

DESCRIPTION OF PROJECT/STUDY DESIGN

Built upon the findings of REACH I, REACH II was funded in 2001 to design and test a single multi-component intervention among family caregivers of persons with Alzheimer's Disease or related disorders. The overall objectives of REACH II are to 1) identify and reduce modifiable risk factors among diverse family caregivers of patients with Alzheimer's Disease or a related disorder, 2) enhance the quality of care of the care recipients, and 3) enhance the well-being of the caregivers. This competing renewal will build on existing infrastructure and results obtained from its parent multi-site feasibility study, REACH I. REACH I explored the effectiveness of different interventions to reduce burden and distress of family caregivers in six participating sites. Detailed analyses of these data suggest specific components of the REACH I interventions may be efficacious in improving caregiver outcomes.

The design of the REACH II intervention is guided by a careful consideration of the existing literature as well as the experience and findings from REACH I. The overriding message from both of these sources is that caregiving presents multiple challenges that are not easily addressed. As a result, there exists no single, easily implemented, and consistently effective method for achieving clinically significant effects among caregivers or care recipients. The REACH II intervention approach targets multiple components of the stress-health model and focuses on five areas linked to caregiver stress health processes: safety, self-care, social support, emotional well-being; and problem behaviors. Because there is considerable variability in the needs of caregivers, we use a Risk Appraisal Questionnaire to determine how much emphasis we place on each of the treatment components. The tailoring of the intervention will be guided by the individual profiles of the Risk Appraisal. In order to deliver the intervention in a cost-effective manner we use a combination of in-home visits augmented by telephone based technology found to be effective in REACH I.

The study design is a multi-site, two group randomized clinical trial, comparing the active intervention to an information only control. Unlike REACH I, which implemented a variety of active interventions at 6 different sites, this study will implement the same two interventions at each of five participating sites: Birmingham, Memphis, Miami, Palo Alto, and Philadelphia. Across the five sites we expect to enter 600 (120 per site) caregiver-care recipient dyads with a goal of 510 completing the protocol. The 15% missing data rate at six months is based on data from REACH I (5% attrition, 10% missed visits). Differential attrition among race/ethnic groups was not found in REACH I and is not expected in the proposed study. The dyads will be randomized into two equal sized groups, a multi-component core intervention group or a standardized information-only control group. Equal numbers of African Americans/Blacks, Hispanics/Latinos, and Caucasians/Whites will be assigned to the two groups at each site. Thus, each site will enter 120 dyads (40 African Americans/Blacks, 40 Hispanics/Latinos, and 40 Caucasians/Whites) with the goal of completing the six-month assessment.

The study will be conducted in two study Phases. Phase 1 will involve intervention refinement and staff training in how to conduct the new intervention protocol; in Phase 2, the randomized clinical trial will be conducted. A uniform battery of predictor and outcome measures will be collected at baseline and six months. The primary outcome is a multivariate measure comprised of indicators in five domains: depressive symptoms, burden, self-care, social support, and change in problem behaviors. We predict that overall, individuals assigned to active treatment will demonstrate better outcomes on the composite multivariate measure than individuals assigned to the control condition. Cost-effectiveness and clinical significance of the intervention will also be evaluated.

To summarize, this study promises to:

- Test a potent multi-component intervention.
- Assess the intervention's impact on ethnically diverse populations.

- Provide new measurements for assessing the quality of care provided by caregivers and tools for identifying caregivers at risk for adverse outcomes.
- Evaluate the cost effectiveness and public health significance of the intervention.

REACH II CAREGIVER INCLUSION/EXCLUSION CRITERIA

Inclusion criteria:

1. Age: 21 years or older
2. Family member of the care recipient
3. Must live with the care recipient or share cooking facilities
4. Must have a telephone that will enable use of CTIS system
5. Must plan to remain in the recruitment area for the duration of the intervention and follow-up.
6. Caregiver role for more than 6 months
7. Must provide on average 4 hours of supervision or direct assistance per day for the care recipient
8. Risk Screening Tool: must have a total score of at least 1 for questions 1 – 3, and a total of at least 2 for questions 4 – 9

Exclusion criteria:

1. Non-English, non-Spanish speaking
2. Active treatment (chemotherapy, radiation therapy) for cancer
3. Imminent placement of care recipient into a nursing home or with another caregiver (within 6 months)
4. Involvement in another clinical trial for caregivers
5. Participant in REACH I study
6. SPMSQ: ≥ 4 errors (see instructions for second level review on the following page)

REACH II CARE RECIPIENT INCLUSION/EXCLUSION CRITERIA

Inclusion criteria:

1. NINCDS (MD diagnosis) or cognitive impairment (raw score on MMSE of 23 or less)

Exclusion criteria:

1. Non-English, non-Spanish speaking
2. History of Parkinson's Disease or a stroke with no reported decline in memory over the past year.
3. Active treatment (chemotherapy, radiation therapy) for cancer
4. More than three acute medical hospitalizations in past year (other than psychiatric or Alzheimer's Disease related admission)
5. Schizophrenia (onset of delusions before age 45) or other severe mental illness
6. Dementia secondary to head trauma (probable)
7. Blindness or deafness if either disability prohibits them from completion of data collection or participation in the interventions
8. MMSE = 0 and Bedbound (confined to a bed or chair for ≥ 22 hours per day, for at least 4 of the past 7 days)
9. Planned nursing home admission in 6 months
10. Participant in REACH I study

Second Level Review

If the caregiver has been inconsistent with answers or repeated answers, then the interviewer will administer the SPMSQ. If the caregiver misses 4 or more questions, he/she should be excluded from the study.

REACH II MEASURES

The battery of measures developed and used in the REACH II project will be administered to the dyads at baseline and 6 months post-intervention. As shown in Table 1, the battery includes sociodemographic information, measures of caregiver and care recipient health, measures of care recipient functioning, mental health indicators, caregiver burden, social support, quality of care, risk assessment, and service utilization. All participants will complete a project evaluation form at the 6-month assessment point (Tables 2, 3, 4). This questionnaire assesses the caregiver's satisfaction with the project and the caregiver's perceptions of the REACH II Caregiver Network (CTIS system). The REACH II Caregiver Network (CTIS system) also collects real time data on system usage variables such as frequency of use, features selected, individuals contacted, length of call, time and date of call, use of help feature, and duration of feature use per call. Protocols are in place for analysis of these data.

If a care recipient dies during the course of the project, the caregiver will be asked to complete a bereavement battery (Table 3). If the care recipient is placed in an assisted living or nursing home during the course of the project, the caregiver will be asked to complete a placement battery (Table 4). If the caregiver withdraws from the study and does not agree to complete a follow-up battery, a discontinued battery will be administered if caregiver agrees to it.

The primary outcome is a multivariate measure comprised of indicators in five domains: depressive symptoms, burden, self care, social support, and change in problem behaviors. We predict that overall, individuals assigned to active treatment will demonstrate better outcomes on our composite multivariate measure than individuals assigned to the control condition.

Table 1. Baseline Battery Measures

Category	Name of Measure/Form	Citation/Source	Items	Time	Comments	α
Demographic information	CG/CR demographic	REACH I, 1995	21	8 min	Provides basic descriptive data on CGs and CRs.	N/A
CR cognition	MMSE	Folstein et al., 1975	11	12 min*	* Note: this time will not count in CG interview length	.829
CR quality of care	Personal Appearance	Various sources	13	2 min	Interviewer observation of CR's personal appearance	
CR physical impairment	ADL/IADL	Katz et al., 1963 Lawton et al., 1969	18	12 min	CG proxy report of CR functioning	.836
CR behavior	Revised Memory and Problem Behavior Checklist (RMBPC)	Teri et al., 1992	31	15 min	CG proxy report of the problems CR is experiencing	.785
Burden	Revised Memory and Problem Behavior Checklist (RMBPC)	Teri et al., 1992	31	see above	CG is asked about the burden of each behavior	.785
	Burden Interview	Zarit et al, 1985	12	5 min	Items ask about role strain and personal strain in the caregiver	
Positive aspects of caregiving	Positive Aspects of Caregiving	REACH I, 1995	11	3 min	Based in part on other measures of positive aspects (e.g., Lawton et al., 1991)	.906
Vigilance demands	Vigilance	REACH I, 1995	4	3 min	Items ask about time spent supervising CR	
Desire to institutionalize	Desire to Institutionalize	Morycz, 1985	6	3 min	Assesses the CG's desire to institutionalize the CR	
CR medications	CR Medications	REACH I, 1995	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken	N/A
CG medications	CG Medications	CHS	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken	N/A
CG depression	CES-D	Radloff, 1977	13	6 min	Contains 12 of the original 20 CES-D items plus a question regarding the cg's improvement in mood in the past six month.	
Sleep quality	CG sleep quality	Pittsburgh Sleep questionnaire	2	1 min	Measures sleep quality	
Self care and health behaviors	CG self care	REACH I, 1995	4	1 min	Measures ability to care for oneself	
Comorbidities	Comorbidity	(Juster, 1993)	13	5 min	Measures comorbidity.	
Illness and work	Illness and work		3	1 min	Ask time lost at work and activities due to illness	
Overall health	Overall health	Various sources	3	1 min	Assesses CG's view of own general health	
Symptoms	CG symptoms	Jenkins, Kreger, & Hurst, 1980	21	5 min	Measures health symptoms.	
CG disability	CG disability	Schulz, Newsom, Mittelmark, et al, 1997.	2	1 min	Level of disability	
Received support	Received support	Krause, 1995; Barrera et al., 1981	3	8 min	ISSB as modified by Krause	
Social interaction	Lubben Social Network Index (SNI)	Lubben, 1988;	4	N/A	Eliminates helping, and living arrangement questions	
Negative interaction	Negative Interaction Subscale	Krause, 1995	4	N/A	Interpersonal conflict	
Satisfaction with support	Satisfaction with Support	Krause, 1995	4	N/A	Tangible, emotional, information support	
CG religiosity/spirituality	Religiosity/Spiritual Coping	Pargament, et al, 1998 REACH I, 1995	9	4 min	Assess CG's religiosity and the degree to which their faith helps them cope with stress	
CG social activities	Social activities	REACH I, 1995	7	4 min	Satisfaction with the amount of time spent engaging in recreational activities	.835
CG quality of care	Quality of Care	Various sources	40	8 min	Evaluates living environment, aspects of abuse, and exemplary caregiving	
CG risk	Risk Appraisal	Various sources	51	10 min	Questions form an indicator of risk for the CG. Evaluates education, safety, caregiving skills, social support, caregiver emotional and physical well-being.	
Service utilization	Formal Care and Services	REACH I	19	14 min	Includes in-home services & medical services; obtains info about CG and CR and data for cost estimates	N/A
Cost	Formal Care and Services	REACH I	19	see above	Follow-up questions of frequency of use, difficulty with paying for services, and desire for services unable to afford	N/A

Total time estimate for full battery = 115 mins.

Table 2. Follow-up Battery Measures

Category	Name of Measure/Form	Citation/Source	Items	Time	Comments	α
Demographic information	Follow-up Sociodemographics	REACH I, 1995	7	5 min	Modified CG/CR sociodemographic form to fit follow-up situation	N/A
CR cognition	MMSE	Folstein et al., 1975	11	12 min*	* Note: this time will not count in CG interview length	.829
CR quality of care	Personal Appearance	Various sources	13	2 min	Interviewer observation of CR's personal appearance	
CR physical impairment	ADL/IADL	Katz et al., 1963 Lawton et al., 1969	18	12 min	CG proxy report of CR functioning	.836
CR behavior	Revised Memory and Problem Behavior Checklist (RMBPC)	Teri et al., 1992	31	15 min	CG proxy report of the problems CR is experiencing	.785
Burden	Revised Memory and Problem Behavior Checklist (RMBPC)	Teri et al., 1992	31	see above	CG is asked about the burden of each behavior	.785
	Burden Interview	Zarit et al, 1985	12	5 min	Items ask about role strain and personal strain in the caregiver	
Positive aspects of caregiving	Positive Aspects of Caregiving	REACH I, 1995	11	3 min	Based in part on other measures of positive aspects (e.g., Lawton et al., 1991)	.906
Vigilance demands	Vigilance	REACH I, 1995	4	3 min	Items ask about time spent supervising CR	
Desire to institutionalize	Desire to Institutionalize	Morycz, 1985	6	3 min	Assesses the CG's desire to institutionalize the CR	
CR medications	CR Medications	REACH I, 1995	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken	N/A
CG medications	CG Medications	CHS	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken	N/A
CG depression	CES-D	Radloff, 1977	13	6 min	Contains 12 of the original 20 CES-D items plus a question regarding the cg's improvement in mood in the past six month.	
Sleep quality	CG sleep quality	Pittsburgh Sleep questionnaire	2	1 min	Measures sleep quality	
Self care	CG self care	REACH I, 1995	2	1 min	Measures ability to care for oneself	
Comorbidities	Comorbidity	(Juster, 1993)	12	5 min	Measures comorbidity.	
Symptoms	CG symptoms	Jenkins, Kreger, & Hurst, 1980	21	5 min	Measures health symptoms.	
CG disability	CG disability	Schulz, Newsom, Mittelmark, et al, 1997.	2	1 min	Level of disability	
Received support	Received support	Krause, 1995; Barrera et al., 1981	3	2 min	ISSB as modified by Krause	
Social interaction	Lubben Social Network Index (SNI)	Lubben, 1988;	4	2 min	Eliminates helping, and living arrangement questions	
Negative interaction	Negative Interaction Subscale	Krause, 1995	4	2 min	Interpersonal conflict	
Satisfaction with support	Satisfaction with Support	Krause, 1995	4	2 min	Tangible, emotional, information support	
CG religiosity/spirituality	Transition Religiosity/Spiritual Coping	Pargament et al., 1998 REACH I, 1995	8	4 min	Modified versions of Religiosity Form, dropping item that is unlikely to change over the course of the study.	
CG social activities	Social activities	REACH I, 1995	7	4 min	Satisfaction with the amount of time spent engaging in recreational activities	.835
CG quality of care	Quality of Care	Various sources	40	8 min	Evaluates living environment, aspects of abuse, and exemplary caregiving	
CG risk	Risk Appraisal	Various sources	51	10 min	Questions form an indicator of risk for the CG. Evaluates education, safety, caregiving skills, social support, caregiver emotional and physical well-being.	
Service utilization	Formal Care and Services	REACH I	19	14 min	Includes in-home services & medical services; obtains info about CG and CR and data for cost estimates	N/A
Cost	Formal Care and Services	REACH I	19	see above	Follow-up questions of frequency of use, difficulty with paying for services, and desire for services unable to afford	N/A
Program evaluation	Program Evaluation Form	REACH I	21	10 min	Items relate to satisfaction and social validity of the intervention and perception of the CTIS system.	N/A

Table 3. Bereavement Battery Measures

Category	Name of Measure/Form	Citation/Source	Items	Time estimate	Comments
Demographics	Bereavement Sociodemographics	REACH I	6	4 min	Modified CG/CR sociodemographic form to fit bereavement situation.
Service utilization/cost	Transition Formal Care and Services	REACH I	15	10 min	Modified version of the Formal Care and Services form
Sleep quality	CG sleep quality	Pittsburgh Sleep questionnaire	2	1 min	Measures sleep quality
Self care	CG self care	REACH I, 1995	2	1 min	Measures ability to care for oneself
Comorbidities	Comorbidity	(Juster, 1993)	12	5 min	Measures comorbidity.
Symptoms	CG symptoms	Jenkins, Kreger, & Hurst, 1980	21	5 min	Measures health symptoms.
CG disability	CG disability	Schulz, Newsom, Mittelmark, et al, 1997.	2	1 min	Level of disability
CG depression	CES-D	Radloff, 1977	13	6 min	Contains 12 of the original 20 CES-D items plus a question regarding the cg's improvement in mood in the past six month.
Received support	Received support	Krause, 1995; Barrera et al., 1981	3	2 min	Modified Social Support form to fit bereavement.
Social interaction	Lubben Social Network Index (SNI)	Lubben, 1988;	4	2 min	Modified Social Support form to fit bereavement.
Negative interaction	Negative Interaction Subscale	Krause, 1995	4	2 min	Modified Social Support form to fit bereavement.
Satisfaction with support	Satisfaction with Support	Krause, 1995	4	2 min	Modified Social Support form to fit bereavement.
CG Grief	Bereavement	Various sources	25	8 min	TRIG designed to measure grief-related depression; Circumstances Surrounding Death examines CG preparedness
CG social activities	Social activities	REACH I, 1995	7	4 min	Satisfaction with the amount of time spent engaging in recreational activities
CG Risk	Bereavement Risk Appraisal	Various sources	25	10 min	Modified risk appraisal to fit bereavement situation.
CG medications	CG Medications	CHS	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken
Program evaluation	Program Evaluation Form	REACH I	21	10 min	Items relate to satisfaction and social validity of the intervention and perception of the CTIS system.

Table 4. Placement Battery Measures

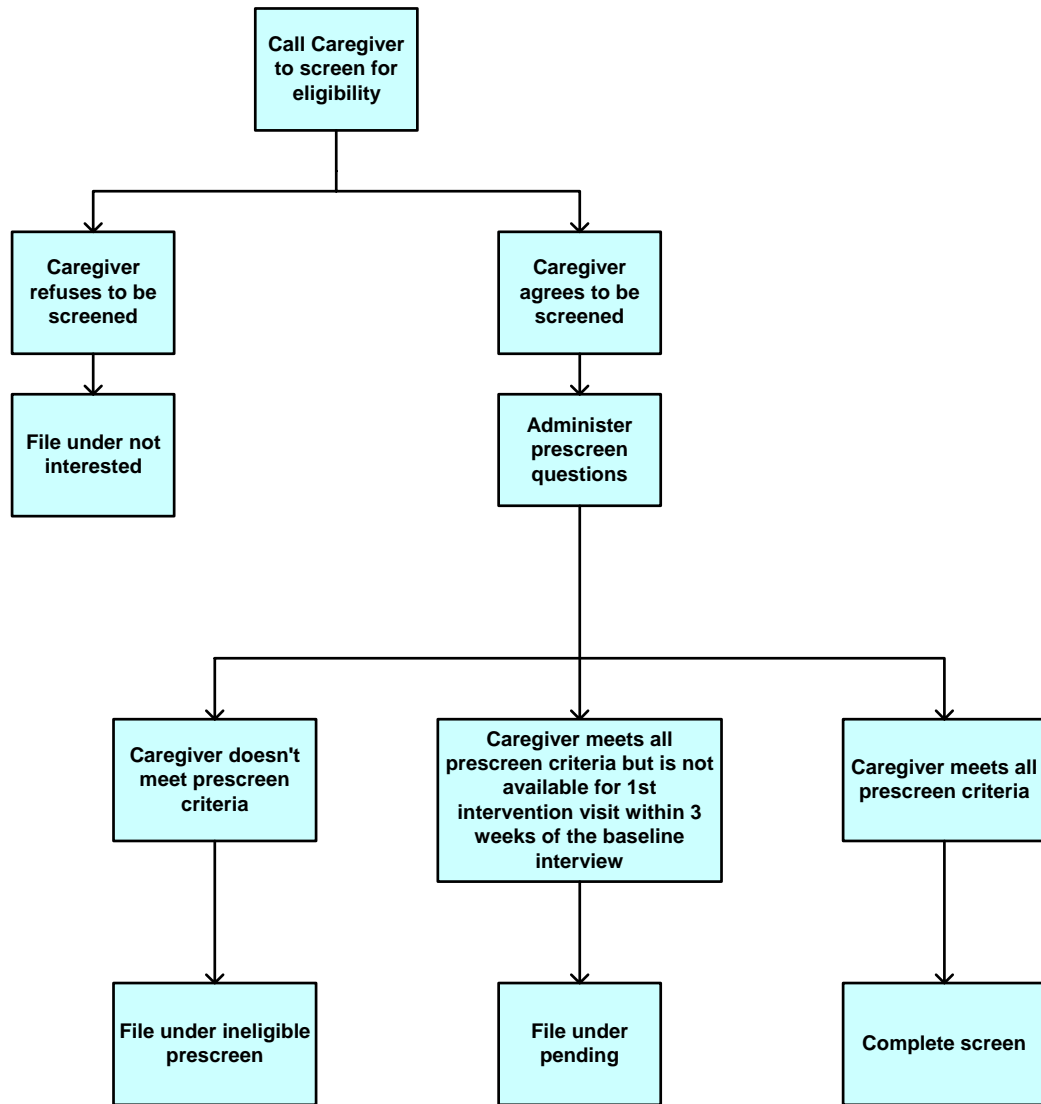
Category	Name of Measure/Form	Citation/Source	Items	Time estimate	Comments
Demographics	Placement Sociodemographics	REACH I	9	8 min	Modified CG/CR sociodemographic form to fit placement situation.
CR behavior	Transition Revised Memory and Behavior Problem Checklist (RMBPC)	Teri, 1992	3	5 min	Assesses perceived change in CR's cognition, behavior and mood
CG burden	Transition Burden Interview	Zarit, 1985	11	5 min	Measure of caregiver burden through questions which address role strain and personal strain of CG
Service utilization/cost	Transition Formal Care and Services	REACH I	15	10 min	Modified version of the Formal Care and Services form
Sleep quality	CG sleep quality	Pittsburgh Sleep questionnaire	2	1 min	Measures sleep quality
Self care	CG self care	REACH I, 1995	2	1 min	Measures ability to care for oneself
Comorbidities	Comorbidity	(Juster, 1993)	12	5 min	Measures comorbidity.
Symptoms	CG symptoms	Jenkins, Kreger, & Hurst, 1980	21	5 min	Measures health symptoms.
CG disability	CG disability	Schulz, Newsom, Mittelmark, et al, 1997.	2	1 min	Level of disability
CG depression	CES-D	Radloff, 1977	13	6 min	Contains 12 of the original 20 CES-D items plus a question regarding the cg's improvement in mood in the past six month.
Received support	Received support	Krause, 1995; Barrera et al., 1981	3	2 min	Modified Social Support form to fit placement.
Social interaction	Lubben Social Network Index (SNI)	Lubben, 1988;	4	2 min	Modified Social Support form to fit placement.
Negative interaction	Negative Interaction Subscale	Krause, 1995	4	2 min	Modified Social Support form to fit placement.
Satisfaction with support	Satisfaction with Support	Krause, 1995	4	2 min	Modified Social Support form to fit placement.
CG religiosity	Transition Religiosity/Spiritual Coping	Pargament et al., 1998 REACH I, 1995	8	4 min	Modified versions of Religiosity Form, dropping item that is unlikely to change over the course of the study.
CG social activities	Social activities	REACH I, 1995	7	4 min	Satisfaction with the amount of time spent engaging in recreational activities
CR placement	Placement	REACH I	16	8 min	Measures extent of help provided by CG, perceived problems with facility, cost of institutionalization
CG risk	Placement Risk Appraisal	Various sources	27	10 min	Modified risk appraisal to fit placement.
CG medications	CG Medications	CHS	2	N/A	Prescription and non-prescription meds from brown bag are listed/coded at sites; length depends on number of meds taken
Program evaluation	Program Evaluation Form	REACH I	21	10 min	Items relate to satisfaction and social validity of the intervention and perception of the CTIS system.

Table 5. Discontinued Battery Measures

Category	Name of Measure/Form	Citation/Source	Items	Time estimate	Comments
CR behavior	Transition Revised Memory and Behavior Problem Checklist (RMBPC)	Teri, 1992	3	5 min	Assesses perceived change in CR's cognition, behavior and mood
CG burden	Transition Burden Interview	Zarit, 1985	11	5 min	Measure of caregiver burden through questions which address role strain and personal strain of CG
CG depression	CES-D	Radloff, 1977	13	6 min	Contains 12 of the original 20 CES-D items plus a question regarding the cg's improvement in mood in the past six month.
Received support	Received support	Krause, 1995; Barrera et al., 1981	3	2 min	Modified Social Support form to fit discontinued battery.
Social interaction	Lubben Social Network Index (SNI)	Lubben, 1988;	4	2 min	Modified Social Support form to fit discontinued battery.
Negative interaction	Negative Interaction Subscale	Krause, 1995	4	2 min	Modified Social Support form to fit discontinued battery.
Satisfaction with support	Satisfaction with Support	Krause, 1995	4	2 min	Modified Social Support form to fit discontinued battery.
CG preventative health risk	Preventative Health	Various sources	13	5 min	Modified risk appraisal –only CG preventative health items.

REACH II Detailed Project Flowchart

A. Initial Eligibility Assessment



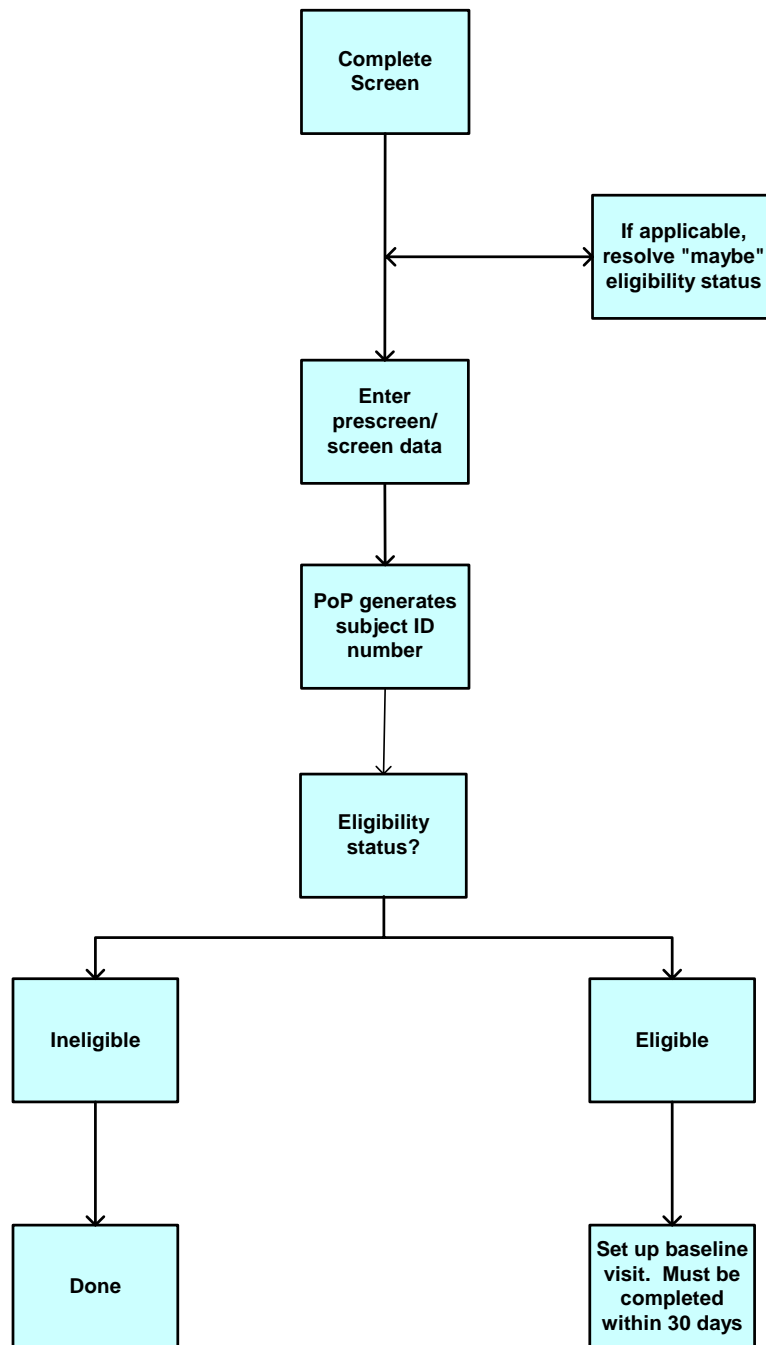
Windows:

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:

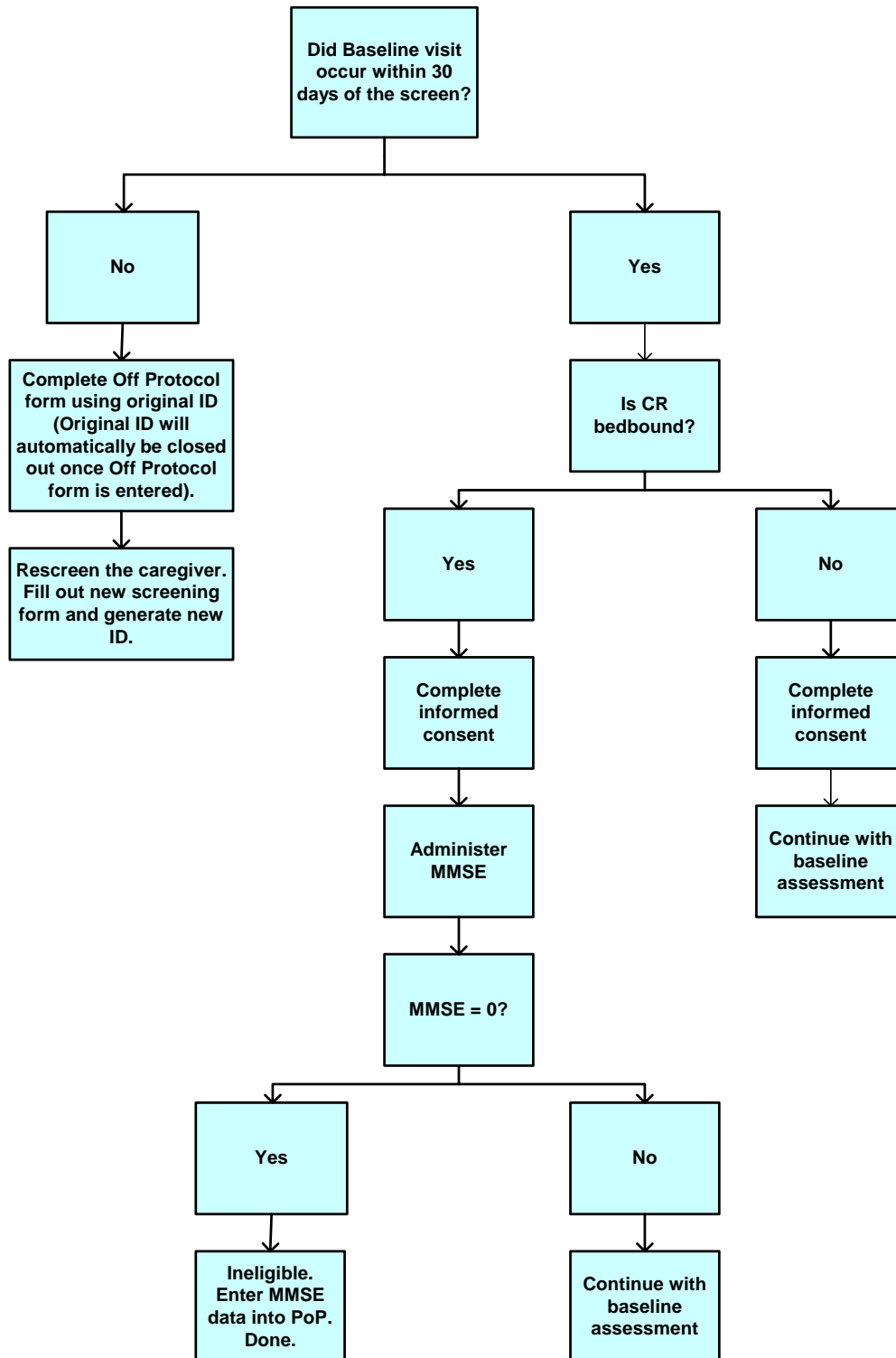
Baseline interview occurs > 30 days after screen
 Caregiver randomized > 3 days after baseline interview
 First intervention visit outside of 21 day window
 Six month interview completed outside of -7/+ 30 day window

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

