Document date 20161017

Statistical analysis plan for

Increased Adherence to Physical Activity on Prescription (FAR) through mindfulness - a randomized study in primary care (FAR-MIND)

Statistical Analysis Plan (SAP)

Power calculation

A sample size of a full-scale intervention study with a follow-up time of 12 months was calculated on a 1:1 relationship between two groups (PAP and combination) and estimated to $n = 375$ in each group, based on a power analysis with 5% significant-level and a power of 80%. Dropout was expected to be 30%. The calculation was based on other studies with self-reported compliance to PAP as an outcome measure, where 50% of the participants followed the recommendation on physical activity from the PAP. We estimated an increase from 50% to 62.5% of self-reported adherence to PAP. The pilot-study sample size is based on the assumed patient flow and due to a limited project budget. In this pilot study, we aimed to include approximately 30 participants in each arm, which is in concordance with a general flat rule, using a minimum of 30 participants to be able to estimate a parameter.

Randomisation

The randomisation of the three intervention groups (PAP, combination, mindfulness) was stratified by the patients' age and sex, with three age groups: 40–49, 50–59 and 60–65 years. The randomisation was done by a minimisation method with a random element; as minimisation variables in the randomisation, we used age and sex to get the groups as equal as possible. The randomisation was done in the statistical programme STATA version 15 (StataCorp, College Station, TX).

intervention outcome

All measurements and questionnaires were collected at baseline, after 3 months and after 6 months.

The primary intervention outcome was a change in the level of physical activity, self-reported and measured by ACTi Graph GT1X activity monitors. We used the same definitions and methods to handle the activity monitor data as in previously published research regarding physical activity [1, 2]. Activity monitor data were divided into sedentary, light physical activity (LIPA) and moderate to vigorous physical activity (MVPA). The participants were instructed to wear the activity monitor daily for a week before randomisation, at 3 months and at 6 months follow-up. Wear time was defined by subtracting non-wear time from 24 hours. Non-wear time was defined as at least 60 consecutive minutes with no movement (0 counts per minute), with allowance for a maximum of 2 min of counts between 0 and 100 [1, 3]. We considered ≥ 600 min wear time per day for at least 4 days to be valid compliance [1, 2]. Due to a small sample size, we did not demand four consecutive days with valid wear time, and we did not differ between weekdays and weekends. The average was expressed as total counts divided by wear time in minutes per day (counts per minute) and averaged over worn days. Registrations below 100 counts per minute were determined as being sedentary [1, 2, 4]. 100–2019 counts per minute were considered LIPA, and > 2020 counts per minute as MVPA [1, 2]. The results are presented as percentage sedentary, LIPA or MVPA per valid day and averaged over the number of valid days [2] self-reported daily activity (e.g. gardening, slow walks, biking) was measured by an eight-step scale (0 = 0 min/week, 7 ≥ 300 min/week), and self-reported leisure time activity (e.g. running, football) was measured by a seven-step scale (0 = 0 min/week, 6 ≥ 200 min/week).

Secondary intervention outcomes

Change in self-rated health (SRH) between baseline and follow-up, measured with a five-step scale (1–5): very poor, poor, fair, good or very good.

Change in blood pressure, weight or serum lipids between baseline and follow-up.

Change in insomnia problems as measured with insomnia severity index (ISI) [5] between baseline and follow-up.

Change in mindfulness was measured with five facets of the mindfulness questionnaire (FFMQ) [6] between baseline and follow-up.

Statistical methods

Group comparison analysis will be conducted using the chi-square test for categorical variables. Quantitative variables will be analyzed using ANOVA or Kruskal-Wallis for normally distributed and non-normally distributed variables, respectively. Relationships between different variables will be examined using regression analyses

The intervention effect on changes in outcome measures will be examined by analysing average group differences (PAP, combination, mindfulness) in baseline score and change in each outcome between baseline and 3- and 6-month follow-up using a linear mixed-effects model. Each model included the time variable and group as indicator variables and an interaction between time and group to estimate treatment differences in change over time, adjusted for baseline measures and considering the correlation between repeated measurements. We will not adjust for the minimisation variables from the randomization in the analysis. Statistical analyses were done using STATA version 15 (StataCorp, College Station, TX).

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