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## Effectiveness of Smartphone Devices in Promoting Physical Activity and Exercise in Patients with Chronic Obstructive Pulmonary Disease: A Systematic Review

María del M. Martínez-García, Juan D. Ruiz-Cárdenas, and Roberto A. Rabinovich

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- Q3.** Au: Please advise if the term ‘taken’ should be changed to ‘interpreted’ in the text ‘data should be taken with caution’ and in subsequent occurrences for readability.
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- Q5.** Au: Please check the usage of the word ‘pillars’ in the text ‘The promotion of physical activity (PA) is one of the fundamental pillars in the management’ for correctness.
- Q6.** Au: Please rephrase the text ‘and a decreased of 13%’ for clarity.
- Q7.** Au: Please rephrase the sentence ‘This issue together with the spacing of the buttons and ...’ as it exceeds the maximum word limit.
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# Effectiveness of Smartphone Devices in Promoting Physical Activity and Exercise in Patients with Chronic Obstructive Pulmonary Disease: A Systematic Review

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## ABSTRACT

The objectives of this systematic review were to analyse existing evidence on the efficacy of smartphone devices in promoting physical activity (PA) in patients with chronic obstructive pulmonary disease (COPD) and to identify the validity and precision of their measurements. A systematic review was undertaken across nine electronic databases: WOS Core Collection, PubMed, CINAHL, AMED, Academic Search Complete, Cochrane Central Register of Controlled Trials, SciELO, LILACS and ScienceDirect. Randomized and non-randomized controlled clinical trials were identified. To attain additional eligible articles, the reference lists of the selected studies were also checked. Eligibility criteria and risk of bias were assessed by two independent authors. A total of eight articles met eligibility criteria. The studies were focused on promoting PA ( $n = 5$ ) and the precision of device measurements ( $n = 3$ ). The effectiveness of smartphones in increasing PA level (steps/day) at short and long term is very limited. Mobile-based exercise programs reported improvements in exercise capacity (i.e. incremental Shuttle-Walk-Test) at short and long term (18.3% and 21%, respectively). The precision of device measurements was good-to-excellent ( $r = 0.69–0.99$ ); however, these data should be taken with caution due to methodological limitations of studies. The effectiveness of smartphone devices in promoting PA levels in patients with COPD is yet too soon to be shown. Further high-quality studies are needed to evaluate the effectiveness of smartphone devices in promoting PA levels. *Registration number: CRD42016050048.*

Q1

Q2

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## ARTICLE HISTORY

### KEYWORDS

Cell phones; exercise therapy; lung diseases; physical fitness

## Introduction

The promotion of physical activity (PA) is one of the fundamental pillars in the management of patients with chronic obstructive pulmonary diseases (COPD). Reduced levels of PA in patients with COPD have been associated with a higher rate of disease progression, increased rates of hospital admissions and mortality (1, 2). Interventions facilitating follow-up assessment and self-monitoring of PA levels using pedometers have been recommended to promote behavioural changes to avoid PA decline (3). A systematic review of randomized controlled trials on PA self-monitoring using pedometers reported an increase in steps per day of 27% over baseline and an average of 2,500 steps more than the control group, highlighting these devices as a useful tool to improve PA levels in patients with COPD (4).

Advances in hand-held technology offers potential to integrate these devices into smartphone applications (App), allowing health care personnel and researchers to objectively monitor activity levels in real-time (e.g. intensity, frequency and duration) and to promote an active life style. With this objective control, the evolution of the patient's treatment can be easily monitored and modified individually, thus avoiding demotivation which can lead to the abandonment of the practice of

PA and, therefore, to treatment failure. In this new approach, several systematic reviews (5, 6) have reported improvements in PA levels through the use of smartphone devices among different populations. However, no previous study has completed an exhaustive review of the role of these devices in promoting PA levels in patients with COPD.

The objectives of this systematic review were (i) to analyse existing evidence on the efficacy of smartphone devices in promoting PA in patients with COPD and (ii) to identify the validity and precision of their measurements.

## Material and method

### Design

This systematic review was designed according to the *Preferred Reporting Items for Systematic reviews and Meta-Analyses* (7) guidelines and was registered in the international database of systematic reviews PROSPERO: CRD42016050048.

In order to ensure that no similar systematic review had been carried out previously, the Cochrane Library and the International Registry of Systematic Reviews Database (PROSPERO) were consulted.

### Search strategy and information sources

45 A bibliographic search was performed in the *WOS Core Col-*  
*lection, PubMed, CINAHL, AMED, Academic Search Complete,*  
*Cochrane Central Register of Controlled Trials (CENTRAL),*  
*SciELO, LILACS and ScienceDirect* computerized databases.  
 The last search was performed on May 14, 2017.

50 The terms included in the search strategy were: *mobile*  
*phone, smartphone, cell phone, physical activity, fitness, exercise,*  
*training, intervention, pulmonary disease, validity, precision, reli-*  
*ability.* Finally, the reference lists of the included studies were  
 manually searched. In order to obtain additional articles, the  
 55 reference lists of the included studies were reviewed. For more  
 details on the search strategies used, please refer to protocol (8).

### Eligibility criteria

The revised articles had to be published in international peer  
 review journals or as full-text entries in international scientific  
 60 conferences. These studies had to focus on the promotion or  
 validity of smartphone devices to record PA levels in patients  
 with COPD. Those studies that showed results as a whole with-  
 out any discernment between patients with COPD and those  
 with other diseases were excluded. Two reviewers independently  
 65 selected the articles after reading the full text. Disagreements  
 were resolved by consensus between the two reviewers.

### Data extraction

The PICOS (7) strategy was used for the extraction of data.  
 This strategy takes into account the participants' characteristics,  
 70 the type of intervention, the characteristics of the comparison  
 group, the results reported and the study's design. In addition,  
 data on the origin of the study (authors, year, population and  
 objectives) were also extracted.

75 From the articles that tested the precision of the device, the  
 data on smartphone placement, sampling frequency, software  
 and data precision were extracted.

### Risk of bias assessment

The risk of bias assessment included an adequate sequence  
 generation, concealment of allocation sequence, blindness of  
 80 evaluators, use of intention-to-treat analysis, and description  
 of losses and exclusions. Studies without clear descriptions of  
 an adequate sequence generation or how the allocation list was  
 concealed were considered not to have fulfilled these criteria.  
 The evaluation was performed independently by two reviewers  
 85 and disagreements were resolved by consensus between the two.

## Results

### Identification and selection process

90 A total of 89 articles were identified in the computerized  
 databases. Additionally, 1 potentially eligible article was  
 retrieved after analysing the reference lists of those identi-  
 fied through the search strategy (Figure 1). After eliminating  
 duplicates, 51 full-text articles were examined to assess their

eligibility. Out of these, 39 articles did not meet the established  
 inclusion criteria, while 4 articles were excluded because the  
 sample was composed by patients with COPD and patients with  
 95 type II diabetes and the results were not provided separately.  
 Finally, 8 articles were included in the qualitative synthesis of  
 this systematic review.

### Characteristics of the studies and risk of bias

The selected articles focused on two different categories: those  
 100 who aimed to increase PA levels developing an active lifestyle  
 program through a smartphone device ( $n = 5$ ) (9–13) and those  
 who observed the precision of the smartphone devices com-  
 pared to validated tri-axial accelerometers ( $n = 3$ ) (14–16).

The design of the studies was non-randomized controlled  
 105 clinical trials ( $n = 3$ ) (14–16) and randomized controlled clinical  
 trials ( $n = 5$ ) (9–13) whose publication period ranged between  
 2008 (12) and October 2016 (11).

All studies had a high risk of bias in at least one field; 62.5%  
 of articles presented adequate sequence generation (5 of 8)  
 110 (9–13), no article reported on concealment of allocation  
 sequence and only one reported on blinded evaluators (11),  
 62.5% used intention-to-treat principle (5 of 8) (9, 10, 12, 13,  
 16) and 100% of the articles described losses to follow-up and  
 115 exclusions (8 of 8) (9–16).

### Characteristics of the participants

The sample size of the studies included in the present review  
 was 374 participants aged between 18 and 89 years (9–16). All  
 participants were patients diagnosed with COPD (GOLD I, II  
 and III classification) (9–16).  
 120

### Devices used by studies

Four of the eight studies used the tri-axial accelerometers inte-  
 125 grated into the smartphone devices to measure PA levels (11,  
 14–16) and two other studies used external tri-axial accelerom-  
 eters through which these parameters were recorded and sent  
 to the smartphone device through Bluetooth<sup>®</sup> connection (9,  
 10). Finally, two studies used the mobile device to control the  
 parameters of a walking training program through a music  
 player software integrated into the smartphone. The software  
 collected the time used at a previously fixed intensity without  
 130 the need to use an accelerometer (12, 13) (Table 1).

### Active lifestyle programs

Only five studies among the eight included in this review  
 performed an active lifestyle program (9–13). The frequency  
 of the programs was 4–7 days a week (9–13) with a duration  
 135 between 4 weeks (9, 10) and 12 months (11, 12). Three stud-  
 ies provided real-time feedback of the PA level (number of  
 steps) through the smartphone device (9–11). Patients were  
 encouraged to achieve their personalized physical activity goal  
 viewing the smartphone screen and receiving motivational text  
 140 messages (9–11). The personalized physical activity goal was  
 adjusted to +20% of baseline measure (11) or fixed to 50%  
 of the physical activity level based on 56 healthy individuals

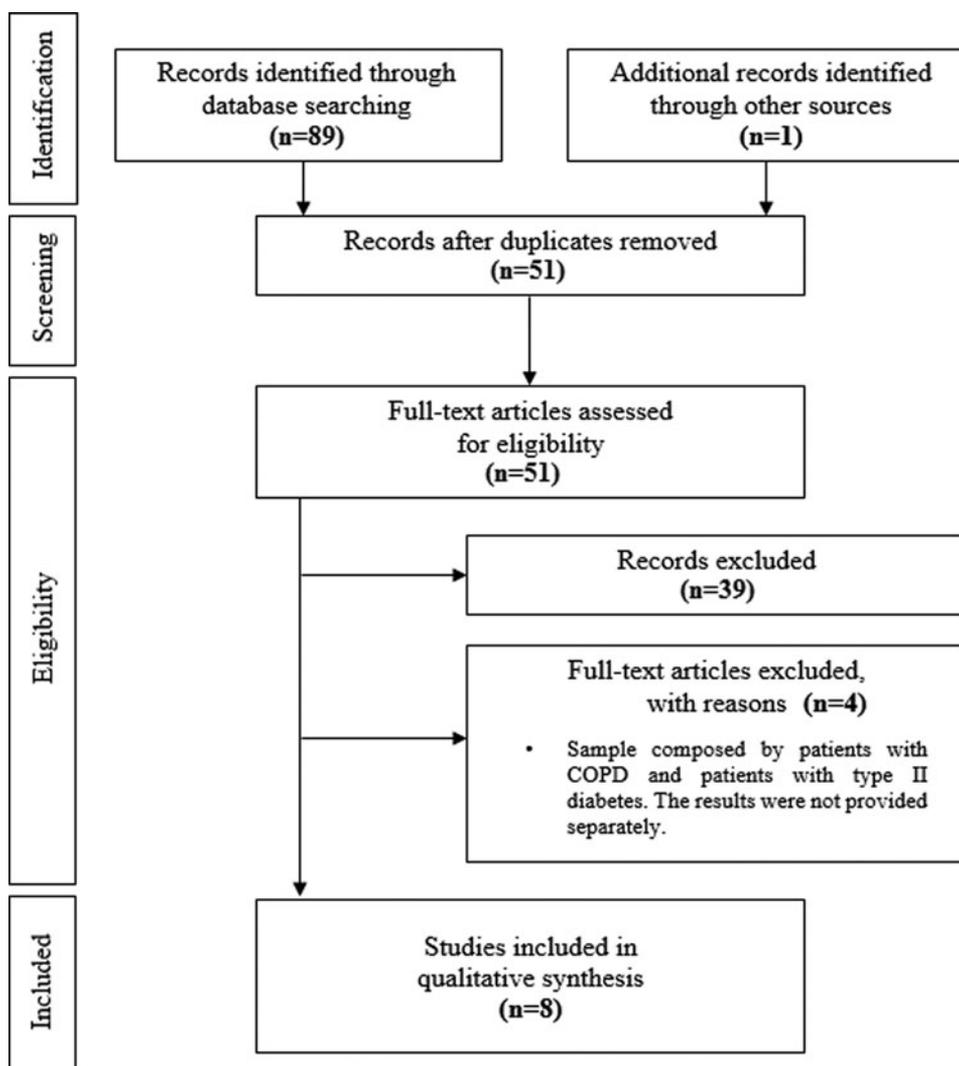


Figure 1. Flow chart of the selection process of the studies.

145 (9, 10). Moreover, two studies (12, 13) designed an exercise  
 150 program using a music player integrated into the smartphone.  
 The subjects were instructed to walk to the rhythm of the  
 music played by the mobile device which was previously set  
 to an equivalent intensity of 80% of the estimated V'O2max  
 through the incremental Shuttle Walk Test (ISWT). The inten-  
 sity was reevaluated every 4 weeks during the first 3 months

(12, 13). When patients pressed the smartphone's music player,  
 the device software recorded the session time. The duration  
 of the training sessions lasted until they could not keep up.  
 Then the subject stopped the playback. The subjects in the  
 control group, consisting of patients with similar character-  
 istics, were verbally asked to perform daily walking at home  
 (Table 2).

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Table 1. Devices used by the studies to control physical activity and exercise.

Author (year)	Smartphone	External device
Liu et al. (2008) (12)	Sony Ericsson K600i (Sony, Tokyo, Japan)	No
Tabak et al. (2014) (9)	HTC P3600/3700 (HTC, New Taipei, Taiwan)	Sensor MTX-W (Xens Technology, Enschede, Holland)
Tabak et al. (2014) (10)	HTC P3600/3700 (HTC, New Taipei, Taiwan)	Sensor MTX-W (Xens Technology, Enschede, Holland)
Wang et al. (2014) (13)	n/m	No
Juen et al. (2014) (16)	Motorola Droid Mini (Motorola, Illinois, USA)	No
	Samsung Galaxy Ace (Samsung, Seoul, South Korea)	
	LG Optimus Zone (LG, Seoul, South Korea)	
Juen et al. (2015) (15)	Samsung S5 (Samsung, Seoul, South Korea)	No
	Samsung Galaxy Ace (Samsung, Seoul, South Korea)	
	Motorola Droid Mini (Motorola, Illinois, USA)	
	Samsung Galaxy Ace (Samsung, Seoul, South Korea)	
	LG Optimus Zone (LG, Seoul, South Korea)	
Vorriink et al. (2016) (11, 14)	HTC Desire A8181 (HTC, New Taipei, Taiwan)	No

n/m, not mentioned.

Table 2. Physical activity programs controlled through a smartphone device.

Author (year)	Sample	Task	Training program			Results
			Intensity	Frequency	Duration	
Tabak et al. (2014) (9)	EG: n18 EG: n14 62.2 (9.7) years (8M) COPD FEV <sub>1</sub> p: 48.7% (16.7)	Objective line (feedback) and motivational messages	Objective line: 50% of PA level based on healthy subjects	≥4 days/week	4 weeks (3 feedback)	EG: Steps/day increased by 5–8% (340–505 steps) ns at second to third week. There was a relationship between adherence and changes in PA level ( $r = 0.62$ ; $p = 0.03$ ) CG: Steps/day decreased 13% (609 steps) ns at fourth week
Tabak et al. (2014) (10)	CG: n16 67.9 (5.7) years (11M) COPD FEV <sub>1</sub> p: 56.4% (10.6)	Objective line (feedback) and motivational messages	Routine care (physiotherapy and medication)	≥4 days/week	4 weeks (3 feedback)	EG: Steps/minute increased after correcting the reactivity effect (13%); 104 steps; $p = 0.008$ CG: No results available
Vorrink et al. (2016) (11)	EG: n102 EG: n62 62 (9) years (42M) COPD FEV <sub>1</sub> p: 59% (20)	Objective line (feedback) and motivational messages	Objective line: +20% of baseline measure	7 days/week	12 months	EG: Steps/day decreased (2.5%); 159 steps; $p < 0.001$ at 12 months CG: No differences between groups in step/day and 6MWT distance were found

Liu et al. (2008) (12)	EG: n30 EG: n24 (71.4 ± 1.7 years) (30M) COPD FEV <sub>1</sub> p: 45.2% ± 3.2 CG: n30 CG: n24 (72.8 ± 1.3 years) (30M) COPD FEV <sub>1</sub> p: 46% ± 2.8 EG: n14 EG: n12 (71.4 ± 1.9 years) (14M) COPD FEV <sub>1</sub> p: 67.5% ± 4.9 CG: Walking	EG: Walk to the rhythm of the music with a smartphone  CG: Walking	80%VO <sub>2</sub> max ISWT	No instruction	7 days/week	12 months (3 months supervision; 9 months self-management)	EG: The time of walking increased by 26.7% (502 seconds) at 3 months ISWT distance increased by 21% (68.4 m) at 12 months CG: ISWT distance tendency towards decrease across time ( $p = 0.07$ )
Wang et al. (2014) (13)	CG: n16 EG: n14 (71.9 ± 2.7 years) (14 H) COPD FEV <sub>1</sub> p: 58.2% ± 4.2	EG: Walk to the rhythm of the music with a smartphone	80%VO <sub>2</sub> max ISWT	No instruction	7 days/week	6 months	EG: ISWT distance increased by 18.3% (58.5 m) at 6 months  CG: ISWT distance decreased by 13% (28.9 m) at 6 months

Data are presented as mean and standard deviation (SD) or standard error of mean (±). n, subject number; M, male; EG, experimental group; CG, control group; <sup>a</sup>final sample after losses during follow-up; COPD, chronic obstructive pulmonary disease; ns, not significant; ISWT, incremental shuttle walking test; FEV<sub>1</sub>, forced expiratory volume in 1 second as percentage; FEV<sub>1</sub>p, forced expiratory volume in 1 second as percentage predicted; 6MWT, 6-minute walking test.

Overall, the included studies reported no significant changes in PA level at the end of the intervention (9–11). Only one study showed improvements in the time of walking, patients were able to improve up to 26.7% (35 minutes of walking) at 12 weeks compared to baseline but a plateau was reached during the self-managed period (the following 9 months). Additionally, Tabak et al. (10) reported a significant increase of 13% (104 steps/minute) in steps per minute at short term (4 weeks) in the experimental group, but this increase was observed only after reducing the baseline by 13.21% (–121.5 steps/minute) in order to correct the reactivity effect caused by the smartphone, i.e. the increase in PA level simply by wearing a pedometer (17). The results in the control group were very similar and no differences were found between groups.

Improvements in exercise capacity were evaluated in three of the included studies (11–13). The results showed improvements of 18.3% (58.5 m) and 21% (68.4 m) compared to baseline (walking distance during ISWT) at 6 and 12 months, respectively (12, 13) and a decreased of 13% (28.9 m) at 6 months was observed in the control group (13). However, the study with the longest intervention (12 months) and highest sample size reported no differences between groups for any analysed variable: steps per day, metabolic equivalent, 6-minute walk test performed on a 10-m course (18), dyspnoea, emotional function, self-control and body mass index. Furthermore, both groups decreased their levels of physical activity in a similar way, indicating no interaction caused by the intervention (11).

Adherence to the use of the mobile device was very high 89–100% (9, 11), interestingly 86% of patients used the mobile device more days than prescribed (9). Adherence to the program moderately correlated with changes in PA levels (9). However, there were patient dropouts in all studies during the follow-up process (9–11). Although most of the participants left for personal and health-related problems, an elevated number of participants (fifteen subjects) dropped out due to technical problems or dissatisfaction with devices (9–12) while another six were excluded because they were not sufficiently compliant to the program (9, 10).

### Precision of smartphone devices

The precision of the smartphone devices (*Motorola Droid Mini*, *Samsung Galaxy Ace*, *LG Optimus Zone*, *Samsung S5*, *HTC Desire A8181*) was compared with validated tri-axial accelerometers (*Zephyr BioHarness*, *Actigraph GT3X*, *SenseWear PRO ArmBand*) (14–16) and assessed through an 8-day recording of everyday activities (14) or by walking ten laps in a ten-metre hallway (15, 16). The devices were placed at L3 level (15, 16) or on the right arm of the subject (14) recording at a sample frequency of 10–60 Hz (14–16).

The authors reported a very high precision of the smartphone devices. The analysis of variance (ANOVA) between each of the signals from the smartphone and the gold standard showed a probability of differences (*F-test*) below  $1.114 \times 10^{-4}$  when the smartphone was ported by one subject walking during ten laps in a ten-metre hallway (15, 16). Additionally, the reliability between the smartphone device (*HTC Desire A8181*) and the validated accelerometer (*BHC0100 SenseWear PRO ArmBand*) when both were ported by 10 subjects during everyday activities

reported a range of  $r = 0.69$ – $0.99$  (Pearson's correlation coefficient) (14). However, several missing data were reported due to problems with the smartphone device (14) (Table 3).

### Discussion

The interventions that facilitate self-monitoring of PA levels have been recommended to improve behavioural changes related to physical inactivity (3). The latest technical innovations in smartphone devices provide additional tools for the self-monitoring of PA levels (6) and the possibility of improving health-related habits in patients with COPD. However, the scientific evidence consulted does not highlight smartphone devices as an effective tool to increase PA levels in patients with COPD. The studies did not report differences in PA levels when compared to the control group that performed routine physiotherapy and medication care (9–11). This can be due to several methodological aspects: (i) authors did not blind participants to study aims during the first week of PA baseline-measurement, (ii) subjects in the control group who were carrying a pedometer were not blinded to the step count display, (iii) the validity and precision of the data collected through their smartphone devices was not verified (9–11), these issues could lead to differences in their results.

Previous studies have observed changes in participants' activity level (steps/day) by the simple way to wearing a pedometer (17, 19), this phenomenon is called reactivity effect and could be minimized when patients are blinded to the study aim or to the step count display (19). Therefore, greater differences could have been found if participants would have been blinded. In this context, Tabak et al. (10) observed a decrease in the number of steps/day in the control group after the second week of intervention which could be explained by a return to baseline values caused by a previous reactivity effect. Thus, after adjusting for the reactivity effect caused by the smartphone device, they reported a 13% increase in PA levels in the experimental group after 4 weeks of intervention.

Although several authors have shown increases in PA levels after performing a short-term intervention (4–12 weeks) using pedometers (20–22), long-term studies (12 months) do not confirm these results (23–25). In a recent study by Moy et al. (24), an increase in the number of steps/day was observed at 4 months compared to the control group and a return to baseline levels after 12 months of intervention. Liu et al. (12) showed improvements in the time of walking after a mobile-home-based program at 12 weeks; however, a plateau was reached during the following 9 months. In the same way, Vorrink et al. (11) did not report changes in PA levels during 12 months of intervention. These results suggest that although small improvements can be observed in short-term interventions, the results for long-term interventions do not appear to be promising.

Although the reported adherence to wearing the smartphone device was significantly high and there was association between program adherence and improvements in PA level, a high rate of data and participants were lost in all studies (9–13). An important issue is the high loss rate (35.4%) caused by problems related to the smartphone device: technical problems, missing data or dissatisfaction with devices (9–12). The development and design of the smartphone application is a fundamental aspect in the

**Table 3.** Precision of mobile devices compared to validated tri-axial accelerometers.

Author (year)	n	App	Smartphone			Tri-axial accelerometer			Results
			Model	Frequency	Placement	Model	Frequency	Placement	
Juen et al. (2014) (16)	1	MoveSense	Motorola Droid Mini Samsung Galaxy Ace LG Optimus Zone	10 Hz	Belt (L3)	Zephyr Bio Harness	10 Hz	Belt (L3)	Probability of differences ( <i>F-test</i> ) in every model of 2.2e-16
Juen et al. (2015) (15)	1	MoveSense	Samsung S5 Samsung Galaxy Ace	60 Hz	Belt (L3)	Actigraph GT3X	60 Hz	Belt (L3)	Confidence interval 0.001 Probability of differences ( <i>F-test</i> ): Samsung S5 (1.114e-4) Samsung Galaxy Ace (9.36e-5)
Vorriink et al. (2016) (14)	10	eHealth	HTC Desire A8181	n/m	Belt	BHC0100 SenseWear PRO ArmBand	n/m	Right arm	Confidence interval 0.001 Association (Pearson correlation): Minimum ( <i>r</i> = 0.69; <i>p</i> < 0.05) Maximum ( <i>r</i> = 0.99; <i>p</i> < 0.05) Mean ( <i>r</i> = 0.88) (SD: 0.12)

App, application; Hz, hertz; SD, standard deviation; n/m, not mentioned.

adherence and subsequent treatment success. Elderly people have difficulty in accurately pressing the buttons of the smartphone screen (26). This issue together with the spacing of the buttons and the size of the devices (14) makes the need to design mobile applications with an interface that allows to minimize the losses due to technical problem or discomfort which could be a strategy to increase adherence and improve PA level in COPD patients. A recent study of Bartlett et al. (27) reported differences between three persuasive-App designs for encouraging PA in patients with COPD, authors informed about the importance of selecting an adequate design approach for encouraging PA levels supporting our previous idea.

The fact that no study aiming at promoting PA levels verified the validity and precision of their devices (9–11) might be biasing the results. Although the authors favour the use of smartphone devices as a valid and precision tool for the objective control of PA in a clinical environment (14–16), in research environments the evidence is still scarce. A recent systematic review (6) indicated that smartphone devices had a precision of 52–100% when carried by a sample composed mostly of overweight and healthy adults. However, these devices often have a high error when used in chronic elderly patients mainly due to their slow speed of walking, i.e. shuffling gait, which sometimes leads to the underestimation of the number of steps (28). Although those studies focused on analysing the validity of these devices reported good to excellent precision in patients with COPD and healthy subjects, these data should be taken with caution due to the methodology used by the authors (14–16). While the accelerometers Actigraph GT3X and SenseWear PRO ArmBand have been previously validated in elderly and patients with COPD (29, 30), to our knowledge the Zephyr BioHarness accelerometer used as gold standard in one study (16) has not been previously validated in a sample with these characteristics, therefore it could be an incorrect use as gold standard. Additionally, the statistical method used to calculate the validity of the smartphone device is incomplete. The ANOVA, used in two of the three studies (15, 16), is a method that yields information only on the differences between means of two sets of data but not on the individual differences of the data (31). Therefore, this test should not be used in isolation to assess the smartphone validity (32). Similarly, Pearson's correlation coefficient used in the last study (14) yields information on the degree of association between two sets of data, however, it does not detect any systematic errors. In this way, it is possible to have two datasets that are highly correlated but not highly repeatable (31, 32). Finally, the sample size of the studies assessing precision between devices was very low (14–16). A concurrent-validity study performed in only one subject in terms of methodological design is incorrect mainly because the inter-individual variability is not considered. A device should be tested in more than one subject to report in terms of validity (31, 32). Thus, data concern to the validity and reliability of smartphone devices for measuring steps per day in patients with COPD is very poor and further high-quality studies are necessary.

### Limitations

Despite a rigorous approach towards data collection and synthesis, this review is not without limitations. Since publication bias

exists (small studies with negative effects are unpublished or less accessible than larger studies) (33), the searches performed in this systematic review may not have introduced the entire grey literature on this topic, so the results must be taken with caution. In any case, the inclusion of grey literature tends to attenuate the effect. Additionally, two researchers assessed the risk of bias and the study selection process. Because there were no discrepancies between them, there was no need for a third opinion.

The promotion of PA through smartphone devices constitutes an increase research field. Only eight studies were included in this systematic review, not all studies used validated smartphone devices and most interventions were performed at short term which could be influencing their results. There is little evidence and its low methodological quality hinders any robust conclusions about its effectiveness. The present review has observed methodological issues which further studies can use to improve their designs and to clarify the effects of smartphone interventions for improving PA levels in patients with COPD.

### Conclusions

The effectiveness of smartphone devices in promoting PA and exercise in patients with COPD is yet too soon to be shown. Future studies of high quality are needed to evaluate the effectiveness of these devices in the promotion of PA and physical exercise before its clinical recommendation.

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### Declaration of interest

The authors declare no conflict of interests with the contents of this manuscript.

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