Exergame Study for Family Caregivers

NCT05032872

Study Protocol and Statistical Analysis Plan

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Study Protocol and Statistical Analysis Plan

The current study was approved by the Institutional Review Board at Brandeis University (#20104R). Informed consent was obtained from each participant before the study. Ethical considerations were taken into account at all times. The study had a data and safety monitoring plan in place, as well as a safety officer assigned to it. Any adverse event was documented and reported. The clinical trial was registered at the US National Institutes of Health (ClinicalTrials.gov) # NCT05032872.

Participants

Power analyses showed that 56 people were required for a power of .80 at $p<.05$, with a medium effect size (based on previous intervention studies (Robinson et al., 2019) for the analysis of changes in outcome measures from the pretest to the posttest. A total of 80 participants enrolled in the study. Recruitment took place from August 2021 to January 2022, with primary data collection completed in March 2022. Participants were recruited by outreaching to caregiver and older adult organizations, via social media sites, participant recruitment sites (e.g., caregiver forums, registry), and flyers posted in senior centers. Inclusion criteria included family caregivers who are providing care to a loved one (e.g., relative, spouse, friend) who is 65 years or older and is either frail, has a disability, or has confirmed diagnosis of at least one chronic illness (e.g., heart disease, diabetes, arthritis, kidney disease, stroke, ADRD, HIV-AIDS, etc.). Participants also must own an Android smartphone with Google play store/internet access, be familiar with smartphone app usage, able to walk for at least 20 minutes at a time and be comfortable with wearing a Fitbit and using the study-related app. Exclusion criteria included anyone who is currently participating in any other physical activity study/interventions, engages in vigorous exercises for more than 5 hours per week, knows anyone who participated or is currently participating in the study, had a recent cardiovascular event or fall in the past 6 months, or makes more than 2 errors on the Short

Portable Mental Status Questionnaire (Pfeiffer, 1975). Participants kept the Fitbit after completing the study and received $25 for completing all aspects of the study.

As shown in the consort diagram in Figure 1, a total of 567 potential participants were screened (either by completing an online screening form or by phone call), of which 417 did not meet our eligibility criteria. Of all eligible participants (N=150), 70 did not respond to messages we sent them to schedule a phone call and to receive their oral informed consent. A total of 80 participants gave their oral informed consent and were randomized into either the control condition (n=42) or the treatment condition (n=38). Of the 80 randomized participants, 76 participants completed the pretest and 72 participants started the intervention in one of the three cohorts (cohort 1: n=22, cohort 2: n=22, cohort 3: n=28) to make the social groups manageable, with an equal number of people in each condition for each cohort. Sensitivity analyses were conducted to ensure the baseline characteristics of the three cohorts did not differ from each other. A total of 66 participants (treatment: n=31, control: n=35) completed the posttest.

Study Design

The social exergame app, Go&Grow, could provide physical, social, and health benefits for family caregivers because of its simple interface for physical activity-related gamification (flowers can be selected and will grow based on the user's completion of daily step goals) and social contact features (users can post stories, share virtual gardens, and react to other users' stories). Participants could also follow workout tutorials implemented to Go&Grow from the National Institute of Health (NIH) Go4life (National Institute on Aging at NIH, 2020), and log and track their workouts on a daily and weekly basis (Figure 2). More details on the description of the full Go&Grow app can be found in the Lin et al., 2020 paper. Each day, the app sent notifications

to remind participants to use the app and asked participants to rate their daily mood using a mood slider.

The treatment group (social exergame condition) used the full version of Go&Grow with the social contact features, which allowed users to view, like, reply to, post a story, and view other users' gardens. They also received in-game rewards (unlock new flowers to grow each week) if they posted stories. The control group (exergame non-social condition) used Go&Grow without the social contact features; therefore, they were not able to unlock new flowers (Figure 2).

Procedure

The current study was a two-armed randomized control trial with a pretest (baseline week 1 and 2), weekly assessments at the end of each week (week 1 to 8), and a posttest (after week 8). All participants were blinded to their conditions. Both groups received the same frequency of contact from researchers and followed the same procedures throughout the study period.

All contact and data collection were done remotely. Participants who were interested in joining the study were instructed to fill out an online screening form which included the screening items for inclusion and exclusion criteria. If participants were eligible based on the screening, a research assistant reached out to the participant within three days to obtain informed consent. Participants received a copy of the informed consent through email during the informed consent process. Research assistants went over the informed consent with participants over the phone and participants provided consent orally. Once participants agreed to take part in the study, research assistants sent participants a link to complete the demographic survey (including covariates) and the pretest. Upon completion of the demographic survey and the pretest, participants were shipped a Fitbit Inspire 2 tracker, instruction materials, a face mask, and a stylus pen to their home postal address.

Session 1 (Pretest). A research assistant trained the participants in both conditions to use the Fitbit by phone and with an instructional manual, an approach that has been effective in previous studies (Bisson et al., 2021; Robinson et al., 2019).

Week 1-2 (2-Week Baseline). Participants in both conditions would wear the Fitbit for two weeks to obtain baseline steps. Both conditions also completed a weekly survey for weeks 1 and 2. Each measure collected during this period was averaged to create a baseline score.

Week 3 – 8 (6-Week Intervention Period). On the first day of week 3, research assistants trained participants on how to use Go&Grow with the instructional guide and phone consultation for both conditions. After the training, participants in both conditions started using the app while continuing to wear the Fitbit for 6 weeks. They were reminded daily with app-based notifications to wear their Fitbit and use the Go&Grow app. The reminder for the treatment condition also included the message: “Don’t forget to share your stories to unlock new flowers”. Participants continued completing weekly surveys for 6 weeks.

After week 8 (Posttest). All participants completed a posttest, which was the same as the pretest.

Measures

The current study consisted of measures from the pretest, weekly assessments at the end of each week (week 1 to 8), and a posttest (after week 8). The same measures were used for both conditions. All questionnaires were administered through Qualtrics links sent to each participant via the Eztexting platform or through email. Participants' electronic data (steps and app usage data) were collected using a secure server from Brandeis University, and the data were kept confidential.

Data Analyses

First, we examined all baseline characteristics between both conditions and all three cohorts. To test the research questions, multilevel models (MLM) and the R package lme4 were utilized. Analyses were conducted for the full sample with intent to treat for everyone who completed the pretest (N=76), as missing data in outcome variables could be handled through multilevel analysis. Sensitivity analyses were also conducted for those who had completed both the pretest and posttest, and those results are shown in the tables in the supplementary. Changes in well-being (loneliness, stress, affect, each subscale of caregiver's stress), physical activity (percent change in the number of steps from baseline to the intervention, MCID, minutes active, and each subscale for the self-reported physical activity), and social support (overall social support and each subscale of social connectedness scale), were examined with a 2 (condition) by 2 (time) analysis examining whether the treatment and control conditions differed in the amount and direction of change from the pretest to the posttest controlling for the covariates. We also explored whether there was a condition by time interaction in secondary outcomes for exercise self-efficacy, life satisfaction, and sense of control. In order to conduct more sensitive analyses, we also did planned comparisons because of our apriori predictions. Furthermore, multilevel models were tested to examine whether usage of the social features of the app for the treatment group predicted changes in physical activity. Using the PROCESS Macro model in SPSS (Hayes, 2013), mediation models were tested for mechanisms of change for whether increased social support and physical activity in turn led to better well-being. Covariates including app use were included in all mediation models.