



Jan 25, 2020 PLOS One

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1 Works for me

dx.doi.org/10.17504/protocols.io.8vhhw36





ABSTRACT

The following protocol has been used in the research title: Comparison of balance changes after inspiratory muscle or Otago exercise training.

Aim of the study is to investigate whether community-dwelling older adults undertaking 8 weeks of unsupervised, home-based inspiratory muscle training would improve balance and physical performance outcomes, similarly to care home residents, undertaking 8 weeks of instructor-led, group-based Otago exercise program.

The following document describes in details (step-by-step) the protocols used.

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0227379

THIS PROTOCOL ACCOMPANIES THE FOLLOWING PUBLICATION

Ferraro FV, Gavin JP, Wainwright TW, McConnell AK (2020) Comparison of balance changes after inspiratory muscle or Otago exercise training. PLoS ONE 15(1): e0227379. doi: 10.1371/journal.pone.0227379

Testing Environment

1 Environmental conditions were standardised; test sessions took place in a temperature-controlled laboratory (20 to 22 °C; humidity < 70%). Testing and re-testing sessions were scheduled at a similar time of the day (between 8:00 and 11:00 am) to minimise potential effects of diurnal variation.



Atkinson G, Reilly T (1996). Circadian variation in sports performance.. Sports medicine (Auckland, N.Z.).

Participants

Written informed consent to take part in the study and to use photographs for scientific publication, was obtained from all participants before testing.

Participants were familiarised with all test procedures before testing by verbal explanation, with the aid of participant information sheets.

On test days, participants were requested to avoid drinking alcohol or caffeinated beverages and taking any substances known to affect, or may, affect human physiological functions.

They were also required to dress in a tracksuit or shorts and t-shirts, with plimsolls or trainers.

Anthropometric Measurements

3 Demographic information was collected before testing.

Free-standing stature was measured to the nearest 0.1 cm with a stadiometer (SECA 217, Birmingham, UK), on which participants stood barefoot with heels together and arms by their sides, with the buttocks and scapulae in contact with the stadiometer.

Participants were instructed to look straight ahead and take a deep breath upon measurement. Stature was measured as the maximum distance from the floor to the vertex of the head.

The body mass in minimal clothing was recorded using an electronic weighing scale (Mc 780 MA, Tanita Body Composition Analyser, Amsterdam NL).

Questionnaires

4 Health check questionnaire.

Health check questionnaires were completed before testing to ensure each participant met the following exclusion criteria: having fallen in the past two years, heart conditions preventing physical activity, receiving beta-blocker medication, vertigo in the past six months and diabetes.

Copy of the health check questionnaire attached:

Health Check Form.docx

The Activities-Specific Balance Confidence (ABC) Scale.

It presents 16 items of assessment from vestibular balance (e.g. stand on tiptoes) to functional mobility (e.g. get into or out of a car). Each item is rated on a scale ranging from 0% "no-confidence" to 100% "complete confidence". The overall score is calculated by adding each item score and then dividing it by the total number of items.

The time required to administer the test was between 5 and 10 minutes.

Copy of the questionnaire attached:

ABC-Scale.pdf



Powell LE, Myers AM (1995). The Activities-specific Balance Confidence (ABC) Scale.. The journals of gerontology. Series A, Biological sciences and medical sciences.

Oswestry Disability Index (ODI) 2.0.

The questionnaire consists of 10 items divided into pain intensity during movement, personal care (e.g. getting dress), lifting,

walking, sitting, standing, sleeping, sex life, social life, and travelling. Each item consists of six statements correlating to scores of 0 (lower disability) to 5 (greatest disability).

Copy of the questionnaire attached:

Oswestry_Low_Back_Disability.pdf



Fairbank JC, Pynsent PB (2000). The Oswestry Disability Index.. Spine.

The Mini-Mental State Examination (MMSE)

The MMSE includes 11 questions divided into two sections, the first requiring vocal responses, covering orientation, memory and attention; the second requiring the ability to name things, follow verbal and written commands, write a sentence spontaneously and copy a complex polygon (similar to a Bender-Gestalt figure)

Several sources of bias are known to influence MMSE, including age, education, cultural and socioeconomic background. However, in the context of this study, the risk of bias was considered minimal, as participants were of similar age, educational level, and cultural and socioeconomic background.

Score interpretation is reported as follows: absence of cognitive impairment (total score between 25-30); mild impairment (total score between 20-25); moderate impairment (total score between 10-20); severe impairment (total score between 0-10).

For the purpose of this study, only participants with absence of cognitive impairment were recruited (using a total score of 25 as cutoff). The time required to administer the questionnaire was between 5 and 10minutes.

Copy of the questionnaire attached:

MiniMentalStateExamination.pdf



Mungas D, Marshall SC, Weldon M, Haan M, Reed BR (1996). Age and education correction of Mini-Mental State Examination for English and Spanish-speaking elderly.. Neurology.

Pulmonary Function

5 Forced vital capacity (FVC) and Forced expiratory volume (FEV₁).

Forced respiratory measures were conducted using hand-held spirometer (SpiroUSB, Care Fusion, Wokingham, Berkshire, UK), with Care Fusion software, following the guidelines of the American Thoracic Society.

Participants performed forced breathing manoeuvres at least five and no more than eight times until variability was within 5% in three consecutive manoeuvres, from which the higher score was collected.

All measurements were made with participants in a seated position wearing a nose clip.

Sufficient time for resting was allowed between measurements (1 to 2 minutes) and verbal encouragement was provided during maximal effort as following:

"Breatheforcefully and without hesitation with the nose-clip on, inhale until your lungs are as full as they can possibly be and then blow out through the mouthpieces hard and fast as you can...keep going, out, out, squeeze out, then breathe in as fast as you can...big deep breath, keep going."

The time required to administer the test was between 10 and 15 minutes.

The spirometry test was completed as the first assessments, in order to record any sign of asthma, COPD or other conditions that could have to exclude participants for taking part. The conditions were monitored trough the Tiffeneau-Pinelli index (i.e. FEV_1/FVC) and only participant with a ration > 0.7 was included in the research.



Graham BL, Steenbruggen I, Miller MR, Barjaktarevic IZ, Cooper BG, Hall GL, Hallstrand TS, Kaminsky DA, McCarthy K, McCormack MC, Oropez CE, Rosenfeld M, Stanojevic S, Swanney MP, Thompson BR (2019). Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement.. American journal of respiratory and critical care medicine.

https://doi.org/10.1164/rccm.201908-1590ST

Peak Inspiratory Flow Rate (PIFR).

Peak inspiratory flow rate is an index of maximal inspiratory muscle shortening velocity. The PIFR was measured using the Powerbreathe $^{\text{(B)}}$ K5 (POWERbreathe International Ltd. Southam, UK) and the Breathe-Link 2.0 software.

Participants were instructed to perform between 15 and 30 maximal inspirations, as fast and deep as they could, starting from complete exhalation, with 30 seconds rest between each.

All measurements were made in a seated position and with nose-clip attached. The measurements were repeated until three values were obtained that differed by no more than $0.10 \, \text{l s}^{-1}$. The time required to administer the test was between 10 and 15 minutes.



Langer D, Jacome C, Charususin N, Scheers H, McConnell A, Decramer M, Gosselink R (2013). Measurement validity of an electronic inspiratory loading device during a loaded breathing task in patients with COPD.. Respiratory medicine. https://doi.org/10.1016/j.rmed.2013.01.020

Respiratory Muscle Function

6 Maximal Static Respiratory Muscle Function.

A hand-held mouth pressure meter MicroRPM (Micro Medical Ltd, Rochester, Kent, UK) was used for the determination of maximal inspiratory pressure (MIP) during a quasi-static effort (i.e. Mueller manoeuvre), in conjunction with Micro Medical PUMA software (Micro Medical Ltd, Rochester, Kent, UK) for recording the measurements.

The pressure meter incorporates a small air vent, which prevents the production of artificially high pressures generated by the muscles of the buccal cavity when the glottis is closed. The vent was small enough (~1 cm) that it did not significantly affect lung volumes during maximum efforts.

Participants breathed via a flanged mouthpiece while wearing a nose-clip. The device was capable of measuring differential pressure between 300 cm H_2O . Since MIP measurements are dependent on lung volume, each effort was initiated from residual volume or total lung capacity, respectively.

The test manoeuvre consisted of isolated concentric muscle contractions to avoid the variability that is caused by the stretch-shortening cycle of the respiratory muscles. All manoeuvres were sustained for 3 to 4 seconds while seated, and participants

were instructed to exert efforts rapidly and maximally.

In addition, participants were provided with strong verbal encouragement in support:

"Breathe in hard - pull, pull, pull";

Before testing, all participants practised the Müller manoeuvres three times, and measurements were repeated at least five, but no more than eight times, until variability was < 10% in three consecutive manoeuvres, from which the best was recorded. The required time to administer the test was between 10 and 15 minutes.



Ferraro FV, Gavin JP, Wainwright T, McConnell A (2019). The effects of 8 weeks of inspiratory muscle training on the balance of healthy older adults: a randomized, double-blind, placebo-controlled study. Physiological reports.

https://doi.org/10.14814/phy2.14076

Peak Inspiratory Muscle Power (PIP).

Using the POWERbreathe $^{(8)}$ K5 with Breathe-Link 2.0 software participants inhaled with maximal effort against six discrete load settings: 40%, 50%, 55%, 60%, 70% and 80% of their [baseline] MIP.

Three trials were performed for each of the loading intensities with 30 seconds rest intervals between efforts, for a total of 18 maximal inspiratory manoeuvres.

All loads were assigned randomly using free software available on randomizer.org. All manoeuvres were performed seated, wearing the nose-clip and within a 20 minutes period.

Participants received visual feedback of pressure from the Breathe-Link 2.0 software to prepare them for the magnitude of the ensuing inspiratory efforts and were instructed to inhale with maximal effort as rapidly as possible.



Evans JA, Whitelaw WA (2009). The assessment of maximal respiratory mouth pressures in adults.. Respiratory care.



Langer D, Jacome C, Charususin N, Scheers H, McConnell A, Decramer M, Gosselink R (2013). Measurement validity of an electronic inspiratory loading device during a loaded breathing task in patients with COPD.. Respiratory medicine.

https://doi.org/10.1016/j.rmed.2013.01.020

7 Mini-balance evaluation systems test (mini-BEST).

The mini-BEST is a clinical balance measure that contains 14 items, divided into four domains: i)anticipatory postural adjustments, ii) postural responses, iii) sensory orientation and iv) stability in gait.

Each task is scored on a three-point scale from zero to two, where zero indicates that the participant is unable to perform the task whereas two means that the participant is able to complete the task without difficulties.

The maximum score is 28 points. A cut-off score of 16 has been suggested to define people with balance disorders. The mini-BEST takes between 15 to 20 minutes to complete and has been shown to have a minimal detectable change of 3.5/28 and standard error of measurement of 1.26.

For the purpose of this study the latest version, freely downloaded on www.BESTest.us, was used.

- Franchignoni F, Horak F, Godi M, Nardone A, Giordano A (2010).

 Using psychometric techniques to improve the Balance Evaluation

 Systems Test: the mini-BESTest.. Journal of rehabilitation medicine.

 https://doi.org/10.2340/16501977-0537
- Yingyongyudha A, Saengsirisuwan V, Panichaporn W, Boonsinsukh R (2016). The Mini-Balance Evaluation Systems Test (Mini-BESTest) Demonstrates Higher Accuracy in Identifying Older Adult Participants With History of Falls Than Do the BESTest, Berg Balance Scale, or Timed Up and Go Test.. Journal of geriatric physical therapy (2001). https://doi.org/10.1519/JPT.00000000000000000
- Godi M, Franchignoni F, Caligari M, Giordano A, Turcato AM, Nardone A (2013). Comparison of reliability, validity, and responsiveness of the mini-BESTest and Berg Balance Scale in patients with balance disorders.. Physical therapy. https://doi.org/10.2522/ptj.20120171

Physical Performance

8 30 second Sit to Stand Test (30sSTS).

The procedure involves counting the number of sit to stand transitions that a participant can complete in 30 seconds. To facilitate reproducibility and standardisation, a standard armless chair, with 46 cm seat height was used, aware that this approach fails to accommodate for the variety of heights of participants resulting in greater or lesser knee flexion angles.

Participants performed the test with arms across their chest, sitting at the chair edge with hips in neutral abduction and rotation, not touching the seatback. Participants were blindfolded during the test, to minimise potential effects of vision on the performance.

For participants safety the chair was placed next to the wall, to block it from slipping during the test. After 15 seconds of usual sitting, they were instructed to rise, and then become seated as fast as possible and with a full range of motion, for 30 seconds, with both feet maintaining contact with the floor.

Counting commenced on the command "3, 2, 1 and go". The principal investigator (FF) was standing nearby the participants to prevent actual falls, and no practice trial or verbal encouragements were provided.

The pre-activation 30 seconds sit-to-stand (30sSTSPA).

This procedure was used to determine the effect of acute, pre-inspiratory muscle activation on the 30sSTS task.

Briefly, adequate rest intervals between 30sSTS and 30sSTS_{PA}were provided (2 to 5 minutes), participants then performed 30 repetitions of forceful inhalations against a load equivalent to 50% of their [baseline] MIP, followed by forceful inhalation 80% of [baseline] MIP until repetition failure.

 $Verbal\ encouragement\ was\ provided\ during\ the\ 80\%\ loading\ phase.\ When\ participants\ were\ unable\ to\ inhale\ forcefully\ for\ three\ consecutive\ attempts,\ they\ were\ instructed\ to\ stop\ the\ forced\ inspiration\ and\ to\ perform\ the\ 30sSTS_{PA}$



Mourey F, Grishin A, d'Athis P, Pozzo T, Stapley P (2000). Standing up from a chair as a dynamic equilibrium task: a comparison between young and elderly subjects.. The journals of gerontology. Series A, Biological sciences and medical sciences.



Lomax M, McConnell AK (2009). Influence of prior activity (warm-up) and inspiratory muscle training upon between- and within-day reliability of maximal inspiratory pressure measurement..

Respiration; international review of thoracic diseases.

https://doi.org/10.1159/000211229

Timed Up and Go test (TUG).

The TUG consists of measuring the time required to stand up from a chair, walk 3 meters, turn around, walk back to the chair and sit down again; with a lower time-to-completion indicates better performance/mobility.

A standard armless chair (46 cm of height) was used. Participants sat, at the command "3, 2, 1 and go", they were instructed to stand up, walk a distance of 3 meters at a comfortable and safe pace, turn around a cone, walk back to the chair, and sit down again. No walking aid or assistance was provided during the test. All participants performed the test once, before measurement, for familiarisation. The time was recorded in seconds with digital stopwatches, and the test required between 10 and 15 minutes to complete.

Cognitive Timed Up and Go (TUG_C).

Participants were asked to perform the same task previously explained for TUG, while being instructed to count down backwards aloud in threes, from a random number between 80 and 100. The number was announced by the principal investigator (FF) immediately before the instruction to commence the test (i.e. "3, 2, 1, the number is 100 and go"). The starting number was not repeated and the first number spoken was the result of the first calculation. The time was recorded with a digital stopwatch, from when participant's buttocks left the back of the chair and ended when the participant's buttocks touched the seat of the chair.

Motor Timed Up and Go (TUG_M).

Participants were asked to perform the same task previously explained for TUG, whilst holding a 70 cm wide tray, atop of which was a glass (diameter 8 cm, height 9.5 cm) filled with water (1 cm away from th

e top of glass). Time was recorded using a digital stopwatch from when participant's buttocks left the back of the chair and ended when the participant's buttocks touched the seat of the chair. In addition, participants did not know the results until all three tests (TUG, TUG_C and TUG_M) were completed to avoid any influence on performance.

Barry E, Galvin R, Keogh C, Horgan F, Fahey T (2014). Is the Timed Up and Go test a useful predictor of risk of falls in community dwelling older adults: a systematic review and meta-analysis.. BMC geriatrics.

https://doi.org/10.1186/1471-2318-14-14



Shumway-Cook A, Brauer S, Woollacott M (2000). Predicting the probability for falls in community-dwelling older adults using the Timed Up & Drest.. Physical therapy.

Sit-Up Test.

An isometric sit-up was employed to assess anterior trunk muscle endurance.

Participants required to sit on an examination bench and place the upper body against a support with a 60° angle from the testbed. Both the knees and hips were flexed to 90°. The arms were folded across the chest and feet were secured with straps. Participants were instructed to contract their abdominal muscles and maintain the position while the support was pulled back of approximately 10 cm at the command "3, 2, 1 and go".

Time to the limit of tolerance was recorded. The test ended if participants experienced discomfort, or could no longer hold the starting position. No encouragement was provided during the measurement.



McGill SM, Childs A, Liebenson C (1999). Endurance times for low back stabilization exercises: clinical targets for testing and training from a normal database.. Archives of physical medicine and rehabilitation.

Biering-Sørensen test.

The procedure requires participants to lie prone on an examination table with the iliac crest on the edge of the table. The lower body was fixed to the table by two straps around the pelvis and the knees, while the principal investigator (FF) held the participant's ankles.

Before the beginning of the test, the participants were allowed to rest the upper body on the treatment table. Then, they were asked to lift the upper body, with arms behind their head and maintain the trunk in neutral alignment for as long as possible.

The time to the limit of tolerance was recorded for subsequent analysis. During the test, small perturbations may occur naturally while maintaining the required position and this could produce a false assumption of fatigue. Thus, the test was terminated if participants were in discomfort, or if there were a $> 10^{\circ}$ variation from the neutral alignment. No encouragement was provided during the trunk muscles endurance measurements.

- Latimer J, Maher CG, Refshauge K, Colaco I (1999). The reliability and validity of the Biering-Sorensen test in asymptomatic subjects and subjects reporting current or previous nonspecific low back pain.. Spine.
- Demoulin C, Vanderthommen M, Duysens C, Crielaard JM (2006).

 Spinal muscle evaluation using the Sorensen test: a critical appraisal of the literature.. Joint, bone, spine: revue du rhumatisme.

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