

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

Keywords: Alzheimer Disease, Dementia, Brain Diseases, Central Nervous System Diseases, Nervous System Diseases, Tauopathies, Neurodegenerative Diseases, Neurocognitive Disorders, Mental Disorders

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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). 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 BrainCare Notes (BCN) mobile telehealth system. Participants will be recruited from two health systems and randomly assigned to either the BCN intervention arm or usual care comparator. Data will be collected at baseline and 3- and 6-month follow-up. The primary outcomes of this trial are: (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. Secondary outcomes are caregiver burden and patient BPSD 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 potential 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)

Protocol Version 1: Study # 1606267154

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 In 2019, 16.3 million informal or family caregivers provided 18.6 billion hours of unpaid care to the 5.8 million Americans living with ADRD.² 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.^{3,4} 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.¹³ 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.^{14,15,16}

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 BrainCare Notes (BCN) (see Fig. 1). Participants will be recruited from two health systems and randomly assigned to either the BCN intervention arm or usual care comparator. BCN is a mobile telehealth application (app) for informal caregivers of patients with ADRD, which delivers 24/7 psychoeducation and caregiver support, caregiver-reported assessment of patient BPSD, and tools for self-management and caregiver-clinician communication.

The primary outcomes of this trial are 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. Secondary outcomes are caregiver burden and patient BPSD at 3 and 6 months, assessed by the Neuropsychiatric Inventory.

This study has a planned enrollment of 60 patient-caregiver dyads. Dyads are recruited from two health systems in Indianapolis, Indiana, USA: 1) geriatric clinics specializing in patients with cognitive impairment at Eskenazi Health, a safety net public healthcare system; and 2) primary care clinics at Indiana University (IU) Health, a nonprofit academic healthcare system.

The target sample of 60 dyads (30 per group) was chosen to obtain adequately precise statistical estimates of the feasibility outcomes.¹⁷ With this sample size there is also 80% power to detect a large effect size of 0.75 standard deviations between the two groups.

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.

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). Informed consent will be obtained from the patient or legally authorized representative and separately from the caregiver by a trained Research Assistant (RA)

or Research Coordinator(RC). Individuals 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. 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 Indiana University 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 are loaded in REDcap.

Description of Intervention:

The primary intervention of this study is the delivery of the BCN app, an evidence-based mobile app for informal caregivers of patients with ADRD. 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. Personal, relatable stories are used to anchor information modules, and show how caregiving challenges are universal across cultures. BCN provides patient and caregiver self-assessment tools in the form of the HABC Monitor, a clinically validated test on cognitive, functional, and behavioral symptoms and caregiver distress.¹⁸ This assessment is delivered through the app, and securely communicates the results to practicing clinicians. The results of these assessments are used to personalize the CareNotes given to the caregiver. Caregivers are also given the ability to browse, save and arrange recommended Notes, or create their own. Lastly, the app offers a secure messaging system that connects caregivers and clinicians.

Caregivers in dyads randomized to BCN receive a HIPAA compliant BCN app link to download the 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 the study for the study duration.

A research assistant will orient participants to the device, provide training on the BCN software, and troubleshoot technical issues in person or remotely. Participants will receive daytime technical support by phone or electronically. 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:

Patients and informal caregivers randomized to the usual care comparator group 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 led by a care coordinator according to an individualized care plan.

Assessments and Outcomes:

Assessments will be performed at baseline pre-randomization and at 3- and 6-month follow-up post-randomization. The primary outcomes assessed pertain to feasibility and are: (a) recruitment rate, (b) data completion, (c) BCN usability, (d) BCN acceptance, and (e) BCN use. The secondary outcomes 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 assessed on an ongoing basis throughout the duration of the trial. Recruitment rate will be collected continually 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 and computed after the final assessment by calculating # 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.

BCN usability will be assessed in the BCN intervention group at 3 and 6 months by the Simplified System Usability Scale (SUS),¹⁹ a 10-item questionnaire with statements about usability (e.g., “Learning to use Brain CareNotes was quick for me”) and a 5-point response scale (strongly disagree to strongly agree), based on the original validated SUS.²⁰ BCN acceptance will be assessed in the BCN intervention group at 3 and 6 months as the mean score on the Behavioral Intention questionnaire. It is a 4-item questionnaire and uses a 7-point response scale from 0 (not at all) to 6 (a great deal).^{21,22} Behavioral intention is the canonical measure of technology acceptance. BCN use will be collected continually from captured server activity for log-in; survey initiation; survey completion; Notes browsed, saved, created, and edited; assessment history access; 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.

Informal caregiver burden will be assessed by calculating the Neuropsychiatric Inventory (NPI)-Caregiver Distress score (possible range from 0–60) from the NPI assessed at baseline, 3, and 6 months.²³ Patient behavioral and psychological symptoms of dementia (BPSD) will be assessed by calculating the NPI total score (possible range from 0-144) from the researcher-administered 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. We will also record 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. Medical data for the patient will also be collected. Health literacy will be assessed by the Single Item Literacy Screener (SILS).²⁴

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 SUS²⁰; (d) BCN acceptance on the Behavioral Intention 3-item scale;¹⁶ and (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 evaluate the ability of the BCN intervention to reduce 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), the intervention main (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 evaluate the ability of the BCN intervention to reduce 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. They will review a formal report prepared quarterly by research staff, to communicate the study's progress, data collection, and participant safety. Investigators will meet at least every two weeks with the study team to review ongoing study progress, data collection 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 1.

Table 1
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 2
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/NC T03119259, IU IRB: Study # 1606267154 |
| | 2b | |
| | | Clinical Trials. NCT03119259 Clinicaltrials.gov/ct2/show/NC T03119259 |
| | | 4/18/2017 |
| | | IU IRB: Study # 1606267154 |
| | | National Institute for Health |
| | | National Institute on Aging |
| | | TB, BS (tbraly@iu.edu) |
| | | RH, PhD (rjholden@iu.edu) 317-278-5323 |
| | | 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 |
| | | Alzheimers Disease, Dementia |
| | | mHEALTH app BrainCare Notes |
| | | Sexes eligible for study: both |
| | | Accepts healthy volunteers: no |

| | | |
|----------------------------|----------|--|
| Title | 1 | Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial |
| | | 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 BrainCare Notes 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 |

| | | |
|--|----------|--|
| Title | 1 | Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial |
| | 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 BrainCare Notes |
| 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 |

| | | |
|--|----------|---|
| Title | 1 | Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial |
| Outcomes | 12 | See assessments and outcomes |
| Participant timeline | 13 | See Fig. 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 randomiaztion |
| 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 |

| Title | 1 | Technology Intervention to Support Caregiving for Alzheimer's Disease (I-CARE): Study Protocol for a Randomized Controlled Pilot Trial |
|----------------------------------|-----|--|
| 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 |

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 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:

Recruitment and Retention

Participants will be recruited from two large healthcare systems in central Indiana. Burden will be minimized by giving the option of remote data collection and data collection at a location convenient to the participants. Research staff will be in regular contact with participants to maintain engagement.

A possible obstacle is variation between usual care in the two healthcare systems. Patients with ADRD receive additional care at Eskenazi Health, compared to usual primary care at IU Health. Therefore, 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 in-person assessments.

Technology Accessibility and Risks

Another challenge 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 study provides hardware devices and unlimited data plans to those who need them, as well as assistance with software installation and subsequent technical support needs. 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.²⁵

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.²⁶ 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 advantage of being easily scalable. An app such as BCN could be easily shared with a broader pool of study participants or members of the public with very low overhead. 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: Braincare Notes

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

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.

Funding:

ICARE is funded by NIH Grant 1R21AG062966 (Holden & Boustani, co-PIs).

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. All authors provided critical feedback and edited the final manuscript.

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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.

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Figures

Figure 1

Flow Diagram

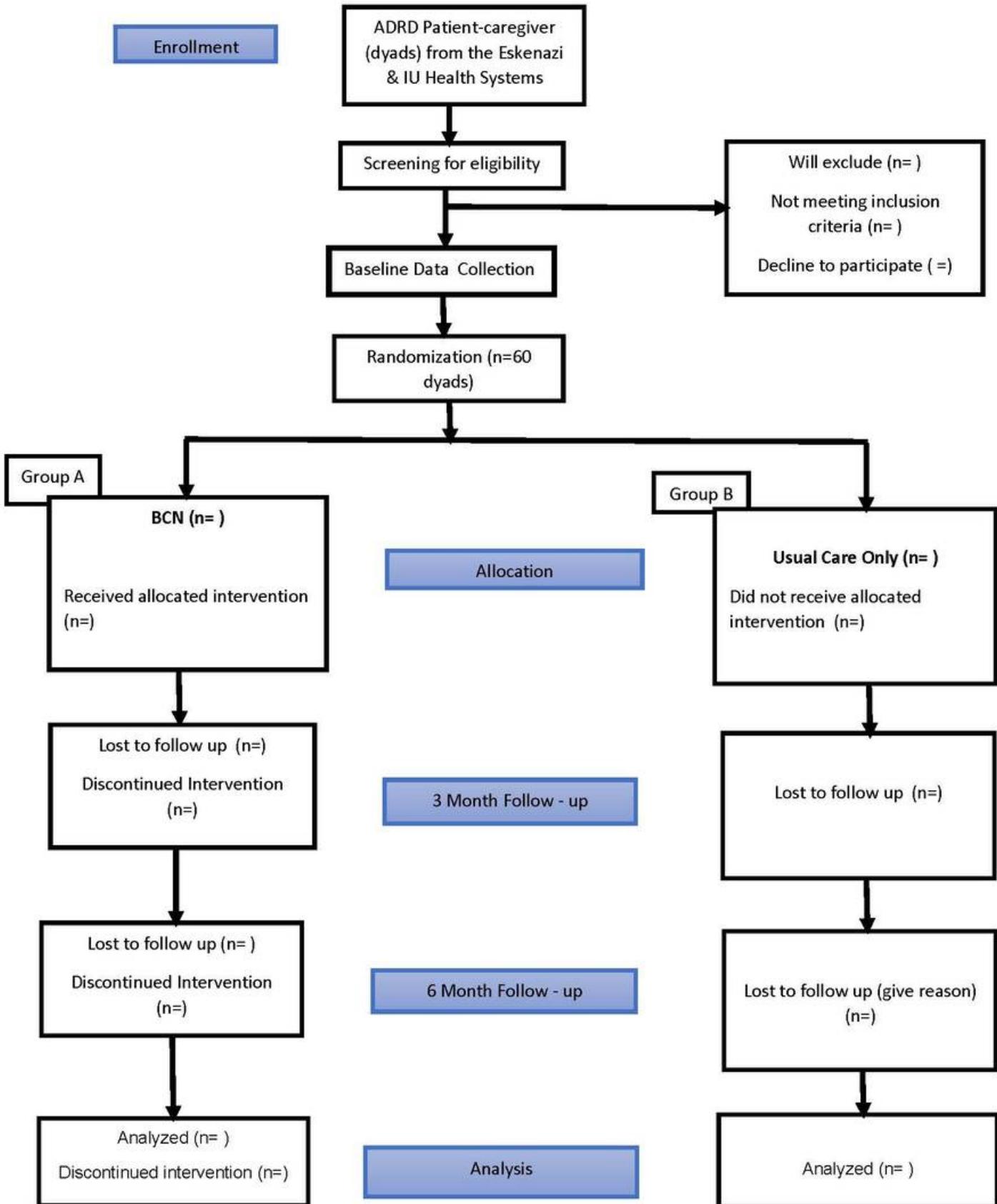


Figure 1

Study Flow Diagram

Supplementary Files

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