Statistical analysis plan (SAP)

Official study title: Effects of adding home-based power training to a multidisciplinary weight management service: A randomised clinical trial

NCT number: Not yet assigned

Date: Version 1.1, 27/03/2018

Sponsor: University of Hull, Hull, UK

Prepared by: Dr Samuel T. Orange, Postdoctoral researcher, Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, UK

1. Objective

The main objective of this study is to evaluate whether home-based power training can promote weight loss and improve physical function, strength, power and quality of life in adults with severe obesity. We also aim to investigate whether performing resistance exercises as fast as possible can yield further improvements in muscle power and physical function compared with traditional slow-speed resistance training.

2. Primary outcome

The primary outcome was the adjusted mean difference in lower-limb power at 3-months, as measured in the sit-to-stand transfer with a wearable inertial (PUSH, PUSH Inc., Toronto, Canada). The device is worn on the participant's forearm and measures acceleration in the upwards phase of the movement. Power is then calculated as velocity x force, where velocity is the integral of acceleration, and force is the product of mass and acceleration (Orange, Metcalfe, et al., 2018). This was chosen as the primary outcome because the power generated via the sit-to-stand is a critical determinant of several measures of physical function (Orange, Marshall, Madden, & Vince, 2018).

Secondary outcomes

The secondary outcomes were as following:

- Feasibility (recruitment rates, attrition rates, number of patients lost to follow-up, exercise adherence rates, number and type of adverse events)
- Body mass
- Anthropometry (waist circumference, hip circumference, waist to hip ratio)
- Physical function (six-minute walk test, timed up-and-go, 30-second chair sit-to-stand)

- Muscle strength (shoulder press one repetition maximum, seated row one repetition maximum, isometric mid-thigh pull).

- Shoulder press power and velocity

- Sit-to-stand velocity

- Health-related quality of life (EuroQol 5-level questionnaire, EuroQoL visual analogue scale, Obesity and Weight Loss Quality of Life Instrument, Weight-related symptom measure).

- Exercise-responses (sessional heart rate, session duration, total number of repetitions performed each session, step count).

3. Sample size

The primary outcome was difference in lower-limb power at 3-months. Balachandran et al. (2014) is the only previous study to have compared strength training versus power training in obese adults, reporting a Hedge's g effect size in lower-limb power of 0.9, which converts to d = 0.95 (Lakens, 2013). Therefore 37 participants (19 per group) were required to detect an effect of d = 0.95 (f = 0.475) in an analysis of covariance (ANCOVA) given α = 0.05, 1-β = 0.8, and numerator df = 1, which was calculated using G*Power version 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007). We did not account for attrition rate because we will perform our analyses by intention to treat.

4. Statistical analysis

Analyses will be performed by intention to treat using SPSS (IBM SPSS, version 24.0, Chicago, IL). Descriptive statistics (mean ± SD) will be presented at baseline to characterise participants. Feasibility outcomes will also be presented with descriptive statistics (i.e. recruitment rates, attrition, adherence and adverse events). Exercise responses will be averaged across the 12-week intervention then compared with independent t-tests. Between-group

differences in outcomes at 3-months and 6-months will be assessed by analysis of covariance ANCOVA with baseline values, age and sex as covariates. We will also calculate Hedge's g effect size using the formula: ([difference in adjusted means between-groups] / pooled SD). 0.5 SDs will denote a minimum important difference (Norman, Sloan, & Wyrwich, 2003). Changes from baseline within-groups will be examined with one-way repeated-measures ANOVAs and subsequent Bonferroni-corrected planned contrasts. The assumption of sphericity will be assessed with Mauchly's test, and in the case of significant violations, the Greenhouse-Geisser epsilon correction will be applied. Statistical significance will be set at a two-tailed $p < 0.05$.

5. Missing data

To increase precision of estimates and comply with intention to treat, missing data at 3-month and 6-month endpoints will be multiply imputed using the Markov chain Monte Carlo (MCMC) algorithm with 20 iterations. At the end of the 20 iterations, one imputed data set is created and the process was repeated to generate 20 imputed data sets, which will then be pooled according to Rubin's rules (2004). For participants who have missing data at 3-months, baseline values and other covariates (group, age, sex, resistance training adherence) will be entered into the imputation model. When data are missing at 6-months, baseline and 3-month endpoint values with covariates will be used to impute missing values. Outcomes with missing data at baseline will not be included in the analysis.

References

Balachandran, A., Krawczyk, S. N., Potiaumpai, M., & Signorile, J. F. (2014). High-speed circuit training vs hypertrophy training to improve physical function in sarcopenic obese adults: a randomized controlled trial. *Experimental Gerontology, 60*, 64-71. doi:10.1016/j.exger.2014.09.016

Faul, F., Erdfelder, E., Lang, A. G., & Buchner, A. (2007). G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav Res Methods, 39*(2), 175-191.

Lakens, D. (2013). Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. *Front Psychol, 4*, 863. doi:10.3389/fpsyg.2013.00863

Norman, G. R., Sloan, J. A., & Wyrwich, K. W. (2003). Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Med Care, 41*(5), 582-592. doi:10.1097/01.Mlr.0000062554.74615.4c

Orange, S. T., Marshall, P., Madden, L. A., & Vince, R. V. (2018). Can sit-to-stand muscle power explain the ability to perform functional tasks in adults with severe obesity? *J Sports Sci*, 1-8. doi:10.1080/02640414.2018.1553500

Orange, S. T., Metcalfe, J. W., Liefeith, A., Marshall, P., Madden, L., Fewster, C., & Vince, R. V. (2018). Validity and reliability of a wearable inertial sensor to measure velocity and power in the back squat and bench press. *The Journal of Strength & Conditioning Research*.

Rubin, D. B. (2004). *Multiple imputation for nonresponse in surveys* (Vol. 81). New York: John Wiley & Sons.