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Effectiveness of physical activity monitors in adults: systematic review and meta-analysis

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# ABSTRACT

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To estimate the effectiveness of physical activity monitor (PAM) based interventions among adults and explore reasons for the heterogeneity.

# DESIGN

Systematic review and meta-analysis.

# STUDY SELECTION

The electronic databases MEDLINE. Embase. SPORTDiscus, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched on 4 June 2021. Eligible randomised controlled trials compared interventions in which adults received feedback from PAMs with control interventions in which no feedback was provided. No restrictions on type of outcome measurement, publication date, or language were applied.

# DATA EXTRACTION AND SYNTHESIS

Two reviewers independently extracted data and assessed risk of bias. Random effects metaanalyses were used to synthesise the results. The certainty of evidence was rated by the Grading of **Recommendations Assessment and Evaluation** (GRADE) approach.

# MAIN OUTCOME MEASURES

The three primary outcomes of interest were physical activity, moderate to vigorous physical activity, and sedentary time.

# RESULTS

121 randomised controlled trials with 141 study comparisons, including 16743 participants, were included. The PAM based interventions showed a

# WHAT IS ALREADY KNOWN ON THIS TOPIC

Modern physical activity monitors have the potential to be used as facilitators for behavioural change, providing direct feedback on activity to the user

In 2007 a systematic review reported that use of physical activity monitors could increase physical activity, but few studies were included and the effect estimate was affected by imprecision

Since 2007 several studies have been published with different conclusions about the effectiveness of physical activity monitors

# WHAT THIS STUDY ADDS

This comprehensive and methodologically sound systematic review and metaanalysis summarises the existing body of evidence covering 121 studies, including 16743 participants

This study provides evidence for using physical activity monitors for enhancing physical activity and moderate to vigorous physical activity

Large scale studies and studies investigating sedentary time in general, especially among overweight participants, are needed to clarify evidence gaps identified here

moderate effect (standardised mean difference 0.42. 95% confidence interval 0.28 to 0.55) on physical activity, equivalent to 1235 daily steps; a small effect (0.23, 0.16 to 0.30) on moderate to vigorous physical activity, equivalent to 48.5 weekly minutes; and a small insignificant effect (-0.12, -0.25 to 0.01)on sedentary time, equal to 9.9 daily minutes. All outcomes favoured the PAM interventions.

# CONCLUSIONS

The certainty of evidence was low for the effect of PAM based interventions on physical activity and moderate for moderate to vigorous physical activity and sedentary time. PAM based interventions are safe and effectively increase physical activity and moderate to vigorous physical activity. The effect on physical activity and moderate to vigorous physical activity is well established but might be overestimated owing to publication bias.

# STUDY REGISTRATION

PROSPERO CRD42018102719.

# Introduction

Physical inactivity, an activity level insufficient to meet current recommendations, has a large impact on global public health, as it is one of the major risk factors for non-communicable diseases and is estimated to be responsible for 9% of all premature deaths globally.<sup>1</sup> Physical activity, any bodily movement produced by skeletal muscles that requires energy expenditure,<sup>2</sup> has been quantified with physical activity monitors (PAMs) for research purposes for decades.<sup>3</sup> However, as well as tracking and measuring physical activity, modern PAMs hold the potential to be used as facilitators for behavioural change, providing direct feedback on physical activity to the user.<sup>4</sup> A novel systematic review by Bravata and colleagues in 2007 reported that PAMs could be effectively used to increase physical activity levels among adults.<sup>5</sup> However, the number of randomised controlled trials included was low, and the effect estimate was affected by imprecision. Furthermore, several randomised controlled trials have been published since 2007 with different conclusions about the effectiveness of the PAMs. Some trials have reported promising effect sizes,<sup>6-12</sup> some have reported inconclusive results owing to a lack of power or intervention effects, 13-19 and some have reported negative findings on intervention effects.<sup>20-24</sup> Even though several systematic reviews have investigated the effectiveness of PAMs, they have all been focused on specific populations or specific types of PAM or have included a limited number of randomised controlled trials.<sup>5 25-46</sup> On the basis of the published literature, PAMs are expected to be effectively increasing physical

activity behaviour in general. Nevertheless, as no systematic review has included all available studies, the evidence on the effectiveness of PAM based interventions promoting physical activity among all adults needs to be systematically reviewed according to best practice recommendations from the Cochrane Collaboration to provide high quality guidelines for a diverse audience with an interest in general medicine and public health.<sup>47</sup>

The objective of this systematic review and metaanalysis was to estimate the effect on physical activity, moderate and vigorous physical activity, and sedentary time from PAM based interventions compared with control interventions in which the participants did not receive feedback from PAMs in participants aged 18-65 years. Subsequently, we examined whether the effectiveness was affected by characteristics of studies and participants.

#### Methods

This systematic review and meta-analysis was conducted according to the recommendations from Cochrane and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.<sup>47 48</sup> The study protocol holds a detailed description of the methods, has been registered in the PROSPERO database, and has previously been published.<sup>49</sup>

#### **Eligibility criteria**

We included randomised controlled trials and randomised crossover trials. For studies to be considered eligible for inclusion, more than 80% of the study participants had to be above 18 years of age and below 65 years of age. We calculated age distributions by following the methods used by Hall and colleagues.<sup>50</sup> We included studies comparing any PAM based intervention in which the participants received feedback on their physical activity level from the PAMs. The PAMs may be portable or wearable, electronic or mechanical, and driven by accelerometers, pedometers, or global positioning systems. In all control interventions, the participants could not receive any feedback on their physical activity level from the PAMs

## Outcomes

The three primary outcomes of interest were changes in physical activity, moderate to vigorous physical activity, and sedentary time. If more than one relevant outcome was reported in a study on physical activity, we favoured daily step counts followed by daily metres walked and daily energy expenditure. Finally, if no objective measure was available for physical activity, we used self-reported measures. If more than one relevant outcome was reported in a study on moderate to vigorous physical activity, we favoured objectively measured activity followed by self-reported activity. If more than one relevant outcome was reported in a study on sedentary time, we favoured objectively measured sedentary time followed by self-reported sedentary time. For all three primary outcomes, we used the individual study definitions of physical activity, moderate to vigorous physical activity, and sedentary time. If a study reported only either physical activity or moderate to vigorous physical activity, we included the study results in the specific analysis only for that outcome. We extracted reported adverse events and dropouts.

#### Search methods for identification of studies

We searched the electronic databases MEDLINE, Embase, SPORTDiscus, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) on 4 June 2021. The search string combined relevant keywords and MeSH/thesaurus terms for PAMs and study design. The search matrix is reported in the study protocol along with the full search strings.<sup>49</sup> We contacted the authors of all unobtainable studies or studies with missing data. We applied no restrictions on language or publication date. Two reviewers (CK and VW) independently used citation pearl growing to hand search references of eligible studies and reviews identified from the search. We searched the database ClinicalTrials.gov to identify ongoing trials. We contacted the study authors of trial protocols if the trial status was uncertain (for example, if the anticipated completion date was overdue but no published study could be identified).

#### Study selection, data extraction, and risk of bias

A combination of two reviewers (RTL, VW, CBK, CK, JC) independently screened all titles and abstracts of identified studies. At least one of the reviewers assessed the full text of articles judged to be eligible, and consensus on eligibility was reached by discussion. Two reviewers (RTL, VW, CBK, CK, CBJ, JC) independently extracted data and assessed risk of bias using the RoB 2.0 tool.<sup>51</sup> Disagreements between reviewers were solved by consulting a third reviewer. To provide the most realistic comparisons, we used the most active control interventions as comparators if more than one control group was available in a study (for example, other non-PAM based behavioural change interventions over usual care interventions over wait list). We imputed median values as means and extracted the standard deviation; estimated it from the standard error, 95% confidence interval, P value, or interguartile range; or measured it on a graph, as recommended by the Cochrane Handbook.<sup>52</sup> Studies without any quantification of variance for endpoint scores had standard deviations imputed from baseline measures.

# Data synthesis

As described in a previous study protocol,<sup>49</sup> we calculated the effect size as a standardised mean difference of the final scores and summarised it using a Hartung-Knapp-Sidik-Jonkman random effects meta-analysis after adjustment to Hedges' g.<sup>53 54</sup> We estimated the risk ratio for adverse events and dropouts, and studies with zero events were given 0.5 events for both the intervention and control group to

be included.<sup>55</sup> We extracted no follow-up data after the end of intervention scores.

We tested the heterogeneity of results by using the Cochrane Q test and quantified it as I<sup>2</sup> values and the between study variance  $\tau^2$ . We assessed small study bias by calculating the Egger's test score; if this was significant, we used a trim and fill method to adjust for small study bias by removing the studies that caused the small study bias and then imputing missing studies on the bias corrected estimate.<sup>56 57</sup> Furthermore, we used a non-parametric Spearman's rank correlation test to investigate the relation between standardised mean difference and standard error; as a non-protocol defined sensitivity analysis, we used a Copas selection model to investigate the possibility of unpublished trials.<sup>58</sup> For all statistical analyses, we considered an  $\alpha$  level of 0.05 to be statistically significant. We used RStudio version 1.3.1093, using R version 4.0.3, for all analyses and illustrations.

#### Subgroup analyses and analysis of heterogeneity

We investigated heterogeneity by doing subgroup analyses and stratified analyses on the following nominal variables: diagnoses, feedback frequency, and content of control intervention (active versus nonactive control). The description of these analyses can be found in the study protocol. However, we did not do the protocol defined analyses on type of intervention other than feedback from PAMs (for example, different types of behavioural change intervention or medical interventions related to the specific patient population of individual studies) owing to the complexity of the prevailing classification. We did not do the protocol defined subgroup analyses on whether the participants received feedback on their disease risks according to their physical activity level owing to insufficient data. Two reviewers (JC and RTL) independently rated the certainty of evidence for each outcome by using the Grading of Recommendations Assessment and Evaluation (GRADE) approach (domains used to assess the certainty of the evidence were risk of bias, inconsistency, indirectness, imprecision, and publication bias).<sup>59 60</sup> We used the Cochrane rule of thumb (<0.4 interpreted as a small effect, 0.4-0.7 interpreted as a moderate effect, >0.7 interpreted as a large effect) to re-express the standardised mean differences in the summary of findings.<sup>61</sup> As a sensitivity approach, we did cumulative meta-analyses to investigate by which year the pooled estimates were positive with at least a clinically relevant small effect (standardised mean difference <0.2 with 95% confidence).<sup>62</sup> Another deviation from the study protocol was the use of gross national income per capita as a measure of a country's economy to explain the heterogeneity of the study results, over the protocol defined use of a country's gross domestic product. We did this because the World Bank uses gross national income to classify low, lower middle, upper middle, and high income countries.<sup>63</sup>

Some studies used non-blinded or non-sealed PAMs to assess the study groups during baseline and

endpoint weeks. To investigate whether the pooled effect estimates were affected directly by bias due to deviations from the intended control interventions, we did a non-protocol defined sensitivity analysis to analyse whether the control groups were considered to be exposed for feedback from the PAMs.

#### Patient and public involvement

Because this review did not focus on any specific patient population, no patients were directly involved in setting the research question or the outcome measures or in the design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. However, the members of the research team have worked with physical activity behaviour among different patient populations, which have inspired this review. Patient representatives will be included in the dissemination of results, including the use of lay summaries describing the research and its results for non-scientific audiences.

#### Results

In total, we included 121 studies with 141 study comparisons and 16743 participants.<sup>6-12</sup> <sup>14-24</sup> <sup>64-167</sup> The search was conducted on 4 June 2021 and identified 18253 unique study references. Hand searching of 59 relevant reviews identified five additional studies.<sup>717593106110</sup> We contacted 105 study authors for obtaining of full text or protocol details, confirmation of trial status, or sharing of preliminary or missing relevant data. The 67 unobtainable studies excluded as "no full text" were conference abstracts, inaccessible trials, or completed trial registrations for which the study report could not be found and the authors did not respond. Figure 1 shows the study selection process and reasons for exclusion in the full text screening.

#### Characteristics of included studies

All 121 included studies were conducted in high income countries except for eight studies that were conducted in upper middle income countries.<sup>12 80 87 104 123 129 150 156</sup> Most of the included studies were European (31%) or North American (40%). Most of the studies were categorised as including mainly healthy participants (47%), followed by studies that reported including overweight participants (17%) and studies that reported including participants with cancer (12%). In total, 62% of the included studies used passive control comparisons, meaning that most of the control groups' participants received no active intervention content; 81% of the included studies used goal setting for the intervention group participants; and almost all (97%) of the included studies provided daily feedback on physical activity for the intervention group participants. The median duration of intervention among the included studies was 12 weeks. The median baseline daily step count was 6994, and the median body mass index was 27.8. The median age of the participants was 47 years, and the median proportion of female participants was

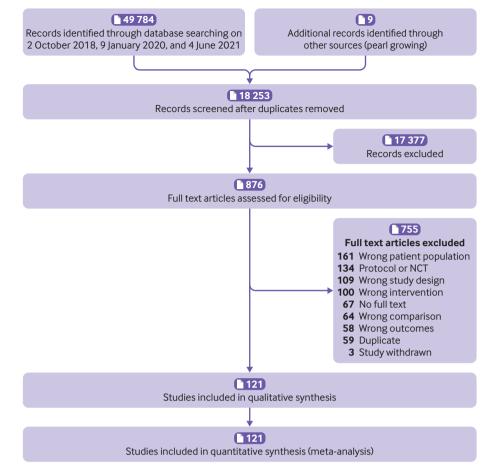


Fig 1 | PRISMA flow diagram illustrating selection of studies. NCT=National Clinical Trial registry

77%. The median sample size of the included studies was 69. Table 1 summarises the characteristics of the included studies, with detailed summary statistics and references. Appendix 1 provides information about interventions, types of PAM used in the intervention and for measuring outcomes, and further study level characteristics.

# Risk of bias in individual studies

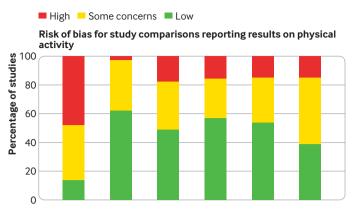
Risk of bias assessments in individual studies, including reasons, are listed in the characteristics of included studies in appendix 1. Figure 2 illustrates the risk of bias for the three outcomes.

#### Effects of interventions on physical activity

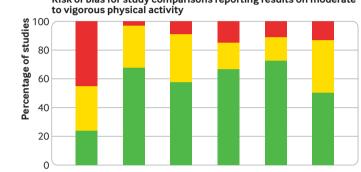
We included 103 studies including results for 12 840 participants in the meta-analysis on physical activity. <sup>6-12</sup> <sup>14-16</sup> <sup>18-24</sup> <sup>64-69</sup> <sup>73-80</sup> <sup>82</sup> <sup>83</sup> <sup>85-94</sup> <sup>96-101</sup> <sup>103</sup> <sup>104</sup> <sup>106-126</sup> <sup>128-137</sup> <sup>139-141</sup> <sup>143</sup> <sup>145-148</sup> <sup>150-154</sup> <sup>156</sup> <sup>158</sup> <sup>159</sup> <sup>161-164</sup> <sup>167</sup> The overall standardised mean difference was 0.42 (95% confidence interval 0.28 to 0.55;  $I^2$ =81%) in favour of the PAM interventions. When we transformed the standardised mean difference to a weighted mean difference on daily steps using a median standard deviation of 2940 steps, <sup>145</sup> the pooled effect equated to 1235 (95% confidence interval 823 to 1617) daily steps in favour of the intervention. No methodological heterogeneity (whether active or passive control

interventions were used; whether objective or selfreported outcome instruments were used; whether goal setting was applied; whether the participants received feedback daily, weekly, or monthly; how long the interventions lasted; what gross national income the study country had; or how the studies were assessed in terms of risk of bias) or clinical heterogeneity (participant population, baseline step count, age of participants, sex distribution of participants, or body mass index of participants) explained the heterogeneity of the results significantly or relevantly. Because of funnel plot asymmetry (positive Eggers' test, intercept 2.03 (95% confidence interval 1.32 to 2.75)) and, therefore, a risk of small study bias, we applied a trim and fill method in which 36 fictive studies were added, giving an adjusted standardised mean difference of 0.15 (-0.02 to 0.32). A Copas selection model suggested that 69 studies were left unpublished and gave an adjusted standardised mean difference of 0.15 (0.06 to 0.24). A cumulative metaanalysis showed that the standardised mean difference has been significantly larger than 0.25 since 2014. Two comparisons had standard deviations imputed for daily steps,<sup>110 165</sup> as did one comparison for weekly walking minutes.<sup>91</sup> Three comparisons reported only change scores and were included in the analysis after calculation of the end of treatment standardised mean difference.<sup>16 125</sup> Three studies reported results

Table 1   Characteristics of included studies		
Characteristics	No (%) of studies (n=121)	No (%) of participants (n=16743)
Continent		
Africa <sup>123129</sup>	2 (2)	103 (0.6)
Asia 6 10 79 86 90 102 103 115 131 141 150 154 162	14 (12)	1681 (10.0)
Australia <sup>7</sup> 16 65 70 75 78 108 111 113 114 130 134 146 147 157 165 168	15 (12)	1510 (9.0)
Europe <sup>8</sup> 1315 18 20 21 23 64 66-69 72 83 88 89 92 97 107 112 116 117 119 121 127 128 135 145 148 149 152 155 158 163 164 166 167 169 170	37 (31)	8047 (48.1)
North Ameri <sup>1639</sup> 11 14 17 19 22 24 71 73 74 76 82 84 85 91 94-96 98-101 105 106 109 110 118 120 122 124 125 132 136 140 142 143 152 153 159-161 171 172	48 (40)	5071 (30.3)
South Ameri <sup>(a128087104156</sup>	5 (4)	331 (2.0)
Population		
Participants with cancer <sup>8 22247176 89 102 106 117 134 141 143</sup>	14 (12)	1630 (9.7)
Participants with cardiovascular disease <sup>90</sup>	1 (1)	37 (0.2)
Participants with diabetes <sup>15,16,78,101,118,122,140,155,162,163</sup>	10 (8)	1177 (7.0)
Healthy participants <sup>679101214192123646670757883858688939697100103104107-112114119121123128131132136139145-148151152154157-159172</sup>	57 (47)	9103 (54.4)
Participants with musculoskeletal disorders <sup>72,105,153,161</sup>	4 (3)	436 (2.6)
Participants with neurological disorders <sup>11124 164 167</sup>	4 (3)	399 (2.4)
Participants who are overweight <sup>1873748284</sup> 919294959899113115120125127135137138142	20 (17)	2754 (16.4)
Participants with psychiatric disorders <sup>130 149</sup>	2 (2)	120 (0.7)
Participants with pulmonary disorders <sup>80 87 116 156</sup>	2 (2)	375 (3.3)
Participants with other disorders <sup>65 129 133 150 166</sup>	5 (4)	712 (2.2)
Methods		
Active control interventions <sup>7</sup> 8 10 11 14 16-18 21-24 64 66-68 70 71 73 74 76 78 79 82-86 89 91 93 95 97 100-109 113-115 117 121 122 124 127-133 135-137 140 143 147 149 154 156-158 161 163-167 172	46 (38)	5522 (33.0)
Passive control interventions 69 12 15 19 22 65 69 72 75 80 87 88 90 92 94 96 98 99 110-112 116 118-120 123 125 134 138 139 141-143 146 148 150-153 155 158 160 162 168 171	75 (62)	11 221 (67.0)
Goal setting <sup>7</sup> 8 10-12 15-18 21-24 64-67 69-76 78-80 82-89 92-97 99-102 104-108 110-114 118-122 124 125 127-133 135 137-143 145 147 148 150-156 158 160-167 172	98 (81)	14 381 (85.9)
No goal setting <sup>6</sup> 9 14 17 19 22 67 79 90 91 98 103 109 115 117 123 134 136 146 149 158 159	23 (19)	2362 (14.1)
Daily feedback <sup>6-12</sup> 14-24 64-124 126-167	117 (97)	16451 (98.3)
Weekly feedback <sup>19 127</sup>	2 (2)	209 (1.2)
Monthly feedback <sup>87125</sup>	2 (2)	83 (0.5)
Other characteristics-median (interquartile range)		
Country gross national income per capita (US\$; No of studies=121)	52 448* (42 300-65 118)	118)
Intervention length (weeks; No of studies=121)	12 (8-12)	
Baseline step count (No of studies=59)	6994 (5158-8230)	
Age of participants (years; No of studies=108)	47.1 (39.0-52.5)	
Sex distribution (% of female participants; No of studies=116)	76.8 (56.4-96.0)	
Mean body mass index (No of studies=102)	27.8 (24.4-30.7)	
Median total No of participants (No of studies=12.1)	69 (39-152)	



Risk of bias for study comparisons reporting results on moderate to vigorous physical activity



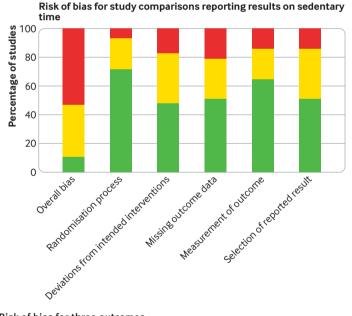


Fig 2 | Risk of bias for three outcomes

from dichotomous outcomes and were included in the analysis after calculation of the odds ratio and estimation of the individual standardised mean difference.<sup>18 89 101</sup>

# Effects of interventions on moderate to vigorous physical activity

We included 63 studies including results on 8250 participants in the meta-analysis on moderate to vigorous physical activity.7 11 12 15 20 22-24 67 69-74 76 82-87 90 92-95 97-100 102 105 106 108 111 114-117 119 124 126-128 132 134

# 138 142 143 145 146 149 153 155 157 162-164 166 167 172 The overall

standardised mean difference was 0.23 (0.16 to 0.30:  $I^2$ =67%) in favour of the PAM interventions. When we transformed the standardised mean difference to a weighted mean difference on weekly minutes of moderate to vigorous physical activity using a median standard deviation of 211 minutes,<sup>165</sup> the pooled effect equated to 48.5 (33.8 to 63.3) minutes of moderate to vigorous physical activity in favour of the intervention. The following covariates and risk of bias items explained some of the heterogeneity of the results. Studies using objective outcome instruments for moderate to vigorous physical activity reported a lower standardised mean difference (0.14, 0.06 to 0.22) than did studies using self-reported measures (0.42, 0.22 to 0.62). Studies with low risk of bias arising from the randomisation process were found to have a larger standardised mean difference (0.28, 0.16 to 0.40) than studies with some concerns (0.04, 0.00 to 0.08) and those with high risk of bias (0.17, -3.10 to 3.44). Studies with high risk of bias in selection of the reported results were found to have a lower standardised mean difference (0.05, -0.04 to 0.14) than studies with some concerns (0.31, 0.20 to 0.42) and those with low risk of bias (0.24, 0.09 to 0.38). No other methodological heterogeneity (whether active or passive control interventions were used; whether goal setting was applied; whether the participants received feedback daily, weekly, or monthly; how long the interventions lasted; what gross national income the study country had; or how the studies were assessed in terms of other risk of bias domains) or clinical heterogeneity (participant population, baseline step count, age of participants, sex distribution of participants, or body mass index of participants) explained the heterogeneity of the results significantly or relevantly. Because of funnel plot asymmetry (positive Eggers' test, intercept 1.00 (0.59 to 1.42)) and the consequent risk of small study bias, we applied a trim and fill method in which 22 fictive studies were added, giving an adjusted standardised mean difference of 0.06 (-0.01 to 0.13). A Copas selection model suggested that 21 studies were left unpublished and gave an adjusted standardised mean difference of 0.10 (0.03 to 0.17). A cumulative metaanalysis showed that the standardised mean difference has been significantly larger than 0.15 since 2016. One comparison had standard deviations imputed for weekly moderate to vigorous physical activity.<sup>67</sup> Two comparisons reported only change scores and were included in the analysis after calculation of the end of treatment standardised mean difference.<sup>111 142</sup> One study reported results from dichotomous outcomes and was included in the analysis after calculation of the odds ratio and estimation of the individual standardised mean difference.84

#### Effects of interventions on sedentary time

We included 38 studies including results on 5634 participants in the meta-analysis on sedentary time.<sup>13</sup> 22 23 64 66 67 70 73 82 87 92-94 98 99 103 105 113 114 116 117 119 121 126-128 130 143 146 149 152 153 155 157 160-163 172 The overall standardised mean difference was -0.12 (-0.25 to 0.01:  $I^2$ =66%), favouring the PAM intervention as the intervention groups were less sedentary. When we transformed the standardised mean difference to a weighted mean difference of daily sedentary minutes using a median standard deviation of 87.2 minutes. the pooled effect equated to 9.9 (-0.8 to 21.8) daily minutes of sedentary time less in the intervention groups. Participant population groups were found to explain some heterogeneity (P<0.001), primarily driven by the results from studies with overweight participants having an effect size favouring the control interventions (0.11, -0.02 to 0.23) compared with the other participant populations. Country's gross national income was correlated with the effect of the interventions (coefficient 0.01, 95% confidence interval 0.00 to 0.02) per US\$10000 (£7390; €8794) increase). No other methodological heterogeneity (whether active or passive control interventions were used; whether objective or self-reported outcome instruments were used; whether goal setting was applied; whether the participants received feedback daily, weekly, or monthly; how long the interventions lasted; or how the studies were assessed in terms of risk of bias) or clinical heterogeneity (baseline step count, age of participants, sex distribution of participants, or body mass index of participants) explained the heterogeneity of the results significantly or relevantly. No funnel plot asymmetry, and therefore no risk of small study bias, was found. A cumulative meta-analysis showed that the pooled estimate has been stable around a small effect since 2020. One comparison had standard deviations imputed for weekly sitting minutes.<sup>67</sup>

Appendix 2 shows the forest plots from the random effects meta-analyses. Appendix 3 gives the full results from the subgroup analyses and meta-regressions.

#### Adverse events and discontinued interventions

With 224 (6.4%) adverse events among 3501 intervention group participants and 186 (5.5%) adverse events among 3355 control group participants, we found no significant association between group allocation when summarising the risk of experiencing an adverse event in 34 studies (relative risk 1.1, 95% confidence interval 0.93 to 1.30;  $I^2$ =0%). With 931 (10.1%) of 9201 intervention group participants discontinuing the interventions and 713 (8.5%) among 8374 control group participants discontinuing the interventions, we found no significant association

between group allocation when summarising the risk of discontinuing interventions in 117 studies (relative risk 1.1, 0.96 to 1.20;  $I^2=16\%$ ).

#### Non-protocol defined sensitivity analyses on whether control group participants were considered to receive feedback from PAMs

We found no effect from whether the control group participants were considered to be exposed for nonblinded PAMs in baseline and endpoint measurement weeks for physical activity and moderate to vigorous physical activity. For sedentary time, the studies in which the control group was considered to receive feedback had a less favourable effect size (0.06, -0.62 to 0.74) than the other studies (-0.14, -0.27 to -0.00).

#### Summary of findings and risk of bias across studies

The following includes a summary of findings, an effect size interpretation, and a grading of the certainty of evidence (table 2).<sup>59 61</sup>

#### Physical activity

The standardised mean difference for physical activity of 0.42 (0.28 to 0.55) equates to a moderate effect that translates to a weighted mean difference of 1235 (823 to 1617) daily steps, with more steps in the intervention groups. Certainty in the effect estimate was rated as low. The considerable amount of heterogeneity ( $I^2$ =81%) could not be explained by any covariates or risk of bias items. Furthermore, the funnel plot asymmetry and findings from the trim and fill method and the Copas selection model suggest an overestimation of the effect, possibly due to publication and small study bias. Therefore, the certainty in the estimate was downgraded owing to inconsistency and the risk of small study bias due to funnel plot asymmetry.

#### Moderate to vigorous physical activity

The standardised mean difference for moderate to vigorous physical activity of 0.23 (0.16 to 0.30) equates to a small effect that translates to a weighted mean difference of 48.5 (33.8 to 63.3) minutes weekly moderate to vigorous physical activity time more in the intervention groups. Certainty in the effect estimate was rated as moderate. The substantial amount of heterogeneity ( $I^2$ =67%) was partially explained by outcome instrument type and risk of bias items. As the risk of bias items were counterintuitively explaining

Outcome	No of studies	No of participants	-	5% CI)	SMD (95% CI)	² (%)
Physical activity	103	12 840			0.42 (0.28 to 0.55)	81
Moderate to vigorous physical activit	y 63	8250			0.23 (0.16 to 0.30)	67
Sedentary time	38	5634			-0.12 (-0.25 to 0.01)	66
		-0.4	-0.2 0	0.2 0.4 0.	.6	

Fig 3 | Random effects meta-analysis adjusted to Hedges' g on effect of interventions on physical activity, moderate to vigorous physical activity, and sedentary time. SMD=standardised mean difference

Outcomes	Anticipated absolute effects*	SMD (95% CI)	No of study compari- sons and participants	Certainty of evidence†	Comments
Physical activity	SMD translates to weighted mean difference of 1235 (95% Cl 823 to 1617) daily steps, with more steps in intervention groups	0.42 (0.28 to 0.55) in favour of intervention	103 studies; 12 840 participants	Low‡§	None
Moderate to vigorous physical activity	SMD translates to weighted mean difference of 48.5 (33.8 to 63.3) minutes weekly MVPA, with more time in intervention groups	0.23 (0.16 to 0.30) in favour of intervention	63 studies; 8250 participants	Moderate§	None
Sedentary time	SMD translates to weighted mean difference of 9.9 (-0.8 to 21.8) daily sedentary minutes, with less time in intervention groups	-0.12 (-0.25 to 0.01)	38 studies; 5634 participants	Moderate	None
Adverse events	224 (6.4%) adverse events among 3501 intervention group participants; 186 (5.5%) adverse events among 3355 control group participants	Relative risk 1.1 (0.93 to 1.30)	34 studies; 6856 participants	High	No heterogeneity
Discontinued intervention (dropout)	931 (10.2%) of 9201 intervention group participants discontinued interventions; 713 (8.5%) of 9201 control group participants discontinued interventions	Relative risk 1.1 (0.96 to 1.20)	117 studies; 17 575 participants	High	No heterogeneity

CI=confidence interval; MVPA=moderate to vigorous physical activity; SMD=standardised mean difference.

\*Absolute effects are calculated from SMDs and relevant standard deviation, as described in methods section.

tGrading of Recommendations Assessment and Evaluation (GRADE) Working Group grades of evidence: high certainty (very confident that true effect lies close to estimate of effect); moderate certainty (moderately confident in effect estimate: true effect is likely to be close to estimate of effect, but possibility that it is substantially different exists); low certainty (confidence in effect is likely to be close to estimate of effect); very low certainty (very little confidence in effect estimate: true effect is likely to be substantially different from estimate of effect); very low certainty (very little confidence in effect estimate: true effect is likely to be substantially different from estimate of effect); very low certainty (very little confidence in effect).

‡Downgraded by one level owing to inconsistency (unexplained heterogeneity).

§Downgraded by one level owing to publication bias.

¶Downgraded by one level owing to imprecision of results.

heterogeneity (high risk of bias studies reported lower effects), no downgrading due to risk of bias was needed. Furthermore, the funnel plot asymmetry and findings from the trim and fill method and the Copas selection model suggest an overestimation of the effect, possibly due to publication and small study bias. In summary, the certainty was downgraded only owing to risk of small study bias due to funnel plot asymmetry.

#### Sedentary time

The standardised mean difference for sedentary time of -0.12 (-0.25 to 0.01) equates to a small effect that translates to a weighted mean difference of 9.9 (-0.8 to 21.8) daily sedentary minutes less in the intervention groups. Certainty in the effect estimate was rated as moderate. The overall effect estimate was affected by imprecision, as the upper and lower confidence interval limits represent a large effect and no effect, respectively. The substantial amount of heterogeneity ( $I^2$ =66%) was partially explained by differences in participant population and country gross national income to a small extent. Thus, the certainty of evidence was downgraded owing to imprecision.

#### Adverse events and discontinued interventions

For both the risk of adverse events and risk of discontinuing the intervention, no heterogeneity was present. Thus, no downgrading was needed, and the certainty in the evidence was rated high for both outcomes.

#### Discussion

The finding that PAM based interventions effectively enhance physical activity levels was expected from previous systematic reviews on adult outpatients<sup>5</sup>; older adults<sup>25</sup>; overweight participants<sup>26</sup>; patients with chronic obstructive pulmonary disease,<sup>27 28</sup> multiple sclerosis,<sup>29</sup> rheumatic or musculoskeletal diseases,<sup>30 31</sup> cardiometabolic conditions,<sup>32 173</sup> or type 2 diabetes<sup>33-35</sup>; former healthcare patients<sup>36</sup>; patients in cardiac rehabilitation and with cardiovascular disease<sup>37 38</sup>; and sedentary adults.<sup>39 40</sup> Previously, related systematic reviews have focused on more narrow modalities, such as step counting alone,<sup>41</sup> electronic devices or other accelerometers but excluding pedometers,<sup>42 43</sup> fitness trackers,<sup>44</sup> or PAMs available to consumers.<sup>45</sup> Finally, one systematic review has been published with overlapping but not similar aims, which included fewer randomised controlled trials.46 Therefore, this is the first systematic review to summarise the entire body of evidence across different patient populations and different types of PAM. Our finding of a moderate effect on physical activity, equivalent to 1235 (95% confidence interval 823 to 1617) daily steps, and the small effect on moderate to vigorous physical activity, equivalent to 48.5 (33.8 to 63.3) minutes weekly MVPA time, are both clinically relevant. An increase of 1000 daily steps has previously been reported to reduce all cause mortality by 6-36%.<sup>174</sup> This association has a non-linear pattern, with the strongest association in people with fewer than 8000 daily steps.<sup>175 176</sup> Recent results for moderate to vigorous physical activity show the maximal reduction in risk of mortality to be at around 20-25 minutes of daily moderate to vigorous physical activity.<sup>177</sup> These findings support the conclusions of a systematic review investigating associations between mortality and physical activity levels and including individual data for 36383 participants, in which any physical activity level was associated with a substantially lower risk of mortality compared with the least active group.<sup>177</sup> Because of the above, the re-expression of the standardised mean difference for moderate to vigorous physical activity as a small effect might be misleading when the translated effect estimate is close to a third of the recommended level of weekly moderate to vigorous physical activity<sup>2</sup>; hence, a small effect on the physical activity behaviour could still very well be highly relevant clinically.

The small effect on sedentary time (-0.12, -0.25 to 0.01), which translates to a weighted mean difference

of 9.9 (-0.8 to 21.8) daily sedentary minutes less in the intervention groups, might be found owing to the imprecision of the results. However, even if the estimated effect is close to the true effect size, the result lacks the clinical relevance of physical activity and moderate to vigorous physical activity, as larger effects are probably needed to reduce clinically relevant outcomes significantly.<sup>177 178</sup> However, as the strongest inverse correlation between physical activity and sedentary time has been found between light physical activity and sedentary time,<sup>179</sup> the lack of effect might be explained by participants increasing their moderate to vigorous physical activity, and thus also their physical activity, when receiving feedback from PAMs. This explanation remains theoretical, as it is outside the aim of this systematic review and meta-analysis. The lack of a clinically relevant effect on sedentary time is still noteworthy, however, as this systematic review cannot support the use of PAMs to reduce sedentary time alone.

# Factors affecting expected effect of physical activity monitoring

As seen in the subgroup analyses on physical activity, the standardised mean differences for different methodological factors and across participant populations are somewhat comparable. Thus, no clinical or methodological heterogeneity explained the heterogeneity of the results on physical activity sufficiently, and the moderate effect should be expected in most settings, no matter the population of interest.

For moderate to vigorous physical activity, some heterogeneity was explained by studies using selfreported outcome instruments reporting a larger effect than studies using objective outcome instruments. This could be explained by the questionable validity of commonly used physical activity questionnaires for assessing moderate to vigorous physical activity<sup>180</sup>; however, as the randomisation should handle any validity imbalances between groups, and thus the endpoint effect size, this explanation remains theoretical and outside the primary aim of this study. Future studies investigating moderate to vigorous physical activity should include objective outcome instruments, as self-reported outcome instruments might overestimate the effects of the intervention. Other explanations for heterogeneity of the results on moderate to vigorous physical activity include risk of bias items. However, as these explanations remain counterintuitive, with low risk of bias studies having larger effects, they are not discussed any further.

For sedentary time, the heterogeneity of the results was explained to a very small degree by studies with higher gross national income having a greater effect; however, as this result is clinically irrelevant (correlation coefficient 0.01 (0.00 to 0.02) per US\$10000 increase), the finding is not discussed any further. Lastly, the heterogeneity of the results on sedentary time was also explained by differences in participant populations, with studies including overweight participants reporting a result favouring the control interventions

(0.11, -0.02 to 0.23). This could be due to overweight participants experiencing an ambiguous and even counterproductive influence from feedback from PAMs similar to the findings identified in a small study with young adults with depression or anxiety.<sup>181</sup> However, as no explanation was found from the baseline body mass index reported in the included studies, the above finding could also be due to chance alone. For the present, the use of PAMs to reduce sedentary time among overweight participants cannot be supported, and the results should be investigated further in future studies. Finally, however, all of these findings are secondary to the aim of this systematic review and meta-analyses and could, therefore, be due to chance alone.

## Publication bias

The effect sizes on physical activity and moderate to vigorous physical activity might both be affected by publication bias and small study bias. The protocol defined trim and fill adjustment added 36 and 22 fictive studies for physical activity and moderate to vigorous physical activity, respectively, and the effect sizes were adjusted to small and clinically irrelevant for physical activity and moderate to vigorous physical activity, respectively. However, an empirical evaluation of the trim and fill adjustment concludes that it might lead to an excessively conservative estimate.<sup>58</sup> Because of this, we used the non-protocol defined Copas selection model as an alternative sensitivity analysis and adjustment method to the trim and fill method.<sup>182 183</sup> The Copas selection model supported the trim and fill method for both outcomes, but it was not as conservative on moderate to vigorous physical activity as the former alternative. Statistical evaluation and especially correction of small study bias are complex; even though the expected true effect sizes for physical activity and moderate to vigorous physical activity might be overestimated, the results still suggest and support the use of PAM interventions.

#### Strengths and limitations of study

With its 121 included studies, this study stands as the largest available systematic review and meta-analysis investigating the effect of PAMs on physical activity behaviour. Furthermore, it includes all populations (healthy individuals and patients) and provides precise estimates of the effect sizes for physical activity and moderate to vigorous physical activity. The following limitations should, however, be considered when interpreting the results. Firstly, a substantial amount of heterogeneity was found for all outcomes and explained to some degree only for moderate to vigorous physical activity and sedentary time. Secondly, studies conducted in high income countries are overrepresented, as only eight studies were conducted in non-high income countries, all upper middle income countries.<sup>12 80 87 104 123 129 150 156</sup> Consequently, the external validity of our results is limited to high income countries. Thirdly, studies with a high female participation rate are overrepresented, limiting the external validity to female populations. However, as

the percentage of female participants in the studies did not explain any heterogeneity, the influence of gender seems to be low. Fourthly, the studies all used objective PAMs as intervention tools but included a variety of physical activity outcome instruments, including selfreported measures (according to appendix 3, 42% of comparisons for physical activity, 45% for moderate to vigorous physical activity, and 48% for sedentary time), which also explained some heterogeneity for moderate to vigorous physical activity. As previously discussed, self-reported outcome measures have a low validity for moderate to vigorous physical activity, which might explain the finding. The inclusion of studies using self-reported measures might limit our results; however, as self-reported measures seem to affect the effect estimate only for moderate to vigorous physical activity, the inclusion could also be seen as a strength for physical activity and sedentary time. Finally, some patient populations appear in only a few studies and thus few participants (cardiovascular, musculoskeletal, neurological, psychiatric, and pulmonary patient populations). This limits the generalisability to these populations, as the effect sizes might be driven by other populations. But as no evidence indicates that these populations will react differently to feedback from PAMs or suggests that they will have negative or unexpected effects, the results should apply equally.

#### Implications for practice and research

The certainty of the evidence for a moderate effect on physical activity was rated low and could very well be changed by future studies. The effect estimate might also be overestimated owing to publication bias and small study bias. The certainty of the evidence for a small effect on moderate to vigorous physical activity was rated moderate, and it is likely to be close to the true effect. However, the effect estimate might also be overestimated owing to publication bias and small study bias and affected by studies with selfreported instruments reporting larger effects. However, according to the cumulative meta-analysis, the effect estimates on physical activity have been stable for some years, which should inform future studies and encourage comparisons only where needed (for example, large scale studies on physical activity and moderate to vigorous physical activity to avoid small study bias and studies on sedentary time in general and especially among overweight adults).

Even though the effects might be overestimated, clinically relevant effects on physical activity and moderate to vigorous physical activity should be expected when implementing PAMs among healthy or patient populations. These perspectives and recommendations, however, do not apply to studies investigating the effects on sedentary time, as we provide an imprecise effect estimate with low clinical relevance on sedentary time. Because of this, future investigations on sedentary time are encouraged.

In summary, this systematic review and metaanalysis summarises the results of 121 randomised controlled trials and is the first large summary to conclude that although individual studies might show different results, this is most likely due to the expected heterogeneity of the effects among individuals and not because one type of PAM intervention is superior to others. In the future, researchers should investigate how PAMs can be used in combination with other behavioural change contents or how PAMs might affect sedentary time.

#### Conclusions

This systematic review and meta-analysis identified 121 studies with 141 comparisons investigating the effect of PAMs. We summarise the results from 16743 unique participants and provide low certainty of evidence for a moderate effect on physical activity equal to 1235 daily steps more, moderate certainty of evidence for a small effect on moderate to vigorous physical activity equal to 48.5 minutes weekly moderate to vigorous physical activity time more, and moderate certainty of evidence for a small but insignificant effect on sedentary time equal to 9.9 daily sedentary minutes less in the intervention groups. Because of the certainty of evidence, future studies could change the overall estimates and are encouraged to investigate how PAMs can be used in combination with other interventions or how PAMs can be used to reduce sedentary time.

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Data sharing: The statistical analysis plan and dataset can be available from the corresponding author on reasonable request.

The lead authors (the manuscript's guarantors) affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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#### Web appendix: Appendix 1-3