

**Study Title:** Efficacy Study of Kinto Care Coaching for Dementia Family Caregivers

**NCT number:** [NCT05916664](https://clinicaltrials.gov/ct2/show/NCT05916664)

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## **STUDY PROTOCOL**

### **STUDY RATIONALE**

Caring for individuals living with dementia presents unique challenges for caregivers, including changing roles and responsibilities, financial concerns and planning, increased emotional and health strains, and decreased well-being. Research has found significant benefits from caregivers who participate in evidence-based programs. However, many of these programs are not scalable nor sustainable outside of a research context. To date, few studies have leveraged technology to address this issue for engaging and intervening with informal family and friend caregivers.

### **DESCRIPTION OF THE *KINTO CARE COACHING INTERVENTION* PROGRAM**

*Kinto Care Coaching Intervention* is an innovative program that uses technology via a mobile app to address the needs of informal caregivers of persons living with dementia. Program components include: 1) an initial assessment of care needs; 2) an initial one-on-one virtual care coaching meeting that develops an Action Plan that includes both financial and caregiver support goals; 3) interactive and on-going support and educational resources through the mobile app; 4) access to support groups; and 5) on-going chat groups, with both their care coach and support group peers.

### **CONCEPTUAL MODEL AND STUDY HYPOTHESES**

The Stress Process Model (SPM) for Caregivers was the conceptual model used for the study premise and for selecting measures and study hypotheses. The SPM has been widely used in research on stress and coping for caregivers. The domains of the SPM include: 1) Background and Care Context, 2) Objective and Subjective Stressors, 3) Coping and Social Support Resources, 4) Secondary Stressors: Role and Intra-Psychic Strain, and 5) Psychosocial Well-Being Outcomes. Prior studies extend the SPM's category of "coping and social support" to include interventions. For the current study, the *Kinto Care Coaching Intervention* was conceptualized as such in improving outcomes for caregivers. The SPM guided study hypotheses that included hypothesized significant improvements for participants in the intervention condition as compared to participants in the waitlist control condition for the following secondary stressors and psychosocial well-being outcomes : Unmet Needs; Unmet Needs Distress; Financial Self-Efficacy; Dyadic Relationship Strain and Role Captivity; Emotional Health Strain; Caregiver Mastery; Personal Gain; Loneliness; Caregiver Burden; Anxiety Symptoms; and Depressive Symptoms. Exploratory hypotheses also were examined and included measures of Instrumental Activities of Daily Living (IADL)/Personal Activities of Daily Living (PADL) Difficulty; IADL/PADL Distress; Cognitive Difficulty; Cognitive Distress; Behavioral Frequency; and Behavioral Distress.

### **DESIGN AND PROCEDURES**

A randomized controlled trial research design was used to examine the efficacy of the *Kinto Care Coaching Intervention*. After consenting to participate in the study, caregivers completed the baseline/Time 1 survey and were then randomly assigned to the intervention condition or the waitlist control condition. Participants in the intervention condition received the *Kinto Care Coaching Intervention* that used technology via a mobile app to implement the 6-week structured protocol that consisted of the following: 1) initial assessment of care needs; 2) an initial one-on-one virtual care coaching meeting that developed an Action Plan that included both financial and caregiver support goals; 3) interactive and on-going support and educational resources through the mobile app; 4) access

to support groups; and 5) on-going chat groups, with both their care coach and support group peers. Participants randomly assigned to the waitlist control condition were eligible to receive a modified version of the intervention after completion of the study.

To examine intervention efficacy, outcomes were assessed across time that included both short-term and long-term impacts. In total, participants completed 3 surveys: Time 1 (Baseline); Time 2 (after program completion); and Time 3 (45 days after Time 2). All evaluation surveys were completed via Survey Monkey. Once participants completed all 3 of the evaluation surveys, they received a \$120.00 gift certificate as compensation for their time.

## **II. Statistical Analyses Plan**

### **Preliminary Data Analyses:**

Data were cleaned including examining missing data and addressing any out-of-range values. All Time 1 measures were tested for reliability using Cronbach's alpha, with alphas equal to or greater than .70 demonstrating good reliability. Independent t-tests, one-way ANOVAs, and chi square tests were conducted to ensure random assignment resulted in equivalent groups between the intervention and waitlist control conditions on select demographic and caregiving characteristics and to identify covariates to include in subsequent analyses. With respect to attrition analyses, independent t-tests, one-way ANOVAs, and chi-square tests were used to examine if there were any significant differences on select demographic and caregiving characteristics and the Time 1 scale scores for each outcome between participants who completed the study protocol and those who did not.

### **Primary Analyses:**

To examine intervention efficacy, outcomes were assessed across time that included both short-term and long-term impacts. Separate 2 (condition: intervention, waitlist control) x 3 (time: Time 1, Time 2, Time 3) repeated measures general linear models were used to examine mean group differences across time between the intervention and waitlist control groups for each outcome measure. The repeated measures analyses indicated whether there was any significant change across time for each outcome measure based on whether participants received the intervention or had not received the intervention. Employment status was included as a covariate in all analyses to control for the significant difference found at baseline between the two conditions. For significant outcomes that did not meet the Sphericity assumption, the Greenhouse-Geisser correction was used and reported for degrees of freedom. For outcome measures that were found to be significant, additional post-hoc pairwise comparison with a Bonferroni correction were conducted to examine where the change occurred across the different data collection periods (i.e., Time 2, Time 3).