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

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> In the middle of our fourth year (February 2019) we met our enrollment target (enrolled 490 participants into the study; target N is 482) using our two remaining active data sites (Lackland AFB & Wright-Patterson AFB). The vast majority (86%) assigned to the treatment condition completed all three appointments. Survey completion rates for treatment completers at the one-month (96%) and six-month follow-up (95%) points are high. Currently we have 18 participants still pending completion of six-month follow-up survey. We received approval for a six-month no-cost extension to complete final follow-up survey and begin data analyses. All regulatory requirements for the study (IRB Annual Progress Report & HRPO Continuing Review Approval) were met. An end-of-project team meeting occurred March 2019.					
<b>15. SUBJECT TERMS</b> Military personnel, marital relations, couple therapy, primary care					
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Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants  
in Military Primary Care  
Year 4 Annual 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 is 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 are (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 is being conducted at four military primary care clinics at Lackland, Andrews, Luke, 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?

	Timeline	
	Months	% complete
<b>Major Task 1: Complete all preparatory work for project start.</b>		
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%
<b>Major Task 2: Begin RCT; Participant recruitment, intervention, assessment</b>		
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%
<b>Major Task 3: Continue RCT; Begin 6 mo. f/u assessments</b>		

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% as of Feb19
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	0%

## 2. What was accomplished under these goals?

### *Protocol-level accomplishments:*

- a. Processes and documentation required for participant consenting, administering and management of baselines measures, providing incentive payments, and obtaining and managing follow-up measures IAW IRB-approved protocol are all established and functioning effectively.
- b. The team holds a monthly teleconference to discuss updates and recruitment plans.
- c. In February 2019 we met our enrollment target (enrolled 490 participants into the study; target N is 482) using our two remaining active data sites (Lackland AFB & Wright-Patterson AFB). The majority (86%) assigned to the treatment condition completed all three appointments.
- d. Survey completion rates for treatment completers at the one-month (96%) and six-month follow-up (95%) points are high. Currently we have 18 participants still pending completion of six-month follow-up survey (see attached CONSORT chart).

### *Site-Specific Accomplishments:*

#### Lackland AFB, Texas.

- a. Maj Abby Fields continues to serve as the sole therapist at Lackland AFB. Maj Fields provided the MC to all treatment couples enrolled at Lackland AFB and any continues to provide the MC to any control couples that are interested in receiving the MC upon completion of their final six-month survey. Ms. Michaela Rogers continues to serve as the RA at Lackland AFB. Ms. Rogers worked closely with Maj Fields to recruit and consent couples into the study. Currently, participant recruitment has concluded and Ms.

Rogers is continuing to follow already enrolled participants with follow-up survey questionnaires. The last treatment and control couples are “due” for their final questionnaires on 2 October 2019 and data collection will conclude.. A total of 59 participants (29 couples 1 individual) were enrolled at Lackland in the past year.

#### Wright-Patterson AFB, Ohio

- a. Following Dr. Martorano’s retirement in January 2019, Maj Michael Ann Glotfelter served as the therapist at WPAFB. Ms. Ashley Fedynich and Dr. Jeff Cigrang worked closely with Dr. Martorano and Maj Glotfelter throughout the year to recruit and consent couples at WPAFB. Currently, Ms. Fedynich is continuing to follow already enrolled participants with follow-up survey questionnaires. The last treatment and control couples are “due” for their final questionnaires on 7 November 2019 and data collection will conclude. A total of 24 participants (12 couples) were enrolled at Wright-Patterson in the past year.

### 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 Internal Behavioral Health Consultants (IBHCs) at four medical treatment facilities in the Air Force. The project also provides ongoing clinical supervision to the nine IBHC. These nine psychologists are quickly becoming the most experienced therapists in the world for implementation of a brief relationship intervention in the 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? N/A

### 5. What do you plan to do during the next reporting period to accomplish the goals?

- a. Complete handful of remaining follow-up surveys
- b. Offer Marriage Checkup to any remaining control couples following completion of their six-month survey.
- c. Begin data analysis and report writing

## 6. **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 four 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. None

**Products**      Nothing to report

**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 include providing clinical supervision to therapists on MC.	U.S. Department of Health and Human Services
Capt 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
Maj Michael Ann Glotfelter	AI	6	Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center in 2016. Most recently, Maj Glotfelter is serving as the local PI at Wrgiht-Patterson AFB.	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	NA

			as primary POC for study at Wright-Patterson AFB. Scheduled, consented, completed baseline assessments for all participants.	
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 results, converts to database for statistical analyses. Prepared minutes from MC weekly teleconferences. Assisted Ashley in conducting weekly teleconferences for the Research Assistants.	NA
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.	
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**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. Participant Enrollment: Actual versus Projected.
- b. COHORT chart
- c. Quad Chart

# 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) Achieved 100% of projected enrollment goal, (2) effectively completing 1 month & 6 month follow-up surveys (3) granted six-month no-cost extension to complete all surveys, begin 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					
<b>Estimated Budget (\$878,979)</b>		<b>\$20,300</b>	<b>\$350,000</b>	<b>\$350,000</b>	<b>\$158,679</b>

## 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, analyze and share results

## Budget Expenditure to Date

Projected Expenditure: \$878,979.00

Actual Expenditure: \$796,750.30 through 8/31/19

Approved by:

Juwanna Higgins

Digitally signed by Juwanna Higgins  
Date: 2019.09.26 11:00:03 -04'00'

## Appendix A

### Marriage Checkup Enrollment June 2019



