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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>  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					
<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 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?

	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%
<b>Subtask 2: Hiring and Training of Study Staff</b>		
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	84% as of 1 Sep 18
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. 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)

Luke AFB, Arizona.

- 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.

<b>Name</b>	<b>Project Role</b>	<b>Nearest person month worked</b>	<b>Contribution to Project</b>	<b>Funding Support</b>
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	NA

			Research Assistants (Rosalyn Pace, Virginia Cruse, Sarah Young, and currently Michaela Rogers). Participated in team teleconferences.	
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 Wright-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 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 results, converts to database for statistical	NA

			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

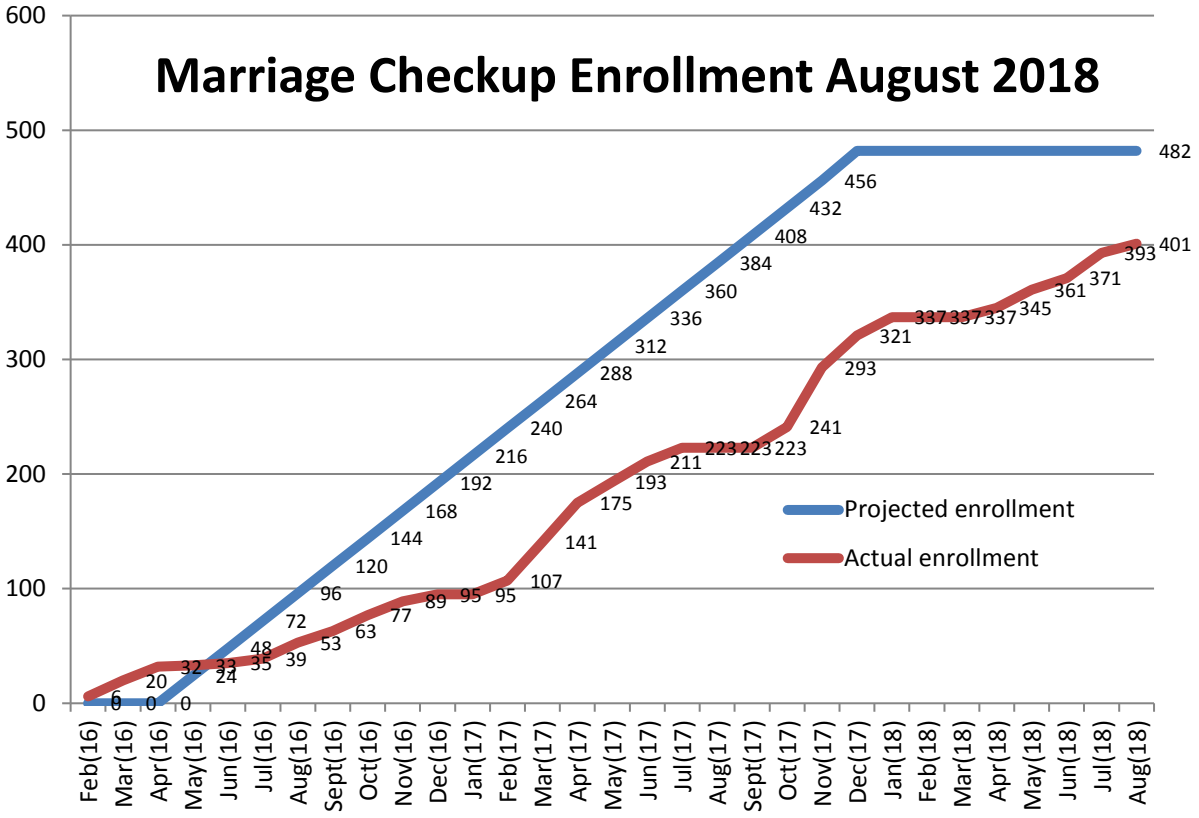
**Special Reporting Requirements**

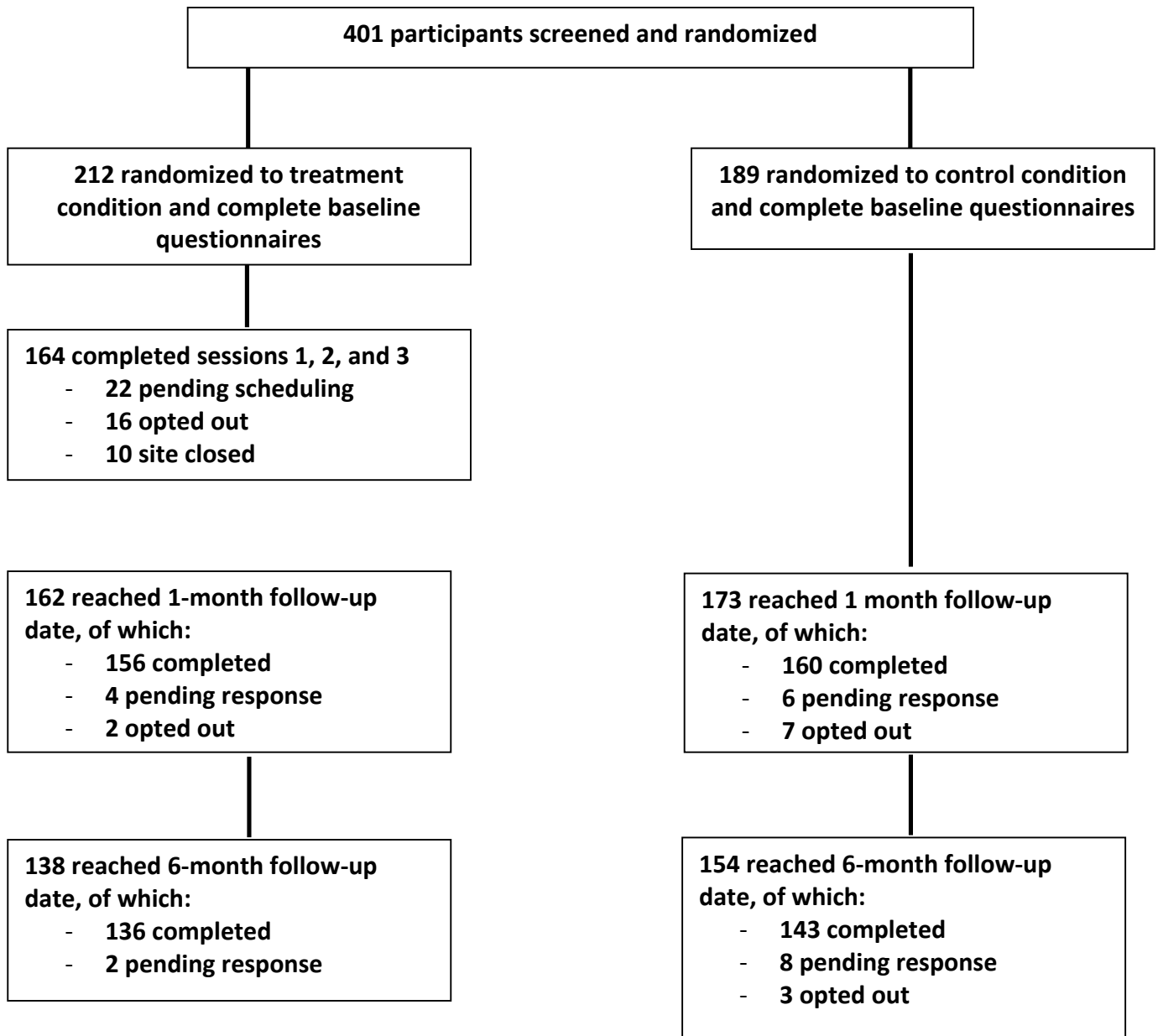
See attached quad chart

**Appendices**

- a. Participant Enrollment: Actual versus Projected.
- b. COHORT chart
- c. Quad Chart

# Marriage Checkup Enrollment August 2018





# 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 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.

## 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>		\$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, analyze and share results

## .Budget Expenditure to Date

Projected Expenditure: \$878,979.00

Actual Expenditure: \$686,791.03 through 8/31/18

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