TITLE PAGE

Examining adherence to the use activity monitoring devices to improve physical activity in adults with cardiovascular disease: A systematic review

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Word count: 6811 (including references)

This is the author's manuscript of the article published in final edited form as:

Marin, T. S., Kourbelis, C., Foote, J., Newman, P., Brown, A., Daniel, M., … Clark, R. A. (2019). Examining adherence to activity monitoring devices to improve physical activity in adults with cardiovascular disease: A systematic review. European Journal of Preventive Cardiology, 26(4), 382–397. https://doi.org/10.1177/2047487318805580

ABSTRACT

Background

Activity monitoring devices are currently being tested to facilitate and monitor physical activity. No prior reviews have examined adherence to the use of activity monitoring devices amongst adults with cardiovascular disease.

Methods

Literature from June 2012 to October 2017 was evaluated to examine the extent of adherence to any activity monitoring device used to collect objective physical activity data. RCTs comparing usual care against an activity monitoring device in a community intervention for adults from any cardiovascular diagnostic group were included. A systematic search of databases and clinical trials registers was conducted using Joanna Briggs Institute methodology.

Results

Of the ten eligible studies, two studies reported on pedometer use, and eight on accelerometers. Six studies addressed our primary outcome with a mean adherence of 59.1% at last follow up; range 39.6% to 85.7% at six months. Studies lacked equal representation by gender (28.6% female) and age (range 42 to 82 years).

Conclusion

The results of this review have demonstrated we may be over stating results from current research due to adherence issues. Results showed physical activity tracking in women and young adults have been understudied.

Funding: This study was funded by a National Heart Foundation of Australia Vanguard Grant, Award ID 101443 and supported by a Heart Foundation Future Leader Fellowship (App ID: 100847). Protocol registration number: CRD42018094781.

KEYWORDS: Adherence, Activity monitoring device, Accelerometer, Pedometers **(216/250 words)**

INTRODUCTION

Rationale

Cardiovascular disease (CVD) remains the leading cause of death and disability globally and is a significant burden on healthcare systems.^{1, 2} In 2015, it was estimated that 17.7 million people died from CVD, representing 31% of all global deaths.² Although, historically, women have been underrepresented in cardiac care,^{3, 4} men and women experience the same rates of CVD.²

Practitioners have long recognized the importance of physical activity (PA) for the maintenance of good health and the prevention of chronic diseases, such as CVD.⁵ Returning to activities of daily living and maximizing physical capacity is an important component of the cardiac rehabilitation process.⁶ Initiation of PA, along with the uptake of other risk factor modifications, is highly beneficial to the treatment and ongoing maintenance of CVD.^{6, 7}

Activity monitoring devices and smartphone applications are a cost-effective alternative to promoting PA and such devices, designed to improve PA in adults with CVD and other chronic conditions, are currently being tested.⁸⁻¹¹ Additionally, activity monitoring devices have been shown to affect PA behavior change.¹²⁻¹⁴ These technologies overcome limitations associated with traditional in-person exercise programs that often have costly resource and labor requirements and are time intensive.¹⁵ Despite the emergence of accelerometer technology in the 1950s and its increasing use in the 1970s as the technology advanced,¹⁶ it is only in the more recent years that activity tracking devices have become truly wearable, accessible and portable with minimal inconvenience to the user.

To understand whether interventions using such devices have been effective, we need to not only identify whether behavior change occurred, but the extent to which participants did what was asked of them. This is fundamentally important because inefficient regimen effect can be responsible for an ineffective intervention, and non-significant results.¹⁷ Rate of adherence to the use of activity monitoring devices as specified by the study protocol is a crucial parameter when evaluating programs. However, many studies often report outcomes rather than participant commitment to the intervention,¹⁸ leaving adherence under-reported or not reported at all.

There is a rapidly increasing variety of commercial fitness trackers (e.g. the Fitbit[™] range of wearable activity tracking devices) and associated smartphone applications widely used to support exercise goals. Their popularity within the general population suggests that they are likely to be perceived as acceptable to potential research participants. Unlike research-specific devices, such as the ActiGraph[™] series of accelerometers that may be expensive and require specialized software to

analyze, these consumer devices are generally relatively inexpensive, unobtrusive to wear and require minimal interaction to share data. This is particularly true if the functions are embedded in smartphone applications that enable multiple types of data recording on a single, commonly carried device.

A high proportion of the population already carry smartphones and the rate of ownership in developed economies was estimated at above 70% in 2015.¹⁹ The use of such wearable PA monitors offers significant potential for researchers and clinicians working to promote or measure PA. Furthermore, validation studies of the accuracy of commercially available activity tracking technology have been undertaken.²⁰⁻²² Functionality of such devices includes accelerometry, step counting (pedometers), visual feedback, activity progression, encouragement, social interaction and Global Positioning System (GPS) tracking, with some more sophisticated platforms incorporating more than one or all types of measurement.²⁰

Activity monitoring devices and applications have the potential to make a direct and real-time impact on self-management of PA and offer clinicians real world assessments of their patients' daily activity patterns.²¹ Historically the collection of an individual's activity level data hasrelied on either direct observation or self-report (which can be cumbersome and potentially inaccurate), the latest generation of activity monitoring devices is frequently connected to a central internet platform for remote data sharing, thus enabling the collection of objective data. Although, limited data storage and transmission capabilities often means that participants are still self-reporting the readings from their devices. For research purposes we need to determine if the translation of these types of devices into reliable data collection tools, outside of a controlled environment, is acceptable to participants and will provide reliable and useful data. Irrespective of the type of device and how it is worn or carried, for valid and useful research data to be collected it must be operating and carried/worn by the participants for the expected duration of the study.

User acceptance and perceived usefulness are known to be associated with a long-term adoption of health mobile applications,²³ and studies assessing the effectiveness and feasibility of activity monitoring devices as a modality within a PA intervention have previously been undertaken. Such studies, however, have focused on chronic conditions (such as diabetes⁸ and COPD⁹), risk factors,^{10, 12, 15} specific device types,²⁴ or specific populations (e.g., children/youth^{25, 26}).

A preliminary search of the Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports and the Cochrane Central Register of Controlled Trials found no systematic reviews focusing specifically on the adherence in the use of activity monitoring devices by adults with CVD. Therefore, this review has synthesized the current findings around adherence in the use of activity devices or applications where study participants, with a confirmed diagnosis of CVD, have generated objective data measuring PA (not self-reported in a log or activity diary). In addition, the observed changes in PA and perceived acceptance of activity monitoring devices, intended to promote changes in PA, have been included.

Objectives

This review examines any adherence to the use of devices or applications used to improve PA in adults with CVD. Specifically, the objectives were to: 1. Quantify the extent of adherence (as specified by the study protocol) in the use of activity monitoring devices in the last five years; 2. Determine if the extent of adherence differs by gender, age, length of study, types of device and how the device was worn; 3. Determine if the wearing of an activity tracking device changes participants' level of PA; and 4. Determine the perceived acceptability (satisfaction) of participants using an activity monitoring device or application to change levels of PA. This review provides an important resource to inform the development of future study protocols in this research area.

METHODS

Protocol and registration

This systematic review was undertaken using a protocol peer reviewed by JBI²⁷ and registered with PROSPERO.²⁸

Eligibility criteria

The inclusion criteria used were as follows: randomized control trials (RCTs) that compared an intervention for participants (aged 18 years and over) from any cardiovascular diagnostic group, who used an activity monitoring device in a research study within a community setting, to usual care. Eligibility included participants who have experienced one of the following cardiac events: Heart Failure (HF); cardiomyopathy conditions; medically managed acute myocardial infarction (STEMI-elevation MI, non-STEMI elevation MI) – including or excluding post-MI revascularization; medically managed coronary artery disease (CAD) (e.g., stable angina); revascularization procedures including percutaneous coronary interventions and/or coronary artery bypass graft (CABG) surgery; post-insertion of implementable defibrillator and permanent pacemaker; repair and replacement of valve device(s); device implant for ventricular assist; and heart transplant. Studies assessing stroke, those including participants less than 18 years of age, or where devices required the physical transcription of data by a participant or researcher (e.g., writing down or entering the daily step count), were excluded.

Usual care included promoting increases in PA to participants through printed material, verbal, and/or digital form (i.e. audio/video, CD-ROM, website, iPad or other tablet device, computer, basic step counter, computer/internet based program) and following normal daily PA behaviors and routines without directive to achieve increases in PA. Eligible studies did not include the use of a device or application that monitored activity as the comparator. Studies were included where they evaluated a device (worn or carried) or application to monitor PA (i.e. steps, distance travelled, GPS, time active, intensity, duration, rate, acceleration etc.) in a community context.

Outcomes

This review considered studies that described PA as an outcome measure, although not necessarily considered by the included study as one of the outcomes of the RCT and therefore not reported as such. PA is usually defined in terms of intensity, duration, and rate of activity; ²⁹ however, steps, floors climbed, and total distance travelled were also considered in this review. Whilst rate of activity can be assessed in determinations of planned PA (e.g., fitness classes, or runs per week), in the current review overall PA accrued in daily living is considered. Perceived acceptability (participant's

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satisfaction) of using a PA device or application in interventions intended to promote increases in PA is also reported.

Specifically, three outcomes were addressed: one primary and two secondary. The primary outcome was: adherence to the use of activity monitoring device to promote PA (adherence to the study protocol can be assessed by self-report, standardized or non-standardized instruments, reported as the feasibility of the intervention, evaluated from the extent of attrition or retention or documented as compliance). Secondary outcomes included: effect of device on PA levels (measured as duration, rate and intensity of PA, steps, floors climbed, distance travelled), and perceived acceptability (satisfaction) of using an activity monitoring device or application.

Information sources

The search strategy was designed to find both published and unpublished articles in the English language only. This was due to limited access to translators and budgetary constraints. Papers published from June 2012 to October 2017 were included representing a period of increasing availability and acceptance of activity tracking devices in the general population and their incorporation into research protocols.

Search

An electronic search was designed and performed by an experienced research librarian (PN) on 6 October 2017 using the following databases: Medline; CINAHL; PsycINFO; Scopus; Web of Science; Cochrane Central Register of Controlled Trials; ANZ Clinical Trials Registry; Clinicaltrials.gov; and WHO International Clinical Trial Registry Platform. It is noted that Embase has not been included in the search strategy as this database is unavailable at Flinders University. The reference list of all studies selected were screened for additional studies not already included in the search to inform the findings, and in the case of missing or incomplete data, corresponding authors were contacted. A copy of the detailed search strategy can be found in Appendix I.

Study selection

Following the search, all citations were collated and uploaded into Endnote and duplicates removed. Titles and abstracts were screened by two independent reviewers (TM and CK) for assessment against the inclusion criteria. If consensus could not be reached a third reviewer (RC) would assess. Full text articles were retrieved for those studies meeting the inclusion criteria, or to determine eligibility if the title and abstract did not provide enough information. The details of the selected studies were imported into JBI SUMARI³⁰ and comprehensively assessed against inclusion criteria (TM and CK).

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If consensus could not be reached the third reviewer (RC) would assess. Full text studies that did not meet these criteria were excluded and reasons entered into the PRISMA flow diagram (Figure 1).

Study protocol definitions

Tracking Devices

A recent review by Ridgers and colleagues²⁵ identified the key elements of an activity tracking device as being electronic, wearable, using sensors to track the user's movements and having the ability to provide feedback beyond a basic display. Building upon this, an activity monitoring device in this review is defined as a wearable electronic device or smartphone application which records some aspect of movement or location for which the data can be downloaded and analyzed.

Adherence

Adherence is defined as "the extent to which a person's behavior (taking medication, following a diet or exercise plan, and/or executing lifestyle change) corresponds with the recommendations from a health care professional".^{31, p.3} Therefore, the measurement of adherence largely depends upon the nature of the study protocol and the recommendations provided. In this context there are no restrictions on how adherence is measured. The current review included studies where adherence to a device was assessed by self-report, standardized or non-standardized instruments, reported as the feasibility of the intervention, evaluated from the rate of attrition or retention or documented as compliance.

Physical Activity Interventions

Interventions promoting improvements in PA in daily living that used a PA device or application, for example, where participants are asked to use and manage an activity monitoring device or application and provide these data (as were determined by the study protocol) to the study were included. Devices which required the physical transcription of data by a participant or researcher (e.g. writing down or entering the daily step count) were excluded.

Data collection process

Study characteristics and outcome data were systematically extracted by one reviewer (TM) and thoroughly checked for accuracy and completeness by a second independent reviewer (CK). Contact was made with corresponding authors to determine the inclusion of eight studies as some required information was unavailable in the manuscripts. This resulted in an additional three studies being excluded from the review (see Appendix II for full list of excluded studies).

Data items

Data items extracted were: characteristics of eligible studies (author and data of publication, setting and country, sample size, study population (mean age and gender of the participants), intervention group (IG) description, type of device and where worn, and duration of the follow-up period); and data relating to primary and secondary outcomes (summary of outcome measure and results). The outcomes previously described were considered to assess inclusion. Overall means and standard deviations (SDs) of age and proportion of gender for all participants at the point of randomization are reported. Where demographic data were not available individually by IG and control group (CG) numbers are provided as overall only. Where intention-to-treat analyses were not undertaken, and some loss to follow up was experienced, results in the primary outcome table are adjusted to include all randomized participants, to assess actual, rather than adherence rates after attrition.

Risk of bias in individual studies

Within study critical appraisal was performed for all included articles at the study level using the JBI standardized critical appraisal instrument for RCTs.³² To minimize the risk of bias, methodological quality was assessed by two independent reviewers (TM and CK) and disagreement was resolved by discussion or referral to a third reviewer (RAC). This information was used in assessing the strength of the body of evidence being reviewed.

Summary measures

Summary measures used to address the primary and secondary outcomes were: percentages to determine rate of adherence, mean number of steps per day, mean energy expended and mean number of minutes spend doing PA to assess changes in PA using objective data, and percentages of user acceptability.

Synthesis of results:

As insufficient studies were identified that addressed the same, or similar, research question, a metaanalysis was not performed. A narrative synthesis of the study characteristics, methodological quality, summary of outcome measures, and statistical significance is provided.

Risk of bias across studies:

A summary of findings providing an assessment of risk of bias across studies was undertaken using GRADEPro GDT software. The GRADE approach for grading the quality of evidence was followed presenting a narrative synthesis of the evidence based on study limitations (risk of bias) including, indirectness, inconsistency, imprecision, and publication bias.

RESULTS

Study selection

The electronic search identified 1,653 records and an additional 14 were identified from clinical trials registries. Following de-duplication, the title and abstract of 1,667 citations were screened and 74 papers were selected for full title and abstract assessment. Sixty-four papers were excluded of which 46 did not meet our selection criteria, 14 were incomplete studies (abstracts or protocols), and two were duplicates of previous publications. An additional two studies were excluded as we were unable to contact the authors. Ten studies were identified for inclusion in this review – the first being published in 2012.

Study characteristics

The ten RCTs included were conducted in nine developed countries; Australia,³³ Belgium,³⁴ Canada,³⁵ France,³⁶ Germany,³⁷ Norway,³⁸ Portugal,³⁹ the United Kingdom,⁴⁰ and the United States of America (Table 1).^{41, 42} Studies included a total of 849 (27.7% female) participants ranging in age from 42 to 82 years (mean age range 54 to 70.2 years), who had been previously diagnosed with an eligible cardiac event. The study populations included those with ACS,^{33-36, 39-41} HF,^{34, 36, 42} and CHD.^{36, 37} All RCTs included the wearing or carrying of a device that objectively measured PA; ten using an accelerometer and two a pedometer. Follow up times ranged from one to 12 months.

Risk of bias within studies

All ten studies included had important methodological weaknesses. Randomization was adequately concealed in only five studies,^{33, 35, 39, 40, 42} blinding of the outcome assessors was found for four,^{34, 37, 38, 42} intention to treat analysis was undertaken in only three,^{35, 36, 38} and participant blinding was not used in the any of the RCTs. Overall, only two studies^{35, 38} reached a quality score greater than 65% (Table 2).

Results of individual studies

Six studies^{33, 36, 37, 39, 40, 42} addressed our primary outcome (adherence) and involved 556 participants (33.1% female). Mean adherence for these six RCTs was 59.1% at last follow up time; ranging from 39.6% to 85.7% at 6 months. In three of the studies^{33, 40, 42} adherence rates were presented for two time points – first and second follow-up; however, in all six, final follow-up was at six months. Two studies^{33, 42} reported the rate of adherence as decreasing with time (76.4% and 39.0% to 58.3% and 27.0% respectively) and in the other⁴⁰ the adherence rate remained constant (39.6%); however, these data should be interpreted with caution due to the methodological limitations of studies.

Where devices were worn/carried by both IG and CG and PA data were collected objectively, IG participants showed a greater adherence in four of the studies.^{33, 37, 39, 42} Varnfield and colleagues³³ found a significant difference in adherence rates between IG and CG (p<0.05) concluding that the use of a smartphone as part of their care assessment platform (IG) was more effective in keeping participants in rehabilitation (80% compared to 47% in the CG), and as effective in improving health outcomes.³³

Table 4 shows the studies that addressed our secondary outcomes; objective measurement of PA, and user acceptability to the device. There were nine RCTs involving 798 participants (27.6% female), that collected objectively measured PA. The majority of these RCTs^{33-35, 37, 40-42} used steps per day from baseline to follow up as an outcome measure. Change in steps per day was significantly different (p<0.05) between IG and CG in four of these studies,^{35, 37, 40, 43} two reported non-significant results,^{34, 42}, and in one study³³ significance was not reported. The one study reporting changes in steps using a pedometer reported an increase of 1,973.9 steps per day as compared to the RCTs reporting PA using accelerometers where steps per day increased from 497⁴⁰ to 1,586³⁷ in the IGs. Two studies^{36, 39} reported PA as energy expended at different intensity levels and again significant differences between IG and CG were reported.

There were two studies^{33, 34} addressing this review's last outcome involving 259 participants (15.1% female). Both reported very high acceptability to using a device (97% and 85% respectively). In 2015, Frederix and co-authors³⁴ reported a 95% acceptance to their tele-rehabilitation program with 44% saying they were very satisfied and 51% satisfied. More recently, Varnfield and colleagues³³ used an accelerometer in a smartphone purely as a motivational tool and reported that 85% of participants found the step counter to be motivational in reaching their CR goalsteam.³³

Risk of bias across studies

The certainty of evidence for the three outcomes was Generated using GRADEPro GDT software (Table 5). Certainty was moderate for the primary (adherence) and first secondary outcome (PA levels), due to methodological heterogeneity of studies and no intention-to-treat analysis which may have impacted the adherence to the device and the mean number of steps/level of PA reported. Evidence for the acceptability outcome was provided by qualitative self-report feedback and the certainty of evidence has been downgraded to very low accordingly.

DISCUSSION

Summary of evidence

No reviews have previously examined adherence to the use of activity monitoring devices amongst participants with a confirmed diagnosis of CVD. This systematic review has examined the extent of adherence to any activity monitoring device used to collect objective PA data between 2012 to 2017. Of the 1,667 citations reviewed, ten RCTs were eligible for inclusion suggesting that this area has not been well researched. Six studies addressed the primary outcome (adherence) involving 556 participants (33.1% female). Overall, adherence across these six studies was 59.1% at last follow up time; ranging from 39.6% to 85.7% at six months.

The primary outcome for this review is adherence to a device used to objectively measure PA, distinct from PA assessed by self-report.⁴⁴ However, the inclusion criteria allowed studies that included the objective measurement of PA and also examined adherence to the study protocol assessed by selfreport, standardized or non-standardized instruments, reported as the feasibility of the intervention, evaluated from the extent of attrition (i.e. abandonment of wearing the tracking device) or retention, or documented as compliance. In two studies, 33, 40 adherence was defined only as adherence to the protocol. In these studies, it was not possible to ascertain whether the non-adherers, although not completing, or adhering to, the protocol, had indeed adhered to using the device. A systematic review, conducted to establish measures available to assess self-reported adherence to home-based rehabilitation programs, found a gap in the literature for well-developed measures available to capture adherence.¹⁷ Rather than simply record numbers of those attending/not attending, or completing an intervention, it is suggested that a well validated and reliable self-report measure may provide extra support to clinicians in determining whether their prescribed exercise regime if effective, needs adjusting or if the patient needs further support. In the paper by Varnfield and colleagues,^{33, p.1774} a significant difference (p<0.05) in adherence to their CR program, between IG and CG, is reported as mainly attributed to "dislike of group based classes, lack of personalized exercise programs, return to work demands, family commitments and poor motivation" concluding that the use of a smartphone in conjunction with a home based cardiac rehabilitation program overcame some of these key barriers.

A systematic review conducted by Bravata and colleagues,⁴⁵ regarding the use of pedometers to increase PA, found that across 26 studies (8 randomized controlled trials and 18 observational studies), having a step goal was an important predictor of increased PA. Lau and colleagues⁴⁶ found consistent evidence supporting the improvement of psychosocial variables (e.g., self-efficacy⁴⁷) through information and communications technology (ICT) interventions; however, the evidence for the change in behavioral variables, such as PA level, was less consistent. Barriers are likely to exist and differ at each of the levels of behavior change.⁴⁸ According to a study investigating the use of

activity monitoring devices for the self-management of chronic conditions,⁴⁹ there are three key critical components to the long-term adherence to activity monitoring devices: formation of habit; social motivation; and goal reinforcement feedback. Additionally, usability is named as a key factor in the meaningful use of activity monitoring devices. As Goldberg and colleagues^{50, p.s194} purport, *"functionality is for naught if not used effectively, efficiently, and safely by its human users."*

Guiraud and co-authors³⁶ analyzed a group of participants who had previously been non-compliant to PA and participation in a CR program. They were subsequently randomized into activity monitoring device and non-device wearing groups to assess adherence to the device. This evaluation is important in that it provides evidence for those who may be able to adhere to a program of exercise or protocol; however, who are unable to adhere to the use of an activity monitoring device, and vice versa. In other settings, studies have shown that using pedometers to observe levels of can be useful to indicate adherence to activity programs.⁵¹ Further research is needed to uncover whether adherence to a protocol may be a confounder in assessing adherence to the device.

While pedometers are becoming an item of everyday wear in the general population,⁵² the use of accelerometers for research purposes has also seen a dramatic increase in use more recently^{53, 54} and due to their size, ease of use, and non-invasiveness, they are commonly used to as an objective method for assessing PA in field-based research.⁴⁴ Compared to pedometers, accelerometers provide an increase in the accuracy of data,⁵⁵ are superior to self-report,⁵⁶ and have the ability to integrate prompts and cues, reward mechanisms and self-monitoring of behavioral outcomes.⁵⁷ In this current review, two studies reported on pedometer use and eight on accelerometers. The following devices were identified: Accelerometers (ActiGraph,^{39, 42} Aipermon 440,³⁷ Sensewear Pro3,^{38, 40} tri axial Yorbody,³⁴ and single axis Accelerometer³⁶); and the Yamax Digiwalker³⁵ and tri-axis technology (3D)⁴¹ pedometers; although, Anderson⁴¹ describes his pedometers as having tri-axis technology and measuring vertical acceleration, indicating technology closer to an accelerometer. One study used systems integrated with online platforms and a tablet device and but did not state the brand of accelerometer.⁴²

A recent review on the use of wearable devices to promote PA¹⁵ warns that there have been few studies evaluating their efficacy in promoting PA and research is needed to determine effectiveness, especially in marginalized communities, and with children and adolescents. It was not possible to ascertain any meaningful differences between countries, communities or settings in this review due to the small number of studies conducted in developed countries all with similar health practices and technologies. Furthermore, there is no representation in this review from developing countries or marginalized populations. Participants in the RCTs eligible for this review ranged in age from 42 to 82 years. Lau and colleagues⁴⁶ also concluded that very few systematic reviews have documented the

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effects of ICT-based interventions on PA behavior in children and adolescents specifically. In one of the few studies found to include participants aged less than 40 years⁵⁸ a marked attrition to wearing an activity tracker for six weeks was shown in a small study of undergraduate students aged 20 to 24 years. Attrition at two weeks was 50%, 75% at four weeks, and only three participants were reported adhering for the full six weeks (11.5%). A variety of reasons for non-adherence were reported ranging from 'the device was uncomfortable to wear' to 'I forgot to put it on in the morning' although the authors noted, that although participants seemed to object to carrying the activity trackers, most had no trouble in remembering to carry their keys, wallets, and mobile phones. One participant in the study complained that "physical activity trackers should be inconspicuous" while another remarked on the frustration in having "to remember to take it out of my pocket and put it on the new clothes I am wearing" when changing her clothes or taking a shower.^{58, p.7} The low mean adherence rate (59.1%) identified may be a consequence of the age of the participants and raises the question of what technology is more suitable for this age group, and the possibility that accelerometry more suited to a young demographic. In addition to the lack of younger participants found in this review, from 849 participants only 28.6% (n=243) were female. It is known that women are under-represented in cardiac care⁴ despite men and women experiencing the same rates of CVD.² Gender differences in the adoption of PA trackers have been understudied and are rarely reported,⁵⁸ and this review has found a lack of empirical research in this area. Research is warranted to understand the gender differences in this area.59

The effectiveness and validity of using activity monitoring devices to record and collect subjective PA data has been shown,⁴⁵ however, now emerging are ethical considerations around the use of accelerometry. To stimulate discussion in the literature, Fuller, Shareck and Stanley⁶⁰ propose four areas needing to be addressed: informed consent; privacy and confidentiality; mitigation of risk; and the additional considerations of marginalized (vulnerable) populations. One example of this is the volume of data that are produced from an accelerometer. Data may give a detailed account of a participant's movements and activities during a set period, much of which may not be relevant to the research and so not easily described in the protocol, or adequately represented in a consent form. Alternatively, giving the participant the ability to pause or delete data which they may deem private, may impact negatively on the research intent.⁶⁰

Limitations

As with any systematic review, its strength depends on the data reported in the individual studies that meet the criteria and report on the outcomes. This review included ten eligible studies each with notable methodological weaknesses. Randomization was adequately concerned in only five studies, intention to treat analysis was undertaken in only three, and assessment of outcome was blinded in

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six. Data should therefore be interpreted with care. In addition, there was a high heterogeneity between studies and for each of the variables addressed in our second objective. Therefore, the authors were unable to undertake an overall meta-analysis, or sub-analyses to provide evidence for our second objective: to determine if the extent of adherence differs by gender, age, length of study, types of device and how the device was worn.

CONCLUSIONS

This review highlights the lack of evidence for the adherence to the use of activity monitoring devices. Review outcomes suggest that the evidence is not equally presented by age and gender, nor does it address the specific needs of using this technology in marginalized communities. As research addressing the use of activity monitoring devices evolves and the objectively collected physical activity data is further validated, challenges remain to ascertain the effectiveness of using activity monitoring devices as we move from subjective (self-report) to objective data. In addition, there are ethical issues that will need to be addressed surrounding consent to, and risk from, using such devices and consideration of privacy, confidentiality and clinical outcomes.

FUNDING

This study was funded by a National Heart Foundation of Australia Vanguard Grant, Award ID 101443 and RAC is supported by a Heart Foundation Future Leader Fellowship (App ID: 100847).

AUTHOR CONTRIBUTIONS

TM, CK and RAC contributed to the conception of the work. PN contributed to the acquisition, analysis, or interpretation of data for the work. TM and CK drafted the manuscript. All authors critically revised the manuscript and gave final approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

DECLARATION OF CONFLICTING INTERESTS

The authors declare that there are no conflicts of interest.

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LEGEND OF TABLES AND FIGURES

Figure 1: PRISMA diagram of the study selection process
Table 1: Characteristics of included studies
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Table 3: Summary of Primary Outcome: Adherence to using the device
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Appendix I - Search Strategy applied across databases

Appendix II – Table 5: Reasons for excluding studies (n=64)



Figure 1: PRISMA 2009 Flow Diagram

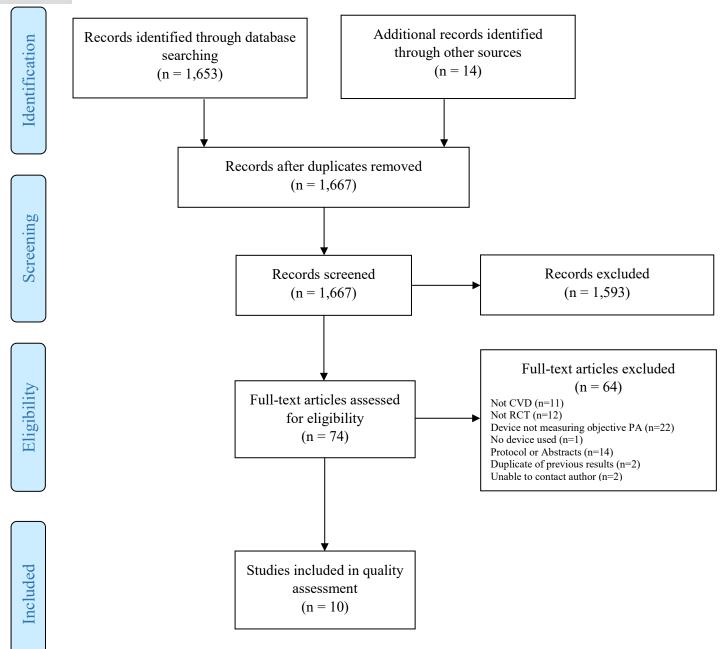


Table 1: Characteristics of included studies

Study	Country (setting)	Participants	Age in years mean (SD) [range]	Female n (%)	CVD diagnosis	Device (worn)	Intervention	Follow-up (length of study)
Anderson, Harris et al. 2015 ⁴³	US	N=38 IG: n=18 CG: n=20 (usual care)	57.0 (10.8) [46.2 – 67.8] IG: 56.6 (10.6) CG: 59.4 (12.9)	IG: 3 (17) CG: 8 (40)	CAD (PCTA, stent, CABG, MI, angina)	Pedometer (unknown)	Pedometer worn 3 months to measure steps/day (during waking hours). Mailed back in reply-paid envelope	3 months
Christle, Schlumberger et al. 2017 ³⁷	Germany	N=70 IG: n=35 CG: n=35 (usual care)	70.0 (SD 9.0) [61 – 79] IG: 70.0 (8.0) CG: 70.0 (9.0)	28 (39) IG: 14 (39) CG: 14 (39)	CD (AHA - Class C mod/high)	Accelerometer (hip)	Once-weekly individualized combined exercise (10 days)	6 months
Devi, Powell et al. 2014 ⁴⁰	UK; GPs	N=94 IG: n=48 CG: n=46 (usual care)	[56.1 – 76.3] IG: 66.3 (8.3) CG: 66.2 (10.1)	IG: 14 (29) CG: 10 (22)	CHD	Accelerometer (R upper arm)	Web-based cardiac rehabilitation program "ActivateYourHeart" delivered via the internet (no face to face) – accelerometer worn 2 weekdays (12 hours/day)	1 & 6 months
Frederix, Hansen et al 2015 ³⁴	Belgium	N=139 IG: n=69 CG: n=70 (usual care)	61.0 (9.0) [52 – 70] IG: 61.0 (9.0) CG: 61.8 (8.0)	25 (18) IG: 10 (14) CG: 15 (21)	CAD or CHF	Accelerometer (pocket)	6-week web-based, comprehensive tele-CR (from weeks 6 to 12 of CR) plus usual 12- week center-based CR	1½ & 6 months
Guiraud, Granger et al. 2012 ³⁶	France; CRP at clinic	N=29 IG: n=19 CG: n=10 (usual care)	57.4 (12.4) [41.9 – 73.6] IG: 54.5 (12.6) CG: 62.9 (10.7)	5 (17) IG: 2 (11) CG: 3 (30)	CAD, HF	Accelerometer (waistband)	Wore accelerometer for 8 weeks; telephone feedback and support (data automatically uploaded to web portal)	2 months
Houle, Doyon et al. 2012 ³⁵	Canada	N=65 IG: n=32 CG: n=33 (usual care)	[50 – 68] IG: 58.0 (8.0) CG: 59.0 (9.0)	14 (21.5) IG: 6 (19) CG: 8 (25)	ACS (unstable angina, STEMI or non-STEMI)	Pedometer (hip)	Pedometer-based program, PA behavior (average steps/day) associated with a diary to record other PA besides walking	3, 6, 9, & 12 months
Malmo et al. (2014) ⁶¹	Norway	N=51 IG: n=26 CG: n=25	[48 – 71] IG: 56.0 (8.0) CG: 62.0 (9.0)	IG: 6 (23) CG: 3 (22)	AF (non- permanent)	Accelerometer (upper arm)	Device (SenseWear Pro 3) was worn for at least 4 consecutive days both during the 4- week baseline period and the two last weeks of the intervention period	1 and 5 months

		(habitual PA)						
Ribeiro, Oliveira et al. 2017 ³⁹	Portugal (Outpatient clinic)	N=138 IG: n=71 CG: n=67 (usual care)	[45 – 67] IG: 54.0 (9.0) CG: 58.0 (9.0)	IG: 23 (92) CG: 20 (80)	MI	Accelerometer (right hip)	8-week aerobic exercise program plus usual medical care and follow-up. Filtered digitized acceleration signals were recorded by accelerometers	2 months
Varnfield, Karunanithi et al. 2014 ³³	Australia	N= 120 IG: n=60 CG: n=60 (usual care)	[46.1 – 66.3] IG: 55.7 (10.4) CG: 55.5 (9.6)	14 (12) IG: 9 (15) CG: 5 (8)	MI	Accelerometer (smartphone)	Two supervised exercise and 1 hour of educational sessions on a weekly basis for 6 weeks at one of four Health Service District community centres. Smartphone (Nokia N96, Nokia Inc preinstalled with health diary (Wellness Diary, Nokia Research) and activity monitoring (StepCounter, Nokia Research) used for health and exercise monitoring, and delivery of motivational and educational materials to participants.	6 months
Young, Hertzog et al. 2016 ⁴²	US, Nebraska	N=105 IG: n=54 CG: n=51 (usual care)	70.2 (12.2) [58.0 – 82.4] IG: 68.7 (11.8) CG: 71.8 (12.6)	70 (67) IG: 29 (53) CG: 38 (75)	HF (Class II-IV)	Accelerometer (waist)	Usual care plus 12 week (PATCH) self- management (SM) training and coaching program delivered by telephone plus in two phases: a one-on-one in-hospital SM training session and post discharge reinforcement sessions (twice a week for weeks 1–2, once a week for weeks 3–6, & every other week for weeks 7–12) delivered by telephone.	1, 3 & 6 months
CR: cardiac rehabi	Notes: *no significant baseline differences between groups; ACS: acute coronary syndrome; AHA: American Heart Association; CABG: coronary artery bypass graft; CG: Control group; CD: cardiac disease; CR: cardiac rehabilitation; CRP; cardiac rehabilitation maintenance program; IG: Intervention group; PA: Physical Activity; PCI: percutaneous coronary intervention; PHC: Primary Healthcare; STEMI: ST- elevation myocardial infarction; UK: United Kingdom; US: United States; 10wer/decrease; 1 higher/increase							

Table 2: Risk of bias within studies

	Anderson et al. 2015	Christle et al. 2017	Devi et al. 2014	Frederix et al 2015	Guiraud et al. 2012	Houle et al. 2012	Malmo et al. 2014	Ribeiro et al. 2017	Varnfield et al. 2014	Young et al. 2016	Overall
JBI RCT critical appraisal tool	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
1. Was true randomization used for assignment of participants to treatment groups?	U	Y	Y	Y ^a	U	Y ^a	Y ^a	Y	Y	Y	8 (80.0)
2. Was allocation to treatment groups concealed?	U	N	Y	N	U	Y ^a	N	Y	Y	Y	5 (50.0)
3. Were treatment groups similar at baseline?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Ν	9 (90.0)
4. Were participants blind to treatment assignment?	U	N ^a	N	N	U	N ^a	N	N	Ν	N	0 (0.0)
5. Were those delivering treatment blind to treatment assignment?	N	Y	N	N	U	N	N	N	N	N	1 (10.0)
6. Were outcome assessors blind to treatment assignment?	N	Y	N	Ya	U	Ν	Ya	N	Ν	Y	4 (40.0)
7. Were treatments groups treated identically other than the intervention of interest?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10 (100.0)
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Y	N	Y	Y	Y	N	Y	Y	N	Y	7 (70.0)
9. Were participants analyzed in the groups to which they were randomized?	N	Ν	Ν	Ν	Y	Y	Y	Ν	Ν	Ν	3 (30.0)
10. Were outcomes measured in the same way for treatment groups	Y	Y	Y	Y	Y	Y	Y	Y	Ν	Y	9 (90.0)
11. Were outcomes measured in a reliable way?	Ν	Y	Y	Y	Y	Y	Y	Y	Y	Y	9 (90.0)
12. Was appropriate statistical analysis used?	Ν	N	N	Ν	Ν	Y	Y	Ν	Ν	Ν	2 (20.0)
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	9 (90.0)
	5 (38.5)	8 (61.5)	8 (61.5)	8 (61.5)	7 (53.8)	9 (69.2)	10 (76.9)	8 (61.5)	5 (38.5)	8 (61.5)	

a Information obtained from primary research author; U Unable to contact author on this matter

Study	Adherence to device:	Results (n=number of participants analyzed)	Adherence rate at follow- up (%)
Guiraud et al. 2012 ³⁶	Accelerometer procedure and use of web portal	 Overall 100% adherence to device for both IG and CG at 2 months CG 36.8% of the IG achieved target for moderate-intensity PA at 2 months 	100.0
Christle et al. 2017 ³⁷	Wore accelerometer on hip for 10 days (min 10hrs/day)	 IG (n=30) 84% adherence at 6 months CG (n=30) 77% adherence at 6 months Non-completion: n=1 (IG) developed muscle pain resulting in a discontinuation of exercise n=7 (2 IG, 5 CG) discontinued due to reasons unrelated to clinical status or the intervention n=2 (IG) were not included in the analyses due to incomplete data 	85.7
Varnfield et al. 2014 ³³	Used accelerometer (smartphone) to record ≥ 30 minutes of moderate activity on most days of the week	 IG (n=26) ↑ than CG - adherence to program (94%)* at 4 weeks ↑ than CG - completion of program (80%)* at 6 months Non-completion: logistical (2%); change in health (9%); difficultly in using IT tools (7%); lack of motivation (2%); improved health (2%) and other (5%) CG (n=46) ↓ than IG - adherence to program (68%)* at 4 weeks ↓ than IG - completion of program (46%)* at 6 months Non-completion (>70%): logistical (25%); completing life demands (14%); change in health (14%); change in criteria (2%); study design (10%); lack of motivation (4%); privacy (2%); and other (2%) 	58.3
Ribeiro et al. 2017 ³⁹	Wore accelerometer 7 consecutive days; measured PA ≥ 8 hours/day	 IG (n=71) 45.1% (32) at 8 weeks Non-completion: 2.8% (2) not adhere to protocol (<80% exercise sessions) 54.9 (39) no 7-day and/or 8hr/day PA record CG (n=67) 43.3% (29) at 8 weeks Non-completion: 6.0% (4) lost to follow up 56.7% (38) no 7-day and/or 8hr/day PA record 	44.2
Devi et al. 2014 ⁴⁰	Wore accelerometer 2 weekdays (12 hours/day) – IG only	 IG (n=48) 39.6% (19) completed the intervention (6 months) 60.4% (29) did not progress past stage 3 (1 month) 	39.6

Table 3: Summary of primary outcome: Adherence to using the device

		o average 3 log-ins/week/participant – over program mean=18.68 (SD 13.13, range 1-51)	
Young et al. 2016 ⁴²	Wore accelerometer on waist daily	 IG (n=51) 45.1% (23) reported 7 days/week at 3 months 54.9% (28) reported 0-6 days/week exercise at 3 months 38.0% (19) reported 7 days/week at 6 months 62.0% (31) reported 0-6 days/week exercise at 6 months CG (n=49) 34.0% (16) reported 7 days/week at 3 months 66.0% (31) reported 0-6 days/week exercise at 3 months 17.4% (8) reported 7 days/week at 6 months 82.6% (38) reported 0-6 days/week exercise at 6 months 	27.0
program; CR		control group; CI: confidence interval; CMP: cardiac rehabilitation ention group; IT: information technology; PA: physical activity; R	

Study	Objective PA measured by <u>accelerometer</u>	Result	p value
Christle, Schlumberger et al. 2017 ³⁷	Change in steps/day from baseline	 IG ↑ steps / day (+1586) at 6 months CG ↓ steps / day (-838) at 6 months 	<0.01
Devi, Powell et al. 2014 ⁴⁰	Change in steps/day from baseline	 IG ↑ steps/day (+497) at 6 weeks CG ↓ steps/day (-861) at 6 weeks 	< 0.02
Frederix, Hansen et al 2015 ³⁴	Change in steps/day from baseline	 IG ↑ steps/day (+351) at 6 weeks IG ↑ steps/day (+785) at 6 months CG ↑ steps /day at 6 months 	ns
Young, Hertzog et al. 2016 ⁴²	Change in steps/day from baseline	 IG ↑ steps/day at 3 and 6 months ↑ Kcal/kg/day at 3 and 6 months ↑ daily minutes of moderate/vigorous activity at 3 and 6 months 	ns
Guiraud, Granger et al. 2012 ³⁶	Energy expended, time doing moderate intensity PA PA and time spent at different intensity levels (mean minutes)	 IG ↑ total energy expended at 2 months ↑ energy expended at moderate intensity at 2 months ↑ time spent at moderate intensity PA at 2 months 	0.004 0.013 0.002
Ribeiro, Oliveira et al. 2017 ³⁹	Minutes PA/day: sedentary PA; light PA; moderate-to-vigorous PA; total PA (counts/minute)	 IG ↑ moderate-to-vigorous PA (mins/day) at 2 months CG o unchanged moderate-to-vigorous PA (mins/day) at 2 months 	0.030 0.024
Varnfield, Karunanithi et al. 2014 ³³	Step number, duration and intensity	 IG ↑ in walking speed at 1.5 months ↑ steps per day at 1.5 months 	NR
Study	Objective PA measured by pedometer		
Anderson, Harris et al. 2015 ⁴³	Change in steps/day from baseline	 IG ↑ steps/day (+1973.9) at 3 months CG ↓ steps per day (-1369) at 3 months 	0.010
Houle, Doyon et al. 2012 ³⁵	> 7500 steps/day at each time point	 IG ↑ % at 6, 9, and 12 months (p=0.01; 0.03; 0.04) Interaction effect (group by time) in PA level was different between groups from baseline to 6-month follow-up (p=0.033) 	0.033
Study	User acceptability	Result	
Frederix, Hansen et al. 2015 ³⁴	Qualitative - offline feedback forms	 97% acceptability in using motion sensor and easy to use) 95% (65/69) acceptability in tele rehability program: very satisfied (44%, 30/69); sat 35/69). 	tation
Varnfield et al. 2014 ³³	Acceptability to step counter	 >85% found step counter to be motivation reaching CR goals 	
	ol group; GPS: Global Positioning System ns: non-significant; PA: physical activity	; IG: Intervention group; ↓lower/decrease; ↑highe	er/increase;

Table 4: Summary of secondary outcomes: Effectiveness and Satisfaction

Table 5: GRADE SUMMARY OF FINDINGS

Extent of adherence to the use of an activity monitoring device to collect objective physical activity data; including effect of device on PA and acceptance of device

Patient or population: Adults (aged 18 years and over) with CVD

Setting: Community

Intervention: Use of an activity monitoring device to collect objective physical activity data

Comparison: Usual care

Outo	comes	Impact	№ of participants (studies)	Certainty of the evidence (GRADE)
P1:	Rate of adherence to activity monitoring device to promote PA assessed with: rate of adherence (percentage). Follow up: mean 6 months.	Mean adherence 59.1% (range 39.6-85.7). There was heterogeneity of setting, intervention, type of device, where device worn and means of collection of data across six studies.	493 (6 RCTs)	⊕⊕⊕⊖ MODERATE ª
S1:	Effect of device on PA levels assessed with: steps per day/level of activity/energy expended. Follow up: mean 6 months.	Increase in steps/day was significantly different between intervention and controls ($p<0.05$) in the 4 of 6 studies where this was reported. One study did not report significance and the last two studies reported a significant difference in energy expended/time spent doing PA.	798 (9 RCTs)	⊕⊕⊕⊖ MODERATE ^ь
S2:	Perceived acceptability (satisfaction) of using an activity monitoring device or application to promote increases in PA assessed with: qualitative feedback Follow up: mean 6 months.	Two studies reported the participant's acceptability and satisfaction towards the device. These data were self-report collected using feedback forms. Acceptability to device was reported for more than 85% of participants.	259 (2 RCTs)	⊕○○○ VERY LOW a, c

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

- a. Methodological heterogeneity of studies
- b. No intention-to-treat analysis may have impacted on mean number of steps/level of PA reported

c. These data are qualitative collected from feedback forms.

APPENDIX I– SEARCH STRATEGY APPLIED ACROSS DATABASES

Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

#

Searches

- 1 cardiovascular diseases/
- 2 exp heart diseases/
- 3 exp Coronary Artery Bypass/
- 4 exp Myocardial Revascularization/
- 5 exp heart transplantation/
- 6 Percutaneous Coronary Intervention/ or Angioplasty, Balloon, Coronary/
- 7 Heart Valve Prosthesis/
- 8 Pulmonary embolism/
- 9 ((myocardial or cardiac or heart) adj2 (infarct* or isch?emi*)).tw.
- 10 (coronary adj2 (syndrome* or disease* or event* or occlusion* or stenos* or thrombo*)).tw.
- 11 (myocard* adj2 revasculari?ation).tw.
- 12 (STEMI or NSTEMI).tw.
- 13 (ST adj2 (elevat* or depress*)).tw.
- 14 "heart transplant*".tw.
- 15 angina.tw.
- 16 (heart adj2 (failure or attack or bypass or disease*)).tw.
- 17 ((heart or cardiac or myocard*) adj2 (fail* or insufficien* or decomp*)).tw.
- 18 (HFpEF or HFrEF or left ventricular ejection fraction or ((preserved or reduced) adj ejection fraction)).tw.
- 19 (LV dysfunction or (diastolic adj (dysfunction* or failure*)) or (systolic adj (dysfunction* or failure*))).tw.
- 20 pulmonary embolism*.tw.
- 21 CABG.tw.
- 22 (coronary adj2 bypass).tw.
- 23 PTCA.tw.
- 24 angioplast*.tw.
- 25 PCI.tw.
- 26 (Percutaneous adj2 intervention*).tw.
- 27 (stent* adj3 (heart or cardiac*)).tw.
- 28 (heart valve adj1 (device* or artificial or prosthesis)).tw.
- 29 cardiomyopath*.tw.
- 30 cardiovascular disease*.tw.
- 31 or/1-30
- 32 accelerometry/ or actigraphy/ or ambulatory monitor/
- 33 exp exercise/ or physical conditioning, human/ or physical fitness/ or Exercise Movement Techniques/

34 32 and 33

(Fitbit or (samsung adj2 gear*) or Vivofit or Vivoactive or Vivosmart or Vivomove or Vivoki or

- 35 garmin* or "Apple watch" or verily or TomTom or "Touch cardio" or "spark cardio" or sensewear or activPAL or Actiheart).tw.
- 36 ((pebble or jawbone) adj6 (activit* or exercis* or wrist* or wear* or track* or monitor* or record* or monitor* or step or stepping)).tw.
- 37 (polar and (A300 or A360 or M200 or M400 or M430 or M430 or M460 or M600 or V650 or V800 or Loop2)).tw.
- 38 ("Google fit" or (apple adj6 (health adj6 app)) or FollowMee or RunDouble or C25K or "Couch to 5k" or Endomondo or "sports tracker" or sports-tracker or strava or smartphone*).tw.
- 39 ((accelerometer* or GPS or actigraph* or actimetr* or "ambulatory monitor*") adj8 (activ* or exercis* or fit or fitness or step or steps or stepping)).tw.
- 40 ((physical activity or PA or exercis* or step or steps or stepping) adj5 (monitor* or measur* or track* or record*)).tw.
- 41 smartphone/ or Mobile Applications/
- 42 ((app or apps or application*) adj4 (phone* or mobile* or cell*)).tw.
- 43 pedometer*.tw.
- 44 "fitness track*".tw.
- 45 "fitness monitor*".tw.
- 46 "activity track*".tw.
- 47 ("activity monitor*" or wearable* or "step counter*").tw.
- 48 or/34-47
- 49 controlled clinical trial.pt.
- 50 randomi#ed.ab.
- 51 clinical trials as topic.sh.
- 52 randomly.ab.
- 53 trial.ti.
- 54 or/49-53
- 55 31 and 48 and 54
- 56 limit 55 to yr="2012 -Current"

PsycINFO <1806 to October Week 1 2017>

#

Searches

- 1 cardiovascular disorders/
- 2 exp heart disorders/
- 3 heart surgery/
- 4 ((myocardial or cardiac or heart) adj2 (infarct* or isch?emi*)).tw.
- 5 (coronary adj2 (syndrome* or disease* or event* or occlusion* or stenos* or thrombo*)).tw.
- 6 (myocard* adj2 revasculari?ation).tw.
- 7 (STEMI or NSTEMI).tw.
- 8 (ST adj2 (elevat* or depress*)).tw.

9 "heart transplant*".tw.

10 angina.tw.

- 11 (heart adj2 (failure or attack or bypass or disease*)).tw.
- 12 ((heart or cardiac or myocard*) adj2 (fail* or insufficien* or decomp*)).tw.
- 13 (HFpEF or HFrEF or left ventricular ejection fraction or ((preserved or reduced) adj ejection fraction)).tw.
- 14 (LV dysfunction or (diastolic adj (dysfunction* or failure*)) or (systolic adj (dysfunction* or failure*))).tw.
- 15 pulmonary embolism*.tw.
- 16 CABG.tw.
- 17 (coronary adj2 bypass).tw.
- 18 PTCA.tw.
- 19 angioplast*.tw.

20 PCI.tw.

- 21 (Percutaneous adj2 intervention*).tw.
- 22 (stent* adj3 (heart or cardiac*)).tw.
- 23 (heart valve adj1 (device* or artificial or prosthesis)).tw.
- 24 cardiomyopath*.tw.
- 25 cardiovascular disease*.tw.
- 26 or/1-25
- 27 actigraphy/
- 28 exercise/ or physical activity/ or physical fitness/
- 29 27 and 28

(Fitbit or (samsung adj2 gear*) or Vivofit or Vivoactive or Vivosmart or Vivomove or Vivoki

- 30 or garmin* or "Apple watch" or verily or TomTom or "Touch cardio" or "spark cardio" or sensewear or activPAL or Actiheart).tw.
- 31 ((pebble or jawbone) adj6 (activit* or exercis* or wrist* or wear* or track* or monitor* or record* or monitor* or step or steps or stepping)).tw.
- $_{32}$ (polar and (A300 or A360 or M200 or M400 or M430 or M430 or M460 or M600 or V650 or V800 or Loop2)).tw.
- 33 ("Google fit" or (apple adj6 (health adj6 app)) or FollowMee or RunDouble or C25K or "Couch to 5k" or Endomondo or "sports tracker" or sports-tracker or strava or smartphone*).tw.
- 34 ((accelerometer* or GPS or actigraph* or actimetr* or "ambulatory monitor*") adj8 (activ* or exercis* or fit or fitness or step or steps or stepping)).tw.
- 35 ((physical activity or PA or exercis* or step or steps or stepping) adj5 (monitor* or measur* or track* or record*)).tw.
- 36 exp Cellular Phones/ or exp Mobile Devices/
- 37 ((app or apps or application*) adj4 (phone* or mobile* or cell*)).tw.
- 38 pedometer*.tw.
- 39 "fitness track*".tw.
- 40 "fitness monitor*".tw.
- 41 "activity track*".tw.
- 42 ("activity monitor*" or wearable* or "step counter*").tw.
- 43 or/29-42

44 clinical trials/
45 randomi#ed.ab.
46 randomly.ab.
47 trial.ti.
48 or/44-47
49 26 and 43 and 48
50 limit 49 to yr="2012 -Current"

Scopus

(TITLE-ABS-KEY(((myocardial OR cardiac OR heart) W/2 (infarct* OR isch?emi*)) OR (coronary W/2 (syndrome* OR disease* OR event* OR occlusion* OR stenos* OR thrombo*)) OR (myocard* W/2 revasculari?ation) OR STEMI OR NSTEMI OR ("ST" W/2 (elevat* OR depress*)) OR "heart transplant*" OR angina OR (heart W/2 (failure OR attack OR bypass OR disease*)) OR ((heart OR cardiac OR myocard*) W/2 (fail* OR insufficien* OR decomp*)) OR HFpEF OR HFrEF OR "left ventricular ejection fraction" OR ((preserved OR reduced) W/1 "ejection fraction") OR "LV dysfunction" OR (diastolic W/1 (dysfunction* OR failure*)) OR (systolic W/1 (dysfunction* OR failure*)) OR "pulmonary embolism*" OR CABG OR (coronary W/2 bypass) OR PTCA OR angioplast* OR PCI OR (Percutaneous W/2 intervention*) OR (stent* W/3 (heart OR cardiac*)) OR ("heart valve" W/1 (device* OR artificial OR prosthesis)) OR cardiomyopath* OR "cardiovascular disease*")) AND (TITLE-ABS-KEY(Fitbit OR (samsung W/2 gear*) OR Vivofit OR Vivoactive OR Vivosmart OR Vivomove OR Vivoki OR garmin* OR "Apple watch" OR verily OR TomTom OR "Touch cardio" OR "spark cardio" OR sensewear OR activPAL OR Actiheart OR ((pebble OR jawbone) W/6 (activit* OR exercis* OR wrist* OR wear* OR track* OR monitor* OR record* OR monitor* OR step OR steps OR stepping)) OR (polar and (A300 OR A360 OR M200 OR M400 OR M430 OR M430 OR M460 OR M600 OR V650 OR V800 OR loop2)) OR "Google fit" OR (apple W/6 (health W/6 app)) OR FollowMee OR RunDouble OR C25K OR "Couch to 5k" OR Endomondo OR "sports tracker" OR "sports-tracker" OR strava OR smartphone* OR ((accelerometer* OR GPS OR actigraph* OR actimetr* OR "ambulatory monitor*") W/8 (activ* OR exercis* OR fit OR fitness OR step OR steps OR stepping)) OR (("physical activity" OR "PA" OR exercis* OR step OR steps OR stepping) W/5 (monitor* OR measur* OR track* OR record*)) OR ((app OR apps OR application*) W/4 (phone* OR mobile* OR cell*)) OR pedometer* OR "fitness track*" OR "fitness monitor*" OR "activity track*" OR "activity monitor*" OR wearable* OR "step counter*")) AND ((ABS (randomi?ed OR randomly) OR TITLE (trial)) AND PUBYEAR > 2011)

Cochrane

((myocardial or cardiac or heart) near/2 (infarct* or isch?emi*)) or (coronary near/2 (syndrome* or disease* or event* or occlusion* or stenos* or thrombo*)) or (myocard* near/2 revasculari?ation) or STEMI or NSTEMI or ("ST" near/2 (elevat* or depress*)) or "heart transplant*" or angina or (heart near/2 (failure or attack or bypass or disease*)) or ((heart or cardiac or myocard*) near/2 (fail* or insufficien* or decomp*)) or HFpEF or HFrEF or "left ventricular ejection fraction" or ((preserved or reduced) near/1 "ejection fraction") or "LV dysfunction" or (diastolic near/1 (dysfunction* or failure*)) or (systolic near/1 (dysfunction* or failure*)) or "pulmonary embolism*" or CABG or (coronary near/2 bypass) or PTCA or angioplast* or PCI or (Percutaneous near/2 intervention*) or (stent* near/3 (heart or cardiac*)) or ("heart valve" near/1 (device* or artificial or prosthesis)) or cardiomyopath* or "cardiovascular disease*":ti,ab,kw and itbit or (samsung near/2 gear*) or Vivofit or Vivoactive or Vivosmart or Vivomove or Vivoki or garmin* or "Apple watch" or verily or TomTom or "Touch cardio"

"spark cardio" or sensewear or activPAL or Actiheart or ((pebble or jawbone) near/6 (activit* or exercis* or wrist* or wear* or track* or monitor* or record* or monitor* or step or steps or stepping)) or (polar and (A300 or A360 or M200 or M400 or M430 or M430 or M460 or M600 or V650 or V800 or loop2)) or "Google fit" or (apple near/6 (health near/6 app)) or FollowMee or RunDouble or C25K or "Couch to 5k" or Endomondo or "sports tracker" or "sports-tracker" or strava or smartphone* or ((accelerometer* or GPS or actigraph* or actimetr* or "ambulatory monitor*") near/8 (activ* or exercis* or fit or fitness or step or steps or stepping)) or (("physical activity" or "PA" or exercis* or step or steps or stepping) near/5 (monitor* or measur* or track* or record*)) or ((app or apps or application*) near/4 (phone* or mobile* or cell*)) or pedometer* or "fitness track*" or "fitness monitor*" or "activity track*" or "activity monitor*" or wearable* or "step counter*":ti,ab,kw Publication Year from 2012 to 2017

Web of Science

TS=(((myocardial OR cardiac OR heart) NEAR/2 (infarct* OR isch?emi*)) OR (coronary NEAR/2 (syndrome* OR disease* OR event* OR occlusion* OR stenos* OR thrombo*)) OR (myocard* NEAR/2 revasculari?ation) OR STEMI OR NSTEMI OR ("ST" NEAR/2 (elevat* OR depress*)) OR "heart transplant*" OR angina OR (heart NEAR/2 (failure OR attack OR bypass OR disease*)) OR ((heart OR cardiac OR myocard*) NEAR/2 (fail* OR insufficien* OR decomp*)) OR HFpEF OR HFrEF OR "left ventricular ejection fraction" OR ((preserved OR reduced) NEAR/1 "ejection fraction") OR "LV dysfunction" OR (diastolic NEAR/1 (dysfunction* OR failure*)) OR (systolic NEAR/1 (dysfunction* OR failure*)) OR "pulmonary embolism*" OR CABG OR (coronary NEAR/2 bypass) OR PTCA OR angioplast* OR PCI OR (Percutaneous NEAR/2 intervention*) OR (stent* NEAR/3 (heart OR cardiac*)) OR ("heart valve" NEAR/1 (device* OR artificial OR prosthesis)) OR cardiomyopath* OR "cardiovascular disease*") AND TS=(Fitbit OR (samsung NEAR/2 gear*) OR Vivofit OR Vivoactive OR Vivosmart OR Vivomove OR Vivoki OR garmin* OR "Apple watch" OR verily OR TomTom OR "Touch cardio" OR "spark cardio" OR sensewear OR activPAL OR Actiheart OR ((pebble OR jawbone) NEAR/6 (activit* OR exercis* OR wrist* OR wear* OR track* OR monitor* OR record* OR monitor* OR step OR steps OR stepping)) OR (polar and (A300 OR A360 OR M200 OR M400 OR M430 OR M430 OR M460 OR M600 OR V650 OR V800 OR loop2)) OR "Google fit" OR (apple NEAR/6 (health NEAR/6 app)) OR FollowMee OR RunDouble OR C25K OR "Couch to 5k" OR Endomondo OR "sports tracker" OR "sports-tracker" OR strava OR smartphone* OR ((accelerometer* OR GPS OR actigraph* OR actimetr* OR "ambulatory monitor*") NEAR/8 (activ* OR exercis* OR fit OR fitness OR step OR steps OR stepping)) OR (("physical activity" OR "PA" OR exercis* OR step OR steps OR stepping) NEAR/5 (monitor* OR measur* OR track* OR record*)) OR ((app OR apps OR application*) NEAR/4 (phone* OR mobile* OR cell*)) OR pedometer* OR "fitness track*" OR "fitness monitor*" OR "activity track*" OR "activity monitor*" OR wearable* OR "step counter*") AND (TI=(trial) OR TS=(randomi?ed OR randomly))

Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2011-2017

APPENDIX II – EXCLUDED STUDIES

Study	Reason for exclusion
Not CVD	
Dasgupta et al. (2014)	Not CVD
Glynn et al. (2014)	Not CVD
Hornbuckle et al. (2012)	Not CVD
Kendzor et al. (2017)	Not CVD
Kraus et al. (2012)	Not CVD
Martin et al. (2012)	Not CVD
Pagels et al. (2012)	Not CVD
Petrella et al. (2012)	Not CVD
Richardson et al. (2014)	Not CVD
van den Berg et al. (2017)	Not CVD
Zhang et al. (2017)	Not CVD
	NOLCVD
Not an RCT	
Albert et al. (2017)	Not RCT and device did not measure PA
Cheng et al. (2016)	Not RCT (does not address outcomes)
Hannah et al. (2015)	Not RCT
Huffman et al. (2015)	Not RCT
Jehn et al. (2013)	Not RCT
McCarthy et al. (2013)	Not RCT
Pfaeffli et al. (2015)	Not RCT (mixed methods research design)
Ramadi et al. (2016)	Not RCT
Sangster et al. (2017)	Not RCT
Thorup et al. (2016)	Not RCT
Yates et al. (2015)	Not RCT
Zile et al. (2013)	Not RCT
No objective data collected	
Aamot et al. (2012)	Device (HR monitor) did not measure levels of PA
Acanfora et al. (2016)	Device did not measure levels of PA
Almeida et al. (2015)	Device not used to monitor physical activity
Alsaleh et al. (2012)	Device not used to measure PA
Balsam et al. (2013)	Device not used to monitor PA
Barnason et al. (2009)	Daily steps from accelerometer self-reported into diary
Borland et al. (2014)	Device (KeepWalking LS2000 pedometer) self-reported log
Chang et al. (2015).	IG kept a daily recording of the number of steps taken
Chomiuk et al. (2013)	No device to measure PA
Dougherty et al. (2016)	Data are transcribed into logs
Izawa et al. (2012)	Patients performed self-monitoring of their physical activity
Johnston et al. (2016)	Device (smartphone-based interactive support tool)
Lau et al. (2016)	Pedometer - recording exercise in an exercise log
Li et al. (2015)	PA duration recorded by participant into a diary
Midence et al. (2016)	Pedometer readings entered into an activity log
Peterson et al. (2012)	Pedometer used to provide feedback and reinforcement
Reid, Morrin et al. 2012	From the author "From the log book"
Sangster, Furber et al. (2015)	Used pedometer as motivational tools only.
Salvi, Ottaviano et al. 2017	From author: "study is 10 years old, wearables didn't exist"
Seto et al. (2012)	Device (mobile phone) not used to monitor physical activity
Varenhorst et al. (2012)	Not measuring physical activity
Wolf et al. (2016)	Device (smartphone) does not measure PA
No device used in study	
Aliabad et al. (2014)	No device – questionnaire and treadmill exercise test used
Abstract/protocol/rationale on	
Anderson et al. (2016)	Abstract only – thesis has been retrieved and included
Bernocchi et al. (2016)	Rationale and design only (study not complete)
Brouwers et al. (2017)	Protocol only
Eastwood et al. (2014)	Abstract only. Unable to find study.

Edelmann et al. (2017)	Rationale and design only (study not complete)
Kayser et al. (2016)	Abstract – protocol only
Lin et al. (2015)	Abstract only. Study requested from author - not received
Maddison et al. (2014)	Protocol only. Resultant study not RCT
Recio-Rodriguez et al. (2014)	Protocol only
Sangster et al. (2013)	Abstract (study included)
Snoek et al. (2016)	Rationale and design only (study not complete)
Treskes et al. (2017)	Rationale and design only (study not complete)
Varnfield et al. (2012)	Abstract only (the RCT: Varnfield 2014 included)
Yudi et al. (2016)	Protocol only
Duplicate study	
Malmo et al. (2016)	Duplicate study
Walters et al. (2012)	Duplicate of Varnfield
Unable to contact authors	
Frederix, et al. (2015)	Unable to contact author re: measurement of PA
Takase et al. (2015)	Insufficient information. No answer from author