

ICPSR 4354

Resources for Enhancing Alzheimer's Caregiver Health (REACH II), 2001-2004

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Questionnaire for OP: Off Protocol Form

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CODEBOOK

Off Protocol Form

(OP)

OFF PROTOCOL FORM

PLEASE USE THIS FORM TO REPORT ANY DEVIATION FROM THE REACH II PROTOCOL

1. Date this form completed ____ / ____ / ____ **OPDAT**
Month Day Year

2. Interviewer's Name: _____
Last, First

2.1 REACH II certification number _____ **CERT**

I. Protocol Deviations (Check all that apply)

Screening

() 3. Rescreening occurred after baseline. **SCGTBA**

3.1 Enter old screening ID: **OLD2**

Randomization

() 4. Ineligible participant randomized. **INELR**

() 5. Wrong treatment assigned. **WTMTA**

() 6. Wrong treatment given. **WTMTG**

() 7. Randomization more than 3 days from baseline interview. **RLATE**

() 8. Randomization completed prior to baseline **RBFRB.**

() 9. Eligible participant not randomized. **EPNRN**

(9.1 Specify: **SEPNR** _____)

() 10. Participant randomized to wrong stratum. **WSTRA**

10.1 Specify which stratum (*check all that apply*)

() CG relation to CR **CGCR**

Incorrect assignment	Correct assignment
() 1. Non-Spouse	() 1. Non-Spouse
() 2. Spouse RELAI	() 2. Spouse RELAC

() CG identity **CGID**

Incorrect assignment	Correct assignment
() 1. Hispanic	() 1. Hispanic
() 2. White	() 2. White
() 3. Black IDI	() 3. Black IDC

Core Battery

() 11. Interview conducted by non-certified individual. **NONC**

() 12. Interview completed over the phone. **PHDON**

() 13. Follow-up missed. **FOMIS**

13.1 Specify which follow-up: **MISS**

3-month control call	5-month control call	6-month follow-up interview
1 ()	2 ()	3 ()

() 14. Follow-up completed outside of the window. **FOOUT**

14.1 Specify which follow-up: **LATE**

3-month control call	5-month control call	6-month follow-up interview
1 ()	2 ()	3 ()

() 15. Project Evaluation not completed. **PENCO**

() 16. Mini-Mental completed at a different time than core battery. **MMDCB**

() 17. Mini-Mental not completed. **MMNCO**

() 18. Interview required multiple sessions. **IRMSS**

18.1 Number of sessions required to complete interview: **NUMSS**

Intervention

IGT21 () 19. First intervention session greater than 21 days from randomization

Intervention Refusals

- CTISP** () 20. CTIS phone.
CTISS () 21. Participation in CTIS support groups.
CGNBK () 22. Caregiver notebook.
HOMEV () 23. Home visits.
BEHPR () 24. Behavioral prescriptions.
SMNGM () 25. Stress management module.
INALL () 26. Further participation in intervention.

Endpoint Data Unavailable

INCO () 27. Interview incomplete - Caregiver withdraws consent after interview started.

INCOS (27.1 Specify: _____)

CGWCN () 28. Caregiver withdraws consent.

- CHCG** () 28.1 Change of caregiver.
CGFST () 28.2 Caregiver felt that the study was too time consuming.
CGDRN () 28.3 Caregiver is displeased with randomization.
ILLNS () 28.4 Illness.

ILLCG () 28.4.1 Caregiver.
ILLCR () 28.4.2 Care Recipient.

CRDE () 28.5 Care Recipient Death.

CGWOR () 28.6 Other reason.

ORSPE (28.6.1 Specify: _____)

LOCUK () 29. Caregiver cannot be located / location unknown.

CGDE () 30. Caregiver death.

CGEXC () 31. Caregiver excluded from study.

EXC1-EXC2 (31.1 Specify: _____)

Other Protocol Deviation

OTOP () 32. Other.

OTOP1-OTOP2 (27.6.1 Specify: _____)