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Edwards, A., Graham, D., Bloxham, S. and Maguire, G.

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Please cite this publication as follows:

Edwards, A., Graham, D., Bloxham, S. and Maguire, G. (2016) Efficacy of inspiratory muscle training as a practical and minimally intrusive technique to aid functional fitness among adults with obesity. Respiratory Physiology & Neurobiology, 234. pp. 85-88. ISSN 1569-9048.

Link to official URL (if available):

http://dx.doi.org/10.1016/j.resp.2016.09.007

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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.

Authors: AM Edwards[1,2], D Graham[2], S Bloxham[1], GP Maguire[2-3]

[1]University of St Mark & St John, Plymouth, United Kingdom

[2]James Cook University, Cairns Institute, Cairns, Australia

[3]Baker IDI Heart and Diabetes Research Institute, Melbourne, Australia

Running head: Inspiratory muscle training and obesity

Corresponding author:

A.M. Edwards PhD

Dean, Faculty of Sport & Health Sciences

University of St Mark & St John

Plymouth

United Kingdom

Tel: +44 1752 636700

Email: aedwards@marjon.ac.uk

ABSTRACT

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

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

Results: Inspiratory muscle strength was significantly improved in EXP (19.1 cmH$_2$0 gain; $P<0.01$) but did not change in PLA. Additionally, the post training walking distance covered was significantly extended for EXP ($P<0.01$), but not for PLA. Bivariate analysis demonstrated a positive association between the change (%) of performance in the walking test and BMI ($r = 0.78$; $P<0.01$) for EXP.

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

Key words:

Obesity, physical activity, respiratory disorders, chronic disease

INTRODUCTION

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

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

The act of inspiration is the primary cause of work when breathing. This occurs whereby the chest and lungs expand to accommodate an increased volume of air, while expiration is largely passive, particularly when resting or only exercising at moderate intensity (Otis et al., 1950). Consequently, a pre-exercise training programme specifically designed to enhance the performance of inspiratory muscles for adults with obesity might lessen subconscious inhibition of exercise performance (Ekkekakis et al., 2009), reduce respiratory muscle fatigue (Salome et al., 2008) and promote improved performance in response to exercise challenges (Edwards et al., 2008; Edwards and Cooke, 2004). In support of this perspective, a study of hospitalized obese adults demonstrated an aggressive two month intervention of supervised respiratory (inspiratory and expiratory) muscle training coupled with diet and physical training significantly improved both respiratory muscle endurance and the distance covered in a 6-minute walking test (~11% gain) (Villiot-Danger et al., 2011). While the results of that experiment strongly suggest respiratory muscle training may be of value to obese individuals, its findings are not directly applicable to non-hospitalised individuals due to the multidimensional nature of the intervention and the supervisory requirements of such an intense protocol. A less aggressive, but potentially equally effective strategy, is via inspiratory muscle training (IMT) using a portable inspiratory-resistance training device (Edwards, 2013; Edwards et al., 2012).

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

MATERIAL AND METHODS

Participants

Sixty seven adults (37 males and 30 females) volunteered for this study, provided written informed consent prior to participation and were randomly allocated to either experimental (EXP: *n*=35; m=19, f=16) or placebo (PLA: *n*=32; m=18, f=14) group as matched parallel pairs based on body mass index (BMI) and history of smoking. Inclusion criteria were (i) BMI >27 kg/m^2 and (ii) being free of respiratory or cardiovascular diseases. The physical characteristics of the two groups are shown in Table 1. Ethical clearance for this study was provided by the Research and Ethics committee of James Cook University.

Study Overview

Baseline physical assessments were made of mass, height, blood pressure, standard spirometry (FVC, FEV_1), maximal inspiratory muscle pressure (MIP), 6-minute walk test performance and estimation of maximal aerobic power ($\dot{V}O_2$ max). Following these measures, all individuals undertook familiarization with a portable inspiratory-resistance training device (PowerBREATHE, UK). This device was pre-set to either 55% of individualized maximal inspiratory effort (EXP) or to the minimum device setting equivalent to approximately 10% of maximal inspiratory effort (PLA) and thereafter used during the experiment (Edwards, 2013). Over the 4-week period, both groups performed

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

Study procedures

Lung function and inspiratory muscle performance

Spirometry measurements were undertaken at baseline and repeated post-programme. These included forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) . These procedures were completed using a hand held training device (Microlab-Spirometry SN M20364, USA).

In addition to standard spirometry measures, maximal static inspiratory mouth pressure (MIP) was also measured. This was assessed at residual volume following a slow and complete expiration using a mouth pressure meter (PowerBREATHE KH1 INSPIRATORY METER, Gaiam, UK). The best of three maximal efforts were analysed for all measures. These procedures were completed similarly with our earlier methodology (Edwards 2013).

Functional exercise capacity

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

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

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

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

Statistical analyses

Statistical software package SPSS (version 18.0, SPSS, Chicago, Illinois) was used for all statistical analyses. Parametric pre- and post-training results and group interactions were statistically compared using two-way repeated measures analyses of variance (group x time) (ANOVA). Post hoc Tukey tests were used to examine differences between datasets where indicated by ANOVA. Associations were examined using Pearson Product Moment Correlations. To ascertain an appropriate sample size for the study, analysis was based on an anticipated mean improvement (SD) in the six minute walk test of those in the EXP in the PLA group (Edwards et al., 2008). Probability values of <0.05 were considered significant and all tests were two sided. All results are expressed as means (SD) unless otherwise stated.

RESULTS

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

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

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

Additionally, assessment of standard spirometry variables (FVC and FEV_1) also did not identify differences between groups at either baseline or post-training (Table 2).

The MIP assessment revealed a significant group x time ANOVA interaction effect ($P<0.01$). Subsequent post hoc Tukey HSD test evaluation demonstrated MIP improved significantly over the 4-week intervention for EXP (66.7 ±10.5 to 85.8 ±9.3cmH_2O; $P<0.01$). However, MIP did not significantly change for PLA (68.4 ±11.7 to 77.7 ±10.8 cmH_20; NS). There was a between group difference following the intervention where EXP demonstrated significantly greater MIP than PLA ($P<0.01$).

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

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

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

DISCUSSION

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

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

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

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

Although this study was much larger and robust than our previous pilot study (Edwards et al., 2012) it did not include a concurrent IMT strategy with exercise intervention. The use of IMT in conjunction to an exercise training intervention could be expected to further augment performance as has been the case in athletes (Edwards et al., 2008). Nevertheless, a 4-week period of IMT demonstrates the usefulness of the technique over a short period, but a longitudinal intervention with and without concurrent exercise would be worthwhile to determine whether training effects are sustainable.

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

Acknowledgements:

The authors would like to thank research students for their support in data collection.

Disclosure:

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

No external funding was provided for this project

Ethical approval for this project was provided by the Human Research and Ethics Committee of James Cook University (ref: H5450)

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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

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

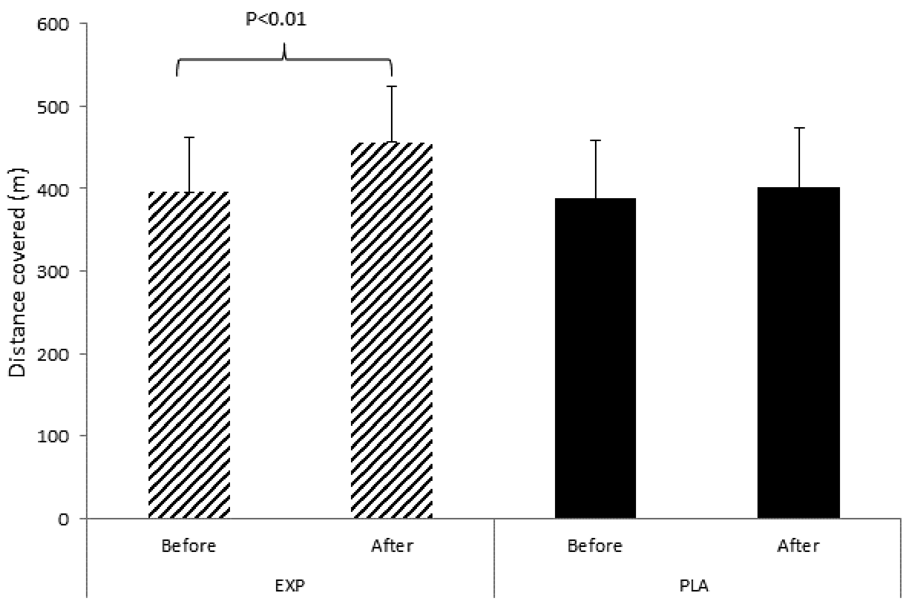
Table 2. Lung function and maximal aerobic power variables prior to and following the 4-week intervention.

	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

Mean ± SD.

Figure captions:

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



P<0.01
600
500
400
300
200
100
0
Distance covered (m)
Before
After
Before
After
EXP
PLA