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Title: Efficacy of inspiratory muscle training as a practical and minimally intrusive technique to aid functional fitness among adults with obesity.

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Running head: Inspiratory muscle training and obesity

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25 **ABSTRACT**

26

27 *Objective:* To examine the efficacy of inspiratory muscle training (IMT) as a non-
28 intrusive and practical intervention to stimulate improved functional fitness in adults with
29 obesity. As excess adiposity of the chest impedes the mechanics of breathing, targeted re-
30 training of the inspiratory muscles may ameliorate sensations of breathlessness, improve
31 physical performance and lead to greater engagement in physical activity.

32 *Methods:* Sixty seven adults (BMI = 36 ± 6.5) were randomized into either an
33 experimental (EXP: n=35) or placebo (PLA: n=32) group with both groups undertaking a
34 4-week IMT intervention, comprising daily use of a inspiratory resistance device set to
35 55% (EXP), or 10% (PLA) of maximum inspiratory effort.

36 *Results:* Inspiratory muscle strength was significantly improved in EXP (19.1 cmH₂O
37 gain; P<0.01) but did not change in PLA. Additionally, the post training walking distance
38 covered was significantly extended for EXP (P<0.01), but not for PLA. Bivariate analysis
39 demonstrated a positive association between the change (%) of performance in the
40 walking test and BMI ($r = 0.78$; P<0.01) for EXP.

41 *Conclusion:* The findings from this study suggest IMT provides a practical, self-
42 administered intervention for use in a home setting. This could be a useful strategy for
43 wider scale public health implementation and concurrent application of physical activity
44 initiatives.

45

46 **Key words:**

47 Obesity, physical activity, respiratory disorders, chronic disease

48

49 **INTRODUCTION**

50

51 Adults with obesity commonly experience shortness of breath at rest and during exercise
52 compared to healthy normal weight adults (Mandal and Hart, 2012; Villiot-Danger et al.,
53 2011; Luce, 1980; Salome et al., 2008; Ladosky and Botelho, 2001). This is typically due
54 to excess adiposity of the chest which impedes the actions of the inspiratory muscles,
55 leading to an inability to exercise effectively and is associated with conditions such as
56 obesity hypoventilation syndrome and sleep apnea (Olsen and Zwillich, 2005; Aldabal
57 and Bahammam, 2009). As physical inactivity exacerbates breathing inadequacy by
58 detraining inspiratory and skeletal muscles (Villiot-Danger et al., 2011; Salome et al.,
59 2008; Edwards et al., 2008) the primary purpose of this study was to examine whether or
60 not an inspiratory muscle training (IMT) programme undertaken in a home setting might
61 both strengthen the muscles of respiration of adults with obesity and thereby increase
62 their capacity to performance exercise (Edwards et al., 2012). The application of such an
63 unobtrusive, self-administered and practical intervention might prove a meaningful public
64 health intervention for wider scale implementation. Improved performance of detrained
65 inspiratory muscles in people with obesity would be expected to enable greater capacity
66 to engage and perform exercise through improvements to breathing (Ladosky and
67 Botelho, 2001) but as yet few studies have examined this issue among out-patients
68 (Arena and Cahalin, 2014; Edwards et al., 2012), although, encouraging gains have been
69 demonstrated among athletic groups (Edwards et al., 2008; Griffiths and McConnell,
70 2007; Romer et al., 2002).

71

72 Many physical activity interventions have been developed which aim to improve health
73 outcomes for adults with obesity by reducing excess body weight (Villiot-Danger et al.,
74 2011). However, the effectiveness of exercise is often restricted by factors associated
75 with premature fatigue, such as breathlessness (Luce et al., 1980; Salome et al., 2008).
76 Such sensations of fatigue could diminish the motivational drive to commence a physical
77 training programme or affect the sustainability of participation (Ekkekakis, 2009;
78 Edwards and Polman, 2013).

79

80 The act of inspiration is the primary cause of work when breathing. This occurs whereby
81 the chest and lungs expand to accommodate an increased volume of air, while expiration
82 is largely passive, particularly when resting or only exercising at moderate intensity (Otis
83 et al., 1950). Consequently, a pre-exercise training programme specifically designed to
84 enhance the performance of inspiratory muscles for adults with obesity might lessen
85 subconscious inhibition of exercise performance (Ekkekakis et al., 2009), reduce
86 respiratory muscle fatigue (Salome et al., 2008) and promote improved performance in
87 response to exercise challenges (Edwards et al., 2008; Edwards and Cooke, 2004). In
88 support of this perspective, a study of hospitalized obese adults demonstrated an
89 aggressive two month intervention of supervised respiratory (inspiratory and expiratory)
90 muscle training coupled with diet and physical training significantly improved both
91 respiratory muscle endurance and the distance covered in a 6-minute walking test (~11%
92 gain) (Villiot-Danger et al., 2011). While the results of that experiment strongly suggest
93 respiratory muscle training may be of value to obese individuals, its findings are not
94 directly applicable to non-hospitalised individuals due to the multidimensional nature of

95 the intervention and the supervisory requirements of such an intense protocol. A less
96 aggressive, but potentially equally effective strategy, is via inspiratory muscle training
97 (IMT) using a portable inspiratory-resistance training device (Edwards, 2013; Edwards et
98 al., 2012).

99

100 As obese individuals are well known to experience shortness of breath to a greater extent
101 than healthy normal subjects (Salome et al., 2008) it is therefore likely that a programme
102 of IMT training will be particularly meaningful for obese individuals. The aim of this
103 study is therefore to investigate whether a programme of IMT will improve inspiratory
104 muscle strength and functional performance as assessed by the self-paced 6-minute walk
105 test (Enright 2003).

106

107 MATERIAL AND METHODS

108

109 Participants

110

111 Sixty seven adults (37 males and 30 females) volunteered for this study, provided written
112 informed consent prior to participation and were randomly allocated to either
113 experimental (EXP: $n=35$; $m=19$, $f=16$) or placebo (PLA: $n=32$; $m=18$, $f=14$) group as
114 matched parallel pairs based on body mass index (BMI) and history of smoking.
115 Inclusion criteria were (i) BMI >27 kg/m² and (ii) being free of respiratory or
116 cardiovascular diseases. The physical characteristics of the two groups are shown in
117 Table 1. Ethical clearance for this study was provided by the Research and Ethics
118 committee of James Cook University.

119

120 Study Overview

121 Baseline physical assessments were made of mass, height, blood pressure, standard
122 spirometry (FVC, FEV₁), maximal inspiratory muscle pressure (MIP), 6-minute walk test
123 performance and estimation of maximal aerobic power ($\dot{V} O_2$ max). Following these
124 measures, all individuals undertook familiarization with a portable inspiratory-resistance
125 training device (PowerBREATHE, UK). This device was pre-set to either 55% of
126 individualized maximal inspiratory effort (EXP) or to the minimum device setting
127 equivalent to approximately 10% of maximal inspiratory effort (PLA) and thereafter used
128 during the experiment (Edwards, 2013). Over the 4-week period, both groups performed

129 2 x 30 daily inspiratory efforts [15-16]. The assessments were then repeated following the
130 4-week intervention. Adherence and compliance to the training protocol were regularly
131 checked and no participants reported experiencing issues or difficulties.

132

133 **Study procedures**

134

135 *Lung function and inspiratory muscle performance*

136

137 Spirometry measurements were undertaken at baseline and repeated post-programme.

138 These included forced vital capacity (FVC) and forced expiratory volume in 1 second

139 (FEV₁). These procedures were completed using a hand held training device (Microlab-

140 Spirometry SN M20364, USA).

141

142 In addition to standard spirometry measures, maximal static inspiratory mouth pressure

143 (MIP) was also measured. This was assessed at residual volume following a slow and

144 complete expiration using a mouth pressure meter (PowerBREATHE KH1

145 INSPIRATORY METER, Gaiam, UK). The best of three maximal efforts were analysed

146 for all measures. These procedures were completed similarly with our earlier

147 methodology (Edwards 2013).

148

149 *Functional exercise capacity*

150

151 Participants were instructed to “*walk as far as you can in six minutes without running or*
152 *jogging*” in accordance with previously validated techniques for a 6-minute walk test
153 (Gibbons et al., 2001). Distance covered (m) and heart rates were recorded at the
154 conclusion of the 6-minute period. This test is a clinically relevant and common
155 procedure which provides an effective measure of functional walking capacity in
156 untrained, sedentary adults (Enright, 2003; Hulens et al. 2003; Gibbons et al., 2001).

157

158 Using a validated heart rate derived algorithm, maximal aerobic power ($\dot{V} O_2 \text{ max}$) was
159 estimated from a sub-maximal single stage 4-minute walking test (Ebbeling et al., 1991).
160 All participants were requested to perform an individually determined brisk and constant
161 walking pace ranging from 3.5 to 5 km/h for 4-minutes on a treadmill in accordance with
162 the protocol.

163

164 The study participants were required to wear a heart rate watch and a chest strap
165 transmitter (Polar, T31 Coded Transmitter, Australia) during exercise testing.

166

167 The CR10 Borg Scale was used to ascertain ratings of perceived exertion RPE as an
168 index of fatigue perception in response to exercise (Borg, 1982).

169

170 **Statistical analyses**

171

172 Statistical software package SPSS (version 18.0, SPSS, Chicago, Illinois) was used for all
173 statistical analyses. Parametric pre- and post-training results and group interactions were

174 statistically compared using two-way repeated measures analyses of variance (group x
175 time) (ANOVA). Post hoc Tukey tests were used to examine differences between
176 datasets where indicated by ANOVA. Associations were examined using Pearson
177 Product Moment Correlations. To ascertain an appropriate sample size for the study,
178 analysis was based on an anticipated mean improvement (SD) in the six minute walk test
179 of those in the EXP in the PLA group (Edwards et al., 2008). Probability values of <0.05
180 were considered significant and all tests were two sided. All results are expressed as
181 means (SD) unless otherwise stated.

182

183 **RESULTS**

184

185 Evaluation of distance covered in response to the 6-minute walking test revealed a
186 significant group x time ANOVA interaction. As expected, there was no difference
187 between groups at baseline. Within-group comparisons for time (pre- to –post-training)
188 indicated EXP significantly improved distance covered (m) in response to the 6-minute
189 walk test from baseline to post-training (60.6 ± 25.7 m gain; $P < 0.01$). Conversely, the
190 distance covered by PLA was not significantly extended over the 4-week intervention
191 period (13.3 ± 35.9 m gain; NS).

192

193 ***** FIGURE 1 HERE *****

194

195 The estimation of $\dot{V} O_2$ max in response to treadmill walking did not identify a significant
196 difference between EXP and PLA at either baseline or after the intervention (Table 2).

197 Additionally, assessment of standard spirometry variables (FVC and FEV₁) also did not
198 identify differences between groups at either baseline or post-training (Table 2).

199

200 The MIP assessment revealed a significant group x time ANOVA interaction effect
201 (P<0.01). Subsequent post hoc Tukey HSD test evaluation demonstrated MIP improved
202 significantly over the 4-week intervention for EXP (66.7 ±10.5 to 85.8 ±9.3cmH₂O;
203 P<0.01). However, MIP did not significantly change for PLA (68.4 ±11.7 to 77.7 ±10.8
204 cmH₂O; NS). There was a between group difference following the intervention where
205 EXP demonstrated significantly greater MIP than PLA (P<0.01).

206

207 Heart rate responses to the 6-minute walk test were unchanged for both EXP (124±14 and
208 121 ±15 b/min) and PLA (118 ±15 and 116 ±11 b/min) from pre- to post-training.

209

210 RPE evaluations undertaken after exercise were not different between groups and did not
211 change significantly from baseline to post-training in either EXP (2.7 ± 0.7 to 2.7 ± 0.8)
212 or PLA (2.7 ±1.7 to 2.9 ±1.8).

213

214 A significant correlation was observed between % change of distance covered in the 6-
215 minute walk test (pre- to post-training) and baseline BMI (r = 0.78; P<0.01). This effect
216 between a participant factor and intervention response was specific to EXP. There were
217 no meaningful associations identified in PLA.

218

219

220 **DISCUSSION**

221

222 The main finding of this study was that a 4-week period of inspiratory muscle training
223 (IMT) appears efficacious for improving inspiratory muscle strength and the functional
224 fitness of obese and overweight participants. As these effects were not evident in PLA, it
225 suggests that IMT may be a meaningful intervention with which to augment physical
226 performance outcomes for overweight and obese individuals. The results of our study
227 support and exceed those from our earlier pilot data (Edwards et al., 2012) and also from
228 hospitalized obese individuals (Villiot-Danger et al., 2011). As these results were
229 achieved with a considerably less aggressive intervention it seems likely that such a
230 practical technique might be suitable for wider implementation.

231

232 In our study, post-test evaluations of perceived exertion did not differentiate the groups,
233 despite a significant improvement in walking performance for EXP. This suggests
234 individuals may have paced themselves according to physical sensations (Suzuki et al.,
235 1995, such as a tolerable level of physical discomfort the individuals were prepared to
236 endure in the 6-minute task (Ekkekakis, 2009; Edwards and Polman, 2013). As such,
237 participants would (and did) experience the same level of tolerable physical discomfort
238 during the 6-minute walk test at both baseline and post-training. The difference would
239 therefore not be evident in a change to the perceived exertion but in a changed
240 (improved) outcome of a greater walking distance covered.

241

242 Bivariate analysis revealed an interesting association between data sets whereby the (%)
243 change from baseline to post-training in distance covered for the 6-minute walk test was
244 positively related to BMI for EXP ($r = 0.78$; $P < 0.01$). This suggests individuals with a
245 higher BMI might be expected to gain the most from an IMT intervention, possibly due
246 to the greater post-training performance and resistance to fatigue of inspiratory muscles
247 (Verges et al., 2007; Zerah et al., 1993).

248

249 MIP results for EXP remained beneath levels reported for healthy subjects (Voliantis et
250 al., 2001) suggesting that continuation of IMT beyond a 4-week period could be
251 meaningful to an obese population where detraining effects may be substantial. There are
252 very limited data in this area and, therefore, further studies may elucidate whether
253 extending the period of IMT prior to physical training and also utilising concurrent (IMT
254 and physical) training improve performance outcomes for obese individuals.

255

256 Although this study was much larger and robust than our previous pilot study (Edwards et
257 al., 2012) it did not include a concurrent IMT strategy with exercise intervention. The use
258 of IMT in conjunction to an exercise training intervention could be expected to further
259 augment performance as has been the case in athletes (Edwards et al., 2008).

260 Nevertheless, a 4-week period of IMT demonstrates the usefulness of the technique over
261 a short period, but a longitudinal intervention with and without concurrent exercise would
262 be worthwhile to determine whether training effects are sustainable.

263

264 In summary, IMT may provide a practical, minimally intrusive intervention to augment
265 both inspiratory muscle strength and walking distance among overweight and obese
266 adults. The beneficial effects of this treatment were similar to those previously reported
267 from vigorous, supervised training among hospitalised obese patients (Villiot-Danger et
268 al., 2011). Our findings indicate similar effects could be expected without the need for
269 hospitalisation and indicate that IMT can easily be performed in the home environment.
270 Therefore, IMT appears a useful strategy to enhance walking performance in overweight
271 and obese individuals which may prove to be a meaningful priming (pre-exercise)
272 intervention with which to stimulate performance adaptations and greater future
273 engagement with physical activity.

274

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277

278 **Disclosure:**

279

280 None of the authors had a conflict of interest regarding any aspect of this work.

281

282 No external funding was provided for this project

283

284 Ethical approval for this project was provided by the Human Research and Ethics

285 Committee of James Cook University (ref: H5450)

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369

370 Table 1. Participants' characteristics

	EXP (n = 35)	PLA (n=32)
Age (years)	46 ± 7.5	48 ± 11.0
Height (cm)	172.4 ± 9.1	169.9 ± 10.8
Mass (kg)	107.3 ± 33.6	101.5 ± 26.6
BMI (kg/m ²)	36.8 ± 7.4	35.2 ± 5.9
Systolic blood pressure (mm Hg)	135.9 ± 15.1	135.7 ± 13.7
Diastolic blood pressure (mm Hg)	87.8 ± 13.5	88.7 ± 20.9

371 Mean ± SD. There were no statistically significant differences between the physical
 372 characteristics of EXP and PLA groups.

373

374 Table 2. Lung function and maximal aerobic power variables prior to and following the
 375 4-week intervention.

	EXP		PLA	
	Pre (n=35)	Post (n=35)	Pre (n=32)	Post (n=32)
FVC (l)	3.3 ± 0.9	3.2 ± 0.7	3.1 ± 0.8	3.1 ± 0.7
FEV ₁ (l)	2.7 ± 0.8	2.8 ± 0.9	2.6 ± 0.7	2.7 ± 0.5
Estimated $\dot{V}O_2$ max (ml/kg/min)	39.4 ± 10.1	39.5 ± 10.3	38.3 ± 11.1	38.5 ± 11.2

376 Mean ± SD.

377

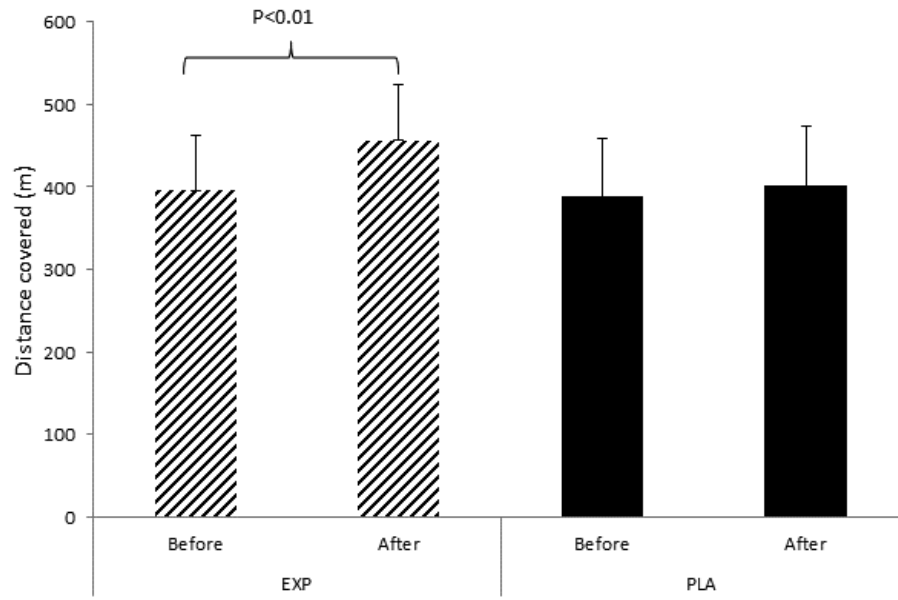
378

379 **Figure captions:**

380

381 **Figure 1.** Distance covered (metres) in response to the 6-minute walk test for both
 382 experimental (EXP; n=35) and placebo (PLA; n=32) groups. * = significant difference
 383 between baseline and post-training distance covered (P<0.01). Means ±SD and individual
 384 (before and after training) results are displayed.

385



386