Analysis plan

The Diabetes Patient-Reported Outcome Measures Trial (DiaPROM)

NCT03471104

30 January 2019

Pilot trial data analysis

We will use Stata SE V.15 for Windows for all statistical analyses,49 and for data entry range checks for data values will be performed. We will report the recruitment of participants and the number of trial dropouts descriptively (frequencies and percentages). Further, we will report the means, SD and CI of the DDS and the other outcome measurements before and after the intervention period for both the intervention and control groups. As the study is a pilot and the sample size is small, we will not perform inferential statistics and analyse between-group calculations. The participants' PAID scores will be analysed descriptively (mean, SD), as well.

We will transcribe verbatim and analyse participants' and healthcare providers' experiences with the intervention by using thematic analysis. Thematic analysis is a flexible qualitative method without any specific theoretical foundation and consists of six steps: (1) transcribing, reading and rereading, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming the themes, and (6) producing the report.

Planned data analysis for the evaluation study

To assess both short- and long-term effects of the intervention, we will collect one pre-intervention measure and two post-intervention (after 1 and 2 years) measures for both the intervention and control group. All analyses will be on an intention-to-treat basis, and we will compare intervention and control groups for each follow-up time using linear mixed effects models with DDS as the primary outcome measure. All models will define intervention, time and intervention-by-time interaction as fixed effects (all categorical), whereas a random intercept will be specified to account for correlated observations of the same individual (an exchangeable correlation structure assumed). To obtain *p* values or 95% CI for difference in DDS means between the comparison groups at different time points, we will perform a post-hoc test for pairwise comparison accounting for multiple testing. To test whether the predicted DDS means change differently over time, we will use the likelihood ratio test by comparing the log-likelihood between models with and without the intervention-by-time interaction. In linear mixed effects models, all available DDS measures for an individual will be used for estimation even though certain measures may be missing on follow-up for that individual. The model will produce unbiased estimates provided the data are missing at random. As this is a block-randomized trial, we will assume that the comparison groups are similar in all aspects except the treatment.