2018

INDIANA PALLIATIVE EXCELLENCE IN ALZHEIMER CARE EFFORTS
- RANDOMIZED CONTROL TRIAL
(IN-PEACE- RCT)

NCT # 03773757

Informed Consent Forms
Dated 3/29/2018

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

INDIANA PALLIATIVE EXCELLENCE IN ALZHEIMER CARE EFFORTS- RANDOMIZED CONTROL TRIAL (IN-PEACE- RCT)

Study # 1707549593

CONSENT FORM: Primary Caregiver (for self) About this research

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this study is voluntary

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to improve the care of people with memory problems or dementia and his/her primary caregiver. We are trying to see if gathering information about people with dementia, from their caregiver, in addition to providing education, management techniques, assistance with decision-making, and support to caregivers, can improve the care of people with memory problems living in the community, especially as the illness advances. Person and caregiver dyads will be randomly assigned to the intervention arm or usual care arm.

You were selected as a possible participant because you are the primary caregiver to someone with memory problems residing in the community setting.

The study is being conducted by Dr. Greg Sachs and the Indiana University Center for Aging Research. It is funded by the National Institutes of Aging (NIA).

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 225 participant-caregiver dyads (450 total) subjects who will be participating in this research. 112 dyads will be in the intervention arm, and 113 dyads will be in the usual care arm of the study.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

All caregivers will be asked a series of questions that will take about forty-five minutes. We will ask these same questions again every three months for two years. Interviews will be conducted in person at the doctor's office, or at the participant's home, based on the preferences of the participant.

Those assigned to the usual care arm will have access to education and informational materials from the local chapter of the Alzheimer's Association and other community resources and will be reminded of these resources throughout the study.

Caregivers assigned to the intervention arm, in addition to the quarterly questions described above, will have monthly phone calls with a Nurse or Social Worker, in the capacity of a Dementia care coordinator (DCC). We are especially interested in gathering information on the symptoms the person with memory problems is having, including: pain, sadness, or other symptoms. The Dementia Care Coordinator will help the primary caregiver and doctor better treat the symptoms the patient is experiencing.

We will be asking the primary caregiver about symptoms the caregiver may be experiencing while caring for the person with memory problems.

We will provide additional education and support to the caregiver in the role caring for someone with memory problems.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

We do not expect any physical risks to participating in this research. You might feel uncomfortable or upset answering some of the questions about the participant's experience with memory loss. There are some questions that could upset some people, though this is not likely to occur. If you are upset by any questions, we can skip those questions or stop the interview. Our social worker or one of our program doctors will be able to speak with anyone who becomes upset and needs additional assistance.

There is also the risk of loss of confidentiality.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

The benefits to participation in the study that are reasonable to expect are: access to a greater level of health care with the potential for improved quality and outcomes of care. Caregivers and persons with memory problems may experience personal benefits including improvements in mood, problem behaviors, and function. The educational and support materials may make home management of symptoms and issues easier for the caregiver. This is the main benefit to your taking part in our program.

WILL I RECEIVE MY RESULTS?

We may learn things about you and the person with memory problems from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Research results may include: ratings of symptom severity for the person with memory problems, behaviors, depression, and stress. Results will be returned if they reach a severity threshold and may require action from primary care provider of the caregiver or person with memory problem. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?

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. No information which could identify you will be shared in publications about this study. The participant's evaluation results will be combined with similar information collected about other subjects. The results will be reported or published

only as totals, averages, and summaries. No one will be able to link any of the reported or published information to the participant. A unique study number, not the participant's name or social security number, will identify his/her evaluation data. Any information that identifies him/her will be kept in a separate, locked file. All electronic identifiable information will be secured on password protected computers. Only study personnel will have access to this information.

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, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the and National Institutes of Health (NIH), etc., who may need to access your medical and/or research records.

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

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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will receive payment for taking part in this study. The caregiver/ person with memory problems dyad, will receive a $30 gift card to a local grocery store as a token of appreciation for completing the baseline and every 3 month outcome assessments for the duration of two years.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study , contact the researcher, Dr. Greg Sachs, at 317-278-5570. After business hours, please call the IU Geriatrics geriatrician on call at (317) 880-0000.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify the Research Assistant at time of withdrawal or at quarterly outcome assessment. The Research Assistant document your intentions to withdrawal from the study.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: research team is unable to complete study activities (outcome assessments, interventions) after reasonable attempts have been made to contact and/or schedule research activities with you. After three consecutive failures to complete research activities, you will be removed from the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature: **Date**:_____

_____

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: **Date**:_____

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

INDIANA PALLIATIVE EXCELLENCE IN ALZHEIMER CARE EFFORTS- RANDOMIZED CONTROL TRIAL (IN-PEACE- RCT)
Study # 1707549593
CONSENT FORM: Primary patient (for self) OR

Proxy consent for person with dementia

About this research

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

[If consent provided by Proxy] Because people with moderate to severe memory problems may have impaired decisional capacity and are unable to provide their own informed consent to participate in research, we are asking you to give consent on behalf of the participant. (The caregiver will sign a separate consent form for his/her participation in this study.)

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this study is voluntary
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to improve the care of people with memory problems or dementia and his/her primary caregiver. We are trying to see if gathering information about people with dementia, from their caregiver, in addition to providing education, management techniques, assistance with decision-making, and support to caregivers, can improve the care of people with memory problems living in the community, especially as the illness advances. Person and caregiver dyads will be randomly assigned to the intervention arm or usual care arm.

You were selected as a possible participant because you have been identified as someone with moderate to severe memory problems residing in the community setting.

The study is being conducted by Dr. Greg Sachs and the Indiana University Center for Aging Research. It is funded by the National Institutes of Aging (NIA).

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 225 participant-caregiver dyads (450 total) subjects who will be participating in this research. 112 dyads will be in the intervention arm, and 113 dyads will be in the usual care arm of the study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

We will ask the primary patient, if they are able to participate in the interview, a series of questions that will take about fifteen minutes. We will ask these same questions again every three months for **two years.** We will asking the primary caregiver questions about the primary patient's symptoms including: pain, sadness, or other symptoms.

The primary patient/ caregivers dyads assigned to the usual care arm will have access to educational and information materials from the local chapter of the Alzheimer's Association and other community resources and will be reminded of these resources throughout the study.

Those caregivers of the dyads assigned to the intervention arm, in addition to the quarterly questions described above, will have monthly phone calls with a Nurse or Social Worker, in the capacity of a Dementia Care Coordinator (DCC).

We are especially interested in gathering information on the symptoms the person with memory problems is having, including: pain, sadness, or other symptoms. The Dementia Care Coordinator will help the primary caregiver and doctor better treat the symptoms the patient is experiencing.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
We do not expect any physical risks to participating in this research. The primary patient might feel uncomfortable or upset answering some of the questions about his/her experience with memory loss. If you are upset by any questions, we can skip those questions or stop the interview. Our social worker or one of our program doctors can be able to speak with anyone who becomes upset and needs additional assistance.

There is also the risk of loss of confidentiality.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
The benefits to participation in the study that are reasonable to expect are: access to a greater level of health care with the potential for improved quality and outcomes of care. Caregivers and persons with memory problems may experience personal benefits including improvements in mood, problem behaviors, and function. The educational and support materials may make home management of symptoms and issues easier for the caregiver. This is the main benefit to your taking part in our program.

WILL I RECEIVE MY RESULTS?
We may learn things about you and your caregiver from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Research results may include: ratings of symptom severity for the person with memory problems, behaviors, depression, and stress.
Results will be returned if they reach a severity threshold and may require action from a primary care provider.

You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?

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. No information which could identify you will be shared in publications about this study. The participant's evaluation results will be combined with similar information collected about other subjects. The results will be reported or published only as totals, averages, and summaries. No one will be able to link any of the reported or published information to the participant. A unique study number, not the participant's name or social security number, will identify his/her evaluation data. Any information that identifies him/her will be kept in a separate, locked file. All electronic identifiable information will be secured on password protected computers. Only study personnel will have access to this information.

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, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the and National Institutes of Health (NIH), etc., who may need to access your medical and/or research records.

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

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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed

before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will receive payment for taking part in this study. The primary patient/caregiver dyad, will receive a $30 gift card to a local grocery store as a token of appreciation for completing the baseline and every 3-month outcome assessments for the duration of two years.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Dr. Greg Sachs, at 317-278-5570. After business hours, please call the IU Geriatrics geriatrician on call at (317) 880-0000.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify the Research Assistant at time of withdrawal or at quarterly outcome assessment. The Research Assistant document your intentions to withdrawal from the study.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: research team is unable to complete study activities (outcome assessments, interventions) after reasonable attempts have been made to contact and/or schedule research activities with the primary caregiver/ primary patient dyad. After three consecutive failures to complete research activities, the primary caregiver/ primary patient dyad will be removed from the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

If the study involves individuals who cannot consent for themselves:

Participant's Printed Name:_____

Printed Name of Legally Authorized Representative (LAR): _____

Signature of LAR:_____ **Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____