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
                             Dayton, OH 45435

REPORT DATE:  30 September 2018

TYPE OF REPORT:  Annual Report

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

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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.
At the conclusion of the third year we have enrolled 401 participants into the study. The majority (77%) assigned to the treatment condition have completed all three appointments. Twenty two participants are pending scheduling. Attrition rates at the one-month and six-month follow-up points are low (3% to 2%). Two data collection sites were closed to further enrollment (Andrews & Luke AFB) due to loss of the study therapist. We received approval for a one-year no cost extension to help reach our couple enrollment end-goal (N=241 couples). Our plan is to complete enrollment at end of February 2019 leaving time to complete all six-month follow-up surveys by the new period of performance end date of 31 Aug.
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Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Military Primary Care

Year 3 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?

<table>
<thead>
<tr>
<th>Major Task 1: Complete all preparatory work for project start.</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtask 1: Complete Research Protocol and Regulatory Documents</td>
<td></td>
</tr>
<tr>
<td>Finalize baseline and follow-up measures; prepare data recording forms</td>
<td>1-3</td>
</tr>
<tr>
<td>Establish process for participant incentive payments</td>
<td>1-3</td>
</tr>
<tr>
<td>Refine eligibility criteria, exclusion criteria, screening protocol</td>
<td>1-3</td>
</tr>
<tr>
<td>Finalize consent form &amp; human subjects protocol</td>
<td>1-3</td>
</tr>
<tr>
<td>Finalize methods for participant recruitment</td>
<td>3-6</td>
</tr>
<tr>
<td>Purchase, establish use of IPADS for facilitating on-line baseline assessments</td>
<td>3-6</td>
</tr>
<tr>
<td>Coordinate with Sites for flow chart for all study steps, web data collection and database requirements</td>
<td>3-6</td>
</tr>
<tr>
<td>Coordinate with Sites for IRB protocol submission</td>
<td>1-6</td>
</tr>
<tr>
<td>Coordinate with Sites for State University IRB review</td>
<td>1-6</td>
</tr>
<tr>
<td>Task Description</td>
<td>Week</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)</td>
<td>1-6</td>
</tr>
<tr>
<td>Submit IRB amendments as needed</td>
<td>1-6</td>
</tr>
<tr>
<td>Coordinate with Sites for annual IRB report for continuing review</td>
<td>1-6</td>
</tr>
<tr>
<td><strong>Milestone Achieved: Local IRB approval at all research sites and Universities</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>Milestone Achieved: HRPO approval for all protocols and local IRB approval through State Univ.</strong></td>
<td>6</td>
</tr>
<tr>
<td>Subtask 2: Hiring and Training of Study Staff</td>
<td></td>
</tr>
<tr>
<td>Coordinate with WSU Human Resources for job description design</td>
<td>1-2</td>
</tr>
<tr>
<td>Advertise, interview and hire site-specific study coordinators</td>
<td>2-5</td>
</tr>
<tr>
<td>Coordinate for space allocation for new staff at data collection sites</td>
<td>5-6</td>
</tr>
<tr>
<td>Coordinate military base access for study coordinators</td>
<td>5-6</td>
</tr>
<tr>
<td>Travel to sites to train IBHCs and study coordinators</td>
<td>7-9</td>
</tr>
<tr>
<td><strong>Milestone Achieved: Study coordinators hired</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>Milestone Achieved: IBHCs and study coordinators trained</strong></td>
<td>9</td>
</tr>
<tr>
<td>(Actual date: 6/23/16)</td>
<td></td>
</tr>
<tr>
<td><strong>Milestone Achieved: All sites 100% ready for beginning RCT</strong></td>
<td>9</td>
</tr>
<tr>
<td>(Actual date: 6/23/16)</td>
<td></td>
</tr>
<tr>
<td><strong>Major Task 2: Begin RCT; Participant recruitment, intervention, assessment</strong></td>
<td></td>
</tr>
<tr>
<td>Conduct participant recruitment, baseline and 1-month follow-up assessments</td>
<td>10-15</td>
</tr>
<tr>
<td>Conduct random assignment to MC or wait list stratified by site</td>
<td>10-15</td>
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<tr>
<td>Ensure process for securing documents w/ personal identifiers in PI's office</td>
<td>10-15</td>
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<tr>
<td>Conduct website data transfer, data quality checks, data base management</td>
<td>10-15</td>
</tr>
<tr>
<td>Conduct weekly clinical supervision with IBHCs</td>
<td>10-15</td>
</tr>
<tr>
<td>Conduct weekly supervision with study coordinators</td>
<td>10-15</td>
</tr>
<tr>
<td>Submit amendments, adverse events and protocol deviations as needed</td>
<td>10-15</td>
</tr>
<tr>
<td>Perform data analyses; share output and finding with all investigators</td>
<td>14-15</td>
</tr>
<tr>
<td>Meet recruitment targets (3 couples per site per mo. /total 144 all sites per 12 mo.)</td>
<td>10-15</td>
</tr>
<tr>
<td><strong>Milestone Achieved: RCT began successfully; 1st participant consented, enrolled</strong></td>
<td>10</td>
</tr>
<tr>
<td>(Actual Date: 2/16/2016)</td>
<td></td>
</tr>
<tr>
<td><strong>Major Task 3: Continue RCT; Begin 6 mo. f/u assessments</strong></td>
<td></td>
</tr>
</tbody>
</table>
2. **What was accomplished under these goals?**

*Protocol-level accomplishments:*

a. Processes and documentation required for participant consent, 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. A total of 401 participants (198 couples, 5 individuals) have been consented into the study and randomized to conditions as of 9/1/2018. The majority (77%) of couples assigned to the treatment condition have completed all three appointments and several recently enrolled are still pending completion (see attached CONSORT chart).

d. Participant attrition (lost to follow-up) from the study has been low and equally distributed across treatment and control conditions. As of 1 September, attrition at the one-month follow-up is 2% for treatment participants and 4% for control participants. Similarly, attrition at six months is currently 2% for control and no treatment couples that made it to the six-month questionnaire have opted out (see attached CONSORT chart).

*Site-Specific Accomplishments:*

Randolph AFB & Lackland AFB, Texas.

a. Dr. Jennifer Mitchell left her position at Randolph AFB in November 2016. Since Dr. Mitchell’s departure, there has not been a replacement therapist added to the protocol at Randolph. Advertisement for the study is posted at Randolph with interested couples enrolled at Lackland AFB site.
b. Research Assistant, Virginia Cruse, left her position. Sarah Young was added as her replacement and IRB approved to interact with couples on 2 March 2018. In August 2018, Sarah Young left Marriage Checkup to pursue another position. Michaela Rogers was IRB approved on August 17, 2018 to interact with couples.

c. Current total participant enrollment at Lackland AFB as of 1 September 18: 140 participants (68 couples)

d. Current total participant enrollment at Randolph AFB as of 1 September 18: 11 (5 couples)

Andrews AFB, Maryland.

a. We are no longer enrolling or recruiting participants at Andrews Air Force Base. Five couples are still completing follow-up questionnaires which are being managed by Ashley Fedynich, the local RA at Wright-Patterson AFB. All follow-up questionnaires will be completed by November 2018.

b. Current total individual enrollment at Andrews AFB as of 1 September 18: 82 (41 couples)


a. Angela Kenzlowe received IRB approval on 30 October 2017 to serve as a therapist and local PI at Luke AFB. However, due to staff relocating, we are no longer recruiting or enrolling participants at Luke AFB as of April 2018. All follow-up questionnaires are complete and were managed by Ashley Fedynich, local RA at Wright-Patterson AFB.

b. Current total participant enrollment at Luke AFB as of 1 September 18: 114 (57 couples)

Wright-Patterson AFB, Ohio

a. On 11 April 2018, Dr. Raymond Martorano received IRB approval to serve as a therapist on the Marriage Checkup study. Additionally, 17 August 2018 Michael Ann Glotfelter was added back onto the protocol to serve as the local PI at Wright-Patterson. Ashley Fedynich and Dr. Jeff Cigrang are serving as the local Research Assistants

b. Current total participant enrollment at WPAFB as of 1 September 18: 54 (27 couples)

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. We are now operating out of two bases (Lackland AFB and WPAFB). We will continue to enroll couples until reaching our target number of 241 couples. Right now we need 43 couples to reach our recruitment goal. We plan to have all recruitment completed by February 2018.
   b. While there has been a high turnover in Research Assistants at Lackland AFB, we are hoping to bring Michaela up to speed quickly and meet our recruitment goal for September. She has already started advertisement of the study on social media and via on-base posters and advertisements.

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 three 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. As noted in our most recent quarterly report, we are clear of the regulatory consequences from the non-serious noncompliance found in the IRB audit from May 2017. We have had to close two sites in the past year (Luke AFB, Andrews AFB) due to the therapist(s) leaving the
study. Fortunately, we’ve achieved getting Wright-Patterson AFB open for enrolling participants in May 2018 and have since enrolled 27 couples. Our challenge going forward is to maintain momentum at our remaining two sites in order to reach our study enrollment goals by the end of February 2019.

**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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Project Role</th>
<th>Nearest person month worked</th>
<th>Contribution to Project</th>
<th>Funding Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Jeffrey A. Cigrang</td>
<td>PI</td>
<td>6</td>
<td>Served as the Principal Investigator for the Marriage Checkup (MC) project. Led effort to prepare, submit, &amp; 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.</td>
<td>NA</td>
</tr>
<tr>
<td>Dr. James Cordova</td>
<td>Co-PI</td>
<td>6</td>
<td>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.</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>Capt Abby Fields</td>
<td>Co-PI</td>
<td>6</td>
<td>Served as Air Force PI for IRB purposes. Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center. Helped supervise</td>
<td>NA</td>
</tr>
<tr>
<td>Name</td>
<td>Role</td>
<td>Years</td>
<td>Responsibilities</td>
<td></td>
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<tr>
<td>Maj Michael Ann Glotfelter</td>
<td>AI</td>
<td>6</td>
<td>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 Wright-Patterson AFB.</td>
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</tr>
<tr>
<td>Ashley Fedynich</td>
<td>Graduate Student and Research Assistant</td>
<td>6</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Emily Maher</td>
<td>Graduate Student</td>
<td></td>
<td>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 analysis.</td>
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</table>
analyses. Prepared minutes from MC weekly teleconferences. Assisted Ashley in conducting weekly teleconferences for the Research Assistants.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Description</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Dawn-Kessler Walker</td>
<td>AI</td>
<td>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.</td>
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</tr>
<tr>
<td>Michaela Rogers</td>
<td>Research Assistant</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Raymond Martorano</td>
<td>AI</td>
<td>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.</td>
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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**

b. COHORT chart
c. Quad Chart
Marriage Checkup Enrollment August 2018

Projected enrollment
Actual enrollment
401 participants screened and randomized

212 randomized to treatment condition and complete baseline questionnaires
- 164 completed sessions 1, 2, and 3
  - 22 pending scheduling
  - 16 opted out
  - 10 site closed

189 randomized to control condition and complete baseline questionnaires
- 173 reached 1-month follow-up date, of which:
  - 160 completed
  - 4 pending response
  - 7 opted out

- 154 reached 6-month follow-up date, of which:
  - 143 completed
  - 8 pending response
  - 3 opted out

- 138 reached 6-month follow-up date, of which:
  - 136 completed
  - 2 pending response
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.

Timeline and Cost

<table>
<thead>
<tr>
<th>Activities</th>
<th>CY 15</th>
<th>CY 16</th>
<th>CY 17</th>
<th>CY 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparatory work for project start</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Begin RCT; meet recruitment targets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue RCT; report 6 mo. f/u results</td>
<td></td>
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<td></td>
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<tr>
<td>Complete RCT and qualitative data collection</td>
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Estimated Budget ($878,979)
- Preparatory work for project start: $20,300
- Begin RCT; meet recruitment targets: $350,000
- Continue RCT; report 6 mo. f/u results: $350,000
- Complete RCT and qualitative data collection: $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, analyze and share results

Budget Expenditure to Date
Projected Expenditure: $878,979.00
Actual Expenditure: $686,791.03 through 8/31/18

Accomplishments: (1) Achieved 83% of projected enrollment goal, (2) effectively completing 1 month & 6 month follow-up surveys (3) granted one-year no-cost extension to help reach final enrollment goal.

Approved to Submit by: Glen Jones
Digitally signed by Glen Jones Date: 2018.09.25 10:55:20 -04'00'