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[Intervention Protocol]

Wearable cardiac monitoring using smart-devices for the detection of atrial fibrillation in adults

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To evaluate the efficacy of wearable smart-devices for the detection of atrial fibrillation.

BACKGROUND

Description of the condition

Cardiac arrhythmias are common in the adult population. Atrial fibrillation (AF) is the most commonly sustained cardiac arrhythmia, with a lifetime risk of 37% after the age of 55 years. It is reported to affect between 2.7 and 6.1 million people in the USA (January 2014). AF is recognised as one of the most common causes of hospitalisation and emergency department visits (Gallagher 2019). It is associated with a five-fold increased stroke risk and is a key contributing factor in approximately 30% of strokes in the elderly (Kannel 1981). Many of these strokes are highly preventable, through enhanced methods for detection and treatment optimisation including anticoagulation prescription and interventions to support long term adherence and persistence with anticoagulation (Brieger 2018). Opportunistic point-of-care screening for AF in people aged ≥ 65 years was recommended in the 2018 Australian Heart Foundation and Cardiac Society of Australia and New Zealand Clinical Guidelines for the Management of Atrial Fibrillation (GRADE quality: moderate; strength of recommendation: Strong) (Brieger 2018).

Description of the intervention

Over the last decade there has been significant innovation and proliferation in the availability of new consumer-grade wearable monitoring technologies. There has been widespread adoption by both consumers and healthcare professionals in the context of variable evidence to support effectiveness (Piwek 2017). Cardiology has an extensive track record of using wearable medical devices to monitor both heart rate and rhythm (Ip 2019). The Holter monitor is an example of the traditional approach to cardiac monitoring for an extended duration in the community setting. This well-known ambulatory electrocardiographic monitor is designed so that wearers are able to maintain their daily activities with negligible risk and inconvenience (Bonewit-West 2018). The Holter monitor (ambulatory continuous electrocardiography) remains the 'go to' device for prolonged, continuous cardiac monitoring in clinical practice to identify atrial fibrillation (Liao 2007). Advantages of Holter monitoring include its relatively low cost, ready availability, reliability and accuracy, and capacity to review multiple leads. Yet there are many disadvantages, including the reliance on lead technology, the potential for artifact, the need for a 24-hour period of continuous recording, and wearer-level factors such as obtrusiveness, discomfort, and stigma of use.

There has been a sharp increase in the development of new and novel detection methods that include the use of wearable and smartphone technologies. Smart-devices are defined as wearable electronic technology worn on the surface of the skin for the detection and acquisition of cardiac activity data (Qin 2018). There is a broad range of new smart-devices available, including wrist-worn watches and bands; adhesive dermal patches; smart weight scales; and clothing such as wearable vests, pajamas, harnesses, and socks. Examples such as Kardia Band, AliveCor, Kardia Monitor, and Zio patch have all demonstrated high sensitivity and specificity to detect arrhythmic episodes (Bolourchi 2015; Bumgarner 2018; Halcox 2017). Some of these devices provide continuous and uninterrupted monitoring, which can be helpful to detect very short durations of arrhythmic episodes that may contribute to the cause of stroke (Lip 2017). Guidelines advise that devices providing a medical quality electrocardiogram (ECG) trace are preferred to pulse-taking or pulse-based devices for screening because an ECG is normally required to make and confirm a diagnosis of AF (Brieger 2018). Recent trials recommend that longer-term monitoring (e.g. external/ wearable devices) should be used for people with embolic stroke of uncertain source (ESUS); there is strong evidence that indicates the longer duration of monitoring is associated with higher rates of AF detection in people with ESUS (Afzal 2015 Kamel 2013). However, the use of traditional external or wearable monitors should depend on local availability and resources (Stroke Foundation 2021).

How the intervention might work

Wearable technologies for cardiac monitoring measure ambulatory ECG, heart rate and rhythm using electrodermal sensors (Wang 2017), bioimpedance (Malfatto 2016), and dielectric tissue properties as an indicator of preclinical changes in intravascular volume status (Amir 2016). Devices require active wearer engagement that ranges from wearing the device with no further active input to actively logging data into a device to link symptoms with ECG data. Data can be continuously or intermittently collected, transmitted, or stored and retrieved at a later time. Establishing the effectiveness of contemporary wearable cardiac monitoring technologies that are less intrusive, and are more likely to be readily adopted in the community, will potentially increase the detection of new onset arrhythmia. This in turn will assist in alerting users of these wearables of cardiac arrhythmia and promptly direct users to a healthcare professional to seek medical advice. Effective opportunistic screening could lead to diagnosis of an underlying cardiac arrhythmia, that would otherwise have been unknown.

Why it is important to do this review

Recent innovation and technological advances in this area have been significant and rapid. It is critical to review the underpinning evidence supporting any recommendations for use of wearable cardiac technologies in adults with AF. Analysts estimate spending on wearables will exceed 52 billion US dollars in 2020, with consumer growth increasing by 38% in 2019 and 48% in 2020 (Gartner 2019). The same analysts estimate that 10% of all wearables will be ‘smart’ (i.e. having sensory effectiveness while being unobtrusive) by 2023; these could be in the form of a smart-watch, ear-worn device, sports-watch, wristband or smart-clothing (Gartner 2019). At present, there is a lack of precise evidence or consensus regarding the use of contemporary wearable cardiac technologies in clinical practice. The purpose of this review is to establish the efficacy of wearable smart-devices for AF detection. It is anticipated that this Cochrane Review will generate new precise evidence to inform clinical practice guideline recommendations, policy advice and clinical practice recommendations.

OBJECTIVES

To evaluate the efficacy of wearable smart-devices for the detection of atrial fibrillation.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), whether randomised at the level of the participant or as a cluster-randomised design. We will include cross-over trials. We will include studies reported as full text, those published as abstracts only, and unpublished data.

Types of participants

We will include adult participants (≥ 18 years of age) who do not have an arrhythmia on study entry and have not had a previous diagnosis of any type of cardiac arrhythmia. We will exclude participants with prior diagnosis of arrhythmia (AF, atrial flutter, or atrial tachycardia); participants previously prescribed anticoagulation; living with an implantable pacemaker, defibrillator, or both. The purpose of this review is to ascertain opportunistic diagnostic yield. As such, exclusion criteria have been selected in order to ensure that the study population of interest is restricted to those participants that do not have pre-existing arrhythmias.

Types of interventions

We will include trials comparing a wearable cardiac monitoring smart-device with usual care. The approach to usual care for the detection and identification of cardiac arrhythmia, Holter monitoring or real-time ECG recording in association with symptoms, is universally consistent. Devices may include wrist-worn smart-watches and bands; adhesive dermal patches; and smart-clothing, including wearable vests, t-shirts and harnesses. We will exclude studies that focus on implantable cardiac monitoring devices and wearable technologies that are not defined as smart-devices, e.g. Holter monitors.

Types of outcome measures

Reporting one or more of the outcomes listed here in the trial is not an inclusion criterion for the review. Where a published report does not appear to report one of these outcomes, we will access the trial protocol and contact the trial authors to ascertain whether the outcomes were measured but not reported. If relevant trials measured these outcomes but did not report the data at all, or not in a usable format, we will include them in the review as part of the narrative. We will assess outcomes at the longest available follow-up.

Primary outcomes

1. Diagnostic yield (incidence of newly diagnosed AF)
2. Irregular pulse notification or AF of greater than 30 seconds (at least one event)

Secondary outcomes

1. Emergency department presentation (at least one event)
2. Contact with a doctor or health provider (at least one event)
3. Prescribed a new medication
4. Quality of life (e.g. 12-item Short Form (SF-12), 36-item short-form (SF-36), quality of life in AF patients (QLAF), Atrial Fibrillation Quality of Life Questionnaire (AFQLQ), quality of life questionnaire for patients with atrial fibrillation (AF-QoL)
5. Adverse events (we will assess each adverse event individually as a separate outcome, including false positives of irregular pulse notifications)

Search methods for identification of studies

Electronic searches

We will identify trials through systematic searches of the following bibliographic databases.

- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library
- MEDLINE
- Embase
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- IEEE Explore (Institute of Electrical and Electronics Engineers)

We will adapt the preliminary search strategy for MEDLINE (Ovid) (Appendix 1) for use in the other databases. We will apply the Cochrane sensitivity-maximising RCT filter to MEDLINE (Ovid) (Lefebvre 2011), and adaptations of it to the other databases, except CENTRAL.

We will also conduct a search of ClinicalTrials.gov (www.ClinicalTrials.gov) and the World Health Organization International Clinical Trials Registry Platform (ICTRP) Search Portal (www.who.int/clinical-trials-registry-platform/the-ictrp-search-portal) for ongoing or unpublished trials.
We will search all databases from their inception to the present, and we will impose no restriction on language of publication or publication status.

Searching other resources

We will check reference lists of all included studies and any relevant systematic reviews identified for additional references to trials. We will also examine any relevant retraction statements and errata for included studies.

Data collection and analysis

Selection of studies

Two review authors (SCI and CF) will independently screen titles and abstracts for inclusion of all the potential studies we identify as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. If there are any disagreements, a third author will be asked to arbitrate (RW). We will retrieve the full-text study reports/publications, and two reviewer authors (CF and SCI) will independently screen the full-text and identify studies for inclusion. They will identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third person (RW). We will identify and exclude duplicates and collate multiple reports of the same study so that each study rather than each report is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (Liberati 2009). Covidence will be used for the screening process (Covidence 2021).

Data extraction and management

We will use a data collection form for study characteristics and outcome data, which we will pilot on at least one study in the review. One review author (CF) will extract study characteristics from included studies. We will extract the following study characteristics.

1. Methods: study design, total duration of the study, details of any 'run in' period, number of study centres and location, study setting, and date of the study.
2. Participants: N randomised, N lost to follow-up/withdrawn, N analysed, mean age, age range, gender, inclusion criteria, and exclusion criteria.
3. Interventions: intervention, comparison.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for the trial, and notable conflicts of interest of trial authors.

Two review authors (SCI and CF) will independently extract outcome data from included studies. We will resolve disagreements by consensus or by involving a third person (RW). One review author (CF) will transfer data into the Review Manager file (Review Manager 2020). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the data extraction form. A second review author (SCI) will spot-check study characteristics for accuracy against the trial report. Covidence will be used for data extraction and management (Covidence 2021).

Assessment of risk of bias in included studies

Two review authors (SCI and CF) will independently assess the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We will resolve any disagreements by discussion or by involving another author (RW). We will assess the risk of bias according to the following domains.

1. Random sequence generation
2. Allocation concealment
3. Blinding of participants and personnel
4. Blinding of outcome assessment
5. Incomplete outcome data
6. Selective outcome reporting
7. Other bias

In addition to the above, we will also assess the following biases for cluster-randomised trials and cross-over RCTs.

Cluster-randomised trial

1. Recruitment bias
2. Baseline imbalance
3. Loss of clusters
4. Incorrect analysis
5. Comparability with individually randomised trials

Cross-over RCT

1. Whether the cross-over design is suitable
2. Whether there is a carry-over effect
3. Whether only first period data are available
4. Incorrect analysis
5. Comparability of results with those from parallel-group trials

We will grade each potential source of bias as high, low or unclear, and provide a quote from the study report together with a justification for our judgement in the risk of bias table. We will summarise the risk of bias judgements across different studies for each of the domains listed. Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the risk of bias table.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

For cluster-randomised trials and cross-over RCTs, we will use recommendations from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017).

Measures of treatment effect

We will analyse dichotomous data as risk ratios (RRs) with 95% confidence intervals (CIs) and continuous data as the mean difference (MD) or standardised mean difference (SMD) with 95% CIs. We will use the MD if studies use the same outcome measures. If studies have used different instruments to measure an outcome (such as different quality of life instruments), we will use the SMD with 95% CIs instead.

We will enter data presented as a scale with a consistent direction of effect. We will narratively describe skewed data reported as medians and interquartile ranges.

Unit of analysis issues

We do not anticipate any unit of analysis issues with the studies we plan to include. The unit of analysis will be the participant. If we identify any non-standard designs (e.g. cross-over or cluster-randomised trials), we will only use the data from the first period of cross-over trials, as per the recommendations from the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021). For multiple-armed trials, we will combine any smart-device arms so that there is a single intervention arm, and combine any conventional methods to create a single control arm. We will use the longest duration follow-up from each study to avoid double-counting participants from the same trial. For cross-over trials we will use data only from the first period.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). Where possible, we will use the Revman calculator to calculate missing standard deviations using other data from the trial, such as confidence intervals, based on methods outlined in *The Cochrane Handbook* (Higgins 2021). Where this is not possible, and we think the missing data could introduce significant bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We will visually inspect forest plots to consider the direction and magnitude of effects and the degree of overlap between confidence intervals. We will use the I^2 statistic to measure heterogeneity among the trials in each analysis, but acknowledge that there is substantial uncertainty in the value of I^2 when there is only a small number of studies. We will also consider the P value from the Chi^2 test. If we identify substantial heterogeneity (I^2 greater than 50%), we will report it and explore possible causes through prespecified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible small study biases for the primary outcomes.

Data synthesis

We will undertake meta-analyses only where this is meaningful, i.e. if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense. We will use a random-effects model as we expect some heterogeneity in the interventions.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses.

1. Age (≥ 65 years versus < 65 years)
2. Sex (women versus men)

We will use the formal test for subgroup differences in Review Manager (Review Manager 2020), and base our interpretation on this.

Sensitivity analysis

We plan to carry out the following sensitivity analyses, to test whether key methodological factors or decisions have affected the main result.

1. Only including studies with a low risk of bias. We will exclude studies that are at a high or unclear risk of bias for random sequence generation, allocation concealment, and incomplete data.
2. Where missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by conducting a sensitivity analysis that excludes them.

Summary of findings and assessment of the certainty of the evidence

We will create a summary of findings table using the following outcomes.

- Diagnostic yield (incidence of newly diagnosed AF)
- Irregular pulse notification or AF greater than 30 seconds
- Emergency department presentation
- Contact with a doctor or health provider
- Prescribed a new medication
- Quality of life
- Adverse events (including false positives of irregular pulse notifications)

We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of evidence as it relates to the studies which contribute data to the meta-analyses for the prespecified outcomes. We will use methods and recommendations described in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2017), using GRADEpro software (GRADEpro GDT). We will justify all decisions to downgrade the quality of studies using footnotes, and we will make comments to aid the reader's understanding of the review where necessary.

Judgments about the certainty of evidence will be made by two review authors (SCI and CF) working independently, with disagreements resolved by discussion or involving a third author (RW). Judgments will be justified, documented, and incorporated into reporting of results for each outcome.

We plan to extract study data, format our comparisons in data tables, and prepare a summary of findings table before writing the results and conclusions of our review.

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APPENDICES

Appendix 1. Preliminary MEDLINE (Ovid) search strategy

1 wearable electronic devices/ (2001)
2 fitness trackers/ (472)
3 (Wear* adj4 (device* or tech* or patch*)).tw. (6101)
4 ((external or wear* or patch*) adj4 monitor*).tw. (3323)
5 (Kardia* or AliveCor or Zio patch).tw. (178)
6 (Smart watch* or smartwatch*).tw. (385)
7 (Fitbit or apple watch*).tw. (599)
8 ((activit* or fitness) adj3 track*).tw. (1978)
9 (Smart adj4 (cloth* or garment* or shirt* or vest* or harness* or band* or patch*)).tw. (277)
10 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 (12847)
11 Atrial Fibrillation/ (53875)
12 atrial fibrillation*.tw. (67522)
13 auricular fibrillation*.tw. (933)
14 atrium fibrillation*.tw. (11)
15 af.tw. (38646)
16 a-fib.tw. (155)
17 Atrial Flutter/ (5779)
18 atrial flutter*.tw. (5547)
19 auricular flutter*.tw. (276)
20 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 (96363)
21 (cardiac or heart).tw. (1153843)
22 20 or 21 (1217250)
23 10 and 22 (1703)
24 randomized controlled trial.pt. (501922)
25 controlled clinical trial.pt. (93576)
26 randomized.ab. (473437)
27 placebo.ab. (206106)
28 drug therapy.fs. (2187143)

29 randomly.ab. (329474)
30 trial.ab. (498731)
31 groups.ab. (2023680)
32 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 (4659387)
33 exp animals/ not humans.sh. (4678989)
34 32 not 33 (4038810)
35 23 and 34 (307)

CONTRIBUTIONS OF AUTHORS

CF: responsible for the conception and design of the protocol, responsible for coordinating and completing the protocol, including writing the protocol.
RW: contributed to the conception, design and writing of the protocol.
SCI: contributed to the conception, design and writing of the protocol.

DECLARATIONS OF INTEREST

CF declares a grant from the Heart Foundation of Australia for a Postdoctoral Research Fellowship, National Health and Medical Research Council Investigator Grant, and payment from Elsevier for peer review and editorial work.

RW declares having no conflicts of interest.

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