

# **The impact of accelerometer and pedometer-use on physical activity and glycaemic control in people with Type 2 diabetes: a systematic review and meta-analysis**

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Impact Statement:

The increasing popularity of physical activity monitors and the associated motivational effects on the wearer in the general population suggests a possible role within Type 2 diabetes management. This systematic review shows that activity monitor-use increases free-living physical activity in people with Type 2 diabetes, and suggests that accelerometers have a similar effect to pedometers despite functional differences. Together both can initiate activity behaviour in sedentary users, on which to build additional interventions. Available trials however do not provide evidence that activity monitors alone produce significant improvement in clinical outcomes.

## **ABSTRACT**

### **Background**

Pedometer-use, without support, increases physical activity levels in the general population. However, evidence of benefit for Type 2 diabetes is unclear and not systematically reviewed for accelerometers.

### **Objectives**

To examine the impact of using physical activity monitoring devices (pedometers and accelerometers) on free-living physical activity and HbA<sub>1c</sub> in people with Type 2 diabetes.

### **Methods**

We conducted a systematic literature review. Bibliographic databases included Medline, Embase, Web of Science, CINAHL, SportDiscus, and Cochrane Central Register of Controlled Trials. We included controlled trials evaluating interventions based on the use of pedometers or accelerometers to promote physical activity in people with Type 2 diabetes. Primary outcomes were physical activity (mins/week or steps) and HbA<sub>1c</sub> (mmol/mol (%)). Secondary outcomes were weight, blood pressure and lipid profile.

### **Results**

Twelve trials (1,458 participants) were identified. Nine trials studied pedometers and three accelerometers. Random-effects meta-analysis showed an overall increase in physical activity (standardized mean difference; 0.57; 95% CI 0.24, 0.91) in the intervention groups. Accelerometers and pedometers produced a similar effect size. No significant differences were observed in HbA<sub>1c</sub>, BMI, blood pressure, and lipid profile.

### **Conclusions**

People with Type 2 diabetes, provided with an accelerometer or pedometer, substantially increase free-living physical activity. There is no evidence that monitor-use alone improves HbA<sub>1c</sub> or other clinical outcomes. Further trials are needed to compare the relative effects of activity monitors within differing complex interventions.

## INTRODUCTION

One of the main factors underlying Type 2 diabetes is an imbalance between energy expenditure and intake. Physical activity increases energy expenditure, improving glycaemic control and therefore reducing the risk of diabetes-related complications [1]. Physical activity also exerts an indirect health benefit through influencing weight loss and blood pressure [2]. However the majority of people with Type 2 diabetes are either not physically active, or are less active than people without diabetes [3, 4].

Free-living physical activity, defined as “non-formal and self-directed PA”, offers advantages over structured exercise in terms of convenience and acceptability [5]. Evidence suggests that this type of physical activity can reduce mortality and morbidity both in sedentary people [6,7,8] and in people with Type 2 diabetes [7, 9, 10]. However increased free-living physical activity is usually achieved through complex and resource-intensive interventions, which are usually not feasible in routine clinical care [11].

The increasing commercial success of physical activity monitoring devices (pedometers and accelerometers) indicates a public acceptability and enthusiasm for self-monitoring, within the general population. Pedometers are tilt devices that simply display step-count. Accelerometers, a more recent technology, utilise time-based movement sensors, logging the time and intensity of activity and periods of inactivity. 'Steps', being a popular metric for users, are estimated via algorithms, and often displayed on accelerometers. For the purposes of this study we will consider pedometers as those devices that can only log step count, and accelerometers as those which can log time and intensity of activity.

Available evidence suggests that the routine use of activity monitors can motivate modest but significant increases in physical activity within the general population [12] and within obesity research [13] and have beneficial effects on body weight [14]. A number of reviews have also reported a positive impact of activity monitors on people with Type 2 diabetes [15-19]. The additional information displayed on accelerometers such as exercise intensity or estimated expended calories, may enhance the effect of some behaviour change techniques (such as goal setting or feedback on performance), increasing motivation and therefore physical activity [20-22].

However, no systematic review has specifically examined the effects of accelerometer-use alone, or contrasted the impact of pedometers and accelerometers on physical activity behaviour within Type 2 diabetes.

Our primary aim was to systematically review the impact of accelerometer and pedometer-use on free-living physical activity and HbA<sub>1c</sub> in people with Type 2 diabetes. Secondary objectives were to investigate the effects on blood pressure, lipid profile and body weight.

## **METHODS**

This review was conducted according to a protocol (PROSPERO CRD42015025980) and is reported in line with PRISMA guidelines [23].

### **Data Sources and searches**

We conducted electronic searches in Medline, EMBASE, Science Citation Index & Conference proceedings Citation Index (ISI Web of Knowledge), Cumulative Index of Nursing and Allied Health (CINAHL), SportDiscus, and The Cochrane Central Register of Controlled Trials (CENTRAL) using pre-defined search strategies (Online Appendix 1) designed by an experienced information specialist (NR). Searches extended from 1945 to Aug 2016 and included all studies published in English and abstracts translated into English. Manual searching of relevant references using the snowballing technique (starting from the selected studies) was performed by one of the authors (RB). Search results were stored and managed using the reference manager software EndNote 7.0.

### **Study Selection**

Eligible studies included randomized controlled trials (RCTs), cluster RCTs, non-randomized controlled studies and crossover studies. The studies had to evaluate interventions based on the use of accelerometer or pedometer to increase free-living physical activity. Physical activity was considered to be “free living” if specifically stated or adequately described in the methods as being non-formal and self-directed (5). We included studies in adults (18 years and older) with Type 2 diabetes. Composite interventions with diet, or other strategies, outside of routine care were included, provided the role of the activity monitor within the intervention was clearly reported and a similar comparator group, without the monitor, was present. Studies of compound devices utilising both pedometer and accelerometer technology, were included and counted as accelerometers due to the appearance of data displayed to the participant. We excluded interventions based on monitoring technologies in smartphone apps, because they frequently include additional features (e.g., sending reminders, motivational messages, or sharing monitoring data on social media) with potential to induce behaviour change through other mechanisms not strictly related to physical activity monitoring (e.g., provision of general encouragement, instructions, contingent rewards, or information about others’ approval). For comparator groups, we included usual and enhanced usual-care strategies and behavioural interventions minus the activity monitor, allowing the effect of the monitor to be differentiated.

Titles and abstracts of relevant citations retrieved by the search were screened for eligibility. Full texts were obtained and read for those meeting the selection criteria. Studies meeting the criteria, according to two independent reviewers (RB, IRC), were selected for inclusion. Any disagreements were solved by consensus with a third reviewer (AF).

### **Data extraction and quality assessment**

We used structured forms to extract data on study design, intervention duration, sociodemographic characteristics of the participants, sample size, setting, device type, and trial outcomes (physical activity; HbA<sub>1c</sub>; lipid profile; blood pressure and body weight).

Risk of bias was independently appraised by two reviewers (RB and IRC) using the Cochrane Collaboration's tool [24]. We quantified reviewer agreement on trial 'risk of bias' using Cohen's  $\kappa$  coefficient [25]. Disagreements were solved by consensus with a third reviewer (AF). The methodological quality of each article was classified according to six aspects: selection bias, study design, confounders, blinding, data collection and withdrawals and dropouts.

### **Data synthesis and analysis**

Results were summarized quantitatively and qualitatively. Trials were qualitatively summarized in terms of brief descriptions of the intervention and outcomes. We extracted the mean and standard deviation (SD) of the reported measures for free-living physical activity, HbA<sub>1c</sub> levels (mmol/mol)(%) and blood pressure (mmHg).

Data for each outcome was pooled using random-effects models (chosen at protocol stage due to heterogeneity between the different interventions). Overall differences between intervention and control groups were calculated using standardized (SMD) or weighted mean differences (WMD), as appropriate, with 95% confidence intervals (95%CI). Heterogeneity was quantified by the  $I^2$  statistic, where  $I^2 > 50\%$  was considered evidence of substantial heterogeneity [24]. Heterogeneity, where identified, was explored, through sub-group analysis by: type of monitoring device, duration of diabetes and intervention duration. Sensitivity analyses were performed to test the effect on outcomes of monitor intervention, alone or nested and full or partial randomization. For each meta-analysis, funnel plots and Egger's test were used to examine potential publication bias.

All meta-analyses were conducted using STATA V12.0. We set a threshold of  $P=0.05$  to accept statistical significance.

## RESULTS

The search process is summarized in the PRISMA flow diagram (Figure 1). By screening of title and abstracts, 4352 initial citations were reduced to 146 for further review by full text. After inter-reviewer consensus 19 studies were excluded and 12 studies were selected for the review [26-37].

[Figure 1 here]

### Features of the trials

The main characteristics of the twelve trials identified are summarized in Table 1. Individual trial characteristics and outcomes are summarized in Online Appendix 2. The trials included a total of 1,458 participants. Eight trials were set in differing countries, covering three continents. Interventions were delivered in a narrow range of settings; either primary care (four studies) or combined hospital diabetes out-patient clinics and primary care (eight studies). Four trials were conducted in urban settings, one rural and two mixed (not specified in five studies). Ten trials examined the impact of the intervention on physical activity, and nine on HbA<sub>1c</sub>.

[Table 1 here]

### Participants

Participants were diverse in terms of age (ranging from 35 to 89 years). The average HbA<sub>1c</sub> levels across trials ranged from 48 to 63mmol/mol (6.5% -7.9%). The mean duration of diabetes for each study ranged from 0.5-6 years (four studies), to 7-11 years (three studies) and was not specified in five studies. Due to similar eligibility criteria, participants from all studies were physically mobile, with no diabetic, renal, cardiovascular or neurological complications. In ten trials participants displayed high average levels of sedentary behaviour and obesity. Three trials excluded patients on insulin therapy [27, 35, 36]. One trial specifically targeted recently diagnosed Type 2 diabetes [27]. One trial specifically examined patients with Type 2 diabetes and co-morbid depression [33].

### Interventions

Interventions were diverse in design and duration. Mean intervention including follow-up time was eight months, ranging from five weeks [26] to 18 months [34]. Nine and three studies were of pedometers [27-31, 34-37] and accelerometers [26, 32, 33] respectively. Five studies [26, 27, 29, 31, 32] comprised activity monitors alone, with minimal additional intervention (usually a motivational manual). In the remaining studies the activity monitor was nested within a complex intervention, where the effect of the behavioural component was minimised by a matched comparator. There was a diverse range of behavioural interventions based on the degree and type of supervision. Studies

comprising supervised interventions were group-based [29, 31, 36] with the remainder one-to-one; either in-person (seven studies) or telephone-based [33, 34]. Six studies encouraged setting self-derived activity targets, four were set and supervised by staff and two studies set no specific goal [29, 35]. All but one “routine care” controls were, in practice, enhanced care, usually involving provision of additional clinic visits and educational materials. Control group physical activity measurement methods varied from blinded devices to self-report questionnaires (Online Appendix 2).

Intervention providers were research staff in seven studies, routine healthcare professionals in four studies and both in one study. Information on the fidelity of intervention delivery was reported in two studies, employing scripted counselling to ensure consistency in one study [36] and staff review meetings and participant rotation in the other [33].

### **Risk of bias**

Inter-rater agreement was high for assessing risks of bias ( $k = 0.68$ ). The risks in each domain for individual studies are described in Figure 2.

Potential sources of bias were: lack of blinding of participants, staff and of outcome assessment, incomplete outcome data, and underpowered sample sizes. Other sources of bias involved intervention implementation, recruitment methods and eligibility criteria.

Nine studies reported numbers of participant withdrawals for each group. Mean study completion rates were 87.8 %, where stated, ranging from 97.7% [27] to 60.0% [29]. There was little data on differences in characteristics between completing and non-completing participants. Observed baseline  $VO_2$  fitness and pre-study activity levels were lower in non-completers than completers in two other studies ([34] and [28], respectively). One study noted a male predominance in non-completers [29]. One study observed greater satisfaction levels with pre-study activity levels in the non-completers [33]. In the remaining studies no significant differences were reported between completers and non-completers. Within completers, no studies described the differences in characteristics between full and partial adherence participants. Data on intervention adherence was reported in six studies, with adherence levels ranging from 50% to 90%.

[Figure 2 here]

### **Impact of the interventions on free-living physical activity**

Data from ten trials reporting the impact of the interventions on free-living physical activity were pooled in a random-effects meta-analysis (Figure 3). The pooled SMD between intervention ( $n=691$ ) and control ( $n = 681$ ) groups was 0.57 (95%CI 0.24, 0.91) with considerable inter-study heterogeneity ( $I^2 = 84.0\%$ ).

[Figure 3 here]

Sub-group analysis by monitor type suggested an absence of significant differences between accelerometers (0.56 95%CI 0.27; 0.85) and pedometers (0.54 95%CI 0.10; 0.98). Sub-grouping by duration of diabetes, suggested a possible increased effect in diabetes diagnosed within five years; 0.82 (95%CI 0.11; 1.54) vs 0.58 (95%CI -0.12; 1.28) (Online Appendix 3). There were no differences between studies grouped by length of intervention of less than 12 months; 0.51 (95%CI 0.11; 1.13) vs 12 months or more; 0.68 (95%CI 0.30; 1.07) (Online Appendix 4). Egger's test found no evidence of publication bias ( $p=0.27$ ) (Online Appendix 5)

### **Impact of the interventions on HbA<sub>1c</sub>**

Data from nine trials reporting the impact of the intervention on HbA<sub>1c</sub> were pooled in a random effect meta-analysis (Figure 4). The pooled weighted mean difference of activity monitor use ( $n=552$ ) above control ( $n=542$ ), was -0.10 mmol/mol (95% CI -0.13, -0.06). No heterogeneity was identified ( $I^2=0\%$ ). Sub-grouping by monitor type did not affect this result. Egger's test found no evidence of publication bias ( $p=0.37$ ) (Online Appendix 6).

[Figure 4 here]

### **Impact on the interventions on secondary outcomes**

The impact of the intervention on secondary outcomes is reported in Online Appendix 7a-c. There was no effect on systolic blood pressure across seven studies ( $n=534$ ); -0.05mmHg (95% CI -2.1; 2.0) ( $I^2=0\%$ ). Similarly, there was no effect on the standardised mean difference of pooled weight and BMI data in seven studies ( $n=182$ ); +0.10 (95% CI -0.2; 0.3) ( $I^2=26\%$ ), and of total cholesterol or LDL cholesterol (five studies,  $n=142$ ) -0.06 (95%CI; -0.3; 0.2), ( $I^2=0\%$ ). Qualitative data was recorded in five of the studies.

### **Sensitivity analyses**

Testing of the effects of monitor alone or nested within a complex intervention, on the primary outcome effect estimates, did not substantially alter our main results. Effects of quasi-randomisation were also non-significant, demonstrating that the assumptions within the inclusion criteria were approximately correct (Online Appendix 8). All studies were funded through academic sources.



## DISCUSSION

In this systematic review we identified twelve trials evaluating the impact of interventions based on the use of physical activity monitor devices (pedometers or accelerometers) in people with Type 2 diabetes. We observed that the use of these devices produced an SMD relative increase in free-living physical activity by 0.57, or approximately one hour per week. There were no significant differences between accelerometers and pedometers. No significant effects were observed on HbA<sub>1c</sub>, BMI, blood pressure, and lipid profile.

### Strengths and limitations of the review

This systematic review used robust methods for study identification, data extraction, and analysis, based on data from controlled trials and including a large sample size ( $n=1458$ ), with no evidence of significant publication bias. By including recent trials in this field this review provides new evidence supporting the use of monitoring devices to promote free-living physical activity in people with Type 2 diabetes, and was the first to examine accelerometers, distinct from activity monitors overall. This may provide an important first step to towards increasing the volume or intensity of PA necessary to improve long-term health outcomes.

Our results may be affected by the inherent difficulties of blinding staff or participants in this type of study. In addition the diversity of co-interventions, staff supervision and comparator groups, led to heterogeneity in the pooled estimate of physical activity level ( $I^2=84\%$ ), which was partially mitigated by our sub-group analyses. However, there were insufficient numbers of studies of similar co-interventions, such as diaries or counselling, to allow pooling and meta-analysis. Further research is warranted specifically on components of interventions that might boost monitor effectiveness. The inclusion of control groups receiving “enhanced usual-care” may have resulted in an underestimation of the impact of the interventions for real world application. However, this served to unify diverse diabetic management-types, and also acted as a partial blinding procedure by making both experimental and control groups appear similar to participants. All study participants were physically mobile, without diabetic complications and averaged HbA<sub>1c</sub> of 60 mmol/mol (7.6%). Whilst this improved trial combinability, the applicability of the review’s results to higher ranges of HbA<sub>1c</sub> is reduced.

### Comparison with previous reviews

Previous reviews have evaluated the effect of activity monitor-use in Type 2 diabetes, by examining pedometers alone or by non-specified pooling of both monitor types. Our review confirms the positive findings from two previous reviews, with lower number of trials and participants, which reported significant increases of 1,822 steps per day (equivalent to around 115 min/week) [18] and of 2,042

steps per day (130 min/week)[19]. The effect-size observed in our review is lower but still clinically relevant when considering the high sedentary levels in people with Type 2 diabetes [20].

No previous review has directly compared accelerometers and pedometers. Our review indicates no significant difference in physical activity between device types, possibly surprising given their functional differences. Non-significant increases, observed in shorter duration type 2 diabetes and longer duration trials, warrant future research.

The lack of impact on HbA<sub>1c</sub> observed in our review generally concurs with previous reviews which reported either no effect [17, 18] or a small effect (3mmol/mol) (-0.23%) [19] in glycemic control. In terms of other clinical outcomes, this review generally concurs with previous reviews which found no effect in blood pressure [15], and a small, not clinically relevant effect, on body weight [16, 19]. Although physical activity is known to improve these clinical outcomes, the effect-size from monitor-use may be insufficient to stimulate change within the trial duration. This lack of impact could also be partially explained by the fact that our meta-analyses were largely dominated by interventions based on pedometer use. Whereas pedometers may be successful in promoting walking, they are not intended to promote other more intense forms of physical activity, which are known to be more effective in improving clinical outcomes [21].

### **Limitations of available evidence and future research needs**

Most of the trials identified in our review included participants with well-controlled baseline HbA<sub>1c</sub> levels and reported mid-trial medication changes. This important limitation of current evidence could partially explain the lack of observed impact on HbA<sub>1c</sub> and indicates research needed at higher levels of HbA<sub>1c</sub>, given that such people are averagely more sedentary and may respond differently, for a given level of physical activity [38]. Less than half of the trials studied participants for more than six months, despite the interest in whether initial improvements with monitors are sustained in the long term. This may have contributed to the lack of observed impact on clinical outcomes,

Post-trial qualitative follow up and network type studies would allow data capture on social spreads of monitor buying and long term behaviour change, particularly with the increasing popularity of consumer devices. Indeed many of the included studies would be difficult to repeat with current levels of monitor prevalence.

Future research should examine the extent to which simple interventions based on the use of activity monitors and automatic feedback systems can achieve similar gains to those observed from resource-intensive behavioural programs. Further studies are also needed to identify potential co-interventions that may be added to monitor use to synergize impact.

Nested qualitative studies may prove a valuable resource to better understand the psychological factors potentially leading to the observed increased behaviour change in monitor-based interventions and the influence on other aspects of diabetes self-management such as diet and medication adherence.

Evidence on the modulating effects of age, gender and ethnicity on engagement and effect-size is currently required.

Many of the reviewed activity monitors had limitations, notably that pedometers and accelerometers are unable to detect other non-walking forms of free-living physical activity, such as gardening, swimming or cycling. Recent advances in data processing and integration with smartphones, indicates a need for research into newer devices, in particular new functions and their interaction with people with Type 2 diabetes.

## **CONCLUSIONS**

In this systematic review we observed that, in Type 2 diabetes, the use of accelerometers or pedometers increases free-living physical activity by approximately one hour per week, but exerts no effect on HbA<sub>1c</sub> or other clinical outcomes. This represents an important, low cost, low input “first step” towards increasing exercise behaviour in this clinical group. Data on sustained or delayed change in the long term is lacking and warrants studies of both longer duration and periods of post-intervention follow-up of months or years. Further research into integration with other behavioural change components is indicated with clarification on which intensities and types of activity add benefit.

Future research design should also capture the indirect benefits of interventions, such as smoking cessation or peer-effects, which may be missed by current outcome measures.

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### **Competing interests:**

None Declared

### **Abbreviations:**

PA, Physical activity; HbA<sub>1c</sub>, Glycated haemoglobin

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## TABLES

**Table 1. Characteristics of the studies and of the interventions.**

	Accelerometer (n = 3, 25 %)		Pedometer (n = 9 , 75 %)		Total (n = 12, 100 %)	
	N	%	N	%	N	%
<b>Study characteristics</b>						
Trial site						
USA+ Canada	2	66.7	3	33.3	5	41.7
Europe+UK	1	33.3	4	44.4	5	41.7
Australasia	0	0	2	22.2	2	16.7
Design						
RCTs	3	100	7	77.8	10	83.3
QRTs	0	0	2	22.2	2	16.7
Primary outcome measure						
Physical activity	3	100	7	77.8	10	83.3
HbA1c	1	33.3	8	88.9	9	0.75
Study length						
<12 months	2	66.7	5	55.6	7	58.3
>12 months	1	33.3	4	44.4	5	41.7
Simple monitor intervention	1	33.3	6	66.7	7	58.3
Nested in complex intervention	2	66.7	3	33.3	5	41.7
<b>Participant characteristics</b>						
Number of participants	197	15.2	1102	84.8	1299	100
Average duration of diabetes						
<5years	1	33.3	2	22.2	3	0.25
>5years	2	66.7	4	44.4	6	0.5
N/A	1	33.3	2	22.2	3	0.25

RCT, Randomized controlled trial; QRT, Quasi randomized trial; HbA1c, glycated haemoglobin; n, number of trials



## **FIGURES**

Figure 1. Flowchart of articles included at each stage of the screening process

Figure 2. Risks of bias of individual studies

Figure 3. Standardized mean difference in size of effect of the intervention compared with control for physical activity.

Figure 4. Weighted mean difference in size of effect of the intervention compared with control for HbA1c