The Effect of Thoracic Muscle Energy Technique on FVC and FEV_1 Measurements

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Abstract

Background and Objectives

Current research on respiratory diseases is mainly focused on the effects of drug treatments, however much less work has looked into the use of manual treatments of patients with symptoms of respiratory dysfunction. Studies currently being conducted through Victoria University are attempting to investigate whether manual treatments, such as HVLA and Lymphatic Pump Techniques have an effect on lung function. There has however been no research into the effect of Muscle Energy Technique (MET) on measurable respiratory function even though it is such a widely used technique. This study aims to identify whether MET leads to a measurable change in ventilatory function in asymptomatic individuals.

Methods

Thirty volunteers were randomly assigned to either a treatment (thoracic MET) or control group (no treatment). Ventilatory function (FVC and FEV_1) was recorded by spirometry pre, immediately post, 10 minutes post and 20 minutes post-intervention. Volunteers in the treatment group received a single treatment involving two MET's into rotation and side bending of the thoracic spine bilaterally. The control group received no treatment, instead resting for the same duration as the treatment.

Results

Between groups comparisons were conducted for pre-intervention, immediately post, 10 minutes post and 10 minutes post-intervention. No significant changes, within or

between groups, were observed in ventilatory function (FVC and FEV_1) either immediately 10 minutes post or 20 minutes post-intervention with MET applied to the thoracic spine. Likewise no significant changes in the control group were seen.

Conclusion

Thoracic MET performed on asymptomatic volunteers had no significant effect on FVC or FEV_1 measurements immediately post, 10 minutes post or 20 minutes post-intervention.

Key Words

muscle energy technique, osteopathy, ventilatory function, spirometry, thoracic spine

INTRODUCTION

Respiratory dysfunction is one of the most common conditions in our society today, affecting more than 5 million Australians, comprising diseases like asthma, Chronic Obstructive Pulmonary Disease, and respiratory infections, which can go on to cause secondary structural restrictions of the thorax and ribs.[1] Inversely, mechanical restriction of the thorax can cause a reduction in vital capacity, which is associated with increased susceptibility to respiratory infection.[2]

Most of the current research into treatment of respiratory conditions [3] has focused on the efficacy of drug regimens, however much less work has looked into the use of manual treatments of patients with symptoms of respiratory dysfunction. Some studies currently being conducted through Victoria University are attempting to investigate the issue of whether manual therapy treatments have an effect on lung function. These include the effect of HVLA and Lymphatic Pump Techniques on respiratory function as measured using spirometry. There has however been no research into the effect of Muscle Energy Techniques on measurable respiratory function even tough MET is such a widely used technique and considered to have few contraindications[4] and be particularly safe.[5]

In the years since 1958, when Fred Mitchell Sr published the first details of MET, numerous practitioners have enhanced and modified the original MET model.[5] There are several possible explanations given as to why MET has been seen to be beneficial. These include the shortened segmental muscle theory, post-isometric relaxation, connective tissue changes, venous and lymph drainage, changes in trans-synovial flow, inhibition of

pain and altered motor control and muscle recruitment.[6] MET requires that the practitioner takes a dysfunctional or motion-restricted muscle-joint complex to its physiologically restrictive barrier, then asks the patient to perform an isometric contraction of either the antagonist or agonist muscle followed by a complete relaxation. After relaxation the practitioner moves the muscle-joint complex to a new restrictive barrier.[5] Despite the extensive use of MET as a treatment modality, there has been very little research into the efficacy of MET.[6] Previous studies have demonstrated that MET to the cervical, thoracic and lumbar regions[7-9] can produce significant mechanical changes to spinal range of movement.

While research into the effect of MET is limited, evidence indicating MET aiding ventilatory function is even more sparse. The effects of other osteopathic and manual medicine techniques on ventilation have been investigated, but with somewhat mixed results. Some of these studies include rib-raising techniques on FEV_1 and FVC in people with asthma,[10] the effects of Osteopathic Manipulative Treatment (OMT) in adults with asthma,[11] and the effect of massage therapy on children with asthma.[12] Other therapists[13-14] studied the effect of proprioceptive musculoskeletal education without exercises (Alexander technique) on respiratory function. There has also been investigation into the effects of proprioceptive neuromuscular facilitation (PNF) on respiration,[15] and the utilisation of active and passive rib stretches,[16] attempting to elicit a change in FVC and FEV_1. Both of these methods are manual therapy techniques more closely linked to MET.

In light of the varied results from the research that has been conducted in this field it is evident further investigation is required into the use of manual therapy on respiratory dysfunction. This study aims to identify whether a treatment involving two muscle energy techniques leads to a measurable change in ventilatory function in asymptomatic individuals.

MATERIALS AND METHODS

Participants

Thirty asymptomatic volunteers (16 male, 14 female; age 25.6 ± 3.5; range 21 to 38) were recruited by convenience sampling after responding to advertisements posted around Victoria University. All volunteers gave written informed consent and underwent a screening procedure to establish their suitability prior to the commencement of data collection. The Victoria University Faculty of Human Development Ethics Committee approved the study. Volunteers were excluded if they smoke cigarettes; suffered from any URTI, cold flu or virus in the past month; had been diagnosed in the past 10 years with any extensive thoracic dysfunction; or suffered from any other pathology that affected their normal breathing and/or respiration. Asymptomatic volunteers were recruited due to sampling convenience, a decreased likelihood of respiratory distress associated with spirometry and previous therapeutic studies have found significant results with these types of participants.[8,10,13,14]

Procedures

Pulmonary function test and anthropometric measurements were performed in the same consulting room, by the same researcher, on the same day. Height and weight measurements were recorded prior to commencement with a stadiometer (calibrated to ±0.5cm) and a Seca-754 mechanical flat scale (calibrated to ±0.1kg). Female participants were provided with a gown, and asked to remove their bra or any tight fitting supportive underwear ten minutes prior to pulmonary function testing in order to prevent variation in the result.

Measurement of Respiratory Values

A standard instruction protocol on how to use the spirometer was provided for each of the participants, along with a demonstration and familiarisation trial. Spirometric measurements followed the Standardised protocol for FVC and FEV_1, advocated by the ATS.[17] The participant takes a maximum forced inspiration followed by a maximum forced expiration until no more can be exhaled. A minimum of three technically acceptable expiratory manoeuvres were performed, and a maximum of eight manoeuvres were allowed if there was a large variability between expiratory breaths. Ventilatory measures were recorded using a volumetric spirometer (Vitalograph Compact II 66.000) that was calibrated after each participant. The participants were seated on an examination bench with their nose occluded (using a nose peg). The highest FEV_1 value must be within 0.2L of the second measure. The end of the FVC test was determined by a constant volume for at least one second after an exhalation time of six seconds has elapsed or by cessation of expiration for clinical reasons.[17]

Pre-intervention FVC and FEV_1 values (0 time) were taken after 10 minutes of rest in a supine position. The intervention techniques were then applied. Lung function measures were taken immediately following, and then at 10 and 20 minutes post-intervention. To maintain consistency with the baseline value (0 time), subjects were instructed to lie down between expiration efforts at each time interval.

Group allocation

Volunteers were randomly assigned (computer randomization) to either control (n=15) or treatment (n=15) groups. The examiner recording the respiratory measurements was blinded to the treatment allocation of the volunteers. Following the pre-intervention respiratory measurements, participants were sent for either treatment or control with the treating examiner in another room.

Intervention phase

Thoracic Muscle Energy Technique

Intervention took place in a separate room to the respiratory testing. A registered experienced Osteopath conducted all MET interventions. Subjects in the treatment group were treated firstly with general rotational thoracic MET in an attempt to increase thoracic rotation in both directions, while also increasing movement between individual ribs. A second technique, a general side-bending thoracic cage release was also applied. These techniques were chosen as both rotation and side-bending in the thoracic spine facilitates most movement between the individual ribs and also the thoracic vertebrae.[4]

Technique 1 (from Tucker& Deoora[18])

The patient was seated with arms across their chest, with the examiner behind them. The examiners' right and left hands are holding the patient's left arm and left posterior rib cage, respectively. The right rotation barrier was then engaged. The examiner's left arm resisted a 5 second isometric contraction of left rotation by the patient. After each isometric effort, a new rotation barrier was engaged and the patient repeated the isometric contraction with four repetitions. This was repeated on the opposite side.

Technique 2 (from Tucker & Deoora[18])

The patient was seated with arms across their chest, with the examiner behind them. The examiners' right and left hands are holding the patient's left axilla and left iliac crest, respectively. The examiners' right knee acted as a fulcrum under the patient's right rib cage, while the examiners' body also acts to stabilize the patient. The right side-bending barrier was then engaged. The examiner resisted a 5 second isometric contraction of left side-bending by the patient. After each isometric effort, a new rotation barrier was engaged and the patient repeated the isometric contraction with four repetitions. This was repeated on the opposite side.

The control group were not treated, but were directed to rest in the treatment room for approximately 5 minutes. Immediately post-intervention ventilatory function was recorded. Post-intervention FVC and FEV_1 were assessed in an identical manner to the pre-intervention FVC and FEV_1 procedures. To eliminate potential problems associated

with inter-examiner reliability, the post-testing FVC and FEV_1 readings were taken by the original examiner.

Statistical Methods

Data was reported as Mean ± SD. A randomized, controlled, test-retest design was used, where the participants provided their own baseline measurements (pre-intervention ventilatory function). The initial effect of treatment intervention was measured by the differences of pre- and post-intervention ventilatory function (0, 10, 20 min.). Statistical analysis in the form of a factorial split plot analysis of variance (SPANOVA) was performed on the mean differences, between and within groups, of pre and post-test scores for FVC and FEV_1 measurements using SPSS (Version 12 for windows). An alpha level $p<0.05$ was accepted as the arbiter of significance throughout this study.

RESULTS

The means and standard deviations for ventilatory function (FVC and FEV_1) for the experimental and control groups are presented in Tables 1 and 2. Neither FVC nor FEV_1 measurements were significantly different between the experimental and control groups. This evidence suggests that thoracic MET dos not affect ventilatory function in the 20 minutes post-intervention.

Table 1. FVC group means and standard deviations pre- and post-intervention (0, 10, 20 min.) for the experimental and control groups, with percent change from pre-intervention

Forced Vital Capacity (FVC) in L				
Time	**Pre-intervention (-10)**	**Post-intervention (0)**	**Post-intervention (+10)**	**Post-intervention (+20)**
Experimental Group	4.497 ± 0.918	4.492 ± 0.94	4.497 ± 0.935	4.481 ± 0.957
% Δ from pre-intervention	N/A	-0.198	-0.067	-0.528
Control Group	4.625 ± 1.042	4.614 ± 1.033	4.589 ± 0.997	4.576 ± 1.002
% Δ from pre-intervention	N/A	-0.224	-0.6	-0.911

Table 2. FEV_1 group means and standard deviations pre- and post-intervention (0, 10, 20 min.) for the experimental and control groups, with percent change from pre-intervention

Forced Expiratory Volume in 1 Second (FEV_1) in L				
Time	**Pre-intervention (-10)**	**Post-intervention (0)**	**Post-intervention (+10)**	**Post-intervention (+20)**
Experimental Group	3.831 ± 0.803	3.836 ± 0.822	3.841 ± 0.828	3.823 ± 0.838
% Δ from pre-intervention	N/A	0.057	0.169	-0.384
Control Group	3.967 ± 0.815	3.985 ± 0.798	3.949 ± 0.804	3.933 ± 0.794
% Δ from pre-intervention	N/A	0.55	-0.407	-0.78

Note: a – sign indicates a decrease in volume from pre-intervention values

DISCUSSION

This study provides no evidence to suggest that ventilatory function, measured by FVC and FEV_1, is significantly altered in asymptomatic volunteers treated with thoracic MET, at any time post–intervention. No significant changes in ventilatory function were observed in the control group. In both treatment and control groups there was a mean decline in FVC and FEV_1 post-intervention. However there was a trend in the treatment group that saw ventilatory function remain more constant and not drop off as much or as rapidly as in the control group.

While there is evidence for the use of MET to increase cervical, thoracic and lumbar spine range of movement,[7-9] there still remains no evidence to suggest this is an effective technique as a treatment protocol for respiratory efficiency.

de Murashkin's[16] study involved the administration of active and passive rib stretches on FVC and FEV_1 in asymptomatic people. The results showed that neither of the stretching treatments were effective in altering the expiratory lung volumes in subjects with normal pulmonary function. However the asthmatic patients in the study, treated using the same protocol, did have significant increases in lung function. Although the asymptomatic individuals in the de Murashkin[16] study showed no significant change in ventilatory function, all participants felt as though they had benefited from the treatment. Unlike previous manual medicine studies[8,10,13,14] utilizing asymptomatic patients, these findings, along with those of this current study, suggest that in order for this technique to be of

value clinically, individuals that may benefit from this technique would need to have a pathological respiratory restriction, limiting normal ventilatory function.

Bockenhauer et al[11] found that Osteopathic Manipulative Techniques (OMT) increased upper and lower thoracic forced expiratory excursion in asthmatics. Although there was a trend towards improved peak expiratory flow rates and improvement of asthmatic symptoms these were not statistically significantly different to the sham techniques. Subjective reports from Bockenhauer's participants indicated that they believed that the treatment aided their respiratory function, in spite of the non-significant result. Unfortunately, the OMT performed in this study utilised four different osteopathic manoeuvres in sequential order, making it impossible to credit any one procedure as being most effective for increasing expiratory excursion. This study[11] indicated that despite there being no change in respiratory function, there was an improvement in the biomechanics of the thoracic region. This may have also been the case in the current study. Regardless of the absence of a significant change in ventilatory performance there may have been a mechanical improvement to the thorax as a result of the treatment.

The use of proprioceptive neuromuscular facilitation (PNF) as a treatment technique is similar to that of MET, with the aims of the therapy being to stretch and also facilitate specific muscles or joints, with both active and passive components.[5] Nitz and Burke[15], while investigating the effects of PNF in subjects with myotonic dystrophy found this technique to be the main contributor to improvement in oxygen saturation (PO_2). PNF also resulted in lowered respiratory rate and heart rate, along with a 377 – 556% increase

in thoraco-abdominal motion. PNF is believed to assist initiation of inspiration, increase volume and chest wall range of motion and strengthen respiratory muscles.[15,19] Mechanical stimulation of the chest wall proprioceptors during PNF of deep breathing may also enhance the activity of underlying intercostal muscles. This research backs up the contention that this type of manual technique is useful for treating people with a restriction in ventilation.

The previously mentioned PNF and stretching studies[15,16] indicate that changes seen in ventilatory parameters are the result of improvements made to the musculoskeletal mechanics of the thoracic region. The application of the study by Nitz and Burke[15] indicates that the volunteers participating in the current study did not have any pre-existing musculoskeletal restrictions sufficient to affect normal ventilation.

Contrasting this evidence is an investigation into the effects of rib raising technique on FVC and FEV_1 in people with asthma[10] that indicated a significant change in respiratory function in both asthmatics and non-asthmatics, as a result of the treatment. Interestingly, there was no significant difference between both groups although there was a trend of the asthmatics benefiting more. The authors believe the positive outcomes may result from improvement in the mechanics of the lungs, however the precise mechanism relating to this change is not known.

From these results it may be suggested that in the absence of any diagnosed pathology or symptoms relating to decreased respiratory function, manual therapy may improve lung

function in asymptomatic people. Although an improvement in respiratory measurements was still noted with asymptomatic individuals (non-asthmatics), rib raising is a different type of manual technique to that of MET. The therapeutic changes seen in the Wheatley et al[10] study may work on a different mechanism of action compared with MET, and can therefore not be directly compared with the results of this current study.

Austin and Pullin[13] and Austin and Ausabel[14] found enhanced respiratory muscular function in normal adults after lessons in Alexander technique (AT). In these studies, instructors gave verbal, hands-on, and mirror instruction to develop the subject's proprioceptive awareness of musculoskeletal positioning, especially of the spine. Spirometry tests demonstrated that subjects showed significant increases in all test parameters (FEV_1, FVC, Maximum Inspiratory and Expiratory Pressures), indicating that the study of the technique improves respiratory muscular function. Possible mechanisms for the changes include increased length and decreased resting tension of muscles of the torso, which in turn may increase their strength, increase thoracic compliance, and/or enhance coordination. In contrast to the current study, subjects in these studies received up to 20 private AT lessons at weekly intervals.

Field et al[12] found massage therapy for children with asthma decreased behavioural anxiety and cortisol levels, improved attitudes towards asthma and increased pulmonary function. This study, like those of the AT studies involved multiple treatments, with daily administration of massage over a 30-day period. The authors believed that the daily

massage may lead to improved airway tone, decreased airway irritability and better control over their asthma.

The massage and Alexander technique studies[12-14] indicate that these treatments can produce a significant effect over a period of multiple interventions. This more extensive application of therapy over a longer period may be significant in seeing a positive effect with the use of MET with ventilatory measures, as a therapeutic response from manual therapy is not always immediately apparent from the initial treatment.[20]

One difficultly in the use of spirometry that may have affected some participants in the current study is that of familiarisation and practice over time with the spirometric manoeuvre. This can lead to a learning effect and therefore has the possibility of altering the participant's performance over the course of the testing period. As only three of the participants were already familiar with spirometry, there is a chance that this phenomenon occurred. It cannot be assumed that this altered the results one way or another.

Limitations and Recommendations for future research

The use of asymptomatic subjects, with no thoracic dysfunction, is not necessarily a reflection of how effective a therapeutic manual technique can be. In a clinical situation, where most patients are symptomatic, the value of MET for treating respiratory dysfunction may be more applicable. Symptomatic volunteers could be used in future studies to evaluate the effects of MET for increasing respiratory efficiency. An MET

applied to the diaphragm; either alone or in combination with those techniques used in this study, may facilitate greater activation of the main muscle of respiration. This could result in a greater ventilatory force being achieved after treatment. Also multiple treatments of volunteers may result in a significant difference in ventilatory function. A one off treatment protocol might not benefit all volunteers, as can be seen with other manual therapies taking multiple treatments to elicit a therapeutic effect.

In this study there seemed to be a fatigue response as the testing wore on with an overall decrease in ventilatory function. More time between ventilatory efforts (15 minutes instead of 10 minutes) may eliminate this phenomenon in the future.

CONCLUSION

The use of a single treatment involving two thoracic MET's on asymptomatic volunteers showed no significant change in ventilatory function (FVC and FEV_1) immediately following, 10 minutes post, or 20 minutes post-intervention. Further investigations are required to establish the effectiveness of thoracic MET in a clinical setting with symptomatic subjects.

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Information for Participants Involved in Research

Project
"The Effect of Thoracic Muscle Energy Technique on FEV_1 and FVC Measurements."

Investigators
Cameron Gosling and Craig McKenzie

Location
Osteopathic Medical clinic, 4th Floor, 301 Flinders Lane, Melbourne

Purpose and Plan of the Study
You have been invited to participate in a study into the effect that Muscle Energy Techniques (MET) have on breathing measurements. The aim of this study is to identify whether a manual medicine technique can produce a measurable change in the breathing function in asymptomatic people. MET is a treatment technique used to strengthen and lengthen shortened, contractured or spastic muscles, and mobilize restricted joints, reducing local oedema and passive congestion. This study particularly looks at improving the function of the chest cage muscles and bones, therefore increasing the volume of air able to enter and exit the lungs, via the use of muscle energy techniques. Involvement in this study entails the person to voluntarily participate in receiving osteopathic techniques to be carried out on them, firstly with general thoracic MET in an attempt to increase thoracic rotation in both directions, while also increasing movement between individual ribs. A second technique, a thoracic cage release will also be applied in order to facilitate an increase in respiratory muscles function. The testing procedure requires you to present to the Osteopathic Clinic 10 minutes before the treatment commences. At the completion of the study you will be debriefed regarding the results of the study and thanked for participating.

Exclusion Criteria
An individual will be excluded from the study if the following criteria apply:
Participants who fail to provide informed written consent; Participants who smoke cigarettes, or any other form of elicit drug; Participants who, in the past month have suffered from any upper respiratory tract infection (URTI), cold, influenza or virus; Participants who have been diagnosed in the past 10 years with any extensive abnormal thoracic dysfunction (ie: asthma, severe scoliosis, rib fracture); Those participants who suffer form any other pathology that effects their normal breathing and/or respiration; Participants who are non-compliant with testing criteria.

Procedure:
All volunteers will be screened to determine suitability for inclusion and to rule out factors that prevent participant eligibility, as mentioned above. A consent form will then be signed to enable participation.

For female participants only: Female participants will be provided with a gown, and asked to remove my bra or any tight fitting supportive underwear ten minutes prior to pulmonary function testing in order to prevent variation in the results.

A spirometer will then be used to measure and record the lung function for that participant - giving FEV_1 and FVC values. The participant takes maximum forced inspiration followed by a maximum forced expiration until no more can be exhaled.
FEV_1 - (forced air blown out of the lungs in the first second)
The volume of air blown out of the lungs in the first second of maximal expiration after a maximal inspiration and is a useful measure of how quickly full lungs can be emptied.
FVC - (total amount of air forcibly blown out of the lungs)
The maximum volume of air that can be exhaled during a forced expiration.

The Osteopathic approach being used (MET) involves the patients active contraction of certain muscle group to equalise a deliberately executed force rendered by the therapist. After relaxation the practitioner moves the muscle-joint complex to a new restrictive barrier.

FEV_1 and FVC (after 10 minutes of rest) will be measured for each participant prior to the application of the treatment. Participants will then be treated using MET applied to the upper chest and diaphragm. FEV_1 and FVC will be measured again immediately after treatment, and then at 10 and 20 minute intervals post-treatment. A minimum of three and no more than eight technically acceptable expiratory manoeuvres will be performed, with the highest value being recorded.

Ethical Issues Arising

Participants should be aware that data from this study would be used only for the purpose investigating the aims as stated above. You will at no time be personally identified in any published data from this study, and all data, on completion of analysis will be held by the university and will be available only to the researchers.

Safety

All possible precautions will be taken to ensure your safety during this study. The testing will take place in the Osteopathic Medical clinic under the supervision of staff and investigators. You will be encouraged to report any problems you may experience during or after the testing protocol. Any practitioner carrying out the techniques will have updated first aid qualifications. Therefore, in the event of any respiratory episode or problem, the basic first aid protocols will be put in place.

Potential Benefits to participants

To date there are no studies that indicate whether MET administration to the thoracic region and diaphragm, has an effect on breathing function. The information gained in this study may open up avenues for further research into how Osteopathic treatment can be used to improve respiratory function.

Voluntary participation

Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time for any reason.

Confidentiality

Only the investigators will have access to confidential data that identifies you by name. All information and data will be kept strictly confidential. Participants will not be named in any research reports.

Questions

At any time before or during the study, you will be free to discuss any questions regarding the study, and will be encouraged to do so with the principle investigator or any of the co-investigators. If you have any questions related to ethical issues or issues regarding your rights please contact the investigators at the numbers below.

Contact phone numbers:

Cameron Gosling	Investigator	(03) 92481290
Craig McKenzie	Student Investigator	(03) 92481111

Please read the form of consent carefully and complete if you wish to participate in this study. You are under no obligation to continue and may withdraw from the study at any time. Individual results will remain confidential, although participants may chose to view their own particular results.

Any queries about your participation in this project may be directed to the researcher (Name: Craig McKenzie ph. 9248 1111) or Principal Researcher (Cameron Gosling ph. 9248 1290). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

Consent Form for Participants Involved in Research

CERTIFICATION BY PARTICIPANT
I**,**
of

certify that I am at least 18 years old and that I am voluntarily giving my consent to participate in the experiment entitled "The Effect of Thoracic Muscle Energy Technique on FEV_1 and FVC Measurements," being conducted at Victoria University of Technology by Cameron Gosling and Craig McKenzie

I certify that the objectives of the experiment, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the experiment, have been fully explained to me by Cameron Gosling or Craig McKenzie and that I freely consent to participation involving the use on me of these procedures.

Procedures:
Involvement in this study entails that I voluntarily participate in receiving osteopathic techniques to my thoracic region. This also involves pulmonary function tests and anthropometric measurements, which will be carried out in the same consulting room, by the same researcher, during the afternoon. I give permission for my height and weight measured to be recorded prior to commencement with a stadiometer and an electronic scale respectively (both calibrated accordingly). The testing procedure requires me to present to the Osteopathic Clinic ten minutes before my treatment commences, and 20 minutes thereafter. At the completion of the procedure I will be thanked for participating.

_____

For female participants only:
As a female participant I understand that I will be provided with a gown, and asked to remove my bra or any tight fitting supportive underwear ten minutes prior to pulmonary function testing in order to prevent variation in the results.

_____

I understand that if I feel any discomfort, respiratory fatigue, or difficulty breathing at any time throughout the procedure or during use of the spirometer, that I will be able to stop, or if necessary, refrain from further involvement.

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this experiment at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed: **.....**

Witness other than the experimenter: **.....**

Date: **.....**

Any queries about your participation in this project may be directed to the researcher (Name: Craig McKenzie ph. 9248 1111) or Principal Researcher (Cameron Gosling ph. 9248 1290). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).