Archivos de Bronconeumología xxx (xxxx) xxx–xxx

Sociedad Española de Neumología y Cirugía Torácica SEPAR

ARCHIVOS DE
Bronconeumología

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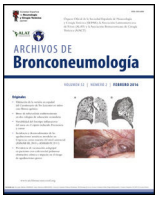

Scientific Letter

Effects of an In-Hospital Motivational Programme on Physical Activity Levels of Individuals with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease Undergoing Rehabilitation: A Randomized Controlled Trial

To the Director,

Reducing symptoms and improving exercise capacity, physical activity (PA) levels and health-related quality of life are the main goals of comprehensive management of people with COPD or chronic heart failure (CHF).[1] The benefits of PA are undisputed.[2] In addition to pharmacological intervention, rehabilitation programmes (RP) are used to increase PA.[3–5] Interventions to promote PA in the hospital setting can prevent deconditioning and maintain physical function during hospital stay.[6] Unsupervised PA interventions, can improve symptoms and exercise capacity, are safe, and have a high adherence rate.[7]

This randomised controlled trial (RCT) evaluated whether an in-hospital motivational programme supported by a health-tracking device, in addition to standard inpatient RP, might be effective in increasing PA levels in people with COPD or CHF.

The RCT was approved by the Ethical Committee of the Istituti Clinici Scientifici (ICS) Maugeri IRCCS (CE 2608, 09/02/2022), Italy, and registered on Clin Trial Gov (NCT05318482).

People with COPD according to the Global Strategy for Prevention, Diagnosis, and Management of COPD (GOLD)[4] airway obstruction classes II–IV and people with CHF according to New York Heart Association (NYHA) class II or III were included. Major comorbidities, any conditions limiting movement, refusal to perform the RP or to participate in the study were exclusion criteria. The structured RP for individuals with COPD or CHF consisted of two daily sessions for endurance exercise (30-min cycling, treadmill or reclining) as described elsewhere.[4,8] Within 24 h of admission, participants were randomised to study or control group. In addition to the RP both groups underwent an educational session on topics of interest and were provided with an electronic wrist device equipped with a podiatrist, operated by a dedicated smartphone mobile software application via a Bluetooth connection, allowing participants to monitor their daily steps. Control group had to maintain and increase PA during hospital stay using visual feedback from the mobile application without any supervision. Study group was provided a daily motivational face-to-face session. Besides the medical and behavioral history, the motivational programme was based on an individualized exercise plan with low-to-moderate in walking activities, information on the health benefits of PA, daily meetings with a therapist to address barriers to PA and reinforce motivation to increase motivation and commitment to change. In addition, study group underwent daily monitoring of improvements in number of steps, potential changes in programme based on progress and participant feedback. The target number of steps was defined as a 10% daily increase from the previous target, if achieved; if not, the new target was the same as the previous day. As an additional self-monitoring tool, study group had to keep a diary of their daily steps. Participants were able to track weekly progress using the mobile software application on the smartphone, synchronised with the device.

Outcome measures were: Physical Activity Scale for the Elderly (PASE) questionnaire, 48-h PA monitoring of daily steps assessed by a health tracker (primary outcome), six-minute walking test (6MWT: distance and % predicted), one-minute sit-to-stand (1MSTS), quadriceps strength, Exercise Motivations Inventory-2 (EMI-2), Beck Depression Inventory (BDI). The proportion of participants achieving the minimal clinically important difference (MCID) in the outcomes was recorded.[9–15]

A sample size of 50 participants (25 per group) was estimated as necessary to detect a statistically significant difference between groups using a t-test with alpha = 0.05 and beta = 0.90. Inferential statistical analysis was performed per protocol mode. The difference between groups in post-programme response was assessed using *t*-tests for unpaired data for continuous variables and Chi-squared test (χ^2 tests) for categorical and binary variables. Pre-post changes within groups were calculated using paired *t*-tests. Multivariate linear regression was performed using a stepwise method. A *p*-value less than 0.05 was considered significant.

Baseline characteristics of the participants are shown in Table 1. The 28 RP sessions were performed for 14 days (twice daily). Eleven participants (22%) dropped out due to exacerbations, without any significant difference between COPD and CHF. Therefore, 39 participants (15 CHF, 24 COPD) completed the study. No significant differences were found between participants completing the study and those dropping out.

The study group gradually increased daily steps with a sharper increase after day 11, showing a greater improvement after RP ($p = 0.0044$). This group had also significantly greater post-RP improvements in 1MSTS ($p = 0.0215$) and quadriceps strength ($p = 0.0338$), but not in other outcome measures (Table 2). The proportion of participants reaching the MCID was significantly higher in study than in control group for daily steps and 1MSTS, but not for quadriceps strength or 6MWT (12 participants in study group (66.6%) and 6 controls (28.6%), $p = 0.017$ for daily steps; 10 in study group (55.5%) and 5 controls (23.8%), $p = 0.042$ for 1MSTS; 4 (22.2%) in the study group and 1 control (5%), $p = 0.104$ for quadriceps strength; 16 (88.8%) in the study group and 13 controls (61.9%), $p = 0.3749$ for the 6MWT. According to the monitor

https://doi.org/10.1016/j.arbres.2024.11.008

Please cite this article as: M. Vitacca, M. Paneroni, E. Zanelli et al., Effects of an In-Hospital Motivational Programme on Physical Activity Levels of Individuals with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease Undergoing Rehabilitation: A Randomized Controlled Trial, Archivos de Bronconeumología, https://doi.org/10.1016/j.arbres.2024.11.008

Table 1
Characteristics of the study population.

	Study group $N=18$	Control group $N=21$
CHF ($n=15$), n (%)	8 (44.4%)	7(33.3%)
EF, %	49.63 ± 15.45	51.43 ± 12.62
COPD ($n=24$), n (%)	10 (55.5%)	14 (66.6%)
FEV_1, %	42.55 ± 15.63	52.86 ± 15.53
FVC, %	80.36 ± 20.38	82.31 ± 22.21
FEV_1/FVC	48.08 ± 16.54	53.22 ± 16.39
GOLD II, n (%)	3 (30)	6 (42.9)
GOLD III, n (%)	4 (40)	7 (50.0)
GOLD IV, n (%)	3 (30)	1 (7.1)
Male, n (%)	9 (50.0%)	12 (57.14%)
Age, years	69.74 ± 9.23	68.13 ± 8.66
BMI, ratio	26.61 ± 8.27	27.09 ± 6.84
MMSE, score	28.31 ± 1.49	27.60 ± 1.79
CIRS1, score	1.81 ± 0.38	1.83 ± 0.45
CIRS2, score	3.55 ± 1.98	4.05 ± 2.46
PASE, score	94.62 ± 35.49	93.81 ± 34.49
EMI-2, score	105.83 ± 61.71	118.05 ± 59.33
BDI, score	9.44 ± 7.63	10.38 ± 5.71
SF-12 PCS, score	33.14 ± 9.06	33.93 ± 8.02
SF-12 MCS, score	50.09 ± 10.25	47.50 ± 9.61
Quadricep strength, kg	21.32 ± 6.14	22.13 ± 8.33
1MSTS, n	22.67 ± 8.27	20.00 ± 4.39
6MWT, m	357.22 ± 120.19	324.52 ± 102.50
6-MWT, % prd	64.14 ± 19.11	58.18 ± 18.69
Daily steps, n ($n=46$)	3552.83 ± 1869.95	3981.57 ± 3830.04
SPPB, score	10.28 ± 1.36	9.67 ± 1.46

Data are shown as mean ± SD or n (%). Abbreviations: n = number, CHF = chronic heart failure, EF = ejection fraction, COPD = Chronic Obstructive Pulmonary Disease, GOLD = Global Strategy for Prevention, Diagnosis, and Management of COPD, BMI = body mass index, CIRS = Cumulative Illness Rating Scale, PASE = Physical Activity Scale for the Elderly, EMI-2 = Intrinsic Motivations Inventory-2, BDI = Beck Depression Inventory, SF-12 = Short Form-12, PCS = Physical Condition Scale, MCS = Mental Condition Scale, 6MWT = 6-min walking test, 1MSTS = 1-min sit-to-stand test, SPPB = Short Physical Performance Battery, MMSE = Mini Mental State Examination.

recordings, study group showed a greater improvement in daily total active time ($p=0.0052$) and % of active time ($p=0.0084$) after RP as compared to controls, with an average increase by approximately 34 minutes and a greater increase in daily steps ($p=0.0044$). Study group reduced the percentage of daily time spent lying, sitting, and standing and increased the percentage of the time spent active ($p=0.0008$), which was statistically superior to the control group.

According to multivariate linear regression, factors best explaining the change in daily steps after RP, were in order of performance: higher baseline number of chair-rises at 1MSTS, higher CIRS score, lower number of steps/day, higher distance at 6MWT, being male and in study group.

Individual daily cost/participant was 0.77 ± 0.15€ for control and 5.98 ± 0.15€ for study group ($p<0.0001$). Total physiotherapist time was 239.10 ± 6.08 and 32.20 ± 6.34 min for study and control group, respectively ($p<0.0001$).

Ours is one of the first RCTs evaluating the effects of an in-hospital motivational programme potentially useful to increase PA in people with COPD or CHF in addition to standard RP. Using the wearable-device it was able to improve the primary outcome, PA, as assessed by daily steps. It was also associated with an increase in daily active time.

Collaborative self-management or coaching strategies, including unsupervised programmes and/or pedometer feedback or web-based interventions are promising in increasing PA, but not in improving acute care utilisation or survival.[16–18] However, the whole programme required the cost of a more than a seven-fold increase in physiotherapist time. Whether this cost-benefit ratio is affordable for the healthcare systems needs to be discussed.[19]

Despite improvement in 6MWT, control group did not improve daily steps, confirming the dissociation between exercise capacity (as assessed by 6MWT) and PA highlighting the need to assess PA and exercise capacity with different tools (in this case daily steps and 6MWT, respectively) and to add other strategies to improve PA (e.g. our motivational programme). Our 28 sessions over 14 days may seem short. However, 28 sessions would be delivered in a four-week programme (once a day). Our two daily session schedule was chosen on the basis of our previous findings showing that exercise tolerance plateau can be observed in people with COPD after 12 days of in-hospital endurance training.[20]

We need further research to determine optimal intervention design, timing, and participant selection specifically for changing sedentary behaviour and increasing PA in diseases other than COPD and CHF.

CRediT authorship contribution statement

Michele Vitacca: Conceptualization, Methodology, Writing – original draft, Writing – review and editing. **Mara Paneroni:** Methodology, Supervision, Investigation, Formal analysis, Writing – original draft, Writing – review and editing. **Emanuela Zanelli:** Investigation, Writing – review and editing. **Beatrice Salvi:** Data curation, Visualization, Writing – review and editing. **Gloria Fiorini Aloisi:** Data curation, Investigation, Writing – review and editing. **Nicolino Ambrosino:** Writing – original draft, Writing – review and editing. **Simonetta Scalvini:** Conceptualization, Supervision, Writing – review and editing.

Artificial intelligence involvement

The authors have not partially or totally produced software or tools with the help of any artificial intelligence.

Table 2
Post-programme changes in outcome measures.

	All $N=39$	Study group $N=18$	Control group $N=21$	p value
PASE, score	91.89 ± 31.71	94.62 ± 35.50	93.81 ± 34.49	0.9427
EMI-2, score	5.79 ± 27.83	8.72 ± 27.71	−1.43 ± 35.70	0.3309
BDI, score	−1.31 ± 3.86*	−1.06 ± 3.19	−1.52 ± 4.42	0.7110
SF-12 PCS, score	7.65 ± 10.07*	8.76 ± 10.96*	6.60 ± 9.38*	0.2849
SF-12 MCS, score	3.12 ± 9.03	4.63 ± 9.20	1.69 ± 8.89	0.5475
6MWT, m	73.44 ± 48.12*	65.28 ± 37.90*	80.43 ± 55.38*	0.3336

Data are shown as mean ± SD. Abbreviations: n = number, PASE = Physical Activity Scale for the Elderly, EMI-2 = Exercise Motivations Inventory-2, BDI = Beck Depression Inventory, SF-12 = Short Form-12, PCS = Physical Condition Scale, MCS = Mental Condition Scale, SPPB = Short Physical Performance Battery, 1MST = 1-min sit-to-stand, 6MWT = 6-min walking test.

* p-Value < 0.005 in pre-to-post difference within group.

Funding of research

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

Acknowledgements

The authors thank Adriana Olivares and Laura Comini for critical revision and technical assistance. This research was supported by the "Ricerca Corrente" Funding scheme of the Ministry of Health, Italy.

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