

DATA AND SAFETY MONITORING BOARD (DSMB) SAMPLE REPORTS

The following pages contain sample tables and figures that will be included in interim monitoring reports submitted to the DSMB. Some of the tables and figures have been partially or fully completed (based upon fictitious data) to illustrate how the REACH II investigators expect they may look upon completion of the study, and to provide a clearer picture of how the tables will be formatted.

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II. Recruitment and Subject Status

Table 1. Enrollment by Site and Race

Date: _____

Site	Randomized		Eligible Pending Randomization			Eligible Not Randomized	Eligible Not Randomized			Screened Not Eligible			Screened
	Control	Active	Past 30 Days	Past 60 Days	Total	Current	Past 30 Days	Past 60 Days	Total	Past 30 Days	Past 60 Days	Total	Total
Birmingham:	30												
Black	10												
White	10												
Hispanic	120												
Memphis:													
Black													
White													
Hispanic													
Miami:													
Black													
White													
Hispanic													
Palo Alto:													
Black													
White													
Hispanic													
Philadelphia:													
Black													
White													
Hispanic													
Total													

Category Definitions: Randomized – Participants that met all inclusion/exclusion criteria and consented to participate in study.
 Eligible Pending Randomization – Participants that met all inclusion/exclusion criteria but consent to participate in study is pending.
 Eligible Not Randomized – Participants that met all inclusion/exclusion criteria and refused to participate in study.
 Screened Not eligible – Participants screened that did not meet inclusion/exclusion criteria.
 Screening – All participants screened for the study.

Figure 1.a Comparison of Target to Actual Cumulative Enrollment by Month (Overall)

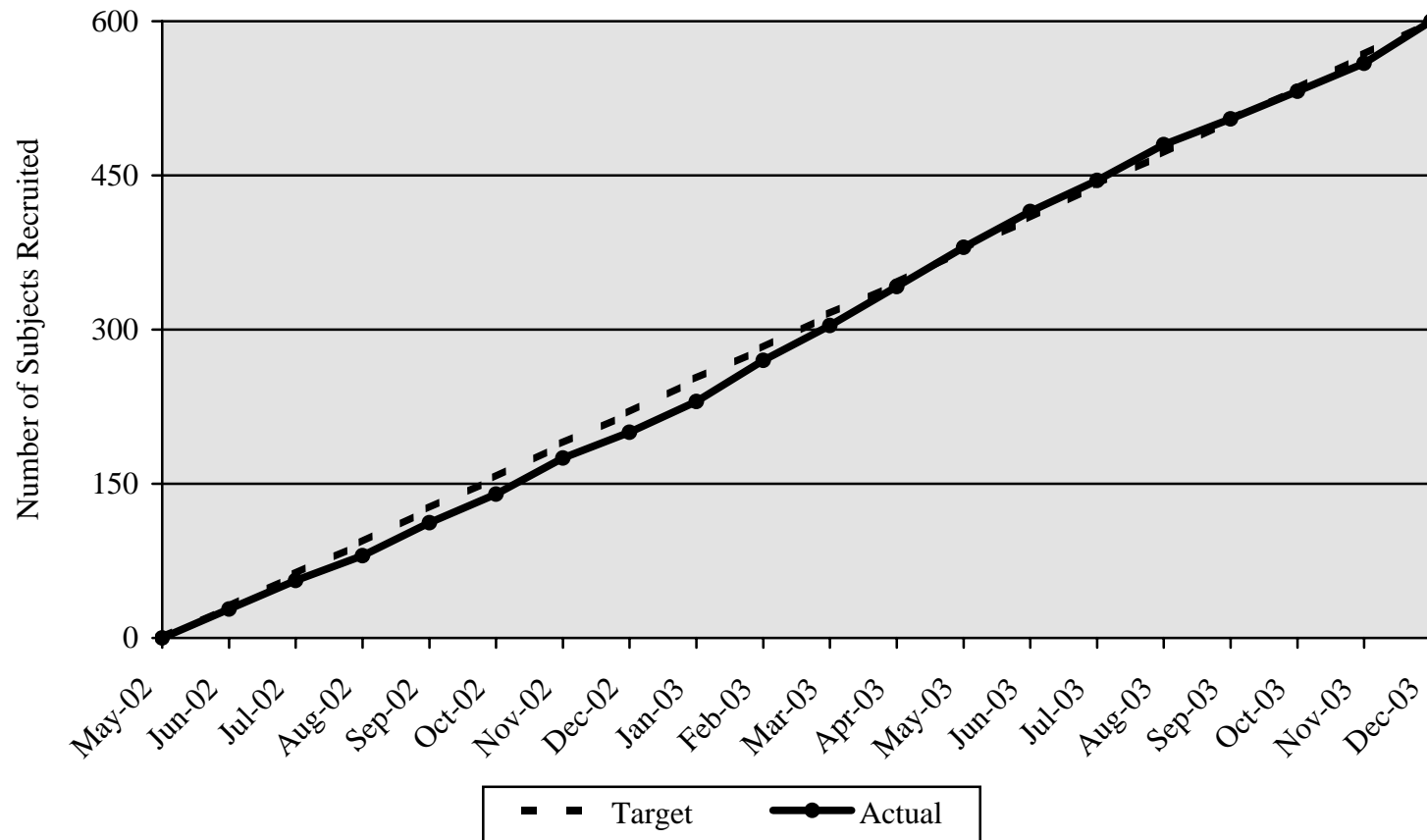


Figure 1.b Comparison of Target to Actual Cumulative Enrollment by Month (Black/African-American)

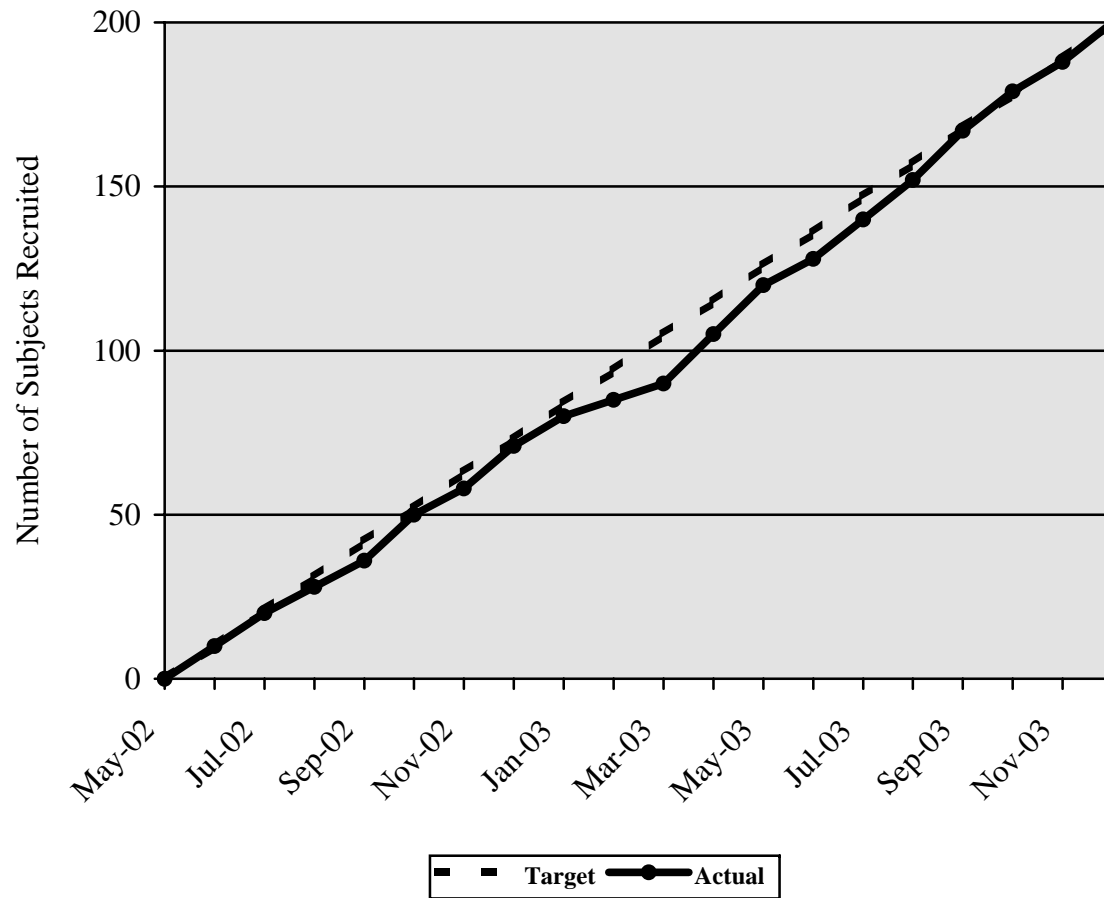


Figure 1.c Comparison of Target to Actual Cumulative Enrollment by Month (White/Caucasian)

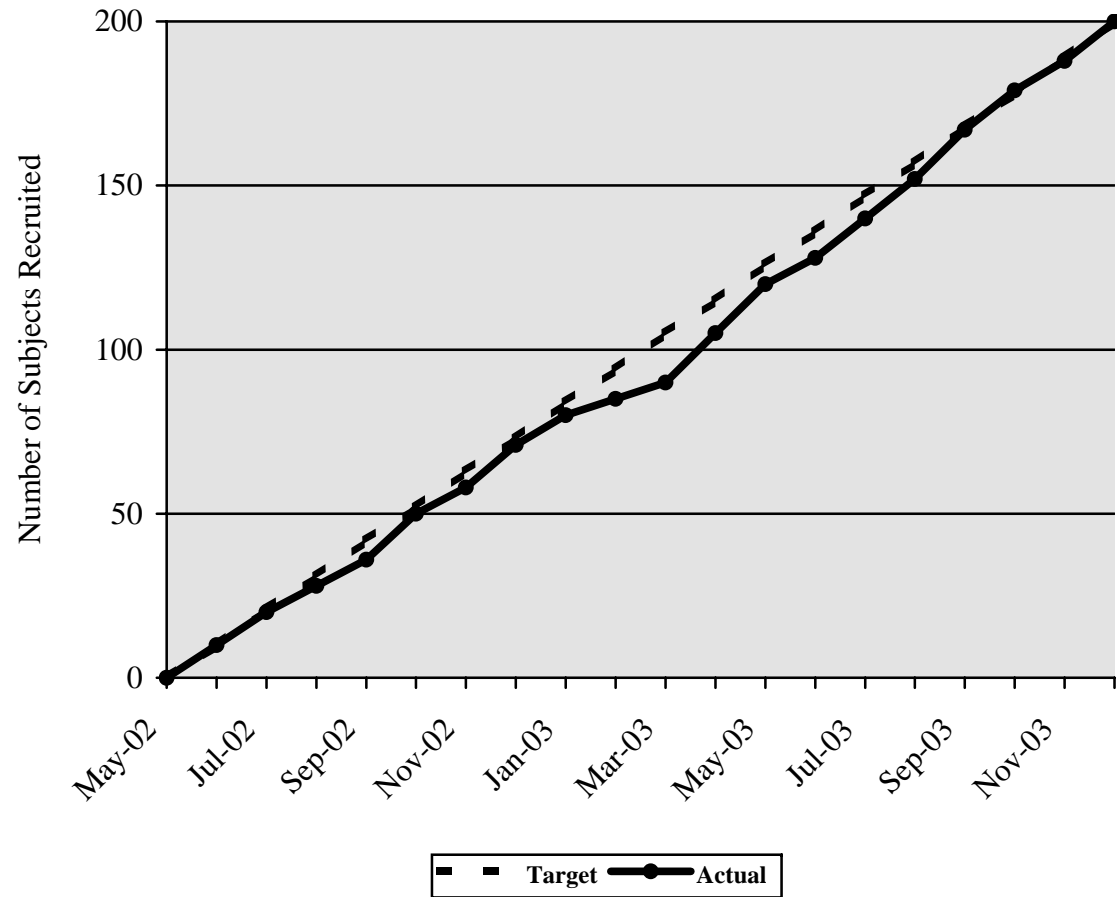


Figure 1.d Comparison of Target to Actual Cumulative Enrollment by Month (Hispanic/Latino)

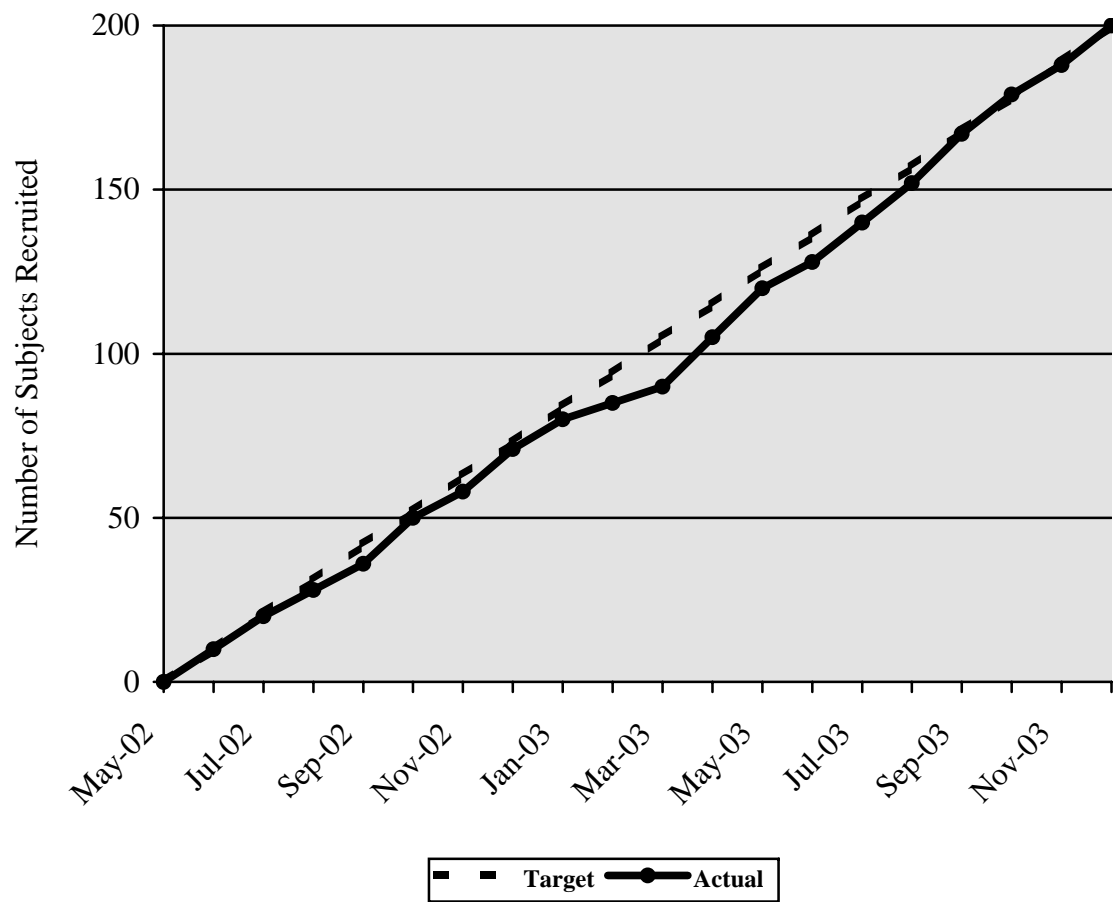


Figure 2.a Comparison of Target to Actual Enrollment by Site (Overall)

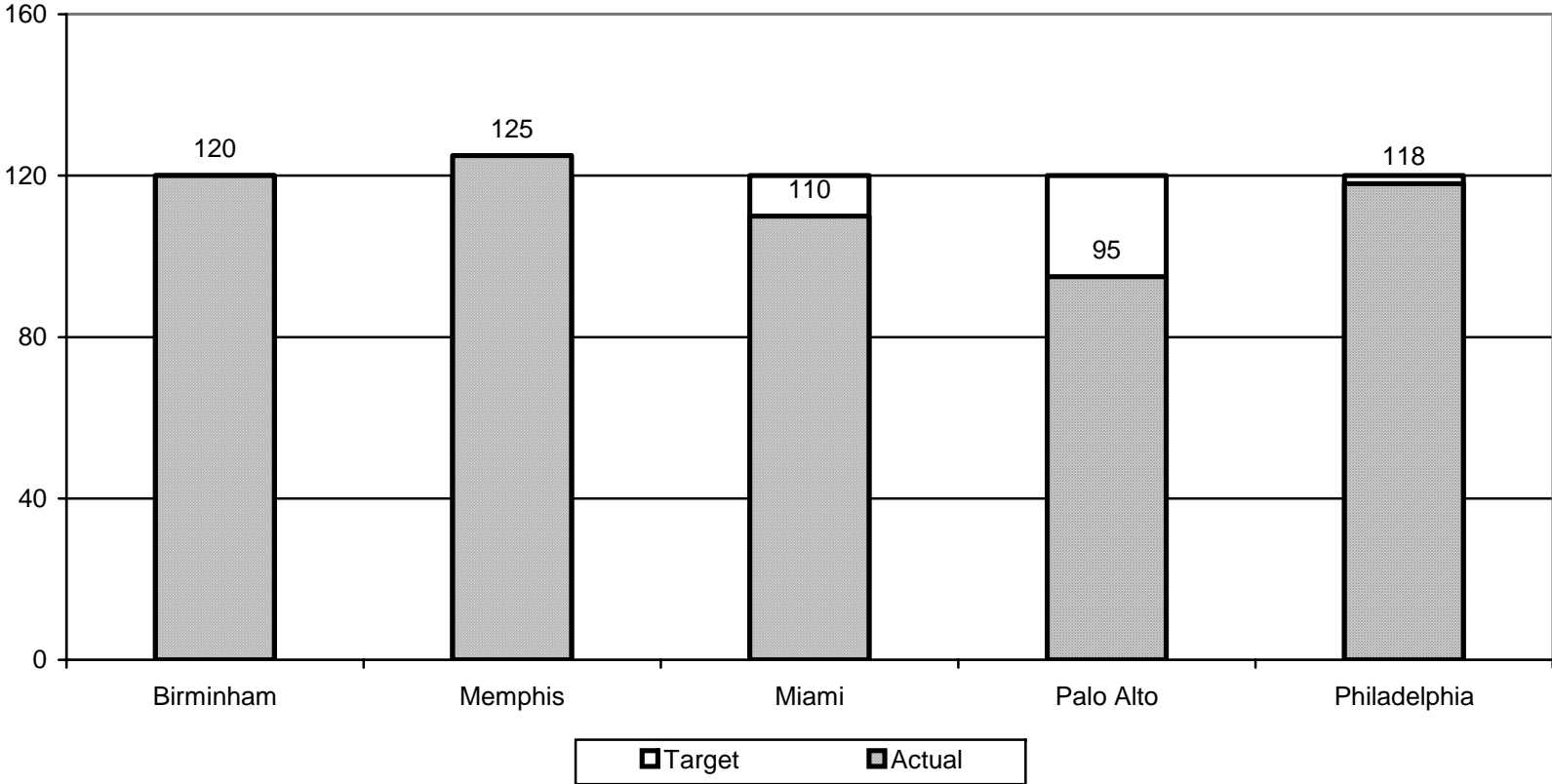
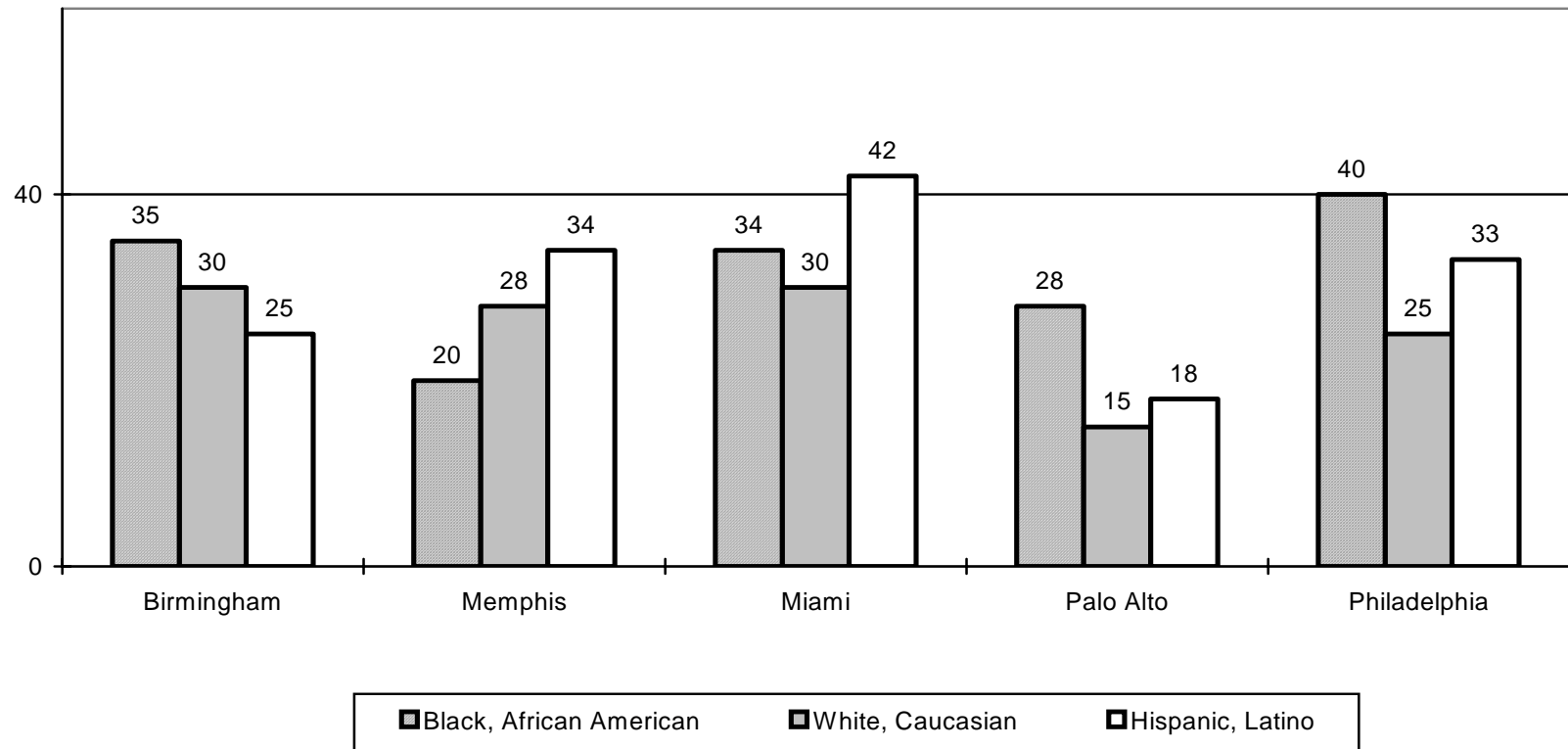


Figure 2.b Comparison of Target to Actual Enrollment by Site by Race¹



¹ 40 is expected number

III. Description of Study Sample

Table 2a: Caregiver Characteristics by Race/Ethnic Identity

	Black		White		Hispanic		TOTAL	
	N	%	N	%	N	%	N	%
Age								
Median (range)								
Mean (sd)								
Sex								
Male								
Education								
Did Not Finish HS								
HS Diploma								
Post-HS Education								
Marital Status								
Married								
Not Married								
Caregiver Income								
Less than \$20,000								
\$20,000 - \$39,999								
\$40,000 and above								
Years living with CR								
Median (range)								
Mean (sd)								
Relationship to CR								
Spouse								
Child								
Sibling								
Other								
Employed								
Full or Part Time								
Retired								
Unemployed								
CES-D								
Median (range)								
Mean (sd)								
RMBPC								
Median (range)								
Mean (sd)								

Table 2b: Caregiver Characteristics by Race/Ethnic Identity and Treatment Group

	Black n =		White n =		Hispanic n =		TOTAL n =	
	Control n (%)	Active n (%)	Control n (%)	Active n (%)	Control n (%)	Active n (%)	Control n (%)	Active n (%)
Age Median (range) Mean (sd)								
Sex Male								
Education Did Not Finish HS HS Diploma Post-HS Education								
Marital Status Married Not Married								
Caregiver Income Less than \$20,000 \$20,000 - \$39,999 \$40,000 and above								
Years living with CR Median (range) Mean (sd)								
Relationship to CR Spouse Child Sibling Other								
Employed Full or Part Time								
CES-D Median (range) Mean (sd)								
RMBPC Median (range) Mean (sd)								

Table 3a: Care Recipient Characteristics by Race/Ethnic Identity

	Black		White		Hispanic		TOTAL	
	N	%	N	%	N	%	N	%
Age								
Median (range)								
Mean (sd)								
Sex								
Male								
Education								
Did Not Finish HS								
HS Diploma								
After HS								
ADL								
Median (range)								
Mean (sd)								
IADL								
Median (range)								
Mean (sd)								
MMSE Score								
Median (range)								
Mean (sd)								
RMBPC								
Behavior Frequency								
Median (range)								
Mean (sd)								

Table 3b: Care Recipient Characteristics by Race/Ethnic Identity and Treatment Group

	Black n =		White n =		Hispanic n =		TOTAL n =	
	Control n (%)	Active n (%)	Control n (%)	Active n (%)	Control n (%)	Active n (%)	Control n (%)	Active n (%)
Age Median (range) Mean (sd)								
Sex Male								
Education Did Not Finish HS HS Diploma After HS								
ADL Median (range) Mean (sd)								
IADL Median (range) Mean (sd)								
MMSE Score Median (range) Mean (sd)								
RMBPC Behavior Frequency Median (range) Mean (sd)								

IV. Safety Assessment

Table 4. Adverse Events by Race/Ethnic Identity

	Black n=200	White n=	Hispanic n=	TOTAL N=600
Number of Adverse Events	5			
	n (%)	n (%)	n (%)	n (%)
Type of Event				
Depression	1 (20)			
Driving	4 (80)			
Gun in house				
Harmful to self				
Harmful to others				
Tx related?				
Unrelated				
Possible				
Probable				
Definitely				
Action Taken				
None				
...				
Outcome				
Resolved				
Continue/Control				

Table 5. Adverse Events by Site and Treatment Group

	Birmingham n=120		Memphis n=		Miami n=		Palo Alto n=		Philadelphia n=		TOTAL N=600	
	Control n = 60	Active n = 60	Control n = 60	Active n = 60	Control n = 60	Active n = 60	Control n = 60	Active n = 60	Control n = 60	Active n = 60	Control n = 60	Active n = 60
Number of Adverse Events	10	10										
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Type of Event												
Depression	5 (50)											
Driving	5 (50)											
Gun in house												
Harmful to self												
Harmful to others												
Severity												
Mild												
Moderate												
Severe												
Life-threatening												
Action Taken												
None												
...												
Outcome												
Resolved												
Continue/Control												

Table 6: Adverse Events and Alerts*

Site	Participant	Intervention Group	Race	Event/Alert	Date Identified	Date Responded	Treatment Related**	Description of Actions and Outcomes
Birmingham	00001DDE	Active	White	Depression	5 May 02	7 May 02	2	Counseling

* Alerts:

- Depression
- Gun in home
- Driving
- CG threatening to hurt him/herself
- CG threatening to hurt others

****Intervention Relationship:**

- 0 = Definitely unrelated
- 1 = Unlikely
- 2 = Possibly related
- 3 = Probably related
- 4 = Definitely related

V. Data Processing

Table 7a: Status of Data Processing of Forms at Coordinating Center, Since Start of Study

	Birmingham (N=)	Memphis (N=)	Miami (N=)	Palo Alto (N=)	Philadelphia (N=)
# Eligible					
# Randomized					
Collect-Enter					
Mean					
Median					
Range					
Enter-Verify					
Mean					
Median					
Range					
Verify - Prepare					
Mean					
Median					
Range					
Collect-Prepare					
Mean					
Median					
Range					
%>30 days					

Category Definitions:

Collect – Enter: Time from form collection to forms entry into site PC’s

Enter – Verify: Time from initial forms entered to forms verified (double entered)

Verify – Prepared: Time from forms verified, cleaned & prepared for transfer to the Coordinating Center

Collect – Prepare: Time from form collection to forms prepared for transfer to the Coordinating Center

% > 30 Days: Percentage of forms that took more than 30 days from form collection to form preparation.

Table 7b: Status of Data Processing of Forms at Coordinating Center, for the past two months

	Birmingham (N=)	Memphis (N=)	Miami (N=)	Palo Alto (N=)	Philadelphia (N=)
# Eligible					
# Randomized					
Collect-Enter					
Mean					
Median					
Range					
Enter-Verify					
Mean					
Median					
Range					
Verify - Prepare					
Mean					
Median					
Range					
Collect-Prepare					
Mean					
Median					
Range					

Category Definitions:

Collect – Enter: Time from form collection to forms entry into site PC’s

Enter – Verify: Time from initial forms entered to forms verified (double entered)

Verify – Prepared: Time from forms verified, cleaned & prepared for transfer to the Coordinating Center

Collect – Prepare: Time from form collection to forms prepared for transfer to the Coordinating Center

Table 8: Number of Contacts (In-Home and By Telephone)

		In-Home Contacts			Telephone Contacts		
Assignment	N	Mean Number of Contacts	Range in Number of Contacts (min, max)	Number of Participants with no contacts	Mean Number of Contacts	Range in Number of Contacts (min, max)	Number of Participants with no contacts
Birmingham Black White Hispanic TOTAL							
Memphis Black White Hispanic TOTAL							
Miami Black White Hispanic TOTAL							
Palo Alto Black White Hispanic TOTAL							
Philadelphia Black White Hispanic TOTAL							

Table 9: Overall Subject Status by Site

	SITE																																																																																																																																																																																																																																																																																																																																																																																																				
	BIRMINGHAM		MEMPHIS		MIAMI		PALO ALTO		PHILADELPHIA		TOTAL																																																																																																																																																																																																																																																																																																																																																																																										
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Table 10: Follow-up Summary Report by Site

	Birmingham		Memphis		Miami		Palo Alto		Philadelphia		Total	
Participants Randomized												
Interview Follow-up Status												
	N	%	N	%	N	%	N	%	N	%	N	%
Interviews expected:												
Completed												
Incomplete												
Past due												
Missed												
Due in next two months												

Table 11: Off-Protocol Events by Site

Off-Protocol Events by Site

Data as of

	Sites											
	Birmingham		Memphis		Miami		Palo Alto		Philadelphia		Total	
	N=		N=		N=		N=		N=		N=	
	n	%	n	%	n	%	n	%	n	%	n	%
Caregivers with any off protocol event												
Interview conducted by a non-certified interviewer												
Missed follow-up visit												
Ineligible participant randomized												
Randomized to wrong intervention												
Visits not completed												
Baseline												
6 month												
Caregiver discontinued participation												
Reason:												
Change of caregiver												
Placement												
Travel too difficult												
Too time consuming												
Caregiver moved												
Caregiver cannot be located/location unknown												
Caregiver displeased with randomization												
Illness												
Death												
Other												

Off-Protocol Events by Site (continued)

Data as of 04/04/2000

	Sites											
	Birmingham		Memphis		Miami		Palo Alto		Philadelphia		Total	
	N=		N=		N=		N=		N=		N=	
	n	%	n	%	n	%	n	%	n	%	n	%
Follow-up Interview outside window												
Interview completed Over the phone												
Baseline > n days from screen												
Randomization > 3 days From Baseline												
Randomization > 42 days from last screen												
Failed intervention Guidelines												
Participant attended fewer than n interventions												
etc												
Other off-protocol events												