

Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial

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Study Protocol

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Abstract

Background: Informal caregivers of patients with Alzheimer's disease and related dementias (ADRD) manage a complex spectrum of patient behavioral and psychological symptoms of dementia (BPSD). Mobile health information technologies have quickly become sources for modern social support and chronic disease management. These technologies can improve our understanding of how to care for patients with ADRD and their informal caregivers. A mobile telehealth intervention could help reduce caregiver burden and BPSD.

Methods: This is a pilot randomized controlled trial of 60 dyads of patients living with ADRD and their caregivers, to test the feasibility and estimate the effect of the Brain CareNotes (BCN) mobile telehealth system. Participants will be recruited from two health systems. Participants will be randomly assigned to either the BCN intervention arm or usual care comparator. Data will be collected at baseline, 3- and 6-month follow-up. The primary objectives of this trial are to assess feasibility outcomes: (a) recruitment rate; (b) data completion; (c) BCN usability; (d) BCN acceptance; and (e) BCN use, assessed either on an ongoing basis or at 3- and 6-months post-intervention. A secondary objective was to estimate the intervention's effects on caregiver burden and patient BPSD outcomes at 3 and 6 months, assessed by the Neuropsychiatric Inventory.

Discussion: The study will assess the intervention feasibility and effect size of the BCN telehealth system as a potentially scalable and lower-cost solution for addressing the ADRD public health crisis.

Trial Registration: Clinical Trials. NCT03119259. Registered 4/18/2017.
[Clinicaltrials.gov/ct2/show/NCT03119259](https://clinicaltrials.gov/ct2/show/NCT03119259)

Background:

Caring for someone with Alzheimer's disease and related dementias (ADRD) is associated with higher rates of psychological morbidity and burden, social isolation, financial hardship, and deterioration of physical health.¹ Much care is administered by informal caregivers, who are family or friends who provide regular care outside of a formal professional role to those people who are unable to function independently.² In 2019, 16.3 million informal caregivers provided 18.6 billion hours of unpaid care to the 5.8 million Americans living with ADRD.³ This care has been valued at a nationwide contribution of \$244 billion.³ Informal caregivers of patients with ADRD manage a complex spectrum of patients' behavioral and psychological symptoms related to dementia (BPSD); BPSD are major contributing factors to caregivers' burden and adverse health outcomes.^{2,4} Excessive caregiver burden leads to higher unplanned hospitalization rates and poorer quality of life.^{5,6} The National Alzheimer's Project Act recognizes the need for interventions that "enable family caregivers to continue to provide care while maintaining their own health and well-being."⁷ A variety of interventions have been shown to be effective in reducing both BPSD symptoms and caregiver burden.^{8,9,10} However, with the threefold increase of the number of

Americans living with ADRD projected for 2050, an effective intervention would also need to be easily scalable if it were to meaningfully address these problems.¹¹

Mobile health and telehealth technologies offer a means of addressing these issues.¹² Internet-based technologies have been shown to be an effective means of intervention for older adults in general.¹³ Although a recent systematic review suggests potential benefits of mobile applications for persons with cognitive impairment, telehealth applications, which connect patients and informal caregivers to healthcare professionals, were rarely studied in these populations, especially among persons with ADRD and their informal caregivers.¹⁴ However, factors such as age, education, and cognitive impairment can make utilizing this approach less effective, thus highlighting the need for effective design and careful testing for usability, acceptability, and actual use.^{15,16,17}

Methods:

Study Design:

This is a randomized controlled pilot trial of 60 ADRD patient-caregiver dyads to test the feasibility and estimate the effect on caregiver burden and BPSD of the mobile telehealth technology Brain CareNotes (BCN) (see Figure 1). Participants will be recruited from two health systems and randomly assigned to either the BCN intervention arm or usual care comparator. Study participation will last for 6 months.

The primary goal of this trial is to test the feasibility outcomes of: (a) recruitment rate; (b) data completion; (c) BCN usability; (d) BCN acceptance; and (e) BCN use, assessed either on an ongoing basis or at 3- and 6-months post-intervention. Secondly, the trial will estimate the intervention's effect on outcomes of caregiver burden and patient BPSD at 3 and 6 months, assessed by the Neuropsychiatric Inventory.

The target sample was chosen to mirror a dyad-per-research-staff enrollment rate over the course of the trial comparable to what would be needed for a larger trial powered to detect intervention effects on caregiver and patient outcomes. This sample size of 60 dyads was judged to produce adequately precise confidence intervals around estimates of the feasibility outcomes.¹⁸ With this sample size there is also 80% power to detect a large effect size on caregiver and patient outcomes of 0.75 standard deviations between the two groups.

Setting and Participants

This study has a planned enrollment of 60 patient-caregiver dyads. There will be a recruitment of 30 dyads in the intervention arm and 30 dyads in the usual care comparator. Dyads will be recruited from two health systems in Indiana, USA: 1) geriatric clinics specializing in patients with cognitive impairment at Eskenazi Health, a safety net public healthcare system serving Indianapolis, Indiana; and 2) primary care clinics at Indiana University (IU) Health, a nonprofit academic healthcare system. All dyads contain both a patient with a diagnosis of ADRD and an informal caregiver who manages their care. Patients with

ADRD and their caregivers are key intervention targets because they are at high risk of BPSD and BPSD-related adverse effects on caregivers, respectively. BPSD in this population are a top contributor to hospitalization, nursing home placement, and new disease or disability.

Description of Intervention:

The primary intervention of this study is the delivery of the BCN mobile telehealth application (app), a mobile app for informal caregivers of patients with ADRD. BCN delivers 24/7 psychoeducation and caregiver support. In addition, there are caregiver-reported assessment of patient BPSD and tools for self-management and caregiver-clinician communication. BCN provides 24/7 access to information on caregiving delivered through 'bite-sized' CareNotes, which convert evidence-based best practices into simple, single sentences offering practical advice. For example, advice for everyday care during mealtime is to "Offer regular drinks to avoid dehydration." Personal, relatable stories are used to anchor information modules and show how caregiving challenges are universal across cultures. These stories were prepared by dementia care professionals based on past experiences with actual patients. BCN provides patient and caregiver self-assessment tools in the form of the Healthy Aging Brain Care (HABC) Monitor, a clinically validated test of caregiver perceptions of cognitive, functional, and behavioral symptoms and caregiver distress.¹⁹ This assessment is delivered through the mobile app, and securely communicates the results to practicing clinicians. The results of completed assessments are available in real time to clinicians, who presently receive daily alerts indicating new completed assessments and are expected to review and document all new assessments. The results of these assessments are used to personalize the CareNote advice cards given to the caregiver. In this regard, the recommended CareNote advice cards presented to a user are algorithmically selected based on individual item scores on the assessment. Caregivers are also given the ability to browse, save, edit, and arrange recommended advice cards. Lastly, the app offers a secure messaging system that connects caregivers and clinicians. The messaging is available 24/7 to both parties, although clinicians are expected to use the messaging during work hours. In the present delivery of the intervention, community health workers with training in coaching caregivers of persons with dementia on behavioral symptom management receive a daily morning email informing them whether new messages have been received, with the expectation they will check for and respond to messages throughout the day. Regardless of who initiates the messaging, the responsible clinician communicates with caregiver users through the BCN secure messaging system. When a user completes a BPSD self-assessment via the BCN app, this is treated as an assessment comparable to phone or in-person assessment by a clinician and can therefore be used in place of those. However, use of BCN does not replace other services or visits for purposes other than BPSD assessment.

Caregivers in dyads randomized to BCN will receive a HIPAA compliant BCN application link to download the mobile app to their personal mobile device if the device meets minimum technical requirements. If the caregiver does not have a mobile device meeting minimum requirements, a smartphone device with unlimited network data plan from AT&T and the BCN app installed, will be provided by research staff for the duration of the study.

A research assistant (RA) will orient participants to the device, provide training on the BCN software, and troubleshoot technical issues in person or remotely. Participants will receive technical support by phone or electronically by members of the study team, during work hours. They will also be provided paper and in-app help manuals. Hardware, software, and connectivity check-ups will be provided by study research personnel as needed.

Description of Usual Care Comparator:

All patients and informal caregivers in both the intervention and usual care arms will receive usual primary care provided by Eskenazi Health or IU Health. Additionally, usual care for patients with ADRD at Eskenazi Health includes care in the Aging Brain Care (ABC) clinical program, delivered by an interdisciplinary team including expertise in geriatric medicine, social work, and nursing, led by a care coordinator according to an individualized care plan.

Inclusion/Exclusion Criteria:

Participant eligibility criteria are: the patient has received a diagnosis of possible or probable Alzheimer's disease or related dementia from a physician at Eskenazi Health or IU Health; the caregiver is at least 18 years of age and does not have a visual impairment significant enough to interfere with their ability to use BCN; both patient and caregiver are community-dwelling in central Indiana; and both patient and caregiver are willing to participate according to the study protocol. Exclusion criteria are: the patient or their informal caregiver does not have the ability to communicate in English.

Recruitment and Retention

Participants will be recruited from two large healthcare delivery systems in Indiana. Dyads will be screened using the Inclusion/Exclusion criteria listed above by a RC or RA, using each system's respective electronic health records system. Eligible dyads will be called by RAs and RCs to see if they are interested in study participation. To minimize the burden of study participation, subjects will receive the option of remote data collection by phone and data collection at a location convenient to the participants, the default for the latter being the patient's home. Research staff will be in regular contact with participants to maintain engagement.

Due to variation between usual care in the two healthcare systems, study site will be recorded as an indicator to include as a covariate in analyses.

A challenge to the success of the proposed study is achieving adequate enrollment and retention. Enrolling older adults including persons with ADRD is uniquely challenging and retention is complicated by an approximate 8% annual attrition due to death alone. This study will also require enrolling two individuals per dyad, who must consent to a 6-month study period and three assessments.

Ethics & Informed Consent:

This trial was approved by the Indiana University Institutional Review Board (IRB# 1606267154) and is registered on [clinicaltrials.gov](https://www.clinicaltrials.gov) (NCT03119259). Both health systems approved the studies through their internal approval system. The two health systems do not have independent IRBs and instead have an arrangement with the university IRB for their studies. Informed consent will be obtained from the patient or legally authorized representative and separately from the caregiver by a trained RA or RC. Individuals will receive verbal and written information about consent and HIPAA authorization, including answers to all their questions and a copy of the documents. Each individual or their surrogate must provide verbal or written documented consent and HIPAA authorization to participate. Consent by proxy will be used for a patient if any of the following three conditions is met:

1. The patient has an MMSE score = 17
2. The patient is unable to answer any of the following 4 questions correctly:
 - a. What do you understand is wrong with your brain health right now?
 - b. Can you please explain in your own words the choices I have presented to you?
 - c. If you decide to participate in this study, what good things might happen and what harm might occur?
 - d. Can you please explain how you decided to participate (or not participate) in this study?
3. The patient's provider states that the patient does not have the capacity to consent to participation in the study based upon the provider's knowledge of the patient.

When consent by proxy is used, research personnel will also seek the assent of the patient.

Risks of trial participation are expected to be minimal and rare. Participants or their surrogates can choose to withdraw from the study at any time, for any reason. All research personnel are IRB-approved and appropriately trained on confidentiality and enrollment procedures. Eligible and enrolled participants' data will be collected, shared, and maintained in accordance with the IU IRB and HIPAA guidelines. Only IRB-approved study team members will have access to the collected data. In addition, all consented participants will be assigned a unique study identifier upon enrollment. The data will be stored in a secure Research Electronic Data Capture (REDCap) database on a password-protected IU server. REDCap was specifically developed around HIPAA security guidelines.

Randomization:

This randomized controlled pilot trial utilizes a randomization block to sort subjects into the BCN intervention or usual care comparator group in a 1:1 manner. The randomization blocks were created by the PI, approved by an independent biostatistics faculty member, and loaded in REDCap by the team biostatistician. Masking/blinding to randomization was not implemented.

Assessments and Outcomes:

Assessments will be performed at baseline pre-randomization and at 3- and 6-month follow-ups post-randomization, as shown in Table 1. The caregiver is contacted by phone to schedule each appointment. The feasibility outcomes assessed are: (a) recruitment rate, (b) data completion, (c) BCN usability, (d) BCN acceptance, and (e) BCN use. The outcomes measured to estimate effect sizes of the intervention are caregiver burden and patient BPSD. Assessments will be performed by appointment on the phone or in person. Participants will receive \$25 per assessment, up to \$75 in total for the entire project.

Recruitment rate and data completion will be collected via timestamped research records in REDCap on an ongoing basis throughout the duration of the trial. Recruitment rate will be collected continually via timestamped research records in REDCap and computed at the end of the accrual period by calculating # approached, # agreeing, # consenting, and # consenting / # approached. We will also calculate the monthly rate. Data completion will be collected continually in the REDCap study database and computed after the final assessment by calculating # of complete assessments per consenting participant / total possible assessments. We will separately compute missing data and attrition for all causes vs. death in the intervention vs. control groups. A data manager will assist in feasibility data capture and reporting.

BCN usability will be assessed in the BCN intervention group at 3 and 6 months by the Simplified System Usability Scale (SUS),²⁰ a 10-item questionnaire administered to caregivers. The Simplified SUS contains statements about usability (e.g., "Learning to use Brain CareNotes was quick for me") answered on a 5-point response scale (strongly disagree to strongly agree) and is modified from the original validated SUS.²¹ BCN acceptance will be assessed in the BCN intervention group at 3 and 6 months as the mean score on the Behavioral Intention questionnaire administered to caregivers. It is a 4-item questionnaire and uses a 7-point response scale from 0 (not at all) to 6 (a great deal).^{22,23} Behavioral intention is the accepted measure of technology acceptance. BCN use will be collected continually from captured server activity for log-in; survey initiation; survey completion; use of CareNotes advice cards; and messages sent and received. We will compute daily, weekly, and monthly use rates for each use type and for any use at 3 and 6 months.

The Neuropsychiatric Inventory (NPI) will be administered to caregivers, measuring caregiver-reported patient behavior and obstacles to caregiving.²⁴ Informal caregiver burden will be assessed by calculating the NPI-Caregiver Distress score (possible range from 0-60) from the NPI assessed at baseline, 3, and 6 months. Patient BPSD will be assessed by calculating the NPI total score (possible range from 0-144) from the NPI at baseline, 3, and 6 months.

Additional Data Collection:

Demographic data for both the caregiver and patient will be collected after enrollment, including age, gender, race, ethnicity, education level, employment status, annual household income, living situation, and insurance status. The total hours over the previous two weeks the caregiver spent with the patient and the duration of time the caregiver has been caring for the patient will be recorded,. Medical data for the

patient will also be collected. Health literacy will be assessed by the Single Item Literacy Screener (SILS).²⁵

Analyses:

The completeness and distributions of all variables will be checked. We will check the shape of continuous distributions to detect strong deviation from normality and will apply normalizing transformations as needed for highly non-normally distributed variables (e.g., NPI). Internal consistencies of scale scores will be assessed with Cronbach's coefficient alpha. Two-sample t-tests and chi-square tests will be used to compare demographic and clinical characteristics of the participants between the two groups at baseline.

The primary aim is to evaluate the feasibility of BCN as an intervention. The following variables will be determined to test this:

- (a) a recruitment rate per month
- (b) completion on primary outcome measures
- (c) mean score on the 10-item SUS²¹
- (d) BCN acceptance on the Behavioral Intention 3-item scale¹⁷
- (e) % weekly BCN use

Analyses for (a) and (b) will be descriptive in nature and no statistical tests will be calculated. For (c), we will calculate the mean and standard deviation for the composite SUS to calculate the 90% confidence interval. For (d) and (e), we will calculate the proportion of patients with BCN acceptance and weekly BCN use and then calculate 90% confidence intervals.

A secondary aim is to estimate the effect of the BCN intervention on caregiver burden. A linear mixed model will be used to compare the two groups on the mean total NPI-Caregiver Distress scores at 3 and 6 months, using an analysis-of-covariance (ANCOVA) style of model in which the baseline measure of the outcome variable is included as a fixed effect. Time (3, 6 months), intervention (BCN vs. usual care), and the interaction between time and intervention will be included in the model to test for group differences at each time point. If NPI is highly positively skewed, as we have observed in prior research, we will perform a transformation on NPI, such as $\log(NPI+1)$, to satisfy model assumptions. All analyses will be intention to treat (ITT) and additional sensitivity analyses will assess the effect of imputing missing outcomes using several multiple imputation techniques (both missing at random and not missing at random).

Another secondary aim is to estimate the effect of the BCN intervention on BPSD. Analyses will be performed as described above for caregiver burden, except the outcome will be the NPI total score.

Data and Safety Monitoring Plan and Board:

The Principal Investigators and an independent Safety Officer will be responsible for data and safety monitoring, with support from the team's data manager and biostatistician. Research staff will prepare for them a formal report communicating the study's enrollment progress, data collection, and participant safety. Investigators will meet at least every two weeks with the study team to review ongoing study progress and participant safety and will review and discuss every reportable event within 48 hours. The frequency for reviewing data in this study differs according to the type of data and is summarized in Table 2.

All data for each participant will be compiled in a single REDCap database. REDCap offers secure access, regular backup, data validation, and structured data collection via mobile devices for all interviewer-administered assessments. Medical and care process data will be collected from electronic medical records and entered into the REDCap database. Data on device use will be obtained via server queries and uploaded to REDCap. Recruitment process data will be directly input into REDCap by research staff. A staff biostatistician or data manager will perform the merging of all data streams using unique identifiers assigned to the study participants. They will regularly review data for data entry errors and other irregularities.

Special Considerations:

A challenge for this study is ensuring that those randomized to receive BCN have adequate ongoing access to BCN technology. We have addressed this challenge by applying iterative user-centered design and testing of BCN, paying consideration to the needs and abilities of middle aged and older adult caregivers. The user-centered design and testing process included a study of processes and unmet needs of the current clinical program,²⁶ followed by the app designers convening individual and group meeting of caregivers and clinicians to discuss needs and design ideas. Thereafter, we collected initial feedback from caregivers on screen mockups and features, followed by a brief field test of the application with 11 caregivers who used BCN on an Android device. In the post-test usability interview, we assessed caregivers' perceived usefulness, usability, desirability, and credibility of the app and adjusted the app to address problems. When possible, the BCN app is installed directly on the caregiver's smartphone. Those dyads who need a smartphone are provided a smartphone with an unlimited data plan for the duration of the study. We will document the proportion who require such additional assistance, as this may ultimately affect the real-world implementation of an intervention like BCN. Assistance with software installation and subsequent technical support needs are provided for all study participants. We have also budgeted for network and development support to monitor and remediate (e.g., with patches) any emergent technical malfunctions, operating system changes, or security vulnerabilities during the study. These steps are important to reducing the risks of systematically excluding more vulnerable participants and creating or increasing inequalities in technology studies.²⁷

Discussion:

Reducing caregiver burden and minimizing BPSD are important for improving wellbeing and reducing other health risks of ADRD caregiving. Mobile and telehealth technology applications are promising interventions to improve these outcomes in a scalable manner.¹⁴ However, before a technology is deployed to a large sample or in clinical practice, it must be evaluated for usability, acceptance, and potential efficacy. This is especially needed to avoid the potential for harm or waste of effort when the technology is intended for older and cognitively impaired individuals, those who provide them informal care, or other vulnerable groups. The present randomized controlled pilot study aims to collect the necessary evidence to determine the viability of the BCN telehealth system.

If found to be feasible and potentially efficacious, BCN and other mobile technologies have the potential to be scalable. An app such as BCN could be shared with a broad pool of study participants or members of the public through existing public app marketplaces and can be downloaded on personal devices or accessed via a website. Although the cost of an intervention such as BCN would have to be further assessed, once it is built, major anticipated technology costs include software and security maintenance. Additional costs may be related to time spent by a community health worker reviewing data entered by caregivers into the app and participating in secure messaging. A telehealth system also allows collaborative, interdisciplinary care from individuals as diverse as geriatricians, care coordinators, nurses, social workers, community health workers, informal caregivers, and community members. The breadth of involvement and the low barriers to access permit contributions to care from larger “workforces,” for example community health workers, volunteers, or a network of informal caregivers. This is an important advance given anticipated increases in the demand for ADRD care and the limited number and cost of geriatricians and memory care specialty services. Another, more prospective potential for a telehealth system is to deliver care or health coaching through or assisted by artificial intelligence.

Overall, if successful, this pilot study can serve as a test case for a new way of delivering better care to patients with ADRD and their caregivers.

Abbreviations

ABC: Aging Brain Care

ADRD: Alzheimer’s Disease and Related Dementias

BCN: Brain CareNotes

BPSD: Behavioral and Psychological Symptoms of Dementia

HIPAA: Health Insurance Portability and Accountability Act

IRB: Institutional Review Board

IU: Indiana University

HABC Monitor: Healthy Aging Brain Care Monitor

RA: Research Assistant

RC: Research Coordinator

REDCap: Research Electronic Data Capture

SUS: System Usability Scale

Declarations

Trial Status: Enrolling. Date recruitment began: 11/2017. Approximate date recruitment will be completed: 04/30/2021. Latest protocol version approved 05/14/2020 (Amendment 011) Indiana University IRB study # 1606267154.

Competing Interests: MB is the founder of and hold equity in Preferred Population Health Management, LLC, an Information Technology company. The authors have no conflicts of interest to disclose.

Consent for Publication: Not applicable.

Ethics approval and consent to participate: This trial has been approved by the Indiana University IRB. Informed consent will be obtained from all study participants or their surrogates. A sample consent form has been included in the additional documents.

Availability of data and materials: Not applicable.

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Author Contributions: RH and MB developed the theoretical framework of the study. RH and MB planned the study and approved the initial study protocol. TB drafted the manuscript with significant contributions from DM, RH, and MB. TB, JB, BT, and RH were responsible for draft revisions. All authors provided critical feedback and edited the final manuscript.

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Tables

Table 1: Assessment Schedule

	Patient/Caregiver Demographics	Neuropsychiatric Inventory (NPI)	Single Item Literacy Screener	System Usability Survey	Behavioral Intervention – BCN Acceptance
Baseline	✓	✓	✓		
Month 1				✓	✓
Month 3		✓		✓	✓
Month 6		✓		✓	✓

Table 2: Frequency of Review

Data Type	Frequency of Review		
	Each Occurrence	Quarterly	Annually
Self-reported adverse events	X		
Serious adverse event meeting prompt reporting criteria	X		
Summary of serious adverse events		X	
Protocol violations/noncompliance		X	
Summary of adverse events			X
Subject accrual / randomization		X	
Withdrawal rates		X	
Subject complaints		X	
Compliance to interventions		X	
Out of range data			X
Reassessment of risk-to-benefit			X

Table 3: SPIRIT Checklist

Title	1	Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial
Trial registration	2a	Clinical Trials. NCT03119259. Registered 4/18/2017. Clinicaltrials.gov/ct2/show/NCT03119259 , IU IRB: Study # 1606267154
	2b	
		Clinical Trials. NCT03119259 Clinicaltrials.gov/ct2/show/NCT03119259
		4/18/2017
		IU IRB: Study # 1606267154
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		Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial
		Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial
		United States of America
		Alzheimer's Disease, Dementia
		mHEALTH app Brain CareNotes
		Sexes eligible for study: both
		Accepts healthy volunteers: no
		Patient diagnosed with ADRD, Caregiver provides majority of care to patient
		Non-english speaking, HABC score = 0
		Interventional
		Allocation: randomized intervention model
		Primary purpose: harm reduction
		Pilot trial
		11/25/2019
		120 (60 dyads)
		Ongoing

3/30/2020, v1.0

Feasibility of trial for Brain CareNotes app efficacy

NPI total and caregiver burden score (time frame: 6 months; not designated as a safety issue)

Protocol version	3	See Authors, Author Contributions
Funding	4	NIA: Grants Management Specialist: John Bladen, Email: bladenj@nia.nih.gov, Phone: 301-496-1472, Fax: 301-402-3672; Program Official: Melissa S Gerald, Email: geraldmel@nia.nih.gov, Phone: 301-402-4156, Fax: 301-402-0051
Roles and responsibilities	5a	None
	5b	NIA: Grants Management Specialist: John Bladen, Email: bladenj@nia.nih.gov, Phone: 301-496-1472, Fax: 301-402-3672; Program Official: Melissa S Gerald, Email: geraldmel@nia.nih.gov, Phone: 301-402-4156, Fax: 301-402-0051
	5c	The NIA had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.
	5d	N/A
Introduction		
Background and rationale	6a	See Background
	6b	See Methods
Objectives	7	To test the feasibility and estimate the effect on caregiver burden and BPSD of the mobile telehealth technology Brain CareNotes
Trial design	8	
Methods: Participants, interventions, and outcomes		
Study setting	9	Eskenazi Health, a safety net public healthcare system; IU Health,, a nonprofit academic healthcare system
Eligibility criteria	10	See Inclusion/Exclusion Criterion
Interventions	11a	See Study Design, Description of Intervention
	11b	See assessment/outcomes
	11c	None
	11d	N/A
Outcomes	12	See assessments and outcomes

Participant timeline	13	See Figure 1, Assessments and Outcomes
Sample size	14	n= 60 dyads
Recruitment	15	See recruitment and retention
Methods: Assignment of interventions (for controlled trials)		
Allocation – Sequence generation	16a	See Randomization
Allocation – Concealment mechanism	16b	See Randomization
Allocation – Implementation	16c	See Description of Intervention
Blinding (masking)	17a	N/A
Blinding (masking) – emergency unblinding	17b	N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	See assessment/outcomes
Data collection methods– retention	18b	See recruitment and retention
Data management	19	See assessment/outcomes, Data and Safety Monitoring Plan and Board
Statistical methods – Outcomes	20a	See analysis
Statistical methods– additional analyses	20b	N/A
Statistical methods– analysis population and missing data	20c	N/A
Methods: Monitoring		

Data monitoring— formal committee	21a	See Data and Safety Monitoring Plan and Board
Data monitoring— interim analysis	21b	See Data and Safety Monitoring Plan and Board
Harms	22	See Data and Safety Monitoring Plan and Board
Auditing	23	See Data and Safety Monitoring Plan and Board
Ethics and dissemination		
Research ethics approval	24	Done, see attached IRB Approval
Protocol amendments	25	N/A
Consent or assent	26a	See Description of Intervention
	26b	See Description of Intervention
Confidentiality	27	See Ethics & Informed Consent
Declaration of interests	28	See COI Disclosure
Access to data	29	N/A
Ancillary and post-trial care	30	N/A
Dissemination policy	31a	N/A
	31b	See Author contributions
	31c	N/A
Appendices		
Informed consent materials	32	See attached consent form
Biological specimens	33	N/A

Figures

Figure 1

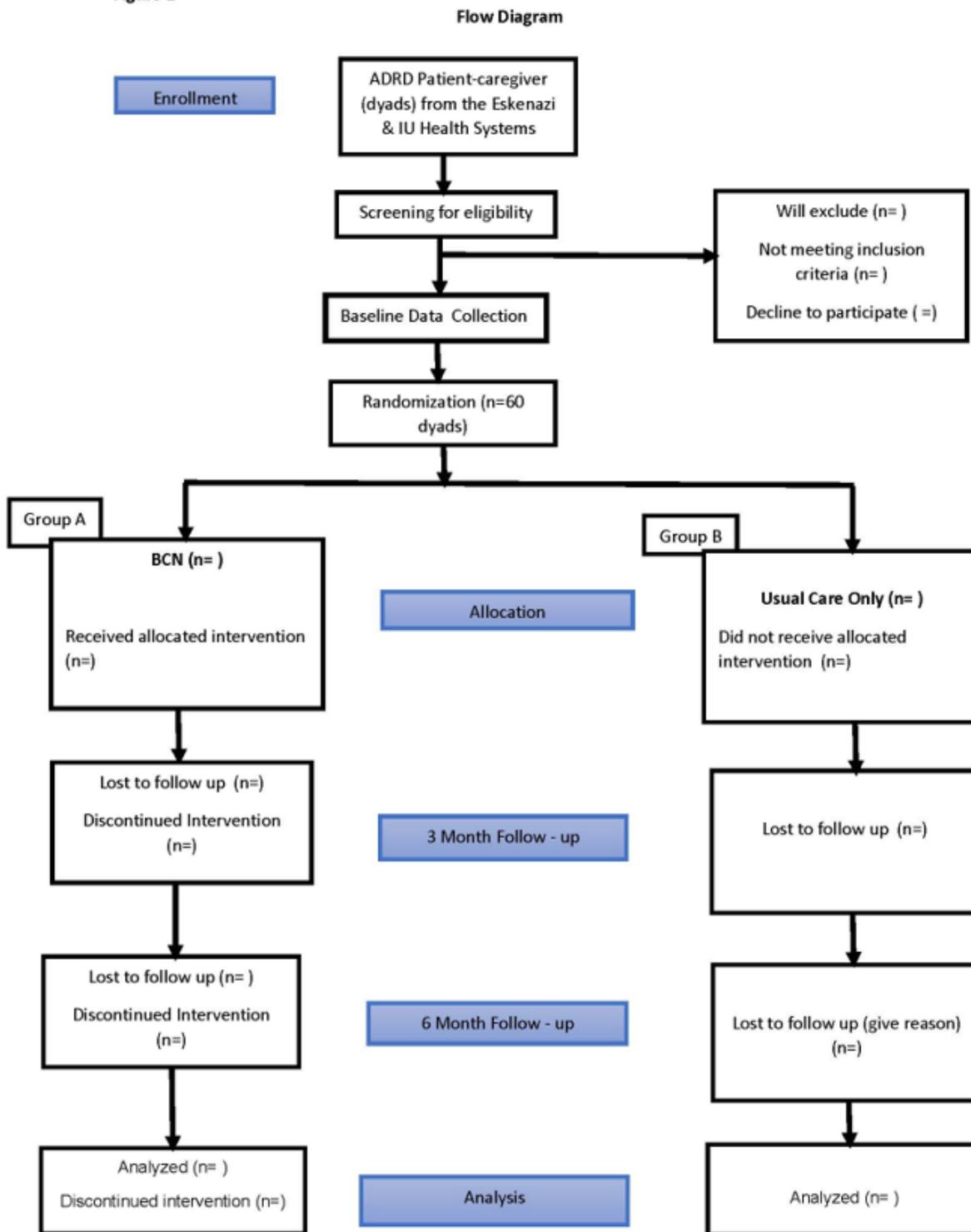


Figure 1

Study Flow Diagram

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRITchecklist.xlsx](#)
- [ApprovalLetterMarch2020Renewal.pdf](#)
- [NIHNOA1R21AG06296601.PDF](#)
- [PilotJournalCoverLetterICARE.docx](#)