Title

A review of current use of commercial wearable technology and smartphone apps with application in monitoring individuals following total hip replacement surgery.

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Abstract

The advent of commercially available wearable activity monitors and smartphone apps allows objective digital monitoring of daily activities of patients before and after THR surgery. A wide variety of wearable activity monitors and smartphone apps are being marketed to assist with enhancing physical activity following surgery. A systematic review of commercial wearable technology and smartphone apps was undertaken to assess the evidence supporting their efficacy in assisting rehabilitation and patient monitoring following THR. A search was conducted using the electronic databases including Medline, CINAHL, Cochrane, PsycARTICLES and PubMed of studies from January 2000 to January 2019. Five studies met the eligibility criteria. A review of the studies found very little evidence to support long term efficacy of the technology in enhancing rehabilitation and patient monitoring post THR. Future work is required to establish which commercially available monitoring technology is most valuable to patients, which ones improve clinical outcomes post THR, and what are the best economical models for their deployment.

Keywords: Total hip replacement, wearables, smartphone apps, rehabilitation, patient monitoring.

Introduction

Total hip arthroplasty (THR) is among the most successful operations and is performed in an increasing number of individuals around the world with the primary aim of reducing pain and improving function [1]. However, an objective evaluation of physical function and performance status post-surgery is difficult because patients spend the majority of their postoperative rehabilitation outside the clinic and self-report to providers using subjective methods such as patient reported outcomes measures (PROMs) [2].

Despite concerns over standardization [2], PROMs offer insight into an individual's daily, and results are generally positive. However, discrepancies are seen when PROMs are compared to performance based function [3] and a number of studies have suggested caution with only using subjective data as the measure of recovery [3, 4, 5]. In addition, compared with pre-operative function, post-operative activity levels are low and many individuals become socially isolated following surgery [6, 7].

The launch of commercially available wearable devices such as activity monitors and smartphone apps allows objective monitoring of daily activities. In addition to their growing popularity [8], these devices are equipped with a wide variety of different sensors and algorithms to collect and display physical activity data. Different devices have advantages and disadvantages, including cost, comfort, ease of use, and immediacy of feedback provided. Some are likely to be more suited for research and others for clinical purposes working as a 'virtual trainer' to motivate people to complete an exercise programme [9].

Several studies have compared activity tracking wearables and smartphone apps. Their aim is to analyse their reliability and assess their effectiveness on increasing rehabilitation adherence. A number of limitations in their performance have been identified. Fokkema, Kooiman [10] identified the need for further validation of activity monitors in slower walking populations. Bahadori, Wainwright [11] also found that despite a wide range of apps currently available to individual following THR and total knee replacement (TKR), there was significant variability in their quality. Sanders, Loveday [12] reviewed the characteristics and measurement properties of currently available, self-monitoring wearables for

health self-monitoring, sedentary behaviour and personal activity detection. They reviewed various aspects of these devices, and found that there is still a need for further development to self-monitor sedentary behaviour.

Although overall, advances in wearable technology has enabled several studies to use more valid and reliable objective measures of physical activity, the picture related directly to THR remains unclear [13, 14, 15] and to date, there has been no systematic review of studies objectively measuring personal activity after THR. Therefore, the aim of this review is to systematically identify all studies which utilised commercially available activity monitors or smartphone apps to measure physical activity in individuals both before and after THR.

Method

This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (www.prismastatement.org/PRISMAStatement). A computer-based search was completed in January 2019 using the mySearch Database (Bournemouth University). This included Cochrane Database of Systematic Reviews library, CINAHL Complete®, Science Citation Index and Medline®. Articles published in the English language from January 2000 to January 2019 were reviewed. Search strategy terms are outlined in Table 1 and Table 2. Studies included were commercially available activity trackers and smartphone apps capable of providing feedback to the end user following THR surgery.

The most popular wearable devices on the market [16] were chosen for this systematic review and included: Fitbit, Garmin, Apple, Misfit, Polar, Samsung Gear, TomTom, and Lumo. A second systematic search strategy was also employed to capture the smartphone apps across the five most popular smartphone app stores: iTunes; Google Play; Windows Mobile; Blackberry App World; and Nokia Ovi for analysis. Once the initial searches were completed, the results were manually filtered to remove duplicates. Two independent reviewers (SB and SC) then screened journal titles and abstracts for relevance until only 74 papers remained (see Figure 1 for flowchart). Any disagreements between reviewers were discussed with IS and resolved by consensus. Studies included were commercially available activity trackers and smartphone apps capable of providing feedback to the end user following THR surgery.

As this study utilised information that was available in the public domain and there was no interaction with patients or retrieval of personal data, the Health Research Authority (HRA) ethics database [17] confirmed ethics approval was not required and therefore not sought.

[Table 1 near here]

[Table 2 near here]

[Figure 1 near here]

Data extraction process

SB extracted data to a standardised table, details found in Table 3 and Table 4.

[Table 3 near here]

[Table 4 near here]

Data quality

The Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) [18] and Risk of Bias in Randomized trials (RoB 2.0) [19] tool was used to assess the risk of bias. ROBINS-I includes seven domains including confounding, selection of participants into the study, classification of interventions, deviations from the intended interventions, missing data, measurement of outcomes, and selection of the reported result. The categories for risk of bias judgements for ROBINS-I are 'low risk', 'moderate risk', 'serious risk', and 'critical risk' of bias [18]. RoB 2.0 includes six domains including randomization process, timing of identification, recruitment of participants, deviations from intended intervention, missing outcome data and measurement of outcomes. The categories for risk of bias judgements for RoB 2.0 are ‘low risk’, ‘high risk’ and ‘some concerns’.

Results

Classification of technologies and application in patient monitoring

Five studies were identified which utilised currently available commercial wearable activity monitors and smartphone apps to measure physical activity before to after THR.

Wearable Activity Monitor Devices

Toogood, Abdel [20] used an activity monitor (Fitbit) in a cohort of 33 patients undergoing elective primary THR, and aged above 60 years who were mobile pre-operatively. Age, gender, BMI, surgical approach, length of stay, and discharge disposition were extracted from the medical records. All patients wore a Fitbit wireless accelerometer on their operated side ankle for 30 days after discharge. A mean step count was obtained for all patients on each post-operative day. The patient computer or mobile device transmitted data to a web service that was accessible by investigators who reviewed the data each day. The mean compliance over 30 days was 26.7 days of use. There was a clear trend towards increased activity with passage of time. Additionally, Fitbit data showed correlation between age, BMI, surgical approach and destination of patient at the time of discharge from hospital. Toogood, Abdel [20] concluded that at-home remote monitoring using Fitbit monitor is viable and can be a great help to those patient who recover slowly.

A randomized control study by Van der Walt, Salmon [21] used Garmin Vivofit® 2 to assess the activity levels of 163 patient following THR and TKR surgery. Eligible patients were all adults undergoing primary elective hip or knee replacement surgery. Invited two week prior to their surgery, patients received a Garmin Vivofit® 2 upon acceptance to take part. On day 1 after arthroplasty, randomisation was performed, creating two equal numbered groups of 'Feedback Group' or 'No Feedback Group'. In the 'The Feedback Group', patients were able to see their step counts and were given a daily step goal. The goal of 7000 steps by week 6 was selected as this is the recommended daily step count for healthy older adults (>65). Participants in the "Non- Feedback Group" continued to wear the device with the display obscured for 2 weeks after surgery and were not given a daily step goal. In addition, all patients completed patient reported outcome questionnaires (PROMS) preoperatively and at 6 months after

surgery. Van der Walt, Salmon [21] found that patients who received feedback from the Garmin Vivofit® 2 with a daily step goal were significantly more active than those in the 'No Feedback Group'. However there was no significant difference between the groups in PROMS at 6 months.

Smartphone Activity Monitor Apps

Wang, Tong [22] aimed to evaluate the effect of an Internet-based home orthopaedic care platform on patients' functional joint recovery, quality of life and activities of daily living after hip replacement. In this randomized clinical study, 400 THR patients were monitored by 18 local departments of Orthopaedic surgery using a free smartphone messaging app called WeChat. Patients were either given routine care or introduced to an intervention care using the WeChat platform. Using the platform, specially trained nurses interacted with patients on: Clinical Broadcast, Question and Answer Application, Appointment Application and Rehabilitation Exercise. Patients were able to upload pictures or videos from their rehabilitation exercises. The patients in the two groups were compared in terms of functional recovery (Harris hip score), quality-of-life score (MOS SF-36) and activities of daily living (Barthel index) at 3 and 6 months after discharge. This study found that after 6 months of continuous intervention, the scores for the intervention group were significantly higher than those in the control group. Overall, the smartphone app provided a platform for extended care management outside of the hospital, which can be extremely helpful for patients following THR surgery.

A study by Krumsvik and Babic [23] utilised a user-centred approach to report on the user experience of smartphone apps to reduce post-THR adverse event. The authors believed that the outcome of an adverse event has a huge impact on patient well-being, societal costs, as well as the reputation of healthcare. Therefore, an app which is capable of empowering patients, not only through providing general information, but also through capturing patient specific data such as pain level, anxiety, mobility, progress, and quality of recovery is also needed. A smartphone application designer, a female nurse who had recently undergone THR and a physiotherapist were invited to take part in the study. They were assessed with respect to the interaction flow, information content and self-reporting functionalities. SafeTHA app was designed to allow the patient to report any complication following a

THR surgery using a diary platform which the physiotherapist is able to check and reply to with any advice. The study concluded that the SafeTHA app is a practical, sufficient and intuitive way of monitoring patient post-THR, however one cannot solely rely on the application.

Crizer, Kazarian [24] used a mobile step-tracking application to record daily steps of 589 patients post THR (n=301) and TKR (n=288). The goal of this prospective, single-centre study was to evaluate and compare an objective measure of postoperative recovery, daily step-count with PROMS. Following consent from patients, the step-tracking app was downloaded to their smartphone. Steps were recorded and monitored by prospective surgeons for 4 weeks before surgery and 12 weeks thereafter. Patient-reported lower extremity functional scale (LEFS) scores were recorded at 1, 6, and 12 weeks, postoperatively. LEFS scores were correlated to weekly median daily steps for a 4 week period just before surgery, as well as for each of the first 12 consecutive weeks after THR/TKR. Crizer, Kazarian [24] found that for THR patients, recovery of physical activity was rapid, as the median patient surpassed their baseline step counts after only 5 weeks, after which further functional improvement was slow and steady. Overall, in both THR and TKR patients, physical function improved over the first 12 weeks as measured by both steps and LEFS. There is a weak correlation between step counts and LEFS scores suggesting that subjective measures may provide only part of the story. Crizer, Kazarian [24] suggested that objective measures such as a step count using a simple smartphone app could be a helpful and practical addition to the surgeon's armamentarium for monitoring the recovery of their patients.

Risk of Bias in individual studies

The risk of bias for the five studies included for review is outlined in Table 5. Given the lack of studies available following screening process, quality assessment was not a factor for inclusion or exclusion within the systematic review, but was utilised to facilitate interpretation of findings. Two reviewers (SB and SC) completed the quality assessment, with any discrepancies resolved through discussion.

[Table 5 near here]

Discussion

Clinical assessments and the evidence of use

The main goal of activity monitor wearable and smartphone apps is to monitor and encourage patient activities during rehabilitation. Clinical trials are crucial to assess the success of the new technologies, in particular when additional clinical results show improvement in patient condition. However, many studies have relied primarily on subjectively reported personal activity levels, a method hampered by reporting biases and inadequate reliability and validity compared to objective methods, such as body-worn accelerometers [25]. Advances in technology have signalled the release of several studies in patients undergoing TKR surgery [26], spinal surgery [27], stroke [28], and arm rehabilitation [29, 30] using more valid and reliable objective measures of physical activity, but the picture related to THR remains unclear.

The systematic search found five papers, of which two were adopting randomised trials to assess the commercially available technology for monitoring patients post THR. The papers generally had various levels of bias (Table 5); however, blinding of participants and personnel and blinding of outcome assessment were consistently reported to have a high risk of bias.

In general, all of the studies agreed that subjective measures (PROMS) alone may provide only part of the story and therefore, objective measures for tracking postoperative recovery should be utilised in the patients' surgical pathways. Patients who received feedback from a commercial activity tracker or smartphone app had significantly higher activity levels after THR compared to patients who did not receive feedback [21, 22, 24]. It is also important to acknowledge that currently an optimal rehabilitation pathway post THR has not been defined [31], therefore the question of what rehabilitation programmes wearables should help to facilitate and deliver remains unanswered. Therefore, in the meantime, simple, objective measures such as step count could be useful tool in managing patient expectation regarding their personal activity level post THR.

Evidence demonstrating changes at 1 year was not reported in any of the studies; therefore, it remains unclear what long-term changes may occur after THR. Of the studies reporting improvement in activity

level after THR, the clinical significance was unclear and impacted by a risk of methodological bias. The accuracy of activity monitors at low speed has been previously questioned specially in the first days after surgery when activity level is expected to be at a slower rate [32, 33]. There is also no evidence to support the reliability of the step-tracking application used in Crizer, Kazarian [24] and when mobile apps are used as the point of contact between patients and healthcare providers, reliability is dependent on the level of academic education and self-efficacy [34] which were not considered in the interpretation of the study outcome.

Wang, Tong [22] reported a large effect in functional recovery, quality-of-life score and activities of daily living at 3 and 6 months after discharge. However, this study was vulnerable to bias regarding reporting of recruitment handling of potential factors confounding the measurement of personal activity. Furthermore, there are two major concerns, one related to the interpretation of data and the other on the impact of the innovation. Evidence shows that patient reported physical function after THR/TKR does not correlate with objectively assessed function [3, 35, 36]. More importantly, use of applications such as WeChat which have been designed primarily for messaging and social media to discuss patient data is forbidden in most European countries with implementation of GDPR [37]. Therefore, despite agreeing with the effectiveness of an internet-based home orthopaedic platform, this innovation would be challenging to implement outside China.

It is worth noting that none of the studies examined or reported on the health economics aspects of introducing the technology. Even if evidence is collected that supports the clinical benefit of wearable devices, without such data, they are unlikely to be widely adopted in health care systems [38].

Interestingly, wearable activity monitors are among the fastest growing area in consumer technology [16] and in some cases by the time a study has gained approval, participants have been tested, data analysed, and reports have been written and gone through the peer review process, wearable technology or smartphone app has been updated to the next model or has become obsolete [16]. Thus, the wearable activity monitors used in the studies reviewed here have also been marketed to have the potential to measure other activities in different clinical trials [8]. Therefore, we have summarised the (Table 6)

characteristics of different types including the sensor use, price, battery life and tracking features of the two products (Fitbit™, Garmin®) examined. This could be beneficial to readers whom are interested of using these trackers in future studies.

[Table 6 near here]

Availability of brands is another interesting topic. Since 2011, 432 unique devices from 132 different brands were introduced to the market [8]. Out of the brands currently available, the five most often used in research projects are Fitbit™, Garmin®, Misfit, Apple, and Polar [8, 16]. In addition, these brands have all existed for several years and are likely to stay on the market for the immediate future. Nevertheless, it is worth considering that a high article count, clinical trials or reliability study of a particular device does not automatically imply suitability of that device for every study. Fitbit™ and Garmin® which were utilised in the studies reviewed here, both allow third party programs to access, run and communicate on their devices [39, 40]. Nevertheless, Apple, Misfit, Polar and Samsung also offer similar capabilities [8]. For projects that require remote access to patient's data such as THR trials, these features are essential.

Smartphone apps however are slightly more challenging to generalise. In the UK there is no official requirement to register smartphone or tablet apps either as software or devices with the Medicines and Healthcare products Regulatory Agency (MHRA) [41]. Whereas in the USA, Food and Drug Administration (FDA) [42] have recently announced a regulatory program, aiming to ensure that the quality of the apps is sufficient before it is available to the public. The guidelines [42] that are available are just that, so it depends on what the app does and the level of patient risk associated with it as to whether it should be classified as a medical device or not. Furthermore, at the time of writing, none of the apps included in our review have been included in the 'NHS approved' list [43] nor had any shown evidence that they had volunteered to take part in the FDA software and app precertification program. Nonetheless, new possibilities are becoming available with the use of smartphones and apps to estimate as well as physical activity [44] but studies are required to assess their reliability for the measurement of activity and angles in different walking speeds.

The studies included in this review demonstrate that the technology (activity monitors, and smartphone apps) are safe and feasible, and that they show promise in measuring physical activity before and after THR. In contrast, there is lack of evidence supporting sustained use or effects on health outcomes, as studies have primarily focused on establishing the feasibility of monitoring activity and the association of measured activity with short-term benefits.

Recommendation for future research

As the wearable activity monitors and smartphone apps in THR research evolves, the challenges in clinical measurements, development, adherence, privacy, and clinical integration need to be addressed before these devices are broadly adapted as a clinical and self-assessment tools. Several of our key recommendations and clinical directions are as follow. First, we believe that involving patients in goal setting is essential and will define the use of the appropriate activity monitor. A good compliance is an important part of a well delivered clinical trial and greatly influenced by patients characteristics [34]. Second, the biggest deficit following THR surgery is the walking speed and step length among THR patients [45]. Activity monitors allow an objective measure of those parameters, and by only considering step count we are not addressing gait adaptations which persist after surgery. Third, a limitation from all of the studies reviewed here is the uncertainty around the accuracy of the activity trackers. The Consumer Technology Association (CTA) have developed protocols to evaluate devices for step count [46], sleep validity [47] and a standard for heart rate is expected to be released in 2020. More standards and protocols should be developed for other parameters such as heart rate, intensity and activity profiles. A guideline recommendation has been published recently [16] and should be utilised to help evaluate devices in a standardize format. In addition to these guidelines, it is recommended to use a single activity monitor in a particular study. Fourth, wearables should be regarded as facilitators rather than drivers of change in health behaviour [48]. Future research protocols should be designed with an aim to develop a behaviour change program that utilise wearable activity monitors or smartphone apps to offer a more organized and engaging experience than use of the device alone.

Limitations

There is limited data specifically investigating the use of commercial wearable technology and smartphone apps with THR pathways. Although of good methodological quality, the studies employed different protocols making generalisability difficult. In addition, the Krumsvik and Babic [23] study was a user design report which suffered from serious risk of bias. Furthermore, we only summarised characteristics of the two brands (Fitbit™, Garmin®) and their current iteration of activity trackers which is most used across all clinical research [8]. We did not collect information about all devices that have existed at some point. This was done with the aim to reduce the burden on researchers with difficulties of selecting a suitable activity monitor for research.

Conclusion

Commercially available activity monitoring wearables and smartphone apps have the potential to engage patients as advocates in their personalized care, as well as offer health care providers objective assessments of their patients' daily activity patterns. However, this review finds very little evidence to support their long term efficacy in enhancing rehabilitation pathways post THR. Future work is required to establish which monitoring technology is most valuable to patients, which improve clinical outcomes post THR, and what are the best economical models for their deployment.

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