Long-term efficacy and effectiveness of a behavioural and community-based exercise intervention (Urban Training™) to increase physical activity in patients with COPD. A randomised controlled trial

Ane Arbillaga-Etxarri1,2,3,4, Elena Gimeno-Santos1,2,3,5,6, Anael Barberan-García5,6, Eva Balcells2,7,8, Marta Benet1,2,3, Eulàlia Borrell9,10,11, Nuria Celorrio12, Anna Delgado1,2,3, Carme Jané13, Alicia Marin8,14, Carlos Martín-Cantera10,13,15, Mónica Monteagudo10,15, Nuria Montellà9,10,11, Laura Muñoz16, Pilar Ortega17, Diego A Rodríguez1,2,7,8, Robert Rodríguez-Roisín6, Pere Simonet10,18,19, Pere Torán-Monserrat10,11, Jaume Torrent-Pallicer1,2,3, Pere Vall-Casas20, Jordi Vilaró21, Judith Garcia-Aymerich1,2,3

1 ISGlobal, Barcelona, Spain
2 Pompeu Fabra University (UPF), Barcelona, Spain
3 CIBER Epidemiología y Salud Pública (CIBERESP), Barcelona, Spain
4 Physical Activity and Sports Sciences, Faculty of Psychology and Education, University of Deusto, Donostia-San Sebastián, Spain
5 Respiratory Clinic Institute, Hospital Clinic of Barcelona, Barcelona, Spain
6 Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)-Hospital Clínic, University of Barcelona, Barcelona, Spain
7 Pneumology Department, Hospital del Mar, Institut Hospital del Mar d'Investigacions Mèdiques (IMIM), Barcelona, Spain
8 CIBER Respiratory diseases (CIBERES), Bunyola, Illes Balears, Spain
9 Sant Roc Primary Healthcare Centre, Institut Català de la Salut (ICS), Badalona, Spain
10 Institut Universitari d’Investigació en Atenció Primària Jordi Gol (IDIAP Jordi Gol), Barcelona, Spain.
11 Institute for Health Science Research Germans Trias i Pujol (IGTP), Badalona, Spain.
12 Hospital de Viladecans, Viladecans, Spain
13 Passeig de Sant Joan Primary Healthcare Centre, Institut Català de la Salut (ICS), Barcelona, Spain
14 Pneumology Department. Hospital Germans Trias i Pujol, Badalona, Spain
15 Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Spain.
16 Agency for Health Quality and Assessment of Catalonia (AQuAS), Barcelona, Spain
17 Pneumology Department, Hospital de Mataró, Mataró, Barcelona, Spain
18 Viladecans 2 Primary Healthcare Centre, Institut Català de la Salut (ICS), Viladecans, Spain
19 University of Barcelona, Barcelona, Spain
20 Universitat Internacional de Catalunya (UIC), Barcelona, Spain
21 FCS Blanquerna, Global Research on Wellbeing (GRoW), Ramon Llull University, Barcelona, Spain

Corresponding author: Judith Garcia-Aymerich. Barcelona Institute of Global Health (ISGlobal), Dr. Aiguader 88, 08003 Barcelona, Spain. Tel. +34 932147380; Fax + 34 932147302. E-mail: judith.garcia@isglobal.org

Take home message: Urban Training in COPD increased physical activity after 12 months but not in self-reported non adherent patients

Keywords: chronic obstructive pulmonary disease, urban training, physical activity, behavioural change, active aging, randomised controlled trials, interventions.

Urban Training™ is trademark registered in Spain (ref 3502702/9).
ABSTRACT

There is a need to increase and maintain physical activity in patients with chronic obstructive pulmonary disease (COPD). We assessed the 12 months efficacy and effectiveness of the Urban Training™ intervention on physical activity in COPD patients.

This randomised controlled trial (NCT01897298) allocated 407 COPD patients from primary and hospital settings 1:1 to usual care (n=205) or Urban Training™ (n=202). Urban Training™ consisted of a baseline motivational interview, advice to walk on urban trails designed for COPD patients in outdoor public spaces, and other optional components for feedback, motivation, information and support (pedometer, calendar, physical activity brochure, website, phone text messages, walking groups, and a phone number). Primary outcome: 12 months change in steps/day measured by accelerometer.

Efficacy analysis (with per protocol analysis set, n=233 classified as adherent to the assigned intervention) showed +957 [184 to 1731] steps/day adjusted [95% CI] 12 months difference between Urban Training™ and usual care. Effectiveness analysis (with intention to treat analysis set, n=280 patients completing the study at 12 months including unwilling and self-reported non adherent patients) showed no differences between groups. Leg muscle pain during walks was more frequently reported in Urban Training™ than usual care without differences in any of the other adverse events.

Urban Training™, combining behavioural strategies with unsupervised outdoor walking, was efficacious in increasing physical activity after 12 months in COPD patients, with few safety concerns. However, it was ineffective in the full population including unwilling and self-reported non adherent patients.
INTRODUCTION

Patients with chronic obstructive pulmonary disease (COPD) are substantially less active than their healthy peers [1] and this inactivity has been consistently related to a worse prognosis of the disease [2]. Thus, helping patients to adopt a more active lifestyle is a major goal in COPD management. Unfortunately, how to produce and maintain such behavioural change remains a challenge [3, 4].

Based on the beneficial effects of behavioural strategies on changing physical activity in patients with chronic diseases [5], recent COPD studies have focused on these kinds of interventions. Some of them, including physical activity counselling, pedometers or telecoaching (by computer or mobile technology), have reported increases in physical activity at short-term (up to 4 months) [6–8]. However, few studies followed patients one year or more [6, 9–11] and only one of them showed a sustained increase in physical activity, which was limited to a subset of patients [9]. Thus, one of the main difficulties of interventions to modify physical activity in COPD patients is to achieve a more prolonged long-term effect.

Given that currently available interventions are based mostly on patients’ individual factors (biological and psychological), we argue that customising the interventions to patients’ interpersonal (social support and cultural practices) and environmental (social, built and natural) determinants of physical activity [12] could help to maintain the increase in physical activity at long-term. Indeed, a report from the World Health Organisation suggests that interventions adapted to the local context and/or using the existing social support and community structures are the most successful [13]. In COPD, patients who live with others, walk the dog, take care of grandchildren or have an active dyad have higher physical activity levels than those who do not, regardless of COPD severity and other individual characteristics [14–16], which suggests that interpersonal and environmental factors are key to build on future interventions.

Based on these premises we designed an intervention (so-called Urban Training™) consisting of motivational interviewing, availability of outdoor walking trails specifically designed for exercise training of COPD patients [17] and other support components. We hypothesised that Urban Training™ could encourage COPD patients to increase and maintain at long term their walking activity because walking in public spaces is an extended cultural practice well integrated into the daily lifestyle of our COPD patients - elderly inhabitants of Mediterranean cities [18].
We assessed the efficacy and effectiveness of the Urban Training™ intervention on physical activity level after 12 months follow-up in patients with COPD. Secondary outcomes include severe COPD exacerbations, functional exercise capacity, body composition, health-related quality of life, anxiety and depression.

METHODS

Study patients
Details on patients’ recruitment, randomisation and blinding (table S1) are provided in the online supplementary material. Briefly, we selected all subjects with a diagnosis of COPD according to the American Thoracic Society and European Respiratory Society (ATS/ERS) recommendations (post-bronchodilator forced expiratory volume in the first second (FEV₁) to forced vital capacity (FVC) ratio <0.70) [19] who were seen in any of the participating 33 primary care and five hospital health centres from five Catalan seaside municipalities. We excluded patients with severe or life-threatening comorbidities, or those clinically unstable. The Ethics Committees of all participating institutions approved the study, along with the request for complete information exemption from patients, and all participants provided written informed consent.

Study design and interventions
This is a prospective, multicentre, parallel-group, randomised controlled trial registered at clinicaltrials.gov (NCT01897298) and reported according to the 2010 CONSORT statement [20] and its extension for non-pharmacological interventions [21]. Patients were allocated 1:1 to the Urban Training™ intervention or usual care groups using random block sizes of 6, 8 and 10. The study consisted of four visits (figure 1): enrolment and baseline data collection; additional baseline data collection, randomisation and intervention one week later; 12 months data collection; and additional 12 months data collection one week thereafter.

Both groups received the usual standardised pharmacological and/or non-pharmacological treatment for COPD, including pulmonary rehabilitation, to the discretion of their physician and without any intervention by the research team.

Usual care: we provided patients with general health counselling and the European Lung Foundation (ELF) information brochure of "Living an active life with COPD" which includes the recommendation to complete at least 30 min of moderate physical activity at least 5 days per week [22].
The Urban Training\textsuperscript{TM} intervention consisted of the following six components (figure 2) detailed in the online supplementary material. (1) At baseline, a respiratory physiotherapist adequately trained in behavioural strategies used motivational interviewing techniques \cite{23}, integrated with a stage-matched approach \cite{24}, for a maximum of one hour. The interview was centred on empathy, reflective listening, affirmation, and addressed patients’ resistances (personal difficulties, barriers and limitations) to elicit a behavioural change. Information on the remaining components of the intervention (see below) was provided during this interview. During the follow-up period, the physiotherapist administered up to four phone calls lasting 5-10 min to maintain motivation, depending on patients’ self-efficacy and stage of change. (2) Participants received a dossier containing various maps of Urban Training\textsuperscript{TM} walking trails, previously validated \cite{17}, according to their mobility options and preferences. Concisely, trails of different intensities (low, moderate or high, combining urban elements of varying intensity [stairs, ramps and types of surfacing]) were available in several walkable public spaces (boulevards, beaches and parks) of the five municipalities. The physiotherapist provided a complete explanation of trails characteristics and instructed patients to train following the FITT principle (Frequency, Intensity, Time, and Type) \cite{25}. Each patient was advised to start with a trail of intensity appropriate to his/her baseline dyspnoea and 6-min walk distance (6MWD), and instructed how to increase progressively the volume (number of walks per day on the same trail) and/or the intensity of the trails during the following 12 months according to their symptoms and motivation (figure S1). In all cases, the instructions were to walk at least one trail per day at least 5 days per week, at a pace reaching a dyspnoea Borg scale between 4 and 6 \cite{26}. (3) Patients were provided with both a pedometer and a personalised calendar to monitor their physical activity and keep motivation. (4) Patients also received the same ELF’s information brochure as the usual care group and the link to the project website (http://www.entrenament-urba.cat/). They were requested to provide a personal cell phone number where they would receive phone text messages every 2 weeks with educational or motivational messages. (5) Once per month during the follow-up period, patients could join a walking group for walking a trail accompanied by an experienced physical activity trainer. (6) Patients were provided a phone number to contact the physiotherapists for any questions during follow-up. Of note, the Urban Training\textsuperscript{TM} intervention was proposed as a supplement to the physical activities of patients’ daily life and in no case as a substitute activity.

\textbf{Procedures}

Full details and references on study procedures and quality control are available in the online supplementary material. Briefly, we obtained both at baseline and at 12 months the following data
from all patients using standardised procedures: (i) socio-demographic variables, smoking status, the modified Medical Research Council dyspnoea scale (mMRC), the Clinical COPD Questionnaire (CCQ), the COPD Assessment Test (CAT), the Hospital Anxiety and Depression scale (HAD), and cognitive impairment (by the Phototest) by an interviewer-administered questionnaire; (ii) the 6-min walk distance (6MWD) test; (iii) weight, height, body mass index (BMI) and fat free mass index (FFMI) by physical examination and bioelectrical impedance; (iv) FEV$_1$ and FVC by spirometry before and after bronchodilator; (v) comorbidities, pharmacological therapy and the number and severity of COPD exacerbations in the previous 12 months; (vi) physical activity by the Dynaport accelerometer (McRoberts BV, The Hague, The Netherlands) previously validated for COPD [27, 28]. A valid physical activity measurement was defined as a minimum of 3 days with at least 8 h of wearing time within waking hours [29]; compliance with the accelerometer was excellent (at baseline all patients fulfilled this criterion, median wearing days was 7 [range 3 to 7], and median recording time was 14.9 h [range 11.1 to 15, of 15 h maximum from 7 am to 10 pm]; at final visit 6 patients out of 286 (2%) did not fulfill the criterion of wearing time per day and were consequently excluded, among included patients, median wearing days was 7 [range 4 to 7], and median recording time was 14.8 h [range 10.2 to 15]; all patients included at least one weekend day both at baseline and final visit); and (vii) physical activity experience by the Clinical-PROactive Physical Activity (C-PPAC). Additionally, only at 12 months, patients answered a questionnaire about satisfaction with the study components and any potential adverse events actually experienced during or after walks in the previous 12 months. Finally, the physiotherapists administering both interventions noted down patients’ spontaneous report of unwillingness to follow the instructions (e.g. walking at least 5 days per week at least 30 min per day in the usual care group or walking the Urban Training™ trails in the Urban Training™ group) at the baseline visit, as well as the spontaneous report of non-adherence (i.e., not having followed the instructions) at the 12 months visit.

**Study outcomes**

The primary outcome was the change in number of steps per day from baseline to 12 month follow-up. Secondary outcomes were having any severe COPD exacerbation (leading to hospital or emergency-room admission) during the 12 month follow-up; and the 12 month changes in 6MWD, BMI, FFMI, CAT and CCQ total scores, and HAD-anxiety and -depression scores. Exploratory outcomes were the 12 month changes in Phototest score, and total, amount and difficulty C-PPAC scores.
**Statistical Analysis**

To detect a difference of 775 steps per day (primary outcome) between groups (based on previous research about the effects of behavioural interventions in the elderly) [30], with a two-sided \( \alpha=0.05 \) and a power of 80%, assuming a standard deviation of steps per day of 3000 and a correlation between baseline and final steps \( \geq 0.7 \) (based on own data in COPD patients), a sample size of 142 patients per group was necessary. To account for a 30% drop out rate during follow-up, we planned to recruit 202 participants per group (404 in total).

Pre-specified efficacy and effectiveness were analysed with *per protocol* (PP) and intention to treat (ITT) analysis sets, respectively. Briefly, ITT was defined as all randomised patients who completed the study at 12 months and provided a valid record of physical activity while PP was the subset of ITT who were classified as adherent to their corresponding intervention. Adherence was obtained from the interviews. We classified as ‘non adherent’ patients who (i) spontaneously reported at baseline that they were unwilling to follow any of the instructions, or (ii) spontaneously reported at the 12 months visit that they had not been adherent to the study protocol (see Procedures). Remaining patients were labelled as ‘adherent’. To test effectiveness, we built linear or logistic regression models, using the change from baseline to 12 month follow-up as the outcome, the intervention group as the main exposure variable and baseline levels of the corresponding outcome as a covariate (to account for individual differences in baseline levels). In efficacy analysis, we additionally adjusted for the variables related to adherence, since previous literature had shown this adjustment may reduce the selection bias produced by a differential distribution of the reasons that moved participants to be adherent [31].

*Post hoc* analyses included stratification of efficacy results according to subgroups defined by baseline patient characteristics (see online supplementary material). All analyses were redone using repeated measures ANOVA instead of linear regression. Safety analysis set included patients answering the adverse events questions at 12 months. All analyses were conducted with Stata 14.0 (StataCorp, College Station, TX, USA).

**RESULTS**

Between 30 October 2013 and 29 January 2016, 552 stable COPD patients were assessed for eligibility and 407 patients underwent randomisation and received the corresponding intervention (figure 3, table S2). A total of 280 patients (69% of the initial study population) completed the final
visit and constituted the ITT analysis set (table S3). These patients had higher physical activity and functional exercise capacity levels at baseline than those who did not participate in the final visit, both in the usual care and Urban Training™ group (tables S3 and S4). Among followed patients, 233 patients (83% of the ITT) did not report unwillingness or non-adherence to the corresponding intervention and accordingly constituted the PP analysis set. Patients who spontaneously reported unwillingness or non-adherence to the corresponding intervention had lower FEV₁/FVC, were most often a current smoker, had diabetes in a higher proportion, and showed higher values in HAD-depression score than the rest of the patients (table S5).

Baseline characteristics were similar in the PP and ITT analysis sets and between two intervention groups (tables 1, 2 and 3). Patients in the PP analysis set were mostly male (88%), mean (SD) aged 69 (8) years, had mild-to-very severe COPD (FEV₁ 58 (17) % predicted), and preserved functional exercise capacity (505 (81) m in the 6MWD), and walked a mean of 8039 (3964) steps per day.

After 12 months, according to the PP analysis set (efficacy analysis), patients under the usual care group did not change their physical activity whereas those in the Urban Training™ group increased it by 816 steps (figure 4, table 2). In the analysis adjusted by factors independently related to adherence (FEV₁/FVC, smoking, diabetes and HAD-depression score, table S6) and steps at baseline, the adjusted difference in steps between the Urban Training™ and usual care groups was of 957 (95% CI 184 to 1731) (figure 4, table 2). There were no differences between intervention groups in any of the secondary outcomes or in cognitive impairment (exploratory outcome) (table 2). Positive changes (statistically significant better values) of physical activity experience were observed in the intervention group for the total, amount and difficulty scores. Stratification of efficacy results showed no significant differences between groups (figure 5). The adjusted difference in steps at 12 months was 959 (-72 to 1989) for patients with mild-to-moderate COPD and 383 (-860 to 1626) for patients with severe-to-very severe COPD. Patients with higher physical activity levels at baseline had higher increase during follow-up (adjusted difference in steps 1268 (158 to 2379) versus 704 (-429 to 1837)), although there was no sign of statistical interaction.

After 12 months, in the ITT analysis set (effectiveness analysis), there were no differences between intervention groups in any of the primary, secondary or exploratory outcomes (figure 4, table 3). Analyses with repeated measures ANOVA provided very similar results.
Patients in the Urban Training™ group reported higher frequency of lower extremity muscle pain during walks than patients in the usual care group (38 vs. 25%, p=0.031) without differences in any of the remaining adverse events (table 4).

Of the 132 patients of the intervention group participating in the follow-up visit, 70%, 87% and 90% respectively used the trails maps, calendars and pedometers, 31% participated at least once in the walking groups, 41% contacted the researchers via phone during follow-up, and 2% visited the study website. At the 12 months visit, 65% of patients delivered the calendars, and the mean (SD) of fulfilled months was 9 (4). Satisfaction with the study and study staff was very high (mean satisfaction ≥9 in a score ranging from 0 to 10) both in the usual care and Urban Training™ groups (table S7). Satisfaction with the study components in the Urban Training™ group was high or very high: 9.1 (1.6) for trail maps, 9.1 (1.7) for calendars, 9.0 (1.8) for pedometers, 7.5 (2.8) for walking groups, 9.4 (1.0) for phone text messages, 9.5 (1.4) for study phone, and 8.7 (2.3) for study website (table S7).

**DISCUSSION**

This randomised controlled trial showed that the Urban Training™ intervention is more efficacious than usual care in increasing physical activity after 12 months in patients with COPD, with few safety concerns. However, the intervention was not effective according to results with the ITT analysis set, suggesting it improves physical activity only in willing, adherent patients. No effect of the intervention was found on severe COPD exacerbations, functional exercise capacity, body composition, health-related quality of life, anxiety or depression, in either analysis approach.

The main finding of this study is that the Urban Training™ intervention increased physical activity in COPD patients (i) at long-term (after 12 months) and (ii) in a large scale of magnitude. Most studies testing the effects of behavioural physical activity interventions in COPD patients have successfully resulted in positive effects only at short-term (≈3 months) [6, 7], and only one reported a long-term increase that was restricted to a post hoc subgroup analysis [9]. The examination of the content of previous and current successful physical activity interventions allows hypothesising that the combination of motivational interviews, pedometers and diaries/calendars may be key for the long-term effect. The ≈900 steps/day increase observed in the Urban Training™ group lies within the defined limits of the minimal important difference in COPD patients (between 600 and 1100 steps/day) [32] and is higher than the 255 steps/day change observed in the long-term physical activity COPD trial referred to above and the 808 steps/day mean change identified in a review of pedometer-based physical activity interventions in older adults (including follow-ups between 2
weeks and 23 months) [30]. Our contention is that customising walking trails to patients’ individual (e.g., exercise capacity and motivation), interpersonal (e.g., social support and cultural habit of walking) and environmental factors (e.g., lack of steep stairs in walking trails and home proximity or bus access to them) may have contributed to the long-term duration and large magnitude of the intervention effect. Therefore, Urban Training™ appears as an attractive intervention potentially feasible due to its simplicity and reduced burden.

Potential harms of the Urban Training™ intervention need to be discussed. First, patients in the Urban Training™ group reported lower extremity muscle pain in a higher proportion than patients in the usual care group without differences in lower extremity joint pain or other adverse events. This could be attributed to the fact that the Urban Training™ walking trails included ramps and stairs that may promote eccentric work of the leg muscles which may result in muscle but not joint pain [33]. Second, although a recent trial has reported an acute increase in respiratory symptoms after walking in urban polluted areas [34], we did not collect information on these potential adverse events because (i) most of the trails were located in green or blue areas and (ii) residential air pollution exposure was comparable between groups by design. Finally, the fact that patients included in the ITT but not in the per protocol analysis set experienced higher decline in physical activity than those in the per protocol analysis set could suggest that the intervention was harmful for them (which could have made them non adherent). However, this is not supported by the fact that they experienced the same frequency of adverse events during or after walks than the rest of the Urban Training™ group and that a natural decline of physical activity levels has been previously observed in the absence of interventions [35, 36].

The Urban Training™ intervention did not improve most of the secondary and exploratory outcomes. The lack of effect on functional exercise capacity was unexpected since, based on the physiological response generated when walking the trails during the validation study [17], we hypothesised that the intervention could produce effects similar to those of typical exercise training interventions. However, the lack of daily supervision when walking the trails may have hindered patients to regularly achieve a minimum training intensity (e.g., walking at a pace that generates dyspnoea or fatigue scores between 4 and 6 in the Borg scale). Indeed, a previous intervention that increased both physical activity and functional exercise capacity after 3 months had included a close patient supervision by telecoaching [8]. The remaining secondary outcomes (severe COPD exacerbations, body composition, quality of life, anxiety or depression) were not primarily targeted by any of the Urban Training™ components and their improvement was expected only as a result of the expected increase in physical activity. Based on our results, it is tempting to speculate that the
improvement in physical activity levels would need to be sustained for a period longer than 12 months in order to result in measurable changes in the other health outcomes. Another explanation is that our patients already had a relatively good health status as per their values in COPD admissions, quality of life, anxiety or depression; therefore they had little room for improvement. Finally, the Urban Training™ intervention improved patients’ experience of their physical activity (exploratory outcome), in both the amount and difficulty dimensions, which supports that this concept provides complementary information to other related constructs like health-related quality of life or exercise-induced symptoms [37].

The findings of this study are encouraging for COPD research and its management as well as for physical activity promotion in other populations. First, our findings highlight the consideration of patients’ interpersonal (social and cultural) factors and environment when designing further interventions. From the clinical viewpoint, this approach may appear more feasible than others strongly based on technology solutions, particularly in countries with limited healthcare budgets. Second, our study supports the involvement of behaviour specialists in the design and administration of physical activity interventions or an equivalent acquisition of knowledge on behavioural techniques by health professionals who generally exhibit a lack of training in behavioural change techniques [38, 39]. Finally, at the city level, interventions such as the Urban Training™ may contribute towards amortising the investment in public space (otherwise underused during certain times of the day) thus improving its sustainability. In fact, a close collaboration between health professionals and local governments has been promoted for example in the WHO Healthy Cities project and is likely to result in social, economic and health benefits for all [40].

A limitation of the current study is that we defined adherence, and consequently the per protocol analysis set, according to patients report. It is of note that we defined ‘non adherence’ from patients report and ‘adherence’ otherwise. Thus, the ITT analysis set included, in the first place, patients who at baseline spontaneously reported unwillingness to undergo the intervention they had been assigned to. These patients are most often excluded from clinical trials but we decided to keep them (and analyse their data) in order to provide effectiveness estimates. Secondly, the ITT analysis set included also patients who reported at the 12 months visit that they had not been adherent to the intervention they had been assigned to, which in most cases, was due to a family situation (e.g., surgery in the partner). Again, some of these patients would be excluded in traditional clinical trials. Finally, the per protocol analysis set included patients who did not make any spontaneous report in relation to their willingness or adherence, and likely comprised both adherent and non adherent patients thus underestimating the efficacy of Urban Training™.
A second limitation is the apparent discrepancy between efficacy and effectiveness results. Of note, both approaches were pre-specified in our analysis plan given previous reports in the literature about poor adherence to behavioural interventions [9, 41] and the well-known argument against ITT analysis that it underestimates intervention effects in situations of non-adherence [42]. The absence of effectiveness of Urban Training™ suggests the need for research to understand, and eventually identify ways to act on, the determinants of willingness and adherence to behavioural interventions in COPD. In our study, airflow limitation, smoking habits, diabetes and depression symptoms, but not physical activity levels, were related to unwillingness or non-adherence, although collected information was not complete and there are no previous data on these issues to compare with. It has been disputed, also, that the adherence to a given intervention may dramatically change after patients learn of trial’s findings, making the ITT effect estimation different from the actual effectiveness of the intervention in the community [43]. From a clinical viewpoint, patients who are willing to take an intervention such as Urban Training™ may be more interested in per protocol than in ITT effect.

Other shortcomings include the lack of intermediate assessments during the follow-up period, which could have given feedback to patients and would have allowed researchers to distinguish between short- and long-term effects. Also, the fact that ≈30% of patients were lost to follow-up, a comparable figure to previous studies [6, 9, 10], could have biased our results. Finally, our patients exhibited higher physical activity levels than that observed in previous studies [44–47] which could be considered a limitation of our research. However, a comparison of the clinical characteristics and physical activity levels of the patients included in the present and previous studies shows differences in physical activity both between countries (for the same severity of COPD) and within countries (for different severity stages and/or recruitment settings). We consider that, given that the Urban Training™ intervention was designed in a region characterised by relatively high social support, the cultural habit of walking, pedestrian accessibility to most outdoor public spaces, and a mild climate, most Euro-Mediterranean cities would find it feasible. However, other geographic areas would need to conduct a proper adaptation to their social, cultural and environmental characteristics.

Strengths of the study are the novelty of customising the behavioural intervention to patients’ interpersonal characteristics and environment, the large sample size, and the measure of physical activity using an accelerometer. In addition, patients were recruited from primary care and hospitals of several municipalities, with barely any exclusion criteria, and diversity in relevant socio-
demographic, lifestyle and clinical parameters, which make our results generalisable to a wide COPD population. The lack of differences in efficacy when patients were stratified according to their baseline features further supports generalisability of our findings. With regard to the intervention, its simplicity and reduced burden make it possible to adapt it to other populations, including those with other chronic diseases, and/or settings.

In conclusion, the Urban Training™ intervention, combining behavioural strategies with unsupervised outdoor walking, was efficacious in increasing physical activity after 12 months in COPD patients. However, it was ineffective in the full population including unwilling and self-reported non adherent patients. The Urban Training™ intervention had no effect on severe COPD exacerbations, functional exercise capacity, body composition, health-related quality of life, anxiety, or depression.
ACKNOWLEDGMENTS
The authors thank all the technical staff of the Respiratory Diagnostic Centre from Hospital Clínic de Barcelona; Laura Gutierrez, Concepción Ballano, Anna Rodó-Pin, Bea Valeiro, Mireia Admetlló and Sergi Pascual from the Pneumology Department of Hospital del Mar; Alicia Francoso Vicente and Júlia Moraleda Hidalgo from the Pneumology Department of Hospital Germans Trias i Pujol; and Marta Delicado and the Administration Department from the Viladecans 2 Primary care centre for their contribution to conduct the study.

FINANTIAL SUPPORT
The study was funded by grants from Fondo de Investigación Sanitaria, Instituto de Salud Carlos III (ISCIII, PI11/01283 and PI14/0419), integrated into Plan Estatal I+D+I 2013-2016 and co-funded by ISCIII-Subdirección General de Evaluación y Fomento de la Investigación and Fondo Europeo de Desarrollo Regional (FEDER); Sociedad Española de Neumología y Cirugía Torácica (SEPAR, 147/2011 and 201/2011), Societat Catalana de Pneumologia (Ajuts al millor projecte en fisioteràpia respiratòria 2013). ISGlobal is a member of the CERCA Programme, Generalitat de Catalunya. Anael Barberan-Garcia had personal funding from AGAUR 2014-SGR-661, Catalan Government. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

CONTRIBUTORS
AAE and JGA prepared the first draft of the paper; AAE, MB and JGA had full access to the data and carried out statistical analysis. AAE, EGS, ABG, EBo, NC, AD, CJ, AM, CMC, MM, NM, PO, DAR, PS, PTM, JTP, and JGA contributed to data collection and coordination. All authors (i) provided substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work, (ii) revised the manuscript for important intellectual content, (iii) approved the final version, and (iv) agreed to be accountable for all aspects of the work. JGA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
DECLARATION OF INTERESTS

RRR reports receipt of grants/research support from Menarini and Almirall (not related to this study), lectured for Novartis and Takeda, and consulted with Boehringer Ingelheim, Pearl Therapeutics, and TEVA.

PS reports lecture fees from Menarini, Gebro, TEVA, Boehringer Ingelheim, Rovi, AstraZeneca, and GSK (not related with this study).

JGA’s institution has received consulting and lecture fees from AstraZeneca (not related to this study); she has received lecture fees from Esteve and Chiesi (not related to this study).

AAE, EGS, ABG, EBa, MB, EBo, NC, AD, CJ, AM, CMC, MM, NM, LM, PO, DAR, PTM, JTP, PVC, and JV have nothing to disclose.
REFERENCES

1. Vorrink SN, Kort HS, Troosters T, Lammers JJ. Level of daily physical activity in individuals with COPD compared with healthy controls. *Respir Res* 2011; 12: 33.

2. Gimeno-Santos E, Frei A, Steurer-Stey C, et al. Determinants and outcomes of physical activity in patients with COPD: a systematic review. *Thorax* 2014; 69: 731–9.

3. Leidy NK, Kimel M, Ajagbe L, Kim K, Hamilton A, Becker K. Designing trials of behavioral interventions to increase physical activity in patients with COPD: insights from the chronic disease literature. *Respir Med* 2014; 108: 472–81.

4. Singh S. One Step at a Time. Lifestyle Physical Activity Interventions. *Ann Am Thorac Soc* 2016;13(5):586–7.

5. Conn VS, Hafdahl AR, Brown SA, Brown LM. Meta-analysis of patient education interventions to increase physical activity among chronically ill adults. *Patient Educ Couns* 2008; 70: 157–72.

6. Lahham A, McDonald CF, Holland AE. Exercise training alone or with the addition of activity counseling improves physical activity levels in COPD: a systematic review and meta-analysis of randomized controlled trials. *Int J Chron Obstruct Pulmon Dis* 2016; 11: 3121–36.

7. Mantoani LC, Rubio N, McKinstry B, MacNee W, Rabinovich RA. Interventions to modify physical activity in patients with COPD: a systematic review. *Eur Respir J* 2016; 48: 69–81.

8. Demeyer H, Louvaris Z, Frei A, et al. Mr Papp PROactive study group and the PROactive consortium. Physical activity is increased by a 12-week semiautomated telecoaching programme in patients with COPD: a multicentre randomised controlled trial. *Thorax* 2017 May;72(5):415-423.

9. Altenburg WA, ten Hacken NHT, Bossenbroek L, Kerstjens HAM, de Greef MHG, Wempe JB. Short- and long-term effects of a physical activity counselling programme in COPD: a randomized controlled trial. *Respir Med* 2015; 109: 112–21.

10. Coultas DB, Jackson BE, Russo R, et al. A Lifestyle Physical Activity Intervention for Patients with Chronic Obstructive Pulmonary Disease. A Randomized Controlled Trial. *Ann Am Thorac Soc* 2016;13(5):617–26.

11. Moy ML, Martinez CH, Kadri R, et al. Long-Term Effects of an Internet-Mediated Pedometer-Based Walking Program for Chronic Obstructive Pulmonary Disease: Randomized Controlled Trial. *J Med Internet Res* 2016; 18: e215.

12. Bauman AE, Reis RS, Sallis JF, Wells JC, Loos RJJ, Martin BW. Correlates of physical activity:
why are some people physically active and others not? *Lancet* 2012; 380: 258–71.

13. WHO | Interventions on Diet and Physical Activity: What Works. *WHO* 2015.

14. Arbillaga-Etxarri A, Gimeno-Santos E, Barberan-Garcia A, *et al.* Socio-environmental correlates of physical activity in patients with chronic obstructive pulmonary disease (COPD). *Thorax* 2017; 72(9):796-802.

15. Mesquita R, Nakken N, Janssen DJA, *et al.* Activity Levels and Exercise Motivation in Patients With COPD and Their Resident Loved Ones. *Chest* 2017; 151: 1028–38.

16. Chen Z, Fan VS, Belza B, Pike K, Nguyen HQ. Association between Social Support and Self-Care Behaviors in Adults with Chronic Obstructive Pulmonary Disease. *Ann Am Thorac Soc* 2017; 14: 1419–27.

17. Arbillaga-Etxarri A, Torrent-Pallicer J, Gimeno-Santos E, *et al.* Validation of Walking Trails for the Urban Training™ of Chronic Obstructive Pulmonary Disease Patients. *PLoS One* 2016; 11: e0146705.

18. Palacios-Ceña D, Alonso-Blanco C, Jiménez-Garcia R, *et al.* Time trends in leisure time physical activity and physical fitness in elderly people: 20 year follow-up of the Spanish population national health survey (1987-2006). *BMC Public Health* 2011; 11: 799.

19. Celli BR, MacNee W, Agusti A, *et al.* Standards for the diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper. *Eur Respir J* 2004; 23: 932–46.

20. Hopewell S, Clarke M, Moher D, *et al.* CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008; 371: 281–3.

21. Boutron I, Moher D, Altman DG, *et al.* Methods and Processes of the CONSORT Group: Example of an Extension for Trials Assessing Nonpharmacologic Treatments. *Ann Intern Med* 2008; 148: W-60.

22. European Lung Foundation - ELF. Factsheets. Living an active life with COPD. http://www.europeanlung.org/en/lung-disease-and-information/factsheets/english. Data last accessed: May 4 2016.

23. Miller WR, William R, Rollnick S. Motivational interviewing: preparing people for change. Guilford Press, 2002.

24. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997; 12: 38–48.

25. Pescatello L, Arena R, Riebe D TP. ACSM’s Guidelines for Exercise Testing and Prescription.
26. Spruit MA, Singh SJ, Garvey C, et al. An official American thoracic society/European respiratory society statement: Key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med* 2013;188(8).

27. Rabinovich RA, Louvaris Z, Raste Y, et al. Validity of physical activity monitors during daily life in patients with COPD. *Eur Respir J* 2013;42(5):1205–15.

28. Van Remoortel H, Raste Y, Louvaris Z, et al. Validity of six activity monitors in chronic obstructive pulmonary disease: a comparison with indirect calorimetry. *PLoS One* 2012;7(6):e39198.

29. Demeyer H, Burtin C, Van Remoortel H, et al. Standardizing the analysis of physical activity in patients with COPD following a pulmonary rehabilitation program. *Chest* 2014;146(2):318–27.

30. Tudor-Locke C, Craig CL, Aoyagi Y, et al. How many steps/day are enough? For older adults and special populations. *Int J Behav Nutr Phys Act* 2011; 8: 80.

31. Murray EJ, Hernán MA. Adherence adjustment in the Coronary Drug Project: A call for better per-protocol effect estimates in randomized trials. *Clin Trials* 2016;13(4):372–8.

32. Demeyer H, Burtin C, Hornikx M, et al. The Minimal Important Difference in Physical Activity in Patients with COPD. *PLoS One* 2016; 11: e0154587.

33. MacMillan NJ, Kapchinsky S, Konokhova Y, et al. Eccentric Ergometer Training Promotes Locomotor Muscle Strength but Not Mitochondrial Adaptation in Patients with Severe Chronic Obstructive Pulmonary Disease. *Front Physio* 2017;8:114.

34. Sinharay R, Gong J, Barratt B, et al. Respiratory and cardiovascular responses to walking down a traffic-polluted road compared with walking in a traffic-free area in participants aged 60 years and older with chronic lung or heart disease and age-matched healthy controls: a randomised, crossover study. *Lancet* 2017 Dec 5. pii: S0140-6736(17)32643-0.

35. Waschki B, Kirsten AM, Holz O, et al. Disease Progression and Changes in Physical Activity in Patients with Chronic Obstructive Pulmonary Disease. *Am. J. Respir. Crit. Care Med.* 2015; 192: 295–306.

36. Clarenbach CF, Sievi NA, Haile SR, et al. Determinants of annual change in physical activity in COPD. *Respirology* 2017; 22: 1133–1139.

37. Gimeno-Santos E, Raste Y, Demeyer H, et al. The PROactive instruments to measure physical...
activity in patients with chronic obstructive pulmonary disease. *Eur Respir J* 2015; 46: 988–1000.

38. Blackmore C, Johnson-Warrington VL, Williams JE, *et al.* Development of a training program to support health care professionals to deliver the SPACE for COPD self-management program. *Int J Chron Obstruct Pulmon Dis* 2017; 12: 1669–81.

39. Khan A, Dickens AP, Adab P, Jordan RE. Self-management behaviour and support among primary care COPD patients: cross-sectional analysis of data from the Birmingham Chronic Obstructive Pulmonary Disease Cohort. *NPJ Prim Care Respir Med* 2017; 27(1):46.

40. Rydin Y, Bleahu A, Davies M, *et al.* Shaping cities for health: complexity and the planning of urban environments in the 21st century. *Lancet* 2012; 379: 2079–108.

41. Bourbeau J, Bartlett SJ. Patient adherence in COPD. *Thorax* 2008; 63: 831–838.

42. Hernán MA, Hernández-Díaz S. Beyond the intention-to-treat in comparative effectiveness research. *Clin. Trials* 2012 Feb;9(1):48-55.

43. Hernán MA, Robins JM. Per-Protocol Analyses of Pragmatic Trials. *N Engl J Med* 2017; 377: 1391–8.

44. Vorrink SNW, Kort HSM, Troosters T, Zanen P, Lammers JJ. Efficacy of an mHealth intervention to stimulate physical activity in COPD patients after pulmonary rehabilitation. *Eur. Respir. J.* 2016; 48: 1019–1029.

45. Burtin C, Langer D, van Remoortel H, *et al.* Physical Activity Counselling during Pulmonary Rehabilitation in Patients with COPD: A Randomised Controlled Trial. *PLoS One* 2015; 10: e0144989.

46. Watz H, Waschki B, Boehme C, Claussen M, Meyer T, Magnussen H. Extrapulmonary effects of chronic obstructive pulmonary disease on physical activity: A cross-sectional study. *Am. J. Respir. Crit. Care Med.* 2008; 177: 743–751.

47. Egan C, Deering BM, Blake C, *et al.* Short term and long term effects of pulmonary rehabilitation on physical activity in COPD. *Respir. Med.* 2012; 106: 1671–1679.
Table 1. Baseline characteristics of *per protocol* and intention to treat analysis sets.

|                         | Per protocol analysis set | Intention to treat analysis set |
|-------------------------|---------------------------|-------------------------------|
|                         | Usual care n=145*         | Urban Training n=88*          | All n=233                      |
|                         | m (SD) / n (%)            | m (SD) / n (%)                | m (SD) / n (%)                 |
| Age (years)             | 69 (8)                    | 69 (9)                        | 69 (8)                         |
| Female / male           | 17 (12) / 128 (88)        | 12 (14) / 76 (86)             | 29 (12) / 204 (88)             |
| Active smoker           | 29 (20)                   | 20 (22)                       | 49 (21)                        |
| Low socio-economic status† | 105 (73)                | 64 (73)                       | 169 (73)                       |
| Active worker           | 16 (12)                   | 13 (15)                       | 29 (13)                        |
| Dyspnoea (mMRC grade, 0-4) | 1 (1)                    | 1 (1)                         | 1 (1)                          |
| Post-bronchodilator FEV₁ (% pred.) | 58 (18)      | 57 (16)                       | 58 (17)                        |
| Post-bronchodilator FEV₁/FVC ratio | 0.55 (0.12)  | 0.54 (0.10)                   | 0.54 (0.12)                    |
| Airflow limitation (% mild / moderate / severe / very severe)‡ | 10 / 55 / 30 / 5 | 8 / 57 / 31 / 4 | 9 / 55 / 31 / 5 |
| GOLD 2017 assessment (% A / B / C / D)† | 37 / 44 / 7 / 12 | 35 / 52 / 0 / 13 | 36 / 47 / 4 / 13 |
| Cardiovascular disease‡ | 88 (61)                   | 52 (60)                       | 140 (60)                       |
| Diabetes mellitus³      | 37 (26)                   | 25 (29)                       | 62 (27)                        |
| Musculoskeletal diseases§ | 55 (38)                | 30 (34)                       | 85 (37)                        |
| Charlson index, med (IQR) | 2 (1-3)                  | 1 (1-2)                       | 2 (1-3)                        |
| Inhaled corticosteroids (alone or in combination) | 81 (57) | 47 (55) | 128 (56) |
| Long acting bronchodilators (LAMA or LABA, alone or in combination) | 113 (80) | 73 (86) | 186 (82) |
| Pulmonary rehabilitation at baseline | 6 (4) | 5 (6) | 11 (5) |
| Pulmonary rehabilitation during follow-up | 6 (4) | 3 (3) | 9 (4) |

SD: standard deviation; mMRC: modified medical research council; FEV₁: forced expiratory volume in the first second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR: interquartile range; LABA: long acting beta-agonist; LAMA: long-acting muscarinic antagonists.

* Some variables have missing values. Number of missings in per protocol analysis set: 1 in socio-economic status, 10 in active worker, 2 in GOLD 2017 assessment, 1 in cardiovascular disease, diabetes and musculoskeletal disease, 1 in Charlson index, and 6 in inhaled corticosteroids and long acting bronchodilators. Number of missings in intention to treat analysis set: 2 in socio-economic status, 11 in active worker, 3 in GOLD 2017 assessment, 1 in cardiovascular disease, diabetes and musculoskeletal disease, 1 in Charlson index, and 6 in inhaled corticosteroids and long acting bronchodilators.

† III, IV or V in the UK National Statistics Socio-economic classification.
‡ COPD severity classified as: Mild: FEV₁ ≥ 80% pred.; moderate: FEV₁ 50 to 79% pred.; severe: FEV₁ 30 to 49% pred.; very severe: FEV₁ <30% pred.; and A: low risk, low symptoms burden; B: low risk, high symptoms burden; C: high risk, low symptoms burden; D: high risk, high symptoms burden.

†Cardiovascular disease: ICD-10 I00-I99; Diabetes Mellitus: ICD10 E10-E14; Musculoskeletal diseases: ICD-10 M00-M99.
Table 2. Efficacy results \textit{(per protocol analysis set)} of Urban Training\textsuperscript{TM} intervention at 12 months in COPD patients.

|                        | Usual care | Urban Training | Adjusted difference (95% CI) at 12 months\textsuperscript{†} |
|------------------------|------------|---------------|---------------------------------------------------------------|
|                        | n=145\*    | n=88\*        |                                                               |
| **Baseline**           |            |               |                                                               |
| **12 months**          |            |               |                                                               |
| **Primary outcome**    |            |               |                                                               |
| Steps (num/day)        | 7846 (3845)| 7911 (3830)   |                                                               |
| **Secondary outcomes** |            |               |                                                               |
| Any severe COPD exacerbation in previous 12 months, % | 14 | 16\textsuperscript{‡} | 0.15 (-0.7 to 1) |
| 6MWD (m)               | 503 (79)   | 496 (86)\textsuperscript{†} | 509 (83) | 502 (97) | 3.6 (-6.9 to 14.2) |
| BMI (kg/m\textsuperscript{2}) | 28.2 (4.5) | 28.2 (4.5) | 28.3 (4.5) | 28.5 (4.5) | 0.2 (-0.2 to 0.5) |
| FFMI (kg/m\textsuperscript{2}) | 19.6 (3.2) | 19.5 (3.0) | 19.5 (2.8) | 19.5 (2.8) | 0.1 (-0.4 to 0.6) |
| Health-related quality of life (CAT) | 12 (8) | 11 (7)\textsuperscript{‡} | 12 (7) | 10 (7)\textsuperscript{‡} | -0.7 (-2.1 to 0.6) |
| Health-related quality of life (CCQ total) | 1 (1) | 1 (1) | 1 (1) | 1 (1) | -0.1 (-0.3 to 0.1) |
| Anxiety (HAD-A)        | 5 (4)      | 4 (4)\textsuperscript{‡} | 5 (4) | 5 (4) | 0.2 (-0.5 to 0.9) |
| Depression (HAD-D)     | 3 (3)      | 3 (3)         | 3 (3) | 2 (3)\textsuperscript{‡} | -0.5 (-1.1 to 0.1) |
| **Exploratory outcomes** |            |               |                                                               |
| Cognitive status (Phototest) | 37 (5) | 36 (5) | 36 (5) | 36 (6) | 0.5 (-0.4 to 1.5) |
| Physical activity experience (C-PPAC Total) | 79 (12) | 78 (11) | 79 (11) | 84 (11)\textsuperscript{‡} | 5.2 (1.3 to 9.2) |
| Physical activity experience of amount (C-PPAC Amount) | 75 (15) | 74 (14) | 76 (12) | 80 (13)\textsuperscript{‡} | 5.7 (1.1 to 10.2) |
| Physical activity experience of difficulty (C-PPAC Difficulty) | 83 (13) | 81 (13) | 83 (16) | 88 (14)\textsuperscript{‡} | 5.0 (0.3 to 9.6) |

SD: standard deviation; 6MWD: six minute walking distance; BMI: body mass index; FFMI: fat free mass index; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; HAD: hospital anxiety and depression scale; C-PPAC: Clinical visit - PROactive Physical Activity in COPD (higher numbers indicate a better score).

\* Some variables have missing values. Number of missing values at baseline in the usual care group: 1 in severe COPD exacerbations, 18 in FFMI, 2 in HAD-A, 2 in HAD-D, 24 in C-PPAC Total, 23 in C-PPAC Amount and 24 in C-PPAC Difficulty. Number of missing values at 12 months in the usual care group: 5 in severe COPD exacerbations, 7 in 6MWD, 2 in BMI, 2 in FFMI, 1 in CAT, 1 in CCQ total, 1 in HAD-A, 1 in HAD-D, 1 in cognitive status, and 63 in C-PPAC Total, Amount and Difficulty scores. Number of missing values at baseline in Urban Training\textsuperscript{TM} group: 1 in severe COPD exacerbations, 5 in FFMI, 1 in HAD-D and 24 in C-PPAC Total, Amount and Difficulty scores. Number of missing values at 12 months in Urban Training\textsuperscript{TM} group: 2 in severe COPD exacerbations, 1 in 6MWD, 1 in CCQ total, 1 in HAD-D and 47 in C-PPAC Total, Amount and Difficulty scores.

\textsuperscript{†} Multivariable models (linear regression for all outcomes except exacerbations where logistic regression was used) adjusted by group, FEV\textsubscript{1}/FVC ratio, smoking, diabetes, HAD-depression score (see online supplementary material) and the corresponding outcome values at baseline.

\textsuperscript{‡} p-value of final vs baseline <0.05

\textsuperscript{¶} p-value for group differences <0.05
Table 3. Effectiveness results (intention to treat analysis set) of Urban Training\textsuperscript{TM} intervention at 12 months in COPD patients.

| Primary outcome | Usual care n=148* | Urban Training n=132* | Adjusted difference (95% CI) at 12 months\textsuperscript{†} |
|-----------------|-------------------|-----------------------|----------------------------------------------------------|
|                 | Baseline m (SD)    | 12 months m (SD)      |                                                           |
| **Usual care**  |                   |                       |                                                          |
| Primary outcome | m (SD)            | m (SD)                |                                                           |
| **Steps (num/day)** | 7783 (3847) | 7825 (3850) |                                            |
| **Secondary outcomes** | | | |
| Any severe COPD exacerbation in previous 12 months, % | 14 | 17\textsuperscript{‡} | 0.3 (-0.4 to 1.0) |
| 6MWD (m) | 501 (83) | 493 (90)\textsuperscript{†} | 499 (95) | 488 (106)\textsuperscript{†} | -1.5 (-11 to 8) |
| BMI (kg/m\textsuperscript{2}) | 28.3 (4.6) | 28.3 (4.5) | 28.4 (5.0) | 28.5 (5.2) | 0.0 (-0.3 to 0.4) |
| FFMI (kg/m\textsuperscript{2}) | 19.6 (3.2) | 19.5 (3.0) | 19.6 (3.0) | 19.6 (3.1) | 0.1 (-0.4 to 0.5) |
| Health-related quality of life (CAT) | 12 (8) | 11 (7) | 12 (7) | 11 (7)\textsuperscript{‡} | 0.1 (-1.1 to 1.2) |
| Health-related quality of life (CCQ total) | 1 (1) | 1 (1) | 1 (1) | 1 (1)\textsuperscript{‡} | -0.1 (-0.3 to 0.1) |
| Anxiety (HAD-A) | 5 (4) | 4 (4)\textsuperscript{‡} | 5 (4) | 5 (4)\textsuperscript{‡} | 0.2 (-0.4 to 0.9) |
| Depression (HAD-D) | 3 (3) | 3 (3) | 4 (3) | 3 (3)\textsuperscript{‡} | -0.5 (-1.0 to 0.1) |
| **Exploratory outcomes** | | | |
| Cognitive status (Phototest) | 37 (5) | 36 (5) | 36 (5) | 37 (5) | 0.6 (-0.2 to 1.5) |
| Physical activity experience (C-PPAC Total) | 79 (12) | 77 (12) | 78 (12) | 80 (14) | 2.6 (-0.8 to 6.0) |
| Physical activity experience of amount (C-PPAC Amount) | 75 (15) | 73 (15) | 74 (15) | 74 (18) | 1.5 (-2.5 to 5.5) |
| Physical activity experience of difficulty (C-PPAC Difficulty) | 83 (13) | 81 (14) | 82 (15) | 85 (15)\textsuperscript{‡} | 3.8 (-0.2 to 7.9) |
| **SD:** standard deviation; **6MWD:** six minute walking distance; **BMI:** body mass index; **FFMI:** fat free mass index; **CAT:** COPD assessment test; **CCQ:** Clinical COPD Questionnaire; **HAD:** hospital anxiety and depression scale; **C-PPAC:** Clinical visit - PROactive Physical Activity in COPD (higher numbers indicate a better score). |

* Some variables have missing values. Number of missing values at baseline in the usual care group: 1 in severe COPD exacerbations, 18 in FFMI, 2 in HAD-A, 2 in HAD-D, 25 in C-PPAC Total, 24 in C-PPAC Amount and 25 in C-PPAC Difficulty. Number of missing values at 12 months in the usual care group: 5 in severe COPD exacerbations, 8 in 6MWD, 3 in BMI, 3 in FFMI, 2 in CAT, 2 in CCQ total, 2 in HAD-A, 2 in HAD-D, 2 in cognitive status and 64 in C-PPAC Total, Amount and Difficulty scores. Number of missing values at baseline in Urban Training\textsuperscript{TM} group: 2 in severe COPD exacerbations, 12 in FFMI, 2 in CCQ total, 1 in HAD-D and 35 in C-PPAC Total, C-PPAC Amount and C-PPAC Difficulty. Number of missing values at 12 months in Urban Training\textsuperscript{TM} group: 5 in severe COPD exacerbations, 3 in 6MWD, 2 in BMI, 2 in FFMI, 2 in CAT, 3 in CCQ total, 2 in HAD-A, 4 in HAD-D, 2 in cognitive status and 70 in C-PPAC Total, Amount and Difficulty scores. |

\textsuperscript{†} Multivariable models (linear regression for all outcomes except exacerbations where logistic regression was used) adjusted by group and the corresponding outcome values at baseline.

\textsuperscript{‡} p-value of final vs baseline <0.05
Table 4. Adverse events during or after walks in the safety analysis set.

| Event                              | Usual care n=142 | Urban Training n=128 | p-value  |
|------------------------------------|-------------------|----------------------|----------|
| Any adverse event                  | 103 (73)          | 99 (77)              | 0.363    |
| Lower extremity joint pain         | 38 (27)           | 41 (32)              | 0.342    |
| Lower extremity muscle pain        | 36 (25)           | 48 (38)              | 0.031    |
| General malaise or fatigue         | 61 (43)           | 57 (45)              | 0.795    |
| Dizziness                          | 12 (8)            | 9 (7)                | 0.821    |
| Faint                              | 1 (1)             | 0 (0)                | -        |
| Dyspnoea                           | 48 (34)           | 46 (36)              | 0.713    |
| Chest discomfort                   | 9 (6)             | 17 (13)              | 0.064    |
| Palpitations                       | 22 (16)           | 23 (18)              | 0.586    |
| Fall, twist or accident            | 10 (7)            | 13 (10)              | 0.360    |
| Cold, flu or pneumonia             | 24 (17)           | 21 (16)              | 0.913    |
| Heatstroke or dehydration          | 1 (1)             | 2 (2)                | 0.605    |
FIGURES

Figure 1. Study visits and assessments.

Figure 2. Components of the Urban Training™ intervention.

Figure 3. Flow of participants through the trial.

* At baseline, 3 patients did not provide a valid record of physical activity due to technical reasons (e.g., patient entered the swimming pool and spoiled the record).
† Reasons for exclusion between baseline and 12 months were: spending >3 months/year away from their home address (n=7), mental disability (n=3), severe comorbidity limiting survival at one year (n=13), and another severe comorbidity (n=30).
‡ At 12 months visit, 6 patients out of 286 (2%) did not fulfil the criterion of a minimum of 3 days with at least 8 h of wearing time within waking hours.

Figure 4. Efficacy and effectiveness results of Urban Training™ intervention on steps per day (primary outcome) at 12 months in COPD patients

Data are presented as mean and SEM at baseline and 12 months.

Figure 5. Efficacy of Urban Training™ intervention on steps per day (primary outcome) at 12 months in COPD patients according to subgroups based on baseline characteristics.

Data are presented as adjusted difference (95% CI) at 12 months between intervention and usual care groups. Subgroups defined by baseline airflow limitation stages (mild-to-moderate vs. severe-to-very severe), functional exercise capacity (<500 vs. ≥500 m [median value] 6MWD), comorbidity (<2 vs. ≥2 in Charlson index) and physical activity levels (<7100 vs. ≥7100 baseline steps/day, cut-off equivalent to being adherent to physical activity recommendations for older adults) [30].
Figure 1. Study visits and assessments.

Visit 1
- ALL SUBJECTS
- Randomisation

Visit 2
- Urban Training™ Intervention
- Usual care
- 12 months

Visit 3
- Urban Training™ Intervention
- Usual care
- One week

Visit 4
- Urban Training™ Intervention
- Usual care
- One week

Informed consent
Baseline data collection (1):
- Socio demographic
- Smoking status
- Dyspnoea
- Health-related quality of life
- Anxiety and depression symptoms
- Cognitive impairment
- Exercise capacity
- Body composition
- Lung function
- Comorbidities
- Pharmacotherapy
- COPD exacerbations
- Physical activity (accelerometer delivery)

Randomisation
Intervention administration

Baseline data collection (2):
- Physical activity (accelerometer collection)
- Physical activity experience

12-months data collection (1):
- Socio demographic
- Smoking status
- Dyspnoea
- Health-related quality of life
- Anxiety and depression symptoms
- Cognitive impairment
- Exercise capacity
- Body composition
- Lung function
- Comorbidities
- Pharmacotherapy
- COPD exacerbations
- Physical activity (accelerometer delivery)

12-months data collection (2):
- Physical activity (accelerometer collection)
- Physical activity experience
- Satisfaction
- Adverse events
Figure 2. Components of the Urban Training™ intervention.

1. Motivational interviewing

2. Urban Training™ walking trails

3. Pedometer and calendar

4. Pamphlet, website, and phone text messages

5. Walking group

6. Phone number
At baseline, 3 patients did not provide a valid record of physical activity due to technical reasons (e.g., patient entered the swimming pool and spoiled the record).
† Reasons for exclusion between baseline and 12 months were: spending >3 months/year away from their home address (n=7), mental disability (n=3), severe comorbidity limiting survival at one year (n=13), and another severe comorbidity (n=30).
‡ At 12 months visit, 6 patients out of 286 (2%) did not fulfil the criterion of a minimum of 3 days with at least 8 h of wearing time within waking hours.
Figure 4. Efficacy and effectiveness results of Urban Training™ intervention on steps per day (primary outcome) at 12 months in COPD patients

Data are presented as mean and SEM at baseline and 12 months.

**Efficacy**

Adjusted difference in steps (95% CI) at 12 m:
957 (184 to 1730), p=0.015

**Effectiveness**

Adjusted difference in steps (95% CI) at 12 m:
-24 (-741 to 693), p=0.947
Figure 5. Efficacy of Urban Training™ intervention on steps per day (primary outcome) at 12 months in COPD patients according to subgroups based on baseline characteristics.

Data are presented as adjusted difference (95% CI) at 12 months between intervention and usual care groups. Subgroups defined by baseline airflow limitation stages (mild-to-moderate vs. severe-to-very severe), functional exercise capacity (<500 vs. ≥500 m [median value] 6MWD), comorbidity (<2 vs. ≥2 in Charlson index) and physical activity levels (<7100 vs. ≥7100 baseline steps/day, cut-off equivalent to being adherent to physical activity recommendations for older adults) [30].
SUPPLEMENTARY MATERIAL

- METHODS (Complete version)
- Figure S1. Urban Training™ scheme to assign progression in trails intensity* and encouragement level during 12 months of follow-up.
- Table S1. Blinding of Urban Training™ personnel, according to the CONSORT recommendations for non-pharmacological trials.
- Table S2. Baseline characteristics of 407 randomised COPD patients.
- Table S3. Differences between patients participating at 12 months and lost to follow-up.
- Table S4. Differences between patients participating at 12 months and lost to follow-up, by intervention group.
- Table S5. Differences between adherent# and unwilling/non adherent# patients participating at 12 months.
- Table S6. Factors associated with adherence# (multivariable logistic regression model*).
- Table S7. Use of and satisfaction with the study components.
- REFERENCES
METHODS (Complete version)

Study patients
We recruited patients from 33 primary care centres and hospitals from five Catalan [1] seaside municipalities: Viladecans, Gavà, Barcelona, Badalona and Mataró. First, we identified all subjects with a diagnosis of COPD according to the American Thoracic Society and European Respiratory Society (ATS/ERS) recommendations (post-bronchodilator forced expiratory volume in the first second (FEV₁) to forced vital capacity (FVC) ratio <0.70) [2] who were seen in any of the participating health centres. Then we excluded those with at least one of the following exclusion criteria: age<45 years; spending >3 months/year away from their home address; living more than 500 meters from any of the Urban Training™ trails [3] used for the study; or mental disability, severe psychiatric disease, comorbidity limiting survival at one year, or any other severe comorbidity according to medical history. All candidate patients were approached in random order within each municipality (of note, Viladecans and Gavà were grouped because they are conurbated municipalities). Patients were included consecutively in the study until the end of the recruitment period specified for each geographical area. We included only clinically stable patients (defined as at least 4 weeks without antibiotics and/or oral corticosteroids). We finally included a total of 407 COPD patients: 187 from Barcelona, 28 from Badalona, 73 from Mataró, and 119 from Viladecans/Gavà. The Ethics Committees of all participating institutions approved the study, along with the request for complete information exemption from patients, and all participants provided written informed consent. Recruitment began on 30 October 2013, and final outcome assessments were completed on 29 January 2016.

Study design
This is a prospective, multicentre, parallel-group, randomised controlled trial registered at the clinicaltrials.gov online database (NCT01897298) and reported according to the 2010 CONSORT statement [4] and its extension for non-pharmacological interventions [5]. The study consisted of four visits (figure 1 of the main text): the first visit for enrolment and baseline data collection; a second visit one week later for additional baseline data collection, randomisation and intervention; a third visit 12 months after randomisation for 12 months data collection; and a fourth visit one week thereafter for additional 12 months data collection.

Randomisation and blinding
A statistician blinded to study objectives and not involved in any study procedure or analysis created the randomisation sequence using Stata 12.0 (StataCorp, College Station, TX, USA) software. The sequence was stratified by centre with a 1:1 allocation to the Urban Training™ intervention or usual care groups using random block sizes of 6, 8 and 10. At the second study visit, a physiotherapist allocated patients to the corresponding group using a secured computer file, where allocations were ordered according to the randomisation sequence and only available one at a time.

Table S1 shows details on the blinding scheme. Outcome examiners and data analysts remained blinded to the allocation. The physiotherapists who administered the intervention and knew the allocated groups did not perform outcome measurements [6]. Patients were not aware of the existence of the alternative group, as approved by the Ethics Committees.

Interventions
Both groups received the usual standardised pharmacological and/or non-pharmacological treatment for COPD, including pulmonary rehabilitation, to the discretion of their physician and without any intervention by the research team. We implemented diverse measures to avoid contamination (i.e., that participants did not receive the intervention to which they were randomised).

Usual care
Patients assigned to usual care group received general health counselling and were provided with the European Lung Foundation (ELF) information brochure of "Living an active life with COPD" which includes the recommendation to complete at least 30 min of moderate physical activity at least 5 days per week. This recommendation was considered ethically necessary and corresponds to appropriate clinical practice [7].

The Urban Training™ intervention
Patients assigned to the intervention group received the Urban Training™ intervention, always proposed as a supplement to the physical activities of patients’ daily life and in no case as a substitute activity. The intervention consisted of the following six components (figure 2 of the main text):
(1) **Motivational interviewing.** At baseline (in the second visit), a respiratory physiotherapist adequately trained in behavioural strategies used motivational interviewing techniques [8], integrated with a stage-matched approach [9], for a maximum of one hour. The interview was centred on empathy, reflective listening, affirmation, and addressing patients’ resistances (personal difficulties, barriers and limitations) to elicit a behavioural change. Information on the remaining components of the intervention (see below) was provided during this interview. During this interview, patients were questioned about their self-efficacy and motivation levels in a scale between 0 and 10. The physiotherapist identified the stage of change (pre-contemplation, contemplation, preparation, action, maintenance and relapse). During the follow-up period, the physiotherapist administered additional motivational 5-10 min phone calls at different frequencies depending on patients’ baseline motivation and self-efficacy levels: patients with low motivation (score <8) were called at 15, 30, 60 and 180 days, patients with high motivation (score ≥8) but low self-efficacy (score <8) were called at 30, 60 and 180 days, and patients with high motivation and self-efficacy (both scores ≥8) at 180 days.

(2) **Urban Training™ walking trails.** During the motivational interview participants received a dossier containing various maps of walking trails from different areas according to their mobility options and preferences. The design and validation of such walking trails has been previously published [3]. Briefly, we designed walking trails of different intensities (low [green trail], moderate [orange trail] or high [red trail]) in walkable public spaces (boulevards, beaches and parks) of the five seaside municipalities included in the study by combining urban elements of varying intensity (stairs, ramps and different types of surfacing). A validation study showed that the physiological response to and energy expenditure on unsupervised walking these trails increased according to the predefined trails’ intensity and did not change across trails of the same intensity in different public spaces. The physiotherapist provided a complete explanation of trails characteristics and instructed patients to train following the FITT principle (Frequency, Intensity, Time, and Type) [10]. Each patient was advised to start with a trail of intensity appropriate to his/her baseline dyspnoea and 6-min walk distance (6MWD), and instructed how to increase progressively the volume (number of walks per day on the same trail) and/or the intensity of the trails during the following 12 months according to their symptoms and motivation (figure S1). In all cases, the instructions were to walk at least one trail per day at least 5 days per week, at a pace reaching a dyspnoea Borg scale between 4 and 6 [11]. The physiotherapist also explained how to adjust exercise during and after exacerbation episodes.

(3) **Pedometer and calendar.** During the motivational interview, patients were provided with both a pedometer (Onstep 50 Geonaute and Omron) and a personalised calendar. Patients were trained to wear the pedometer all day, and particularly during walks. It was used to help patients monitor their physical activity, so they could maintain or increase their daily step number during the 12 months of follow-up. Patients were instructed to note in the calendar every evening the trails walked that specific day (sticking a green, orange or red colour sticker, depending on trail intensity) and the number of steps walked (according to the pedometer). The calendar was personalised to each patient by making a note about when a change in trails intensity was expected. Calendars also included educational and motivational information.

(4) **Brochures, website and phone text messages.** During the interview, patients also received the same European Lung Foundation information brochure as the usual care group. They were also provided with the link to the project website (http://www.entrenament-urba.cat/) which contains information about the research group, project, general counselling about physical activity, links to other relevant websites, group activity schedule, and a contact phone number. Finally, patients were requested to provide a personal cell phone number where they would receive phone text messages every 2 weeks with educational or motivational messages.

(5) **Walking group.** Once per month during the follow-up period patients could join a walking group for walking a trail accompanied by an experienced physical activity trainer. The schedule of each walking group was provided in the calendars, website and text messages.

(6) **Phone contact.** Patients were invited to telephone the physiotherapists for any questions related to the intervention or their physical activity practice if needed at any moment during follow-up.

**Procedures**

The study consisted of four visits carried out by trained technicians (figure 1 of the main text). At the first visit, all patients answered an interviewer-administered questionnaire, including data on socio-demographic variables, smoking status, dyspnoea (using the modified Medical Research Council scale [mMRC]), health-related quality of life by means of both the Clinical COPD Questionnaire (CCQ) and the COPD Assessment Test (CAT), anxiety and depression symptoms (by the Hospital Anxiety and Depression scale [HAD]), and cognitive impairment (by the Phototest). We also measured, following standardised procedures: functional exercise capacity using the 6-min walk distance (6MWD) test, body composition (weight, height, body mass index [BMI] and fat free mass index [FFMI]) by physical examination and bioelectrical impedance, and lung function (FEV$_1$ and FVC) by spirometry before and after
bronchodilator. We collected information on comorbidities, pharmacological therapy and the COPD exacerbations in the 12 months prior to recruitment from medical records. In the latter case, we obtained the number of exacerbations (defined as an acute worsening of respiratory symptoms that results in additional therapy) and their severity (moderate [ambulatory-treated] or severe [requiring emergency-room or hospital admission]).

During the same first visit, patients were provided a Dynaport accelerometer (McRoberts BV, The Hague, The Netherlands), previously validated for COPD patients [12, 13], to measure objectively physical activity. Patients were instructed to wear it for a week on the centre of lower back with an elastic strap. A valid physical activity measurement was defined as a minimum of 3 days with at least 8 h of wearing time within waking hours [14]. Of note, all patients fulfilled this criterion (median wearing days 7, range 3 to 7; median recording time 14.9 h, range 11.1 to 15 of 15 h maximum from 7 am to 10 pm; 2% and 98% of patients recorded one and two weekend days respectively).

The second visit was carried out after seven days. Patients brought the accelerometer and answered the Clinical-PROactive Physical Activity (C-PPAC) questionnaire to measure physical activity experience [15]. A physiotherapist allocated patients to the corresponding group and provided the corresponding interventions to both groups as detailed above. The physiotherapist also noted down patients’ spontaneous report of unwillingness to follow the instructions (e.g. walking at least 5 days per week at least 30 min per day in the usual care group or walking the Urban Training™ trails in the Urban Training™ group).

At the third visit (12 months after randomisation), we obtained the same information as in the first visit, including the number and severity of exacerbations during the follow-up period. The accelerometer was given and patients returned it one week later (fourth visit). At this fourth visit, 6 patients out of 286 (2%) did not fulfill the criterion of wearing time number and severity of exacerbations during the follow-up period. The accelerometer was given and patients returned it for a week on the centre of lower back with an elastic strap. A valid physical activity measurement was defined as a minimum of 3 days with at least 8 h of wearing time within waking hours [14]. Of note, all patients fulfilled this criterion (median wearing days 7, range 3 to 7; median recording time 14.9 h, range 11.1 to 15 of 15 h maximum from 7 am to 10 pm; 2% and 98% of patients recorded one and two weekend days respectively).

The second visit was carried out after seven days. Patients brought the accelerometer and answered the Clinical-PROactive Physical Activity (C-PPAC) questionnaire to measure physical activity experience [15]. A physiotherapist allocated patients to the corresponding group and provided the corresponding interventions to both groups as detailed above. The physiotherapist also noted down patients’ spontaneous report of unwillingness to follow the instructions (e.g. walking at least 5 days per week at least 30 min per day in the usual care group or walking the Urban Training™ trails in the Urban Training™ group).

At the third visit (12 months after randomisation), we obtained the same information as in the first visit, including the number and severity of exacerbations during the follow-up period. The accelerometer was given and patients returned it one week later (fourth visit). At this fourth visit, 6 patients out of 286 (2%) did not fulfill the criterion of wearing time per day. Among included patients, median wearing days was 7, range 4 to 7; median recording time 14.8 h, range 10.2 to 15; 4% and 96% of patients recorded one and two weekend days respectively. During this fourth visit, patients also answered a questionnaire about satisfaction with the study components and any potential adverse events actually experienced during or after walks in the previous 12 months (follow-up period) including: lower extremity joint pain; lower extremity muscle pain; general malaise or fatigue; dizziness; faint; dyspnoea; chest discomfort; palpitations; fall, twist or accident; cold, flu or pneumonia; and heatstroke or dehydration. Finally, the physiotherapist noted down patients’ spontaneous report of not having followed the intervention instructions during the follow-up period.

Quality control consisted of centralised training sessions, rapid support and supervision of all fieldworkers, periodic recording and checking of questionnaires and tests to identify possible deviations from the protocol, double verification of case report forms, the double entry of data, and at least one visit to each of the participating centres during data collection.

Study outcomes
The primary outcome was the change in physical activity using the number of steps per day from baseline to 12 months follow-up. Secondary outcomes were having any severe COPD exacerbation (leading to hospital or emergency-room admission) during the 12 month follow-up; and the 12 month changes in functional exercise capacity by the 6MWD, body composition measured by BMI and FFMI, health-related quality of life by the CAT and CCQ total scores, and HAD-anxiety and -depression scores. Exploratory outcomes were the 12 month changes in cognitive impairment by the Phototest score and physical activity experience by the total, amount and difficulty C-PPAC scores.

Statistical Analysis
To detect a difference of 775 steps per day (primary outcome) between groups (based on previous research about the effects of behavioural interventions in the elderly) [16], with a two-sided α=0.05 and a power of 80%, assuming a standard deviation of steps per day of 3000 and a correlation between baseline and final steps ≥0.7 (based on own data in COPD patients), a sample size of 142 patients per group was necessary. To account for a 30% drop out rate during follow-up, we planned to recruit 202 participants per group (404 in total). Calculations were done with the software GRANMO 7.10 [17].

Pre-specified efficacy and effectiveness were analysed with per protocol (PP) and intention to treat (ITT) analysis sets, respectively. The ITT analysis set was defined as all randomised patients who did not fulfil any of the following criteria: (i) withdrawn or lost to follow-up during the 12 month follow-up, (ii) death during the 12 month follow-up, (iii) appearance of an exclusion criterion between randomisation and 12 month visit, and (iv) inability to provide a valid record of physical activity. PP analysis set was defined as the subset of ITT who was classified as adherent to their corresponding intervention. Adherence was obtained from the interviews. We classified as ‘non adherent’ patients who (i) spontaneously reported at baseline that they were unwilling to follow any of the instructions, or (ii) spontaneously reported at the 12 months visit that they had not been adherent to the study protocol (see Procedures). Remaining patients were labelled as ‘adherent’.
The characteristics of the usual care and intervention groups at baseline and at follow-up (both PP and ITT analysis sets) were reported as mean and SD for normal distributed quantitative variables, median and IQR for non-normal distributed variables, and number and percentage for qualitative variables. We compared characteristics between followed (ITT analysis set) and lost to follow-up patients using Student’s t, Kruskal-Wallis or chi² tests. We compared characteristics of adherent (PP analysis set) and non adherent patients using Student’s t, Kruskal-Wallis or chi² tests. We built a multivariable logistic regression model to identify the factors associated with adherence in our sample, considering all variables related to adherence in the bivariable analysis with p-value<0.1 and retaining the model with the highest Akaike information criterion (AIC).

We compared baseline and 12 months values for each outcome and intervention group using paired Student’s t or chi² tests. To test effectiveness, we built linear or logistic regression models, depending on the distribution of outcome variables. We used the change from baseline to 12 month follow-up as the outcome, the intervention group as the main exposure variable, and baseline levels of the corresponding outcome as a covariate (to account for individual differences in baseline levels). In efficacy analysis, we additionally adjusted for the variables related to adherence as covariates, since previous literature had shown this adjustment may reduce the selection bias produced by a differential distribution of the reasons that moved participants to be adherent [18, 19].

Post hoc analyses included stratification of efficacy results on physical activity (primary outcome) according to subgroups defined by baseline airflow limitation stages (mild-to-moderate vs. severe-to-very severe), functional exercise capacity (<500 vs. ≥500 m [median value] 6MWD), comorbidity (<2 vs. ≥2 in Charlson index) and physical activity levels (<7100 vs. ≥7100 baseline steps/day, a cut-off equivalent to being adherent to physical activity recommendations for older adults) [16]. All analyses were redone using repeated measures ANOVA instead of linear regression.

Safety analysis set included patients answering the adverse events questions at 12 months. Adverse events at 12 months were compared between groups using chi² or Fisher’s exact tests.

All analyses were conducted with Stata 14.0 (StataCorp, College Station, TX, USA).
Figure S1. Urban Training™ scheme to assign progression in trails intensity* and encouragement level during 12 months of follow-up.

**Baseline functional evaluation**

| Patient profile | Suggested progression | Progression of trails intensity across 12 months | Baseline psychological evaluation | Encouragement across 12 months |
|-----------------|-----------------------|-------------------------------------------------|---------------------------------|-------------------------------|
| Non limitant dyspnea (mMRC 0-1). Good exercise capacity (6MWD ≥350 m). | • Start with low intensity trail.  
• Change rapidly to moderate trails.  
• Keep the rest of the year in high intensity trails  
• Time of walking and/or speed should be increased week by week. | ![Progression Diagram](#) | ![Baseline Psychological Evaluation Diagram](#) | ![Encouragement Level Diagram](#) |
| Moderate dyspnea (mMRC 2). Good or moderate exercise capacity (6MWD ≥350 m or <350 m). | • Start with low intensity trail until achieving good physical condition.  
• Change slowly to moderate trails.  
• Change to high intensity trails depending on breathlessness during ramps, stairs and sand.  
• Time of walking and/or speed should be increased monthly progressively. | ![Progression Diagram](#) | ![Baseline Psychological Evaluation Diagram](#) | ![Encouragement Level Diagram](#) |
| Severe dyspnea (mMRC 3-4). Good or moderate exercise capacity (6MWD ≥350 m or <350 m). | • Start with low intensity trail until patient tolerates walking without rest periods.  
• Try to change to moderate trails after some months.  
• Time of walking and/or speed should increase monthly during year trying to reduce resting time during walks. | ![Progression Diagram](#) | ![Baseline Psychological Evaluation Diagram](#) | ![Encouragement Level Diagram](#) |

* Patients should increase progressively the volume (number of walks per day on the same trail) and/or the intensity of the trails (e.g., moving from low intensity trail to moderate intensity trail) according to their dyspnoea, exercise capacity and achievements, as agreed and recommended by an experienced and trained physiotherapist. The scheme will be appropriately adapted in patients with comorbidities or other personal limitations of any kind (functional, psychological, family issues, etc). Counsellors should also advice patients to reduce the volume and/or intensity of trails during and after exacerbation episodes.
Table S1. Blinding of Urban Training\textsuperscript{TM} personnel, according to the CONSORT recommendations for non-pharmacological trials

| Blinded to:          | Study hypotheses and objectives | Intervention details | Random assignment | Outcome measures |
|----------------------|---------------------------------|----------------------|-------------------|------------------|
| Study participants   | Yes                             | Partially\textsuperscript{1} | Yes               | Partially\textsuperscript{3} |
| Participants’ physicians | Yes\textsuperscript{2}           | Yes\textsuperscript{2}   | Yes               | Partially\textsuperscript{2,3} |
| Technicians (outcomes examiners) | Yes                    | Yes                  | Yes               | No               |
| Counsellors (physiotherapists)        | No                              | No                   | No                | Yes              |
| Researchers          | No                              | No                   | Yes               | Partially\textsuperscript{4} |
| Statisticians (data analysts)         | No                              | Yes                  | Yes               | Partially\textsuperscript{4} |

\textsuperscript{1} Patients were aware of their own intervention but not of the existence of the alternative group nor of the study objectives, as approved by the Ethics Committee.

\textsuperscript{2} Health professionals taking care of the patients were blinded except if, by chance, a member of the research team was the physician of a patient involved in the study. According to these physicians, this situation happened in 10 (2\%) patients.

\textsuperscript{3} Outcomes information was provided to patients if they asked for it and sent to their physicians if patients asked for it. No information in the intervention or study objectives was included.

\textsuperscript{4} Outcomes information was not available until the analysis phase.
Table S2. Baseline characteristics of 407 randomised COPD patients.

|                                | Usual care | Urban Training | All          |
|--------------------------------|------------|----------------|--------------|
|                                | n=205*     | n=202*         | n=407*       |
|                                | m (SD) / n (%) | m (SD) / n (%) | m (SD) / n (%) |
| Age (years)                    | 69 (8)     | 69 (9)         | 69 (9)       |
| Female / male                  | 29 (14) / 176 (86) | 32 (16) / 170 (84) | 61 (15) / 346 (85) |
| Active smoker                  | 42 (20)    | 56 (28)        | 98 (24)      |
| Low socio-economic status†     | 148 (73)   | 143 (71)       | 291 (72)     |
| Active worker                  | 20 (10)    | 28 (14)        | 48 (12)      |
| Dyspnoea (mMRC grade, 0-4)     | 1 (1)      | 1 (1)          | 1 (1)        |
| Post-bronchodilator FEV₁ (% pred.) | 57 (18) | 56 (17) | 57 (18) |
| Post-bronchodilator FEV₁/FVC ratio | 0.55 (0.12) | 0.53 (0.11) | 0.54 (0.12) |
| Airflow limitation (% mild / moderate / severe / very severe)‡ | 10 / 52 / 31 / 7 | 9 / 55 / 28 / 8 | 10 / 53 / 29 / 8 |
| GOLD 2017 assessment (% A / B / C / D)† | 33 / 45 / 7 / 15 | 30 / 55 / 4 / 11 | 31 / 50 / 6 / 13 |
| Cardiovascular disease¶        | 130 (64)   | 124 (63)       | 254 (64)     |
| Diabetes mellitus‡             | 53 (26)    | 61 (31)        | 114 (29)     |
| Musculoskeletal diseases¶      | 80 (39)    | 74 (38)        | 154 (39)     |
| Charlson index, med (IQR)      | 2 (1-3)    | 2 (1-3)        | 2 (1-3)      |
| Inhaled corticosteroids (alone or in combination) | 116 (59) | 106 (55) | 222 (57) |
| Long acting bronchodilators (LAMA or LABA, alone or in combination) | 161 (82) | 160 (83) | 321 (82) |
| Steps (num/day)                | 7605 (3859)| 7489 (4234)    | 7547 (4045)  |
| Any severe COPD exacerbation in previous 12 months | 33 (16) | 17 (9) | 50 (13) |
| 6MWD (m)                       | 486 (92)   | 487 (98)       | 486 (95)     |
| BMI (kg/m²)                    | 28.4 (4.9) | 28.5 (5.0)     | 28.5 (4.9)   |
| FFMI (kg/m²)                   | 19.5 (3.2) | 19.6 (3.2)     | 19.5 (3.2)   |
| Health-related quality of life (CAT) | 12 (7) | 12 (7) | 12 (7) |
| Health-related quality of life (CCQ total), med (IQR) | 1 (1-2) | 1 (1-2) | 1 (1-2) |
| Anxiety (HAD-A), med (IQR)     | 4 (2-8)    | 4 (2-8)        | 4 (2-8)      |
| Depression (HAD-D), med IQR    | 2 (1-5)    | 3 (1-5)        | 2 (1-5)      |
| Cognitive status (Phototest)    | 36 (5)     | 36 (5)         | 36 (5)       |
| Physical activity experience (C-PPAC Total) | 78 (12) | 77 (12) | 78 (12) |
| Physical activity amount (C-PPAC Amount) | 73 (16) | 73 (15) | 73 (16) |
| Physical activity difficulty (C-PPAC Difficulty) | 82 (14) | 81 (15) | 82 (15) |

SD: standard deviation; mMRC: modified medical research council; FEV₁: forced expiratory volume in the first second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR: interquartile range; LABA: long acting beta-agonist; LAMA: long-acting muscarinic antagonists; 6MWD: six minute walking distance; BMI: body mass index; FFMI: fat free mass index; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; HAD: hospital anxiety and depression scale; C-PPAC: Clinical visit - PROactive Physical Activity in COPD (higher numbers indicate a better score).

* Some variables have missing values: 2 in socio-economic status, 13 in active worker, 11 in GOLD 2017, 7 in cardiovascular disease, diabetes and musculoskeletal disease, 7 in Charlson index, 17 in inhaled corticosteroids and long acting bronchodilators, 11 in severe COPD exacerbations, 39 in FFMI, 2 in CCQ score, 2 in HAD-anxiety, 4 in HAD-depression, and 96 in C-PPAC Total, 95 in C-PPAC Amount and 96 in C-PPAC Difficulty Scores.
† III, IV or V in the UK National Statistics Socio-economic classification.
‡ COPD severity classified as: Mild: FEV₁ ≥ 80% pred.; moderate: FEV₁ 50 to 79% pred.; severe: FEV₁ <30% pred.; very severe: FEV₁ <30% pred.; and A: low risk, low symptoms burden; B: low risk, high symptoms burden; C: high risk, low symptoms burden; D: high risk, high symptoms burden.
¶ Cardiovascular disease: ICD-10 I00-I99; Diabetes Mellitus: ICD10 E10-E14; Musculoskeletal diseases: ICD-10 M00-M99.
# Table S3. Differences between patients participating at 12 months and lost to follow-up.

|                           | Followed n=280* | Lost to follow-up n=127* | p-value |
|---------------------------|-----------------|--------------------------|---------|
| Age (years)               | 69 (8)          | 69 (9)                   | 0.419   |
| Female / male             | 36 (13) / 244 (87) | 25 (20) / 102 (80)       | 0.074   |
| Active smoker             | 64 (23)         | 34 (27)                  | 0.392   |
| Low socio-economic status†| 200 (72)        | 91 (72)                  | 0.952   |
| Active worker             | 35 (13)         | 13 (10)                  | 0.461   |
| Dyspnoea (mMRC grade, 0-4)| 1 (1)           | 1 (1)                    | 0.053   |
| Post-bronchodilator FEV₁ (% pred.) | 57 (17) | 56 (18)                  | 0.655   |
| Post-bronchodilator FEV₁/FVC ratio | 0.54 (0.12) | 0.55 (0.12)              | 0.606   |
| Airflow limitation severity (% mild / moderate / severe / very severe)‡ | 10 / 53 / 31 / 6 | 10 / 55 / 25 / 10 | 0.403   |
| GOLD 2017 assessment (% A / B / C / D)‡ | 34 / 48 / 5 / 13 | 26 / 55 / 6 / 13 | 0.481   |
| Any cardiovascular disease§ | 171 (61)   | 83 (69)                  | 0.163   |
| Diabetes mellitus§        | 82 (29)         | 32 (26)                  | 0.549   |
| Musculoskeletal diseases§ | 107 (38)        | 47 (39)                  | 0.926   |
| Charlson index, med (IQR) | 2 (1-3)         | 2 (1-3)                  | 0.910   |
| Inhaled corticosteroids (alone or in combination) | 150 (55) | 72 (62)                  | 0.182   |
| Long acting bronchodilators (LAMA/LABA, alone or in combination) | 225 (82) | 96 (83)                  | 0.879   |
| Steps (num/day)           | 7918 (4190)     | 6730 (3587)              | <0.01   |
| Any severe COPD exacerbation in previous 12 months | 31 (11) | 19 (16) | 0.190 |
| 6MWD (m)                  | 500 (89)        | 456 (102)                | <0.001  |
| BMI (kg/m²)               | 28.4 (4.8)      | 28.7 (5.3)               | 0.562   |
| FFMI (kg/m²)              | 19.6 (3.1)      | 19.5 (3.5)               | 0.786   |
| Health-related quality of life (CAT) | 12 (7) | 12 (7) | 0.950 |
| Health-related quality of life (CCQ total), med (IQR) | 1 (1-2) | 1 (1-2) | 0.762 |
| Anxiety (HAD-A), med (IQR) | 4 (2-8) | 4 (2-8) | 0.906 |
| Depression (HAD-D), med (IQR) | 3 (1-5) | 2 (1-5) | 0.154 |
| Cognitive status (Phototest) | 36 (5) | 36 (6) | 0.639 |
| Physical activity experience (C-PPAC Total) | 78 (11) | 76 (13) | 0.066 |
| Physical activity experience of amount (C-PPAC Amount) | 75 (15) | 70 (17) | 0.036 |
| Physical activity experience of difficulty (C-PPAC Difficulty) | 82 (14) | 81 (16) | 0.424 |

SD: standard deviation; mMRC: modified medical research council; FEV₁: forced expiratory volume in the first second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR: interquartile range; LABA: long acting beta-agonist; LAMA: long-acting muscarinic antagonists; 6MWD: six minute walking distance; BMI: body mass index; FFMI: fat free mass index; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; HAD: hospital anxiety and depression scale; C-PPAC: Clinical visit – PROactive Physical Activity in COPD (higher numbers indicate a better score).

* Some variables have missing values: 2 in socio-economic status, 13 in active worker, 11 in GOLD 2017, 7 in cardiovascular disease, diabetes and musculoskeletal disease, 7 in Charlson index, 17 in inhaled corticosteroids and long acting bronchodilators, 11 in severe COPD exacerbations, 39 in FFMI, 2 in CCQ score, 2 in HAD-anxiety, 4 in HAD-depression, and 95 in PROactive Physical Activity in COPD Total, 96 in C-PPAC Amount and 96 in C-PPAC Difficulty Scores.

† II, IV or V in the UK National Statistics Socio-economic classification.

‡ COPD severity classified as: Mild: FEV₁ ≥ 80% pred.; moderate: FEV₁ 50 to 79% pred.; severe: FEV₁ 30 to 49% pred.; very severe: FEV₁ <30% pred.; and A: low risk, low symptoms burden; B: low risk, high symptoms burden; C: high risk, low symptoms burden; D: high risk, high symptoms burden.

§ Cardiovascular disease: ICD-10 I00-I99; Diabetes Mellitus: ICD10 E10-E14; Musculoskeletal diseases: ICD-10 M00-M99.
Table S4. Differences between patients participating at 12 months and lost to follow-up, by intervention group.

|                          | Usual care       | Urban Training   |
|--------------------------|------------------|-----------------|
|                          | Followed n=148   | Lost to follow- | Followed n=132 | Lost to follow- |
|                          | m (SD) / n (%)   | p-value         | m (SD) / n (%)  | p-value         |
| Age (years)              | 69 (8)           | 0.836           | 68 (9)          | 0.229           |
| Female / male            |                  |                 |                 |                 |
| Active smoker            | 18 (12) / 130 (88) | 0.189          | 18 (14) / 114 (86) | 0.239          |
| Low socio-economic status† | 107 (73)        | 0.902           | 93 (71)         | 0.948           |
| Active worker            | 16 (11)          | 0.600           | 19 (14)         | 0.764           |
| Dyspnoea (mMRC grade, 0-4) | 1 (1)            | 0.021           | 1 (1)           | 0.581           |
| Post-bronchodilator FEV₁ (% pred.) | 58 (18) | 0.279           | 56 (17)         | 0.616           |
| Airflow limitation severity (% mild / moderate / severe / very severe)‡ | 10 / 54 / 30 / 6 | 0.581          | 9 / 51 / 32 / 8 | 0.278           |
| GOLD 2017 assessment (% A / B / C / D)‡ | 36 / 44 / 7 / 13 | 0.288          | 31 / 53 / 3 / 13 | 0.328           |
| Any cardiovascular disease¶ | 90 (61)         | 0.116           | 81 (62)         | 0.649           |
| Diabetes mellitus¶       | 38 (26)          | 0.818           | 44 (34)         | 0.262           |
| Musculoskeletal diseases¶ | 56 (38)         | 0.452           | 51 (39)         | 0.576           |
| Charlson index, med (IQR) | 2 (1-3)         | 0.397           | 2 (1-3)         | 0.396           |
| Inhaled corticosteroids (alone or in combination) | 82 (55) | 0.412           | 68 (52)         | 0.451           |
| Long acting bronchodilators (LAMA/LABA, alone or in combination) | 116 (78) | 0.591           | 109 (83)        | 0.314           |
| Steps (num/day)           | 7784 (3847)      | 0.288           | 8069 (4554)     | 0.007           |
| Any severe COPD exacerbation in previous 12 months | 21 (14) | 0.178           | 10 (8)          | 0.473           |
| 6MWD (m)                  | 501 (83)         | <0.001          | 499 (95)        | 0.008           |
| BMI (kg/m²)               | 28.3 (4.6)       | 0.554           | 28.4 (5)        | 0.812           |
| FFMI (kg/m²)              | 19.6 (3.2)       | 0.706           | 19.6 (3.1)      | 0.978           |
| Health-related quality of life (CAT) | 12 (8) | 0.797           | 12 (7)          | 0.873           |
| Health-related quality of life (CCQ total), med (IQR) | 1 (1-2) | 1 (1-2) | 1 (1-2) | 1 (1-2) |
| Anxiety (HAD-A), med (IQR) | 4 (2-8) | 0.922           | 4 (2-8)         | 0.867           |
| Depression (HAD-D), med (IQR) | 3 (1-5) | 0.830           | 3 (1-6)         | 0.087           |
| Cognitive status (Phototest) | 37 (5) | 0.351           | 36 (5)          | 0.816           |
| Physical activity experience (C-PPAC Total) | 79 (12) | 0.187           | 78 (11)         | 0.221           |
| Physical activity experience of amount (C-PPAC Amount) | 75 (15) | 0.084           | 74 (15)         | 0.226           |
| Physical activity experience of difficulty (C-PPAC Difficulty) | 83 (13) | 0.680           | 82 (15)         | 0.525           |

*Table includes n=148 Usual care, n=57 Urban Training, and p-values for differences between groups.*

†Low socio-economic status: income below the median; ‡Airflow limitation severity: mild ≤30%, moderate 30%-69%, severe 70%-89%, very severe ≥90%; ¶Any cardiovascular disease includes heart disease, peripheral vascular disease, stroke, or transient ischemic attack; Any COPD exacerbation in previous 12 months includes COPD exacerbation requiring hospitalization or urgent medical care; 6MWD (m): 6-minute walk distance; BMI (kg/m²): body mass index; FFMI (kg/m²): fat-free mass index; CAT: chronic respiratory disease symptom assessment tool; CCQ: clinical COPD questionnaire; HAD-A: Hospital Anxiety and Depression Scale Anxiety subscale; HAD-D: Hospital Anxiety and Depression Scale Depression subscale; C-PPAC Total: composite physician-provided physical activity component score.
SD: standard deviation; mMRC: modified medical research council; FEV₁: forced expiratory volume in the first second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR: interquartile range; LABA: long acting beta-agonist; LAMA: long-acting muscarinic antagonists; 6MWD: six minute walking distance; BMI: body mass index; FFMI: fat free mass index; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; HAD: hospital anxiety and depression scale; C-PPAC: Clinical visit – PROactive Physical Activity in COPD (higher numbers indicate a better score).

* Some variables have missing values: 2 in socio-economic status, 13 in active worker, 11 in GOLD 2017, 7 in cardiovascular disease, diabetes and musculoskeletal disease, 7 in Charlson index, 17 in inhaled corticosteroids and long acting bronchodilators, 11 in severe COPD exacerbations, 39 in FFMI, 2 in CCQ score, 2 in HAD-anxiety, 4 in HAD-depression, and 96 in C-PPAC Total, 95 in C-PPAC Amount and 96 in C-PPAC Difficulty Scores.

1 III, IV or V in the UK National Statistics Socio-economic classification.

2 COPD severity classified as: Mild: FEV₁ ≥ 80% pred.; moderate: FEV₁ 50 to 79% pred.; severe: FEV₁ 30 to 49% pred.; very severe: FEV₁ <30% pred.; and A: low risk, low symptoms burden; B: low risk, high symptoms burden; C: high risk, low symptoms burden; D: high risk, high symptoms burden.

3 Cardiovascular disease: ICD-10 I00-I99; Diabetes Mellitus: ICD10 E10-E14; Musculoskeletal diseases: ICD-10 M00-M99.
Table S5. Differences between adherent\* and unwilling/non adherent\# patients participating at 12 months.

|                                         | Adherent\* n=233* | Unwilling / non adherent\# n=47* | p-value |
|-----------------------------------------|-------------------|----------------------------------|---------|
| Age (years)                             | 69 (8)            | 67 (9)                           | 0.288   |
| Female / male                           | 29 (12) / 204 (88)| 7 (15) / 40 (85)                 | 0.636   |
| Active smoker                           | 49 (21)           | 15 (32)                          | 0.105   |
| Low socio-economic status†              | 169 (73)          | 31 (67)                          | 0.452   |
| Active worker                           | 29 (13)           | 6 (13)                           | 0.994   |
| Dyspnoea (mMRC grade, 0-4)             | 1 (1)             | 1 (1)                            | 0.128   |
| Post-bronchodilator FEV₁ (% pred.)      | 58 (17)           | 53 (18)                          | 0.047   |
| Post-bronchodilator FEV₁/FVC ratio     | 0.55 (0.12)       | 0.51 (0.12)                      | 0.032   |
| Airflow limitation severity ( % mild / moderate / severe / very severe)‡ | 9 / 55 / 31 / 5 | 11 / 38 / 36 / 15 | 0.030 |
| GOLD 2017 assessment (% A / B / C / D)§ | 36 / 47 / 4 / 13 | 20 / 54 / 11 / 15 | 0.074 |
| Any cardiovascular disease†             | 140 (60)          | 31 (66)                          | 0.471   |
| Diabetes mellitus‡                      | 62 (27)           | 20 (43)                          | 0.030   |
| Musculoskeletal diseases§               | 85 (37)           | 22 (47)                          | 0.191   |
| Charlson index, med (IQR)               | 2 (1-3)           | 2 (1-3)                          | 0.289   |
| Inhaled corticosteroids (alone or in combination) | 128 (56) | 22 (47) | 0.230 |
| Long acting bronchodilators (LAMA/LABA, alone or in combination) | 186 (82) | 39 (83) | 0.865 |
| Steps (num/day)                         | 8038 (3972)       | 7321 (5143)                      | 0.285   |
| Any severe COPD exacerbation in previous 12 months | 24 (10) | 7 (15) | 0.343 |
| 6MWD (m)                                | 505 (81)          | 472 (118)                        | 0.212   |
| BMI (kg/m²)                             | 28.2 (4.5)        | 29.0 (5.9)                       | 0.336   |
| FFMI (kg/m²)                            | 19.5 (3.0)        | 19.8 (3.6)                       | 0.676   |
| Health-related quality of life (CAT)    | 12 (7)            | 13 (7)                           | 0.223   |
| Health-related quality of life (CCQ total), med (IQR) | 1 (1-2) | 1 (1-2) | 0.112 |
| Anxiety (HAD-A), med (IQR)              | 4 (2-7)           | 5 (2-9)                          | 0.350   |
| Depression (HAD-D), med (IQR)           | 2 (1-5)           | 4 (2-7)                          | 0.040   |
| Cognitive status (Phototest)            | 36 (5)            | 37 (6)                           | 0.365   |
| Physical activity experience (C-PPAC Total) | 79 (11) | 76 (13) | 0.177 |
| Physical activity experience of amount (C-PPAC Amount) | 75 (14) | 72 (19) | 0.191 |
| Physical activity experience of difficulty (C-PPAC Difficulty) | 83 (14) | 81 (14) | 0.411 |

SD: standard deviation; mMRC: modified medical research council; FEV₁: forced expiratory volume in the first second; FVC: forced vital capacity; GOLD: Global Initiative for Chronic Obstructive Lung Disease; IQR: interquartile range; LABA: long acting beta-agonist; LAMA: long-acting muscarinic antagonists; 6MWD: six minute walking distance; BMI: body mass index; FFMI: fat free mass index; CAT: COPD assessment test; CCQ: Clinical COPD Questionnaire; HAD: hospital anxiety and depression scale; C-PPAC: Clinical visit - PROactive Physical Activity in COPD (higher numbers indicate a better score).

* Some variables have missing values: 2 in socio-economic status, 11 in active worker, 3 in GOLD assessment, 1 in cardiovascular disease, diabetes and musculoskeletal disease, 1 in Charlson index, 6 in inhaled corticosteroids and long acting bronchodilators, 3 in severe COPD exacerbations, 30 in FFMI, 2 in CCQ score, 2 in HAD-anxiety, 3 in HD-depression, and 60 in C-PPAC Total, 59 in Amount and 60 in Difficulty Scores.

† III, IV or V in the UK National Statistics Socio-economic classification.

‡ COPD severity classified as: Mild: FEV₁ ≥80% pred.; moderate: FEV₁ 50 to79% pred.; severe: FEV₁ 30 to 49% pred.; very severe: FEV₁ <30% pred.; and A: low risk, low symptoms burden; B: low risk, high symptoms burden; C: high risk, low symptoms burden; D: high risk, high symptoms burden.
Adherence was obtained from the interviews. Patients who (i) spontaneously reported at baseline that they were unwilling to follow any of the instructions, or (ii) spontaneously reported at the 12 months visit that they had not been adherent to the study protocol (see Procedures). Remaining patients were labelled as ‘adherent’.
Table S6. Factors associated with adherence\(^\#\) (multivariable logistic regression model\(^*\)).

| Risk Factor                        | Adherent\(^\#\) OR (95% CI) | p-value |
|-----------------------------------|-----------------------------|---------|
| Active smoker                     | 0.50 (0.24 to 1.03)         | 0.059   |
| Post-bronchodilator FEV\(_1\)/FVC ratio (per one percentual unit) | 1.04 (1.01 to 1.07)         | 0.009   |
| Diabetes mellitus                 | 0.38 (0.19 to 0.75)         | 0.006   |
| Depression (HAD-D)                | 0.90 (0.82 to 1.00)         | 0.040   |

\(^*\) Model built considering all variables related with adherence with p<0.1 (see supplementary table 4) and keeping the model with the highest Akaike information criterion (AIC).

\(^\#\) Adherence was obtained from the interviews. Patients who (i) spontaneously reported at baseline that they were unwilling to follow any of the instructions, or (ii) spontaneously reported at the 12 months visit that they had not been adherent to the study protocol (see Procedures). Remaining patients were labelled as ‘adherent’.
Table S7. Use of and satisfaction with the study components.

| Component                              | Usual care n=144 | Urban Training n=126 |
|----------------------------------------|------------------|----------------------|
|                                        | m (SD)           | m (SD)               |
| Overall satisfaction with the study (0-10) | 9.1 (1.4)       | 9.0 (1.5)            |
| Confidence transmitted by the study staff (0-10) | 9.4 (1.0)       | 9.6 (0.9)            |
| Satisfaction with the time devoted by the study staff (0-10) | 9.3 (1.2)       | 9.3 (1.1)            |
| Satisfaction with the study staff willingness to listen (0-10) | 9.4 (1.0)       | 9.5 (1.0)            |
| Feeling to be in good hands (0-10) | 9.6 (0.8)       | 9.7 (0.8)            |
| Satisfaction with study organisation (0-10) | 9.4 (1.2)       | 9.4 (1.0)            |
| Information brochure                  |                 |                      |
| Use, n (%)                            | 81 (56)         | 70 (56)              |
| Satisfaction among users (0-10)       | 8.9 (1.6)       | 9.1 (1.1)            |
| Trail maps                            |                 |                      |
| Use, n (%)                            |                 | 85 (70)              |
| Satisfaction among users (0-10)       |                 | 9.1 (1.6)            |
| Satisfaction with instructions (0-10) |                 | 9.3 (1.3)            |
| Calendar                              |                 |                      |
| Use, n (%)                            |                 | 109 (87)             |
| Satisfaction among users (0-10)       |                 | 9.1 (1.7)            |
| Satisfaction with instructions (0-10) |                 | 9.5 (1.0)            |
| Pedometer                             |                 |                      |
| Use, n (%)                            |                 | 113 (90)             |
| Satisfaction among users (0-10)       |                 | 9.0 (1.8)            |
| Satisfaction with instructions (0-10) |                 | 9.6 (1.0)            |
| Walking group                         |                 |                      |
| Participation, n (%)                  |                 | 39 (31)              |
| Satisfaction among participants (0-10) |                 | 7.5 (2.8)            |
| Phone text messaging                  |                 |                      |
| Reading them, n (%)                   |                 | 77 (61)              |
| Satisfaction among users (0-10)       |                 | 9.4 (1.0)            |
| Study phone                           |                 |                      |
| Use, n (%)                            |                 | 52 (41)              |
| Satisfaction with the phone among users (0-10) |             | 9.5 (1.4)            |
| Satisfaction with solutions provided among users (0-10) |         | 9.7 (0.7)            |
| Website                               |                 |                      |
| Use, n (%)                            |                 | 3 (2)                |
| Satisfaction among users (0-10)       |                 | 8.7 (2.3)            |
| Satisfaction with instructions (0-10) |                 | 10 (0)               |

SD: standard deviation
REFERENCES

1. Idescat. Institut d’Estadística de Catalunya. Pàgina principal. http://www.idescat.cat/. Data last accessed: Apr 9 2016.

2. Celli BR, MacNee W, Agusti A, et al. Standards for the diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper. *Eur Respir J* 2004; 23: 932–46.

3. Arbillaga-Etxarri A, Torrent-Pallícer J, Gimeno-Santos E, et al. Validation of Walking Trails for the Urban Training™ of Chronic Obstructive Pulmonary Disease Patients. *PLoS One* 2016; 11: e0146705.

4. Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008; 371: 281–3.

5. Boutron I, Moher D, Altman DG, et al. Methods and Processes of the CONSORT Group: Example of an Extension for Trials Assessing Nonpharmacologic Treatments. *Ann Intern Med* 2008; 148: W-60.

6. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P, CONSORT NPT Group. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. *Ann Intern Med* 2017; 167: 40-47.

7. European Lung Foundation - ELF. Factsheets. Living an active life with COPD. http://www.europeanlung.org/en/lung-disease-and-information/factsheets/english. Data last accessed: May 4 2016.

8. Miller WR, William R, Rollnick S. Motivational interviewing: preparing people for change. Guilford Press, 2002.

9. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot* 1997; 12: 38–48.

10. Pescatello L, Arena R, Riebe D TP. ACSM’s Guidelines for Exercise Testing and Prescription. ACSM’s Guidel. Exerc. Test. Prescr. 9th ed. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2013. p. 166–177.

11. Spruit MA, Singh SJ, Garvey C, et al. An official American thoracic society/European respiratory society statement: Key concepts and advances in pulmonary rehabilitation. *Am J Respir Crit Care Med* 2013; 188(8): e13-64.

12. Rabinovich RA, Louvaris Z, Raste Y, et al. Validity of physical activity monitors during daily life in patients with COPD. *Eur Respir J* 2013; 42: 1205–15.

13. Van Remoortel H, Raste Y, Louvaris Z, et al. Validity of six activity monitors in chronic obstructive pulmonary disease: a comparison with indirect calorimetry. *PLoS One* 2012; 7: e39198.

14. Demeyer H, Burtin C, Van Remoortel H, et al. Standardizing the analysis of physical activity in patients with COPD following a pulmonary rehabilitation program. *Chest* 2014; 146: 318–27.

15. Gimeno-Santos E, Raste Y, Demeyer H, et al. The PROactive instruments to measure physical activity in patients with chronic obstructive pulmonary disease. *Eur Respir J* 2015; 46: 988–1000.

16. Tudor-Locke C, Craig CL, Aoyagi Y, et al. How many steps/day are enough? For older adults and special populations. *Int J Behav Nutr Phys Act* 2011; 8: 80.

17. Marrugat J, Vila J, Pavesi M, Sanz F. Estimation of the sample size in clinical and epidemiological investigations. *Med Clin (Barc)* 1998; 111: 267–76.

18. Hernán MA, Hernández-Díaz S. Beyond the intention-to-treat in comparative effectiveness research. *Clin Trials* 2012; 9: 48–55.

19. Murray EJ, Hernán MA. Adherence adjustment in the Coronary Drug Project: A call for better per-protocol effect estimates in randomized trials. *Clin Trials* 2016; 13: 372–8.