INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

I-CARE

This informed consent applies to people involved in managing dementia for themselves or for others.

The following informs you about this research study. Please read this form with care. Ask any questions you may have about this study. Your questions will be answered and you will be given a copy of this document.

1. Who is conducting the study?

The principal investigator is Dr. Richard Holden, PhD, of the Indiana University School of Medicine, Indianapolis. To contact Dr. Holden: (317) 260-1860 , brainsaf@regenstrief.org (e-mail). Portions of this study are sponsored by the US National Institutes of Health (NIH).

2. What is the purpose of this study?

The primary purpose of this study is to test whether adding a mobile health technology application (BCN) to the Aging Brain Care (ABC) Clinical Program and IU Health Physicians Primary Care (IUHP) improves (1) the behavioral and psychological symptoms of patients suffering from Alzheimer's disease and related dementias (ADRD) and (2) the burden of their informal caregivers.

3. What will happen? How long will I be in the study?

We will enroll 60 adult patients receiving care in the ABC clinic and IU Health Primary Care Physician Clinics in Indianapolis and one informal caregiver for each. If you are an ABC clinic patient and agree to participate today, you will be randomized to one of the two study groups: the intervention group (BCN plus ABC Clinical program) or the comparison group (ABC Clinical Program-only). If you are an IUHP patient and agree to participate today, you will be randomized to one of the two study groups: the intervention (BCN only) or the comparison group (Usual care). Each patient and his/her informal caregiver will be treated as one unit (a dyad) in the randomization process. We will enroll 30 dyads in the intervention group and 30 dyads in the comparison group.

If you are *a patient*, then the following things will happen regardless of your group assignment:

a. You (and your informal caregiver) will participate in the ABC Clinical Program or IUHP primary care clinic
b. Study personnel will use the Indiana Network for Patient Care (INPC) to measure your emergency room and hospital visits.
c. Study personnel will collect the following process measures from the ABC Clinical Program tracking software, the eMR-ABC, and from [Eskenazi's/IU Health's] electronic medical record systems: use of anti-dementia medications, antipsychotics, sedatives and care coordination visits.

If you are *an informal caregiver AND you are assigned to the control group*, then the following things will happen:

a. You (and the patient you are caring for) will participate in the ABC Clinical Program and IUHP primary care clinic.
b. Study personnel will conduct a baseline interview with you within about two weeks of enrollment. You will be asked questions about symptoms your patient may be experiencing and your stress related to caregiving. Study personnel will repeat the same interview at 3 and 6 months. All interviews will take place in your home (or other suitable location of your choice) or by phone and the visits by the research staff will be coordinated with you in advance.
c. Study personnel will ask you questions about your emergency room visits, hospital admissions and any unplanned visits to your doctor, at 3- and 6-months interview.
d.
e. Study personnel will collect the following process measures from the ABC Clinical Program tracking software, the eMR-ABC, and from [Eskenazi's/IU Health's] electronic medical record system: use of anti-dementia medications, antipsychotics, sedatives and care coordination visits.

If you are *an informal* caregiver AND you are assigned to the intervention group, then the following things will happen:

a. You (and the patient you are caring for) will participate in the ABC Clinical Program or the IUHP primary care clinic.
b. You will have the BCN software installed on either a personal mobile device (smartphone) if it meets minimal technical requirements or on a device provided by the study, per your preference.
c. Study personnel will orient you to the device, provide training on the BCN software, and troubleshoot technical issues.
d. You will receive daytime technical support by phone or printed and in-app help manuals.
e. Hardware, software, and connectivity check-ups will be provided by study research personnel.
f. Study personnel will conduct a baseline interview with you within two weeks of enrollment. You will be asked questions about symptoms your patient may be experiencing and your stress related to caregiving. Study personnel will repeat the same interview at 3 and 6 months. All interviews will take place in your home or by phone (or other suitable location of your choice) and the visits by the research staff will be coordinated with you in advance.
g. Study personnel will ask you questions about your emergency room visit, hospital admissions and any unplanned visits to your doctor, during the 3 and 6 months interview.
h. Study personnel will use the Indiana Network for Patient Care (INPC) to measure your patient's emergency room and hospital visits.
i. Study personnel will collect the following process measures from the ABC Clinical Program tracking software, the eMR-ABC, and from [Eskenazi's/IU Health's] electronic medical record system: use of anti-dementia medications, antipsychotics, sedatives and care coordination visits.

4. What are the costs to me if I take part in this study?

None.

5. What risks can I expect if I take part in this study?

It is possible that some of the assessment questions could cause discomfort or anxiety. The research personnel will be trained to recognize and minimize any discomfort. While

completing the survey, you can tell the researcher that you feel uncomfortable or do not want to answer a particular question.
Loss of confidentiality is also a risk in this type of data collection. Our data management and quality assurance techniques have proven effective in past trials in maintaining confidentiality, and all study personnel have completed training in Human Subjects Research and HIPAA standards.

6. What are benefits that might result from this study?

a) Benefits to science and humankind that might result from this study: Alzheimer's disease and informal caregiver burden are each recognized as important public health problems. Strategies that improve our understanding of how to care for patients with ADRD and their informal caregivers are urgently needed. Some of potentially beneficial treatments and care approaches are also expensive and difficult to implement so knowledge about their true benefits and cost-saving technological solutions will help us allocate resources more appropriately.
b) Benefits you might get from being in this study: Participation in this proposed study affords access to a greater level of health care with the potential for improved quality and outcomes of care. This may be true for both the experimental and control groups because both are receiving additional care due to participation in the study. Patients and caregivers in the intervention group may personally benefit from the technology-based support provided including improvements in behavioral and psychological symptoms related to dementia.

7. What other things could I do if I decide not to be in this study?

You may choose not to participate in this study. You may choose to stop being in this study at any time, for any reason, and there will be no change to the treatments you now get or could get. This study will not change your treatment. This study has no alternative treatments or options. You may be contacted about other studies.

8. Will I be paid for time spent taking part in this study or for other expenses?

To thank you for your time, you will get $25 for each interview completed by the caregiver. No payment will be made for partially completed interviews.

9. What are reasons why the study's researcher may take me out of this study?

Your participation may be ended by the researcher if they decide there is a safety or health risk.

10. Is this study voluntary? What will happen if I decide to not be in this study?

Being in this study is completely voluntary or up to you. If you do not want to be in the study or want to stop being in the study, there will be no penalty. You will not lose benefits you normally get. Tell the researcher at any time if you want to stop. Please tell your researchers if you have any other worries about the study.

11. Will my information be used for research in the future?

Information collected from you for this study will not be used for future research studies or shared with other researchers for future research. Instead, we would like your permission to contact you for future research studies for which you may be eligible. Please initial one of the following options:_____ Yes, I would like to be contacted for future research studies.
_____ No, I do NOT want to be contacted for future research studies.

12. CONFIDENTIALITY AND PRIVACY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published. Once the study is over, original data will be destroyed.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, any study sponsor, and (as allowed by law) state or federal agencies, such as the Office for Human Research Protections (OHRP), the National Institutes of Health (NIH), etc., who may need to access your medical and/or research records.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:
(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

13. CLINICALTRIALS.GOV

A description of this clinical trial will be available on Clinicaltrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

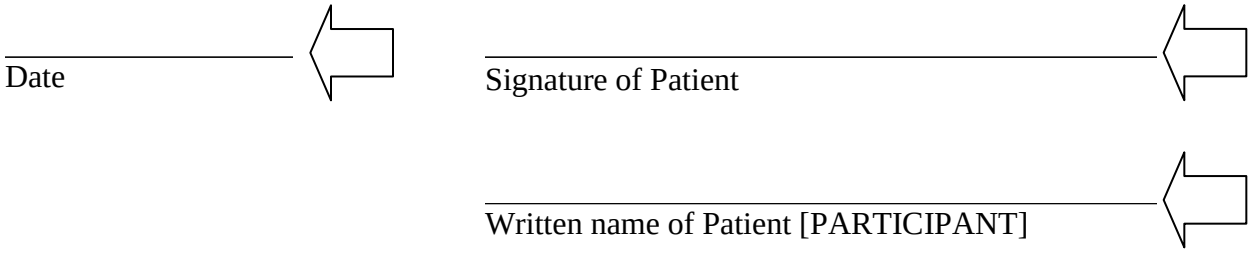
14. CONTACT INFORMATION

For questions about the study, contact the main researcher, Dr. Richard Holden, PhD, (317) 260-1860 , rjholden@iupui.edu (e-mail). If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document.
The material written in it was explained to me verbally.
All my questions have been answered.
I will be given a copy of this informed consent document to keep for my records.
I freely and voluntarily choose to participate.



Date Signature of Patient

Written name of Patient [PARTICIPANT]

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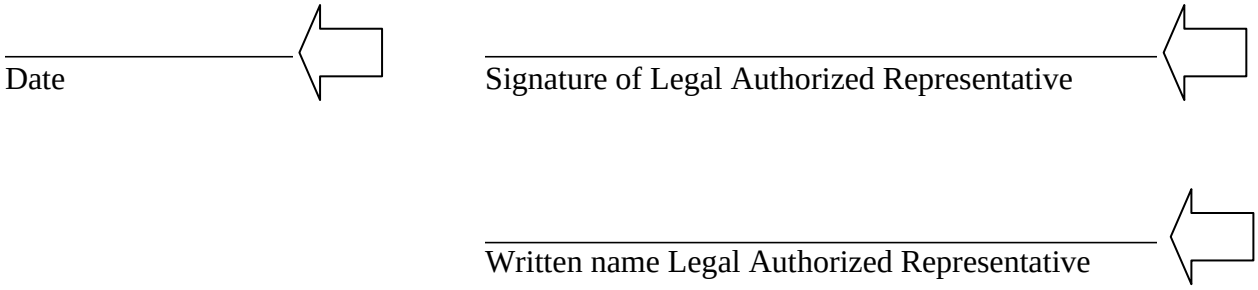
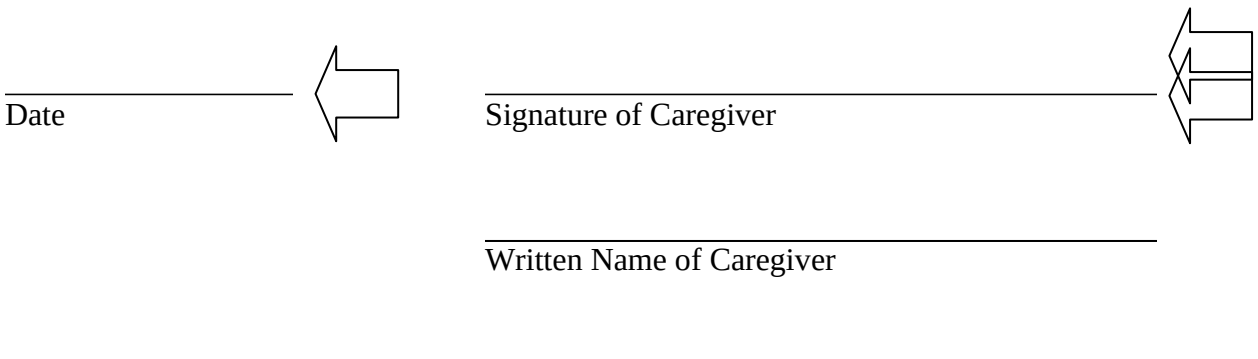


Date Signature of Legal Authorized Representative

Written name Legal Authorized Representative



Date Signature of Caregiver

Written Name of Caregiver

Consent obtained by: Printed Name_____

Signature_____ Date:_____

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