Title: Evaluation of the effectiveness of a home-based inspiratory muscle training programme in patients with Chronic Obstructive Pulmonary Disease using multiple inspiratory muscle tests.

ABSTRACT

Purpose: To evaluate the effectiveness of a home-based Inspiratory Muscle Training (IMT) programme using multiple inspiratory muscle tests.

Method: Sixty eight patients (37M) with moderate to severe COPD (Mean [SD], FEV_1 36.1 [13.6]%pred.; FEV_1/FVC 35.7 [11.2]%) were randomised into an experimental or control group and trained with a threshold loading device at intensity >30% maximum inspiratory pressure (PImax) or < 15%PImax respectively for 7 weeks. Thirty nine patients (23M) completed the study. The following measures were assessed pre- and post-IMT: PImax, sniff inspiratory nasal pressure (SNIP), diaphragm contractility (Pdi,tw), incremental shuttle walk test (ISWT), respiratory muscle endurance (RME), chronic respiratory disease questionnaire (CRDQ), the hospital anxiety and depression scale (HADS) and the SF-36. Between group changes were assessed using one-way analysis of variance (ANOVA).

Results: PImax and perception of wellbeing improved significantly post-IMT [p=0.04 and <0.05 in four domains respectively]. This was not reflected in SNIP [p=0.7], Pdi,tw [p=0.8], RME [p=0.9] or ISWT [p=0.5].

Conclusions: A seven-week, community-based IMT programme, with realistic use of health-care resources, improves PImax and perception of wellbeing but a different design may be required for improvement in other measures. Multiple tests provide a more comprehensive evaluation of changes in muscle function post-IMT.

Chronic obstructive pulmonary disease (COPD) is a major cause of mortality and morbidity worldwide, estimated to become the 4th leading cause of death by 2030 [1]. Rehabilitation strategies based in community settings, such as early discharge schemes and home-based exercise programmes, are important in the management of COPD patients as they are associated with greater patient and carer satisfaction with services [2] and reduced time in hospital [3]. Despite lacking the element of peer-support and social interaction, a benefit often derived from participation in group rehabilitation programmes [4], home-based rehabilitation interventions are ideal for patients who are unable to access centre based programmes due to work/life commitments, profound breathlessness or comorbidities. Inspiratory muscle training (IMT) is a rehabilitation intervention that has been investigated in the context of pulmonary rehabilitation or on its own, with the rationale that an increased inspiratory muscle capacity will improve perception of breathlessness and exercise tolerance during activities of daily living [5-9]. IMT has no side effects and is an attractive rehabilitation intervention for home-based programmes in COPD patients. However, despite positive results in research studies, a recent update on the NICE guidelines for COPD [10] highlighted the lack of evidence that would allow IMT to be recommended more widely by clinicians.

Three main factors contribute to the uncertainty and debate about the clinical benefit of IMT in COPD patients [11, 12]. First, most clinical studies assess the effects of IMT on inspiratory muscle strength using the measurement of maximal inspiratory pressure (PImax) [11]. PImax is a test known to be influenced by patients' motivation and one that requires practice before baseline values can be accepted [13, 14]. It is also similar to the respiratory efforts required for IMT, raising the possibility that patients become better at performing the test rather than being stronger [11]. Other inspiratory muscle tests that could confirm changes in inspiratory muscle strength have rarely been used in IMT research [15, 16]. The Sniff inspiratory nasal

pressure (SNIP), a simple, non-invasive test that complements PImax [14, 17], requires a different manoeuvre to IMT and patients are therefore unlikely to learn how to do the test better during the training period. Although the use of multiple respiratory muscle tests increases diagnostic accuracy, as reported by Steier and colleagues [18] and are recommended in the ATS/ERS guidelines on respiratory muscle testing [19], studies in COPD have yet to use this approach to assess the effects of IMT programmes.

Another factor contributing to the uncertainty of the clinical benefit of IMT is that studies offer limited information on effects on the diaphragm. IMT has been shown to lead to rib cage muscle remodelling [20] but there is no information about remodelling of the diaphragm in COPD patients. Data from an animal model have shown that IMT increases the thickness of the rat diaphragm and leads to fast muscle fiber hypertrophy [21-23]. In COPD patients, Heijdra and colleagues [15] showed increased transdiaphragmatic pressure (Pdi max) following ten weeks of IMT at 60% training intensity. However, Pdi max was assessed using PImax manoeuvres rather than a non-volitional test. No study so far has investigated the effects of IMT on diaphragm contractility in COPD patients using non-volitional methods.

Finally, it is unclear whether the results of laboratory based research studies can be replicated in clinical services. Many positive home-based studies have a long duration of training, ranging from 3 to 12 months [24, 25] and close supervision, which would be unrealistic in community health services. It is unclear whether similar results can be achieved by a more feasible home-based programme.

The purpose of this study was to evaluate the effectiveness of a 7-week, home-based IMT programme on inspiratory muscle strength using SNIP as well as PImax. The secondary aims were to explore changes in diaphragm contractility, using non-volitional bilateral

anterolateral magnetic phrenic nerve stimulation (BAMPS), and to study the effects of our IMT programme on inspiratory muscle endurance, exercise capacity and health status.

METHODS

Design Overview

This was a double blind, randomised controlled trial. The protocol was accepted by the King's College London research ethics committee (LREC no 98-211) and participants gave their informed consent. Sixty-eight COPD patients were allocated into an experimental (PrBr-IMT) and control group (C-IMT) by an independent investigator using the minimisation method. Information about the randomisation was then sent to the physiotherapist who was responsible for setting the IMT device and advising patients about their home training programme. The physiotherapist's role as an independent point of contact ensured that the patients as well as the researcher who performed the assessments and analysed the tests were blinded. Assessments were performed pre- and post-IMT by one researcher (lead author) who was blinded to the group the patients belonged to.

Setting and Participants

Sixty-eight COPD patients (37M) with moderate to severe COPD (Mean [SD], FEV_1/FVC 35.7 [11.2]%; FEV_1 36.1 [13.6]%predicted) volunteered for the study. Patients were recruited from respiratory outpatient clinics at King's College Hospital, GP practices and British Lung Foundation Breathe Easy groups. Patients gave written informed consent and were included in the study if they had no exacerbation of COPD and had not changed their medication for at least 4 weeks prior to the initial assessment. Exclusion criteria included: patients with a1-antitrypsin deficiency, co-existing heart disease, hypertension, cor pulmonale or long term use of oral corticosteroids and patients with significant thoracic musculoskeletal

abnormalities such as kyphosis or scoliosis. Patients unsuitable for magnetic stimulation, for example those with cardiac pacemakers, were also excluded. Nineteen out of the sixty eight patients were studied using bilateral anterolateral magnetic phrenic nerve stimulation (BAMPS) to explore the effects of IMT on diaphragm contractility.

Randomisation and Intervention

Patients were assigned to the experimental (PrBr-IMT) or control group (C-IMT) by an independent investigator using the minimisation method [26]. The PrBr-IMT and C-IMT groups were matched for the following variables: a) age (3 categories: 50-60, 60-70 and >70 years old), b) baseline inspiratory muscle strength (PImax and SNIP combined), c) disease severity (FEV1% predicted) and d) number of participants who performed invasive tests during baseline assessments (2 categories: Yes or No).

Inspiratory muscle training (IMT) programme

The IMT programme was a 7 week, home-based programme using the POWERbreathe® inspiratory muscle trainer (HaB International, Southam, Warwickshire, UK). Patients allocated to the PrBr-IMT started training at 30% of their baseline PImax and increased the intensity once a week as tolerated. This intensity has been shown to train the respiratory muscles [27, 28] and is widely accepted as the minimum training intensity in IMT studies [29, 30]. The threshold load was increased by revolving the load-adjustment valve in the device's handle which increases the inspiratory threshold loading pressure. The average weekly increase in intensity of training was 5% and the mean (SD) intensity at the end of the programme was 62% (SD:11.7) of the baseline PImax. In the C-IMT group, the device was set below 15% PImax, an intensity shown not to train the respiratory muscles and often used in control groups [27-30]. This load remained constant for the duration of the study.

The programme consisted of two IMT sessions per day, one in the morning and one in the afternoon (5 hours apart), six days a week. Each session required patients to take a minimum of 30 breaths in their device. The majority of patients increased the number of breaths to 40 by the end of the second week. Patients were strongly encouraged to take as many of the breaths as possible without a break. They were instructed that if a break was required, this should not exceed 1 min duration and the minimum number of breaths before a break should be five.

The study physiotherapist called all patients (in the experimental and control group) weekly to monitor progress and adherence to the programme but in the PrBr-IMT group only, she encouraged patients to increase the intensity and the number of breaths per session. Patients recorded this information in a diary booklet which was returned to the physiotherapist at the end of the programme. Adherence to the programme was assessed and confirmed by comparing the physiotherapist's notes against each patient's diary notes.

Outcome Measures and Follow-up

Measurements were performed at the beginning and end of the IMT programme by one investigator (lead author) who was blinded throughout. Participants had a run-in period of 3 weeks to familiarise themselves with the volitional PImax and SNIP tests [14] before performing the following assessments:

Lung function

Lung function testing was performed by senior clinical physiologists at the lung function department of King's College Hospital. Measurements were; forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), total lung capacity (TLC), residual volume (RV)

and blood gases. FEV_1 and FVC were measured with a dry bellows spirometer (S Model, Vitalograph, Buckinghamshire, UK) while TLC and RV were measured by constant whole body plethysmography (Auto-link, Morgan Medical, Gillingham, Kent, UK). Blood gases were measured from arterialised ear lobe capillary samples (Rapidlab 248, Chiron, MA, USA).

Respiratory muscle strength

Respiratory muscle strength testing was performed according to ATS/ERS standards [19]. Prior to performing magnetic phrenic nerve stimulation, patients had oesophageal and gastric balloon catheters inserted pernasally. Local anaesthesia was administered to the nasal mucosa using 2% lignocaine gel (Biorex Laboratories,London,UK). The catheters were connected to differential pressure transducers (Validyne MP45, Validyne Corp., Northridge, CA, USA) so that pressure traces could be viewed on the computer screen. Data from pressure measurements were acquired on a Macintosh PowerMac computer running Labview 4.1 software (National Instruments, Texas, USA). The following tests were performed:

Maximum inspiratory pressure (PImax)

Maximum inspiratory pressure is the most widely used test for the assessment of inspiratory muscle strength and its reproducibility, repeatability and normal values have been assessed in COPD [13, 14, 19]. In this study, PImax was assessed from functional residual capacity (FRC) using a flanged mouthpiece (PK Morgan Ltd, Rainham, UK) connected to a metal tube (Fitting et al). The metal tube was connected to a differential pressure transducer and PImax tracings were recorded in real time. Nose clips were worn and patients performed a minimum of 10 efforts to minimise the learning effect [14] with rest intervals of 30-60 seconds between efforts [31, 32]. Visual feedback and strong encouragement were given throughout. A valve in the tube allowed normal breathing before maximal efforts were made and a small lead

incorporated in the tube ensured maintenance of an open glottis. All patients were seated upright with their belt undone and were encouraged to make maximal inspiratory efforts sustained for one second.

Sniff nasal inspiratory pressure (SNIP)

The SNIP is a non-invasive test of global inspiratory muscle strength that compliments the PImax [19] and has good repeatability in COPD patients [14]. It is a more natural manoeuvre than PImax [17] and it is recommended to be included in the assessment of inspiratory muscle strength [18]. Sniff nasal manoeuvres were performed from FRC while seated, without a nose clip [19]. Patients were asked to perform a strong, sharp, maximal sniff. A minimum of 10 efforts were made with rest intervals of 30secs [19]. Custom-made nasal plugs were made from dental putty and were hand-fitted around the tip of an 80cm catheter connected to a pressure transducer (Validyne MP45, Validyne Corp., Northridge, CA, USA). Pressure tracings were accepted for analysis if they had a smooth upstroke, a sharp peak and took a maximum of 400ms from baseline to peak.

Twitch transdiaphragmatic pressure (Pdi,tw)

Twitch transdiaphragmatic pressure (Pdi,tw) is a reliable, non-volitional method of assessing diaphragm contractility [19] that has good within-occasion reproducibility [33]. In our study, diaphragm contractility was assessed using bilateral anterolateral magnetic phrenic nerve stimulation (BAMPS) via two 43mm figure-of-eight coils powered by Magstim 200 stimulators (Magstim Company Ltd, Whitland, Dyfed, Wales) at 100% power output. A minimum of five twitch stimulations were given. A period of 60sec was allowed between stimulations. The optimal stimulation point was identified and marked. To avoid the phenomenon of twitch potentiation [34] patients were asked to remain quiet for 20 minutes before measurements were taken.

Respiratory muscle endurance (RME)

RME was assessed using the constant-level, negative threshold loading method as described by Hart and colleagues [35]. Patients were familiarised with the test in the run-in period. On the day of the pre-IMT assessment, patients had a minimum of two RME tests and the best was accepted for analysis. Threshold pressure during the endurance test was set at 50% Poes max. Task failure was defined as the inability of the subject to achieve the required pressure to open the one-way valve of the threshold system. Time to task failure (TLim) was recorded and the average oesophageal load to capacity ratio for the whole test (PTPoes/Poesmax) was calculated as previously described by Hart and colleagues [35]. This negative threshold loading device, first described by Chen and colleagues [36], comprised of a main cylindrical pressure chamber, 41cm in length and 10cm in diameter. The chamber was connected to a negative pressure generator, a commercial vacuum cleaner (Numatic, Somerset, England, UK), that drew a constant flow of air out of the cylinder. Air circulated between the room and the pressure chamber through an adjustable resistance and created a negative pressure in the chamber. The inlet of the pressure chamber was composed of multiple holes of differing sizes. The resistance of the inlet to flow, which established the desired negative pressure in the pressure chamber, was created and adjusted by selectively obstructing different combinations of holes. A pressure monitor was used to record the pressure in the chamber. Subjects breathed through a flanged mouthpiece connected to a two-way non-rebreathing valve (PK Morgan, Rainham, Kent, UK). When the negative mouth pressure achieved by the subject was more negative than the set value in the cylindrical chamber, the valve opened to allow flow to occur.

Patients were seated, wore noseclips and were allowed to adopt their own spontaneous breathing pattern. Standardised encouragement was given every 30 seconds for subjects to ‘keep going for as long as they could’.

Exercise capacity

Exercise capacity was assessed with the incremental shuttle walk test (ISWT) according to the methods of Singh and colleagues [37] Patients performed a minimum of two tests on the day with at least 20min rest between tests. Heart rate and oxygen saturation were monitored throughout with a hand held pulse oximeter (Model 3700, Omedha, Louisville, CO, USA). The baseline heart rate and oxygen saturation values (HRo and SpO_2o) and the end-of-test values (HRe and SpO_2e) were documented. Breathlessness and leg fatigue were assessed at the beginning (Bo and Lo) and at the end (Be and Le) of the ISWT using the 10-point modified BORG scale.

Health status

A combination of disease-specific and generic questionnaires is recommended for the assessment of health status in various diseases, including COPD, as this strategy provides a more comprehensive assessment of co-morbidities that may affect outcomes [38]. In this study, we used three questionnaires to assess health status: the Hospital Anxiety and Depression scale (HADS), the Chronic Respiratory Disease Questionnaire (CRQ) and the short-form 36 (SF-36). The HADS and SF-36 questionnaires are generic while the CRQ is disease specific. These three questionnaires have been used widely in IMT studies [5,8,9] and were chosen to allow comparison with other IMT studies.

Data analysis

Outcomes and baseline characteristics were described using means and standard deviations. Data from primary and secondary outcome measures were analysed under the null hypothesis that there was no difference in the between-group changes in variables post-IMT. Normality of data was assessed with the Kolmogorov-Smirnov (K-S) test and visual inspection of

histograms. Between-group change in outcome variables was assessed using one-way analysis of variance (ANOVA), for data that were normally distributed. The Mann-Whitney test was used if data were not normally distributed. Agreement between PImax and SNIP pre and post intervention was assessed using Bland-Altman plots. Pearson correlations between these two measures, at each time point and between changes from baseline, were also evaluated.

A p value of < 0.05 was taken as statistically significant. Changes in outcomes are presented as means with 95% confidence intervals (95% CI). Data were analysed using SPSS (17.0) and graphs were created in Graph Pad Prism (version 3.03) and Stata (version 10).

RESULTS

Forty-one patients completed the study and thirty nine were accepted for analysis. Seventeen out of nineteen patients who were studied with BAMPS completed the study. The CONSORT diagram in figure 1 shows the sample sizes throughout the study.

(Insert figure 1 about here)

Baseline characteristics

The two groups were well matched and there was no significant difference between groups for gender, age, MRC scale, BMI, Pack years, FEV_1 and TLC. Table 1 summarises the characteristics of the study participants.

(Insert table 1 about here)

Primary Outcome

PImax and SNIP were positively correlated (r= 0.6, 95% CI 0.30 to 0.79) as seen in figure 2 and the Bland-Altman plots pre-IMT and post-IMT showed agreement between the two measures (figures 3a and b).

Between-group changes in inspiratory muscle tests showed statistical significance for PImax (p=0.04) but not for sniff nasal inspiratory pressure (SNIP) (table 2).

(Insert figure 2 about here)

(Insert figure 3a and b about here)

(Insert table 2 about here)

Secondary Outcomes

Diaphragm contractility

Transdiaphragmatic pressure (Pdi,tw) comparison between groups showed that change was not significantly different post IMT (table 2).

Respiratory muscle endurance

There was no significant change in TLim in the endurance test between groups post IMT. The load to capacity ratio (PTPoes,c/Poesmax) which reflects the breathing pattern adopted during the test showed no significant change post IMT between groups (table 2).

Exercise capacity

Between groups comparison showed no significant difference in distance walked following IMT or of the other variables of the ISWT; end-ISWT HR showed a small but significant difference between groups (table 3).

Health status

There was a significant change in the depression domain (p=0.03) of the HADS questionnaire and significant differences post-IMT in the following domains of the SF-36 questionnaire:

Role limitation due to emotional problems (RE), mental health (MH) and change in health (CH). There was a clinically significant improvement in the dyspnoea and fatigue domains of the CRDQ in the IMT group but between-group comparison showed no statistically significant changes in any of the CRDQ domains. Health status results are seen in table 4. Figure 4 shows the distribution of the anxiety and depression domains in the experimental and control group and figure 5 shows the mean change in the CRDQ domains in the two groups in relation to the minimal clinical important difference.

(Insert table 3 about here)

(Insert table 4 about here)

(Insert figures 4 and 5 about here)

DISCUSSION

This study investigated the effects of a home based IMT programme on inspiratory muscle function, exercise capacity and health status, using multiple tests. This is the first study to use SNIP as well as PImax following IMT in COPD patients and to include the non-volitional test of bilateral anterolateral magnetic phrenic nerve stimulation (BAMPS). The principal finding was that although health status and PImax improved following this seven week programme, other inspiratory muscle tests and exercise capacity did not.

Effects of the IMT programme on inspiratory muscle strength

The SNIP and PImax are both non-invasive tests on inspiratory muscle function that are available to use in community settings without the need for complex laboratory equipment. Our Bland-Altman analysis (Figure 3a and b) showed that there was good agreement between these two measures pre- and post-IMT. However, only PImax improved significantly post-

IMT. This discrepancy in results may be a reflection of the two inherent weaknesses of the PImax test; first, its volitional nature which means that improvement in values may be due to learning how to do the test and second, its similarity with the IMT breathing technique. We sought to address the effect of learning the PImax technique, by familiarising our patients with the manoeuvres in the run-in period prior to baseline assessments [14], as recommended previously [13]. We are confident that there was limited additional learning of the manoeuvre post-IMT as our control group changed by only 3.7% from baseline in PImax. However, it is more difficult to control for the similarity between the pattern of respiratory neuromuscular activation when breathing through a threshold loading device and that of the PImax manoeuvre. Both involve a quasi-static (isometric) contraction of the diaphragm and rib cage muscles at the initial stages when a maximum inspiratory effort is made against a closed airway [19]. The similarity between the technique using the IMT device and the PImax manoeuvre could have resulted in increased neuro-muscular coordination for the particular task. Evidence that training can improve neuromuscular coordination comes from a study that examined the diaphragmatic response to transcranial magnetic stimulation following 'diaphragmatic' training [39] and from an earlier study by the same group [40] which showed significant increases in cortical excitability of the diaphragm motor area following a short IMT programme. These studies suggest that the diaphragm and other respiratory muscles are subject to the same practice-dependent neuro-plasticity as other muscles. The ability of our COPD patients to generate greater maximal inspiratory pressures at the end of the programme may have been partly due to an improvement in respiratory muscle co-ordination for the particular manoeuvre. While improved neuromuscular coordination is a positive outcome, the clinical value of this improvement is questionable as few activities of daily living require this particular pattern of muscle activation.

Our study supports the previously stated argument about the value of using multiple tests to assess inspiratory muscle strength [18] and adds to this argument by highlighting the value of using the non-invasive SNIP for the assessment of inspiratory muscle strength following IMT programmes, since it is difficult to determine how much of the PImax changes are due to improvement in neuromuscular coordination.

We also explored changes in diaphragm contractility using the non-volitional BAMPS in a small number of participants. Our subgroup showed that the non-volitional twitch trans-diaphragmatic pressure (Pdi,tw) did not change following IMT. This may reflect the adaptation of the diaphragm in moderate to severe COPD toward enhanced oxidative and endurance capacity [41, 42] which means there is limited potential for further improvement. Alternatively, a different training protocol may be required to train the diaphragm in moderate to severe COPD patients. As this was an invasive test, requiring insertion of oesophageal and gastric balloon catheters, patients were allowed to opt-out of this assessment. The number of patients that accepted this invasive test was smaller than the total of participants in this study, therefore, we cannot come to a firm conclusion about the effects of 7 weeks of IMT on the diaphragm. However, this study provides the necessary means and standard deviations to allow us to perform power calculations for future studies.

Effects of the IMT programme on respiratory muscle endurance and exercise capacity

Our study showed no improvements in respiratory muscle endurance, as defined by time to task failure (TLim) or the oesophageal load to capacity ratio (PTPoes,c/Poesmax), using a technique which takes into account the breathing strategy when patients breathe against high inspiratory threshold loads [35]. The findings in COPD patients are in contrast to those of a similar IMT programme in healthy young subjects [43]. Hart and colleagues [43] showed

improvement in inspiratory muscle endurance due to changes toward a more efficient breathing pattern that served to protect or postpone diaphragm fatigue. Previous studies have demonstrated the resistance of the COPD diaphragm to fatigue [44, 45] which may partly explain why there was no change in the PTPoes,c/Poesmax in our patients.

In keeping with the results of inspiratory muscle function, there were no improvements in exercise tolerance as measured by meters walked or on perception of breathlessness at the end of the ISWT (BORG scale) between active and control groups. Previous home-based IMT studies that have demonstrated increases in walking distance had longer durations of training [24, 25, 46], therefore it is possible that the duration of our IMT programme was a factor explaining this lack of improvement, although the duration of our programme was typical of UK practice. We did, however, find that the heart rate at the end of the ISWT in the PrBr-IMT group was slightly lower post-IMT than in the control group. This suggests an improvement, even if minor, in aerobic capacity [47, 48]. Although breathlessness at the end of the ISWT did not improve, the small increase in aerobic capacity may have contributed to the perceived improvements in health status at the end of the programme.

Effects of the IMT programme on health status

Perception of wellbeing improved in our study. The depression domain of the HADS and three domains of the SF-36 questionnaire (role limitation due to emotional problems, mental health and change in health) showed improvements. For CRDQ, the improvement in the dyspnoea and fatigue domains in the experimental group were at or above the threshold value of 0.5 which has been identified as a MCID in this questionnaire [49]. Therefore our patients received symptomatic benefit post-IMT which could perhaps be attributed, to some extent, to the small improvement in aerobic capacity.

Reduction of perception of breathlessness during daily activities and improvement in health status is one of the most well accepted effects of IMT [6, 49, 50]. This effect was also evident in our study despite lack of consistent improvement in inspiratory muscle tests or in exercise capacity. Clinically, this is an important positive result, as the home based programme in this study did not include other forms of exercise training known to enhance the effects of IMT [5] and was of shorter duration than some home IMT programmes [24, 25]. Therefore, our study suggests that community IMT programmes of seven week duration are likely to improve wellbeing and perception of breathlessness during activities of daily living in moderate to severe COPD patients even in the absence of improvements in respiratory muscle function and exercise capacity.

Clinical implications, limitations and further research

The intervention in this study was designed to reflect a realistic treatment approach that could be readily delivered within a primary care setting given the limited resources available in the UK and elsewhere. We assessed a heterogeneous COPD group in terms of disease severity (ranging from moderate to very severe), baseline PImax values or dyspnoea intensity during every day activities, reflecting the expected group in a community setting. Adherence to the intervention was good in our study and our group reached a mean pressure of 62% PImax (11.7) at the end of the programme, well above the 30% PImax minimal intensity required to achieve a training effect [27] and similar to other home IMT studies [51, 52]. Our study suggests that a community-based programme, shorter than previously reported in research [24, 25], could be effective in improving PImax and perception of well-being in community patients.

Home based programmes have been shown to be superior to centre-based ones in terms of adherence to exercise [53] and are attractive to many people with COPD who are unable to attend centre-based activities due to work/life commitments or due to limitations to performing exercise such as additional musculoskeletal impairments or profound breathlessness. Therefore, it is of clinical significance that participants have derived important benefits from this home based programme.

However, home-based programmes have limitations when seeking to achieve a training effect. Hill and colleagues [54] trained COPD patients in a laboratory setting and reached a training intensity of 101% PImax by week 8. In the current study, patients had a more individual progression in their IMT training intensity at home, although they were strongly encouraged by the physiotherapist via phone calls. The training intensity that was tolerated by our participants may have contributed to the lack of improvement in diaphragm contractility, respiratory muscle endurance and exercise capacity at the end of the programme. This potential limitation, however, does not explain the lack of improvement in SNIP which should have improved in line with PImax at the end of the training programme, as evidenced by the good correlation between the two measures.

IMT is more likely to be adopted clinically as a rehabilitation option if the design of the training programme takes into consideration resources and costs associated with the regular running of such a programme in community settings. Future studies need to explore the effects of duration or intensity of training on SNIP and diaphragm contractility in community programmes and identify the minimum level that lead to a training effect in COPD patients. Larger sample sizes and more homogenous groups may be needed for this purpose.

CONCLUSIONS

This study examined the effectiveness of a seven-week, community-based IMT programme in moderate to severe COPD patients. Following our programme, COPD patients showed improvements in PImax and perception of wellbeing but not in SNIP or the non-volitional test of diaphragm function, exercise capacity or respiratory muscle endurance. This study suggests that some of the symptomatic benefits of IMT may be independent of changes in inspiratory muscle function. It also highlights that multiple tests provide a more comprehensive assessment of muscle function when seeking to demonstrate changes following IMT programmes.

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Declaration of Interest

The authors have no conflicts of interest. All authors have contributed to the research and have been part of writing up the findings for publication.

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