Mobile Phone Support for Adults and Support Persons to Live Well with Diabetes

NCT04347291

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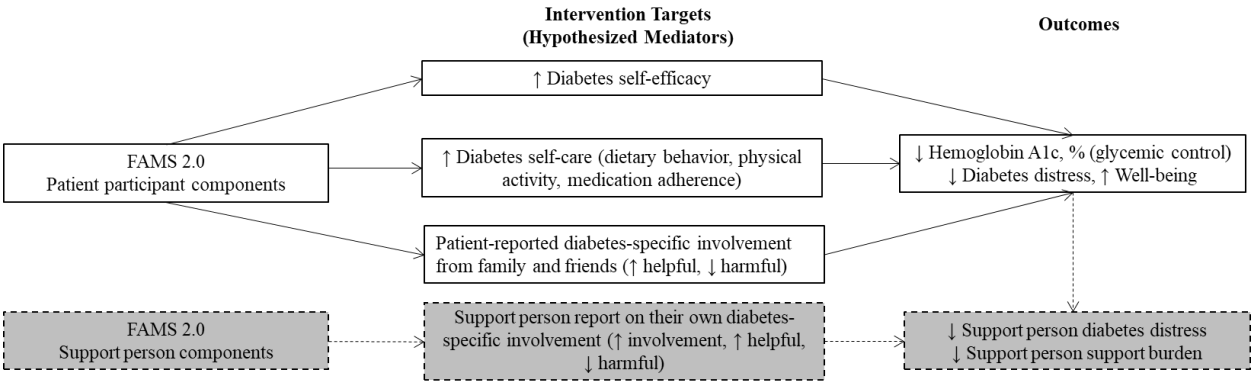
Statistical Analysis Plan for NCT04347291

Our conceptual framework is shown in **Figure 1**. Outcomes include patient participants' HbA1c (primary), diabetes distress and well-being (secondary). Our intervention targets include three hypothesized mediators for patient participants: improved diabetes self-efficacy, improved diabetes self-care behaviors (i.e., dietary behavior, physical activity, and medication adherence), and improved diabetes-specific involvement from family and friends (i.e., increased helpful involvement and reduced harmful involvement). Potential moderators of patient participants' effects are gender, minority race/ethnicity, socioeconomic disadvantage, and support person cohabitation.

Primary support person outcomes are support burden and diabetes distress. Our intervention targets/hypothesized mediators for support persons are self-report on diabetes-specific support provided to the patient participant (i.e., increased involvement, increased helpful involvement and reduced harmful involvement). Exploratory analyses test if improvements in support person outcomes are mediated by improvements in patient participant outcomes (i.e., HbA1c, diabetes distress, well-being). Support person gender and cohabitation are potential moderators of support person effects.

Figure 1. Conceptual Framework. FAMS 2.0, Family/friend Activation to Motivate Self-Care version 2.0 evaluated in this study.



Intention-to-treat principles will be used to analyze all available data with two primary models: repeated measures regression models (generalized estimating equations; GEE) to assess main effects and subgroup effects, and structural equation modeling (SEM) techniques to test mediation. To address missing data, we use multiple imputation via chained equations with a total of M=500 iterations. One imputation model includes baseline, 6- and 9-month data during the intervention and a second imputation model includes baseline and 12- and 15-month data for sustained effects.

To estimate FAMS' main effects and subgroup effects, we will use generalized estimating equations (GEE) with a working-independence correlation structure and identity link. Models will be adjusted for insulin use at baseline and baseline value of the outcome of interest (via a restricted cubic spline with three knots) for each model. We will allow a two-way interaction between time and condition and a two-way spline interaction between time and baseline value of the outcome. Differences between arms will be tested based on a linear combination of regression coefficients at each time point (based on Wald-based test with one degree of freedom). Point estimates and corresponding 95% confidence intervals will be obtained for each follow-up time point, to graphically display trajectories in adjusted mean outcomes difference over 15 months. We will explore subgroups effects (i.e., divided sample) to determine for whom the intervention was most or least effective using the same models as described above.

For each intervention target (**Figure 1**), we fit models as described above. Continuous measures were analyzed using the GEE model. The summative one-item physical activity measure was ordinal, and therefore analyzed using an ordinal regression model (odds ratios obtained on cumulative logit/proportional odds scale). Each model was run three times, to

estimate during (6-months), post (9-months) and sustained (15-months) intervention effects. For mediation analyses, we model between-subjects mediation with path analysis with an SEM framework as suggested in **Figure 1**, including multiple mediators. Mediation models include intervention targets at both 6 and 9 months as mediators and a single outcome (i.e., HbA1c, diabetes distress or well-being). We ran this model separately for each outcome at 9, 12 (H1cA1c only) and 15 months. For parsimony, we restricted the number of mediators guided by findings evaluating intervention effects on these mediators, opting for continuous and sensitive mediator measure(s) of self-care behaviors unless both measures were significantly improved by the intervention. We used Amos version 29 regression imputation function to address missing data, running each imputation separately for each model.

Path coefficients and indirect effects evaluate mediation using 2,000 bootstrap samples for bias-corrected estimates and 95% confidence intervals for effects. Paths from condition to mediators will determine if FAMS 2.0 improved each mediator relative to control, and indirect effects will identify mechanisms by which FAMS 2.0 affected outcomes. In addition to examining mediators of patient participants' outcomes, we examine dyadic mediation by assessing whether support person outcome changes are explained by change in their own involvement and/or by improvements in the patient participants' outcomes (e.g., mediator: change in patient participant HbA1c, outcome: change in support person well-being).