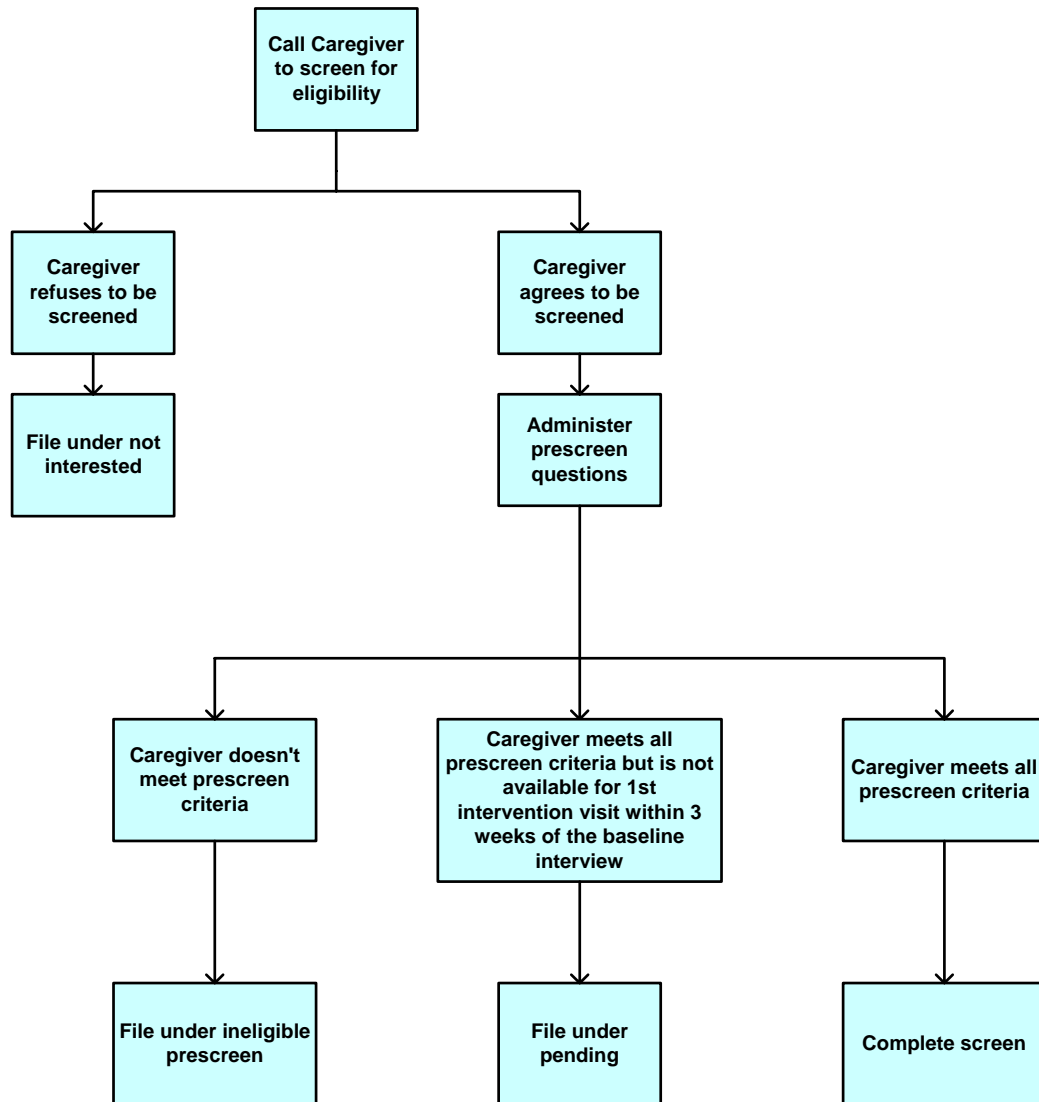


SECTION 4

PROJECT FLOWCHART, RANDOMIZATION PROCEDURES AND SCRIPTS

REACH II Detailed Project Flowchart

A. Initial Eligibility Assessment



Windows:

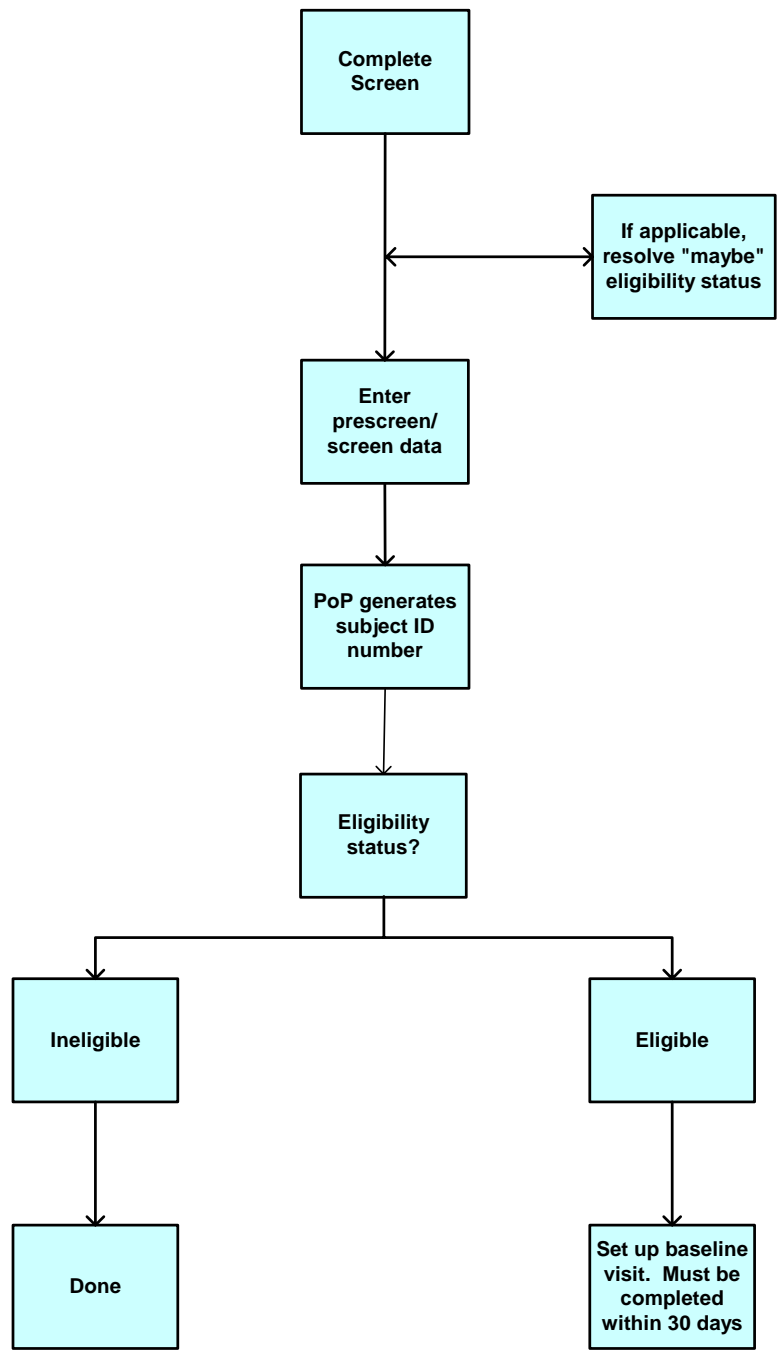
Screen to Baseline - 30 days
 Baseline to Randomization - 3 days
 Baseline to 1st intervention visit - 21 days (goal 1 - 10 days)
 6-month assessment - 7 days prior and 30 days after due date
 Two week turnaround from form completion to data entry

Off Protocol Events:

Baseline interview occurs > 30 days after screen
 Caregiver randomized > 3 days after baseline interview
 First intervention visit outside of 21 day window
 Six month interview completed outside of -7/+ 30 day window

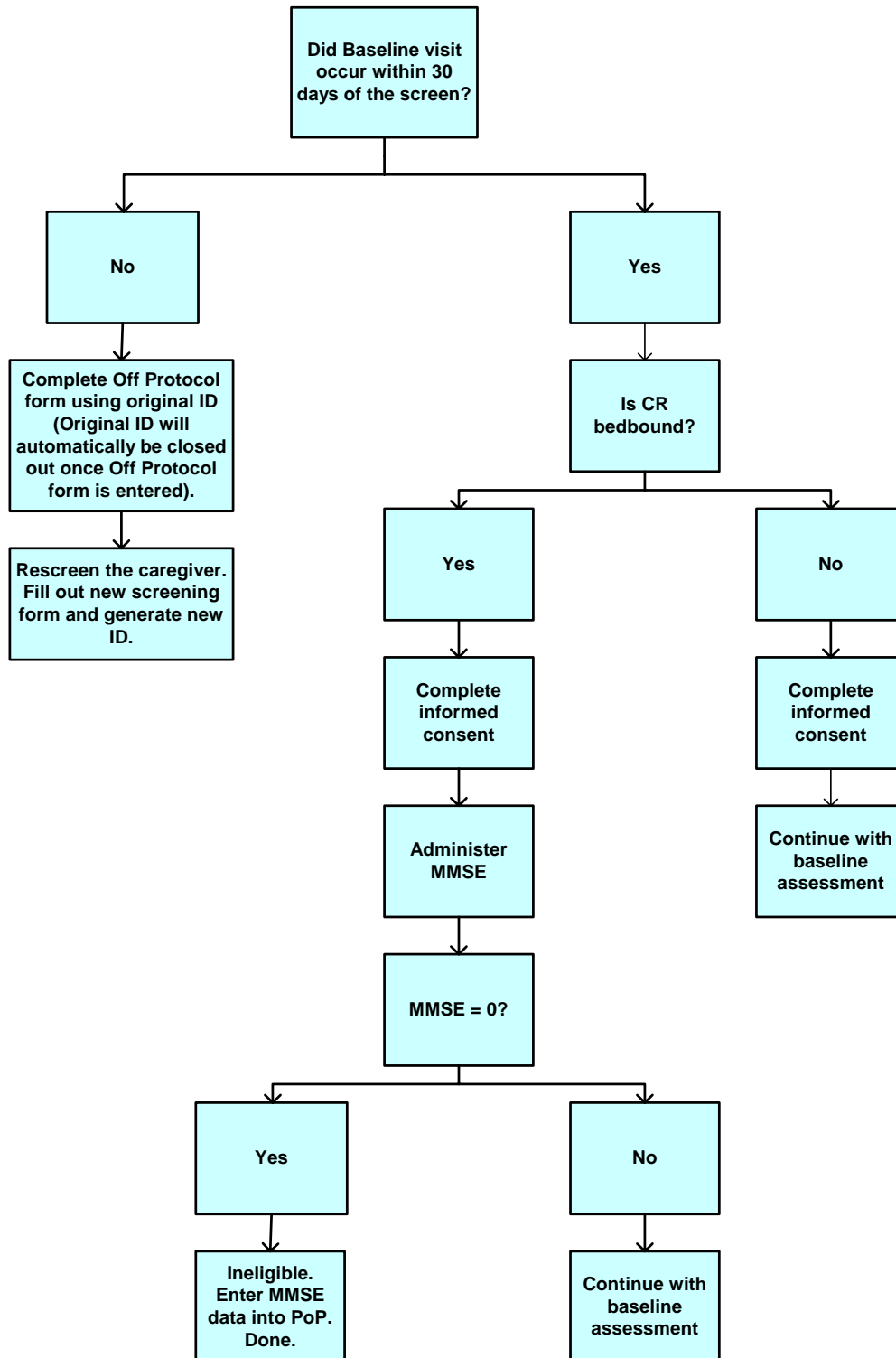
REACH II Detailed Project Flowchart

B. Screen Completion



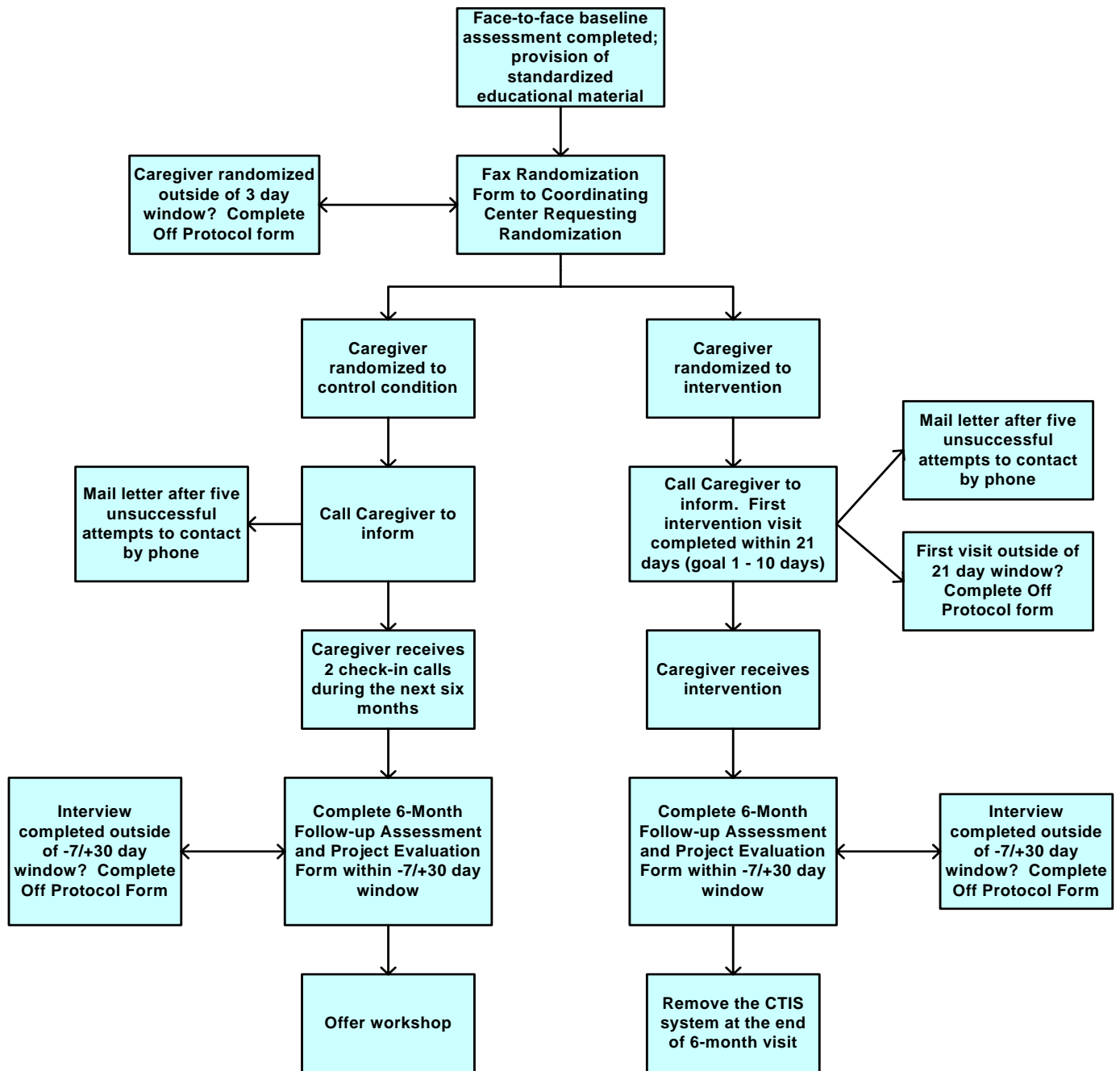
REACH II Detailed Project Flowchart

C. Baseline Assessment



REACH II Detailed Project Flowchart

D. Randomization through 6 Month Follow-up



REACH II RANDOMIZATION PROCEDURES

The randomization procedure will be conducted within the pre-specified strata (CG relationship to CR, and CG self identification (White/Caucasian, Black/African-American, Hispanic/Latino/a). There will be a total of 30 strata (5 sites x 3 race/ethnic groups x 2 relationship groups), each containing approximately 20 subjects. Thus, within each strata, it is expected that 10 persons will be assigned to the active intervention arm and 10 persons assigned to the control condition.

To ensure equal allocation of patients to each arm of the trial (intervention and control) over time, a blocked randomization procedure will be used. The randomization schemes will be prepared before the start of the trial and maintained by the Coordinating Center. Sites will randomize participants by faxing a form, with strata information to the Coordinating Center, thus requesting randomization. The Coordinating Center will then provide the randomization information by faxing a response to the request that contains the assignment (control or intervention) for the participant. The Primary Investigator or the Project Coordinator will maintain log files to assure accuracy and order for the assignments.

TELEPHONE SCREENING FORM SCRIPT

Introduction

Hello, my name is _____ from _____ and

(A) We received (a card/a phone call) from you indicating that you might be interested:

(B) We were given your name by _____ as someone who might be interested:

in a new project called REACH II sponsored by the National Institutes of Health. The purpose of this project is to evaluate the benefits of an in-home program designed to help families caring for individuals with memory problems. (*If referral source unknown ask: May I ask where you heard about our project?*) How are you related to the person for whom you are providing care?

To see if you might be eligible to participate in this project, I would like to take about 10 minutes of your time to ask you some questions. Is this a convenient time?

If yes: Before we begin, let me assure you that anything you say is strictly confidential. Also, there is no cost to participate in this project. Are you ready to begin?

If no: When would be a better time for me to call you back?

Conclusion

Not Eligible: I really appreciate you taking the time to answer my questions. At this time, it does not appear that this program would be good for you. With your permission, we would like to keep your name should there be a program in the future that might be better for you.

Maybe: I really appreciate you taking the time to answer my questions. I would like to review the information you have given me, and call you back to let you know if you qualify for the program. Is this okay? When would be a convenient time for me to call?

Eligible: I really appreciate you taking the time to answer my questions. It appears that this program might be right for you. Let me tell you a little more about what to expect if you decide to participate.

This is a research study of caregivers who care for people with memory problems. Our first visit to you will take about two hours, and we will ask you a variety of questions about both yourself and (CR). We will repeat the same questions after six months, allowing us to see what changes and what remains the same for you.

After the first visit you will be assigned, by chance, to one of two groups. Both groups will receive basic information about caregiving and memory loss and ways to handle the role of a caregiver. If you are assigned to the first group, you will receive up to 9 home visits by a member of the research team staff. During these visits you will be provided with basic information about caregiving and memory loss and learn new ways of managing behavior problems or other areas related to caregiving. A touch-tone screen-phone will also be installed in your home. The screen-phone works like a normal telephone but has additional features that will allow you to interact with a computer system at the University of _____ to access information about caring for someone with a memory problem.

If assigned to the second group, you will receive by mail, helpful information about memory-related problems and caregiving. You will also receive two phone calls to check on how you are doing. At the end of six months you will be invited to a workshop about caregiving and resources that are available to help you provide care.

Each person who joins the study will be paid ___when information is collected at the beginning and when information is collected at six months.

Do you have any questions? Are you willing to participate in the study?

If yes:

With your permission, I would like to arrange a convenient time for _____ to come to your home while your _____(CR) is there and explain this program to you in more detail. This visit should take no longer than two hours. During this visit _____ will provide you with more specific information about the project, will ask you to sign a written consent form giving us your permission to include you in our project, and then ask you some questions about you and _____ (CR's) health and well-being, and some of the difficulties you may be having with taking care of _____(CR).

Some of the questions that we ask will be regarding the prescription and nonprescription medications that you and your family member currently take. To help prepare for this portion of the visit, please place all of your medications and all of your family member's medication in two separate bags prior to the visit.

We will also be asking your permission to record social security numbers and Medicare numbers for both you and _____(CR), so if you could have that information handy as well, we'd appreciate it.

Now, when are the best times to come to your home? _____. Thanks so much for your time and for talking with me.

BASELINE INTERVIEW SCRIPT

Introduction

Thank you for participating in the REACH II project. Your assistance will help us to learn more about how to help people like yourself, provide care of a family member at home. The questions that I will ask you take about two hours. I will be asking a variety of questions about (CR) as well as yourself. They include general background information, questions about your health, activities, and your attitudes or opinions.

All of the information that you give me will be kept strictly confidential. At any time, if you are uncomfortable answering any questions in the survey, you can refuse to answer the questions. You are also free to stop the interview at any time. However, you should know that your answers are very important to us. The completion of the interview is important for scientific purposes.

For most of the questions I will be asking you, there are no right or wrong answers. We are simply interested in your opinions and feelings. If you do not understand any of the questions, you should feel free to ask me to repeat or clarify them. Finally, if you would like to take a break at any time during the session, just let me know.

Conclusion

Thank you for answering our questions. Do you have any questions for me about the REACH II project? At this point I need to go back to my office and randomize you to one of the two groups we discussed. Please remember that this is done randomly or by chance. Someone from the project will call you within the next several days to let you know which group you have been assigned to.

RANDOMIZATION FOLLOW-UP SCRIPT

(This call should be made by the Project Manager or an Interventionist to ensure that the Interviewer remains blind to treatment condition)

Hello, this is _____ from _____ regarding the REACH II project. Is this a convenient time to talk? This will only take a few minutes.

If no: When would be a more convenient time to call you back?

If yes: You have been assigned, by chance, to:

If assigned to intervention: Group A. This is the group in which over the next six months you will receive up to 11 home visit sessions and 5 telephone sessions with a member of our research team who will work with you on areas of caregiving. These visits will provide basic information about caregiving and memory loss and teach new ways of managing behavior problems or other areas of difficulty.

In addition to these visits, a touch-tone screen-phone will be installed in your home. The screen-phone works like a normal telephone but has additional features that will allow you to interact with a computer system at the University of _____ to access information about caring for someone with a memory problem. The system will also allow you to access the research team and will be used for the telephone sessions. Finally, it will allow you to interact with other caregivers like you. You will be taught how to use the system and asked about how useful it was.

If the Project Manager is making the call: I am going to pass your name along to one of our interventionists who will contact you within the next several days to schedule the first home visit. When would be a good time to contact you? I will also give your interventionist some of the information we have talked about so that the two of you will be able to develop a plan to work on some of the caregiving issues we have discussed. Is that ok with you?

If the Interventionist is making the call: My first visit will take about an hour and a half. When would it be convenient for me to come to your home? I also need to ask you a few questions so that we can set up the screen phone prior to coming to your home (refer to caregiver CTIS information sheet).

If assigned to control: Group B. This is the group in which you will receive 2 phone calls to check on you during the next six months. At the end of the six months, you will be invited to a workshop. At this workshop, you will be told about and offered other resources and programs, such as information about community resources and about caregiving and memory loss, and training on new ways of managing behavior problems, stress and coping, or other areas of caregiving difficulty. I'm going to put a package of educational materials in the mail for you this week, and we will be calling you back within the next several months to see how you are doing. Do you have any questions? Thanks again for your involvement with our project.

INTERVENTIONIST 1ST TELEPHONE CONTACT SCRIPT

Hello, this is _____ from the REACH II project at _____.
You've been assigned to the group that will receive home visits and a touch-tone screen phone.
I will be coming to your home to work with you on ways to manage your role as a caregiver.

My first visit will take about an hour and a half. When would it be convenient for me to come to your home? I also need to ask you a few questions so that we can set up the screen phone prior to coming to your home (refer to caregiver CTIS information sheet).

FOLLOW-UP INTERVIEW SCRIPT

Introduction

I appreciate your spending this time with me. About 6 months ago, we asked you a set of questions about you and (CR). Your responses help us to get an idea of what life is like for the two of you. Now that some time has passed, we would like to ask you many of those same questions again. The information you give us will be very helpful as we try to find ways to support caregivers.

I will need about two hours of your time today. Like before, all of the information you give me will be kept confidential, and if you are uncomfortable with a question, you can refuse to answer it. You can also stop the interview at any time, but please remember that the more information you can give us, the more we can learn to help caregivers. Most of the questions have no right or wrong answers. They are questions about your experience, your feelings, or your opinions. If you don't understand a question, feel free to ask me to repeat it or clarify it. We can take a break during the session if you would like to. Do you have any questions before we begin?

PLACEMENT INTERVIEW SCRIPT

Introduction

I appreciate your spending this time with me. About 6 months ago, we asked you a set of questions about you and (CR). Your responses help us to get an idea of what life is like for the two of you. Now that (CR) has moved to a care facility, we would like to ask you many of those same questions again, as well as some new questions. The information you give us will be very helpful as we try to find ways to support caregivers.

I will need about an hour of your time today. Like before, all of the information you give me will be kept confidential, and if you are uncomfortable with a question, you can decline to answer it. You can also stop the interview at any time, but please remember that the more information you can give us, the more we can learn to help caregivers. Most of the questions have no right or wrong answers. They are questions about your experience, your feelings, or your opinions. If you don't understand a question, feel free to ask me to repeat or clarify it. We can take a break during the session if you would like to. Do you have any questions before we begin?

BEREAVEMENT INTERVIEW SCRIPT

Introduction

I appreciate your spending this time with me. About 6 months ago, we asked you a set of questions about you and (CR). Your responses help us to get an idea of what life is like for the two of you. Now that (CR) has passed away, we would like to ask you many of those same questions again, as well as some new questions. The information you give us will be very helpful as we try to find ways to support caregivers, including bereaved caregivers like yourself.

I will need about an hour of your time today. Like before, all of the information you give me will be kept confidential, and if you are uncomfortable with a question, you can decline to answer it. You can also stop the interview at any time, but please remember that the more information you can give us, the more we can learn to help caregivers. Most of the questions have no right or wrong answers. They are questions about your experience, your feelings, or your opinions. If you don't understand a question, feel free to ask me to repeat or clarify it. We can take a break during the session if you would like to. Do you have any questions before we begin?

DISCONTINUED INTERVIEW SCRIPT

Hello Mr./Mrs./Ms. _____. My name is _____ and I am calling from the REACH II project. I understand that ____ months ago you discontinued your participation in the REACH II project. I am wondering if you would be willing to complete the 6 month follow-up interview at this time. This interview would help us to see how things may have changed since we first interviewed you. This would be done during a home visit and would require about one hour of your time. While we are on the phone, could we go ahead and schedule a time for me to come out? Would that be okay with you?

If yes: Thank you. When would be a good time for you?

If no: I realize you're very busy, but I wonder if you would be willing to answer a much shorter set of questions over the phone. This set of questions allows us to collect the most critical information from you without requiring you to spend a lot of time answering questions.

If yes: Thank you very much. We appreciate your participation in the REACH II project. Your participation in completing this short questionnaire will help us to learn more about how to support caregivers. I promise it will only take a few minutes.

I will ask you a handful of the same questions you answered at the beginning of this project so we can see how things may have changed since we first interviewed you.

Like before, all of the information you give me will be kept confidential, and if you are uncomfortable with a question, you can refuse to answer it. Most of the questions have no right or wrong answers. They are questions about your experience, your feelings, or your opinions. If you don't understand a question, feel free to ask me to repeat it or clarify it. Do you have any questions before we begin?

If no: Thank you. Good luck with everything.

CR BEDBOUND & MMSE=0 SCRIPT

(Use upon completion of MMSE (MMSE=0) during baseline interview):

Mr/Mrs. ____ (CG), I would like to take a few moments to talk with you. Would that be ok? You might remember that during the telephone interview, someone from the REACH II team asked you questions about your (CR) being bedbound. She/he probably shared concerns about whether this program would be right for you and mentioned that when I came to meet with you today, I would be asking your (CR) some questions.

At this time, I don't think our program would be helpful to you in caring for your (CR). I would like to leave you with some educational materials on caregiving and dementia and also give you two local phone numbers that you can call to get more information about community resources. I hope this information is helpful to you.

I appreciate you taking the time to talk with me today.

CG UNHAPPY WITH RANDOMIZATION SCRIPT

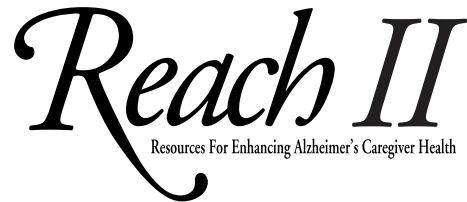
(This script is to be used by the Project Coordinator or person informing study participants of their randomization to ensure that the Interviewer remains blind to the treatment condition):

If assigned to intervention: **Group A**

Hello, Mr/Mrs. ____ (CG). I understand your concerns about participating in Group A, but I want to remind you that your Interventionist, _____, will be sensitive to your needs and structure your participation at a pace that is comfortable for you. Our goal is to help you better understand the problems you may be having as a caregiver for someone with memory loss, and to use the information we learn to help other caregivers like you. We'd appreciate your continuing with the study. You can end your participation at any time, but we hope that you'll remain in the study to help us gain as much information about assisting caregivers as we can.

If assigned to control: **Group B**

Hello, Mr/Mrs. ____ (CG). I understand your concerns about participating in Group B, and I'd like to take a few moments to review some things with you. You'll receive helpful information about memory-related problems and caregiving as well as periodic calls from us to check in and see how you're doing. At the end of the study, you'll also be invited to a workshop to give you further information about caregiving and resources available to you to provide care. Our goal is to help you better understand the problems you may be having as a caregiver for someone with memory loss, and to use the information we learn to help other caregivers like you. We would appreciate your continuing with the study. You can end your participation at any time, but we hope that you'll remain in the study to help us gain as much information about assisting caregivers as we can.



Date

CG Name
CG Address

Dear (CG),

Thank you for completing your first interview with the REACH II Project. This letter is to confirm that you have been assigned, by chance like the flip of a coin, to Group B of the REACH II Project. As a participant in this group, you should expect two telephone calls from us over the next six months. We will simply be calling to check in and see how you are doing. Expect the first of these telephone calls in about three months.

As you know, this project is concerned with developing support services for caregivers of patients with memory problems. We are trying to gain a better understanding of caregivers' experiences in order to develop better ways of helping people like you. Thus, we greatly appreciate having a chance to speak with you over the coming months.

At the end of six months, one of our interviewers will visit you again, asking you questions similar to those in the first interview. Some time after that, you will be invited to a workshop where you will be able to meet other caregivers and learn more from our staff about memory loss, caregiving and local community resources. We will also offer you training in new ways of managing your loved one's behavior problems, coping with stress, and meeting the many other challenges of caregiving.

In the meantime, we are enclosing some educational materials about Alzheimer's disease and caregiving that we hope you will find interesting and informative. We are also providing you with the local telephone numbers of two agencies that can be used as a resource for you in caring for your loved one: The Alzheimer's Association (888) 888-8888 and The Area Agency on Aging (888) 888-8888.

Please contact (name/me) at (888) 888-8888 if you have any questions, concerns or changes to your contact information. Thank you for your cooperation.

Sincerely,

Name
Project Coordinator/Interventionist

Encls