

Long-term Effects of Individualized Follow-up with an App for One Year

NCT05697120

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Statistical analyses plan

The present study is a follow up study of a completed study registered at ClinicalTrials.gov with the following ID: NCT03174106. Some of the data (i.e. baseline characteristics) will be analysed in accordance with previous plan which have been published as results from the RCT and in the published protocol:

Lunde P, Bye A, Bergland A, Nilsson BB. Effects of individualized follow-up with a smartphone-application after cardiac rehabilitation: protocol of a randomized controlled trial. *BMC Sports Science, Medicine and Rehabilitation* 2019; 11: 34. DOI: 10.1186/s13102-019-0148-2.

Lunde P, Bye A, Bergland A, Grimsmo J, Jarstad E, Nilsson BN. *Long-term follow-up with a smartphone application improves exercise capacity post cardiac rehabilitation: A randomized controlled trial*. European Journal of Preventive Cardiology, 2020: p. 204748732090571

IBM SPSS Statistics, Stata, R or other appropriate software will be used for statistical analysis. Continuous, normally distributed baseline data were analysed with an independent t-test to test for differences between groups, and Pearson's chi squared test was used to analyse the categorical data. Baseline differences between cases with and without one-year primary outcome data were analysed using the same statistical tests. For the present follow-up study, the same statistical tests will be used to test for baseline differences between cases with and without five-year primary outcome data. The assessment of missing data will be done based on strategies for dealing with missing data in clinical trials (Dziura et al. 2013).

The data will be analysed in accordance with the intention-to-treat principle. Differences between groups will be assessed using linear mixed models for repeated measurements. We will use a subject-specific random intercept and maximum likelihood estimation with the respective outcome measurement at baseline (post-cardiac rehabilitation). Group (intervention and control), time and the interaction between group and time will be fixed effects as outlined by Twisk (2021). The underlying structure of the model estimates the outcome at each visit (post intervention and 5-year follow-up). We might include additional analysis to explore the change from baseline. P-values ≤ 0.05 will be considered as statistically significant and all tests will be two sided.

Dziura JD, Post LA, Zhao Q, et al. Strategies for dealing with missing data in clinical trials: from design to analysis. *The Yale journal of biology and medicine* 2013; 86: 343.

Twisk, J.W.R. (2021). Analysis of RCT Data with More Than One Follow-Up Measurement. In: Analysis of Data from Randomized Controlled Trials. Springer, Cham. https://doi.org/10.1007/978-3-030-81865-4_3