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A Telephone Intervention for Dementia Caregivers: Background, Design, and Baseline Characteristics

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Abstract

Family caregivers of individuals with dementia are at heightened risk for emotional and mental health problems. Many caregivers do not seek assistance or become isolated in their caregiving role. Multi-component interventions have demonstrated efficacy for reducing emotional distress and burden, although these approaches are potentially costly and are not widely accessible. In response to these issues, we developed the Family Intervention: Telephone Tracking – Caregiver (FITT-C), which is an entirely telephone-based psychosocial intervention. The purpose of this paper is to describe the study design, methodology, and baseline data for the trial. This study uses a randomized controlled trial design to examine the efficacy of the FITT-C to reduce depressive symptoms and burden in distressed dementia caregivers. All participants (n = 250) received a packet of educational materials and were randomly assigned to receive 6 months of the FITT-C intervention or non-directive telephone support. The FITT-C intervention was designed to reduce distress in caregivers and is based on the McMaster Model of Family Functioning and the Lazarus, transition theory, and Folkman Stress and Coping Models. The primary dependent variables were depressive symptoms (Centers for Epidemiological Studies – Depression) and burden (Zarit Burden Interview, Revised Memory and Behavior Problems Checklist – Reaction). Secondary outcome measures included family functioning, self-efficacy, and health-related quality of life. Results of the study will provide important data about the efficacy of a telephone-based approach to reduce distress in dementia caregivers.

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Keywords

Dementia; Caregivers; Telephone; Psychosocial Intervention

1. Introduction

More than 15 million Americans provide 17.5 billion hours of unpaid care each year for persons with dementia [1]. Providing care for an individual with dementia has been shown to be more stressful than caring for a physically-impaired older adult [2]. Family caregivers of individuals with dementia are at heightened risk for a variety of negative health consequences and even their own dementia and death [3-5]. Dementia caregivers report high levels of depression and anxiety and exhibit elevated rates of mood disorders, with about 1/3 of individuals meeting diagnostic criteria for depression [6]. Caregivers often sacrifice their own needs and well-being to provide care for their loved one. In addition, it is common for caregivers to experience feelings of social isolation [7].

A variety of educational, psychosocial, and psychotherapeutic interventions have demonstrated modest success in improving the quality of life and negative consequences associated with dementia caregiving. Many of these studies have methodological problems, such as small sample sizes, lack of appropriate control conditions, or inclusion of non-distressed caregivers. Recently, comprehensive, multicomponent interventions have been developed and tested with dementia caregivers. There is evidence that these interventions can reduce burden and depressive symptoms as well as delay institutionalization of the care recipient [8,9]. Although there is evidence that these interventions are effective, practical implementation on a wide scale and accessibility to family members with extensive caregiving responsibilities restricting their travel are significant challenges.

In response to the need for cost-effective and highly accessible dementia caregiver interventions, we developed a telephone-based, psychosocial intervention for dementia caregivers (Family Intervention: Telephone Tracking – Caregiver; FITT-C). Theoretical underpinnings of the intervention are based on psychosocial transition [10], transactional stress and coping [11], and a systems view of family functioning (i.e., McMaster Model of Family Functioning) [12]. Taken together, the three underlying theories of the FITT-C are geared toward enhancing coping within the caregiver through active problem-solving and facilitating positive changes within the family system. According to these models, dementia caregiving is comprised of potentially stress-inducing transitions that prompt an appraisal process by the caregiver to identify whether resources (particularly those within a family) can be mobilized to cope with the changes. Within these overlapping models, caregiver burden is viewed as a situation in which demands (both perceived and objective) exceed the coping and resources (both perceived and objective). As burden persists, it becomes a stressor in its own right, leading to feelings of helplessness, hopelessness, and depression. Overall, the FITT-C directly targets caregiver appraisal and coping processes to reduce stress, improve caregiver mood and quality of life, and positively impact the family system. In a preliminary study of an earlier version of this intervention, we found that caregivers who received the FITT showed greater reductions in perceived burden and less-severe reactions to memory and behavior problems than individuals in a standard care condition [13].

The purpose of the FITT-C trial was to establish whether an entirely telephone delivered intervention could reduce depressive symptoms and burden in distressed dementia caregivers. Aims of the current paper are to describe the study design, methodology, and

baseline data for a randomized controlled study of the FITT-C intervention compared to non-directive telephone support.

2 Methods

2.1 Participants

Participants included 250 family caregivers and their care recipients who were required to be formally diagnosed with dementia. A diagnosis of dementia was made by a neurologist, geriatrician, or psychiatrist. In cases in which the diagnosis was made by a general practitioner, the study neurologist (BRO) confirmed the diagnosis. We chose to include any dementia subtype (e.g., Alzheimer's disease [AD], vascular, frontotemporal) because of considerable overlap in symptoms among different dementias. FITT-C was designed to be flexible enough to assist caregivers whose care recipient has a predominance of neuropsychiatric, cognitive, or behavioral symptoms. Caregivers were required to endorse experiencing at least two of the following in a screening interview: 1) feeling overwhelmed and stressed; 2) sad mood/depression; 3) anger or frustration; 4) loss of contact with family and friends; 5) conflict in family or family stress; 6) neglecting their own health; 7) demands or pressures of caregiving are too much; 8) exhaustion and fatigue; and 9) not taking care of their own needs or other significant responsibilities.

Caregivers were excluded based on the following criteria: 1) major acute medical illness; 2) English was not their primary language; 3) cognitive impairment as defined by Mini Mental State Examination score falling 1.5 or greater standard deviations below age- and education-corrected normative data; or 4) no access to a telephone. Care recipient inclusion criteria included: 1) formal DSM-IV diagnosis of dementia by a neurologist, psychiatrist, or geriatrician; 2) family member or other adult in caregiver role for at least 6 months, and who provided at least 4 hours of supervision or direct assistance per day for the person with dementia; 3) care recipient lived in the community, including senior/retirement centers, but excluding nursing homes and assisted living centers; and 4) there was no plan for the care recipient to be placed in long term care or the caregiver to end their role within 6 months of study enrollment. Those care recipients with other major medical conditions affecting independent functioning were excluded.

2.2 Procedure

2.2.1 Telephone and in-person screening interviews—Participants were enrolled on a rolling basis over 53 months (March 2008 to August 2012). In addition to physician referrals and referrals from two local hospital memory clinics, we recruited from the community in the following ways: 1) distribution of recruitment flyers to other memory clinics, neurologist and geriatric psychiatrist practices, geriatrician offices, and large primary care physician practices; 2) distribution of flyers and other advertising materials through town and regional senior centers and Councils on Aging, and similar agencies; 3) attendance/presentations at support groups and similar groups at the local Alzheimer's Association chapter; 4) newspaper advertisements targeting communities and publications with large numbers of elderly readers; 5) television advertising on local cable systems; and 6) lectures to both lay and professional groups on the topic of caregiving given by members of the research team on at least a monthly basis.

Potential participants either contacted our research staff by telephone or email or were contacted by research staff after agreeing to contact with their physician or other referral source. Potential participants completed a telephone screening interview to establish that the caregiver and their care recipient met inclusion/exclusion criteria. Prior to the screening,

individuals were read a script (approved by the IRB) describing the duration of the screening (approximately 5 minutes) and that questionnaires would be kept confidential.

If potential participants passed the telephone screen, they were invited for an in-person screening visit, in which informed consent was completed by caregivers and care recipients (when appropriate). Caregivers were given the Mini Mental State Examination (MMSE) to rule out their own cognitive impairment and when necessary, dementia diagnosis was confirmed. If the caregiver obtained an MMSE score below expectations for their age and education, the principal investigator discussed this result with the caregiver and offered referral for more comprehensive evaluation and follow-up.

2.2.2 Randomization—Participants were randomly assigned to receive FITT-C or Telephone Support using the urn randomization procedure, to balance the two conditions on non-treatment variables that might affect outcome [14] (see Table 1 for urn variables and cut off values). This procedure randomly assigns patients to groups, but systematically biases the randomization in favor of balance among the treatment conditions. We randomized on gender of the caregiver, dementia severity, relationship status, dementia type, live-in caregiver or not, and frequency of behavior problems in the care recipient. Frequency of behavior problems was measured with the Revised Memory and Behavior Checklist [15]. We selected a cut-off score of 33, reflecting the mean performance of the sample in the original published study. The number of urns selected for the proposed study is appropriate for the sample size [14]. Randomization occurred immediately following pretreatment assessment.

2.3 Treatment Conditions

All caregivers (regardless of condition) received a packet of educational and resource materials. The resource packet contained a listing of state and local services, national and governmental programs, internet resources, dementia fact sheets, medication fact sheets, publications/brochures, caregiver guides, local respite service information, and specific topic brochures (challenging behaviors, assisting with personal care, communication, safety issues, activities, financial and legal issues, and long term care). Following random assignment, participants received a letter containing a brief biography and photograph of their assigned therapist. Both interventions were entirely telephone-based. To control for attention effects, the frequency of contacts were identical between the conditions. Table 2 summarizes differences between the two treatment arms.

2.3.1 FITT-C Intervention—The FITT-C is a psychosocial intervention entirely delivered over the telephone by trained therapists. Caregivers receive 16 telephone contacts distributed over 6 months that focused on providing dementia education, emotional support, directing caregivers to appropriate resources, encouraging caregivers to attend to their own physical, emotional, and social needs, and teaching caregivers strategies to cope with ongoing problems. The intervention does not provide case management, serve as a question-and-answer hotline, or provide psychotherapy over the telephone.

Caregivers receiving FITT-C were initially oriented to the resource packet and then refer to the materials throughout the intervention to provide ongoing education and information about resources.

The FITT method consists of two stages. The initial stage, Orientation and Psychoeducation, involves providing caregivers with a rationale of the FITT, an introduction to educational and resource materials, and a description of what will happen during future phone contacts. The psychoeducation component of this initial stage involves reviewing information about dementia, and common psychological, emotional, psychosocial, and medical effects of

caregiving (i.e., health, functioning, mood, thinking, and family life). The second stage, Follow-up, involves telephone follow-up contacts in which any new problems are identified, positive and negative changes in caregivers or patients are discussed, psychoeducational information is reviewed and applied for a particular situation, and assistance is provided to help the caregiver solve problems. All follow-up contacts will follow a similar protocol: 1) introduction – identify purpose of call; 2) assessment of current status – identify positive and negative changes since last contact; 3) assessment of key areas – note any changes in each key area of functioning (i.e., health, functioning, mood, social support, and family life)_Repeated review of each of these key areas during every call, implicitly reinforces the need to appraise and reappraise these issues; 4) review of other issues – identify other issues that could be problematic; 5) intervention – provide support and assistance to help caregivers solve problems and utilize family resources; and 6) continuing education – provide an opportunity for caregivers to ask questions about dementia or the care recipient. Therapists can choose the most appropriate intervention from a menu of choices, including supportive approaches (i.e., empathy, giving permission, normalizing, provision of information, validation, or venting) or more active strategies (i.e., bibliotherapy, interpretation, positive reframing, problem solving, reference to resource packet, referral, or setting task directives). Therapists record basic details from each call including duration, interventions used, and issues that require follow-up during the next call. The final two follow-up calls (monthly) address issues of termination by allowing caregivers to anticipate FITT contacts coming to an end, and fostering reliance on the support network established during the intervention. The focus of these calls shifts slightly, with therapists asking caregivers to describe how they handled difficulties over the last month, rather than eliciting changes in key areas. After the final call, the therapist prepares a letter that briefly highlights the progress during the intervention and encourages the caregiver to continue to develop and utilize adaptive coping strategies.

2.3.2 Telephone Support—The control condition was designed to account for nonspecific therapeutic factors such as interpersonal contact and relationship. The approach was based on a nondirective control condition used by Borkovec and Costello in a psychotherapy study for generalized anxiety disorder [16]. Subjects rated the nondirective control condition as having an equivalent amount of credibility and expectancy for change as two active treatment conditions yet had no effect on mental health outcome measures. The primary goal of this condition was to provide non-directive support for caregivers through empathic and reflective listening and open-ended questioning. The contact time and number of contacts were identical to FITT-C, although the content and process differs substantially. The role of the therapist is to provide unconditional positive regard to caregivers and to establish a relationship that mimics support group-style communication. Time is spent establishing rapport with each caregiver allowing him/her to express feelings and issues relevant to their unique experiences. Therapists are only allowed to conduct empathic/reflective listening and venting techniques. In addition, they can collect history about the caregiver and/or care recipient. They are discouraged from providing directive strategies, such as education, problem-solving, advice-giving, or task directives. Although the provision of education was not the focus of this condition, education was not withheld if the caregiver had the wrong information. If education was sought, the therapist attempted to direct the caregiver to educational resources that could be independently explored.

2.3.3. Treatment Schedule—All caregivers received the initial contact (Orientation and Psychoeducation for FITT-C and Orientation only for the MTS). Weekly calls were placed to caregivers for six consecutive weeks. For the remainder of the intervention, calls were made every two weeks. The last two calls were considered termination contacts. Although initial telephone contacts had standardized durations (approximately 60 minutes), follow-up

contacts could vary somewhat in length depending on the severity of caregiver problems (15-30 minutes). Each caregiver was assigned one therapist, who made all telephone contacts with that caregiver. If a caregiver could not be contacted after three separate attempts (i.e., different times/different days), another attempt was not made until the next scheduled contact or if the caregiver contacts the therapist. If two consecutive contacts were missed, the caregiver was considered lost to follow up from the study and considered a dropout. They were sent a letter explaining the reasons for termination and an offer to discuss these reasons with the therapist.

2.3.4. Therapists—Individuals recruited to serve as therapists had experience working with dementia patients and/or their caregivers or psychotherapy experience working with adults. Therapists were required to be at the master's level (including nurses, social workers, clinical psychology graduate students, family therapists). Each caregiver was assigned a therapist, who contacted them throughout the course of the intervention. Therapists were not involved in conducting assessments. Training of therapists in the FITT-C condition involved: 1) expert lectures from a neurologist, a psychiatrist, and neuropsychologists on dementia- and caregiver-related topics (e.g., dementia subtypes, medication, progression of the disease; community resources); 2) reading the FITT-C treatment manual and other written materials; 3) training in theoretical model (i.e., McMaster Model of Family Functioning) underlying the FITT approach; 4) learning specific FITT procedures and practicing intervention delivery through role-playing. The entire training procedures took approximately 14 hours. Following the training program, therapists were required to perform at 80% or better on tests of knowledge of dementia, the FITT-C intervention, and on a skills-based test of intervention competency. Therapists in the TS condition receive four hours of training that included role playing and learning of specific MTS techniques and general information about dementia and caregiving.

2.3.3 Quality Control—Throughout the study, therapists in each condition received weekly 1-hour group supervision with neuropsychologists with expertise in dementia and caregiving (GT & JD). The goal of these sessions was to discuss specific cases, to ensure competent implementation of the treatment, and to reinforce adherence to the intervention. Periodically, consultant experts attended the group supervision to offer continuing education about dementia and to address any issues that arose with specific participants. All telephone contacts were audiotaped, and a subset were reviewed during supervision sessions to ensure adherence and to better guide therapists' intervention strategies. Any deviations from the treatment protocol were brought to the therapist's attention for remediation. In addition, a randomly selected subgroup of tapes were reviewed by a trained research assistant, who rated adherence to the intervention and competence using standardized rating scales.

3. Assessment Procedure & Measures

A trained research assistant who was blind to group assignment conducted all assessments. The baseline assessment was completed face-to-face whereas the remaining assessments at 2, 4, 6, and 9 months were complete by telephone. Caregivers received \$25 for each completed assessment. Therapists did not have access to any assessment results. Outcome measures were selected if they met the following criteria: 1) sound psychometric characteristics; 2) measures of caregiver stress appropriate for this population and goals of the study; 3) measures expected to show effects based on the FITT theoretical model; 4) instruments widely used in previous research on dementia caregiving interventions to ensure comparability with other studies; and 5) measures that are brief enough to be administered by telephone. We selected an assessment battery that is focused on measuring efficacy of FITT-C. Finally, given the cognitive impairment of the patients with dementia, we included measures of certain aspects of patient functioning that could be completed by caregivers.

Caregivers were sent a booklet containing copies of measures to which they could refer during the telephone assessment. The validity and reliability of telephone assessment is well established and has been shown to be an effective strategy with older adults. To ensure comparability between face-to-face and telephone assessments, the first 53 participants completed the ZBI and CES-D face-to-face (FTF) and the same measures by telephone (Tel) within two weeks ($M = 10.3$ days; $SD = 5.2$). There were no statistically significant differences between reliability coefficients for each administration method for either measure (Tel ZBI $r = .90$ vs. FTF ZBI $r = .92$; Tel CES-D $r = .89$ vs. FTF CES-D $r = .90$).

3.1. Primary Outcome Measures

3.1.1. Zarit Burden Interview—The Zarit Burden Interview is 22-item inventory assesses caregivers' subjective feelings of the negative impact of caregiving on emotional and physical health functioning, social life, and financial status [17]. The scale has been shown to have good internal consistency, content validity, and test-retest reliability.

3.1.2 Center for Epidemiology Studies Depression Scale—The Center for Epidemiology Studies Depression Scale is a 20-item measure of depressive symptoms [18]. This measure has adequate reliability and validity. In addition, this scale is shorter than the Geriatric Depression Scale, making it easier to administer over the telephone.

3.1.3. The Revised Memory and Behavior Problem Checklist—The Revised Memory and Behavior Problem Checklist 24-item checklist requires caregivers to rate the frequency of problem behaviors and memory difficulties in patients during the previous week [15]. In addition, caregivers rate their own reaction to each of the behavior problems. Ratings are made on a 5-point scale for frequency of behavior problems (0 = never occurred to 4 = occurs daily or more often) and reactions to these problems (0 = not at all bothered/upset to 4 = extremely). Higher scores reflect higher levels of perceived caregiver burden. The scale has good reliability and validity [15]. The reaction score (RMBPC-R) was used for primary analyses whereas the frequency score (RMPC-F) was used for urn randomization.

3.2 Secondary Outcome Measures

These measures were selected to address other areas of caregiver functioning that could be impacted by the intervention. Two of the measures (FAD and PAC) were added to the outcome battery soon after the trial started and are therefore not available for all participants.

3.2.1 Family Assessment Device (General Functioning scale)—The FAD is a 60-item self-report questionnaire designed to assess the six dimensions of the McMaster Model of Family Functioning, including problem-solving, communication, roles, affective responsiveness, affective involvement, behavioral control, and general functioning. For this study we used the general functioning subscale (consisting of 12 items). Psychometric properties of the scale support its reliability and validity in psychiatric, medical, and nonclinical samples [19]. Caregivers were asked to rate statements about their families along a 4-point Likert scale from strongly disagree to strongly agree. It was emphasized to caregivers to answer according to their perceptions of their family.

3.2.2 Self-Efficacy Questionnaire (SEQ)—The SEQ is a 10-item measure of perceived self-efficacy in family caregivers. The scale is divided into two subscales, symptom management and community support service. Five items correlate with how well caregivers can manage their relative's dementia symptoms and four items correlate how well caregivers utilize support services in the community. Items are presented on a 0-10 scale with higher scales reflecting more self-efficacy. Findings revealed that the internal consistency of the

two factors was sufficient ($\alpha = 0.77$ for symptom management and $\alpha = 0.78$ for support service) [20].

3.2.3. Positive Aspects of Caregiving (PAC)—The PAC scale presents statements about a caregiver's mental or affective state relative to the caregiving experience. Responses are provided on a 5-point Likert-type scale. Items are designed to assess the perception of benefits within the caregiving context, such as feeling useful, feeling appreciated, and finding meaning. Higher scores represent more positive appraisals. The scale has good reliability and validity [21].

3.2.4 EuroQoL—The EuroQoL measures health related quality of life and consists of five questions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and an overall health rating. It uses a time reference of today, and employs a three-category response format (no problem, moderate problem and severe problem). The scale has good validity and reliability [22].

3.4 Dementia Variables

3.4.1 Clinical Dementia Rating (CDR) [17]—This is a scale of dementia severity based on a semi-structured interview with the primary caregiver and the individuals with dementia and was used for urn randomization. Impairment is rated in six categories, including Memory, Orientation, Judgment and Problem-solving, Community Affairs, Home and Hobbies, and Personal Care on a five point scale (0 = no impairment, .5 = questionable dementia, 1 = mild dementia, 2 = moderate dementia, 3 = severe dementia). A global rating is also calculated based on memory and other scores. This rating scale is the most commonly used measure of dementia severity. It also has high inter-rater reliability for both physicians and non-physicians [23].

3.4.2 Activities of Daily Living (ADL)—This is a standardized measure of basic activities of daily living [24]. Caregivers rate whether the care recipient is independent or needs assistance with bathing, dressing, toileting, transferring, continence, and feeding. This scale has been extensively used with dementia populations and in caregiver intervention literature.

3.4.3 Instrumental Activities of Daily Living (IADL)—This 8-item scale measures instrumental activities of daily living, such as using the telephone and taking medications [25]. Caregivers indicate how well the patient can perform each of the tasks on a three-point scale from 0 = unable to do to 2 = needs no help.

3.5 Other Measures

3.5.1 Demographics—Caregivers provided demographic information, including age, gender, race, socioeconomic status, marital status, education, and employment. We also collected information about changes in employment status, duration of dementia, caregivers' length of caregiving, and information about formal or informal assistance with caregiving.

3.5.2 Credibility/Expectancy Questionnaire—The Credibility/Expectancy Questionnaire is a 6-item measure, in which the individual rates the intervention for credibility and expectancy for change. The scale has excellent internal consistency reliability and good test-retest reliability [26]. The scale was administered to caregivers in both groups at the 2-month assessment point only to determine whether individuals in both treatment conditions perceive that the intervention is credible and has the potential to produce change.

3.5.3. Treatment Satisfaction and Acceptability—To ensure that participants were satisfied with the intervention and found it acceptable in terms of goals, procedures, and outcomes, they were asked to rate statements about treatment satisfaction on a 7-point Likert scale.

4. Statistical Analysis

The sample size was determined a priori based on the following: 1) appropriate statistical power to detect expected treatment effects (at least 80%); 2) use of data from our pilot study as a model showing moderate effect sizes [13]; and 3) expectations of subject attrition based on estimates from the pilot study and other dementia caregiver intervention studies (~25%). We planned to enroll 274 participants, conservatively anticipating a 30% attrition rate. Therefore, we would end the study with 192 participants. At this sample size, assuming a common standard deviation for the change scores across the two study groups, we expected power in excess of 80% to detect a standardized difference in the mean change scores of at least $\delta=0.38$ (derived from the pilot study). On the other hand, the pilot study was conducted with a standard care control group. For the current study, we will compare the intervention to a support condition. Therefore, data from the pilot study could somewhat overestimate the effect size. Even with slightly smaller effect sizes, we estimated enough power to detect clinically significant effects. For the current study, we calculated descriptive statistics for the baseline demographic and caregiving characteristics and the primary and secondary outcome variables. We calculated percentages/frequencies for categorical variables and means and standard deviations for continuous variables. To identify any group differences at baseline, we conducted t-tests for continuous variables and chi square tests for categorical variables. We calculated Pearson correlation coefficients to determine relationships between outcome variables.

5. Results

5.1. Recruitment Strategies

Figure 1 presents the recruitment flow through the study. Forty-eight percent of screened caregivers were excluded mainly because they did not meet inclusion/exclusion criteria, were not interested in participating, or because of scheduling issues. We recruited 250 caregivers in the study, which fell short of the proposed sample size (274). However, we retained 85% of the participants at the 6-month assessment point ($n = 213$), which was higher than expected and yielded a larger sample than estimated. Nineteen individuals dropped from the FITT condition and 18 from support, which did not reflect a significant differential attrition rate by group $\chi^2 = .06, p = .81$. The most common reasons for attrition was death of the care-recipient ($n = 10$), lost contact ($n = 8$), never initiated treatment ($n = 6$), and too busy to participate ($n = 5$). Table 3 presents the number of participants recruited based on each strategy divided by those randomized versus those who did not enroll. Most participants were recruited by referral from their provider, followed by advertising, and community contacts.

5.2. Demographics

Table 4 presents the baseline demographic characteristics by study arm for caregivers and care recipients. Caregivers were mostly female, Caucasian, and lived with the care recipient. They were caring for the care recipient for over 3 ½ years. Care recipients were mostly in the mild range of cognitive impairment (i.e., Clinical Dementia Rating = 1) and were mainly diagnosed with probable Alzheimer's disease. Statistically significant group differences were detected for caregivers' educational level, with more years of education in the FITT-C group compared to the Telephone Support condition.

5.3. Baseline Primary and Secondary Outcome Variables

Table 5 presents the means and standard deviations for the baseline values of all primary and secondary outcome variables. There were no significant differences between groups for any of these baseline measures. Caregivers reported elevated levels of caregiver burden and mild depressive symptoms. Table 6 presents inter-correlations among the outcome variables. All outcome variables significantly correlated with depressive symptoms and burden. The correlation between depressive symptoms and burden was .54 ($p < .0001$), suggesting that higher levels of depressive symptoms were associated with higher levels of burden.

Discussion

Although there is empirical support showing the benefit of comprehensive psychosocial interventions for caregivers of individuals with dementia, many of these interventions are costly and could be difficult for caregivers to access. We present a study protocol designed to test the efficacy of an entirely telephone-delivered psychosocial intervention for dementia caregivers. The intervention was systematically developed based on a theoretical framework and thorough pilot testing.

The primary aim of the FITT-C study was to determine whether the telephone intervention could improve depressive symptoms and burden in distressed caregivers of individuals with dementia. Primary outcome variables include the depressive symptoms (CES-D), perceived burden (ZBI), and reaction to memory and behavior problems (RMBPC). We chose inclusion criteria that required caregivers to endorse some degree of distress related to caregiving rather than assuming all dementia caregivers are distressed. As a result, caregivers in this study reported higher levels of depressive symptoms and burden than was seen in our previous study that did not have this inclusion criterion [13]. The issue of whether to require distressed caregivers in interventions studies has plagued researchers, and there is evidence that included distressed and non-distressed caregivers in intervention studies has contributed to inconsistent or inconclusive results [27].

Another important design choice for the current study was the inclusion of an active control condition. Many past caregiver intervention studies have not controlled for contact time or nonspecific effects of relationship, alliance, and support. In these studies, it is difficult to conclude that specific elements of the intervention accounted for any improvements beyond attention and time spent with the caregiver. For the current study, we wanted to show that the specific FITT-C intervention strategies explain any improvements seen in primary and secondary outcome measures. We chose a telephone support condition to match the delivery method and time of the FITT-C and to provide a credible intervention for dementia caregivers. A unique aspect of this study was the inclusion of a measure of expectancy and credibility that will allow us to determine whether the control condition was perceived as a realistic intervention for caregivers. Another way of looking at acceptability of the control condition is differential attrition. We found no differences in dropout rates between the intervention conditions.

The study used multiple recruitment strategies to identify eligible caregivers. By far, the most effective method was professional referrals, accounting for over 60% of individuals randomized. Advertising and contacts with community agencies accounted for most of the additional recruitment sources. We found that about 22% of caregivers did not meet inclusion criteria and 26% could not be scheduled for baseline assessments or were not interested. The relatively high screen fail rate and interest in the study may have been a reflection of our reliance upon professional referral. Retention rates for the study were in the acceptable range (85%) and higher than estimates based on previous studies. One factor that may have enhanced retention in the study was that the telephone was used for intervention

implementation and assessments. We took a number of steps to improve the intervention delivery by telephone (e.g., bios and pictures of therapists) and assessments (e.g., providing response formats). As part of this study, we demonstrated the equivalence of face-to-face and telephone assessments on two of the primary outcome measures.

Urn randomization was used to balance groups on important variables such as gender of the caregiver, dementia severity, relationship status, dementia type, live-in caregiver or not, and frequency of behavior problems. As a result, we found no statistically significant differences between treatment arms for these variables. Among other demographic, caregiving characteristics, and outcome variables, we only found statistically significant differences between intervention arms for education. We will control for this factor when conducting outcome analysis. Individuals assigned to the FITT-C group had more years of education than the control group. Whether this difference impacts outcomes will be examined once the study is complete. We also found that most outcome measures correlated modestly with one another, with the strongest associations explaining 25% of the variance. This finding suggests that in addition to unique contributions from each of the measures, they may be capturing an overlapping construct, such as general distress.

The study has some limitations. The sample is mainly Caucasian, which limits generalizability to other racial and ethnic groups. We made attempts to increase diversity in the sample through community outreach, but were limited by several factors, especially the inclusion criterion that required a formal dementia diagnosis by a specialist. There is evidence that racial and ethnic minorities have inadequate access to specialty care and are influenced by cultural factors about the effects of normal aging and mistrust of the medical establishment [28]. It is important to study interventions in the context of a diverse sample because there is evidence different racial and ethnic groups may show differential response to interventions [8]. It is anticipated that a future trial of the intervention can be implemented in a more diverse sample, possibly by disseminating the intervention into community agencies and other local groups. Another limitation is the short follow-up period of 3 months post-intervention. We will not be able to determine whether the intervention has long term effects beyond this immediate post treatment period.

Conclusions

The FITT-C study is one of a few trials exploring the use of telephone intervention for reducing distress among dementia caregivers. Given the time and pressures of caring for someone with dementia, a telephone intervention has the potential to be highly accessible for caregivers. We demonstrated the feasibility of recruiting and retaining distressed caregivers over the course of the 6-month intervention. Inclusion/exclusion criteria resulted in a group of caregivers reporting high levels of perceived burden and depressive symptoms. We used a rigorous research design to test the efficacy of the intervention by including a control condition that was matched for time and non-specific effects of the intervention. Results of the trial will reveal whether this low cost, accessible intervention has efficacy for reducing distress in dementia caregivers.

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Figure 1.
FITT-C Trial Enrollment Flowchart

Table 1

Urn Randomization Variables

Variable	Assessment	Categories
Caregiver Gender	Self-Report	Female, Male
Dementia Severity	Clinical Dementia Rating	1 = Mild; 2 = Moderate; 3 = Severe
Dementia Type	Medical Record	Alzheimer's; Other
Living Arrangement	Self-Report	Live-in; Not Live-in
Care Recipient Behavior Problems	Revised Memory & Behavior Problems Checklist Frequency Score	≥ 33 = High; <33 = low

Table 2**Contrasts between Telephone Support (TS) and FITT-C Interventions**

	Telephone Support Control Condition	FITT-Caregiver Active Intervention
Process		
	Non-directive history gathering	Structured interview for history gathering
	Participant directed	Therapist directed
	General focus on dementia and related issues	Structured risk assessment and emphasis on key areas for caregiver (health, social support, mood, family functioning) and care recipient (cognition, behavior, mood) functioning
	Improve caregiver functioning through unconditional positive regard for caregiver-directed agenda	Improve caregiver functioning through ongoing assessment and monitoring of key areas (described above) and emphasis on positive aspects of caregiving and family functioning
Materials		
	Therapist Guide	Therapist Manual Education/Community Resource Materials
Session Protocol		
Session 1	Participant directed, unstructured history gathering and review of intervention purpose and process	Manualized 6-step structured protocol that includes orientation to the goals and process of FITT-C, psychoeducation, questions/discussion, assessment of key areas for care recipient and caregiver.
Sessions 2-14 (Follow-up)	Participant directed, unstructured dialogue about experiences with dementia caregiving. Interventions are supportive (e.g., reflective listening, validation, and ventilation).	Structured assessment and re-evaluation of key areas. Caregivers learn to cope with caregiving stress through re-appraisal of the stressor and utilization of resources. Interventions are both supportive (e.g., empathy, normalizing, validation) and active (e.g., education, problem-solving, reframing, referral, task setting, bibliotherapy).
Sessions 15-16 (Termination)	Participant directed, unstructured dialogue. Limited to supportive interventions. Review of caregiving experiences over past 6 months.	Review of helpful interventions, progress, and successes. Ensure identification of key person to replace therapist's supportive role. Therapist summarizes areas of progress and helpful intervention strategies in follow-up letter to caregiver at conclusion of intervention.

Table 3

Number of Participants by Recruitment Method

Recruitment Method	All Participants Screened (n = 477)	Enrolled (n = 250)	Not Enrolled ^a (n = 227)
Professional Referral	240 (50%)	155 (62%)	85 (37%)
Adult Day/Senior Center/Support Groups	37 (8%)	20 (8%)	17 (8%)
Community contacts	67 (14%)	25 (10%)	42 (19%)
Previous Participants	20 (4%)	11 (4%)	9 (4%)
Alzheimer's Association/Elderly Affairs	14 (3%)	4 (2%)	10 (4%)
Advertising	77 (16%)	29 (12%)	48 (21%)
Other/Unknown	22 (5%)	6 (2%)	16 (7%)

^aIneligible or not interested after obtaining more information during screening

Table 4**Caregiver and Care Recipient Demographic Characteristics by Intervention Group**

	Total Sample (n = 250) M (SD)	FITT-C (n = 133) M (SD)	Support (n = 117) M (SD)	p
Caregiver				
Age	62.72 (12.99)	63.32 (12.30)	62.03 (13.75)	.44
Education	14.92 (2.64)	15.26 (2.68)	14.54 (2.55)	.03*
Length of Caregiving (mos)	44.79 (34.26)	45.78 (36.20)	43.66 (32.03)	.62
% female	78%	80%	76%	.54
% spouse	51%	51%	51%	.69
% adult child	42%	44%	41%	.69
% live in	80%	79%	81%	.75
% Caucasian	96%	96%	95%	.42
Care Recipient				
Age	78.06 (10.06)	79.22 (9.11)	76.74 (10.93)	
Time since diagnosis	30.60 (30.77)	32.47 (32.32)	28.46 (28.91)	.32
Time since symptom onset (mos)	53.50 (39.53)	56.61 (44.48)	50.00 (32.96)	.20
ADL	8.94 (2.52)	8.92 (2.50)	8.97 (2.55)	.88
IADL	5.05 (3.69)	5.05 (3.75)	5.05 (3.62)	.99
RMBPC	35.14 (13.18)	35.72 (12.22)	34.48 (14.22)	.46
Frequency				
% Alzheimer's Disease	77%	79%	75%	.55
% CDR = 1	64%	62%	66%	.80
% CDR = 2	31%	32%	29%	.80
% CDR = 3	5%	6%	5%	.80
% female	59%	55%	57%	.53
% Caucasian	96%	96%	95%	.53

Note. ADL = Activities of Daily Living; IADL = Instrumental Activities of Daily Living; RMBPC = Revised Memory and Behavior Problem Checklist; CDR = Clinical Dementia Rating Scale

Table 5

Baseline Scores on Primary and Secondary Outcome Variables

	Total Sample	FITT-C (n = 134)	Support (n = 116)	p
ZBI	38.18 (14.12)	38.17 (13.61)	38.20 (14.73)	.98
CES-D	16.35 (9.99)	17.05 (10.05)	15.56 (9.91)	.24
RMBPC-R	24.10 (14.33)	24.95 (14.09)	23.13 (14.61)	.32
FAD ^a	2.10 (.57)	2.13 (.59)	2.06 (.55)	.45
SEQ SM	29.97 (10.99)	29.70(10.42)	30.28 (11.65)	.68
SEQ SS	24.27 (10.33)	24.18 (10.66)	24.38 (9.99)	.88
EQ-5D VAS	78.45 (16.77)	79.54 (16.22)	77.21 (17.37)	.28
PAC ^b	31.46 (8.61)	31.79 (7.89)	31.09 (9.40)	.70

Note. ZBI = Zarit Burden Interview; CES-D = Centers for Epidemiological Studies Depression Scale; RMBPC-R = Revised Memory and Behavior Problem Checklist – Reaction Score; FAD = Family Assessment Device; SEQ-SM = Self Efficacy Questionnaire Symptom Management; SEQ-SS = Self-Efficacy Questionnaire Support Services; EQ-5D VAS = Quality of Life Visual Analogue Scale; PAC = Positive Aspects of Caregiving

^a
n = 171

^b
n = 220

Table 6

Correlations among outcome variables

	1	2	3	4	5	6	7	8
1. CES-D	--	.54**	-.39**	.36**	.43**	-.36**	-.20*	-.21*
2. ZBI		--	-.21*	.48**	.38**	-.47**	-.30**	-.20*
3. EQ5D VAS			--	-.19*	-.37**	.20*	.18*	.04
4. RMBPC-R				--	-.21**	-.21*	-.18*	-.01
5. FAD					--	-.11	-.19	-.10
6. SEQ-SM						--		.19*
7. SEQ-SS							--	.15
8. PAC								

Note.

* p<.01

** p<.001,

CES-D = Centers for Epidemiological Studies Depression Scale; ZBI = Zarit Burden Interview; EQ-5D VAS = Quality of Life Visual Analogue Scale; RMBPC-R = Revised Memory and Behavior Problem Checklist—Reaction Score; FAD = Family Assessment Device; SEQ-SM = Self Efficacy Questionnaire Symptom Management; SEQ-SS = Self Efficacy Questionnaire Support Services; PAC = Positive Aspects of Caregiving