

1 ***Title: Comparison between two inspiratory muscle training protocols, low loads vs***
2 ***high loads, in institutionalized elderly women: A Double-Blind Randomised***
3 ***Controlled Trial.***

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8 ***Running Head: Inspiratory muscle training in elderly women.***

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15 **ABSTRACT**

16 **Background:** Aging results in a decline in the function of the respiratory muscles.
17 Inspiratory muscle training is presented as a possible solution to attenuate the loss of
18 respiratory function in elderly. The objective of the study was to evaluate and compare
19 the efficacy of two protocols with inspiratory muscle training (IMT), low loads and high

20 loads, to improve respiratory strength, functional capacity and dyspnea in
21 institutionalized elderly women, over 65 years.

22 **Methods:** The study was a controlled, randomised, double-blind trial and with
23 allocation concealment performed on 26 institutionalized elderly women distributed in 2
24 groups, High Intensity Group (HIG) and Low Intensity Group (LIG). Over an 8-week
25 period an IMT protocol was followed 5 days/week, 15 minutes/day. HIG trained with a
26 load of 40% of the maximum inspiratory pressure (MIP) and LIG with 20%. MIP,
27 maximum expiratory pressure (MEP), functional capacity and dyspnea were evaluated.

28 **Results:** After training, in HIG MIP, MEP and functional capacity increased 52%, 16%
29 and 7% respectively ($p=.000$, $p=.001$, $p=.001$) and in LIG 30%, 18% and 9%
30 respectively ($p=.002$, $p=.014$, $p=.001$). The improvement in MIP was significantly
31 higher in HIG than in LIG ($p=.042$).

32 **Conclusion:** Inspiratory muscle training with low and high loads improves respiratory
33 muscle strength and functional capacity in institutionalized elderly women. In addition,
34 high loads were significantly more effective to improve MIP.

35 INTRODUCTION

36 Population ageing is a global phenomenon: Virtually every country in the world is
37 experiencing growth in the size and proportion of older persons in their population.
38 There were 703 million persons aged 65 years or over in the world in 2019. The number
39 of older persons is projected to double to 1.5 billion in 2050 [1].

40 Aging results in a decline in lung function as in other systems. The principal changes in
41 the respiratory system of the elderly include loss of chest wall compliance, decrease in

42 strength of elastic recoil of lung parenchyma, decrease in respiratory muscle strength
43 and decreased responsiveness to hypoxemia and hypercapnia. [2, 3]

44 In this sense, inspiratory muscle training (IMT) appears to be a possible intervention
45 that can minimize harmful effects on respiratory muscles in the elderly. [4]Peripheral
46 muscle exercises promote an increase in respiratory muscle strength and endurance.
47 However, these gains appear to be higher when combined with specific training of the
48 respiratory muscles [5], making this an option to supplement the training of peripheral
49 muscles and generating benefits in different current comorbidities such as hypertension,
50 obesity and diabetes that affect a large portion of the elderly. [6, 7]

51 Aging impairs the autonomic balance reducing the vagal and increasing the sympathetic
52 components of heart rate variability (HRV) and this could be associated with a decline
53 in physical capacity. IMT is a possible tool to attenuate this physical capacity decline in
54 older women. [8]

55 Based on this information, the aim of this study was to evaluate and compare the
56 efficacy of two protocols with IMT, low loads and high loads, to improve respiratory
57 strength, functional capacity and dyspnea in older women.

58 **METHODS**

59 **Study design**

60 The study was a controlled, randomised, double-blind trial and with allocation
61 concealment. The study protocol was approved by the Bioethics Committee of the
62 University of Salamanca (number of registry 365, 22 may 2019).

63 The study was registered in the clinical trials database of the United States National
64 Library of Medicine (www.clinicaltrials.gov) with the number of registration
65 NCT03827356.

66 The research was carried on by Nursing and Physiotherapy Department of University of
67 Salamanca. All volunteers signed a free and informed consent form.

68 **Participants**

69 Institutionalized elderly women aged between 75 and 95 years were included, who had
70 more than 60 points at Barthel Index for Activities of Daily Living [9], were capable of
71 walking without aid from another person and understood the objectives, the evaluations
72 and the intervention of the trial. Exclusion criteria were: some respiratory pathology in
73 the previous 4 weeks, difficulty carrying out the evaluation procedures or the exercises,
74 smokers, presence of hemodynamic instability (heart rate >150 beats per minute (bpm),
75 systolic blood pressure >140 millimeters mercury (mmHg) or diastolic blood pressure
76 >90 mmHg), pulmonary comorbidities, heart disease and neuromuscular or
77 degenerative diseases.

78 The sample size was determined by sampling calculation done from data collected
79 during a pilot study with 10 volunteers, which established a sample of 10 individuals for
80 each group to detect a difference of 12 cmH₂O for MIP, considering a power of 80%,
81 security 95%.

82 **Procedure and Measures of Outcomes**

83 Anthropometric, clinical and demographic data were collected. Participants were
84 completely evaluated at the beginning and at the end of the intervention period.

85 The primary outcomes were respiratory muscle strength, functional capacity and
86 dyspnea. Secondary outcomes were systolic blood pressure (SBP), diastolic blood
87 pressure (DBP), heart rate and oxygen saturation (SpO₂). All of them were evaluated
88 pre- and post-treatment.

89 After the initial evaluation, the participants were randomly distributed in two groups
90 using simple randomization with a computer-generated random numbers. The principal
91 investigator and the participants did not know where they were allocated: High Intensity
92 Group (HIG) or Low Intensity Group (LIG).

93 Respiratory muscle strength

94 Respiratory muscle strength was assessed by measuring maximum inspiratory pressure
95 (MIP) and maximum expiratory pressure (MEP) using a pressure transducer, Elka 15,
96 from residual volume and total lung capacity, respectively. It obtained each
97 measurement in millibar and converted it into the reference unit of centimeter of water
98 (cm H₂O) (1 mbar = 1.01973 cm H₂O), following the rules of the American Thoracic
99 Society/European Respiratory Society (ATS / ERS) [10]. The procedure was repeated at
100 least 3 times or until 2 reproducible efforts (ie, within 5% each other). An interval of
101 about 1 minute was allowed between the measurements to avoid short-term fatigue for
102 respiratory muscles. The higher of 2 reproducible values was considered in the data
103 analysis. MIP was assessed every 2 weeks to set the IMT workload in both groups.

104 Functional capacity

105 Six-minute walk test (6MWT) was used to evaluate functional capacity. This
106 submaximal test measures the distance that a patient can quickly walk on a flat, hard

107 surface in a period of 6 minutes [11]. We followed the statement of the American
108 Thoracic Society (ATS), guidelines for the 6MWT [12].

109 **In addition to measuring the total distance walked, it was evaluated the following**
110 **parameters prewalk and postwalk to check the ability to the test of the elderly**
111 **women. These evaluations were part of the 6MWT protocol:**

112 **Heart rate**

113 **SpO2**

114 **SBP, DBP**

115 **Dyspnea and overall fatigue using the Borg scale [13]**

116 Dyspnea

117 **Modified Medical Research Council (MMRC) was used to measure dyspnea [14].**

118 **It was evaluated before and after 8-week intervention period, in contrast to Borg**
119 **scale which has also been used to evaluate dyspnea as a complement to 6MWT.**

120 **Experimental Protocol**

121 Elderly women performed the intervention protocol over 8 weeks using Treshold IMT,
122 with a frequency of 1 session per day, 5 days a week. The participants carried out 15
123 series of 1 minute with a 1-minute rest between them.

124 Treshold IMT provides consistent and specific pressure for inspiratory muscle strength
125 and endurance training, regardless of how quickly or slowly patients breathe. This
126 device incorporates a flow-independent one-way valve to ensure consistent resistance
127 and features an adjustable specific pressure setting (in cm H₂O) to be set by a

128 healthcare professional. When patients inhale through Treshold IMT, a spring-loaded
129 valve provides resistance.

130 The intensity of training was different in the groups: HIG was adjusted to 40% of MIP
131 and LIG to 20% of MIP, measured during the initial evaluation. The load intensity
132 adjustment was performed each 2 weeks by evaluating the MIP. During the entire
133 period of the intervention protocol, the resistive load was in these percentages. The rest
134 of parameters were the same in both groups.

135 The training protocol of both groups was carried out by a single therapist who
136 supervised all the sessions with IMT, so the adherence to the program was very high
137 and could report the presence of adverse effects (increased fatigue, breathing problems,
138 dizziness or sickness).

139 **Statistical Analysis**

140 The results of the initial characteristics of the sample and statistical analysis of the data
141 were expressed as mean and standard deviation (SD). The Saphiro-Wilk was used to
142 evaluate the normality and homogeneity of the data. To compare initial values, final
143 values and differences between them, parametric tests were used only where a normal
144 distribution is assumed, we used the t-test for independent and paired samples to
145 determine whether the differences in the means of the groups are large enough to
146 allow the assumption that the corresponding population means are different; and the
147 non-parametric Mann-Whitney U-test for independent samples and the Wilcoxon
148 rank-sum test for paired data, both compare median rather than mean. HJ-Biplot was
149 used to reduce the dimension and represent simultaneously the observations and
150 variables in a small space where the interrelations between them are captured.

151 To compare the outcomes and the size of the effect t-test and Mann-Whitney test were
152 used.

153 Biplot methods are techniques for reducing the dimension, specifically the HJ-Biplot
154 allows to jointly represent the same interpretable graph observations and variables, as if
155 it were a multivariate dispersion graph, where the interrelations between them are
156 captured. In our case, patients are represented as points in the plane, so that their
157 position is translated in terms of similarity, that is, two patients with a similar position
158 in the plane have similar characteristics on the variables to study; and the variables used
159 to assess the patient's lung capacity as vectors, where acute angles correspond to direct
160 relationships, right angles reveal independence and obtuse angles refer to inverse
161 relationships.

162 **RESULTS**

163 Between April and June 2019, 59 elderly women were interviewed in their
164 institutionalization centers, 26 participants were selected for the intervention and
165 randomly distributed in the HIG (n=14) or LIG (n=12) (Figure 1). Training adherence
166 was 100%, all the training sessions were supervised by a professional. Following the
167 interventions, there were no adverse events in participants.

168 Baseline characteristics of the sample are shown in Table 1. No differences were found
169 between the groups at the beginning of the trial. There were no losses during the
170 intervention period.

171 Pre and post-intervention primary outcomes comparisons between HIG and LIG are
172 shown in Table 2. Initial values, final values and the difference between them were
173 compared in the statistical analysis.

174 **Respiratory muscle strength**

175 Significant effects were observed on MIP and MEP between pre- and post- treatment, in
176 HIG ($p=.000$, $p=.002$) and LIG ($p=.002$, $p=.0014$). Percentage changes of MIP were
177 significantly different between the groups, in favour of HIG ($p=.025$), so MIP
178 improvement was significantly in HIG.

179 MEP significantly increased after intervention in both groups, and the improvement
180 achieved was similar between them.

181 **Functional capacity**

182 Distance walked at 6MWT significantly increased in both groups after the intervention.
183 6MWT changes were similar between HIG and LIG ($p=.001$, $p=.001$).

184 Heart rate values did not show significant differences between the groups ($p=.116$).

185 SpO₂ changes were similar between HIG and LIG ($p=.156$).

186 SBP decreased after the intervention in HIG, before 6MWT ($p=.009$) and after 6MWT
187 ($p=.036$). DBP did not change after the training in anygroup. No significantly difference
188 between the groups was found.

189 Percentage changes of dyspnea and overall fatigue measured with Borg scale were not
190 significantly different between the HIG and LIG ($p=.872$).

191 **Dyspnea**

192 Dyspnea improved significantly in LIG ($p=.017$), in HIG we observed a decrease of
193 dyspnea but not statistically significant.

194 No statistical differences were found in MMRC improvements between the groups
195 (p=.139).

196 HJ Biplot analysis is shown in Figure 2 and 3, comparison of evaluated parameters
197 evolution during the intervention

198 **DISCUSSION**

199 This is the first study to investigate the effects of a supervised IMT in elderly women
200 comparing two different protocols. Using a double-blind, randomized controlled trial
201 our results revealed that 8-week IMT improves respiratory muscle strength and
202 functional capacity in elderly women. High loads got better results in MIP and low
203 loads in dyspnea. In the rest of studied parameters the results were similar and elderly
204 women achieved an improvement of respiratory muscle strength, functional capacity
205 and dyspnea.

206 **The analyzed sample was elderly institutionalized women with medium age 88**
207 **years and lower respiratory strength values than reference data. According these**
208 **terms, it was decided to train with low loads and the nomenclature agreed for the**
209 **groups was “High intensity group” (HIG) for those patients that trained at 40%**
210 **MIP and “Low intensity group” (LIG) for those that trained at 20% MIP.**

211 Previous scientific evidence on the efficacy of IMT in elderly women is very reduced,
212 these studies used loads of 40-50% MIP as moderate intensity training in women aged
213 between 60 and 80 years. Studies in younger people and studies in patients with any
214 disease, like multiple sclerosis or chronic obstructive pulmonary disease, were
215 consulted, training load was between 20% and 80%, being the main load used 30%.
216 Based on this evidence and analyzing the own characteristics in elderly women, to

217 assign the name “high loads” (intensity training 40% MIP) and “low loads” (intensity
218 training 20% MIP) was decided.

219 **Effects of IMT on respiratory muscle strength**

220 Respiratory muscle strength (MIP and MEP) increased in both groups, high intensity
221 and low intensity. The main improvement was in MIP, and the results found were
222 similar to other studies conducted on elderly people [15-19]. In addition to MIP, there
223 was an increase in MEP, similar in both groups [4]. This can be explained by the neural
224 conditioning resulting from repeated exposures to the same task (learning effect), a
225 mechanism that generates an increase in respiratory muscle strength by improving
226 neuromuscular recruitment pattern [20].

227 One important result from the present study was to find that the increasing in MIP was
228 significantly higher in HIG than in LIG (52.3% vs 29.8%), so high loads were more
229 effective to increase inspiratory muscle strength than low loads. Nowadays there are no
230 trials in older women comparing high loads vs low loads with IMT protocols. Last trials
231 affirm high intensity is more effective than low intensity to improve MIP, but we have
232 to consult trials carried on in general population [21-22].

233 Previous studies in elderly adults reported benefits in MIP between 21-39% [4, 15, 23,
234 24]. Souza H [4], Mills D [23] and Roldan A [24] trained with 50% MIP load and Aznar
235 S [15] with 30%. Our patients trained with high loads (40% MIP) achieved higher
236 increase in MIP (52.3%) than these researchers, and our patients trained with low loads
237 (20% MIP) were within range 21-39% (29.8%). This finding is very significant because
238 recent trials carried out in general population have affirmed high intensity is more
239 effective than low intensity to improve MIP, which is in concordance with our results,

240 but in elderly people is possible to improve MIP with lower IMT loads, as it has been
241 demonstrated in our study group LIG. Training with 20% MIP load improved
242 inspiratory strength similar to previous studies carried out with higher loads in elderly
243 people.

244 Previous studies have shown that in elderly population, the decrease in skeletal muscle
245 mass and function is constant. In people over 65, this percentage reaches a 14% loss.
246 The diaphragm is the main inspiratory muscle, responsible for 75% of inspiration. An
247 equal amount of maintenance and gain becomes essential [25].

248 **Functional capacity**

249 All the elderly women in both groups improved significantly the distance walked
250 measured with 6MWT, corroborating previous studies in elderly patients and
251 demonstrating once again that exercise increases and maintains function and activity in
252 the elderly [16, 26, 27].

253 No differences between HIG and LIG were found after the intervention, in this case, the
254 training intensity was not relevant for 6MWT results. Recent studies evidence IMT
255 increases functional capacity [8, 25-28], but some trials are not able to improve it and
256 only manage to hold the initial results [29, 30].

257 These results demonstrated that respiratory rehabilitation with IMT was able to improve
258 respiratory parameters but also functional capacity in older women. Nowadays, new
259 studies which recruit representative random samples of community based older people
260 are needed to improve knowledge in functional capacity [31].

261 **Dyspnea**

262 Dyspnea improved significantly in LIG, in HIG we observed a decrease of dyspnea but
263 not statistically significant.

264 Recent studies showed IMT improved dyspnea, even if the mechanisms are nowadays
265 poorly understood, accepted theory states dyspnea relief occurred in conjunction with a
266 reduced activation of the diaphragm relative to maximum in the absence of significant
267 changes in ventilation, breathing pattern, and operating lung volumes. Dyspnea is
268 influenced by inspirational muscle strength and the load placed upon the inspiratory
269 muscles. [32, 33]. Pazzianotto E [34] trained with a load of 55% MIP and improved
270 dyspnea (-1.0 ± 0.27 Borg units) in 16 obese women. Huang C [35] improved dyspnea
271 in older subjects training with high loads (75-80% MIP). Ramsook AH [33] improved
272 dyspnea after training with maximum intensity (pre: 7.6 ± 2.5 vs. post: 6.8 ± 2.9 Borg
273 units), but not training with 10% MIP load, with no weekly adjustments. Karadalli M
274 [36] managed to decrease dyspnea training for 6 weeks at 40% of MIP but not training
275 at 5%. These results demonstrated IMT was able to improve dyspnea using higher
276 loads, but lower loads (5-10% MIP) didn't manage to decrease dyspnea. Our results
277 proved an IMT load of 20% MIP improved dyspnea in elderly women, even it was more
278 effective than higher loads (40% MIP) in this parameter. This finding let us establish an
279 IMT load of 20% MIP as minimum load to improve dyspnea in elderly women.

280 IMT is postulated as a great complement to treat dyspnea in elderly women.

281 **General conclusion**

282 The reviewed studies revealed a positive trend for the effectiveness of IMT in
283 improving muscle performance in elderly women but the information to evaluate other
284 outcomes like functional capacity is very limited [37]. There was heterogeneity in the

285 protocols described for this population with respect to the total training time (4-8
286 weeks), intensity (30-80% of MIP), and weekly frequency (5 or 7 sessions). This study
287 will increase evidence to support IMT in elderly women.

288 **Trial limitations and Recommendations**

289 The inclusion of a third group, with the same characteristics of our sample, which did
290 not train with any respiratory dispositive, as a control group, to contrast results.

291 An important limitation is the time of intervention, however as the vast majority of
292 exercise protocols, understanding the “acute” effects of IMT in elderly women, may
293 ensure better programming chronic protocols, and increase our understanding of the
294 possible beneficial and side effects.

295 The lack of follow-up of the volunteers in the subsequent months after the training did
296 not allow to evaluate the long-term efficacy of IMT.

297 Future research that aims to investigate the benefits in institutionalized elderly women
298 obtained with IMT should evaluate spirometry parameters to achieve a global vision of
299 the respiratory system. Follow-up of the volunteers for 6 months would be interesting to
300 meet the efficacy of IMT once the participants stopped using it.

301 **Conclusion**

302 This study showed that an 8-week protocol with IMT improved respiratory muscle
303 strength and functional capacity in elderly women. Training with high loads was more
304 effective to improve inspiratory muscle strength and training with low loads to improve
305 dyspnea. A minimum 20% MIP load was enough to improve dyspnea, inspiratory
306 strength, expiratory strength and functional capacity in elderly women.

307 **Statements**

308 **Acknowledgement**

309 We would like to express our special thanks of gratitude to every woman who
310 participate in this project which will help us to improve the treatments in elderly
311 women.

312 **Statement of ethics**

313 This randomised trial complies with internationally-accepted standards for research and
314 practice reporting. All the subjects signed an informed consent. The study protocol was
315 approved by the Bioethics Committee of the University of Salamanca (number of
316 registry 365, 22 may 2019).

317 **Conflict of Interest Statement**

318 The authors have no conflicts of interest to declare.

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320 There was no external financial support.

321 **Authors' Contributions**

322 CARLOS MARTIN SANCHEZ has been responsible for the design of the protocol, the
323 experimental part and the redaction of the manuscript. Corresponding author and
324 responsible for the integrity of manuscript.

325 FAUSTO JOSE BARBERO IGLESIAS has collaborator in the project to advise in the
326 main themes of the study and to carry out the evaluation material.

327 VICTOR AMOR-ESTEBAN has collaborated in the project to complete statistical
328 evaluation.

329 ANA MARIA MARTIN NOGUERAS has collaborated in the project to advise and
330 guide in the redaction of the manuscript, the statistical evaluation and the proper
331 elaboration of the complete manuscript.

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448

449 **Figure legends**

450 Figure 1: Flowchart of participants

451 Figure 2: HJ Biplot High Intensity Group

452 Figure 3: HJ Biplot Low Intensity Group