**PhD study protocol**

***Working Title***

Can physical activity intervention and/or text messaging improve functional exercise capacity and self-efficacy in adults with OSA?

***Supervisory team***

**Primary supervisor: Dr Margot Skinner**

**Co-supervisors: Associate Professor Debra Waters; Dr Ben Brockway (DSM)**

***Introduction***

Low physical activity levels represent an additional risk factor in adults with obstructive sleep apnoea (OSA), increasing with OSA severity.1  Insufficient physical activity is the fourth leading global risk factor for mortality,2 and accounts for 6% of the disease burden in coronary heart disease.3  Adults with OSA, classified as physically inactive, are high risk for hypertension4 which if untreated is 2-3 times greater than the mortality risk for healthy New Zealand adults.5

70% of adults with OSA are overweight/obese6 and a 10% reduction in weight predicts a 26% improvement in apnoea severity.7 Conversely, weight gain is a predictor for worsening severity of OSA in patients with mild OSA.7  Physical activity intervention may, therefore, offer a possible strategy to offset weight gain, and provide associated health benefits and health cost savings.

Management of OSA with continuous positive airway pressure (CPAP), effectively reduces apnoea severity, but does not address the lifestyle issues associated with being overweight/obese.8 In fact studies on CPAP usage have demonstrated a link with weight gain,9, 10 and no change in physical activity levels.11,12

***Rationale***

Moderate/vigorous exercise may improve health outcomes and support weight loss in adults with OSA.13, 14, 15  Aerobic exercise has demonstrated improvements in apnoea severity.[1](#_ENREF_1)6 However, studies lack rigour e.g. small sample sizes; no control group; reliance on self-reported activity levels.

Data from our phase 1 study indicated that, in a cohort at risk of OSA, there were higher rates of cardiovascular disease, type 2 diabetes, obesity and hypertension than in the general population. Of the total cohort, those who were less physically active were more likely to have uncontrolled hypertension and type 2 diabetes. Almost all participants not meeting the recommended physical activity guidelines were obese. In addition, those subsequently diagnosed with moderate-to-severe OSA were less likely to be meeting WHO physical activity guidelines, were sedentary for longer and more likely to do no physical activity in a typical week when compared with the total cohort of individuals at risk of OSA. Of our total cohort, 48% were typically sedentary for greater than six hours a day. 88% of participants agreed they would like to be more physically active, with low motivation cited as the key barrier to participation.

Adherence to physical activity, and its associated benefits, have not been studied in those with OSA. Studies have shown adherence to exercise/physical activity in other patient populations with chronic diseases is poor, with dropout rates reported to be between 50-90%.17 To improve adherence, barriers to activity need to be identified and overcome and behaviour changed, through use of motivational strategies meaningful to the individual.17

Group physical activity provides support and social connectivity. Key influences on attendance include the development of relationships with participants and the health professionals involved.18 The use of text messaging as a motivational tool is an approach for supporting these individuals, and has been shown to be successful in motivating other patient groups to increase physical activity levels,19 whilst also providing time and cost benefits. Tailoring feedback and customisation of text messages has been associated with greater intervention efficacy.20 To date no studies have explored the use of motivational text messaging in the population with OSA.

***Study objectives:***

In a cohort of adults at risk of obstructive sleep apnoea (OSA):

* To investigate the effects of a 12-week physical activity intervention on physical activity behaviour and a range of relevant health outcomes.
* To compare activity levels and sedentary time during a physical activity programme with and without tailored text messaging intervention.
* To compare physical activity behaviour in those undergoing CPAP treatment with those who are not.
* To objectively measure physical activity levels at three time points (baseline, 12 and 24 weeks) in conjunction with a supervised exercise intervention and compare levels with current World Health Organization weekly recommendations.

***Methods***:

*Aim*: to investigate the effect of physical activity intervention with or without tailored text messaging on physical activity behaviour and exercise self-efficacy and in adults at risk of OSA, and secondly, the effect of CPAP on physical activity and related health outcomes on a subgroup of those diagnosed with moderate-severe obstructive sleep apnoea.

*Primary outcome measure:*positive changes in functional exercise capacity as measured by six-minute walk test.

*Secondary outcome measures:* changes in physical activity behaviour as measured by moderate-vigorous physical activity (MVPA) bouts using accelerometry data, gait speed, muscle strength, self-efficacy, sedentary time, sleep duration/disturbance (as measured by accelerometry), depressive symptoms, quality of life.

*Study design:*

This study is a three-arm pre-test-post-test design with participants being recruited from referrals to the Dunedin Sleep Clinic, with symptoms indicative of OSA, who meet the Dunedin Sleep Clinic threshold for an investigative Embletta overnight sleep study. A convenience sampling method will be used, with participants selected based on availability. This will allow for recruitment of a desired sample size of 150 from the target population: (the Sleep Clinic averages 40 referrals/month, of which approximately 70% meet the eligibility criteria for the study as evidenced by 28 Embletta overnight sleep studies being undertaken each month). Based on an estimated response rate of 60%, the required participant sample will be recruited within ten months.

Each participant will be provided with a personalised exercise programme based on the outcome of the baseline data collected. For practicality, participants from out of town will be allocated to the tailored text messaging group if unavailable to travel. All other participants will be randomised to an intervention group.

The three-arm intervention will be as follows:

Group 1 – weekly supervised exercise group

Group 2 – weekly supervised exercise group plus tailored text messaging

Group 3 – tailored text messaging only

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| --- |
|  BASELINE TESTING PRE EMBLETTA WK 0 |
|  EMBLETTA + ACTIGRAPH DAY 6 |
|  | EXERCISE GROUP, NO TEXTING |  |  |  | EXERCISE GROUP + TEXTING |  |  |  |  TEXTING |  | WK 1 |
|  |  |  |  |  |  |  |  |  |  |  |  |
| REPEAT QUESTIONNAIRES |  | REPEAT QUESTIONNAIRES |  | REPEAT QUESTIONNAIRES | WK6 |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | REPEATBASELINE MEASURES |  |  | TEXT | REPEATBASELINE MEASURES |  |  | TEXT | REPEATBASELINE MEASURES |  | WK 12 |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | REPEATBASELINE MEASURES |  |  |  | REPEATBASELINE MEASURES |  |  |  | REPEATBASELINE MEASURES |  | WK 24 |
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The weekly supervised group exercise will comprise both aerobic and resistance exercises, and be supervised by a physiotherapist. It will be a semi-structured session incorporating a variety of exercise options including, but not limited to, treadmill, static bike, rower, free weights, resistance bands etc. The physiotherapist running the exercise group will be blinded as to whether individuals are receiving text messaging or not.

Text-messaging will be underpinned by Bandura’s social cognitive theory and the concept of self-efficacy. Text messages will be tailored to the individual participant based on their responses from the Stages of Change questionnaire and Exercise Benefits/Barriers Scale and will incorporate individualised motivational statements. These personalised text messages will be sent between five and seven times a week throughout the initial 12 weeks, and for 12 weeks afterwards at a decreasing rate.

*Participants*:

Inclusion criteria:

* Adults referred to the Dunedin Sleep Clinic with symptoms indicative of OSA and an ESS ≥ 11
* Able to walk independently with or without a walking aid

Exclusion criteria:

* An overnight sleep study result with no diagnosis of OSA (excluded from study data analysis)
* Uncontrolled hypertension or unstable angina
* Inability to participate in exercise-based physical activity
* Inability to provide informed consent
* Inability to complete health related questionnaires independently and in English

*Procedures*:

Participants will be sent an appointment letter from the Dunedin Sleep Clinic for an overnight sleep study. An introduction letter, from the Dunedin Sleep Clinic consultant (BB) and primary investigator (MS), informing them of the research study (including participant information sheet) will be included in this initial correspondence. Potential study participants will be followed-up with a phone call from the primary investigator (MS) a few days later. Any questions regarding involvement in the study will be addressed and informed consent gained. Participants will be invited to attend an initial meeting with the researcher (SR), scheduled for six days before their overnight Embletta sleep study, where the following baseline measurements will be taken:

* *Height* will be measured with the participant barefoot with feet together and recorded in metres and centimetres to the nearest 0.1cm using a stadiometer.21
* *Weight* will be measured using a calibrated scale22 and recorded to the nearest 0.1kg. The participant will be measured wearing light clothing and without shoes.
* *Body Mass Index (BMI)* will be calculated as weight in kg divided by height in metres squared.
* *Blood pressure* measurements will be taken using a calibrated monitor23 and recorded after the participant has sat quietly in a chair with back support, with both feet flat on the floor, for at least five minutes prior to measurement. Blood pressure measurement will be taken twice, in the right arm, and the lower of the two readings used. Where the two readings vary markedly, a third reading will be taken.
* *Heart rate* will be recorded in beats per minute with the participant at rest, having sat quietly for at least five minutes. A calibrated pulse oximeter will be used.24
* *Oxygen saturation* will be recorded with the participant at rest, having sat quietly for at least five minutes. A calibrated pulse oximeter will be used.24
* *Neck circumference* will be measured in a standing position, and taken at the level of C4, using an anthropometric tape measure.25 The participant will be asked to stand with their head in the natural resting position and shoulders relaxed. They will be asked to nod their head three times and look straight ahead. Measurements will be recorded in centimetres and millimetres, to the nearest millimetre.
* *Waist circumference* will be measured horizontally on bare skin at the mid-point between the right lower rib margin and the iliac crest using an anthropometric tape measure with the subject in standing and at the end of a normal expiration.26 Measurements will be recorded in centimetres and millimetres, to the nearest millimetre.
* A *six-minute walk test (6MWT)* will be carried out using a 30-metre length with cones positioned every 5 metres. The participant will sit down for 10 minutes prior and be instructed to walk up and down the 30 metre length as far as they can in six minutes, turning at the 30 metre point. The 6MWT is simple and inexpensive to administer, has good test-retest reliability in both older adults and populations with long-term conditions27 and has been widely used in populations with chronic conditions, including obesity.28
* *Gait speed* will be measured over a 10 metre distance. Gait speed is calculated using distance travelled in metres by the time required to travel that distance in seconds (m/s). A gait speed of <0.1m/s indicates poor physical function29 and increased risk for disability, falls and mortality.30
* *Grip strength* will be carried out using a Lafayette handheld dynamometer.31 In standing, the participant will hold the dynamometer in their dominant hand, with the elbow flexed to 90 degrees. The dynamometer will be adjusted if required, so the base rests on first metacarpal (heel of palm), and the handle positioned in the middle of the fingers for a comfortable grip. The participant will be asked to squeeze the dynamometer with maximum isometric effort, and hold for three seconds. No other body movement should occur. Three trials will be undertaken and the mean calculated. The handheld dynamometer has excellent test-retest reliability and excellent intra and interrater reliability in a variety of clinical populations.32
* *Physical activity levels* will be recorded using an Actigraph wGT3X-BT accelerometer.33 Each participant will be asked to wear the accelerometer for seven days and nights, to objectively determine baseline physical activity levels, sedentary time and sleep quality and duration. The final night of wearing the accelerometer will coincide with their overnight Embletta study, to allow for correlation of results to determine reliability. Accelerometry uses triaxial acceleration data to capture physical activity intensity, activity bouts and sedentary bouts. The Actigraph has been used in thousands of clinical studies globally and in patients with a variety of conditions, including obesity, cardiovascular disease and diabetes.34  Wearing of the Actigraph accelerometer will be repeated for another seven-day period for comparison at 12 weeks and 24 weeks.

All baseline measures will be repeated at 12 weeks and 24 weeks.

In addition, each participant will undertake the following questionnaires:

*Functional Outcomes of Sleep Questionnaire (FOSQ)35*

The FOSQ has been widely used in the assessment of sleep disorders. It has established test-retest reliability (r=0.95), good internal consistency (r=0.90) and concurrent validity with the SF-36.

*Short Form-36 (SF-36)36*

SF-36 is a globally used quality-of-life questionnaire and has been translated in more than 50 countries and into at least 22 languages. It has been widely validated for numerous professions and patient populations and correlates strongly with other quality-of-life questionnaires. It provides a comprehensive overview of various tenets of quality-of-life and has been widely used in the population with OSA. The eight subscales have good internal consistency (α = 0.73–0.96) and test-retest reliability (r = 0.60–0.81) and the questionnaire has been validated by its ability to differentiate between clinical morbidities.

*Patient Health Questionnaire (PHQ-9)37*

The PHQ-9 is a widely used self-reported screening tool for depressive symptoms. It has been used in the general population and in cohorts with a variety of conditions, including non-communicable diseases. It has excellent test-retest reliability (r=0.84) and excellent internal consistency (α=0.86).

*General Self-Efficacy Scale (GSE)38*

The GSE is a brief self-administered tool used to assess an individual’s general perceived self-efficacy. It has been translated into 33 languages. It has good internal consistency (α=0.76-0.90) and established criterion-related validity.

*Exercise Benefits/Barriers Scale (EBBS)39*

The EBBS measures an individual’s perceptions of the benefits of, and barriers to, exercise participation. It has good internal consistency (α = 0.95) and established test-retest reliability (r=0.77-0.89).

*Physical Activity Stages of Change Questionnaire (SoC)40*

This four-item self-reported questionnaire categorises an individual into one of the five stages of behaviour change.

Prior to undertaking physical activity, a pre-screening questionnaire will also be undertaken.

*PAR-Q+41*

The PAR-Q+ is a pre-participation screening tool used to determine an individual’s readiness for engaging in physical activity.

All questionnaires will be repeated at six weeks, 12 weeks and 24 weeks.

*Statistical/data analysis*

* Sample size calculation: n=135
* Confidence level = 95%
* Total width of confidence interval = 5
* Standard deviation of variable = 27.2m
* Sample size =150 to allow for drop-outs

Regression analysis will be undertaken to determine differences between those on CPAP and those not.

*Expected Outcomes*

The expected outcomes at completion of this research are as follows:

* Analysis of the effects of a 12-week physical activity intervention on physical activity behaviour and a range of relevant health outcomes
* Comparison of activity levels and sedentary time between groups participating in a physical activity programme with and without tailored text messaging intervention.
* Comparison of physical activity behaviour in those undergoing CPAP treatment with those who are not.
* Analysis of physical activity levels of intervention groups with reference to current World Health Organization weekly recommendations.

***Resources/Funding:***

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| Required resource | Cost | Funding source |
| Actigraph GT3XPB accelerometers x 10 | $2250 | University of Otago (PI’s S account) |
| Actigraph Sleep Features component  | $500 | University of Otago (PI’s S account) |
| Actigraph belts and clips  | $312 | University of Otago (PI’s S account) |
| Text messaging services | $950 | Grant application  |
| Travel reimbursement to participants | $6800 | Grant application  |
| Printing, photocopying and postage costs | $75 | PhD budget |

**TOTAL COSTS $10887**

Those travelling from outside of Dunedin will be provided with travel vouchers as partial reimbursement for attending the baseline assessment session and two follow-up sessions. This will enable inclusion of a broader cross-section of participants to avoid limiting the data to Dunedin-based participants only.

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