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Review

Review

Systematic review of the effectiveness of health-related behavioral interventions using portable activity sensing devices (PASDs)

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ABSTRACT

Background: Portable activity sensing devices (PASDs) have received significant interest as tools for objectively measuring activity-related parameters and promoting health-related outcomes. Studies of PASDs suggest the potential value of integrating them with behavioral interventions to improve intermediate and downstream clinical outcomes.

Objectives: This systematic review describes and evaluates evidence from controlled studies of interventions using PASDs on their effectiveness in health-related outcomes. Study quality was also assessed.

Methods: A systematic literature search was performed of MEDLINE, Cochrane Central Register of Controlled Trials, PsycINFO, EMBASE, and CINAHL databases. We included English-language papers of controlled trials through 2015 reporting the effectiveness of PASDs in improving health-related outcomes in any population. We extracted and analyzed data on study characteristics including design, target population, interventions, and findings.

Results: Seventeen trials met the inclusion criteria from a total of 9553 unique records. Study objectives varied greatly, but most sought to increase physical activity. Studies with a "passive" intervention arm using a PASD with minimal behavioral support generally did not demonstrate effectiveness in improving health-related outcomes. Interventions integrating PASDs with multiple behavioral change techniques were more likely to be effective, particularly for intermediate outcomes such as physical activity and weight loss. Trials had small sample sizes but were generally free of bias, except for blinding and selection bias.

Conclusion: There is insufficient evidence to draw a conclusion about the general health-related benefits of PASD interventions. PASD interventions may improve intermediate outcomes when coupled with multiple behavioral change techniques. Devices alone or with minimal behavioral change support are insufficient to change health-related outcomes.

Key words: physical activity tracker, activity sensor, portable sensor, wearable device, mobile health (mHealth) technology

INTRODUCTION

Portable activity sensing devices (PASDs), including wearable accelerometers and pedometers, have generated considerable interest from health care researchers.[1,2] These devices objectively measure and estimate physical activity, balance control, exercise adherence, activity intensity, and energy expenditure more easily and accurately than self-reporting questionnaires or diaries.[3–6] Mobile information technology (IT) advances – including wireless connectivity, real-time messaging, advanced visualization, and context awareness – also permit these devices to motivate and inform users.[7–9] With decreasing technology costs, PASDs have also penetrated the consumer marketplace with activity trackers (eg, Fitbit devices) and smartphones/smartwatches with sensor-based health applications (eg, Apple Health, Google Fit).[10–12]

PASDs can play 2 important roles in health care delivery and health promotion. First, they provide increasingly powerful measurement, storage, and communication of health-related variables, such as the total amount, duration, frequency, timing, and intensity of physical activity, body postures, and body movements. These are interpreted into activity levels, step counts, fall risk estimates, and other constructs associated with cardiovascular disease,[13] diabetes,[14–16] cancer,[17,18] hypertension,[13] neurological disorders,[19] gait disturbance,[20] and balance impairment and falls.[21,22] Regular assessment or remote monitoring of these measures could result in more timely, personalized, and appropriate therapeutic interventions or preventive strategies, implemented by clinicians or patients themselves.[10,23] Individual-level PASD data can also be aggregated for population health surveillance and subgroup comparisons, as demonstrated by the use of pedometers in US and Japanese national health studies.[23]

The second role PASDs can play in health and health care is in "behavioral informatics" interventions.[24] This involves integrating PASDs into behavioral interventions to improve physical activity or decrease health-related risks.[24,25] For example, devices can help individuals self-monitor physical activity over time,[26] motivate individuals to reduce sedentary behaviors,[25] or provide coaching to improve body balance.[27–29] These behavioral change techniques can be and often are combined and delivered through mobile, web, or desktop IT software linked to PASDs.[30] Such software can facilitate longitudinal tracking, feedback, motivational communication, goal setting, exercise planning, time management, and social media support.[23,31–35]

Enough literature has accumulated to assess whether patients indeed experience better health-related outcomes when exposed to behavioral interventions using PASDs. Prior reviews demonstrated the validity,[26,36,37] feasibility,[37,38] reproducibility,[37] potential efficiency,[3,26,30,38] and acceptance[39] of PASDs. However, the present study is, to our knowledge, the first to systematically review and synthesize evidence from controlled trials testing the health-related effectiveness of PASD-enabled behavioral interventions.

Objectives

The primary aim of this systematic review is to describe and evaluate controlled studies of interventions using PASDs. The review examines the effect of device-based interventions on intermediate outcomes such as physical activity levels and downstream clinical outcomes such as organ function. We hypothesize that intervention effectiveness varies depending on the nature of the behavioral change techniques used. A secondary objective was to evaluate the quality of reviewed trials.

METHODS

We conducted this systematic review of the English-language scholarly literature in accordance with Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines. One reviewer (HA) performed study selection, data extraction, and quality assessment and another (RJH) independently monitored these processes for completeness and accuracy.

Data sources and search queries

We searched 5 online databases from inception to December 30, 2015: MEDLINE (PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO (EBSCO), EMBASE, and CINAHL (EBSCO). Queries covered 3 domains: (1) sensing devices, (2) portability or wearability, and (3) physical (body) activities (for details, see Supplementary Table S1). In addition, reference lists of relevant reviews and empirical studies were checked for eligible studies.

Study selection

Records were downloaded into an EndNote X7.7 (Clarivate Analytics, Philadelphia, PA, USA) library. After removing duplicate records, we screened titles and abstracts for inclusion and exclusion criteria (for details, see Supplementary Table S2). We used a "topic-collated" approach to accelerate screening: instead of sequentially reviewing publications in author or chronological order, we collated records by topics using keyword searches in the EndNote library prior to full-text review.

Studies were included in the systematic review if they were in English, randomized, studied humans of any age, and compared the health-related effectiveness of PASDs in the target population against a control group. Journal and peer-reviewed conference articles were included.

Data extraction

Data were extracted from eligible articles into a spreadsheet. Data included study design, objectives, target population, participant characteristics, interventions, device type, device data capture and processing, principal findings, and adverse events.

Quality assessment

Articles included in the final review were assessed for quality and risk of bias using updated criteria from the Cochrane Consumers and Communication Review Group.[40] Studies were graded as low, unclear, or high for each Cochrane bias domain: selection, performance, detection, attrition, reporting, and other (Cochrane Handbook, Table 8.5.d).[41]

RESULTS

We identified 9771 search records and 4 additional papers through cited reference search (Figure 1). After removing duplicates, we reviewed titles and abstracts for 9553 records. Of these, 920 underwent full-text review. Most articles were excluded because the PASD was used not in the main intervention but to detect objective physical activity levels. A final total of 17 articles met inclusion and exclusion criteria, each using a PASD in the main intervention (Table 1; for more details, see Supplementary Table S3). All 17 met minimal quality standards for review inclusion.

Study characteristics

All 17 reviewed studies were randomized clinical trials with a PASD incorporated into the main intervention (Table 1). A majority (76%) were published after 2010. Eight studies (47%) were conducted in the United States,[28,29,33,34,42,48–50] 1 was a collaboration between researchers in Belgium and Israel,[52] and others were reported by investigators in Australia,[43] New Zealand,[44] Scotland,[45] Iran,[46] Brazil,[47] the Netherlands,[35] Canada,[32] and South Korea.[51] Sample sizes of the trials ranged from 19 to 328, with a median of 57 participants.

The reviewed studies mainly aimed to improve physical activity levels, metabolism, physiologic measures, body measures, balance control, and quality of life (Figure 2).

Three trials (18%) studied multiple intervention groups, comparing the effectiveness of PASDs integrating different behavioral change techniques.[33,34,45] In 9 studies (53%), intervention participants wore PASDs and had access to device data, while controls did

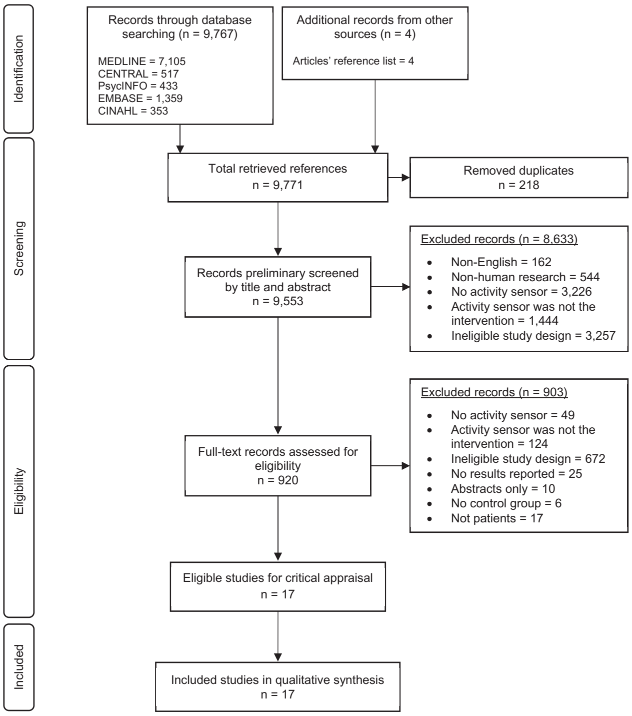

Figure 1. Flow chart of the systematic review.

not use the device.[28,29,34,35,43,45–47,52] In 3 trials (18%), both intervention and control participants used PASDs, but only the intervention group could access device data.[33,42,44] Six additional studies (35%) provided PASDs and access to device data in both trial arms, but intervention participants received individualized exercise plans based on device-assessed activity data, while controls were provided static or no exercise planning.[33,34,48–51]

Target population characteristics

Included studies evaluated the effectiveness of accelerometer-based activity programs among 1665 total participants. Thirteen trials (76%) included men and women,[28,29,32–35,42–44,47–49,51] 3 (18%) studied women only,[45,46,50] and 1 did not specify gender distribution.[52]

Five studies (29%) enrolled younger and older adults,[28,32,43,47,51] 4 trials (24%) enrolled older adults only,[29,35,45,49] 6 trials (35%) included younger adults only,[33,34,42,46,48,50] 1 enrolled adolescents,[44] and 1 did not specify age group.[52] Age distribution was poorly reported, with only 4 trials providing complete age information.[28,29,32,42] Limited information was also reported on race and ethnicity of participants, with only 4 studies reporting distributions of white vs non-white participants,[33,48–50] and 3 reporting Hispanic vs non-Hispanic distributions.[48–50]

Reviewed studies recruited individuals with different diseases or health-related conditions, including type 1 diabetes,[44] type 2 diabetes,[28,42] cardiovascular disease,[33,43] sedentary lifestyle,[34,35,45,48,49] postpartum care,[46] pregnancy,[50] smoking,[47] stroke,[32] metabolic syndrome,[51] chemotherapy-induced peripheral neuropathy (CIPN),[29] and Parkinson's disease.[52]

Utilized portable activity sensing devices

All interventions involved 1 form of PASD to objectively track participants' activity (Table 2). Eight studies (47%) used pedometers to record daily step counts; devices included Omron[45,46,48,49] and Yamax Digiwalker.[43,47] Six trials (35%) used accelerometers to measure motion along 3 axes; devices included BioTrainer,[42] SenseWear,[34] Fitbit Ultra,[50] Fitbug Orb,[33] Tracmor,[35] and X6-2mini.[32] Three studies (18%) used inertial measurement unit (IMU) sensors to measure kinematic parameters for balance assessment; these included LegSys[28,29] and EXLs3.[52] Two trials did not disclose the PASD model used.[44,51] Two studies used a separate PASD to measure physical activity outcomes (eg, step counts) independent of the device that was part of the intervention.[35,45]

Studied interventions

We identified 6 possible categories of PASD interventions, depicted in Figure 3, based on the nature of behavioral change techniques used and whether IT software was used separate from the device itself. The 3 categories of behavior change techniques were: (1) passive self-monitoring, where participants wore a device and its data were available for self-monitoring; (2) goal-based self-monitoring, where participants self-monitored device data with a specific goal in mind; and (3) integrative interventions, involving a PASD and at least 3 behavioral change techniques, including goal-based self-monitoring, motivational messages, coaching or training programs, group-based education, planning, incentives, and combinations thereof.

Technology characteristics

Table 2 summarizes the hardware, software, data retrieval and storage, data processing, and display characteristics of the technology used in reviewed studies.

The IT software involved in behavioral informatics interventions varied in terms of platform (eg, desktop vs smartphone) and type (eg, real-time feedback vs virtual counseling agent). One study[42] used a desktop application to provide graphical feedback of weekly physical activity to participants based on sensor data. In 3 trials, sensor data were stored in a web-based data-management application that provided real-time feedback to participants.[33–35,50] Smartphone applications were also used to collect sensor data and give feedback to participants.[33,50,51] Two studies provided feedback through both smartphone and web applications.[33,50] In another trial, sensor data were downloaded to a tablet-based interactive counseling application, where an animated character delivered personalized exercise coaching.[49] In one study, patients with Parkinson's disease received gait-related audiovisual feedback from smartphone-based training applications.[52] Another interactive training program provided real-time visual feedback on joint positions and angles through processing of inertial sensor-based kinematic data, helping patients understand motor errors and better control balance.[28,29] Other studies did not specify the use of software.[32,43–48]

In all studies, retrieval of data from the device was important to assess study outcomes or deliver the interventions. There were 4 ways to retrieve or transfer data from devices (Table 2). In 5 trials (29%), participants manually entered step counts from a pedometer into daily, weekly, or monthly paper diaries.[43–47] In other studies, sensor data were manually downloaded from the pedometer or accelerometer into desktop software or a web application by participants or investigators,[32,34,35,42,48,49] or participants entered step counts into a smartphone application.[50,51] In fewer cases, sensor data were automatically transferred in real time to a smartphone application[33,52] or a balance training program[28,29] for further processing.

Approaches to processing sensor data (Table 2) included applying algorithms to estimate step counts,[32,33,35,42–52] energy expenditure,[34] or physical activity duration.[32–35,50,52] Mansfield et al.[32] also processed accelerometer data using a customized, trained machine-learning algorithm to detect step counts, walking bouts, and activity

Table 1. Study characteristics of reviewed randomized clinical trials

Reference	Outcome	Intervention duration	Group size	Intervention and comparison group characterization
Paschali et al. (2005)[42]	Exercise adherence	3 months	13	Intervention: accelerometer; recorded daily activity in a paper diary, received individualized exercise plan
			13	Comparison: accelerometer with no access to activity data, received individualized exercise plan
Butler et al. (2009)[43]	Physical activity adherence	6 months	44	Intervention: pedometer; recorded daily steps, received motivating phone calls, set activity goals based on step counts, given brochure on physical activity
			46	Comparison: given brochure about physical activity
Newton et al. (2009)[44]	Physical activity level	12 weeks	38	Intervention: unblinded pedometer; 10 000 steps/day goal, recorded daily step counts, received reminder text messages
			40	Comparison: closed pedometer; received standard care
McMurdo et al. (2010)[45]	Physical activity	6 months	60	Pedometer plus behavioral intervention: pedometer; recorded daily pedometer counts in diaries, attended counseling sessions to increase physical activity, received individualized activity plan and barrier coping plans, received motivational phone calls
			53	Behavioral intervention: no pedometer; recorded walking time outdoors, received motivational phone calls
			66	Comparison: usual care; no pedometer and behavioral intervention
Maturi et al. (2011)[46]	Physical activity and body measures	12 weeks	32	Intervention: pedometer; 10 000 steps/week goal, recorded step counts on a calendar, received individualized motivational consultations, received pamphlet on weight loss
			32	Comparison: usual care; no pedometer
Shuger et al. (2011)[34]	Weight loss and waist circumference	9 months	26	SenseWear armband alone (SWA): SenseWear; had access to real-time web-based personalized weight management, received regular feedback on energy expenditure through web, received weight loss manual, instructed to monitor diet, physical activity
			28	Group-based behavioral weight loss education (GWL): attended weight loss counseling sessions, received weight loss manual, instructed to monitor diet, physical activity
			37	Combined GWL and SWA group (GWL + SWA)
			32	Comparison: weight loss manual; instructed to monitor nutrition and physical activity
Kovelis et al. (2012)[47]	Daily physical activity	1 month	23	Intervention: pedometer; 10 000 steps/day goal, recorded daily step counts
			17	Comparison: booklet on advantages of having an active life, disadvantages of smoking
Adams et al. (2013)[48]	Physical activity	6 months	10	Intervention: open pedometer; set daily goals based on actual step count data, received motivational emails and short text messages, given motivational brochures and motivating feedback, given financial incentives for achieving daily goals
			10	Comparison: pedometer; 10 000 steps/day goal, received motivational emails and short text messages, given brochures to motivate physical activity, given feedback and incentives for submitting pedometer data (but not for meeting daily goals)
Bickmore et al. (2013)[49]	Step counts	12 months	132	Intervention: pedometer; interacted daily with embodied conversational agent software, which provided 5-minconversation consisting of motivational feedback, troubleshooting discussion (if any), and individualized exercise counseling
			131	Comparison: pedometer; recorded step counts daily
Wijsman et al. (2013)[35]	Physical activity level and metabolism	3 months	114	Intervention: accelerometer with access to DirectLife web-based physical activity program; received individualized motivational feedback, set daily goals based on current activity
			112	Comparison: no activity monitor; given no instructions about daily physical activity
Choi et al. (2015)[50]	Physical activity	12 weeks	15	Intervention: open accelerometer with access to activity data; received motivational messages or short videos from an application, set individualized weekly goals
			15	Comparison: open accelerometer with access to data; set goal to reach 8500 steps/day

(continued)

Table 1. continued

Reference	Outcome	Intervention duration	Group size	Intervention and comparison group characterization
Grewal et al. (2015)[28]	Postural stability and daily physical activity	4 weeks	18	Intervention: LegSys; did balance training exercises, visualized movement errors during exercises, received visual and auditory (positive sound) feedback
			16	Comparison: no intervention; no training program
Mansfield et al. (2015)[32]	Walking activity and gait performance	3–26 days	29	Intervention: accelerometer with access to data; physiotherapist and participant collaboratively assigned walking activity goals based on analyzed activity data
			28	Comparison: accelerometer with access to data; physiotherapist discussed daily walking goals based on participant's self-reported walking activity
Martin et al. (2015)[33]	Physical activity	Phase 1: 2 weeks	32	Unblinded, no text message: accelerometer with access to data through Fitbug application
			16	Blinded, with no text messages: accelerometer with no access to activity information
		Phase 2: 2 weeks	16	Unblinded, personalized messages: accelerometer; had access to data through Fitbug, received personalized texts from physician, set 10 000 steps/day goal, received motivational messages
			16	Unblinded, no text messages: accelerometer with access to data through Fitbug
			16	Blinded, no text message: accelerometer with no access to activity information
Oh et al. (2015)[51]	Weight loss	24 weeks	118	Intervention: pedometer with access to data; entered step counts into mobile application; received clinical decision support system algorithm-based feedback, received health education and nutrition consults over the phone based on activity levels and lifestyle
			210	Comparison: pedometer; kept body weight journals, recorded daily step counts on a log sheet, visited hospitals to meet physicians and get consultation about nutrition and exercise
Schwenk et al. (2016)[29]	Balance and gait performance	4 weeks	9	Intervention: LegSys; did balance training exercises, visualized movement errors during exercises, received visual and auditory (positive sound) feedback
			10	Comparison: no intervention; no formal exercise program
Ginis et al. (2016)[52]	Body balance and quality of life	6 weeks	20	Intervention: CuPiD system; used auditory feedback and freeze-of-gait training smartphone applications with 2 inertial measurement units, received positive verbal feedback on optimal gait performance, cued continuously during walking, received booklet of personalized instructions, recorded frequency and duration of training in diary
			18	Comparison: no application or device; received training and recommendations, recorded frequency and duration of training sessions

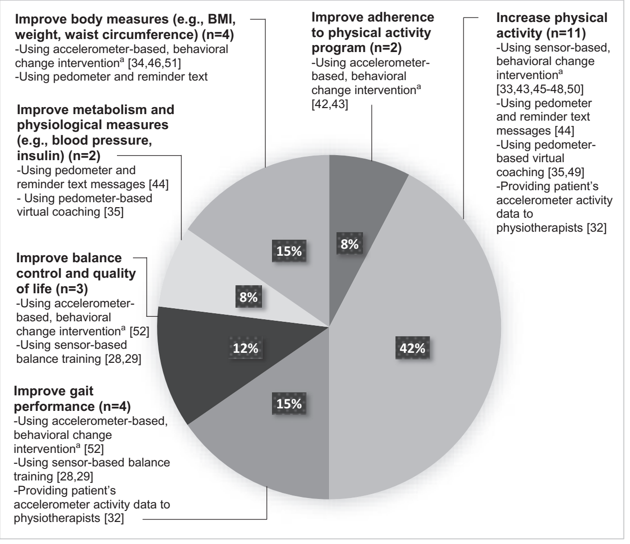

Figure 2. Objectives and studied interventions of the 17 reviewed trials. [a]For example, self-monitoring, motivational messages, goal setting, and exercise planning.

duration. Other studies converted data into graphical feedback on physical activity level[33,42,50,51] or audio feedback with individualized gait advice.[52] Kinematic data in 1 study were used for visual feedback on joint positions and angles.[28,29] Moreover, collected data from sensors were often used to set individualized activity goals.[32,43,45,48–50] In one study, sensor data were integrated with the health care center's server to generate individualized feedback based on a clinical decision support system algorithm.[51]

Effects of interventions on health-related outcomes

Tables 3 and 4 summarize the effects of reviewed interventions on physical activity (Table 3) and other intermediate and downstream health-related outcomes (Table 4). To test the hypothesis that PASD intervention effectiveness depends on the nature of the intervention, these tables organize interventions by the type of behavioral change techniques employed.

Physical activity

Merely providing objective feedback of step counts and activity level to participants for self-monitoring purposes did not effectively increase physical activity level and duration (Table 3).[33,42] Kovelis et al.[47] reported similar results when adding goal setting along with objective step counts for physically inactive smokers, concluding that the interventions were not sufficient to motivate physical activity.

Use of 3 or more behavioral change techniques in the integrative interventions was associated with more promising, though still mixed, evidence for improved physical activity levels. Six of 10 trials reported such improvements with a combination of PASD, motivational messages, exercise plans, and objective activity feedback[33,35,45,46,48,49]; 4 reported no effect.[32,44,49,50] In a study by Bickmore et al.[49] on the effect of a virtual coaching computer program with individualized exercise goals and motivational messages, the intervention was successful at 2 months for increasing daily step counts, but the effect did not last after 1 year. Martin et al.[33] also found no significant effect on activity level and duration when participants received only device feedback; however, there was a significant increase in step counts per day and duration of exercise after the group received motivational text messages, planned exercise goals, and activity-level feedback compared to an attention control

Table 2. Technological characteristics of reviewed studies

Technology	No. of studies	References
Portable activity sensing devices		
Pedometer	8	43–49,51
Accelerometer	6	32–35,42,50
Inertial measurement unit	3	28,29,52
Behavioral informatics software		
No software	6	32,43–48
Desktop application	3	28,29,42
Web-based application	4	33–35,50
Smartphone application	4	33,50–52
Tablet application	1	49
Real-time physical activity feedback	5	33–35,50,51
Interactive virtual coaching	1	49
Audiovisual training program	3	28,29,52
Sensor data retrieval and storage		
Manually entered into diary	5	43–47
Manually entered into software	2	50,51
Manually downloaded from sensor to software	5	32,34,35,42,48,49
Real-time transfer from sensor to software	5	28,29,33,52
Sensor data processing and display		
To measure physical activity level, eg, step counts, energy expenditure, and activity duration	15	32–35,42–52
To provide graphical feedback on physical activity	4	33,42,50,51
To provide audio feedback on gait performance and individualized gait advice	1	52
To provide visual feedback on joint position	2	28,29
To set individualized activity goals	6	32,43,45,48–50
Used EHR-integrated CDSS algorithm for individualized feedback	1	51

EHR = electronic health record; CDSS = clinical decision support system.

Intervention Type	Behavioral Change Techniques	IT	no IT
PASD with Passive Self-Monitoring	SM	[28,29,34,52]	[33,42]
PASD with Goal-Based Self-Monitoring	SM GS	none	[47]
PASD with Integrative Intervention (i.e., three or more behavioral change techniques)	SM GS MM CO ED PL IN	[33-35,49-51]	[32,43-46,48]

SM = self-monitoring; GS = goal setting; MM = motivational messages; CO = coaching or training program; ED = education; PL = planning program; IN = financial incentives. *Studies may be listed multiple times when they had multiple intervention arms.

Figure 3. Categorization of reviewed interventions using portable activity sensing devices (PASDs), based on their use of behavioral change techniques and information technology (IT) software.

group using a device with no access to device data. In contrast, Newton et al.[44] reported that weekly text messages to participants reminding them to wear the pedometer and stay active did not improve either activity level or amount of exercise. McMurdo et al.[45] found an increase in physical activity at 6 months among sedentary elderly women by providing individualized activity plans and motivational messages but no accelerometer.

Three studies reported that interventions with 3 or more behavioral change techniques increased the duration of physical activity[33,35,43]; 3 others reported no effect.[32,44,45] For example, Butler et al.[43] showed a long-term effect of integrative interventions among adult patients participating in cardiac rehabilitation programs, whereas McMurdo et al.[45] reported no effect in sedentary elderly women after 6 months. In the 1 study assessing reported exercise tolerance in metabolic equivalents, the intervention was not effective.[43]

Body measures

Three trials concluded that an intervention using PASDs does not affect body mass index,[34,43,44] while 2 studies reported body mass index improvements in postpartum women[46] and obese adults (Table 4).[51]

Studies reported mixed outcomes of PASDs incorporating motivational messages, goal setting, and objective activity feedback on hip circumference. Maturi et al.[46] found the intervention effective among postpartum women, and Wijsman et al.[35] reported positive results in sedentary older adults. Two studies showed no effect on waist circumference.[34,43]

Physiological measures

Few studies evaluated the impact of PASD interventions on physiological measures, and results were mixed (Table 4). Shuger et al.[34] reported no reduction in body fat percentage after providing objective activity feedback alongside motivational messages and exercise planning to sedentary obese adults, but Wijsman et al.[35] reported a positive change among sedentary older adults. Wijsman et al.[35] also found improvement in HbA1c, while Newton et al.[44] observed no change in HbA1c among type 1 diabetes patients. One study also found that a computerized intervention with motivational messages, when combined with self-monitoring and individualized goal setting, improved fasting serum insulin levels but had no effect on fasting serum glucose levels.[35] Other trials reported no effect on blood pressure,[35,44,51] serum lipid profile,[35,51] or Framingham 10-year risk of heart attack.[35]

Weight loss

Four reports showed that use of PASDs could help patients lose weight (Table 4).[34,35,46,51] The integrative interventions of PASD

Table 3. Reported effectiveness of portable activity sensing devices (PASDs) on physical activity, organized by category of employed behavioral change techniques

Outcomes and Behavioral Interventions	PASD with Passive Self-Monitoring		PASD with Goal-Based Self-Monitoring		PASD with Integrative Intervention	
	Improved	No change	Improved	No change	Improved	No change
Physical activity level						
Self-monitoring		42				
Self-monitoring, goal setting				47		
Self-monitoring, motivational messages, goal setting						
a. Under 6 months					46	32,44
b. 6 months or more					45,48	
Self-monitoring via computer software		33				
Computerized goal setting, motivational message, self-monitoring						
a. Under 6 months					33,35,49	50
b. 6 months or more						49
Computerized balance training program, self-monitoring		28				
Physical activity duration						
Self-monitoring		42				
Self-monitoring, motivational messages, goal setting						
a. Under 6 months					43	32,44
b. 6 months or more					43	45
Self-monitoring via computer software		33				
Computerized goal setting, motivational message, self-monitoring					33,35	
Number of physical activity sessions						
Self-monitoring, motivational messages, goal setting						
a. Under 6 months					43	
b. 6 months or more					43	
Metabolic equivalents						
Self-monitoring, motivational messages, goal setting						43

Effectiveness refers to statistically significant differences between intervention and comparison groups.

Table 4. Reported effectiveness of portable activity sensing devices (PASDs) on outcomes besides physical activity, organized by category of employed behavioral change techniques

Outcomes and Behavioral Interventions	PASD with Passive Self-Monitoring		PASD with Goal-Based Self-Monitoring		PASD with Integrative Intervention	
	Improved	No change	Improved	No change	Improved	No change
Body mass index						
Self-monitoring, motivational messages, goal setting					46	43,44
Self-monitoring via computer software		34				
Computerized goal setting, motivational message, self-monitoring					51	34
Hip circumference						
Self-monitoring, motivational messages, goal setting					46	
Computerized goal setting, motivational message, self-monitoring						35
Waist circumference						
Self-monitoring, motivational messages, goal setting					46	43
Self-monitoring via computer software		34				
Computerized goal setting, motivational message, self-monitoring						
a. Under 6 months					35	
b. 6 months or more						34
Body fat percentage						
Computerized goal setting, motivational message, self-monitoring					35	34
Systolic and diastolic blood pressure						
Self-monitoring, motivational messages, goal setting						44
Computerized goal setting, motivational message, self-monitoring						35,51
HbA1c						
Self-monitoring, motivational messages, goal setting						44
Computerized goal setting, motivational message, self-monitoring					35	
Serum lipid profile						
Computerized goal setting, motivational message, self-monitoring						35,51
Framingham 10-year risk						
Computerized goal setting, motivational message, self-monitoring						35
Fasting insulin level						
Computerized goal setting, motivational message, self-monitoring					35	
Fasting glucose serum level						
Computerized goal setting, motivational message, self-monitoring						35
Weight loss						
Self-monitoring, motivational messages, goal setting					46	
Self-monitoring via computer software		34				
Computerized goal setting, motivational message, self-monitoring						
a. Under 6 months					35	34
b. 6 months or more					34,51	
Insulin total daily dose reduction						
Self-monitoring, motivational messages, goal setting						44
Balance control, postural stability, and gait performance						
Computerized balance training program, self-monitoring	28,29,52					
Quality of life						
Self-monitoring, motivational messages, goal setting						44,45
Computerized balance training program, self-monitoring	28	29,52				
Smoking behavior						
Self-monitoring, goal setting				47		
Computerized goal setting, motivational message, self-monitoring						51
Lung function						
Self-monitoring, goal setting				47		
Lower extremities function						
Self-monitoring, motivational messages, goal setting						45

Effectiveness refers to statistically significant differences between intervention and comparison groups.

with self-monitoring, motivational messages, and goal setting were successful even without providing software.[46] Wijsman et al.[35] and Oh et al.[51] studied the impact of computerized self-monitoring programs with individualized exercise planning and motivational feedback on weight in sedentary elders and obese adults with metabolic syndrome. Participants in the intervention groups lost, on average, 1.5 kg of weight after 3 months[35] and 2.2 kg after 6 months,[51] significantly more than control group participants. Maturi et al.[46] conducted similar interventions, but without IT software, with postpartum women and found a significant mean weight decrease of 2.1 kg after 3 months. Shuger et al.[34] studied 2 types of interventions in the short and long term with physically inactive obese adults. They reported that providing activity-level feedback alone did not result in weight loss; however, adding computerized real-time self-monitoring along with group-based education resulted in an average 9-month weight decrease of 6.59 kg.

Balance control, postural stability, and gait performance

All 3 studies investigating the effect of IMUs on balance control reported positive change (Table 4).[28,29,52] Grewal et al.[28] and Schwenk et al.[29] examined the same computerized system on patients with diabetic peripheral neuropathy and CIPN. By teaching patients better motor and posture control, the intervention resulted in significant reduction of hip, ankle, and center-of-mass sway in both groups. In another study by Ginis et al.,[52] 2 smartphone applications provided real-time feedback on gait abnormalities and freezing-of-gait occurrence alerts to patients with Parkinson's disease. They concluded that the intervention improved balance and gait performance compared to conventional gait training for people with Parkinson's disease.

Quality of life

No improvement in quality of life was observed in 2 trials investigating the effect of pedometers and accelerometers within a behavioral intervention.[44,45] Grewal et al.[28] found that their computerized balance training program and IMU measuring device might improve quality of life in diabetic peripheral neuropathy patients, but not in CIPN patients.[29] Ginis et al.[52] reported no effect of a gait-alerting smartphone-based application on quality of life among patients with Parkinson's disease (Table 4).

Other outcomes

Only 1 study evaluated the effect of interventions on total daily insulin dose and found no significant impact.[44] No improvement in smoking behavior was reported by 2 studies.[47,51] Another study evaluating the effect of self-monitoring plus goal-setting on lung function concluded that there was no improvement among smokers.[47] McMurdo et al.[45] found no improvement in lower extremity function among sedentary older women (Table 4).

Risk of bias in included studies

We evaluated study quality by assessing the risk of bias in the 17 included studies (Figures 4 and 5). *Randomization* was adequate in 14 studies (82%),[28,29,32–35,42,43,45–48,50,51] but the randomization method was unclear in 3 others. *Allocation* was concealed in 10 studies (59%),[28,29,32,33,45–48,50,52] but other studies did not provide enough information to assess allocation concealment. Most studies were not successful in *blinding* participants and research personnel to the allocated interventions.[28,29,32,34,35,42–51] Only 1 study[33] clearly stated that participants and research personnel were blinded; blinding was unclear in another.[52] Blinding the assessors of outcomes was achieved in 7 studies (41%).[29,32–35,42,49] Seven trials (41%)[44–48,50–52] explicitly stated that they did not blind research personnel, and 2 (12%) did not clearly report this.[28,43] The *completeness of outcome data* was adequate in 16 trials (94%), whereas 1 study could not sufficiently collect outcomes due to participant nonadherence.[47] With respect to *selective reporting*, we identified 5 trials (29%) with available study protocols reporting all preselected outcomes[32–34,45,48]; however, not enough information was available to judge selective reporting bias in other studies. In assessing other potential sources of bias, we identified 15 trials (88%) at risk of bias due to small sample size and lack of generalizability.[28,29,32–34,42–44,47–50,52] Some of the trials were also at high risk of selection bias due to self-selected participants[42,43] or imbalanced education level between intervention and control groups.[51] One study had adequate statistical power and was deemed to be free of other bias.[45]

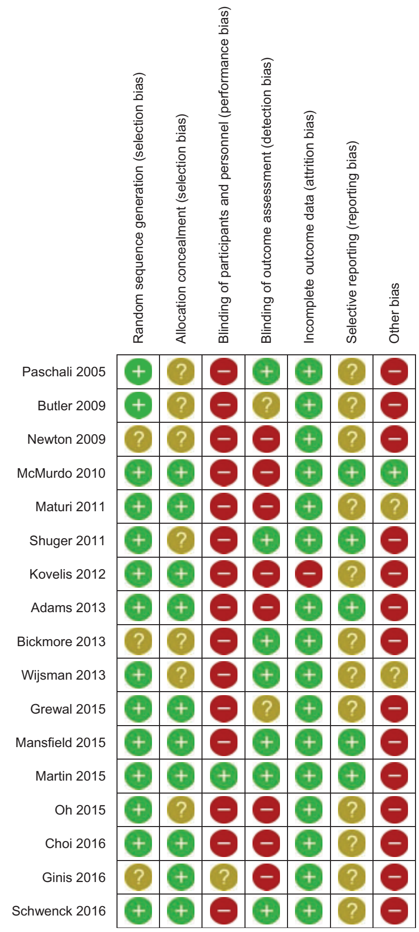

Figure 4. Summary of authors' consensus judgment about of risk of bias for each included study, by various sources of potential bias.

DISCUSSION

Findings on the health-related impact of PASDs are highly diverse, but the majority of research supports a benefit from combining sensors with an integrative set of behavioral change techniques. In contrast to more passive interventions, where the burden is on participants to meaningfully use device data, integrative interventions support the active use of data through training or coaching, motivational feedback, and other behavioral change techniques alongside self-monitoring and goal setting.

The importance of behavioral change techniques

One implication of these findings is that passive interventions – ones where people receive a PASD with minimal further assistance, reinforcement, or additional behavioral change techniques – may not be effective. In other words, the device alone may be insufficient to effect a change in health. This echoes a general concern about the use of health IT as a stand-alone intervention and implies that there is a need to better explicate the role of health IT in behavioral theory.[53,54]

In contrast, when paired with an appropriate array of behavioral change techniques, PASDs can produce benefits, particularly for in-

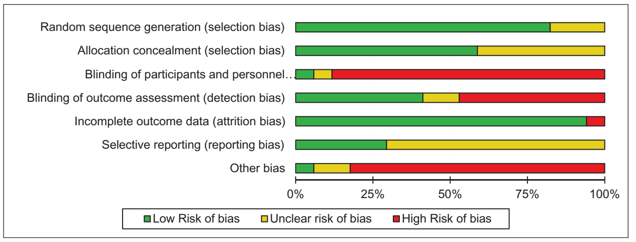

Figure 5. Risk of bias graph based on authors' judgment about risk of bias items, presented as percentages across all included studies.

termediate outcomes such as physical activity or weight loss. Even so, it is unclear whether the PASD itself contributes to these outcomes beyond the behavioral change techniques. A recent study in which participants receiving an integrative weight-loss intervention were randomized to receive a PASD or continue the intervention with no PASD found no long-term differences between the 2 groups.[55] However, further research is needed to test the hypothesis that PASDs provide independent value or interact with behavioral change techniques to amplify their effectiveness. Leveraging interactive and adaptive mobile applications, in particular, might be an appropriate way to investigate the effect of health behavior interventions.[56]

The role of behavioral informatics

In the reviewed studies, IT software often provided a convenient and efficient way of delivering interventions with techniques such as feedback and motivational messaging. Such behavioral informatics interventions were often, though not always, effective at increasing physical activity levels, activity duration, and weight loss. Given the small number of trials and the heterogeneity of software used, it is premature to make any conclusions about the value of IT software in addition to PASD hardware. Other studies report favorable but mixed findings in the literature concerning the effects of behavioral IT interventions, including mobile technology and text-messaging, on health outcomes.[57] While several studies have reported improved HbA1c in patients with type 2 diabetes,[58] adherence to blood glucose measurement and glycemic control in type 1 diabetic adults,[59,60] smoking cessation behavior,[61,62] nutrition education and healthy diet,[62,63] and psychological outcomes,[62] other studies did not report benefits of such interventions for physical activity,[62,64] weight loss,[62] and dietary behavior.[65] This could be the result of the health IT design approaches employed by those studies, with successful health IT being more likely to follow user-centered design principles and therefore yielding higher usability, user satisfaction, acceptability, and performance.[66] For example, systems produced through user-centered design have been effective at improving quality of life in HIV patients[67] and self-management behaviors among lung transplant recipients.[68] Further research should investigate specific software characteristics as well as software design approaches, eg, user-centered design,[66,69,70] that promote effectiveness of PASD interventions.

Health-related outcomes

Notably, few PASD intervention studies assessed downstream clinical outcomes such as organ function and quality of life, and none found an effect of PASD interventions. This generally conforms with the strength of evidence for intermediate as opposed to endpoint effectiveness in the overall literature on consumer-facing health IT.[71,72] More research is needed to assess downstream outcomes and specific PASD intervention approaches most likely to improve clinical outcomes, such as hospitalizations, disease onset, and health-related quality of life.

Quality of reviewed randomized controlled trials

Most examined trials did not follow CONSORT guidelines,[73] the globally accepted standard for efficiently and accurately reporting randomized controlled trial results. Although most reviewed trials reported randomization and measured outcomes, reporting quality for other categories was not acceptable. Participant demographics were poorly reported; only 24% of trials reported age distribution,[28,29,32,42] 1 study did not specify gender distribution,[52] and race/ethnicity information was minimal in 24% of trials.[33,48–50] Poor reporting of key methodological elements may not directly indicate the quality of the trials but limits the ability to assess the validity and generalizability of findings.[73–75] We therefore urge researchers to adopt CONSORT guidelines in reporting randomized controlled trials of PASD effectiveness.[76–78]

Limitations

It is possible that eligible trials were inadvertently excluded from the review. The literature lacks accepted terminology for PASDs and PASD research. PASDs are also referred to as wearable devices, activity monitors, activity sensors, portable devices, wireless activity sensors, and wearable motion detectors. To mitigate the risk of excluding eligible trials, our search queries used these and other search terms, including the names of common PASDs (eg, Actigraph, Fitbit). We recommend using the term "PASD," which refers to the device's primary function (activity sensing) and includes portable devices that are not wearable (eg, phones or devices carried in a pocket or purse). Further, only 1 reviewer screened the publications, increasing the risk of selection bias. However, a second reviewer monitored the process for accuracy to mitigate this risk. Classifying interventions by the nature of behavioral change techniques and IT software integration (Figure 3) is novel to this review and may not accurately represent the taxonomy of PASD interventions. However, there was no other existing taxonomy, and ours was consistent with the intervention groups used in individual studies, which differed by the number of behavioral change techniques and use of software.[28,29,32–35,42–52] Lastly, the outcomes of reviewed studies were too heterogeneous to perform quantitative meta-analysis of the effectiveness of PASD interventions.

Future work

Future research should assess the impact of specific PASD characteristics – including hardware, software, and data transfer and processing elements – on outcomes. Study designs should permit disambiguation of the effect of the PASD itself vs other elements of the intervention, including behavioral change techniques. Studies can also test the hypothesis that integration of PASD with behavioral change techniques is more effective than use of the PASD or behavioral change techniques alone. An important future direction is the study of longitudinal effects, especially given evidence of a lack of lasting effects of PASD interventions.[49] This will also permit assessment of downstream outcomes such as disease onset or resolution.

CONCLUSION

There is insufficient volume or quality of evidence to conclude that PASD interventions are generally beneficial for health. However, PASD interventions might be effective in improving intermediate outcomes when coupled with multiple behavioral change techniques. Devices alone or with minimal behavioral change support appear to be insufficient to change health-related outcomes.

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COMPETING INTERESTS

Authors have no competing interests to declare.

CONTRIBUTORS

HA and RJH contributed to conceptualization, design, analysis, and writing the manuscript. HA performed study selection, data extraction, and quality assessment, monitored by RJH for completeness and accuracy.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

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