FamTechCare Clinical Trial

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NCT02483520

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)

Protocol & Statistical Plan
Last IRB Approval Date: July 7, 2016

B. APPROACH. The proposed study combines randomized clinical trial (Aim 1) and descriptive (Aim 2) designs with cost efficiency analysis (Aim 3) to evaluate the multi-component FamTechCare intervention. FamTechCare uses new technology for caregiver initiated recording of PWD behavior that also captures video of precursors to behaviors and precipitating factors. Videos are automatically uploaded to HIPAA-secure storage for review by a team of dementia care experts who analyze the rich data and provide individualized just-in-time, interventions. An overview of the aims is provided first and details follow in sections below.

Aim 1. A randomized clinical trial with repeated measures will be used to test effects on PWD and caregiver outcomes. Dyads will be randomly assigned to an intervention or an attention control group at each site. Linear mixed modeling with post-hoc comparisons will be used to compare between-group and within-subject outcomes at 1 and 3 months to determine intervention effects on objective PWD and caregiver-reported outcomes. Behavior coding using our established protocols will provide objective measurement of disruptive behaviors (Williams et al., 2009). Behavior coding of post-intervention recordings will also be used to measure caregiver intervention use and effects on behaviors. Caregiver-reported stress, burden, depression, sleep, and confidence in providing care will also be compared. Linear mixed modeling provides examination of each variable to determine its effect size over time and also to determine which outcomes are most sensitive to the intervention.

The randomized repeated-measures design addresses threats to both internal and external validity and is strengthened by multiple replications (Shaddish, Cook, & Campbell, 2002). Caregivers will report treatments (i.e. medications) added during the 3 months to identify any potential influences. The Data Safety Monitoring panel will discuss new treatment developments and their impacts annually. Supervised training and monitoring protocols will assure fidelity. Measurement fidelity will be maintained by using measures with established reliability and validity and by research team training and monitoring. Research assistants (RAs) who code data will be blind to group assignment and video collection time to avoid expectation bias (Polit & Beck, 2007).

Aim 2. An exploratory descriptive design will identify PWD behaviors and precipitants captured in video that each caregiver identifies as their top priority. Content analysis and behavioral coding of videos will identify common behaviors (within the NDDCB framework), links to precipitants, and effective recommendations as a basis for a typology of caregiver interventions for in-home use (Dawson, et al., 1990). Actual caregiver use of interventions will be coded and audio recordings of team conferences will be transcribed and coded. Content analysis of this data will add information about characteristics predicting caregiver use of recommendations.

Aim 3. Caregiver satisfaction with effectiveness and ease of use will be evaluated and select caregivers will be interviewed and observed using FamTechCare. Video review team experts will rate the likelihood of diffusion into practice with a modified Duke Diffusion of Innovation in Long Term Care Battery (McConnell et al., 2010). Costs will be tabulated using traditional methods and compared to outcomes (PWD disruptive behavior and caregiver burden and NH placement intention), using traditional and Data-Envelopment Cost Analyses (DEA).

D1. Sample. Eighty-eight dyads will be recruited from the University of Iowa Hospitals and Clinics (UIHC) and the University of Kansas Alzheimer's Disease Center (KU ADC). KU ADC is the area's major referral center with a clinic evaluating more than 300 new and 600 total patients annually. UIHC is the state and regional leader in tertiary care, providing research and clinical specialty care in Geriatric Psychiatry and Memory Disorders. It is estimated that 50% of family caregivers request professional assistance for managing disruptive behavior; so adequate study recruitment and enrollment is anticipated. If enrollment is not adequate, other dementia care providers (i.e. Alzheimer's Association) will be contacted.

Inclusion criteria for PWD are a diagnosis of AD or other dementia (moderate stage) and residing with a family caregiver who reports disruptive behavior management issues. Exclusion criteria include Huntington's disease, alcohol-related dementia, schizophrenia, manic-depressive disorder, deafness, and mental retardation. Participants with dementia of varied etiology will be included (a covariate factor). Electronic medical record search tools and dedicated research team time will facilitate identification of eligible participants. A trained research assistant (RA) will perform a Functional Assessment Staging of Dementia to confirm moderate dementia (Sclan & Reisberg, 1992) and the each caregiver will complete the Revised Memory and Problem Behavior Checklist (Roth et al., 2003) to verify the presence of disruptive behaviors on the initial home visit.

D2. Power. Sample size for this study was determined using power analysis for the primary hypothesis. The proposed sample size will provide sufficient power to detect between-group differences in outcomes (changes in proportions of behaviorally coded disruptive behaviors of PWD). In our previous research (Williams et al., 2009), the probability of PWD disruptive behaviors decreased from 55% to 26% when nurses used normal talk with PWD instead of elderspeak (patronizing communication similar to babytalk). We anticipate a similar 29% average decrease in the proportion of disruptive behaviors after the FamTechCare intervention. Applying this effect size as the difference between groups with a standard deviation of 35% in both and assigning a Type 1 error of 0.05 results in 93% power for detecting group differences after 3 months in 70 dyads (35 per group).

We also estimate power for detecting between group differences in caregiver-reported burden and other outcomes (stress, sleep, depression, confidence in providing care and psychoactive drug use) at 1 and 3 months (adequate time to address multiple behaviors) using established standards for large (average .81) effect sizes across studies testing psycho-educational interventions like FamTechCare (Gallagher-Thompson & Coon, 2007). We assign a Type I error of 0.05 and assume a similar effect size (estimated between group differences). With average overall effect sizes of 0.81, there is 92% power for detecting differences in 70 dyads. Thus the study is adequately powered to detect outcome differences for PWD and their caregivers.

D3. Enrollment. We will enroll 88 dyads (44 dyads each in Intervention and Control) to compensate for 20% attrition over the 3-month study period, as seen in previous studies. We will enroll 8 subjects in each 3 to 4 month period, 4 at each site. This will be repeated in eleven cohorts (months 4 to 44) using staggered enrollment as part of a feasible implementation plan that rotates HMU units thus reducing equipment and personnel costs, while controlling for effects of history (see D10). Projected enrollment of 88 allows for up to 20% attrition providing a final N of 70 (35 per group) as required per our power analysis. Focus groups conducted during the feasibility study identified strategies to bolster enrollment in this study (dedicated provider recruitment time, multiple sites, and emphasis on ease of use and caregiver control of recordings [privacy]).

D4. Intervention. The multi component intervention includes 1) caregiver recording of symptoms and behaviors, 2) expert team review of recordings transferred via the Internet, and 3) feedback provided to caregivers at home. A HMU (iPod Touch or iPad Mini device) with Behavior Capture software and remote control will be placed in each home for 3 months. Limiting FamTechCare to 3 months is a limitation of this study as PWD develop new symptoms and behaviors as the disease progresses. However, in the feasibility study 3 months was adequate for caregivers to plateau in managing current disruptive behaviors. In practice, using the FamTechCare intervention at intervals as new behaviors develop and change over time may be more realistic.

Recording. Behavior Capture (see appendix E) was developed by Behavior Imaging with NIH SBIR support for monitoring children with autism. **Behavior Capture** uses a "go-back-in time" buffering technology to record when triggered, also capturing video up to 15 to 30 minutes prior to the trigger (we will use a 10 minute "go back" as was effective in our feasibility study). Including antecedents enables effective behavior assessment. **Behavior Connect** provides automatic Internet transfer of video recordings to HIPAA-secure storage.

Feasibility of using this new technology for the FamTechCare intervention was established with 5 caregiver-PWD dyads in our CTSA feasibility study (Williams et al., 2012). We will use and adapt as needed the IRB-approved protocols and procedures, protocols for encrypted HMU units and software configuration using Site Kiosk (a program that limits computer use to research-specific programs), contracts to assure HIPAA protections of video data, and training materials developed by our CTSA study team. Computers will be configured to run the high definition, wide-angle webcam and remote control with preset settings, eliminating the need for caregivers to login with names and password (avoiding added burden). HMU computers run

continuously, ready for caregivers to record when they want feedback by simply pressing a button on the remote control (that fits in a pocket or is worn around the neck). A 5-foot webcam extension cord extends the recording area and the laptop itself is portable and easy for caregivers to move. Although no password is required for the caregivers to start recording, each HMU will connect to a separate account for discreet storage requiring a logon password to limit access and protect confidentiality of the data.

Both groups will record behaviors during daily care for 3 months using a HMU. FamTechCare group videos will be immediately uploaded via the Internet to a HIPAA-secure site for expert team review and feedback in behavior management. The time and attention equivalent control group will receive only a weekly phone call from a nurse, but recorded videos will be held for review and feedback at 3 months. This encourages participation (all participants will benefit from expert video review and feedback during their study involvement).

FamTechCare Intervention. The telehealth nurse will review videos submitted by caregivers within 24 hours to facilitate emergency referrals (delirium, for example). FamTechCare caregivers will receive same-day nurse feedback (using standardized interventions) based on evidence-based protocols (see appendix C) developed by team experts and in the feasibility study (Niedens, 2010; Williams et al., 2012). Individualized, contextually-based interventions developed by the expert team (see examples in appendix D) will be provided to caregivers in their home at least weekly (after each video review meeting).

The telehealth nurse will review and select videos, leading the interdisciplinary team meetings for video review and intervention planning and will interact weekly with caregivers to provide feedback. The internet-based team meetings will be conducted using Zoom HIPPA-secure teleconferencing that supports live, interactive videoconferencing from different locations. Zoom teleconferencing is accessed using a unique weblink to a secure meeting. Using a share screen feature, all group members can watch the videos and simultaneously discuss and develop interventions.

Interventions will be documented on a behavioral care plan form modeled after other studies, providing individualized intervention instructions for a specific disruptive behavior (Burgio et al., 2009). Interventions will initially focus on nonpharmacological interventions. For example, pain interventions may first focus on assisting PWD to report pain, identify person-specific indicators of pain for caregivers to monitor, and teach pain control measures such as relaxation, distraction, and massage to the family caregiver. Our interdisciplinary team includes clinicians and investigators from KUMC and UIHC in partnership with a social worker from the Alzheimer's Association, and home-care nurses. Additional experts, such as a pain management nurse and speech and occupational therapists are available as needed to review videos.

Control Intervention. The control intervention is designed to be equivalent to FamTechCare for time and attention. Control group videos will be held for review and feedback after 3 months. Control caregivers will receive a weekly phone call from the nurse, who will provide standardized disruptive behavior management guidelines per protocol (see appendix C) (Niedens, 2010).

D5. Procedures. Each site will identify potential participants and obtain consent. As soon as 4 participants are enrolled at each site, 2 will be randomly assigned to FamTechCare and the other 2 to the Control group. This is repeated until 11 cohorts are completed. A trained research assistant (RA) will make a home visit to collect demographic data and to complete FAST staging (Sclan & Reisberg, 1992) to confirm that the PWD has moderate stage dementia. Each caregiver will complete the Revised Memory and Problem Behavior Checklist (RMPBC) to verify the presence of disruptive behaviors. The RA will assist caregivers in identifying their 3 most problematic disruptive behaviors/care situations (see D7a) as the focus for recordings and interventions and the HMU will be set up in the area where the most disturbing disruptive behaviors usually occur (as the focus for the first week). The RA will train caregivers in HMU use and provide reference books. Visits will continue until caregivers demonstrate proficiency in recording and moving the HMU using a competency checklist. If the needed, the RA will make a home visit to assist the caregiver in moving the HMU in subsequent weeks.

Caregivers will be asked to record at least one video of their identified priority disruptive behavior/care activity each day. The telehealth nurse will monitor submitted videos and prompt caregivers with reminders if needed.

Caregivers will repeat recordings of each priority disruptive behavior/care activity after using FamTechCare interventions and at 1 and 3 months. Home visits to repeat data collection will be made at 1 and 3 months in both groups.

D6. Descriptive Data. Information about caregivers and PWD that may influence study outcomes will be collected and included as covariate factors (Unruh & Wan, 2004; Yu, Evans, & Sullivan-Marax, 2005; Zimmerman et al., 2005). PWD data will include gender and dementia etiology. Data on caregiver age, competency, relationship to the PWD, and research site will also be collected for covariate analysis.

D7. Measures. The RA will administer survey assessments to caregivers at home. Measures take less than 1 hour total to complete, limiting participant burden. Research assistants **(**RAs) will be trained to administer the assessments with practice and feedback sessions supervised by the PI at each site. A written protocol and a key component checklist will assure fidelity for data collection. As in our past research, 10% of assessment sessions will be audio recorded and content analyzed to establish compliance with data collection protocols.

Measures addressing study aims and hypotheses are outlined in Table 1 and detailed in the text. All measures are reliable and valid for use in dementia care research. Our established content analysis and behavioral coding protocols adapted from our prior research (Herman & Williams, 2009; Williams et al., 2011; Williams et al., 2009; Williams et al., 2005) will be used for data analyses.

TABLE 1. Specific Aims, Outcomes, and Measures

SPECIFIC AIM	Outcome	Measure (number of items and estimated time) & Analysis Plan
1. Determine effects of FamTechCare on PWD & CAREGIVER outcomes at 1 and 3 months.	**PWD** **Disruptive behavior** **Stress** **Medication use** **CAREGIVER** **Burden** **Stress** **Depression** **Sleep disturbance** **Medication use** **Confidence**	**Compare between-group changes at 1- and 3-month:** **Proportions of behaviorally coded disruptive behavior in videos** **Revised Memory Problem Behavior Scores (31 items/15 min.)** **EDA data (Ashametrics)** **Elective psychoactive medication use (5 minutes).** **Compare between-group changes in 1- and 3-month scores on:** **Modified Zarit Burden Scale (12-items/5 min.)** **EDA data (Ashametrics)** **CES-D Scale (15 items/5min.)** **Pittsburg Sleep Quality Index (9 items/5 minutes)** **Caregiver reported psychoactive medication use (5 minutes)** **3 confidence questions (see D7a) (10 min.)**
2. Identify precursors of disruptive behaviors and develop a typology of interventions for caregiver in-home use.	**Describe behaviors and precipitants** **Identify interventions and Evaluate effects**	**Content analysis and behavior coding of caregiver submitted videos and recorded video review team meetings.** **Content analysis of written intervention care plans.** **Behavioral coding and comparison of proportions of disruptive behavior in pre- and post-intervention videos.**
3. Evaluate ease of use, satisfaction, and cost effectiveness using traditional cost methods and Data Envelopment Cost-efficiency Analysis.	**Ease of use** **Satisfaction** **Costs** **Disruptive behavior** **Caregiver Burden** **NH placement**	**Caregivers – Satisfaction with Home Monitoring questionnaire, Interview & Observe 5 caregivers use of FamTechCare & HMUs.** **Professionals – Modified Diffusion of Innovation questionnaire.** **Study records (traditional cost methods).** **Compare group disruptive behaviors (behavioral coding).** **Compare group Zarit Burden Scale scores.** **Compare Desire to Institutionalize Scores (6 items/3 min.).**

D7a. AIM 1: Determine effects of FamTechCare on PWD and caregiver outcomes at 1 and 3 months. Video recordings will be behaviorally coded. Changes in the proportion of PWD disruptive behaviors and stress will be compared between groups to assess FamTechCare effects. Changes in caregiver-reported measures (burden, stress, depression, sleep, confidence, elective psychoactive medication use, and reported PWD disruptive behaviors) will be compared between groups to assess effects at 1 and 3 months.

PWD Disruptive Behaviors. We will compare post-intervention between-group differences in changes in the proportions of PWD disruptive behaviors objectively coded from video recordings and reported by caregivers**.**

Behaviorally Coding of Disruptive Behaviors will be completed using our behavioral coding protocols from our NIH-funded R03 and R01 studies (Herman & Williams, 2009; Williams et al., 2009). We will use the Noldus Observer Video Pro (2003) software program to code disruptive behaviors, based on the operational definitions in the Resistiveness to Care scale (Mahoney et al., 1991). A computer key corresponding to each behavior state (disruptive or cooperative) is depressed when behaviors occur in the real time video recordings. Duration of each behavior state (disruptive or cooperative) is tabulated by the length of time keys remain depressed (until the key corresponding to the alternate, mutually exclusive behavior state is pressed). RAs will be trained using our protocol operational definitions for disruptive behaviors on practice materials until inter-coder agreement reaches 90% or greater. As in our prior studies, we will assess inter-coder agreement on 10% of actual study data. Retraining of coders will be provided if reliability falls below targets. RAs coding video will be blind to group and time of collection. Three recordings of videos of each priority care activity submitted at baseline, 1, and 3 months will be analyzed. The proportion of time disruptive behaviors occur will be compared within individuals and changes in the proportion of disruptive behavior compared between groups.

Caregiver-report Disruptive Behaviors. The 31-item Revised Memory and Problem Behavior Checklist (RMPB). (Roth et al., 2003; L. Teri et al., 1992) elicits caregiver reports of the behavior frequency related to 24 memory, depression, and disruptive behaviors in the past week, with Cronbach's alpha of .785.

PWD Stress. We hypothesize that FamTechCare interventions will reduce disruptive behaviors as well as stress in PWD.

PWD Medication Use. Counts of caregiver reported elective (prn) use of anxiolytics, hypnotics, and antipsychotic drugs taken by PWD in the past week will be compared between groups at 1 and 3 months.

Caregiver Burden. The Modified Zarit Burden Inventory, a 12-item assessment, will be used to measure caregiver burden (Bedard et al., 2001; Burgio, et al., 2009). Caregivers will rate emotional and physical strain on the 5-point Likert scale with possible total scores ranging from 0 (never) to 44 (nearly always). Cronbach's alpha was established at 0.85 in the Resources for Enhancing Alzheimer's Caregiver Health (REACH) study (Burgio, et al., 2009). In addition, the Revised Memory and Problem Behavior Checklist (RMPBC), will be collected as a caregiver report measure of PWD behaviors that also elicits caregiver reports of how bothered the caregiver is due to disruptive behaviors in the past week (Roth, et al., 2003; Teri et al., 1992).

Caregiver Depression. The 15-item **Center for Epidemiological Studies Depression Scale** (CES-D) that queries depressive symptoms over the past 2 weeks will assess caregiver mental health (Radloff, 1977).

Caregiver Sleep Disruption. The Pittsburgh Sleep Quality Index (PSQI), a comparative subjective measure of sleep quality designed and validated as reliable for use in older adults (the majority of caregivers in our sample) will be used (Cronbach's alpha = 0.83). The PSQI differentiates poor from good sleep quality by measuring seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction (Buysse et al., 1989).

Caregiver Confidence. An adapted 3-question measure of caregiver confidence (Teri et al., 2005) will be collected on the initial home visit. The RA will assist caregivers in first identifying the three most disruptive and disturbing PWD behaviors to focus on in the study. Caregivers will 1) estimate the frequency of occurrence of each behavior in the past week (using a 0-4 Likert scale ranging from "none" to "daily or more often"). Caregivers will 2) rate how severe/bothersome the problem was ("trivial" to "severe") and also 3) report their level of confidence in managing each situation ("unable to manage" to "very confident").

Caregiver Psychoactive Medication Use. Counts of caregiver reported elective (prn) use of anxiolytics, hypnotics, and antipsychotic drugs in the past week will be compared between groups at 1 and 3 months.

D7b. SPECIFIC AIM 2: Identify precursors of disruptive behaviors and develop a typology of interventions for caregiver in-home use. Recordings of team video review meetings will be transcribed and coded using qualitative content analysis to determine the most commonly occurring behaviors, precipitants, and recommended interventions within the NDDCB model framework. Interventions for each caregiver's three priority disruptive behaviors will be analyzed for effectiveness using our behavioral coding techniques (Williams et al., 2009). Patterns of disruptive behaviors in relation to antecedents and the caregiving context (i.e. lack of attention, interruption, overstimulation) will be coded using Noldus computer software based on Delgado's functional analysis system (2006). RAs (blinded to group and time of data collection) will code recordings for caregiver intervention use and disruptive target behaviors in PWD. Baseline and post-intervention data will be compared to determine the most utilized and effective interventions. Descriptive information (D6) about the dyad will be examined in relation to use of recommended interventions.

D7c. SPECIFIC AIM 3. Evaluate ease of use, satisfaction, and cost effectiveness of FamTechCare using traditional cost methods and Data Envelopment Cost-efficiency Analysis.

Ease of Use and Satisfaction. The Caregiver Satisfaction with Home Monitoring Survey (see appendix A) is a 12-item Likert checklist scale that ascertains ease of use and perceived satisfaction with the intervention. It will be completed at the end of the caregiver's study involvement. Descriptive results will be reported. In addition, our human factor expert will interview and observe five caregivers regarding FamTechCare HMU use.

Assessment of Diffusion of Innovation. The **Duke Diffusion of Innovation in Long-Term Care Battery** (Cain & Mittman, 2002; Kovach et al., 2008; McConnell et al., 2012; 2010) was adapted to assess critical factors determining likelihood of dissemination of the FamTechCare intervention into practice (see appendix B). The scale assesses perceptions of complexity, ease of use, compatibility with work practices, and observation. The dementia expert video reviewers will complete this questionnaire at the end of the study.

Cost Analyses. We anticipate that some or all intervention costs will be offset by savings for caregiver travel to frequent appointments and for professionals such as reduced health care provider time. We posit that these savings represent only part of the benefits, as reduced caregiver stress may improve caregiver health and reduce health care costs, improve quality of life, and reduce NH admissions. We will not measure these long term outcomes in this study, but we plan to build on this study's cost outcomes in future research. In this study, we will focus on accurately costing the intervention and on computing a simple cost-effectiveness ratio: the added cost for FamTechCare divided by the reduction in objective PWD disruptive behaviors and caregiver burden and desire for NH placement. We will use Cost-effectiveness Analysis (CEA) and Data Envelopment Analysis (DEA) to analyze this type of cost efficiency. CEA allows investigation of the cost of a single outcome; with DEA we investigate efficiency using multiple cost variables and outcomes (Hollingsworth, 2008).

Process-Based Costing of the Intervention. Following Lee et al.(2003), data will be collected to determine costs of the FamTechCare intervention. Specifically, we will identify resources used by caregivers and professionals in the intervention. Primary resource use will include costs for HMU equipment and professional

time spent in home visits, review of video data and care-planning, and providing specific feedback and caregiver instruction for managing behaviors. Other resources measured will include mileage, materials, equipment, phone, internet, and video conferencing. We will tabulate all resources used and calculate the cost of the FamTechCare intervention. We will separately report resource use and resource costs per HMU unit.

Cost Effectiveness Analysis We will focus on collecting accurate cost data for delivering FamTechCare, analyzing the effects of the intervention on costs, and calculating a simple cost-effectiveness ratio. We will use DEA to analyze the net effect of the intervention on costs (Hollingsworth, 2008). This approach tests the hypothesis that the cost of FamTechCare will be offset by reductions in PWD disruptive behavior and caregiver burden. We will calculate a simple cost-effectiveness ratio: the incremental cost of FamTechCare divided by reductions in caregiver desire for NH placement, using the 6-item Desire to Institutionalize Scale (Morycz, 1985) with reported reliability of 0.69 (McCaskill et al., 2010).

D8. Data Management. De-identified descriptive data will be labeled with each participant's unique identifier code and promptly transferred to data files in the REDCap platform. REDCap is managed by the Institute for Clinical and Translational Science, the University of Iowa's CTSA. In REDCap, primary data and data backups are secured in two separate data centers. Operating system security includes secure logins, remote system logging and configuration, and change management. Data encryption occurs both in flight and at rest and copies of data are replicated to the remote data center every 15 minutes to facilitate data recovery. Data will be entered in separate electronic spreadsheets using only identifier codes to assure confidentiality and anonymity (see Human Subjects). Only the research team will have access to the key for participant identification codes.

D9. Data Analyses.
Randomization. Dr. Perkhounkova will develop the randomization scheme using a 1:1 allocation ratio. For each site, random numbers will be generated to determine a sequence of dyad assignment to either control or treatment. To ensure equal numbers in each group, a blocking strategy will be used with blocks of 4 dyads.

Preliminary Analyses. Initial data analysis will involve calculating descriptive statistics for all variables, at all data collection points, including means and standard deviations for continuous variables and frequencies and proportions for categorical variables. Outliers will be investigated for accuracy and possible entry errors. Graphical representation of the data and correlations among variables will be examined. The distributions of continuous variables will be evaluated for normality and homogeneity of variance and appropriate transformations will be applied as needed, or statistical analyses for non-normal data will be utilized. Patterns and site effects of missing data will be examined. A significance level of .05 will be used for statistical tests, except where p-values need to be adjusted to account for the number of tests performed.

Specific Aim 1. Determine the effects of FamTechCare on PWD and CAREGIVER outcomes at 1 and 3 months. Treatment and control groups will be compared at baseline, using appropriate tests (i.e., t, Mann–Whitney U, or Chi-square tests) to identify potential covariates found to influence NDDCB in theory and research, such as dyad relationship type (spouse, child), gender combination (male-male etc.), dementia type (etiology screen), and caregiver age (Cohen-Mansfield et al., 2005; Forbes-Thompson et al., 2006; Kovach et al., 2005; Scott et al., 2005). The outcome variables for this aim will be PWD disruptive behaviors, stress, and psychoactive medication use and caregivers' stress, burden, depression, sleep, and confidence.

A linear mixed model approach for repeated measures will be used to test differences in mean changes in the outcome variables between the treatment and control groups. By using the mixed models approach, we will be able to account for the correlation of outcome measures for the same subject across time points with the selection of an appropriate covariance structure. This analysis can handle incompletely observed subjects by using likelihood estimation methods, and provides valid estimates and tests under the assumption that the data are missing at random (Brown & Prescott, 2006).

The fixed effects in the model will include group (FamTechCare or control), site (UIHC or KU ADC), data collection time (baseline, 1, or 3 months), and all two-factor and three-factor interactions, including treatment by time interaction. A significant treatment by time interaction effect will indicate differences between the two groups. The analysis will be adjusted for important covariates, identified with baseline comparisons. With 70

subjects, 7 covariate factors meet statistical requirements for 5 to 10 subjects per covariate (Tabachnik & Fidell, 2001).

Fit of the models will be assessed using appropriate fit statistics, including Akaike information criterion (AIC) and likelihood ratio tests. To test for specific comparisons of interest, i.e. comparing treatment and control groups in terms of their mean change in PWD's disruptive behaviors, stress, and psychoactive medication use and caregivers' stress, burden, depression, sleep, and confidence (e.g., from baseline to month 3), tests of mean contrasts will be performed using parameter estimates from the fitted mixed models. Significant differences between the two groups, if they are in the expected direction, will support the hypothesis. An additional model per protocol will test changes in outcomes using only dyads in which the caregiver used recommended interventions in subsequent video recorded interactions.

D9b. Specific Aim 2. Identify precursors of disruptive behaviors and develop a typology of interventions for caregiver in-home use. We will use content analysis of caregiver submitted videos and recorded team video review meetings to tabulate the most common symptoms and behaviors. Qualitative content analysis of recorded team meetings for video review and written intervention plans for caregivers will identify key symptoms and behaviors. We will also code behaviors and symptoms exhibited by PWD in pre- and post-intervention videos submitted by caregivers. Counts will be analyzed descriptively to identify the most common symptoms and behaviors and the recommended interventions and their effectiveness.

D9c. Specific Aim 3. Evaluate ease of use, satisfaction, and cost effectiveness of FamTechCare using traditional cost methods and Data Envelopment Cost-efficiency Analysis (DEA).
Cost Effectiveness Analysis (CEA) focuses on cost per unit change in PWD disruptive behavior (ΔPDB), comparing change in the proportion of disruptive behaviors between groups post-intervention. The additional costs for FamTechCare will be termed ΔC. For our CEA we calculate a 95% confidence interval for the ratio ΔC/ ΔPDB, defined as the change in cost per unit change in disruptive behaviors. ΔPDB will be modeled using the linear mixed model. At the end of the analysis we will generate a 95% confidence interval for a ratio, which can be complicated due to non-normality of the distribution of the parameter estimate. However, we will use a bootstrap procedure (Efron & Tibshirani, 1993) to alleviate this challenge. We will repeat this CEA using caregiver burden as the change unit. Our economist co-investigator has published on CEA (Lee, 2008).

Data Envelopment Analysis (DEA) is an ideal approach for assessing efficiency in this study. DEA allows consideration of multiple non-monetary outputs (Cooper et al., 2004; Hollingsworth et al., 1999; Seiford & Thrall, 1990) and uses linear programming to generate a coefficient of efficiency that compares cost factors to outcomes (Seiford & Ahn, 1993), with a large coefficient identifying efficiency. DEA compares cases with similar resources rather than the average or an artificial "ideal" (Charnes et al., 1994). DEA is a form of multi-attribute benchmarking used extensively in hospitals and NHs (Athanassopoulos et al., 1999; Chattopadhyay & Ray, 1996). Our health economist expert will fit a DEA model to investigate the overall efficiency in intervention compared to control in reducing caregiver desire for NH placement (Cooper, et al., 2004; Lee et al., 2009).

D10. Timeline. The initial 4 months of this 4-year study will be used to hire and train research team members in study protocols, to negotiate data protection agreements, and to purchase and configure equipment. The intervention and data collection will be completed in waves (8 participants every 3 to 4 months) during months 4 to 44. Analyses and coding will begin in the second half of year 01 and will continue through Year 04. Data analysis, dissemination and reporting will be completed in the final 6 months.

Research Study Activity	Year 1/Quarter 1 2 3 4	Year 2/Quarter 1 2 3 4	Year 3/Quarter 1 2 3 4	Year 4/Quarter 1 2 3 4
IRB/Train Team	———	Repeat training	as needed	
Each line indicates 8 CG-PWD dyads (4 Intervention & 4 Control)	1-8, 9-16, 17-24	25-32, 33-40, 41-48, 49-56	57-64, 65-72, 73-80	81-88
Coding & Analyses	———			
Report/Dissemination				———