Heart rhythm assessment in elite endurance athletes: A better method?

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ABBREVIATIONS

In order of appearance

CVD	Cardiovascular diseases
CA	Cardiac arrhythmia
AF	Atrial Fibrillation
SCD	Sudden cardiac death
ECG	Electrocardiogram
BA	Benign arrhythmia
MA	Malignant arrhythmia
HR	Heart rate
PAC	Premature atrial complex
PVC	Premature ventricular complex
HCM	Hypertrophic cardiomyopathy
ARVD	Arrhythmogenic right ventricular dysplasia
AV-block	Atrioventricular block
AV-node	Atrioventricular node
SVT	Supraventricular tachycardia
VT	Ventricular tachycardia
MH	Medical history
EST	Exercise stress test

ABSTRACT:

BACKGROUND: Cardiac arrhythmias (CA), especially atrial fibrillation (AF), are relatively common among elite endurance athletes. Conventional diagnostic tools for assessment of rhythm disorders suffer from limited availability, limited test duration time, and usability challenges, particularly under the demanding training conditions of an elite athlete. The current study aimed to evaluate (1) the relationships among training characteristics and health experiences in a large, representative sample of endurance athletes (2) the validity and functionality of the newly developed ECG247 Smart Heart Sensor in an elite athlete training environment.

METHODS: A web-based questionnaire quantifying the relationship between training characteristics and health experiences was developed and delivered in digital format. A total of 1802 men and women completed the questionnaire. In addition, 13 professional cyclists from the UNO-X Pro Cycling Team were examined with the ECG247 Smart Heart Sensor during a 14-day training camp in Spain, December 2021. All ECG data were analyzed by cardiologists at Sørlandet Hospital Arendal, Norway. The athletes also completed a brief questionnaire registering their training (from on-bike monitoring units) and self-assessment of usability parameters after the test.

RESULTS: Diagnosed AF was reported by 52 of the 1802 endurance athletes surveyed (2.9%). Age, annual endurance volume, and subjective performance level were significant predictors for diagnosed AF. During the ECG sensor field test, average continuous ECG test duration was 89±24hours, including an average of 15±5 training hours during each test. The ECG quality from all tests was considered satisfactory for rhythm analysis – also during exercise. The reported usability of the ECG247 Smart Heart Sensor was high. The automatic arrhythmia algorithm reported possible arrhythmia events in 10 of 21 tests (48%); 9 atrial flutter and 4 supraventricular tachycardia. Retrospective manual assessment by physicians revealed normal sinus rhythm in all tests with these false positive events observed during training when heart rate was elevated. No false negative findings were observed.

CONCLUSION: Based on the survey of 1802 endurance athletes, prevalence of diagnosed AF increased with performance level and annual training hours, supporting the need for better ECG monitoring tools. The ECG247 Smart Heart Sensor allowed for high quality ECG monitoring during intensive exercise in athletes. The integrated arrhythmia analyzing algorithm can be further optimized for endurance athletes to reduce false positives associated with the normal “tachycardia” of endurance training.

KEYWORDS: Endurance, Endurance athletes, Atrial Fibrillation, Electrocardiogram, Cardiac screening, cardiovascular diseases in athletes.

SAMMENDRAG:

BAKGRUNN: Hjertearytmier, spesielt atrieflimmer (AF) er normalt blant profesjonelle utholdenhetsutøvere. Konvensjonelle diagnostiseringsverktøy for evaluering av rytmeforstyrrelser er begrenset med tanke på tilgjengelighet, begrenset testvarighet og brukervennlighetsutfordringer. Denne studien sikter mot å evaluere (1) forholdet mellom treningskarateristikk og helseerfaringer i et større, representativt utvalg av utholdenhetsutøvere (2) validiteten og funksjonaliteten av det nye utviklede ECG247 Smart Heart Sensor™ i en profesjonell utøvers treningsmiljø.

METODE: Et digitalt spørreskjema som kvantifiserer sammenhengen mellom treningskarakteristikk og helseerfaringer ble utviklet og utlevert i digitalt format. Totalt 1802 menn og kvinner svarte på spørreskjemaet. I tillegg ble totalt 13 profesjonelle syklister ved UNO-X Pro Cycling Team undersøkt kontinuerlig med ECG247 Smart Heart Sensor™ under en treningssamling i Spania, desember 2021 ved bruk av automatisert algoritmisk deteksjon av arytmihendelser. De samme EKG-dataene ble også analysert av sertifiserte kardiologer ved Sørlandet Sykehus Arendal. Idrettsutøvere fullførte et kort spørreskjema som registrerte treningen deres (fra overvåkingsenheter på sykkel), og utførte en egenvurdering av brukervennlighetsparameterne til EKG-enheten og applikasjonen etter testen.

RESULTATER: Diagnostisert AF ble rapportert av 52 av de 1802 utholdenhetsutøvere (2.9%). Alder, årlig utholdenhetstreningsvolum og subjektivt prestasjonsnivå var signifikante prediktorer ($p=0.001$) for diagnostisert AF. Under EKG-testen var gjennomsnittlig testvarighet var 89±24 timer, inkludert et gjennomsnitt på 15±5 treningstimer under hver test. EKG-kvaliteten fra alle tester ble ansett som tilfredsstillende for rytmeanalyse, også under trening. Den rapporterte brukervennligheten til ECG247 Smart Heart Sensor var høy. Den automatiske arytmialgoritmen rapporterte mulige arytmihendelser i 13 (62%) tester; 9 atrieflutter og 4 supraventrikulær takykardi. Retrospektiv manuell vurdering av leger avslørte normal sinusrytme i alle tester med disse falske positive hendelsene observert under trening når hjertefrekvensen var forhøyet. Ingen falske negative funn ble observert.

KONKLUSJON: Prevalensen av diagnostisert AF steg ved prestasjonsnivå og årlig treningstimer, noe som støtter behovet for et bedre EKG-målingsverktøy. ECG247 Smart Heart Sensor™ viste høykvalitets EKG-opptak under intensiv trening. Den integrerte arytmianalyseringsalgoritmen kan bli optimalisert for denne gruppen for å redusere antallet falske positive tilfeller assosiert med normal «takykardi» av utholdenhetstrening.

NØKKELORD: Utholdenhet, Utholdenhetsutøvere, Atrieflimmer, Elektrokardiogram, Kardiologisk helsesjekk, kardiovaskulære lidelser i utøvere.

STRUCTURE OF THESIS

This thesis consists of three parts:

Part 1 presents the theoretical background for the study, a methodological chapter of how the study was performed, and a chapter discussing the methodology.

Part 2 presents a research paper, written in accordance with the guidelines from the open access journal of Frontiers in Sports and Active Living. Part 2 consists of an IMRAD style manuscript: introduction, methods, results, discussion, and conclusion.

Part 3 consists of appendices. Approvals, informed consents, etc.

PART 1

THEORETICAL BACKGROUND AND METHODS

Ådne Ausland

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1.0 Introduction

The importance of large volumes of training to perform at a high level in endurance sports is well documented among elite athletes (Seiler, 2010; Stöggl & Sperlich, 2015; Tønnessen et al., 2014). Elite endurance athletes' annual training volume typically ranges from 500 to well above 1000 hours (Billat et al., 2001; Metcalfe et al., 2017; Tønnessen et al., 2014). Endurance training is also well-established as one of the most efficacious methods of reducing the risk of developing cardiovascular diseases (CVD). However, there are a growing number of studies suggesting that "excessive" long-lasting and high-volume endurance training may paradoxically *increase* the risk of developing CVD and particularly, specific cardiac arrhythmias (CA). (Goodman et al., 2015; Madias, 2008). Atrial Fibrillation (AF) is one of the most common CA reported among endurance athletes and presents an increasing global health challenge. AF incidence in athletes has recently generated considerable research interest (Andersen et al., 2013; Grimsmo et al., 2011; Lippi et al., 2021; Newman et al., 2021; Sanchis-Gomar et al., 2016). Unfortunately, several episodes of sudden cardiac death (SCD) in sport events due to non-detected CVD or CA have been reported (Goodman et al., 2015; Puffer & Thompson, 2002). Evidence suggests that detecting CVD early can prevent the most serious outcomes of CA and raise awareness among athletes, which again may lead to the athletes remaining calmer in the event of acute CA (Morseth et al., 2018).

Today's gold-standard for diagnosing CA in the general population is a 12-lead electrocardiogram (ECG). A 12-lead ECG is performed by healthcare personnel in a clinical setting and provides a time-limited snapshot of the heart's electrical function. Some specific CA can be highly transient, such as AF, and a clinical 12-lead ECG recording period lasting only a few minutes may fail to detect underlying CA. Continuous ECG-recordings are needed to detect and diagnose specific CA types, including AF, and the equipment used for long-term ECG recordings is often referred to as "Holter monitoring". A Holter monitor system typically requires a recording device worn on the hip and coupled to at least three cables attached to electrodes on the chest. The system is applied to the patient by healthcare personnel and has a limited battery capacity. It is therefore usually worn for ~24-48 hours (Lutfullin et al., 2013). The system is not water repellent, and the cables are movement sensitive. Consequently, the Holter monitor system may limit movements and can loosen or detach with physical activity and hard exercise.

For an elite athlete training daily, the prescription of a Holter monitoring period will disturb training, or completely prevent the athlete from training, thereby decreasing the validity of the ECG monitoring process. Cardiac arrythmias among elite athletes often occur during exercise. Because Holter monitoring loses ECG signal quality during movement, this may limit the intensity or continuity of the exercise (Baggish et al., 2017). 12-lead ECG and Holter monitoring are dependent on assistance from healthcare personnel, and therefore are subject to limited availability, limited test duration time, and usability challenges. In the context of a high-performance endurance sport team, cardiac screening with today's clinical tools becomes so time consuming that it may be intentionally avoided by athletes and coaches despite the appearance of symptoms of concern.

ECG247™ Smart Heart Sensor is a new, mobile, long-term ECG monitoring device that has undergone extensive testing in a home health care setting (Jortveit & Fensli, 2022; Jortveit et al., 2022; Sandberg et al., 2021) and is approved by European directives for medical devices (Appendix 1). According to their website, the ECG247™ device provides continuous monitoring of the heart for up to 7 days and can be used during exercise, as well as tolerating showers. The device is small, wireless, and easy to apply and use without any clinical expertise or assistance (Appsens, 2021). All the data acquired by the sensor is stored through a smartphone application and can be easily downloaded. Acquired ECG data can be transferred from the application directly to a doctor and cardiologist. The user also has real-time feedback regarding their cardiac function during testing. The ECG sensor patch is applied over the sternum and remains attached through the whole monitoring period. Monitoring duration is limited by the integrity of the attachment of the sensor patch to the skin over time (up to 7 days). ECG247 Smart Heart Sensor has not been systematically tested on athletes. If this technology withstands the rough use of elite athletes, it could provide a unique, new method of athlete screening and cardiac monitoring that would dramatically simplify cardiac screening for athletes and induce less stress in athletes subjected to this form of testing.

1.1 Overall goal and purpose

The main goals of this research project were therefore:

1. To investigate a large and diverse sample of endurance athletes and quantify the relationships among their training characteristics and health experiences, including CA and CVD.
2. To evaluate how the ECG247 Smart Heart Sensor technical solution performs in a field setting representative of the demands of high-performance endurance athletes during daily training.
3. To investigate the elite endurance athletes' perception of comfort and usability under the same field conditions and evaluate the overall effectiveness and ease of use of this novel ECG monitoring technology.

2.0 Theoretical framework

2.1 Endurance Sport

Endurance is the capacity to sustain a given velocity or power output for the longest possible time (Jones & Carter, 2000). Endurance sports are characterized by repeated isotonic contractions of large skeletal muscle groups, predominantly fueled by aerobic energy metabolism (Kiely, 2017). A typical endurance sport event involves a race from a start line to a finish line; the fastest participant wins and reaching the finish line requires from 3-4 minutes to several hours. The similarity among these events is that the predominant source of energy metabolism is oxidative metabolism (Coyle, 1999). Despite a 100x range in event duration within "Olympic endurance events", training content across the different endurance sports disciplines is more similar than different. Endurance training involves manipulation of intensity, duration, and frequency of training sessions over days, weeks, and months (Seiler, 2010). Elite endurance athletes annual training load ranges from 500 to well above 1000 hours (Billat et al., 2001; Metcalfe et al., 2017; Tønnessen et al., 2014). The total impact of the training will be determined by the specific muscular loading characteristics of the endurance sport together with the training volume and training intensity distribution (Tønnessen et al., 2014).

2.1.1 When it's too much

Athletes live in a repetitive cycle of stress and recovery. Risk factors associated with both physical and psychological health emerge and increase when the total stress load exceeds the individual tolerance and their recovery capacity (Mountjoy et al., 2018). Extreme training loads are required for elite-athlete success, especially in endurance sports (Soligard et al., 2016). Undeniably, acute fatigue, caused by a single training session or a high weekly training load, is a part of a normal training program among endurance athletes (Tønnessen et al., 2014). However, when the total stress load exceeds restitution capacity, this acute fatigue can eventually progress and manifest into a continuum of performance decrements. These performance decrements often start as short-term but can evolve into a long-term decrement and functional deterioration. In parallel with the long-term decrement in performance capacity, the athletes risk developing long-term injuries and/or illnesses that can negatively impact their current sporting career in addition to life after the sport-career (Meeusen et al., 2013; Schwellnus et al., 2016).

2.2 Arrhythmias among athletes

Cardiovascular disease (CVD) is one of the leading causes of death in the western world, taking an estimated 17.9 million lives each year (Collaborators, 2017). Physical activity and high levels of aerobic capacity are associated with reduced risk of CVD and cardiovascular mortality (Fletcher 1996). Endurance training is the most efficient form of exercise for developing aerobic capacity (Coyle, 1999). On the other hand, chronic endurance training can induce a number of physiological and structural changes to the myocardium, which can in turn increase the likelihood of developing some specific heart arrhythmias (Newman et al., 2021).

Cardiac arrhythmia (CA) is any change in the heart rhythm, i.e., in the pattern of electrical depolarization and repolarization of the myocardium precipitating pump function. The change may be physiological or pathological (Puffer & Thompson, 2002). Arrhythmias vary widely regarding the type and the symptoms. In short, we distinguish these electrical disruptions into two broad categories: benign and malignant. A benign arrhythmia (BA) causes neither symptoms nor hemodynamic dysfunction and has no prognostic significance (Biffi et al., 2008). In contrast, a malignant arrhythmia (MA) is potentially life-threatening and requires medical attention with subsequent treatment. About 5% of detected arrhythmias are MA and are often associated with underlying organic heart disease. However, a MA can also develop in isolation, without additional cardiac disorders (Wu et al., 2020). High performance endurance athletes expose their heart and lungs to many hours per week of high cardiac output, accompanied by substantial increases in both ventricular filling (preload) and systolic pressure (afterload). High cardiovascular training loads may increase the risk of developing specific arrhythmias (Goodman et al., 2015).

2.2.1 Atrial Fibrillation and Flutter

Atrial fibrillation (AF) is the most commonly diagnosed malignant arrhythmia (Lippi et al., 2021), with an increasing prevalence (Svendsen et al., 2021). AF is described as electrical chaos localized in the atria and causing a rapid, irregular heart rate (HR). AF can present as intermittent, persistent, or chronic (figure 1b). Untreated AF is associated with increased risk of stroke, heart failure, and other sequalae. Atrial flutter is similar to AF, but heartbeats remain more organized. However, Atrial flutter is also associated with increased risk of stroke and heart failure and requires equal medical treatment as AF. Atrial Flutter will in this article also be referred to as AF.

The incidence of AF in athletes has been a recent theme of considerable research interest. However, the subjects in these various studies include both elite and non-elite athletes practicing different types of endurance-training like orienteering, distance running, road cycling, and cross-country skiing.

Of 52755 finishers of the annual 90km Vasaloppet cross-country ski race, AF (7,6%) was the most frequently detected arrhythmia over a 10-year follow-up, independent of age and the performance level of the athletes (Andersen et al., 2013). Finishers who had completed the race five times or more were 29% more likely to have experienced AF than those who completed the race only once. Further, finishers who had the fastest finishing time were 30% more likely to have experienced AF than finishers in the slowest group (Andersen et al., 2013). A similar study analyzing data from skiers aged 65 years and older who had participated in the Norwegian Birkebeiner cross-country ski race, found that the skiers were 1.9 times more likely to have AF than an age-matched control group (Myrstad et al., 2014). In parallel with these two studies there are several investigations reporting a greater risk of AF in athletes compared with non-athletes, especially athletes in endurance sports (Andersen et al., 2013; Grimsmo et al., 2011; Lippi et al., 2021; Newman et al., 2021; Sanchis-Gomar et al., 2016).

2.2.2 Athlete's Heart and Sudden Cardiac Death in athletes

Long-term aerobic training generally increases the heart's mass and volume with greater left-ventricular and diastolic volumes both at rest and during vigorous physical activity (Chugh & Weiss, 2015). Moderate cardiac hypertrophy secondary to longitudinal myocardial cell enlargement reflects a fundamental and normal training adaptation of muscle to an increased workload, independent of age (Sanchis-Gomar et al., 2016). The term "athlete's heart" is commonly used for this functional enlargement and is characterized by an increased size of the left-ventricular cavity (eccentric hypertrophy) and modest proportional thickening of the ventricular walls (concentric hypertrophy) due to training (Puffer & Thompson, 2002). The reversible development of this otherwise functional and adaptive "athlete's heart" may increase the chance for some specific arrhythmia, both benign and malignant, including both bradycardia (slow HR) and tachycardia (fast HR) (Biffi et al., 2008). Resting bradycardia is common in trained endurance athletes and HR values below 30 beats per minute during night are reported (Friman & Wesslén, 2000).

Premature heart contractions are “extra” beats that occur one at a time, or sometimes in patterns that alternate with the normal heartbeat (Chugh & Weiss, 2015). The premature beats may occur in atria (PAC) or the ventricles (PVC). A PAC (figure 1c) or PVC (figure 1d) is often described as a “skipped beat.” PVCs and PACs are common and often benign arrythmias which do not require investigation or treatment. However, a PVC/PAC can trigger a longer-lasting arrhythmia, especially in athletes with underlying heart disease (Grimsmo et al., 2011).

Sudden cardiac death (SCD) during exercise is caused by cardiac arrest, a sudden cessation of the heart’s electrical signaling pattern (Goodman et al., 2015). SCD among athletes is very rare and difficult to prevent due to lack of detected symptoms preceding the fatal event (Chugh & Weiss, 2015). The most common cause of SCD is hypertrophic cardiomyopathy (HCM). HCM is a cardiomyopathy with varying degree of hypertrophy of the left ventricle, often with obstruction of the left ventricle and restriction of the left ventricular outflow tract (Biffi et al., 2008). The mechanism for sudden death is presumably malignant ventricular arrhythmias, although extreme bradycardia also may occur. Subjects with suspected HCM should not exercise and should be investigated; A risk assessment should be made; if an athlete wants to continue training at a high-level, treatment with an implantable defibrillator may be warranted (Goodman et al., 2015). In addition, arrhythmogenic right ventricular dysplasia (ARVD) is associated with SCD among athletes (Heidbuchel et al., 2012). ARVD is a rare disease in the myocardium of the right ventricle where muscle tissue in the right ventricle is replaced with fibrous and fatty tissue. It is of utmost importance to recognize and diagnose these rare but potentially fatal conditions in athletes early. These patients should be restricted from sports, and implantable defibrillator treatment may be warranted (James et al., 2013).

2.2.3 Atrioventricular block in athletes

Atrioventricular block (AV-block) is an interruption or delay of electrical conduction from the atria to the ventricles due to conduction system abnormalities in the atrioventricular node (AV-node) or the His-Purklinje system (Mesirca et al., 2021). Conduction delay or block can be physiological if the atrial rate is abnormally fast or pathologic at normal atrial rates. AV-block is generally defined based on a regular atrial rhythm.

In short, AV-block is categorized as 1st degree, 2nd degree subtitled in Mobitz 1 and Mobitz 2, and 3rd degree. First degree AV-block can originate from various locations within the heart's electrical conduction system. The locations of conduction delay include the atrium, AV-node (most common in first-degree heart block), Bundle of His, bundle branches, fascicles, and Purkinje system. Mobitz type I second degree AV-block usually occurs within the AV-block while Mobitz type II second degree AV-block mainly originates from conduction system disease below the level of the AV-node (in the bundle of His and in the bundle branches). In third-degree (complete) AV-block, no atrial impulses (the ECG P-wave) reach the ventricle. This block can occur in the AV-node or in the intranodal specialized conduction system (Brignole et al., 2011). 1st degree AV-block and Mobitz 1 are often diagnosed in athletes and associated with high volumes of endurance training (Mesirca et al., 2021). However, the observations are made without any other symptoms and these arrythmias are normally benign. In contrast, when Mobitz 2 or 3rd degree AV-block is detected in any athletes, they are advised to be treated with an implantable defibrillator which responds when a complete AV-block occurs (Mesirca et al., 2021; Svendsen et al., 2021).

2.2.4 Supraventricular and ventricular tachycardia in athletes

Supraventricular tachycardia (SVT) is a broad term for arrhythmias with high HR that start in the atrium (sitting *above* the ventricles) (Zimmermann & Lutter, 2020). SVT (Figure 1E) causes episodes of a pounding heartbeat (palpitations) that begin and end abruptly. It is more common in older patients with heart diseases and is less common in younger athletic populations, unless there is a known heart condition (Pelliccia et al., 2005). However, these arrhythmias are generally considered relatively benign but, depending on the situation, the abrupt onset can make them dangerous, such as during exercise or competition (Link & Mark Estes, 2010). Athletes have not reported a higher prevalence of developing SVTs compared with the general population (Pelliccia et al., 2005).

In contrast, ventricular tachycardia (VT) is a broad term for arrhythmias with high HR that starts in the ventricles. VT (Figure 1F) is a heart rhythm disorder caused by abnormal electrical signals in the ventricles. The interference results in a rapid HR that keeps the ventricles from filling completely between contractions, compromising blood flow and oxygen delivery to the body (Madias, 2008). The evidence linking ventricular arrhythmia and endurance sports is weaker than that for atrial arrhythmia.

Ventricular arrhythmias are less common than atrial arrhythmias, in both the general population and among athletes (Priori et al., 2015). In general, atrial arrhythmias are not immediately life-threatening. The same cannot be said for ventricular arrhythmia. While most ventricular arrhythmias in athletes are benign, it is also possible that ventricular arrhythmia may precede the diagnoses of a more severe heart condition (Link & Mark Estes, 2010). PVC and VT can be the first signs of diseases such as HCM and ARVD (Priori et al., 2015).

2.3 Cardiovascular screening of athletes

Baseline cardiovascular screening normally consists of a review of the patient medical history (MH) and a physical examination. The examination includes measurement of blood pressure and taking blood samples. Screening also typically includes an echocardiogram (Echo), resting electrocardiogram (ECG) and an exercise stress test (EST) (Svendsen et al., 2021). The patient's MH is important context to address symptoms as is the health history of near relatives. This history can provide a further understanding of what to focus on clinically. The physical examination provides a good understanding of the current cardiac status at the specific moment of the measurement. An Echocardiogram is basically an ultrasound of the heart providing information of the structural status, and is the clinical gold standard for evaluating HCM, and ARVD, among other structural heart diseases (Biffi et al., 2008). A resting 12-lead ECG is the gold standard for the diagnosis of rhythm disorders, it provides a "picture" of the heart's electrical signals from 12 different angles (Puffer & Thompson, 2002). However, because resting ECG measurements are typically collected over only a few minutes in a doctor's office, some arrhythmias that occur quite sporadically, such as AF, may be missed. Therefore, patient screening is often extended with an EST to challenge the heart with a progressive exercise load, often on a bicycle ergometer or motorized treadmill. The exercise stress test is symptom-limited, meaning the patient continues exercising until it is necessary to stop due to chest discomfort, shortness of breath, dizziness, leg fatigue, or generalized fatigue. The physician may also stop the test due to a decline in systolic blood pressure, development of ventricular arrhythmias, or clear-cut ECG positivity (Heidbuchel et al., 2012). The symptom-limit aspect of the test allows it to be used as a general assessment of exercise tolerance, in addition to an assessment of potential ischemic heart disease.

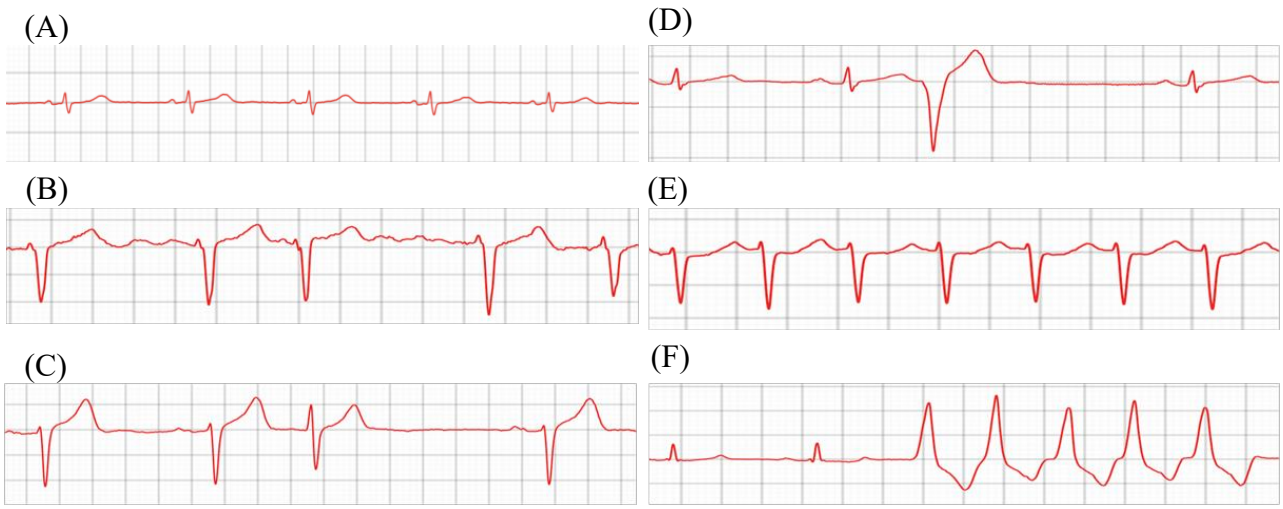


Figure 1. Examples of electrocardiogram excerpts of the following arrhythmias: (A) Electrocardiogram of a heart with a normal sinus rhythm, (B) Typical Atrial Fibrillation, (C) Premature atrial contraction, (D) Premature ventricle contraction, (E) Supraventricular tachycardia, (F) Ventricular tachycardia. All recordings from ECG247 web portal (Appsens, 2022).

2.3.1 Long-term ECG monitoring of athletes

While baseline cardiovascular screening provides an informative evaluation of the current cardiac status, it may fail to capture some arrhythmias or symptomatic events (Sandberg et al., 2021). Therefore, a long-term ECG-recording is often recommended. The most used long-term ECG recording system is the Holter monitor (Figure 2A). Holter-ECG requires a recording device coupled to at least three cables attached to multiple electrodes placed on the chest and is generally worn for 24 to 48 hours due to battery capacity (Kułach et al., 2020). The electrodes must be attached at the hospital, with ECG data collected over several days of wearing the device at home and during daily routines. After this period, the device must be delivered back to the cardiologist for offloading of the ECG data and evaluation. This is a very time-consuming process. The system is bulky and sensitive to both external electric disturbance and movement artifact. In a sport context, the Holter-ECG monitoring approach has major limitations. For instance, the electrodes do not withstand water, so both sweating during exercise and showering after may prematurely shorten the effective duration of the ECG data collection (Sandberg et al., 2021).

Exercise jostles and jiggles wires and electrodes, resulting in disturbance of the ECG signals. These limitations interfere with a lot of the everyday activity of an endurance athlete (Lutfullin et al., 2013).

Today, several systems of long-term ECG monitoring devices are available. These mostly consist of Smart-watches, HR chest straps, and similar devices. These devices may identify cardiac trends that should be further investigated. However, these consumer devices are not approved according to the international guidelines for diagnosis of arrhythmias (Hindricks et al., 2021). The time from an athlete's first symptomatic event to examination can be crucial, the accessibility of the Holter-ECG is limited, and long delays from onset of symptoms to examination may occur (Kułach et al., 2020).

2.3.2 ECG247 Smart Heart Sensor

The ECG247 Smart Heart Sensor (Figure 2B) is a new digital clinical tool for out-of-hospital self-testing of CA which addresses most of the challenges with Holter systems, event recorders, and other devices (Sandberg et al., 2021). The ECG247 Smart Heart Sensor consists of an electrode patch with a lightweight reusable sensor, a smartphone application, a back-end cloud service, and a web portal. The ECG-data can be shared with the patient's doctor through the web-portal, giving the doctor a view over all the data throughout the test. The device has a battery capacity supporting up to 14 days of continuous ECG recording and is water-repellent (Appsens, 2021). This makes it possible to sweat, shower and exercise during a continuous monitoring period. The system is CE certified according to the EU Medical Device Directive (93/42/EEC). However, the device has not been scientifically tested on elite athletes. Therefore, some issues regarding ECG data capture during exercise are not resolved.

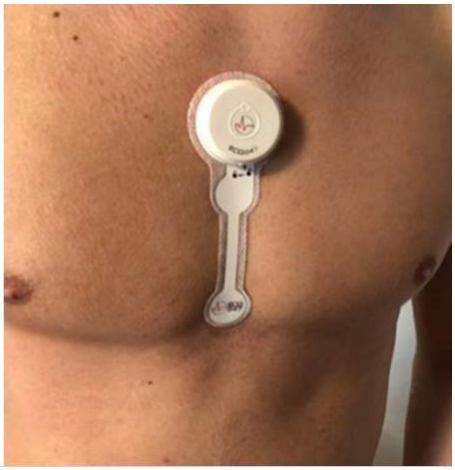
(A)  (B) 

Figure 2. Illustrates two different electrocardiogram devices, (A) Holter monitoring device 5 lead, (B) ECG247 Smart Heart Sensor (Appsens, 2021).

3.0 Methods

3.1 Study design

This master's thesis is a descriptive and observational study in sport science at the University of Agder, Faculty of Health and Sport Science, Department of Sport Science and Physical Education. The project consisted of two separate data sampling methods:

1. A web-based questionnaire (Appendix 2), which investigated endurance athletes and the relationships among their training characteristics and health experiences.
2. A field test of the ECG247 Smart Heart Sensor (Appsens AS, Lillesand, Norway) on elite endurance athletes performing a high volume of endurance training with the goal of evaluating both technical and practical aspects of using this monitoring device in a sports medicine context.

All data collection and testing were performed between November 2021 and January 2022.

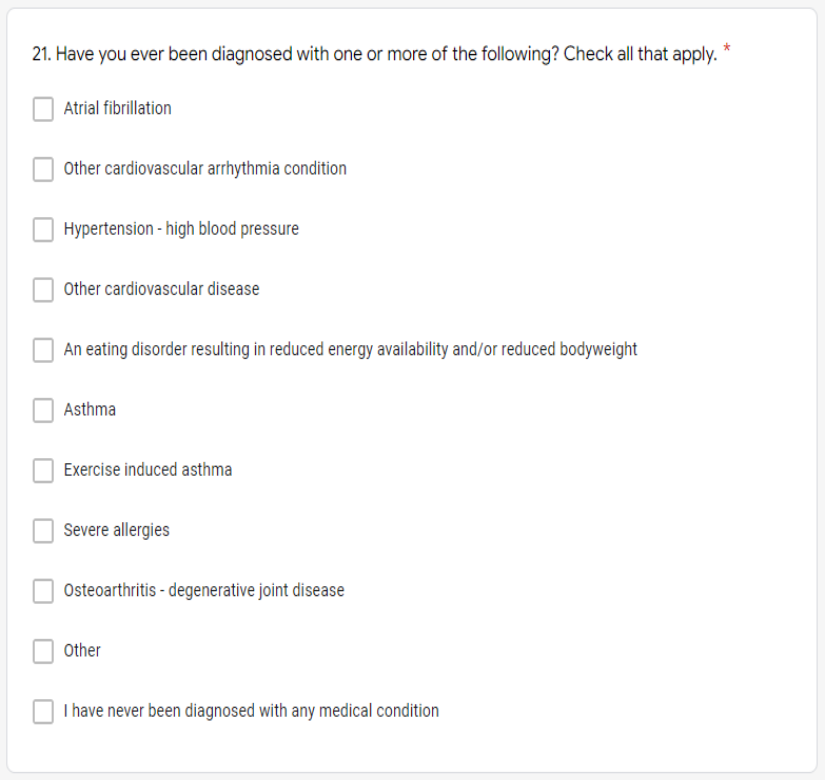
3.2 Web-based Questionnaire

The digital questionnaire investigated endurance athletes and the prevalence of AF, other CA, and other CVDs. The questionnaire consisted of 3 parts:

1. General characteristics of the subjects
2. Training characteristics
3. Health experiences/characteristics

The questions regarding cardiac health were incorporated in the health part of the questionnaire. AF and CA were not in the title or the cover letter (Appendix 3) to prevent participation bias, meaning that athletes that were especially interested or having CVD would be more likely to participate than those who never experienced abnormalities with their heart. The survey also distinguished medically diagnosed conditions from subjective symptomatic events (Figure 3). In the present study, responses to the specific questions regarding cardiac health are presented; remaining results from the questionnaire will be presented elsewhere. Prior to publishing links to the digital questionnaire, pilot testing was conducted on local athletes, colleagues, and fellow master's students to develop and optimize the wording of the questions and minimize the total duration of the questionnaire.

(A)



(B)

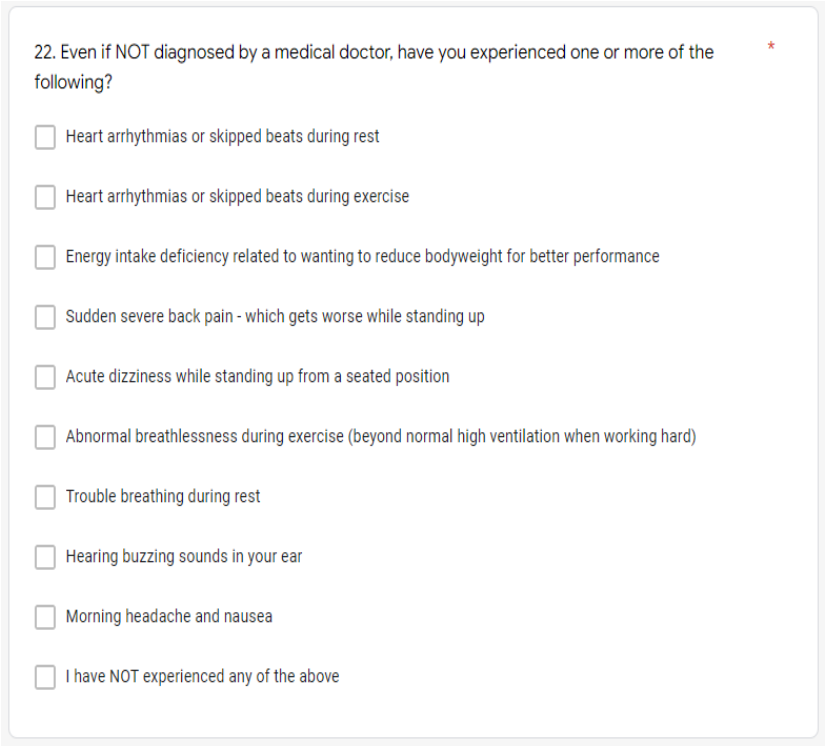


Figure 3: Screenshots of two question groups taken from the questionnaire in Google Forms: (A) Diagnosed conditions, (B) Subjective symptoms.

The digital questionnaire was developed and published in Google Forms (Google, Mountain View, CA, USA). No electronic link between the respondent and their questionnaire responses was possible as this linkage was blocked (Figure 4). The target group consisted of endurance athletes who were at least 18 years, self-described as training regularly, and competing at least occasionally in an endurance sport. Completing the survey required approximately 10-15 minutes. The digital survey was made available from November 8, 2021, and through January 31, 2022. Subjects were recruited via social media (Twitter, Instagram, and Facebook) as well as via targeted emails to sports clubs and organizations in Norway and internationally. A total of 1802 subjects (1342 male, 457 female, 3 non-binary) completed the survey. The characteristics of the participants are presented in Table 1.

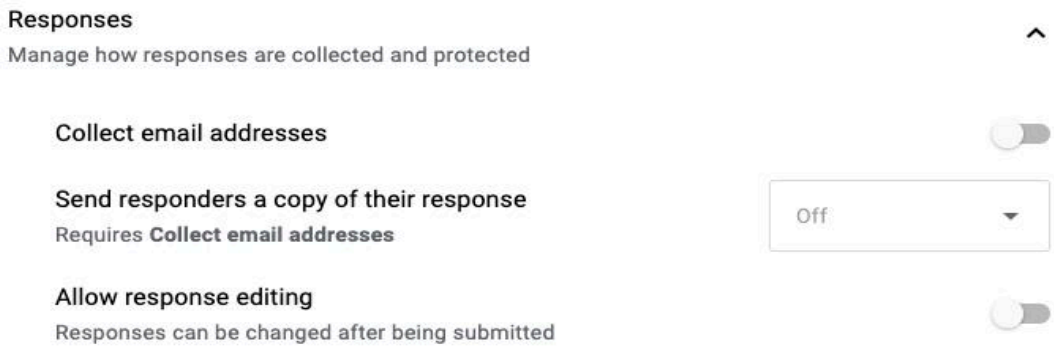


Figure 4: Screenshot from the settings in Google Forms.

Table 1. *Descriptive data for the questionnaire respondents*

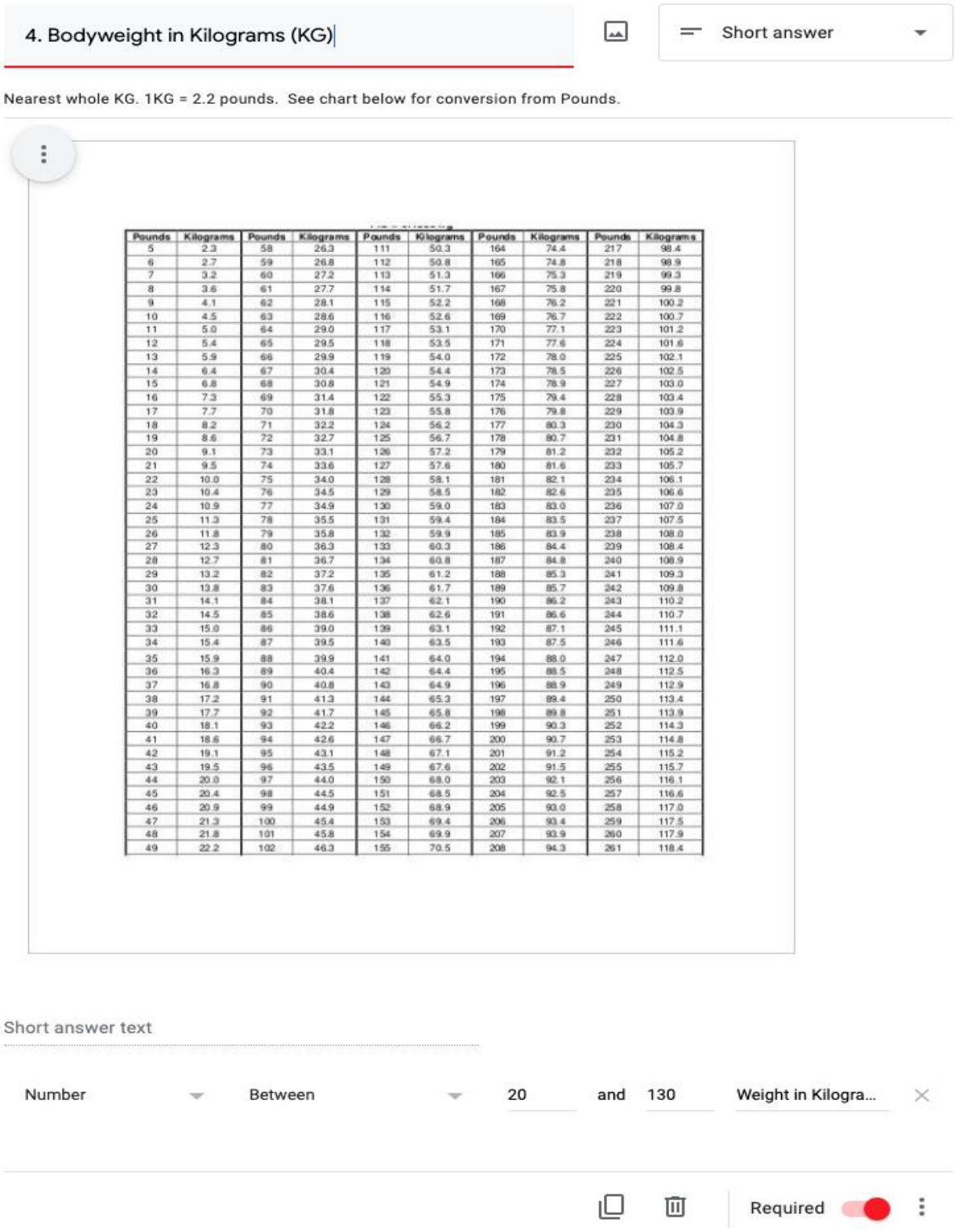
	All (n=1802)
Descriptive	
Age	43 ± 14
Weight (kg)	72 ± 12
Height (cm)	177 ± 10
BMI	23 ± 2.7
Resting HR	48 ± 7
Max HR	183 ± 13
HR reserve	135 ± 15
Training characteristics	
Annual training hours	492 ± 210
Annual endurance training hours	420 ± 190
Annual training sessions	352 ± 122
Average endurance session duration (min)	80.2 ± 32.2
Years of training	15 ± 12

Values are presented as mean ± standard deviation. BMI = Body Mass Index; HR = Heartrate; n = Number of subjects.

The raw data from Google Forms were transferred to Microsoft Excel version 16.0 (MS, Redmond, WA, USA), and all variables were evaluated for obvious errors. Answers from a small number of participants were excluded or adjusted due to obvious errors in reporting, wrong measurement units, or obvious misinterpretation of questions. Every question included an electronical response validation, which gave the participants a notice if their values were unnaturally high or low (Figure 5). With respect for international participation and different measurement unit traditions, conversion charts were included in the questionnaire to help respondents accurately complete questions regarding weight (pounds to kg) and height (inches to meters). Four subjects' answers on weight were adjusted when it was deduced from their gender, height, performance level and other characteristics that they had reported their bodyweight in pounds and not kilograms (pounds to kg).

3.3 Field testing of ECG247

The ECG247 is a single-lead ECG-monitoring device. The monitoring system consists of a one-time “multi-day use” electrode patch that is attached over the sternum, a re-usable ECG sensor and transmitter, a smartphone application, a back-end cloud service, and a web portal (Figure 6). The ECG247 sensor continuously monitors the electrical rhythm of the heart and automatically detects and categorizes arrhythmias in real-time by using artificial intelligence. The ECG-recordings are transferred via Bluetooth to the ECG247 application on a smartphone, and simultaneously uploaded to a back-end cloud service (Figure 7). The user has sole ownership and access to the results in the web portal and can provide permissions for sharing of ECG data with their doctor or other healthcare personnel. User authentication is provided using the Firebase Service (Google, Mountain View, CA, USA), which generates a two-factor authentication required for access to sensitive health information. All information stored in the web portal is coded as Fast Health Interoperability Resources (FHIR). The ECG247 sensor has integrated algorithms for real-time detection of arrhythmias. All detected arrhythmias are uploaded and saved in a back-end cloud service and sorted by severity in the web portal. The user can also manually highlight up to 1 hour of ECG recording by pressing a button on the sensor. This allows the user to “tag” ECG measurements coinciding with a time widow enveloping a subjective experience of a “disturbance in heart rhythm”. The ECG247 system has undergone extensive testing in a home health care setting. However, neither the sensor device nor the specific detection algorithms have been systematically evaluated on endurance athletes performing daily training.



Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms
5	2.3	58	26.3	111	50.3	164	74.4	217	98.4
6	2.7	59	26.8	112	50.8	165	74.8	218	98.9
7	3.2	60	27.2	113	51.3	166	75.3	219	99.3
8	3.6	61	27.7	114	51.7	167	75.8	220	99.8
9	4.1	62	28.1	115	52.2	168	76.2	221	100.2
10	4.5	63	28.6	116	52.6	169	76.7	222	100.7
11	5.0	64	29.0	117	53.1	170	77.1	223	101.2
12	5.4	65	29.5	118	53.5	171	77.6	224	101.6
13	5.9	66	29.9	119	54.0	172	78.0	225	102.1
14	6.4	67	30.4	120	54.4	173	78.5	226	102.5
15	6.8	68	30.8	121	54.9	174	78.9	227	103.0
16	7.3	69	31.4	122	55.3	175	79.4	228	103.4
17	7.7	70	31.8	123	55.8	176	79.8	229	103.9
18	8.2	71	32.2	124	56.2	177	80.3	230	104.3
19	8.6	72	32.7	125	56.7	178	80.7	231	104.8
20	9.1	73	33.1	126	57.2	179	81.2	232	105.2
21	9.5	74	33.6	127	57.6	180	81.6	233	105.7
22	10.0	75	34.0	128	58.1	181	82.1	234	106.1
23	10.4	76	34.5	129	58.5	182	82.6	235	106.6
24	10.9	77	34.9	130	59.0	183	83.0	236	107.0
25	11.3	78	35.5	131	59.4	184	83.5	237	107.5
26	11.8	79	35.8	132	59.9	185	83.9	238	108.0
27	12.3	80	36.3	133	60.3	186	84.4	239	108.4
28	12.7	81	36.7	134	60.8	187	84.8	240	108.9
29	13.2	82	37.2	135	61.2	188	85.3	241	109.3
30	13.8	83	37.6	136	61.7	189	85.7	242	109.8
31	14.1	84	38.1	137	62.1	190	86.2	243	110.2
32	14.5	85	38.6	138	62.6	191	86.6	244	110.7
33	15.0	86	39.0	139	63.1	192	87.1	245	111.1
34	15.4	87	39.5	140	63.5	193	87.5	246	111.6
35	15.9	88	39.9	141	64.0	194	88.0	247	112.0
36	16.3	89	40.4	142	64.4	195	88.5	248	112.5
37	16.8	90	40.8	143	64.9	196	88.9	249	112.9
38	17.2	91	41.3	144	65.3	197	89.4	250	113.4
39	17.7	92	41.7	145	65.8	198	89.8	251	113.9
40	18.1	93	42.2	146	66.2	199	90.3	252	114.3
41	18.6	94	42.6	147	66.7	200	90.7	253	114.8
42	19.1	95	43.1	148	67.1	201	91.2	254	115.2
43	19.5	96	43.5	149	67.6	202	91.5	255	115.7
44	20.0	97	44.0	150	68.0	203	92.1	256	116.1
45	20.4	98	44.5	151	68.5	204	92.5	257	116.6
46	20.9	99	44.9	152	68.9	205	93.0	258	117.0
47	21.3	100	45.4	153	69.4	206	93.4	259	117.5
48	21.8	101	45.8	154	69.9	207	93.9	260	117.9
49	22.2	102	46.3	155	70.5	208	94.3	261	118.4

Figure 5: Illustrates how the electronical response validation was controlled and the conversion scale for pound to kilogram.

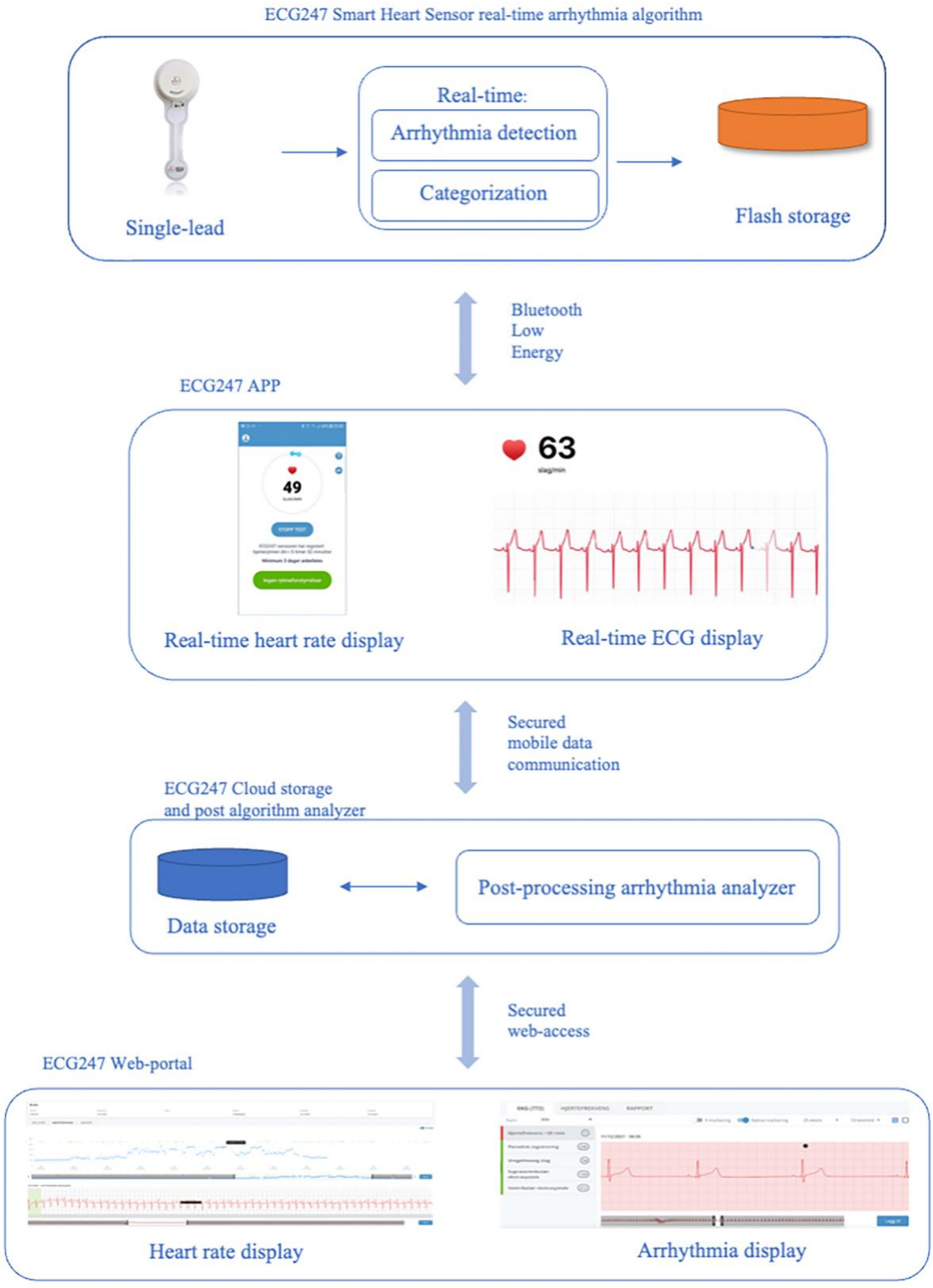


Figure 6: The ECG Smart Heart Sensor system: sensor with real-time arrhythmia detection, smartphone application, bac-end cloud service with postprocessing arrhythmia analyzer, and web portal.

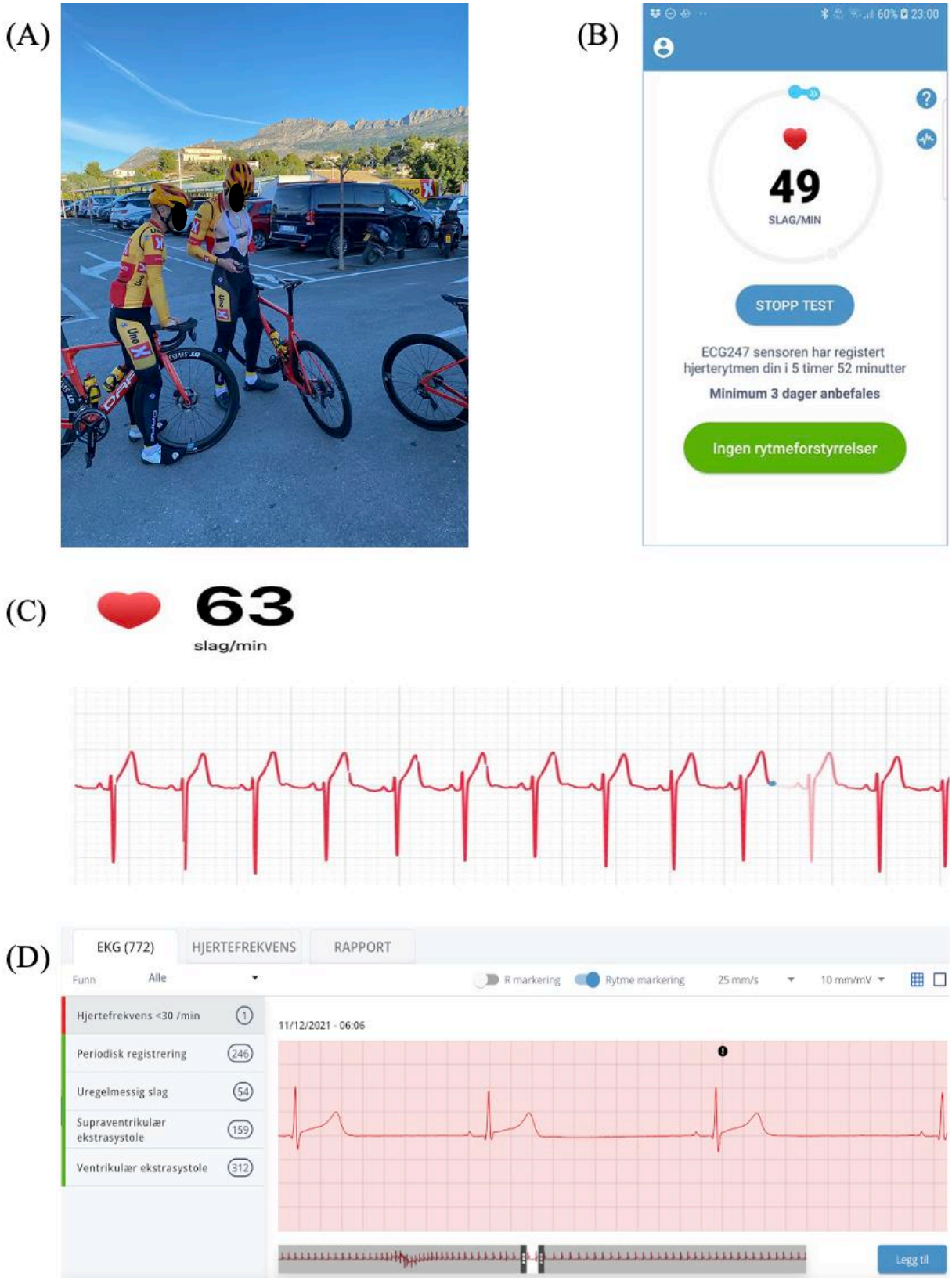


Figure 7: A) The ECG247 sensor placed over the sternum, screenshots from B) the ECG247 mobile application and C) the web portal.

Prior to the field testing of ECG247, preliminary pilot testing in the laboratory was conducted on 6 (4 male, 2 female) fellow master's degree candidates (Appendix 4, 5). The primarily purpose of the pilot test was to investigate how different movements (cycling, XC ski double-poling, running) affected the ECG recordings, as well as investigating the tolerance of the single-use electrode for repeated bouts of exercise and showering. The positive results of this preliminary test were also deemed a necessary pre-condition for further testing with Uno-X. The test protocol in the laboratory consisted of 15min efforts on each exercise modality. These efforts were further divided into 5min segments with small successive increases in work intensity. A 5 min rest period was provided between each 15min exercise bout (Figure 8), and exercise modalities were compared in randomized order. XC ski double-poling (Figure 9A) was performed on a Concept2 Skierg (Concept2, Morrisville, VT, USA), cycling (Figure 9B) on a Wattbike AtomX (Wattbike, Nottingham, England), and running (Figure 9C) on a motorized treadmill (Lode Katana Sport, Lode B. V., Groningen, Netherlands). The results showed a slightly higher disturbance in the ECG recordings when running compared with the two others. In addition, the pilot test showed that the quality of the ECG signal was considered satisfactory for rhythm analysis by a cooperating cardiologist in all the tests within 48 hours of the test period. There was one incident of a false positive AF during the laboratory testing, which highlighted the need for having healthcare professionals available during the field test period.

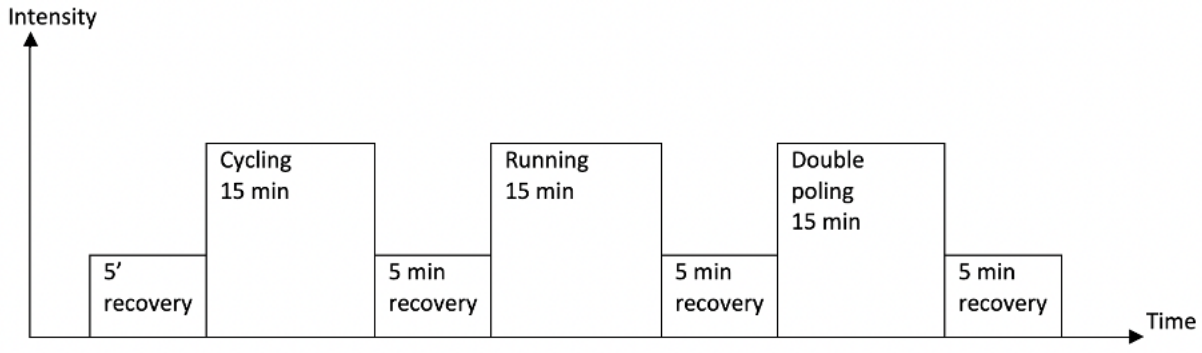


Figure 8: Test protocol for the pilot test of the ECG247. Started with applying the sensor and connect to the participants phones. Recovery consisted of walking and sitting. The intensity increased slightly every 5 minutes during the efforts.

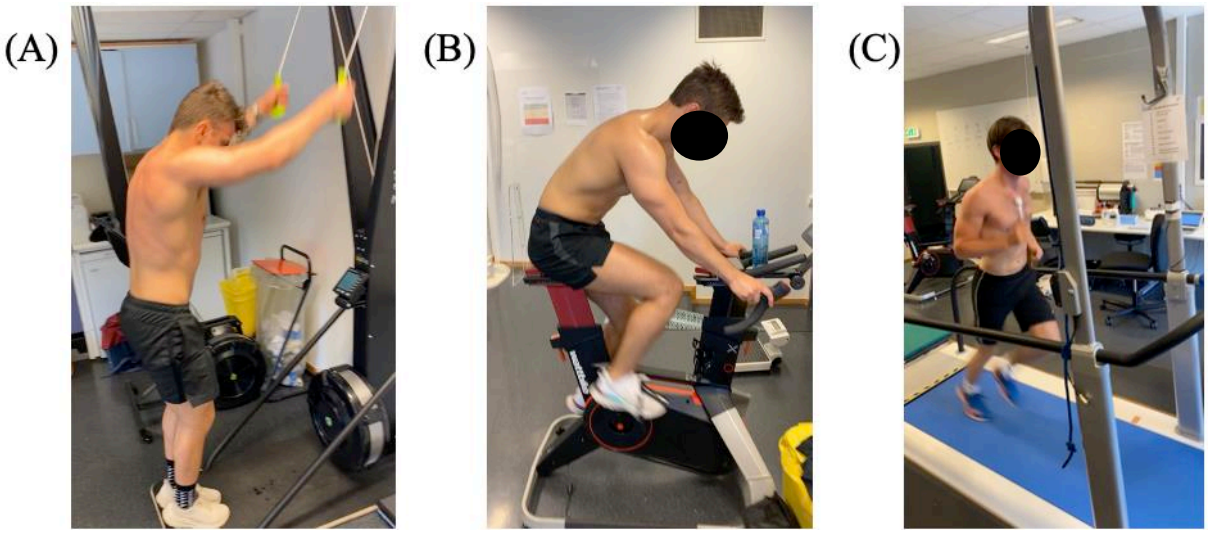


Figure 9: Laboratory exercise modalities evaluated during preliminary testing of ECG24 sensor: (A) XC ski double-poling, (B) Cycling, (C) Running.

UNO-X Pro Cycling Team (https://www.unoxteam.com) is a professional cycling team based in Norway and consists of 3 separate competition teams: Women's World Tour team (international composition, n=12), Men's Pro team (Norwegian and Danish athletes, n=29), and Men's Continental Team (Norwegian and Danish U23 athletes, n=12). The field test was completed during a 14-day training camp in Spain, December 2021, and a total of 13 athletes (9 male) were monitored continuously with the ECG247 sensor. These athletes were selected by the Uno-X team leadership. They participated in an information meeting and provided signed informed consent (Appendix 6) prior to the start of ECG data collection. The athletes agreed to wear the sensor for 3-6 days (depending on quality of the ECG recording). The research project leader (master's candidate) was present at the training camp during the test period and answered questions from athletes. During the training camp, collected ECG recordings were simultaneously reviewed by cardiologists at Sørlandet Hospital Arendal in Norway. Cardiological support was provided during the field-testing period to ensure rapid communication with athletes in the event of detected arrhythmias or if false positive events arose. After completion of the field-testing period, a cardiologist performed a complete manual review of all the complete ECG recordings from every athlete and provided a detailed report via the web portal for each athlete volunteer.

3.4 Statistical analysis

All statistical analyses were performed using SPSS (version 25, IBM, Chicago, IL, USA). Quantitative data with a normal distribution are presented as mean ± standard deviation while prevalence data are presented as number of outcomes and percentage of either a group or all participants. Tables and figures were made using Microsoft Word version 16.0 (MS, Remond, WA, USA) and Microsoft Excel version 16.0 (MS, Redmond, WA, USA). The dataset was checked for missing data and non-normality before statistical tests were performed. Subject characteristics and training characteristics were compared using Crosstabs, with Chi Square, Independent Samples T-tests, and a One-way between groups analysis of variance (ANOVA), with an LSD post-hoc test where appropriate. To identify possible associations between diagnosed AF and selected risk factors, a binary logistical regression analysis was performed. A value of $p<0.05$ was considered statistically significant in all analyses.

3.5 Ethical considerations

The study was carried out according to the Declaration of Helsinki and both data collection methods were approved from a data security perspective by the Norwegian Center for Research Data (Appendix 7, 8) and approved by the Ethics Committee of the Faculty for Health and Sport Science, University of Agder (Appendix 9). No links between personal identification information and the questionnaire and ECG collected in the two data collections were electronically possible and all data has been analyzed at the group level. All responses from athletes to their digital questionnaire response were completely anonymous and could not be linked at the individual level.

Athlete participants were not randomly selected by Uno-X team leadership. Athletes with history of reporting possible arrhythmic symptoms were selected to be among the test participants to participate in the test. Consequently, the cardiologist was brought in early to provide additional information to the athletes. In this process, the cardiologist informed the participants that the current algorithms of the ECG247 were not specifically designed for athletes exercising at high HR. This increased the likelihood of false positive detection of SVT and Atrial Flutter when HR was elevated during training sessions. Therefore, false positive events related to these tachycardia type arrhythmias were anticipated and discussed with the athletes.

4.0 Methodological discussion

4.1 Study design

This was an observational study consisting of a descriptive web-based survey and a non-interventional field test of ECG247™ Smart Heart Sensor. A descriptive research method examines the situation as it exists in the current state and involves the identification of a particular phenomenon based on an observational basis or exploring the relationship between two or more phenomena (Thomas et al., 2015). The main purpose of a descriptive study is to provide an "overall" picture of a phenomena or a population (Polit & Beck, 2018). The Covid-19 situation was unpredictable when planning started. Therefore, two independent data sampling methods were used. In this way, anticipating a scenario with a lock-down or infection outbreak forcing cancellation of the field test, the questionnaire could stand alone as a research project.

4.2 Web-based Questionnaire

The most common descriptive data sampling method is a survey, which includes questionnaires and interviews (Fowler, 2009). The two are largely similar except for the method of asking questions. Questionnaires can be conducted on paper or via digital applications. The questionnaire is therefore a valuable tool for collecting information over a wide geographical area and is efficient for surveying large samples of respondents (Hawkins et al., 2019). The target population in the present study consisted of endurance athletes who were at least 18 years, self-described as training regularly, and at least occasionally competing in an endurance sport. The selection of the sample should be based on the variables specified to be studied (here regular endurance training), and this will affect the generalizability of the results. In this case, it means that the results are only representative of a narrow portion of the general population (Ponto, 2015). However, finding a representative sample of the population to be studied is easier when digital approaches are available due to a larger geographical catchment area. In survey research, the sample size is irrelevant if the sample is not representative to the research question (Kirk-Smith, 1998). A total of 1802 subjects answered the questionnaire, widely distributed across nationalities and endurance sports.

When constructing the questionnaire, researchers are tempted to acquire as much information as possible from the subjects. This desire for completeness often results in a lengthy questionnaire, which in turn results in a smaller participation rate (Thomas et al., 2015). Short, specific questionnaires are more acceptable to respondents and generally result in larger samples, as well as increased likelihood that participants maintain their attention to detail and motivation throughout the questionnaire (Fowler, 2009). The present questionnaire took approximately 10-15 minutes and consisted of closed ended questions in which the response options were prespecified. The questions were answered in checkboxes (Figure 10A), numbers (Figure 10B), or multiple choice (Figure 10C). The questionnaire was divided into three sections:

1. Characteristics of the subjects: Age, nationality, performance level, etc.
2. Training characteristics: Annual training volume, weekly training contents, etc.
3. Medical history: Diagnosed conditions, symptoms, health screening, etc.

Prior to publishing links to the digital questionnaire, pilot testing was conducted on local athletes, colleagues, and fellow master's students to test that the questions were clearly articulated and that the response options were relevant and comprehensive. Also, to address that the results could be analyzed as planned. In a structured instrument, pilot testing respondents were asked to respond to the same questions in the same order. Self-reporting depend on the participants' compliance with the method, the accuracy in validation and diagnosing of different conditions, and how they are defined for the respondents (Thyer, 2010).

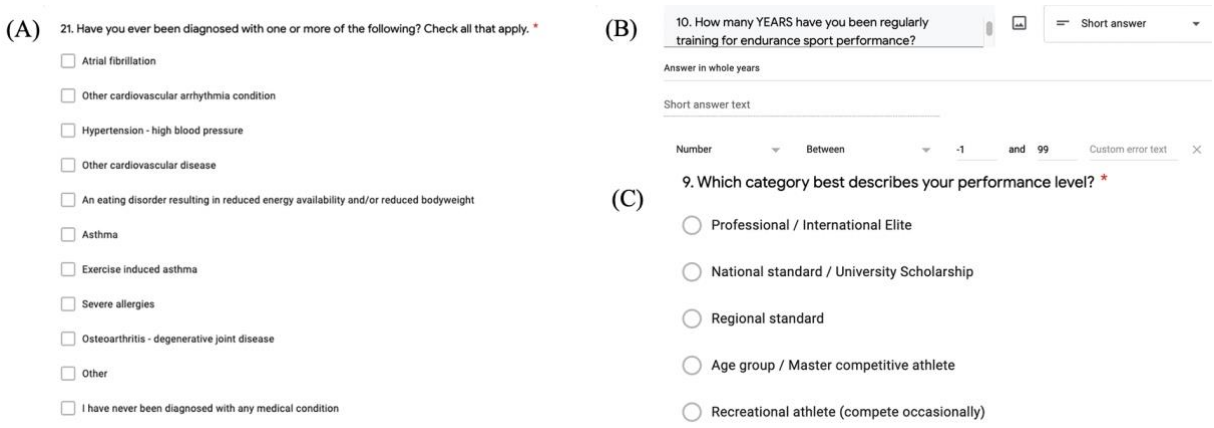


Figure 10: Screenshots from questions with A) checkbox, B) Number, with electronical response validation, and C) multiple choice.

4.3 Field testing ECG247

One of the most important and influential steps in technology development is putting a product through a field test. It is critical to test new technologies in the physical and user environment intended. This is perhaps the truest way to ensure the reliability and future success of a product (Thomas et al., 2015). However, identifying factors that may affect the functionality of a technological solution is more difficult in a field test compared with a laboratory test where factors and protocols are standardized. Therefore, field testing requires on-site observation and self-reporting to address all determents affecting the product. The testing environment and research subjects are equally important; therefore, the test subjects must represent the research question (Polit & Beck, 2018). The purpose of the field test in this present study was to test the ECG247 Smart Heart Sensor on elite endurance athletes performing a high volume of endurance training with the goal of evaluating both technical and practical aspects of using this monitoring device in a sports medicine context. Naturally, athletes from UNO-X Pro Cycling team were a good match to the purpose of testing, and the rigorous environment of a training camp strengthened the validity of the field testing.

4.4 Strength and limitations

The main strengths of the present study were: (a) two independent data sampling methods, which provided a more thorough understanding of the phenomena of interest (CA in endurance athletes), (b) a high number of representative participants in the questionnaire, (c) cooperation with UNO-X Pro Cycling Team, which provided an excellent field-testing environment, and (d) extensive preliminary pilot testing of both sampling methods.

The questionnaire provided a descriptive, quantitative picture of the status among endurance athletes across nationalities and endurance sports. However, both health screening of athletes and health screening in general are performed differently dependent on whether the healthcare service is public or privately provided in the country of residence. The main limitations of the web-based self-report questionnaire are information bias and response accuracy issues. Even with electronical response validations and specific response options it is possible on some questions for subjects to misinterpret questions and submit erroneous responses.

Also, questionnaires asking for quantification of physical activity often result in overestimation of the subjects' training data. In addition, in questionnaires investigating prevalence of different variables, age is a central component connected with higher prevalence. Therefore, age was considered as a determinant variable when investigating prevalence in the groupings with lower average age compared with the average of the whole questionnaire.

A training camp, with a professional cycling team was an appropriate environment for testing whether ECG247 Smart Heart Sensor withstands the use typical use patterns of athlete training several hours daily, showering, etc. In addition, testing the sensor during a training camp was a good simulation for investigating how it performs in a team context. Real-time access to a cardiologist was crucial for this study because it provided both reassurance for the athletes and ensured an optimal analysis process. However, this was not an interventional study, and there was no direct comparison with today's best practice (Holter monitoring) among the same athletes. Cycling is also one of the endurance sports with the least amount of movement in the upper body. Therefore, the present findings should not be generalized to all sports movements.

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PART 2

RESEARCH PAPER

Heart rhythm assessment in elite endurance athletes: A better method?

The following paper is written according to the standards of the following journal:

Frontiers in Sports and Active Living

Frontiers

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Heart rhythm assessment in elite endurance athletes: A better method?

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ABSTRACT

BACKGROUND: Cardiac arrhythmias, especially atrial fibrillation (AF), are relatively common among elite endurance athletes. Conventional diagnostic tools for assessment of rhythm disorders suffer from limited availability, limited test duration time, and usability challenges, particularly under the demanding training conditions of an elite athlete. Among endurance athletes, there is a need for out-of-hospital monitoring to enhance detection of arrhythmias under conditions that are relevant and potentially provocative of underlying pathology. The Norwegian patch ECG247 Smart Heart Sensor has been developed to simplify the assessment of heart rhythm disorders. The current study aimed to evaluate (1) the relationships among training characteristics and health experiences in a large, representative sample of endurance athletes (2) the validity and functionality of the newly developed ECG patch ECG247 Smart Heart Sensor in an elite athlete training environment.

METHODS: A web-based questionnaire quantifying the relationship between training characteristics and health experiences was developed and delivered in digital format. A total of 1802 men and women completed the questionnaire. In addition, a total of 13 professional cyclists from the UNO-X Pro Cycling Team were examined with the ECG247 Smart Heart Sensor during a 14-day training camp in Spain, December 2021. All ECG data were analyzed by cardiologists at Sørlandet Hospital Arendal, Norway. The athletes also completed a brief questionnaire registering their training (from on-bike monitoring units) and self-assessment of usability parameters after the test.

RESULTS: Diagnosed AF was reported by 52 of the 1802 endurance athletes surveyed (2.9%). Age, annual endurance volume, and subjective performance level were significant predictors ($p=0.001$) for diagnosed AF. During the ECG sensor field test, average continuous ECG test duration was 89±24hours, including an average of 15±5 training hours during each test. The ECG quality from all tests was considered satisfactory for rhythm analysis – also during exercise. The reported usability of the ECG247 Smart Heart Sensor was high. The automatic arrhythmia algorithm reported possible arrhythmia events in 13 (62%) tests; 9 atrial flutter and 4 supraventricular tachycardia. Retrospective manual assessment by physicians revealed normal sinus rhythm in all tests with these false positive events observed during training when heart rate was elevated. No false negative findings were observed.

CONCLUSION: Prevalence of diagnosed AF increased with performance level and annual training hours, supporting the need for better ECG monitoring tools. The ECG247 Smart Heart Sensor allowed for high quality ECG monitoring during intensive exercise in athletes. The integrated arrhythmia analyzing algorithm can be optimized for this group to reduce false positives associated with the normal “tachycardia” of endurance training.

KEYWORDS: Endurance athletes, Atrial Fibrillation, Electrocardiogram, Cardiac screening, cardiovascular diseases in athlete

INTRODUCTION

The importance of large volumes of training to perform at a high level in endurance sports is well documented among elite athletes (1-3). Elite endurance athletes' annual training volume typically ranges from 500 to well above 1000 hours (2, 4, 5). Endurance training is also established as an efficacious method of reducing the risk of developing cardiovascular diseases (CVD). However, there are multiple studies suggesting that "excessive" long-lasting and high-volume endurance training may paradoxically *increase* the risk of developing certain types of CVD and particularly cardiac arrhythmias (CA) (6, 7). Atrial Fibrillation (AF) is one of the most common CA reported among endurance athletes and incidence in athletes has been a recent theme of considerable research interest (8-12).

Today's gold-standard for diagnosing CA is a 12-lead electrocardiogram (ECG). An ECG test is performed by healthcare personnel in a clinical setting and provides a time-limited snapshot of the heart's electrical function (13). Some specific CA are highly transient, such as AF, and a 12-lead ECG recording period lasting only a few minutes may fail to detect intermittent CA. Continuous ECG-recordings are needed to detect and diagnose specific CAs, including AF, and the equipment used for long-term ECG recordings is often referred to as "Holter monitoring" (14). A Holter monitor system typically requires a recording device worn on the hip and coupled to at least three cables attached to electrodes on the chest. The system is applied to the patient by healthcare personnel and has a limited battery capacity. It is therefore usually worn for ~24-48 hours (15). The system is not water repellent, and the cables are movement sensitive. Consequently, the Holter monitor system may limit movements and can loosen or detach with physical activity and hard exercise.

For an elite athlete training daily, a Holter monitor prescription will prevent the athlete from training normally, thereby decreasing the validity of the ECG monitoring process. CA among elite athletes often occur during exercise (6). Because Holter monitoring loses signal quality during movement, this may limit the intensity or continuity of the exercise (15). 12-lead ECG and Holter monitoring are dependent on assistance from healthcare personnel, and therefore are subject to limited availability, limited test duration time, and usability challenges. In the context of a high-performance endurance sport team, cardiac screening with today's clinical tools becomes so time consuming that it may be intentionally avoided by athletes and coaches despite the appearance of symptoms of concern.

ECG247™ Smart Heart Sensor is a new, mobile, long-term ECG monitoring device that has undergone extensive testing in a home health care setting (16-18) and is approved by European directives for medical devices (93/42/EEC). It provides continuous monitoring of the heart rhythm for up to 7 days and can be used during exercise. The device is small, wireless, and easy to apply and use without any clinical expertise or assistance (19). All the data acquired by the sensor is stored in a cloud storage through a smartphone application and can be easily accessed by health care professionals. The user also has access to real-time ECG feedback during testing. The ECG sensor patch is applied to the chest and remains attached through the whole monitoring period. Monitoring duration is limited by the attachment of the sensor patch to the skin over time (up to 7 days). ECG247 has not been systematically tested on athletes. If this technology withstands the rough use of elite athletes, it provides a unique new method of athlete screening and cardiac rhythm monitoring in athletes.

The aims of this study were 1) to investigate a large and diverse sample of endurance athletes and quantify the relationships among their training characteristics and health experiences, including CA and CVD. 2) to evaluate how the ECG247 Smart Heart Sensor technical solution performs in a field setting representative of the demands of high-performance endurance athletes during daily training, and 3) to investigate the elite endurance athletes' perception of comfort and usability under the same field conditions and evaluate the overall effectiveness and ease of use of novel monitoring technology

MATERIALS AND METHODS

Study design

The project consisted of two separate data sampling methods:

1. A web-based questionnaire, which investigated endurance athletes and the relationships among their training characteristics and health experiences.
2. A field test of the ECG247™ Smart Heart Sensor (Appsens AS, Lillesand, Norway) on elite endurance athletes performing a high volume of endurance training, with the goal of evaluating both technical and practical aspects of using this monitoring device in a sports medicine context.

All data collection and testing were performed between November 2021 and January 2022.

Web-based Questionnaire

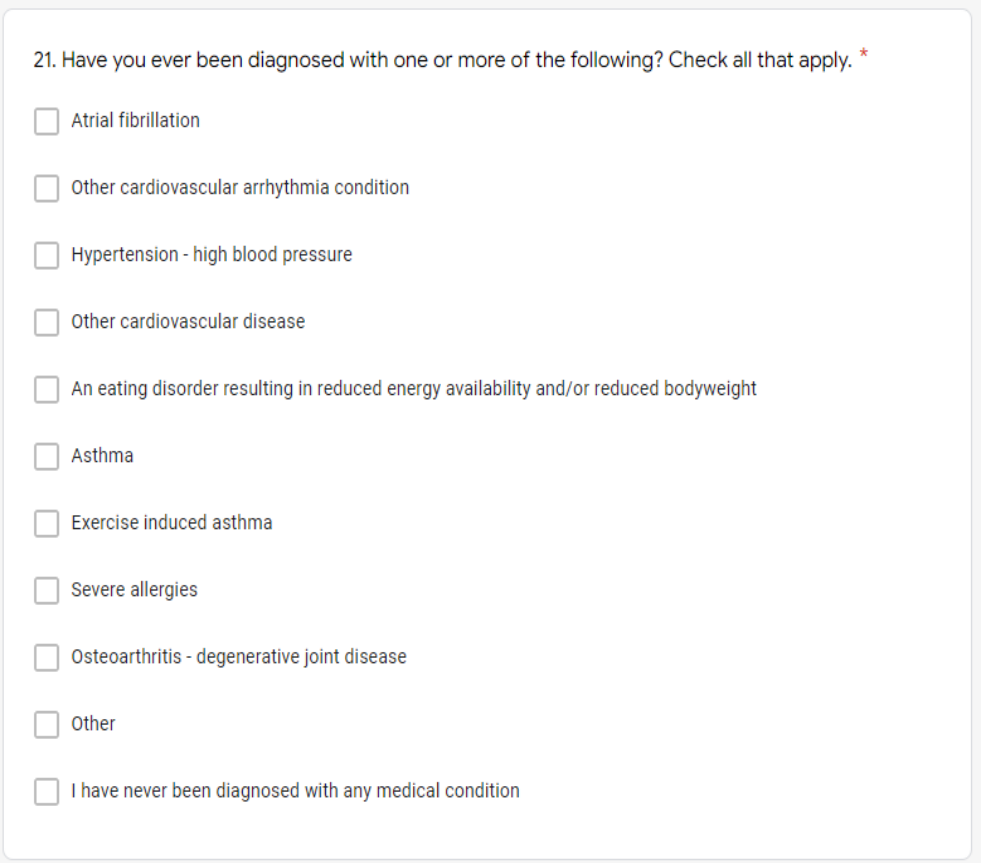
The digital questionnaire investigated endurance athletes and the prevalence of AF, other CA, and other CVDs. The questionnaire consisted of 3 parts:

1. General characteristics of the subjects
2. Training characteristics
3. Health experiences/characteristics

The questions regarding cardiac health were incorporated in the health part of the questionnaire. AF and CA were not in the title or the cover letter to prevent participation bias, meaning that athletes that were especially interested or having CVD would be more likely to participate than those who never had any problems with their heart. The survey also distinguished medically diagnosed conditions from subjective symptomatic events (Figure 1). In the present study, responses to the specific questions regarding cardiac health are presented; remaining results from the questionnaire will be presented elsewhere. Prior to publishing links to the digital questionnaire, pilot testing was conducted on local athletes, colleagues, and fellow master's students to develop and optimize the wording of the questions and minimize the total duration of the questionnaire.

The digital questionnaire was developed and published in Google Forms (Google, Mountain View, CA, USA). No electronic link between the respondent and their questionnaire responses was possible as this linkage was blocked. The target group consisted of endurance athletes who were at least 18 years, self-described as training regularly, and competing at least occasionally in an endurance sport. Completing the survey required approximately 10-15 minutes. The digital survey was made available from November 8, 2021, and through January 31, 2022. Subjects were recruited via social media (Twitter, Instagram, and Facebook) as well as via targeted emails to sports clubs and organizations in Norway and internationally. A total of 1802 subjects (1342 male, 457 female, 3 non-binary) completed the survey.

(A)



(B)

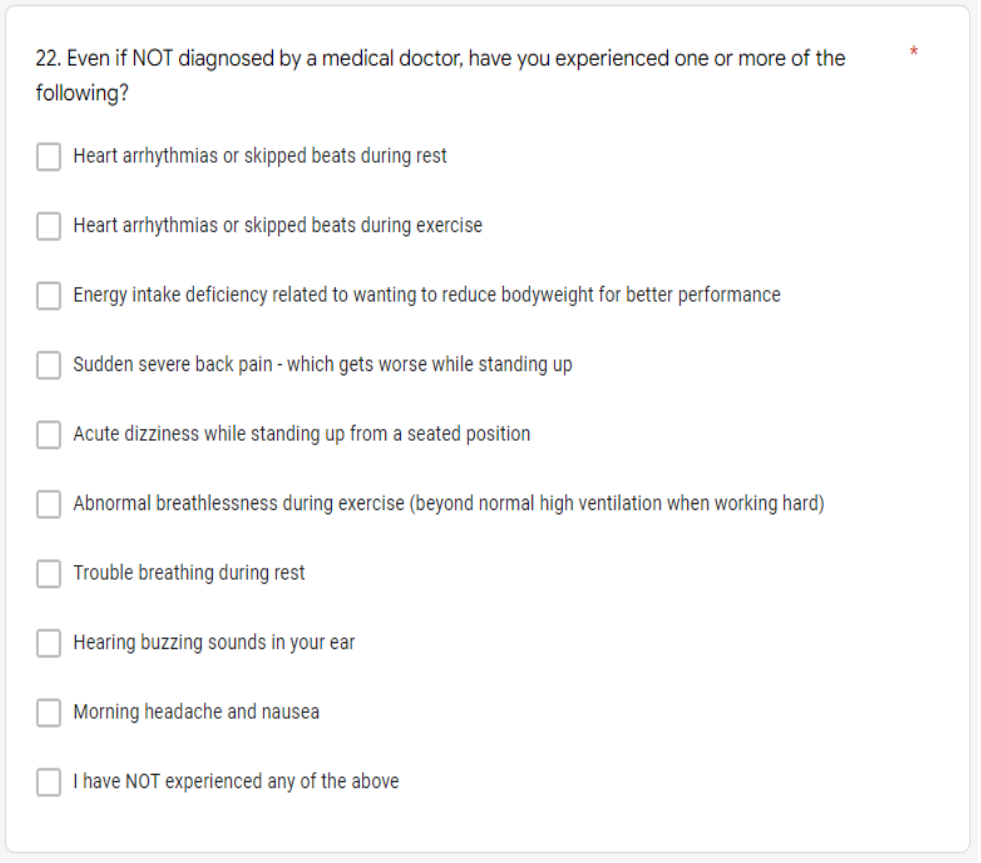


Figure 1: Screenshots of two question groups taken from the questionnaire in Google Forms: (A) Diagnosed conditions, (B) Subjective symptoms.

Field testing of ECG247

The ECG247 is a single-lead patch ECG-monitoring device. The monitoring system consists of a one-time “multi-day use” electrode patch that is attached over the sternum, a re-usable ECG sensor, a smartphone application, a back-end cloud service, and a web portal (Figure 1). The ECG247 sensor continuously monitors the hearth rhythm and automatically detects and categorizes arrhythmias in real-time by using algorithms based on artificial intelligence. The ECG-recordings are transferred via Bluetooth to the ECG247 application on the smartphone, and simultaneously uploaded to the back-end cloud service (Figure 2). The user has ownership and access to the results in the web portal and can provide permissions for sharing of ECG data with their physician or other healthcare professionals. User authentication is provided using the Firebase Service (Google, Mountain View, CA, USA), which generates a two-factor authentication required for access to sensitive health information. All information stored in the web portal is coded as Fast Health Interoperability Resources (FHIR). The ECG247 sensor processes all ECG data through integrated algorithms for real-time detection of arrhythmias. All detected arrhythmias are uploaded and saved in the back-end cloud service and sorted by severity in the web portal. The user can also manually highlight up to 1 minute of ECG recording by activating this function on the sensor via their smartphone. This allows the user to “tag” ECG measurements when they subjectively experience what they perceive to be a disturbance in heart rhythm.

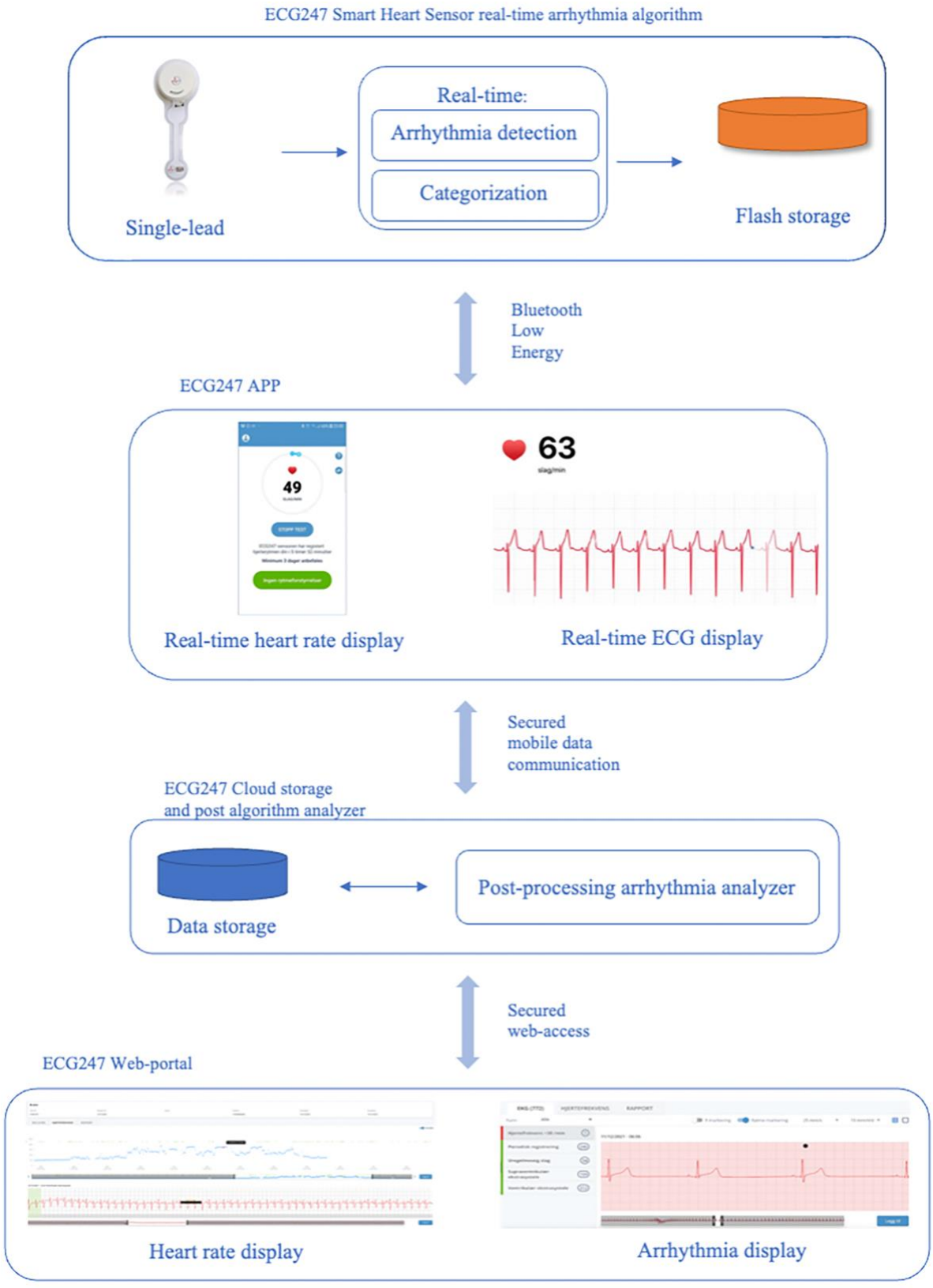


Figure 2: The ECG Smart Heart Sensor system: sensor with real-time arrhythmia detection, smartphone application, bac-end cloud service with postprocessing arrhythmia analyzer, and web portal.

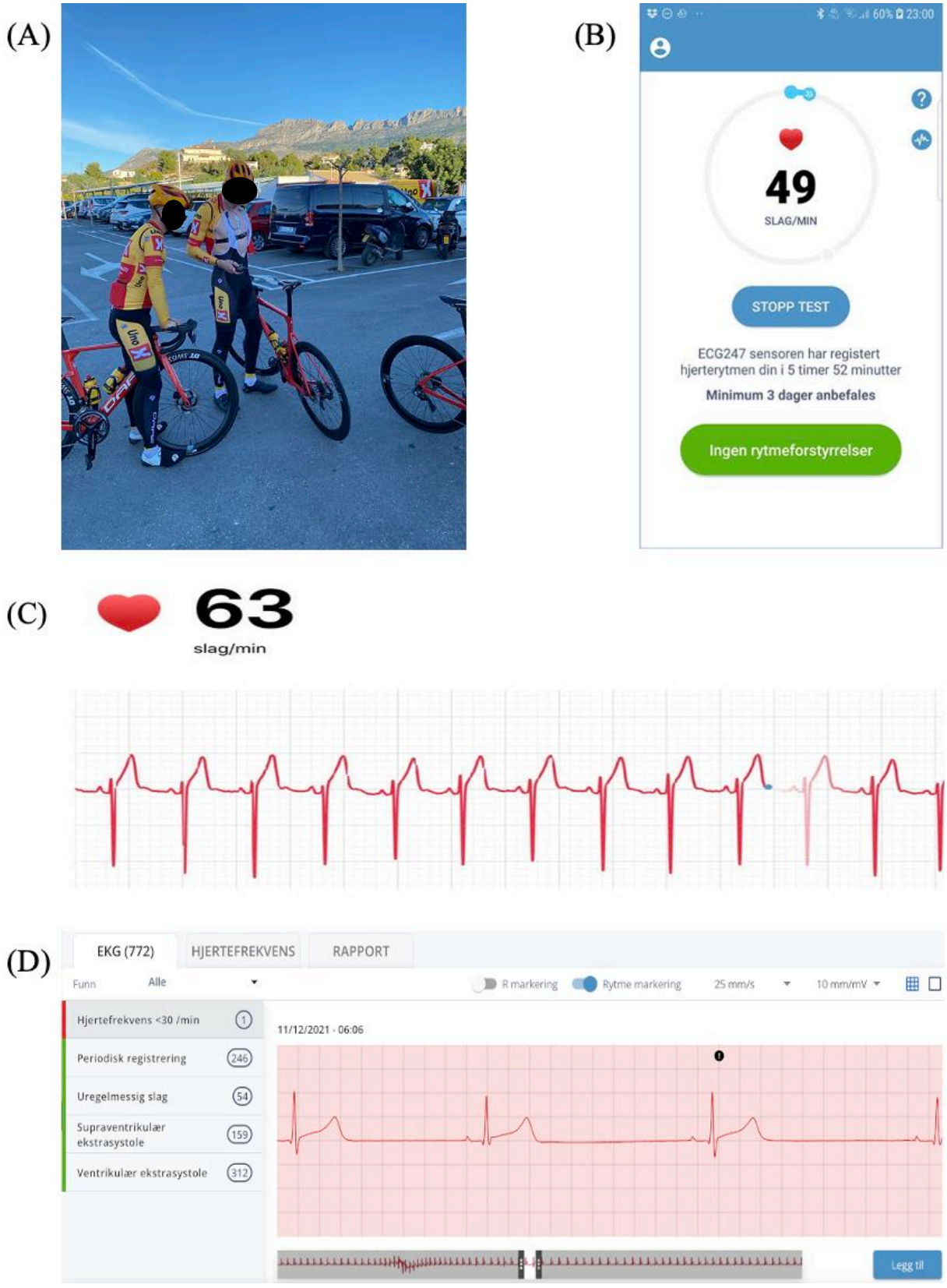


Figure 3: (A) The ECG247 sensor placed over the sternum, screenshots from (B) the ECG247 mobile application and (C) the web portal.

Prior to the field testing of ECG247, preliminary pilot testing in the laboratory was conducted on 6 (4 male, 2 female) fellow master's degree candidates. The primarily purpose of the pilot test was to investigate how different movements (cycling, XC ski double-poling, running) affected the ECG recordings, as well as to evaluate the tolerance of the single-use electrode for repeated bouts of exercise and showering. The positive results of this preliminary test were also deemed a necessary pre-condition for further testing with UNO-X Pro Cycling Team. The test protocol in the laboratory consisted of 15min efforts on each exercise modality, in a randomized order. These efforts were divided into 5min segments with small successive increases in work intensity. A 5 min rest period was provided between each 15min exercise bout (Figure 4). Double-poling (Figure 5A) was performed on a Concept2 Skierg (Concept2, Morrisville, VT, USA), cycling (Figure 5B) on a Wattbike AtomX (Wattbike, Nottingham, England), and running (Figure 5C) on a motorized treadmill (Lode Katana Sport, Lode B. V., Groningen, Netherlands).

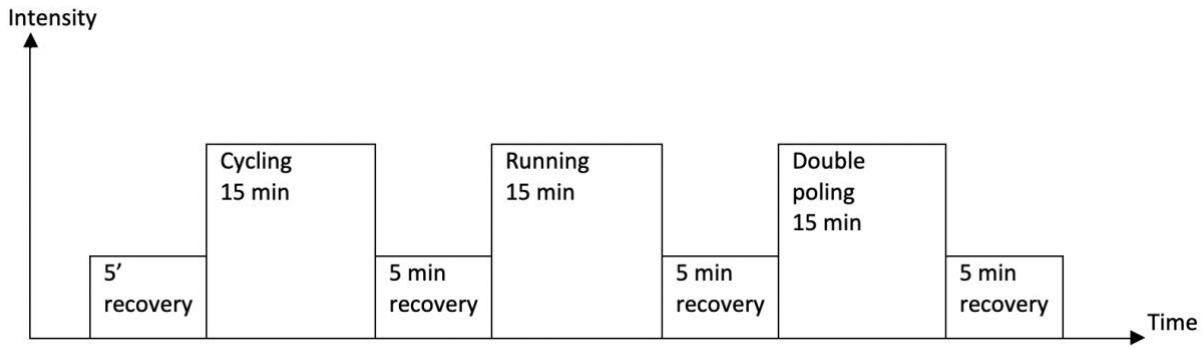


Figure 4: Test protocol for the pilot test of the ECG247. Started with applying the sensor and connect to the participants phones. Recovery consisted of walking and sitting. The intensity increased slightly every 5 minutes during the efforts.

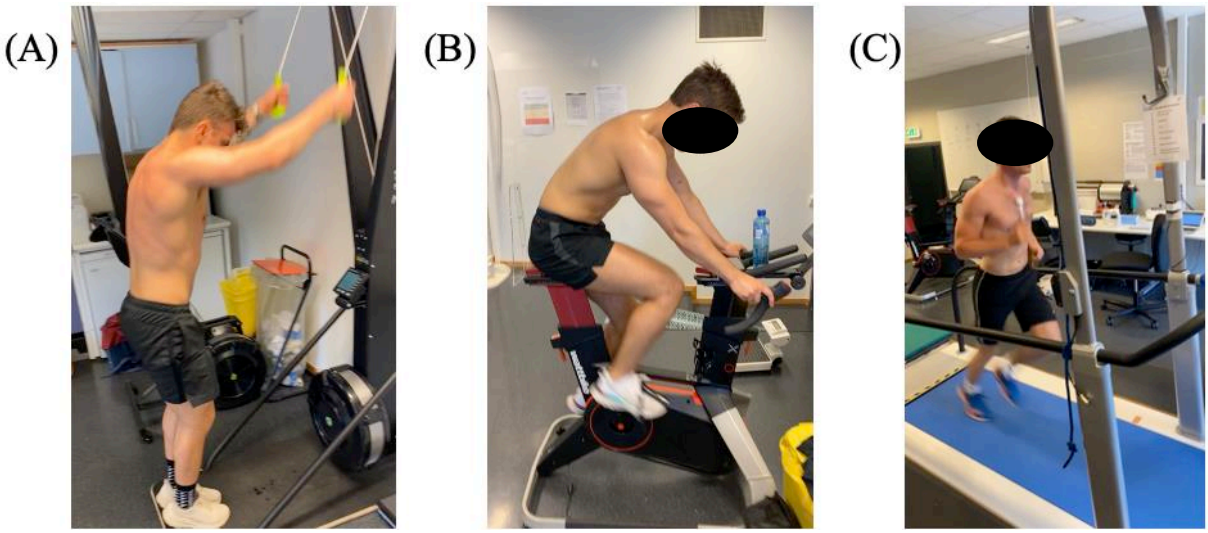


Figure 5: Laboratory exercise modalities evaluated during preliminary testing of ECG24 sensor: (A) XC ski double-poling, (B) Cycling, (C) Running.

The field test was completed during a 14-day training camp for the Uno-X Pro Cycling Team in Spain, December 2021, and a total of 13 athletes (69% male) were monitored continuously with the ECG247 sensor. These athletes were selected from the entire team (~50 athletes) by the Uno-X team leadership. They participated in an information meeting and provided signed informed consent prior to the start of ECG data collection. The athletes agreed to wear the sensor for 3-6 days (depending on quality of the ECG recording). The research project leader was present at the training camp during the test period and answered questions from athletes. During the training camp, collected ECG recordings were simultaneously reviewed by physicians at Sørlandet Hospital Arendal in Norway. Cardiological support was provided during the field-testing period to ensure rapid communication with athletes in the event of detected arrhythmias or if false positive events arose. After completion of the field-testing period, the physicians performed a manual review of the complete ECG recordings from every athlete and provided a detailed report via the web portal for each athlete volunteer.

Statistical analysis

All statistical analyses were performed using SPSS (version 25, IBM, Chicago, IL, USA). Quantitative data with a normal distribution are presented as mean ± standard deviation while prevalence data are presented as number of outcomes and percentage of either a group or all participants. Tables and figures were made using Microsoft Word version 16.0 (MS, Remond, WA, USA) and Microsoft Excel version 16.0 (MS, Redmond, WA, USA). The dataset was checked for missing data and non-normality before statistical tests were performed.

Subject characteristics and training characteristics were compared using Crosstabs, with Chi Square, Independent Samples T-tests, and a One-way between groups analysis of variance (ANOVA), with an LSD post-hoc test where appropriate. To identify possible associations between diagnosed AF and selected risk factors, a binary logistical regression analysis was performed. A value of $p<0.05$ was considered statistically significant in all analyses.

Ethical considerations

The study is carried out according to the Declaration of Helsinki and both data collection methods were approved from a data security perspective by the Norwegian Center for Research Data and was approved by the Ethics Committee of the Faculty for Health and Sport Science, University of Agder. No links between personal identification information and the questionnaire and ECG collected in the two data collections were electronically possible and all data has been analyzed at the group level.

Athlete participants were not randomly selected by Uno-X team leadership. Athletes with history of reporting possible arrhythmic symptoms were selected to be among the test participants. Consequently, the cardiologist was brought in early to provide additional information to the athletes. In this process, the cardiologist informed the participants that the current algorithms of the ECG247 were not specifically designed for athletes exercising at high heart rate (HR). Athletes were informed that the exercise sessions they performed as highly trained athletes increased the likelihood of false positive detection of supraventricular tachycardia (SVT) and Atrial Flutter (AFLU) when HR was elevated during training sessions. Therefore, false positive events related to these tachycardia type arrhythmias were anticipated and discussed with the athletes.

RESULTS

Characteristics for the participants

Characteristics for the 1802 questionnaire participants are shown in Table 1. Mean age of the participants was 43±14 years with a mean annual training volume of 492±210 hours. The gender distribution of the sample were 74.5% (n=1342) male and 25.5% (n=457) female. Three survey participants identified as non-binary. Male participants were taller and heavier than female participants ($p<0.001$) but did not differ systematically in their training characteristics. Females reported higher total annual training hours ($p<0.05$). Based on their similar training characteristics, all subjects are included as one group in subsequent analyses.

Table 1: *Physical and training characteristics by gender*

	Male (n=1342)	Female (n=457)	All (n=1802)
Descriptive			
Age	44 ± 14	41 ± 13	43 ± 14
Weight (kg)	76 ± 10	62 ± 9*	72 ± 12
Height (cm)	180 ± 10	168 ± 10*	177 ± 10
BMI	23 ± 2.5	22 ± 3	23 ± 2.7
Resting HR	47 ± 7	51 ± 8	48 ± 7
Max HR	183 ± 13	182 ± 14	183 ± 13
HR reserve	136 ± 15	132 ± 17	135 ± 15
Training characteristics			
Annual training hours	482 ± 206	523 ± 220*	492 ± 210
Annual endurance training hours	416 ± 196	432.2 ± 196	420 ± 190
Annual training sessions	322 ± 121	336 ± 126	352 ± 122
Average duration	80.3 ± 31.7	80 ± 33.7	80.2 ± 32.2
Years of training	15 ± 13	14 ± 11	15 ± 12

Values are presented as mean ± standard deviation. BMI = Body mass index; HR = Heart Rate; n= Number of participants. * = Female group significant different from Male group (P=<0.05)

Health characteristics in relation to training volume

To investigate possible relationships between annual training volume and the prevalence of the selected health/symptom variables, respondents were divided into four groups based on their annual training volume in hours: 0-250 hours (n=196), 251-500 hours (n=873), 501-750 hours (n=544), and 751+ hours (n=189). Characteristics for these training volume groups are shown in Table 2. Mean age, body weight, and resting HR declined with increasing training volume ($p<0.05$). The overall prevalence of AF among all participants was 2.9% (52 of 1802). AF prevalence in the highest training volume group (≥750 hours/yr.) was modestly higher (4.2%, $p=0.045$). Other CA was reported by 4.2% (88) of the 1802 respondents and there are no significant differences in prevalence among the training volume groups (Table 3).

In contrast, other CVD was higher in the 251-500 hours group (3.6% vs 1 to 2.2% p = 0.025) compared with the other groups. The overall prevalence of other diagnosed CVD was 2.6% (47 of 1802). Interestingly, perceived symptoms of CA during exercise where also more often reported in the 750+ hours group (14.8%, p=0.048) compared with the other 3 groups (7.7 to 10%).

Table 2: *Characteristics and prevalence divided into grouping based on annual training volume*

	0 – 250 hours (n=196)	*251-500 hours (n=873)*	*501-750 hours (n=544)*	*751-1500 hours (n=189)*
Descriptive				
Age (y)	46 ± 14	45 ± 13	42 ± 14	36 ± 14*
Height (cm)	177 ± 8	177 ± 8	176 ± 9	176 ± 10
Weight (kg)	76.8 ± 13.7	73.3 ± 10.9	70.6 ± 11	68.8 ± 11.2*
Body Mass Index	24.4 ± 3.5	23.1 ± 2.5	22.6 ± 2.4	21.9 ± 2.1
Resting HR	51 ± 7	49 ± 7	47 ± 7	45 ± 8*
Maximal HR	180 ± 14	182 ± 13	184 ± 13	188 ± 13
Training Characteristics				
Annual Endurance training hours	169 ± 42	333 ± 42.2	525 ± 97	782 ± 153*
Annual Training Sessions	212 ± 58	292 ± 87	371 ± 117	463 ± 145*

Values are presented as mean ± standard deviation. HR = heart rate; n = number of participants.
* = Significantly different from other groups (p=<0.05).

Table 3: *Diagnosed conditions and symptoms in 4 annual training volume groups*

	0 – 250 hours (n=196)	*251-500 hours (n=873)*	*501-750 hours (n=544)*	*751-1500 hours (n=189)*	*Total (n=1802)*
Diagnosed conditions					
AF	6 (3.1%)	29 (3.3%)	9 (1.7%)	8 (4.2%) *	52 (2.9%)
Other CA	10 (5.1%)	50 (5.7%)	20 (3.7%)	20 (3.7%)	88 (4.2%)
Other CVD	2 (1%)	32 (3.7%) *	12 (2.2%)	1 (0.5%)	47 (2.6%) *
Symptoms of CA					
CA at rest	47 (24%)	187 (21.4%)	96 (17.6%)	45 (23.8%)	375 (20.8%)
CA during Exercise	15 (7.7%)	87 (10%)	45 (8.3%)	28 (14.8%) *	175 (9.7%)

Values are presented as number of respondents and percentage. AF=Atrial Fibrillation; CA=Cardiac arrhythmia; CVD= cardiovascular diseases; n= Number of participants. * = Group significantly different from the other groups (P=<0.05).

The 750+ h training volume group more often reported having performed an echocardiogram (Echo) (48.7%, p=0.000) and exercise stress test (EST) (38.1%, p=0.045) compared with both the general percentage (35.7% Echo, 31.3 EST) and the 0-250 hours group (29.1% Echo, 30.6% EST). A smaller percentage of the sample (13.8%) had undergone 24h ECG monitoring, without any significant training volume group differences (Table 4).

Respondents were asked to report who they spoke to about non-diagnosed symptoms they experienced. Communication with coach was more often reported (p<0.001) among the 750+ group (27.5%) compared with the other groups. In addition, ~1/3 of the highest training volume group (>750 hours/yr.) reported that they kept symptoms to themselves as long as they did not prevent them from training. This percentage was higher (p=0.049) compared with the other groups. Only about 35% of respondents reported that they spoke directly with a medical doctor about non-diagnosed symptoms.

Table 4: *Health screening and communication divided into grouping based on annual training volume*

	0 – 250 hours (n=196)	*251-500 hours (n=873)*	*501-750 hours (n=544)*	*751-1500 hours (n=189)*	*Total (n=1802)*
Cardiac Health Screening					
Echocardiogram	57 (29.1%)	310 (35.5%)	185 (34%)	92 (48.7%) *	644 (35.7%)
Exercise stress test	60 (30.6%)	262 (30%)	170 (31.3%)	72 (38.1%) *	564 (31.3%)
24h ECG	26 (13.3%)	125 (14.3%)	65 (11.9%)	33 (17.5%)	249 (13.8%)
Communication of symptoms					
Coach	17 (8.7%)	65 (7.4%)	90 (16.5%)	52 (27.5%) *	224 (12.4%)
Doctor	74 (37.8%)	318 (36.4%)	187 (34.4%)	65 (34.4%)	644 (35.7%)
Significant others	67 (34.2%)	278 (31.8%)	198 (36.4%)	64 (33.9%)	607 (33.7%)
Keep to myself	50 (25.5%)	237 (27.1%)	139 (25.6%)	61 (32.3%) *	487 (27%)

Values are presented as prevalence and percentage. ECG= Electrocardiogram; n= Number of participants. * = Group significant different from the other groups (P=<0.05).

Prevalence of Atrial Fibrillation / Risk factors for Atrial Fibrillation

Binary logistical regression revealed that age was a weak but statistically significant predictor of AF in the sample. (P<0.001), with a 6% higher OR among the oldest participants compared with the youngest *(OR, 0.939;95% CI,* 0.907-0.970). Reported performance level was also a weak but significant predictor of AF, with the highest-level performers being more likely (p=<0.001) to report diagnosed AF (*OR, 1.968;95%* CI, 1.379-2.807).

Annual endurance training volume was also a very weak but significant predictor (P=0.014) of AF (*OR, 0.990;95%* CI, 0.982-0.998). Otherwise, none of the other variables selected were significantly associated with risk of diagnosed AF (Table 5).

Table 5: *Adjusted odds ratios (ORs) for the prevalence of diagnosed AF*

	B	All participants (n=1802) OR (95% CI)	P value
Age	-0.064	0.938 (0.907 – 0.970)	<0.001*
Gender	-1.284	1.003 (0.999 – 1.008)	0.090
BMI	-0.3	0.722 (0.370 – 1.410)	0.722
Resting HR	-0.019	0.981 (0.940 – 1.025)	0.393
Max HR	0.016	1.016 (0.988 – 1.045)	0.275
Sport	-0.046	0.955 (0.794 – 1.149)	0.627
Performance Level	0.677	1.968 (1.379 – 2.807)	<.001*
Years active	-0.021	0.980 (0.958 – 1.002)	0.072
Annual endurance training volume	-0.010	0.990 (0.982 – 0.998)	0.014*
Annual training sessions	0.008	1.008 (0.999 – 1.016)	0.082

* = Significant (P=<0.05)

Laboratory ECG247 Smart Heart Sensor pilot test

A total of 6 (4 male) subjects completed the preliminary pilot testing in the laboratory. Figure 5 demonstrates the ECG recordings of the different modalities of one of the subjects. Running (Figure 6A) showed more disturbance in the ECG recordings among all subjects compared with cycling (Figure 6B) and XC-ski double-poling (Figure 6C). All ECG recordings was evaluated by a cooperating physician within 48 hours of the test period and considered satisfactory for rhythm analysis in all the tests. The ECG247 sensor integrated algorithm detected one incident of false positive AF in one of the tests.

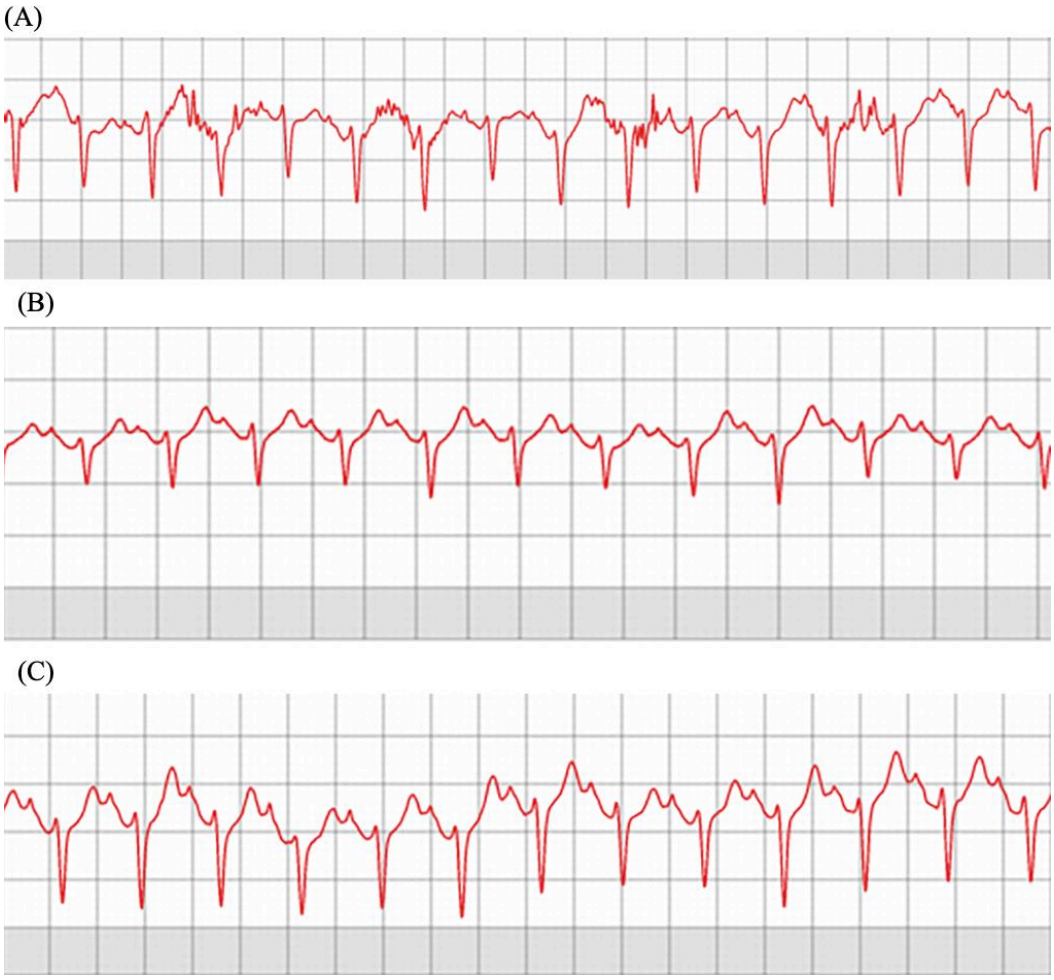


Figure 6: Laboratory exercise modalities evaluated during preliminary testing of ECG247 sensor: (A) Running, (B) Cycling, (C) Double poling XC.

Field test of the ECG247 Smart Heart Sensor

Continuous ECG recordings were successfully collected from all 13 subjects. In 8 of 13 athletes, 2 test periods were performed (involving replacing a single use sensor), resulting in 21 continuous ECG monitoring periods of at least 43 hours collected. New tests were started due to partly detachment of the electrode from the skin (n=1). ECG signal degradation was identified remotely by the physician (n=4), and by request from athletes (n=3). The average age of the participants was 23±4 years (69% males) and the mean athlete test duration time was 144±47 hours, with an average functional duration of 89±24 hours for each ECG patch/test period.

During the test period, an average of 24±6 hours of training was performed by each athlete, with an average of 15±5 training hours for each electrode patch. The ECG quality from all tests was considered satisfactory for rhythm analysis – also during exercise. One short nocturnal episode of bradycardia (heart rate < 30/min) was detected by the ECG247 sensor and verified by the physician. Four short episodes of SVT and nine short episodes of AFLU in ten different athletes were marked by the ECG247 system, but all of these were refuted by the manual assessment of the physicians. User-initiated recordings were performed five times without any pathological ECG findings (Table 6).

Table 6: *Characteristics and diagnostic evaluation for the field tests.*

	Athletes (n=13)	Tests (n=21)
Age (y)	23 ± 4	
Test duration (hours)	144 ± 47	89 ± 24
Training volume (hours)	24 ± 6	15 ± 5
Showers (times)	6 ± 1	4 ± 1
Recording periods< 72 hours	3	3
ECG247 algorithm detection		
AF and Severe arrhythmia	0	0
Bradycardia	1	1
False positive SVT	3	4
False positive AFLU	7	9
False negative	0	0
Patient-initiated recordings		
Recordings	3	5
Physician review	0	0

Values are presented as mean ± standard deviation and prevalence. SVT = Supraventricular tachycardia; AFLU = Atrial Flutter; n = number of participants.

Self-reported usability of ECG247 Smart Heart Sensor

Four participants reported some discomfort (itching) underneath the sensor patch on the chest. Three of these four athletes reported that the itching stopped after the first 24 hours of the test. Nine athletes reported forgetting that they were wearing the sensor from time to time. No athletes reported trouble sleeping or training with the ECG247 sensor. None of the 13 tested athletes reported problems with the connection or Smart phone application. However, 7 athletes reported concerns and questions around results during the test period (Table 7).

Table 7: *Usability of ECG247 Smart Heart Sensor*

	All (n=13)
Itching	4
No reported discomforts	9
Disturbed sleep	0
Disturbed training	0
Disturbed Phone connection	0
Concerns during the test	7

Values are presented as prevalence. n = number of participants

DISCUSSION

The purpose of the web-based questionnaire was to investigate endurance athletes and quantify potential relationships between their training characteristics and health experiences, including CA and CVD. In total, 9.6% of the 1802 respondents reported a diagnosis of some form of CVD. The current population was relatively young (43±14yr) and had a high annual training volume (492±210). Previous studies investigating the general population and the prevalence of AF, CA, and CVDs have consisted of larger samples, an older population, different nationalities with access to different healthcare services (public and private). This makes direct comparison difficult, however, larger studies conducted on the general population can provide a perspective which can be used when investigating athletes. Of 3960 randomly selected British subjects, aged 45 and above, 78 (2%) were diagnosed with AF. Only 0.2% of those aged 45-54 had AF, compared with 8% of the 75 and older group (20).

A similar study analyzing the prevalence of AF in 1.89 million adults in the United States, the prevalence was 0.1% among adults younger than 55 years old and increased to 9% in persons aged 80 years or older (21). Despite the errors with comparing this current study with larger cross-sectional studies and cohort studies, the prevalence of diagnosed AF is reported consistently higher in an endurance trained population (8-12, 22). In contrasty, prevalence of other CA and CVDs are lower compared with larger population studies.

The strongest independent predictor of diagnosed AF is age. Both in the current study and in larger population studies, elderly are more likely to have diagnosed AF (21, 23). Independent of the influence of age, the results from the questionnaire indicate that athletes with the highest volume of annual endurance training had higher prevalence of diagnosed AF. In addition, successive groupings created by demarcations at 250, 500, and 750 annual hours training were associated with higher prevalence of diagnosed AF. This is particularly interesting because the average age of these training volume groups was significantly younger in the higher performance and annual training volume group compared with the other groups. The current questionnaire data does not identify the age of initial diagnosis with AF, and this is a shortcoming of the data that limits its interpretation. It would have been interesting to investigate how much the subjects had been training and how old they were when AF was initially diagnosed. In addition, experienced symptoms of CA (undiagnosed) were higher in the group with the highest annual training volume compared with the other groups.

However, these athletes are constantly living with high daily training volume and may be more sensitively aware of the physiological and perceptual signals and symptoms that occur when exercising. A weakness with generalizing the results from either the groups based on annual training volume, or the groups based on self-reported performance level is the size of the groups. 189 athletes reported 751 or more annual training volume, and 110 identified in the highest subjective performance level group (professional/ international elite). The sample size representing the elite athlete is representative (24). However, comparison with the other groups in the present study should be made with caution given the disparity in sample size.

Communication about health experiences was surveyed in the questionnaire to investigate who the athletes contacted/confided in when experiencing unusual symptoms. The current findings suggest that high performance athletes contacted and talked about unusual/uncomfortable symptoms with coach (46%) more often than doctor (37%).

This reflects the importance of the coach for elite athletes, also when it comes to athlete monitoring and managing athlete health. Studies investigating the coach's credibility for the athletes report that athletes listen to their coach above the advice of doctors and other healthcare personnel (25, 26). In addition, 32% of the highest training volume group (≥750 hours/yr.) reported that they kept symptoms to themselves as long as they did not prevent them from training, which is frightening. Ignoring signals and symptoms could increase the risk of developing long-term injuries and/or illnesses that can negatively impact their current sporting career in addition to life after the sport-career (27, 28).

Cardiac health screening is important for detecting CA or other CVDs; early detection is in many cases connected with lower long term health risk and may prevent larger strokes and other cardiac events in the future (29, 30). The findings in the present questionnaire suggest high rates of cardiac health screening, especially echocardiogram (35.7%) and EST (31.3%) with an increasing testing frequency among athletes with higher annual training volume (48.7% and 38.1%) and performance level (45.4% and 39%). High rate of cardiac health screening among the top performance level and among those with high training volume could be in part explained by contracts with professional teams. In these contracts, a baseline health screening is required, either by the individuals' doctors or by the team's health team. Echocardiogram and EST are often part of these baseline health screenings and do not interfere with everyday training.

However, Echo and EST provide a snapshot of cardiovascular function that is less sensitive to underlying electrical disturbances than long-term ECG recordings. In addition, the general findings of cardiac health screening may be affected by testing algorithms enforced by different national healthcare services. Public healthcare systems often require a symptom profile that provides strong indices for additional tests and is often a more time-consuming process compared with a private healthcare service. In contrast, private healthcare services often have a lower threshold for performing additional diagnostic testing despite less clear symptomology (31).

ECG247 Smart Heart Sensor

This study of the ECG247 Smart Heart Sensor technical performance in 13 endurance athletes from the Uno-X Pro Cycling Team during extensive training verified the ECG quality and usability satisfactory for heart rhythm assessment, also during exercise.

Long-term continuous ECG recording increases the likelihood of detecting paroxysmal AF compared to intermittent ECG recording (32). The findings of the present study suggest that the ECG247 Smart Heart Sensor provides an easier method of monitoring cardiac health continuously, with minor to no negative side effects or annoyances. While conventional diagnostic tools for assessment of rhythm disorders suffer from limited availability, limited test duration time, and usability challenges, particularly under the demanding training conditions of an elite athlete.

The reported usability of the ECG247 Smart Heart Sensor was high, and no athletes reported trouble sleeping or training while wearing the sensor. The project leader present at the training camp during the field testing received a total of 7 athlete concerns during the test period. These concerns arose mainly from reports from the application saying that there was a possible arrhythmia. Most of these events were determined to be false positive. Importantly, no actual ECG arrythmias went undetected (false negative) by the algorithmic solution in over 1800 hours of ECG monitoring.

ECG247 Smart Heart Sensor showed promising usability both on the individual level and in a team training camp context. The sensor enables transition of the assessment of arrhythmias from the hospitals to the athlete's training and competition environment. Professional sports teams are often composed of multinational athletes, with different healthcare services. An out-of-hospital, reusable cardiac rhythm device could make assessment of heart rhythm disorders and heart symptoms cheaper and less time-consuming compared with the conventional hospital methods (Holter monitor). In addition, ECG247 Smart Heart Sensor did not limit exercise in any way, which is a crucial detail when monitoring elite athletes.

The primarily purpose of the pilot test was to investigate how different movements (cycling, double-poling, running) affected the ECG recordings, as well as evaluate the tolerance of the single-use electrode for repeated bouts of exercise and showering. The pilot testing completed as a prelude to the present study illustrates that there are some differences in ECG quality among exercise modalities. There was one incident of a false positive AFLU, which provided perspectives amongst the safety of the athletes. A cardiologist was brought in the help with analyzing of ECG recordings simultaneously during the test period. The quality of the ECG recordings was considered satisfactory for hearth rhythm assessment in the pilot test. However, more work is needed on the different modalities and its influence on the quality of the ECG recordings.

The findings from the present field testing will inform algorithm adaptation for sport medicine applications. This athlete population represented a severe test of the technical solution given the high training volumes performed. The capacity of the solution to deliver continuous, interpretable ECG recordings for at least 48 hours was deemed as a cutoff for minimum viability in a sports medicine context. The arrythmia detection algorithms employed were originally based on a sedentary, primarily elderly population. SVTs and AFLU are electrically similar to the ECG of an athlete exercising with abrupt changes in HR. Therefore, the physician on the research team anticipated a risk of false positive findings associated with the high heart rates achieved during normal training in this elite athlete group. Prior to the field test, athlete volunteers were informed that the integrated arrhythmia analyzing algorithm was sensitive to abrupt HR elevation and might falsely detect events of AFLU and SVTs.

Strength and limitations

The main strengths of the present study were: (a) two independent data sampling methods, which provided a more thorough understanding of the phenomena of interest (CA in endurance athletes), (b) a high number of representative participants in the questionnaire, (c) cooperation with UNO-X Pro Cycling Team, which provided an excellent field-testing environment, and (d) extensive preliminary pilot testing of both sampling methods.

The questionnaire provided a descriptive, quantitative picture of the status among endurance athletes across nationalities and endurance sports. However, both health screening of athletes and health screening in general are performed differently dependent on whether the healthcare service is public or privately provided in the country of residence. The main limitations of the web-based self-report questionnaire are information bias and accuracy response issues. Even with electronical response validations and specific response options it is possible on some questions for subjects to misinterpret questions and submit erroneous responses. Also, questionnaires asking for quantification of physical activity often result in overestimation of the subjects' training data. In addition, in questionnaires investigating prevalence of different variables, age is a central component connected with higher prevalence. Therefore, age was considered as a determinant variable when investigating prevalence in the groupings with lower average age compared with the average of the whole questionnaire.

A training camp, with a professional cycling team was an appropriate environment for testing whether ECG247 Smart Heart Sensor withstands the typical patterns of athlete training several hours daily, showering, etc. In addition, testing the sensor during a training camp was a good simulation for investigating how it works in a team context.

On-time access to a cardiologist was crucial for this study because it provided both reassurance for the athletes and ensured an optimal analysis process. However, this was not an interventional study, and there was no comparison with today's best practice (Holter monitoring). Cycling is also one of the endurance sports with the least amount of movement in the upper body. Therefore, the present findings should not be generalized to all sports movements.

Practical applications

The importance of large volumes of training to perform at a high level in endurance sports is well documented among elite athletes (1-3). The findings in the web-based questionnaire supports that diagnosed AF and perceived symptoms of CA increases in conjunction with performance level and annual endurance training volume despite age. These findings highlight the need for cardiac screening methods which are easily accessible and do not interfere with the everyday training of an elite athlete. The field test of ECG247 Smart Heart Sensor illustrates how the screening of cardiac health can be done in an elite team environment, without any interference of training and sleeping. As mentioned, cycling is one of the endurance sports with the least amount of movement in the upper body. Therefore, additional field testing of this device in other athlete groups, such as runners, is warranted. The pilot testing completed as a prelude to the present study illustrates that there are some differences in ECG quality among exercise modalities. However, more work is needed on the subject.

Conclusion

The present study demonstrates that endurance athletes are in a risk group of developing cardiac arrhythmia and that there is a need for more accessible, out-of-hospital methods for heart rhythm assessment. The study also demonstrates that the ECG247 Smart Heart Sensor allowed high quality ECG monitoring with high usability during intensive exercise in athletes. In order to decrease the rate of false positive results, the integrated arrhythmia algorithm should be further developed for this user group with its high HR and training volume.

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DATA AVAILABILITY

The data that support the findings of this study are available on request from the corresponding author.

DISCLOSURE

The funder had no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, and in the preparation, review, or approval of the manuscript.

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PART 3

Appendices

Contents:

Appendix 1

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: **10000366191-PA-NA-NOR Rev.0.0**

Project No.: **PRJC-601285-2019-MSL-NOR**

Valid Until: **27 May 2024**

This is to certify that the quality system of:

AppSens AS

Bergshaven 17, 4790
Lillesand, Norway

For design, production and final product inspection/testing of:
ELECTROCARDIOGRAPHIC LONG-TERM AMBULATORY RECORDER SYSTEM AND BELONGING SOFTWARE

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 03 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	03-11-2020

Products covered by this Certificate:

Product Description	Product Name	Class
ECG System including:		
ECG247 Smart Sensor	Model: 353 010	IIa
ECG247 Electrode	Model: 353 010	IIa
ECG247 APP		IIa
ECG247 Smart Sensor Software Solution		IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
AppSens AS	Bergshaven 17, 4790 Lillesand, Norway

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

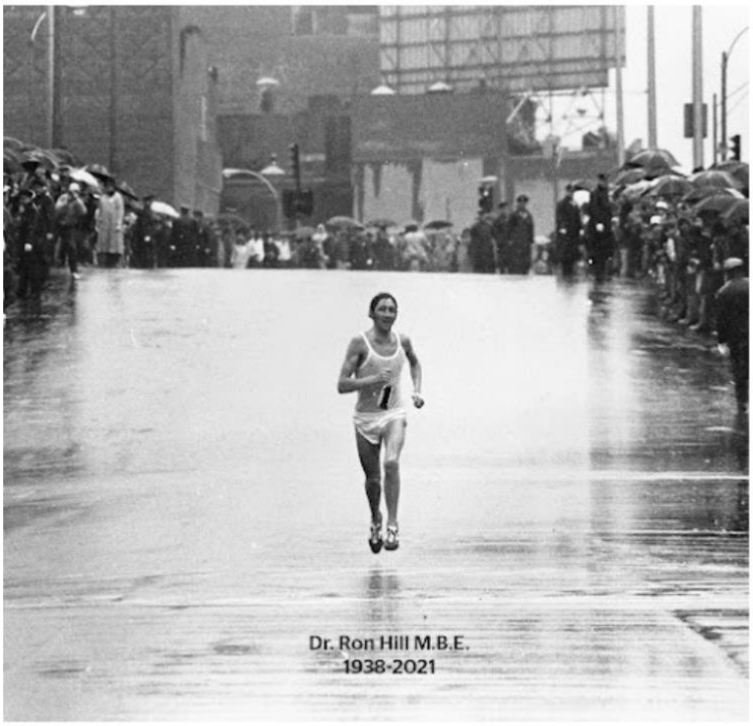
End of Certificate

Appendix 2

Training and Health Characteristics - Endurance Athletes

Masters thesis project in Sport Science

* Required



1. 1. What region of the world du you live in? *

   Mark only one oval.

   - ◯ Europe
   - ◯ North America
   - ◯ South America
   - ◯ Asia
   - ◯ Africa
   - ◯ Oceania
   - ◯ Antarctica (Just in case)

2. 2. Gender *

   Mark only one oval.

   - ◯ Female
   - ◯ Male
   - ◯ Non-binary

3. 3. Age *

   Years

4. 4. Bodyweight in Kilograms (KG) *

Nearest whole KG. 1KG = 2.2 pounds. See chart below for conversion from Pounds.

Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms	Pounds	Kilograms
5	2.3	58	26.3	111	50.3	164	74.4	217	98.4
6	2.7	59	26.8	112	50.8	165	74.8	218	98.9
7	3.2	60	27.2	113	51.3	166	75.3	219	99.3
8	3.6	61	27.7	114	51.7	167	75.8	220	99.8
9	4.1	62	28.1	115	52.2	168	76.2	221	100.2
10	4.5	63	28.6	116	52.6	169	76.7	222	100.7
11	5.0	64	29.0	117	53.1	170	77.1	223	101.2
12	5.4	65	29.5	118	53.5	171	77.6	224	101.6
13	5.9	66	29.9	119	54.0	172	78.0	225	102.1
14	6.4	67	30.4	120	54.4	173	78.5	226	102.5
15	6.8	68	30.8	121	54.9	174	78.9	227	103.0
16	7.3	69	31.4	122	55.3	175	79.4	228	103.4
17	7.7	70	31.8	123	55.8	176	79.8	229	103.9
18	8.2	71	32.2	124	56.2	177	80.3	230	104.3
19	8.6	72	32.7	125	56.7	178	80.7	231	104.8
20	9.1	73	33.1	126	57.2	179	81.2	232	105.2
21	9.5	74	33.6	127	57.6	180	81.6	233	105.7
22	10.0	75	34.0	128	58.1	181	82.1	234	106.1
23	10.4	76	34.5	129	58.5	182	82.6	235	106.6
24	10.9	77	34.9	130	59.0	183	83.0	236	107.0
25	11.3	78	35.5	131	59.4	184	83.5	237	107.5
26	11.8	79	35.8	132	59.9	185	83.9	238	108.0
27	12.3	80	36.3	133	60.3	186	84.4	239	108.4
28	12.7	81	36.7	134	60.8	187	84.8	240	108.9
29	13.2	82	37.2	135	61.2	188	85.3	241	109.3
30	13.8	83	37.6	136	61.7	189	85.7	242	109.8
31	14.1	84	38.1	137	62.1	190	86.2	243	110.2
32	14.5	85	38.6	138	62.6	191	86.6	244	110.7
33	15.0	86	39.0	139	63.1	192	87.1	245	111.1
34	15.4	87	39.5	140	63.5	193	87.5	246	111.6
35	15.9	88	39.9	141	64.0	194	88.0	247	112.0
36	16.3	89	40.4	142	64.4	195	88.5	248	112.5
37	16.8	90	40.8	143	64.9	196	88.9	249	112.9
38	17.2	91	41.3	144	65.3	197	89.4	250	113.4
39	17.7	92	41.7	145	65.8	198	89.8	251	113.9
40	18.1	93	42.2	146	66.2	199	90.3	252	114.3
41	18.6	94	42.6	147	66.7	200	90.7	253	114.8
42	19.1	95	43.1	148	67.1	201	91.2	254	115.2
43	19.5	96	43.5	149	67.6	202	91.5	255	115.7
44	20.0	97	44.0	150	68.0	203	92.1	256	116.1
45	20.4	98	44.5	151	68.5	204	92.5	257	116.6
46	20.9	99	44.9	152	68.9	205	93.0	258	117.0
47	21.3	100	45.4	153	69.4	206	93.4	259	117.5
48	21.8	101	45.8	154	69.9	207	93.9	260	117.9
49	22.2	102	46.3	155	70.5	208	94.3	261	118.4

5. 5. Height in meters (m) Example: 1.80 See conversion chart below for feet and inches to meters *

Height Conversion Chart

Imperial		Metric
ft	in	m
4	0	1.22
4	½	1.23
4	1	1.25
4	1½	1.26
4	2	1.27
4	2½	1.28
4	3	1.30
4	3½	1.31
4	4	1.32
4	4½	1.33
4	5	1.35
4	5½	1.36
4	6	1.37
4	6½	1.38
4	7	1.40
4	7½	1.41
4	8	1.42
4	8½	1.44
4	9	1.45
4	9½	1.46
4	10	1.47
4	10½	1.49
4	11	1.50
4	11½	1.51
5	0	1.52
5	½	1.54
5	1	1.55
5	1½	1.56
5	2	1.57
5	2½	1.59
5	3	1.60
5	3½	1.61
5	4	1.63
5	4½	1.64

Imperial		Metric
ft	in	m
5	6½	1.69
5	7	1.70
5	7½	1.71
5	8	1.73
5	8½	1.74
5	9	1.75
5	9½	1.77
5	10	1.78
5	10½	1.79
5	11	1.80
5	11½	1.82
6	0	1.83
6	½	1.84
6	1	1.85
6	1½	1.87
6	2	1.88
6	2½	1.89
6	3	1.91
6	3½	1.92
6	4	1.93
6	4½	1.94
6	5	1.96
6	5½	1.97
6	6	1.98
6	6½	1.99
6	7	2.00
6	7½	2.01
6	8	2.03
6	8½	2.05
6	9	2.06
6	9½	2.07
6	10	2.08
6	10½	2.10
6	11	2.11

5	5	1.65
5	5½	1.66
5	6	1.68

6	11½	2.12
7	0	2.13

6. 6. What is your typical Resting heart rate (measured in the morning, laying down)?

7. 7. What is your current Maximal heart rate (observed during the last year of training or racing and from an accurate Heart Rate measurement)?

8. 8. What is your primary sport? *

Mark only one oval.

- ◯ Road Cycling
- ◯ MTB Cycling
- ◯ Ultra-distance cycling
- ◯ Distance running
- ◯ Ultra-distance running
- ◯ Triathlon
- ◯ Rowing
- ◯ Swimming
- ◯ Cross-Country skiing or other endurance skiing sports
- ◯ Orienteering
- ◯ Other endurance specific sport

9. 9. Which category best describes your performance level? *

Mark only one oval.

- ◯ Professional / International Elite
- ◯ National standard / University Scholarship
- ◯ Regional standard
- ◯ Age group / Master competitive athlete
- ◯ Recreational athlete (compete occasionally)

Training Characteristics

When answering these questions, it is a good idea to have your training diary accessible. If you are struggling with finding the exact answer to the questions regarding number and volume, try to make the best estimate you can.

10. 10. How many years have you been regularly training for endurance sport performance? *

Answer in whole years

_____

11. 11. What was your total training duration in hours in 2021, including all endurance, strength sessions, speed etc... *

For example, 670 hours. If you do not have the exact number, make a qualified estimate based on weekly training loads, subtracting for vacations, injury time, etc.

_____

12. 12. How much of your total training time (whole hours) in 2021 was ENDURANCE training? (subtract time used on strength training, flexibility sessions, plyometrics, etc.) *

_____

13. 13. What was your total number of training sessions in 2021? *

Be as accurate as your data allows. Make a good estimate if necessary. For example, if you train 5 times a week, and have a couple of vacation/sickness/injury weeks, that adds up to 50wk x 5 sessions per week or ~250 training sessions per year.

_____

During a 1-year season, we often distinguish between three main periods of training: 1. Preparation period. 2. Competition period. 3. Transition period (Off-season). The next few questions will focus on the preparation period.

14. 14. How many times per week did you train, on average, during the preparation period? (If you eat and change your kit between, then that is two training sessions) *

You can use a decimal, for example 8.5 times per week on average, if you have that accuracy in your own diary

15. 15. How many training hours/ week did/will you average during your most recent preparation period? *

Nearest whole hour

Intensity scale: Zone 1 = Low - intensity training - Zone 2-3 = High - intensity training. Use this scale to answer question 15 - 18. (Sylta, 2014).

Intensity zone	Lactate[a] (mmol/L)	Heart rate (% max)	3-zone model	Binary model
5	6.0–10.0	92–97	Zone 3	high-intensity training
4	4.0–6.0	87–92	Zone 3	high-intensity training
3	2.5–4.0	82–87	Zone 2	high-intensity training
2	1.5–2.5	72–82	Zone 1	low-intensity training
1	0.8–1.5	55–72	Zone 1	low-intensity training

Note: The reference values in this scale are guidelines only, and individual adjustments are required.

[a] Measured with lactate pro LT-1710.

16. 16. What was your average weekly number of high intensity endurance training sessions (sessions/wk) during the preparation period? *

You can use a single decimal (2.3 high intensity sessions/wk average) if your data is that accurate

17. 17. What was your average weekly high-intensity endurance training volume (minutes/wk) during the preparation period? *

Example: 2 HIIT sessions of 5 bouts x 6 minutes with 2 min recovery = 30min + 30min = 60minutes of HIT volume

18. 18. What was your average number of weekly low intensity endurance training sessions (sessions/wk)? *

You can use 1 decimal, for example 6.5 LIT sessions per week, if your data is sufficiently accurate.

19. 19. What was your average weekly low intensity endurance training volume (hours/wk) during the preparation period? *

You can use a decimal if your data is that accurate, for example, 12.5 hours per week LIT

Medical History

Questions regarding your health and how you relate to it.

20. 20. Have you ever been diagnosed with one or more of the following *

Check all that apply.

- [ ] Atrial fibrillation
- [ ] Other cardiovascular arrhythmia condition
- [ ] Hypertension - high blood pressure
- [ ] Other cardiovascular disease
- [ ] An eating disorder resulting in reduced energy availability and/or reduced bodyweight
- [ ] Asthma
- [ ] Exercise induced asthma
- [ ] Severe allergies
- [ ] Osteoarthritis - degenerative joint disease
- [ ] Other
- [ ] I have never been diagnosed with any of the above

21. 21. Even if NOT diagnosed by a physician, have you experienced one or more of the following? *

Check all that apply.

- [ ] Heart arrhythmias or skipped beats during rest
- [ ] Heart arrhythmias or skipped beats during exercise
- [ ] Energy intake issues related to wanting to be lighter for presumed better performance
- [ ] Sudden severe back pain - which gets worse while standing up
- [ ] Acute dizziness while standing up from a seated position
- [ ] Breathlessness during exercise (beyond normal high ventilation when working hard)
- [ ] Trouble breathing during rest
- [ ] Hearing buzzing sounds in your ear
- [ ] Morning headache and nausea
- [ ] I have not experienced any of the above

22. 22. If you feel some of the symptoms above or other, do you inform the following about the situation? *

Check all that apply.

- [ ] Coach
- [ ] Doctor or other health personell
- [ ] Physical therapist
- [ ] Significant other
- [ ] Keep it for myself
- [ ] I have not experienced any of the symptoms above

23. 23. Have you ever performed these health screening tests? *

Check all that apply.

- [ ] General blood test
- [ ] Urine test
- [ ] DEXA, MRI or CT scan - for bone density
- [ ] Lung health - Asthma, Eilo etc...
- [ ] Blood pressure
- [ ] 24h blood pressure monitoring
- [ ] 24h Holter monitoring - ECG testing over 24h
- [ ] Exercise ECG - ECG while exercising at the doctor's office
- [ ] Echocardiogram - Ultrasound of your heart
- [ ] I have not performed any of the above medical diagnostic tests

24. 24. Do you regularly (>/= 1x/week) use any medication or painkillers during training or competition? *

Check all that apply.

- [ ] Local corticosteroid
- [ ] Non-steroidal anti-inflammatory drugs - NSAID - Ibuprofen etc.
- [ ] Light (non-prescription) analgesics - Paracetamol, Asprin etc.
- [ ] Strong (prescription) analgesics - Tramadol, Paralgin Forte, etc.
- [ ] Pain- relieving creams/gels - Voltaren, Tiger Balm, Bio Freeze, etc.
- [ ] Asthma medication - Ventolin, ProAir etc.
- [ ] Other similar type of medication not listed
- [ ] I occasionally take pain/anti-inflammatory medication when training or competing
- [ ] I do not take any pain/anti-inflammatory medication when training or competing

Appendix 3

Hello …!

We are conducting a global survey investigating potential relationships between training characteristics and health among endurance athletes. We are also investigating the degree of "health focus" among endurance athletes. This will be part of my master's project in Sport Science at the University of Agder, which aims to shed light on long-term performance development and health in endurance athletes.

You in **…** with your members and followers has been selected as potential respondents based on the sport you are practicing and your culture of training. We would be grateful if you could share the link or QR code below with your members and/or followers! All participants must be 1) at least 18 years old and 2) train and/or compete in endurance sports, this survey is designed to be completed by everyone from recreational endurance enthusiasts to professional/international elite athletes. Completing this survey will create no connection or requirements to the respondents other than the survey.

The survey is digital and will be delivered through the tool Google Forms (duration of 10-15 minutes). We will ensure complete anonymity as this survey does **not** store IP addresses, names, or any information that makes it possible to trace back to individual respondents.

We really value your input and hope you will take the time to both complete the survey and spread it to other endurance athletes. There are templates of potential Instagram, Facebook, and Twitter posts which you can use attached above!

Thank you in advance!

Best regards

Dr. Stephen Seiler – Professor at University of Agder, Department of Sport Science and Physical Education, Kristiansand, Norway

Ådne Ausland – Master's candidate in Sport Science at University of Agder

Questions regarding the survey and the research project can be sent to:

endurance.health.uia@gmail.com

Appendix 4

Vil du delta i forskningsprosjektet

Detecting arrythmias among elite athletes?

Dette er et spørsmål til deg om å delta i pilotfasen av et større forskningsprosjekt hvor formålet er å undersøke om ECG247 kan brukes til å måle hjertets elektriske signaler (elektrokardiogram eller EKG) og diagnostisere spesifikke kardiologiske rytmeforstyrrelser blant idrettsutøvere. I dette skrivet gir vi deg informasjon om målene for dette pilotprosjektet og hva deltakelse vil innebære for deg.

Formål
ECG247 er en ny, trådløst elektrokardiogram (EKG) måler. Ifølge utviklerne måler apparatet kontinuerlig overvåkning av hjerte i opptil 7 døgn og kan brukes under fysisk aktivitet. All data som måleren gir blir lagret gjennom en mobil applikasjon som kan lastes ned på mobiltelefonen, og dataen kan bli sendt direkte til en lege og kardiolog. Dataen fra sensoren blir overført til mobilen og til en skytjeneste som lagrer flere EKG utdrag hver time, og samtidig kan detektere, klassifisere, og lagre «uvanlige» EKG signaler som oppstår. Utprøvingen av ECG247 under fysisk aktivitet vil være en del av en masteroppgave, hvor en av problemstillingene blir undersøkt: Vil den ECG247 tekniske løsning tåle bevegelsen og svettingen assosiert med vanlig utholdenhetstrening under laboratorieforhold?

Hvem er ansvarlig for forskningsprosjektet?
Ådne Ausland er praktisk ansvarlig for prosjektet. Professor Stephen Seiler fra UiA har overordnet ansvar og er veilederen.

Hvorfor får du spørsmål om å delta?
Til denne uttestingen av ECG247 vil studenter ved Instituttet for idrettsvitenskap og kroppsøving bli kontaktet, det er ønskelig at deltakerne har en treningsbakgrunn og utøver utholdenhetstrening på ukentlig basis.

Hva innebærer det for deg å delta?
Hvis du velger å delta i prosjektet, innebærer det at du tar på en ECG247 måler og gjennomfører en enkel laboratorieprotokoll som tar til sammen 1 time med tiden fordelt på løping, sykling og staking. ECG247 måler skal være på i totalt 1-3 døgn for å få en fullstendig utprøving av funksjonaliteten til apparatet. Du skal dusje, trene og ellers være like aktive som du pleier under utprøvingen. Det vil være nødvendig å laste ned ECG247 applikasjonen på mobiltelefonen og dele dataen via mobiltelefonen med prosjektleder.

Det er frivillig å delta
Det er frivillig å delta i prosjektet. Hvis du velger å delta, kan du når som helst trekke samtykket tilbake uten å oppgi noen grunn. Alle dine personopplysninger vil da bli slettet. Det vil ikke ha noen negative konsekvenser for deg hvis du ikke vil delta eller senere velger å trekke deg.

Ditt personvern – hvordan vi oppbevarer og bruker dine opplysninger
Vi vil bare bruke opplysningene om deg til formålene vi har fortalt om i dette skrivet. Vi behandler opplysningene konfidensielt og i samsvar med personvernregelverket.

- Kun prosjektleder og veileder vil ha tilgang til dataen som kommer fra uttestingen.
- All data vil bli lagret på applikasjonen på mobiltelefonen til deltakeren, delingen av dataen gjøres via applikasjonen. Applikasjonen er godkjent i Norge og i EU sammenheng som et medisinsk apparat og datalagringsløsningen er i samsvar med personvernregelverket.
- Informasjon som blir eventuelt publisert fra din deltakelse vil IKKE være mulig å spore tilbake til deg.

Hva gir oss rett til å behandle personopplysninger om deg?
Vi behandler opplysninger om deg basert på ditt samtykke.

Hvor kan jeg finne ut mer?
Hvis du har spørsmål til studien, eller ønsker å benytte deg av dine rettigheter, ta kontakt med:

Ådne Ausland, prosjektleder, epost (aadnea17@uia.no) eller på telefon: 412 69 624

Stephen Seiler, veileder, epost (stephen.seiler@uia.no) eller på telefon: 916 14 587

Med vennlig hilsen

Ådne Ausland

Jeg har mottatt og forstått informasjon om prosjektet *Detecting arrythmias among elite athletes* og har fått anledning til å stille spørsmål. Jeg samtykker til:

- ☐ å delta i laboratorietesting av ECG247
- ☐ å ha ECG247 måleren på i 1-3 døgn

Jeg samtykker til at mine opplysninger behandles frem til prosjektet er avsluttet

---

(Prosjektdeltaker, dato)

Appendix 5

Covid-19: Egenerklæring

- Er du per i dag satt i karantene eller isolasjon?
  - ☐ Ja
  - ☐ Nei

- Har du vært i kontakt med noen som har vært smittet av korona i løpet av de siste 14 dagene?
  - ☐ Ja
  - ☐ Nei

- Har du opplevd noen av følgende symptomer de siste 10 dagene (kryss av for eventuelle symptomer)?
  - ☐ Feber
  - ☐ Hoste
  - ☐ Vond/sår hals
  - ☐ Nei

- Har du opplevd tap av smak- eller luktesans i løpet av de siste 10 dagene?
  - ☐ Ja
  - ☐ Nei

- Har du vært i utlandet/områder med høy smitte de siste 10 dagene?
  - ☐ Ja
  - ☐ Nei

Dato:

Utøver/foresatt:

_____

Appendix 6

UiA Faculty of Health and Sport Sciences

Are you interested in taking part in the research project:

Detecting arrythmias among elite athletes?

We seek your participation in a research project where the main purpose is to investigate if ECG247 can be used for cardiac screening and diagnosing specific heart rhythm abnormalities among active endurance athletes. In this letter we will give you additional information about the purpose of the project and what your participation will involve.

Purpose of the project

ECG247 is a new, wireless electrocardiogram (ECG) unit. The developer reports that the sensor provides continuous cardiac monitoring up to 7 days and can be used during physical activity. The ECG247 application monitors, evaluates, and saves samples of ECG data continuously through Bluetooth on your phone in combination with a cloud-based service. All the data can be shared with your doctor or cardiologist via the ECG247 app on your phone. The ECG247 will detect, classify, and save every unusual ECG signal which may occur. This new technology was originally designed for older, non-athletes living at home and has not been systematically tested on athletes. If this technology withstands the rough use of elite athletes, it provides a unique new method of athlete screening and monitoring that would dramatically simplify cardiac screening and induce much less stress on athletes subjected to this form of testing.

Who is responsible for the research project?

The Faculty of Health and Sport Science at University of Agder is responsible for the project. Ådne Ausland is a master's student and has practically responsibility for the training camp data collection. Dr. Stephen Seiler has the overall responsibility as the academic supervisor and consulting sport scientist for Uno-X. The Department of Cardiology at Sørlandet Hospital is responsible for quality assurance and analysis of the ECG247 data.

Why are you being asked to participate?

For this project, it is desirable that participants compete and train for endurance performance at a high level. Uno-X riders are training many hours a week and represent a very tough but relevant test case! ?

What does participation involve for you?

If you chose to take part in the project, you will wear a small ECG247 sensor on your chest and try to keep your phone near the sensor during the testing period. The test will last for 3-6 days to have a completely testing of the functionality of the sensor. You will shower, train, and otherwise live as normal. Besides wearing the sensor, you will 1) download ECG247 application on your phone and 2) agree to share the data with the project leader. The sensor is small and lightweight; and our experience is that wearers forget they have it on quite quickly.

Participation is voluntary
Participation in the project is voluntary. If you chose to participate, you can withdraw your consent at any time without giving a reason. All information about you will then be made anonymous. There will be no negative consequences for you if you chose not to participate or later decide to withdraw.

Your personal privacy – how we will store and use personal data
We will only use your personal data for the purposes specified in this information letter. We will process your personal data confidentially and in accordance with data protection legislation (the General Data Protection Regulation and Personal Data Act).

- The project leader, supervisor and a certified doctor will have access to the ECG data.
- Samples of your continuously monitored ECG data will be uploaded from the application to an encrypted cloud server. Further sharing of data to approved colleagues will be achieved via the cloud server. The application is approved in Norway and in EU as a medical device and the data storage complies with EU and Norwegian privacy regulations.
- Data that may be published from your participation will be anonymous and will NOT be possible to trace back to your identity.

Your rights:
So long as you can be identified in the collected data, you have the right to:

- access the personal data that is being processed about you
- request that your personal data be deleted
- request that incorrect personal data about you be corrected/rectified
- send a complaint to the Data Protection Officer or The Norwegian Data Protection Authority regarding the processing of your personal data

What gives us the right to process your personal data?
We will process your personal data based on your informed, written consent

Where can I find out more?
If you have questions about the project, or later want to exercise your rights to withdraw, contact:

Ådne Ausland, Project Leader, Mail (aadnea17@uia.no), Telephone: +4741269624

Stephen Seiler, supervisor, Mail (stephen.seiler@uia.no), Telephone: +4791614587

Johanne W. Lavold, Protection officer, Mail (Johanne.lavold@uia.no), Telephone: +4738141328

The Norwegian Centre for Research Data, Mail: (personverntjenester@nsd.no), Telephone: +4753211500

Edvard Sandberg, Sørlandet Hospital, Mail (edvard.sandberg@sshf.no), Telephone: +4740339539

Yours sincerely,

Ådne Ausland

I have received and understood information about the project *Detecting arrythmias among elite athletes* and have been given the opportunity to ask questions. I give my informed consent:

- ☐ To participate in the ECG247 testing
- ☐ To wear the ECG247 sensor for at least 3 days
- ☐ To provide access to training diary
- ☐ To provide access to ECG247 data to project leader and certified doctors

I give consent for my personal data to be processed until the end date of the project.

(Signed by participant, date)

Appendix 7

NSD NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

Hjertearytmi blant utholdenhetsutøvere - Del 1

Referansenummer

800080

Registrert

15.09.2021 av Ådne Ausland - aadnea17@student.uia.no

Behandlingsansvarlig institusjon

Universitetet i Agder / Fakultet for helse- og idrettsvitenskap / Institutt for folkehelse, idrett og ernæring

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Stephen Seiler, stephen.seiler@uia.no, tlf: +4791614587

Type prosjekt

Studentprosjekt, masterstudium

Kontaktinformasjon, student

Ådne Ausland, aadnea17@uia.no, tlf: 41269624

Prosjektperiode

01.11.2021 - 22.05.2022

Status

15.10.2021 - Vurdert anonym

Vurdering (1)

15.10.2021 - Vurdert anonym

Det fremgår av meldeskjema den 15.10.2021 med vedlegg og dialog at det ikke skal behandles opplysninger i prosjektets del 1 som kan identifisere enkeltpersoner verken direkte eller indirekte.
Del 1 av prosjektet trenger derfor ikke en vurdering fra NSD.

HVA MÅ DU GJØRE DERSOM DU LIKEVEL SKAL BEHANDLE PERSONOPPLYSNINGER?
Dersom prosjektopplegget endres og det likevel blir aktuelt å behandle personopplysninger må du melde dette til NSD ved å oppdatere meldeskjemaet. Vent på svar før du setter i gang med behandlingen av personopplysninger.

VI AVSLUTTER OPPFØLGING AV PROSJEKTET

Siden prosjektet ikke behandler personopplysninger avslutter vi all videre oppfølging.

Kontaktperson hos NSD: Karin Lillevold
Lykke til med prosjektet!

Appendix 8

NSD NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

Hjertearytmi blant utholdenhetsutøvere - Del 2

Referansenummer

350657

Registrert

15.09.2021 av Ådne Ausland - aadnea17@student.uia.no

Behandlingsansvarlig institusjon

Universitetet i Agder / Fakultet for helse- og idrettsvitenskap / Institutt for folkehelse, idrett og ernæring

Prosjektansvarlig (vitenskapelig ansatt/veileder eller stipendiat)

Stephen Seiler, stephen.seiler@uia.no, tlf: +4791614587

Type prosjekt

Studentprosjekt, masterstudium

Kontaktinformasjon, student

Ådne Ausland, adne_ausland@outlook.com, tlf: 41269624

Prosjektperiode

01.11.2021 - 22.05.2022

Status

18.10.2021 - Vurdert

Vurdering (1)

18.10.2021 - Vurdert

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet den 18.10.2021 med vedlegg, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte når etisk godkjenning foreligger. Denne skal også lastes opp i meldeskjemaet.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle særlige kategorier av personopplysninger om helse og alminnelige kategorier av personopplysninger frem til 22.05.2022.

LOVLIG GRUNNLAG

Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse, som kan dokumenteres, og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a, jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om:

- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
NSD vurderer at informasjonen om behandlingen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18) og dataportabilitet (art. 20).

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

Appsense AS er databehandler i prosjektet. NSD legger til grunn at behandlingen oppfyller kravene til bruk av databehandler, jf. art 28 og 29.

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

MELD VESENTLIGE ENDRINGER
Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilke type endringer det er nødvendig å melde: https://www.nsd.no/personverntjenester/fylle-ut-meldeskjema-for-personopplysninger/melde-endringer-i-meldeskjema
Du må vente på svar fra NSD før endringen gjennomføres.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Kontaktperson hos NSD: Karin Lillevold
Lykke til med prosjektet!

Appendix 9

Ådne Ausland

Besøksadresse:
Universitetsveien 25
Kristiansand

Ref: [object Object]

Tidspunkt for godkjenning: : 25/10/2021

Søknad om etisk godkjenning av forskningsprosjekt - Hjertearytmi blant utholdenhetsutøvere - en todelt masteroppgave

Vi informerer om at din søknad er ferdig behandlet og godkjent.

Kommentar fra godkjenner:
FEK godkjenner søknaden under forutsetning av at prosjektet gjennomføres som beskrevet i søknaden. FEK påpeker at det må legges til kontaktinfo til NSD.

Hilsen
Forskningsetisk komite
Fakultet for helse - og idrettsvitenskap
Universitetet i Agder

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FAKTURAMOTTAK
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