to AF screening [1], with potential utility for detecting AF and measuring AF burden. However, there is limited research on the acceptability of wearables in older adults.

The SAFER Wearables Study is an ongoing study of the acceptability and performance of wearables for AF screening in older adults. As of April 2024, 21 out of the planned 130 participants had completed the study, providing op-

portunity for an interim analysis. The aim of the interim analysis reported in this paper was to identify factors influencing the acceptability of wearables in this population. This was intended to provide novel insights into factors influencing the acceptability of wearables in older adults, and to inform potential improvements to the study design.

2. Methods

2.1. Participants

The SAFER Wearables Study is enrolling community-dwelling adults aged 65 and over who have previously been screened for AF in the SAFER Programme [2]. To be eligible, potential participants had to be living in private accommodation. The exclusion criteria were: regularly sleeps on front; has a chest wound; previous reaction to, or known allergy to ECG electrodes or silicone; receiving palliative care; and (introduced during the study) has an implantable device (e.g. pacemaker).

Potential participants were invited by two general practices. Those who did not want to take part could provide reasons in a reply slip. Participants provided written informed consent. Ethical approval was provided by the 'East Midlands - Leicester Central NHS Research Ethics Committee' (Rec ref. 20/EM/0255, IRAS 283812). The study is registered at *ClinicalTrials.gov* ([NCT04715555](https://clinicaltrials.gov/ct2/show/study/NCT04715555)).

2.2. Study Procedures

Participants were sent a device pack by mail. Instructions for attaching and using the devices were provided through: (i) a written instruction leaflet; and (ii) a telephone call prior to attaching the devices. Participants were asked to wear all three devices simultaneously for one



Figure 1. The wearables under test: (a) PulseOn Arrhythmia Monitor (Pulseon Arr); (b) PulseOn Optical Heart Rate Tracker (PulseOn OHR); and (c) Bittium Faros 180 chest patch (Faros 180).

week, with the option of removing devices early. At the end of the week, participants completed a questionnaire on their experience of wearing the devices, modelled on the approach in [3]. Informal feedback was collected via telephone calls (typically one call after 2-3 days, one at the end of the week, and occasional additional calls if required).

2.3. Wearable Devices

The three wearable devices used are shown in Fig. 1. The wrist-worn PulseOn Arrhythmia Monitor (PulseOn Arr) device [4] has a similar form factor to a smartwatch without a screen (see Fig. 1(a)). It was used to acquire 30-second, single-lead electrocardiograms (ECGs) corresponding to lead I from the wrist and opposite hand using dry electrodes, and to acquire continuous photoplethysmogram (PPG) signals. The device was configured to vibrate four times per day to prompt the user to record an ECG at 09:00, 12:00, 16:00, and 20:00. It also vibrated if an irregular pulse was detected on the PPG to prompt ECG recording during a possible AF episode (with reduced frequency of vibrations overnight from 22:00 to 06:00).

The wrist-worn PulseOn Optical Heart Rate Tracker (PulseOn OHR) device has a similar form to a wristband (see Fig. 1(b)). It was used to acquire inter-beat-interval data via intermittent PPG measurements every five minutes. The device's display remains turned off unless the user presses a button, when it illuminates for a short time.

The Bittium Faros 180 chest patch (Faros 180) (Fig. 1 (c)) recorded a continuous, single-lead ECG (Bittium, Oulu, Finland). Disposable Blue Sensor VLC wet gel Ag/AgCl electrodes were used (Ambu A/S, Ballerup, Denmark). Participants were provided with spare electrodes, and encouraged to replace electrodes after 3-4 days and additionally as required. The device was configured to record ECG at 125 Hz, without accelerometry, to begin recording on skin contact, with low battery alarms disabled.

The PulseOn Arr and Faros 180 devices are waterproof and their battery life was expected to be approximately one week. In contrast, the PulseOn OHR device is not water-

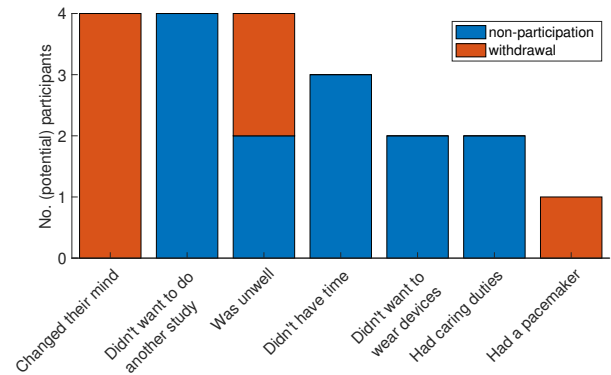


Figure 2. Reasons for not wearing devices, consisting of: reasons for non-participation, and reasons for withdrawal.

proof, so participants were instructed to remove it before washing. Its battery life was expected to be 4-5 days.

3. Results

3.1. Recruitment and Participation

A total of 75 potential participants were invited, 42 of whom consented to take part (56%). Out of the 33 who did not consent, 10 (30%) provided reasons for not wanting to take part. Out of the 42 who consented to take part, 7 (17%) withdrew between consenting and wearing the devices. At the time of performing this interim analysis, 21 of the remaining 35 participants had completed the study.

The reasons for not wanting to take part and withdrawing from the study are summarised in Fig. 2. Four (potential) participants did not want to take part, or withdrew, because they were unwell; and two potential participants did not want to take part because of caring duties. Four participants withdrew after changing their mind, which was likely influenced by unintended delays of several months between initial consent and sending devices.

3.2. Formal feedback

Formal feedback was collected by questionnaire. Out of 21 respondents, five (24%) reported permanently removing the Faros 180 before the end of the seven days because it was causing skin irritation, compared to one for each of the PulseOn Arr and OHR devices. Three reported permanently removing the PulseOn OHR because it had run out of battery. One reported permanently removing the PulseOn Arr because it vibrated at night. Participants also reported removing devices temporarily: to avoid damaging them; because the Faros 180 caused skin irritation; and because the PulseOn Arr vibrated at night.

Fig. 3 presents the results of selected questions from the questionnaire. Most respondents would be happy to wear any of the devices for a week (Fig. 3 (a)). However, there was a trend towards participants preferring the wrist-worn devices (PulseOn Arr and PulseOn OHR) over the Faros 180, as shown by more participants reporting that: (i) the Faros 180 or wristband interfered with their daily activities (b); (ii) the Faros 180 was uncomfortable (c); and (iv) the Faros 180 came off accidentally (d). This trend may have been linked to skin irritation (f). Conversely, more participants reported that the PulseOn Arr device disturbed sleep (e), perhaps as a result of it vibrating at night.

3.3. Informal feedback

The informal feedback captured in telephone discussions is summarised in Table 1. Regarding the Faros 180: eight participants (38%) said it caused skin irritation. Other issues included electrodes becoming detached, and the form factor not suiting women. Regarding the PulseOn Arr device: some participants reported that it did not vibrate at night, whereas others reported that it did. Some participants removed the device at nighttime. Some believed they accidentally set off the device, whilst others didn't notice it vibrating. Regarding the PulseOn OHR device: some participants noticed when its battery ran out.

Table 1. The sentiments expressed in informal feedback by at least two participants.

Sentiment	No. participants (%)
Faros 180 caused skin irritation	8 (38)
Faros 180 electrode detached	4 (19)
Found all devices comfortable	4 (19)
PulseOn Arr vibrated at night	4 (19)
PulseOn Arr set off accidentally	4 (19)
Faros 180 not ideal for women	3 (14)
Didn't notice PulseOn Arr vibrating	3 (14)
PulseOn OHR battery ran out	3 (14)
PulseOn Arr did not vibrate at night	2 (10)

4. Discussion

The main finding of this interim analysis was that most participants would be happy to wear any of the devices for one week. However, the Faros 180 chest patch was not ideal for monitoring over one week: 24% of participants removed it early due to skin irritation, and many (38%) reported that it caused skin irritation. In addition there were concerns over the suitability of its form factor for women. There was a general preference for the wrist-worn devices over the Faros 180, with most participants tolerating both the smartwatch-style device which prompted the user to record ECGs, and the passive wristband-style device. However, some participants removed the wrist-worn ECG device overnight to avoid being woken up by it.

This analysis informs several potential strategies to increase acceptability. First, it may be helpful to use different chest patch electrodes or locations, such as locations for lead I, lead II, or alternative leads suitable for detecting atrial arrhythmias [5]. These locations may be better tolerated by women, and could provide a greater area of skin for electrode attachment. Skin irritation could be reduced if participants varied the electrode position slightly during the week. Second, the PulseOn Arr device's nighttime vibrations should be investigated: if due to an irregular pulse then they could be beneficial, otherwise if due to accidental activation then it may be helpful to inform participants that the device activates if it contacts another part of the body. It would be particularly important to ensure the acceptability of wearables at nighttime if used to detect sleep apnea. Third, informal feedback collection should continue, as it appears a helpful addition. For instance, several more participants reported that the Faros 180 caused skin irritation during informal discussions than in the questionnaire. Fourth, the willingness of participants to wear devices can vary over time, and it is therefore important to minimise the time between initial consent and asking participants to wear devices. Finally, the utility of the Faros 180 data could be increased by increasing the ECG sampling rate (e.g. to 500 Hz) and capturing accelerometry signals.

Key limitations are as follows. First, the study had a one-week duration, whereas it may be of interest to understand their acceptability over longer timeframes. Future participants could be asked whether they would have been happy to wear devices for longer. Second, participants wore three devices simultaneously which may have resulted in the reported acceptability of each device being lower than when wearing only one device.

5. Conclusion

Wearable devices were tolerated for one week by older adults, although the chest patch's electrodes caused skin irritation leading to some participants removing it. Several

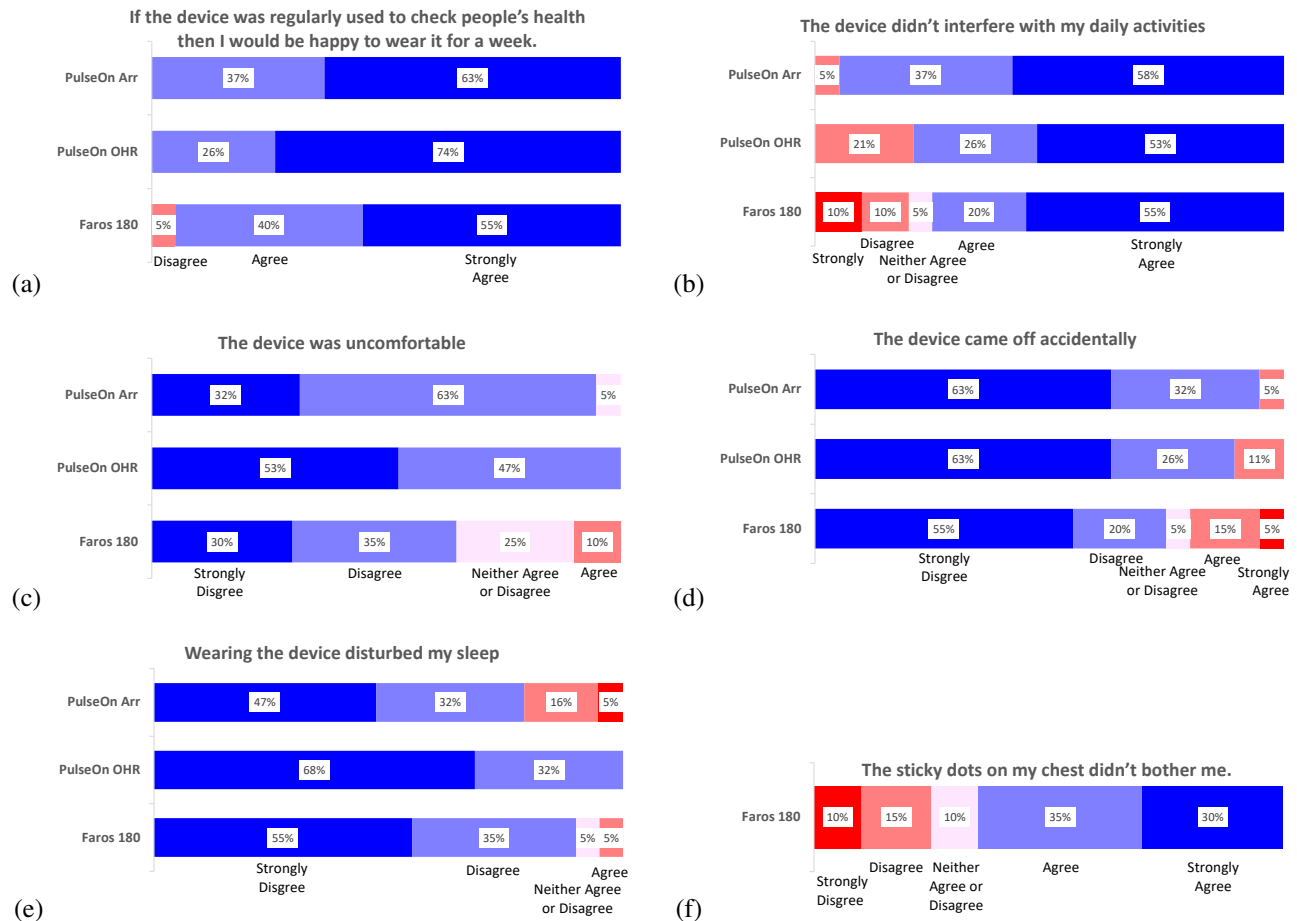


Figure 3. Participants' questionnaire responses.

strategies to increase acceptability were identified.

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