

AWARD NUMBER: W81XWH-15-2-0025

TITLE: Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Military Primary Care

PRINCIPAL INVESTIGATOR: Dr. Jeffrey A. Cigrang

CONTRACTING ORGANIZATION: Wright State University

REPORT DATE: May 2020

TYPE OF REPORT: Final Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release. Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE May 2020		2. REPORT TYPE Final Report		3. DATES COVERED 1 Sep 15 to 29 Feb 20	
4. TITLE AND SUBTITLE Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Military Primary Care				5a. CONTRACT NUMBER W81XWH-15-2-0025	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Jeffrey A. Cigrang, Ph.D., ABPP E-Mail: Jeffrey.cigrang@wright.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) WRIGHT STATE UNIVERSITY 3640 COLONEL GLENN HWY DAYTON OH 45435-0001				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT: The most challenging community problems faced by senior military leaders are closely linked to the quality of marriage relationships. These include family violence, spouse maltreatment, and suicide. Despite the potential high costs of chronic marital distress, very few couples seek therapy. Thus, there is a substantial need in the military for early detection and preventative care for deteriorating couples. The Marriage Checkup (MC) addresses this issue by providing a less-threatening option for couples to seek early preventative care before they have begun to identify as distressed. In our pilot study the original MC was adapted for military couples and fit into the fast-paced environment of primary care. The results of the pilot study provide preliminary evidence suggesting that the MC can be effectively adapted to a military population, and successfully used by behavioral health consultants (BHCs) working in an integrated primary care clinic. The overall purpose of the current study was to build on the pilot study findings by conducting a randomized trial of the military-adapted MC delivered in primary care by BHCs. Specific Aims of the study were (1) conduct a randomized trial comparing MC for use in military primary care clinics to a wait list control condition, (2) examine the effects of MC participation on relationship health at post-treatment and a six-month follow-up period, and (3) determine whether the MC is successful at reaching couples at risk for marital deterioration who would otherwise be unlikely to seek traditional couple counseling. The randomized trial was conducted at four military primary care clinics at Lackland, Andrews, Luke, Randolph, and Wright-Patterson Air Force Bases.					
15. SUBJECT TERMS Military personnel, marital relations, couple therapy, primary care					
16. SECURITY CLASSIFICATION OF: Unclassified			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 15	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	8
5. Changes/Problems.....	9
6. Products.....	9
7. Participants & Other Collaborating Organizations.....	10
8. Special Reporting Requirements.....	13
9. Appendices.....	14

Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants
in Military Primary Care
Final Report

Introduction

The most challenging community problems faced by senior military leaders are closely linked to the quality of marriage relationships. These include family violence, spouse maltreatment, and suicide. Despite the potential high costs of chronic marital distress, very few couples seek therapy. Thus, there is a substantial need in the military for early detection and preventative care for deteriorating couples. The Marriage Checkup (MC) addresses this issue by providing a less-threatening option for couples to seek early preventative care before they have begun to identify as distressed. In our pilot study the original MC was adapted for military couples and fit into the fast-paced environment of primary care. The results of the pilot study provide preliminary evidence suggesting that the MC can be effectively adapted to a military population, and successfully used by behavioral health consultants (BHCs) working in an integrated primary care clinic. The overall purpose of the current study was to build on the pilot study findings by conducting a randomized trial of the military-adapted MC delivered in primary care by BHCs. Specific Aims of the study were (1) conduct a randomized trial comparing MC for use in military primary care clinics to a wait list control condition, (2) examine the effects of MC participation on relationship health at post-treatment and a six-month follow-up period, and (3) determine whether the MC is successful at reaching couples at risk for marital deterioration who would otherwise be unlikely to seek traditional couple counseling. The randomized trial was conducted at four military primary care clinics at Lackland, Andrews, Luke, Randolph, and Wright-Patterson Air Force Bases.

Keywords

Military personnel, marital relations, couple therapy, primary care

Accomplishments

1. What were the major goals of the project?

Major Task 1: Complete all preparatory work for project start.	Timeline	
	Months	% complete
Subtask 1: Complete Research Protocol and Regulatory Documents		
Finalize baseline and follow-up measures; prepare data recording forms	1-3	100%
Establish process for participant incentive payments	1-3	100%
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	100%
Finalize consent form & human subjects protocol	1-3	100%
Finalize methods for participant recruitment	3-6	100%
Purchase, establish use of IPADS for facilitating on-line baseline assessments	3-6	100%
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	3-6	100%
Coordinate with Sites for IRB protocol submission	1-6	100%
Coordinate with Sites for State University IRB review	1-6	100%

Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	100%
Submit IRB amendments as needed	1-6	100%
Coordinate with Sites for annual IRB report for continuing review	1-6	100%
<i>Milestone Achieved: Local IRB approval at all research sites and Universities</i>	3	100%
<i>Milestone Achieved: HRPO approval for all protocols and local IRB approval through State Univ.</i>	6	100%
Subtask 2: Hiring and Training of Study Staff		
Coordinate with WSU Human Resources for job description design	1-2	100%
Advertise, interview and hire site-specific study coordinators	2-5	100%
Coordinate for space allocation for new staff at data collection sites	5-6	100%
Coordinate military base access for study coordinators	5-6	100%
Travel to sites to train IBHCs and study coordinators	7-9	100%
<i>Milestone Achieved: Study coordinators hired</i>	6	100%
<i>Milestone Achieved: IBHCs and study coordinators trained</i>	9 (Actual date: 6/23/16)	100%
<i>Milestone Achieved: All sites 100% ready for beginning RCT</i>	9 (Actual date: 6/23/16)	100%
Major Task 2: Begin RCT; Participant recruitment, intervention, assessment		
Conduct participant recruitment, baseline and 1-month follow-up assessments	10-15	100%
Conduct random assignment to MC or wait list stratified by site	10-15	100%
Ensure process for securing documents w/ personal identifiers in PI's office	10-15	100%
Conduct website data transfer, data quality checks, data base management	10-15	100%
Conduct weekly clinical supervision with IBHCs	10-15	100%
Conduct weekly supervision with study coordinators	10-15	100%
Submit amendments, adverse events and protocol deviations as needed	10-15	100%
Perform data analyses; share output and finding with all investigators	14-15	100%
Meet recruitment targets (3 couples per site per mo. /total 144 all sites per 12 mo.)	10-15	100%
<i>Milestone Achieved: RCT began successfully; 1st participant consented, enrolled</i>	10 (Actual Date: 2/16/2016)	100%
Major Task 3: Continue RCT; Begin 6 mo. f/u assessments		

Continue participant recruitment, baseline and 1-month follow-up assessments	16-21	100%
Continue random assignment to MC or wait list stratified by site	16-21	100%
Continue weekly clinical supervision with IBHC's	16-21	100%
Continue weekly supervision with study coordinators	16-21	100%
Continue website data transfer, data quality check, data base management	16-21	100%
Meet recruitment targets (241 couples by the end of year 4 quarter 2)	16-21	100%
Submit amendments, adverse events and protocol deviations as needed	16-21	100%
Begin 6 mo. Follow-up assessments	16	100%
Begin offering MC to participants in wait list condition	16	100%
Perform data analyses; share output and findings with all investigators	20-21	100%
<i>Milestone Achieved: Report findings to date from 6 month follow-up assessments</i>	21	100%
Major Task 4: Continue RCT and 6 mo. f/u assessments		
Continue participant recruitment, baseline and 1-month follow-up assessments	22-42	100%
Continue random assignment to MC or wait list stratified by site	22-42	100%
Continue weekly clinical supervision with IBHCs	22-42	100%
Continue weekly supervision with study coordinators	22-42	100%
Continue website data transfer, data quality checks, data base management	22-42	100%
Meet recruitment targets (3 couples per site per mo. /total 144 all sites per 12 mo.)	22-42	100%
Submit amendments, adverse events and protocol deviations as needed	22-42	100%
Continue 6 mo. follow-up assessments	22-42	100%
Continue offering MC to participants in wait list condition	22-42	100%
Perform data analyses; share output and finding with all investigators	41-42	100%
<i>Milestone Achieved: Meet final participant enrollment goals; end participant recruitment/enrollment</i>	42	100%
Major Task 5: Complete RCT and qualitative data collection		
Complete remaining 6 mo. assessments	43-54	100%
Complete offering MC to remaining wait list participants	43-54	100%
Begin final data cleaning and primary manuscript preparation	43-54	100%
Disseminate findings (abstracts, presentation, publications, DOD)	43-54	100%
<i>Milestone Achieved: Report findings from 6 month follow-up assessments; report findings from questionnaires evaluating implementation and couples' experience</i>	54	100%

2. What was accomplished under these goals?

A total of 244 active-duty couples were enrolled in the randomized trial between February 2016 and February 2019 across 5 military bases; 128 were assigned to the Marriage Checkup group and 116 to the waitlist control (see CONSORT chart). 113 Couples completed at least 1 of the 3 intervention sessions, with 110 completing all 3. Participants were an average of 32 years old (range: 20 to 53), 68% white, 14% Hispanic/Latino, and 9% Black/African American, had a college education (interquartile range: 14 to 18 years of schooling) and had a median military rank of E5. Twenty-two percent of couples met criteria for relationship distress (Funk & Rogge, 2007). Forty-two percent of couples had previously sought relationship counseling, and 50% indicated they were either uncertain or would not have sought relationship help services if a Marriage Checkup were not available.

Follow-up survey completion rates were high for both the Marriage Checkup group (84% at 1 month, 82% at 6 months) and the waitlist control group (94% at 1 month, 90% at 6 months).

The primary statistical analyses for the RCT was completed in April 2020. Changes in marital satisfaction were statistically significantly higher in the treatment group than the control group at 1 month, and this effect was sustained through 6 month follow. Notably, the average relationship satisfaction in the control group declined over time. Treatment effects corresponded to small effect sizes of Cohen's $d = 0.27$ at both time points. Treatment couples experienced statistically significant small to moderate improvements compared to the control group (Cohen's d from 0.21 to 0.55) at 1 month that were sustained at 6 months across all four couple outcomes of responsive attention, compassion towards their partner, communication skills, and intimate safety. In addition, depression scores significantly decreased in the treatment group relative to the control group at 1 month ($d = 0.22$) and these decreases were sustained through six months ($d = 0.23$) (see Table 1).

3. What opportunities for training and professional development has the project provided?

This project provided initial certification training to conduct Marriage Checkup for Primary Care to nine BHCs at five medical treatment facilities in the Air Force. The project also provided ongoing clinical supervision to the nine BHCs. These nine psychologists have become becoming the most experienced therapists in the world for implementation of a brief relationship intervention in the military primary care setting. Their growing expertise will serve as the foundation in the future for effective dissemination and implementation of Marriage Checkup for primary care in the DoD.

4. How were the results disseminated to communities of interest?

Military Operational Medicine Research Program (JPC-5) has briefed end-users of research products within the DoD. Most recently, the Director of Military

Community Support Programs at Office of Undersecretary Defense for Personnel and Readiness (OUSD P-R) has expressed interest in piloting Marriage Checkup within the Military Family Life Consultant (MFLC) program. We are presently developing a plan to train 50 MFLC providers in delivery of Marriage Checkup and collect data on feasibility and effectiveness.

In October 2019 the results of an analysis of couple baseline data from Marriage Checkup was presented at the Annual San Antonio Combat PTSD Conference. The findings demonstrated the reach of Marriage Checkup to the full range of couples. These included couples with elevated distress and a history of other help seeking as well as low distressed couples who had never sought any relationship help previously.

Cigrang, J., Fields, A.D., Cordova, J.V., Maher, E., Fedynich, A. L., Gray, T.D., & Kessler-Walker, D. *Reaching Active Duty Couples with Relationship Help: The Marriage Checkup in Primary Care.* (2019, October). Poster presented at the 4th Annual San Antonio Combat PTSD Conference, San Antonio, Texas.

Impact

1. What was the impact on the development of the principal discipline(s) of the project?

The principle disciplinary field of the project is behavioral health services in an integrated primary care context. Our experience on the project over the past five years has convinced us that brief relationship assistance can be effectively incorporated into primary care. Our primary care therapists have consistently reported that they enjoy conducting Marriage Checkup and that it is a positive experience for the couples who participate.

2. What was the impact on other disciplines?

The primary care clinic teams at our four data collection sites now have an in-house resource for referring patients who are interested in and may benefit from brief consultation for improving their marital relationship.

3. What was the impact on technology transfer? Nothing to report
4. What was the impact on society beyond science and technology? Nothing to report

Changes/Problems

1. The primary problem across the course of the project was frequent turnover in volunteer providers at our data collection site. The project relied on organic BHCs who were motivated to learn Marriage Checkup and willing to take on role of therapist and local PI. For our active duty BHCs, they were very busy with regular duties and had limited time to oversee day to day operations of the project. They also PCS'd, went TDY, or were deployed. Our civilian contract BHCs were at risk for not having their contract renewed or leaving their current contract for a better paying position. The net result was periodic instability at each

site and disruption in participant enrollment and treatment completion. The project would have benefitted from hiring therapists using grant funds. However, this would have significantly increased the amount of funding required.

2. In the middle years of the project we experienced significant regulatory challenges with the Air Force IRB. Specifically, the requirement for the participant and PI's signatures on the ICD to be witnessed and signed by a third party. Errors in ICD witness documentation were identified in an IRB audit and the IRB required these participants to be reconsented. Ultimately, we had to remove 32 participants from the study due to not being able to achieve reconsenting. Within the year following the conclusion of these regulatory challenges the IRB stopped requiring that ICDs include third party witness signatures.
3. The above problems interfered sufficiently with reaching our enrollment goals that a fourth no-cost extension year was required.

Products A proven Marriage Checkup protocol designed for BHCs working in military primary care clinics that has the potential to extend the reach of effective relationship help to active duty couples.

Participants & Other Collaborating Organization Participants listed in the table below are those currently active on the project. For a list that includes current and previous participants please see most recent quarterly report.

Name	Project Role	Nearest person month worked	Contribution to Project	Funding Support
Dr. Jeffrey A. Cigrang	PI	6	Served as the Principal Investigator for the Marriage Checkup (MC) project. Led effort to prepare, submit, & obtain final IRB approval. Worked with WSU Human Resources to complete all tasks necessary to post positions and hire research assistants. Oversaw work done by subcontract team at Clark University. Coordinated all aspects of study with Air Force.	NA
Dr. James Cordova	Co-PI	6	Primary responsibility for clinical supervision of study therapists. Oversaw all aspects of study at Clark University. Participated in weekly team teleconferences that	U.S. Department of Health and Human Services

			include providing clinical supervision to therapists on MC.	
Maj Abby Fields	Co-PI	6	Served as Air Force PI for IRB purposes. Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center. Helped supervise Research Assistants (Rosalyn Pace, Virginia Cruse, Sarah Young, and currently Michaela Rogers). Participated in team teleconferences.	NA
Ashley Fedynich	Graduate Student and Research Assistant	6	Had primary responsibility for revisions to IRB and other regulatory documents. Prepared drafts of quarterly reports. Took lead in orienting new RAs to study, assisted in completion of their IRB requirements. Scheduled team teleconferences. Prepared documents required for HRPO submission. Served as the local RA at WPAFB. Helped development and implement participant recruitment plan. Served as primary POC for study at Wright-Patterson AFB. Scheduled, consented, completed baseline assessments for all participants.	NA
Emily Maher	Graduate Student		Took over duties from Tatiana Gray at the end of September 2016. Primary team member responsible for use of on-line follow-up surveys. Monitors implementation, downloads de-identified	NA

			results, converts to database for statistical analyses. Prepared minutes from MC weekly teleconferences. Assisted Ashley in conducting weekly teleconferences for the Research Assistants.	
Dr. Dawn-Kessler Walker	AI		Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center starting in January 2017. Helped supervise RA (Rosalyn Pace). Participated in weekly team teleconferences.	NA
Michaela Rogers	Research Assistant		In August 2018, Michaela took over duties as the Research Assistant at Lackland AFB and Randolph AFB from Sarah Young. Michaela will implement a participant recruitment plan and serve as primary POC for the study at Lackland and Randolph AFB. She will manage scheduling, consenting, and completion of baseline assessments for all participants.	
Raymond Martorano	AI		Dr. Martorano served as a therapist seeing couples in the study at Wright-Patterson AFB starting in April of 2018. Dr. Martorano has assisted with the supervision of the local RA's (Ashley Fedynich and Dr. Jeff Cigrang) and participated in monthly team teleconferences.	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No changes

Special Reporting Requirements

See attached quad chart

Appendices

- a. Quad chart
- b. CONSORT chart
- c. Table 1

Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Primary Care

Log #14227006, W81XWH-15-2-0025

PI: Jeffrey A. Cigrang, Ph.D., ABPP

Org: Wright State University

Award Amount: \$878,979



Study/Product Aim(s)

- Recruit service members and their partners who are in committed romantic relationships to participate in a Marriage Checkup (MC) delivered by Integrated Behavioral Health Consultants (IBHC) in primary care.
- Evaluate the efficacy of MC by comparing couples who receive MC to couples on a wait list control condition.
- Determine the ability of MC to attract military couples across a broad range of relationship functioning.
- Obtain qualitative data from IBHCs and couples after conclusion of the intervention study portion to measure MC implementation and factors impacting success.

Approach

Conduct a randomized clinical trial (N=240 couples) at four primary care clinics in the Air Force to evaluate effects of MC participation.



Accomplishments: (1) completed 1 month & 6 month follow-up surveys (2) completed final data cleaning (3) completed primary data analyses.

Timeline and Cost

Activities	CY	15	16	17	18
Preparatory work for project start					
Begin RCT; meet recruitment targets					
Continue RCT; report 6 mo. f/u results					
Complete RCT and qualitative data collection					
Estimated Budget (\$878,979)		\$20,300	\$350,000	\$350,000	\$158,679

Goals/Milestones

CY15 Goal – Complete preparatory work for project start

- ✓ Obtain IRB approval at all sites and Universities
- ✓ Hire site-specific study coordinators.

CY16 Goals – Begin RCT

- ✓ Obtain HRPO approval
- ✓ Complete training for study coordinators and therapists.
- ✓ Begin participant consenting; meet recruitment targets

CY17 Goal – Continue RCT

- ✓ Continue participant consenting, follow-up survey completion.

CY18 Goal – Continue RCT

- ✓ Continue participant consenting, follow-up survey completion

CY19 Goal – Complete RCT

- ✓ Complete follow-up surveys
- ✓ Analyzed and shared results

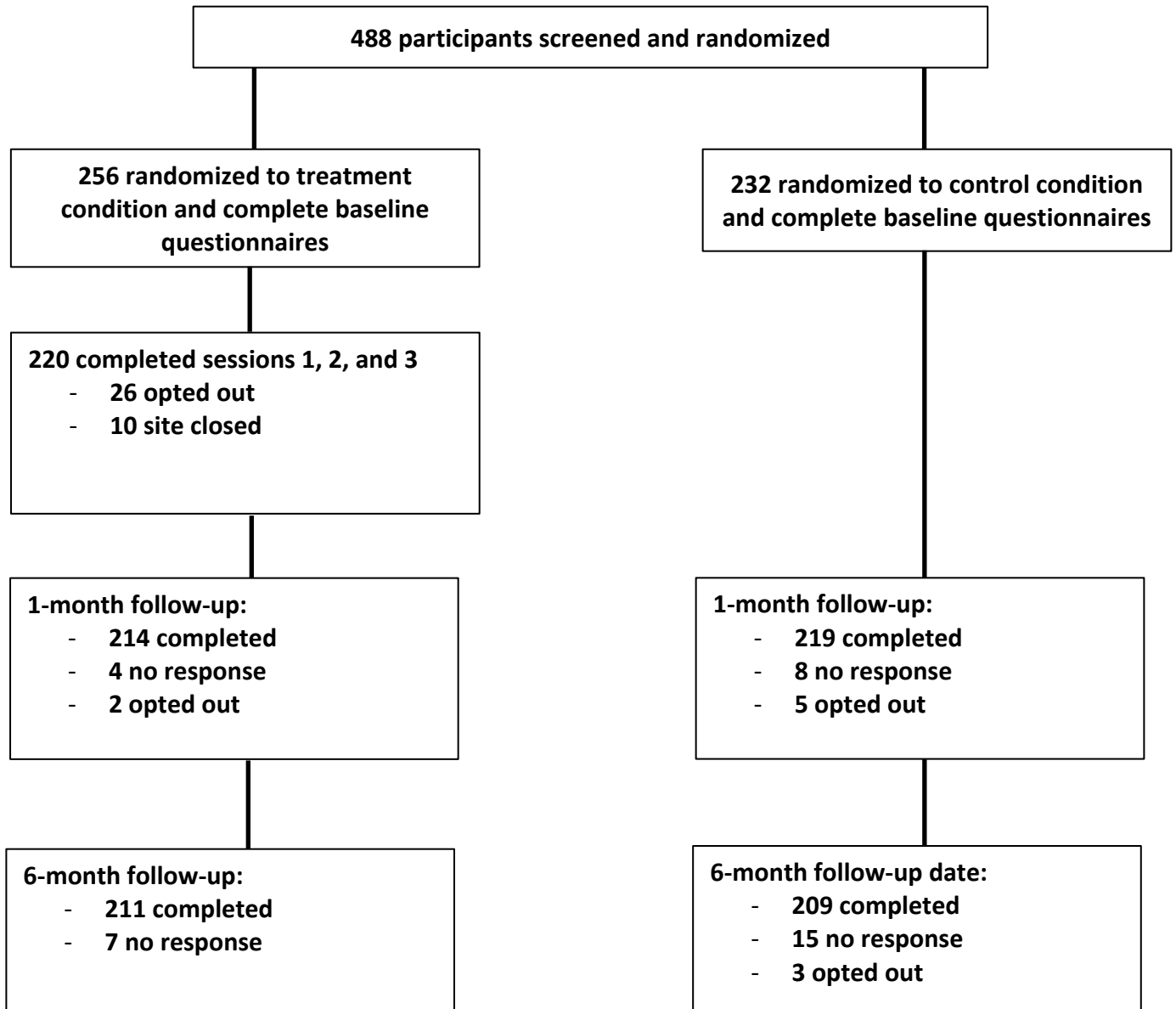


Table 1

Marriage Checkup Treatment Effects

