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and Efficacy of Dialectical Behavioral Therapy

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13. SUPPLEMENTARY NOTES This project contains both a parent project and supplementary project. Included in the final report for the parent study & annual report for the supplement which will be starting a NCE.					
14. ABSTRACT Approximately one third of the Army's completed suicides last year occurred in the post-deployment period (Alvarez 2009) highlighting the importance of studying high-risk suicidal veteran populations. This project proposes two related studies. The first project is a randomized clinical trial of 120 veterans identified with high-risk suicidal behavior comparing the efficacy of Dialectical Behavioral Therapy (DBT) vs. treatment as usual (TAU) on suicidal behavior as a primary outcome measure. A second aim of the project is to examine group differences between 150 veterans at high risk (HR) for suicide and 150 veterans at low risk (LR) in a variety of symptom domains. The randomized clinical trial was completed with 93subjects. Results were notable for improvements in suicidality and secondary outcomes of depression, hopelessness and anxiety in both treatment groups, however there was not a significant difference between the treatment groups. DBT subjects did receive significantly more hours of treatment and for homeless, substance abusing males, there was considerable early drop-out in both arms. Our supplemental funding is to study affective startle as potential marker of suicide risk and as a marker of treatment outcome. Affective startle does significantly differ between Veteran ideators, single and multiple attempters. We are currently collecting additional female Veteran sample in a no-cost extension to be able to perform gender sub-analyses.					
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Introduction:

Approximately one third of the Army's completed suicides last year occurred in the post-deployment period (Alvarez 2009), highlighting the importance of studying high-risk suicidal veteran populations. This project proposes two related studies. The first project is a randomized clinical trial of 120 veterans identified with high-risk suicidal behavior comparing the efficacy of Dialectical Behavioral Therapy (DBT) vs. treatment as usual (TAU) on suicidal behavior as a primary outcome measure. A second aim of the project is to examine group differences between 150 veterans at high risk for suicide and 150 veterans at low risk in a variety of symptom domains. The goal of this will be to identify symptoms associated with suicidal behavior that may advise future treatment.

We will assess symptom domains including mood and substance use in our veteran population by comparing symptoms in low vs. high risk veterans recently discharged from the James J Peters VAMC (JJPVAMC) psychiatric inpatient unit. In addition, we will explore indices of interpersonal function and measure features that have some evidence of offering protection from suicide, which could be viewed as resilience factors. A particular emphasis of the present project is to characterize the nature of the interpersonal dysfunction in high risk individuals, as there exists very good evidence that social isolation, or a lack of a sense of "belonging" puts people at particularly high risk for suicide, in particular in a military sample. We intend to assess the impact of DBT vs. TAU on these symptom domains in addition to their impact on suicidal behavior.

Body:

In October 2011, a supplement to this project was approved to add a physiological measure, affective startle, to the baseline assessment and post- DBT treatment.

Aim 1 relates to a randomized clinical trial of Dialectical Behavior Therapy (DBT) vs. treatment as usual (TAU) in 120 veterans recently hospitalized with high-risk suicidal behavior. This will be accomplished under the leadership of Dr. Marianne Goodman, James J. Peters VAMC, Bronx, NY 10468

Aim 1: To examine, in a randomized controlled trial (RCT), the efficacy of a 6 month treatment with standard DBT (weekly individual sessions, skills training group and telephone coaching as needed) as compared to TAU in 120 veterans recently discharged from an acute psychiatric inpatient stay with high risk suicidal behavior. The primary treatment outcome will be a quantification of suicidal events, as assessed by the Columbia Suicide Severity Rating Scale, which measures suicide attempts, plans and preparations. Our study will be powered to examine treatment assignment differences in this measure. Secondary outcomes will include suicidal ideation, parasuicidal events, treatment compliance, depressed mood, substance abuse and hopelessness.

This aim involves recruiting 120 veterans off the JJPVA "high-risk" suicide list; a designation made primarily after psychiatric inpatient admission for serious suicidal behavioral. High-risk (HR) suicide subjects will undergo a comprehensive diagnostic interview prior to entering the treatment study. Subjects will receive 6 months of TAU vs. DBT but both groups will continue to receive standard psychopharmacology and case management services from their clinic providers. Subjects will receive a battery of assessments at month 6, 12 and 18.

Aim 2 relates to a comparison of high-risk and low-risk suicidal veterans in interpersonal functioning and resilience, in an effort to identify intermediate symptoms that are closely associated with HR suicidal behavior. This will be accomplished under the leadership of Dr. Marianne Goodman, James J. Peters VAMC, Bronx NY 10468

Aim 2: To recruit veterans recently discharged from an acute psychiatric inpatient stay comparing 150 veterans with HR suicidal behavior to 150 veterans without such behavior (LR) in symptom domains focusing on interpersonal functioning and resiliency.

Aim 3 is exploratory and examines the effect of treatment (DBT or TAU) on the putative intermediate symptom domains associated with HR suicidal behavior of interpersonal functioning and resiliency. This will be accomplished under the leadership of Dr. Marianne Goodman James J. Peters VAMC, Bronx NY 10468

Aim 3: To explore the effect of DBT on the candidate intermediate symptoms of interpersonal functioning and resiliency associated with HR suicidal behavior.

Promised work:

Parent Project-

The first 3 months is devoted to training the raters on our assessment and diagnostic battery while we await regulatory approvals. During months 3-6, we expect to perform thirty baseline assessments and 15 high-risk subjects will be randomized to treatment. During months 6-12, 12-18, 18-24, 24-30, we expect that thirty high-risk and thirty low-risk suicidal subjects will receive baseline assessments during each 6 month block. We anticipate that 25 of the high-risk subjects will proceed into treatment during each one of the time blocks. Months 30-36 will target 30 total additional assessments for baseline high and low-risk subjects with 5 of the HR individuals being randomized for treatment. The baseline assessment is a more comprehensive evaluation and we estimate that it will take approximately 6-7 hours with follow-up assessments requiring 1-2 hours.

While we met recruitment goals for Aim 1 of the study, our recruitment for the RTC fell behind. In order to continue recruitment we requested and were granted a fifth year, no cost extension.

The Table below reflects promised work, and new numbers with a 5th year added.

	Baseline assessments (50% HR, 50% LR)	Randomized to treatment (HR only)	Follow-up assessments 6mo 12 mo 18mo		
Months 0-3	-----	-----	----	----	----
			-		
Months 4-6	30	15	----	----	----
			-		
Months 7-12	60	25	12	----	----
			--		
Months 13-18	60	25	19	11	----
			-		
Months 19-24	60	25	19	17	10
Months 25-30	60	25	19	17	15
Months 31-36	30 –	5 –	19	17	15
Months 37-48 (year 4)	New year 4 target- 60 Actual 65 293 to date (goal 300)	New year 4 target-25 Actual 15 90 to date (goal 120)	28	19	30
Months 49-60 (year 5)	New year 5 target- 10 Recruitment just to meet RTC goals	New year 5 target-10 15	15	20	30

Progress to date Parent Study:

Towards accomplishing these aims, we received approval from our local IRB 7/9/09 and local Research and Development approval on 7/15/2009; prior to official funding of the project. This allowed us to *pilot* the intervention, assessments and randomization procedure. Dept of Defense approval was obtained on 4/27/2010; almost four months later that we had projected in our initial statement of work.

Recruitment

During our no-cost extension year, we focused solely on increasing our female Veteran subject pool in order to be able to do gender analyses. In addition, we realized that our LR pool of female veterans needed to be augmented.

Over the past 6 months, we have recruited and successfully assessed an additional **11** females who completed our baseline assessment and affective startle paradigm

For the treatment trial, during our no cost extension year, we completed follow-ups.

Since the inception of the study through 9/31/14, **384** veterans have signed consent (248 high-risk subjects and 136 low-risk subjects) and **340** (221 high-risk and 119 low-risk) have completed baseline assessments. With these numbers, we have surpassed our goal of 300 completed assessments. However, recruitment for the treatment trial remained limited and we randomized a total of 93 subjects to the trial and 53 completed the 6-month treatment.

Summary of Entire Parent Study to date

	<i>High Risk</i>	<i>Low Risk</i>
# consented	248	136
# completed	221	119
# randomized	93	-----
#complete 6 month	53	-----
12 month f/up	49	-----
18 month f/up	43	-----

Randomized Treatment Trial:

To date- **93** subjects have been randomized (to 45 TAU/48 to DBT).

53 subjects have completed the 6-month treatment trial; 25 for DBT and 28 for TAU.

Longitudinal Follow-up at 12 and 18 months:

49 subjects have completed 12-month follow up to date including- 22 DBT subjects and 27 TAU subjects and **43** subjects have completed the entire study (e.g. 18-month completers) including 19 DBT and 24 TAU subject.

Total: **340** of 300 completed baseline assessments (exceeded goals)

93 of 120 randomized to clinical trial

Progress Pertaining to Aim #1

Our Statement of work projected that by study completion we will have 300 baseline assessments finished. Currently we are at 340, and during our no-cost extension year targeted females in order to perform gender sub-analyses.. Data analysis was the focus of our no-cost extension year and we are currently generating several manuscripts. Interim analyses have yielded findings pertaining to the importance of Axis I diagnoses of substance abuse, Axis II diagnoses of borderline personality disorder and responses on the interpersonal psychological survey as important risk factors for identifying "high-risk" veterans (see **Figure 1**).

The identification of the interpersonal psychological survey as a critical instrument has led us to further examine its contents through a computerized implicit task assessment that we will be piloting in year 5 (see Figure 2).

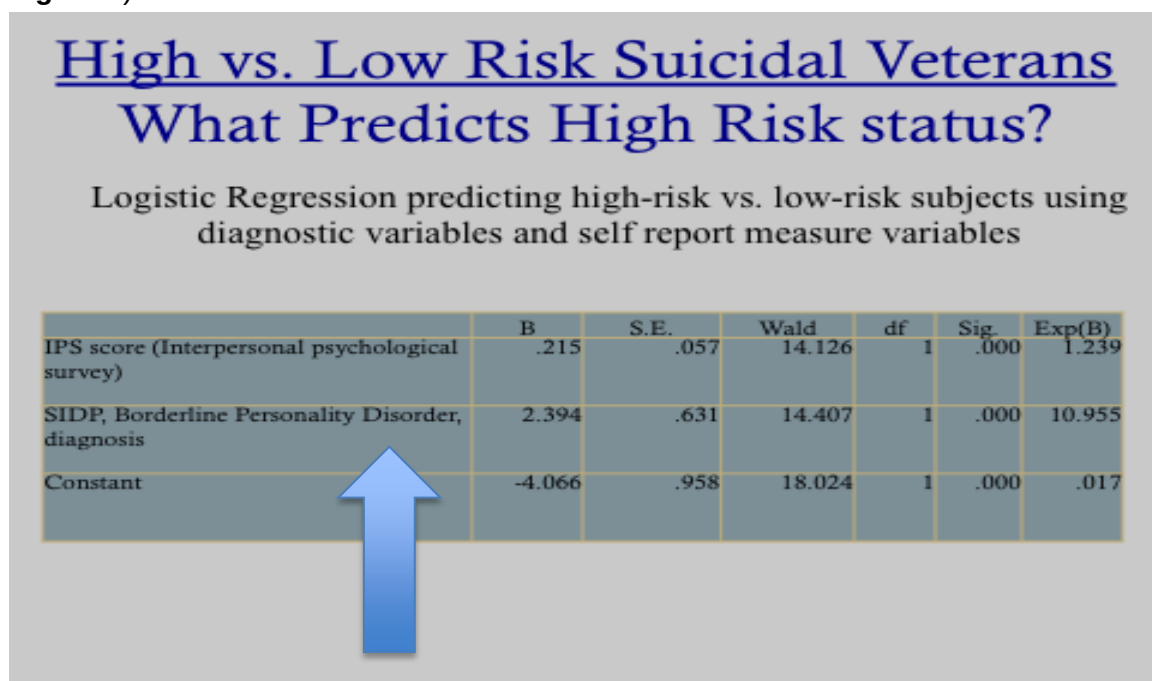


Figure 1- Predictors of Suicide Risk in Veterans

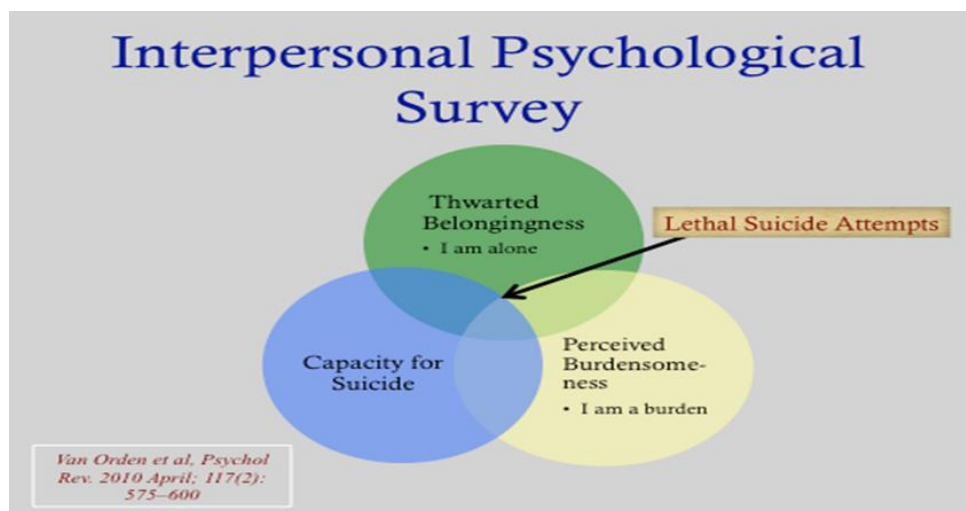


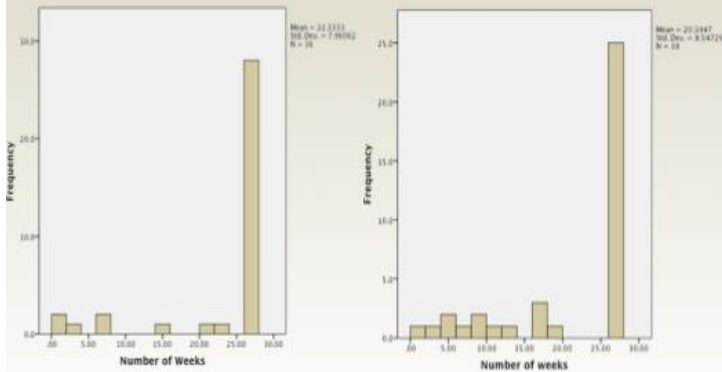
Figure 2- Interpersonal Psychological Survey components

Progress Pertaining to Aim #2

We have randomized 93 subjects to the treatment trial and completed data analyses. Results are pictured below. Our findings indicate that both dialectical behavior therapy (DBT) and enhanced treatment as usual (TAU) were beneficial to suicidal Veterans, but there were no significant differences between treatment groups in our primary or secondary outcome measures (see Aim 2 Figures 1-5). DBT utilized considerably more treatment sessions (see Aim 2-Figure B). Survival Curves for suicide ideation and re-hospitalization also showed no differences (see Aim 2 Figures 6-7).

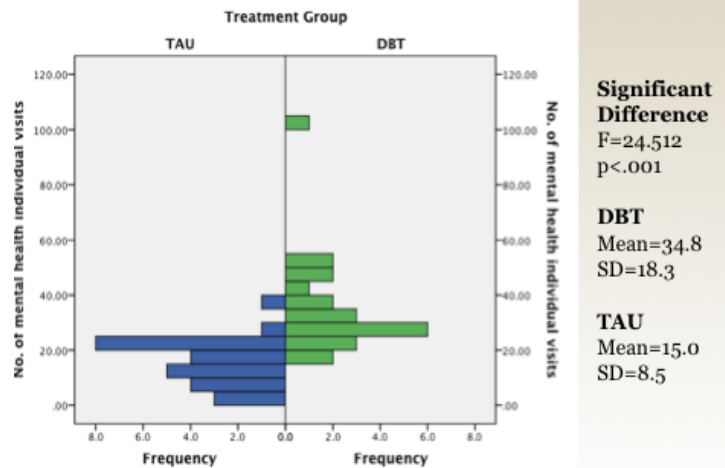
Weeks in TAU Weeks in DBT

28 Completed 25 Completed



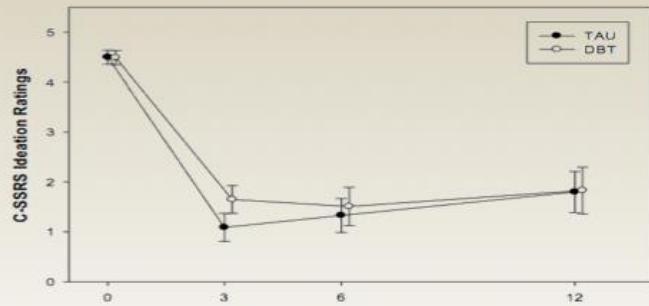
Aim 2- Figure A: # weeks in Treatment

Mental Health Individual Visits



Aim 2- Figure B: # Mental Health Visits by Treatment Group

Figure 1.) Comparison of C-SSRS Ideation Ratings among veterans at high risk for suicide, receiving either Treatment As Usual (TAU) or adjunct Dialectic Behavior Therapy (DBT).



Type III Tests of Fixed Effects ^a				
Source	Numerator df	Denominator df	F	Sig.
Intercept	1	177.723	13.157	.000
TXGRP	1	120.598	.696	.406
VISIT	3	76.995	103.199	.000
AGE	1	164.978	.767	.382
SEX	1	151.432	.157	.693
EDUC	1	163.431	2.117	.148
TXGRP * VISIT	3	77.273	.543	.655

Aim 2- Figures 1-5:

Primary Outcome Measures by Treatment Group-
Figure 1- Suicide Symptomatology (measured by the CSSRS)

Figure 2- Suicide Ideation (measured by the Beck Suicide Ideation scale)

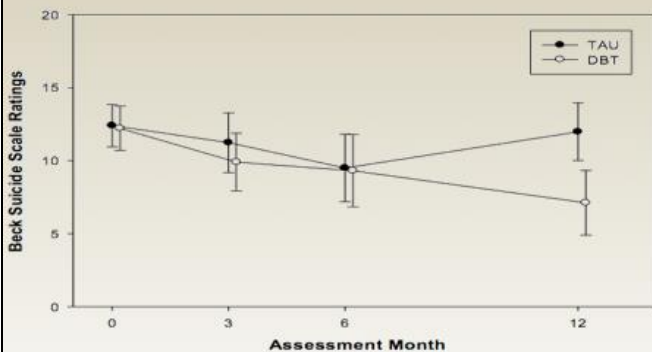
Secondary Outcome Measures by Treatment Group-
Figure 3- Depression (measured by the Beck Depression Scale)

Figure 4- Hopelessness (measured by the Beck Hopelessness Scale)

Figure 5- Anxiety (measured by the Beck Anxiety Scale)

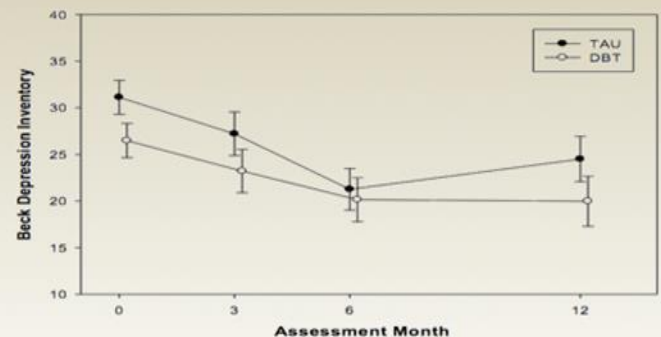
** Note improvements across time in both treatments, however no significant difference between treatment groups

Figure 2.) Comparison of Beck Suicide Scale Ratings among veterans at high risk for suicide, receiving either Treatment As Usual (TAU) or adjunct Dialectic Behavior Therapy (DBT).



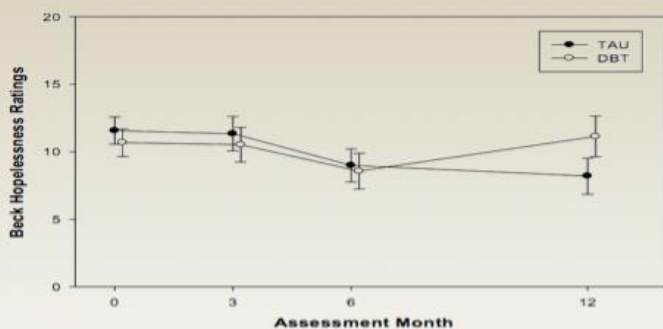
Type III Tests of Fixed Effects ^a				
Source	Numerator df	Denominator df	F	Sig.
Intercept	1	80.496	.191	.664
TXGRP	1	92.898	.873	.414
VISIT	3	119.101	1.976	.199
AGE	1	83.844	1.232	.270
SEX	1	92.020	1.035	.312
EDUC	1	82.442	3.256	.075
TXGRP * VISIT	3	119.379	.890	.448

Figure 3.) Comparison of Beck Depression Inventory among veterans at high risk for suicide, receiving either Treatment As Usual (TAU) or adjunct Dialectic Behavior Therapy (DBT).



Type III Tests of Fixed Effects ^a				
Source	Numerator df	Denominator df	F	Sig.
Intercept	1	89.101	2.267	.136
TXGRP	1	92.459	2.465	.120
VISIT	3	157.464	8.768	.000
AGE	1	86.055	4.877	.030
SEX	1	95.202	1.209	.274
EDUC	1	88.364	.086	.770
TXGRP * VISIT	3	157.431	.432	.730

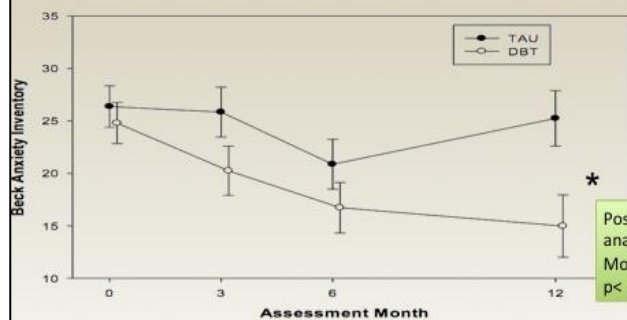
Figure 4.) Comparison of Beck Hopelessness Scale Ratings among veterans at high risk for suicide, receiving either Treatment As Usual (TAU) or adjunct Dialectic Behavior Therapy (DBT).



Type III Tests of Fixed Effects ^a				
Source	Numerator df	Denominator df	F	Sig.
Intercept	1	83.908	3.230	.076
TXGRP	1	88.018	.023	.879
VISIT	3	149.338	2.775	.043
AGE	1	81.911	4.938	.029
SEX	1	90.369	.049	.825
EDUC	1	83.408	.305	.582
TXGRP * VISIT	3	149.104	1.423	.238

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Figure 5.) Comparison of Beck Anxiety Ratings among veterans at high risk for suicide, receiving either Treatment As Usual (TAU) or adjunct Dialectic Behavior Therapy (DBT).

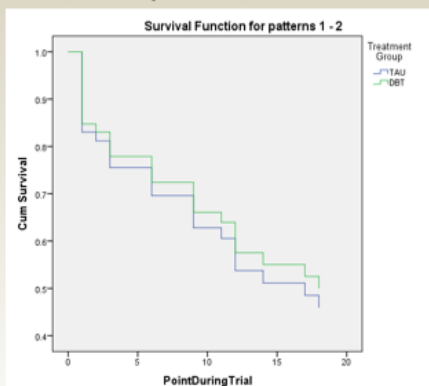


*
Post-hoc
analysis:
Month 12 BAI
p< .021

Type III Tests of Fixed Effects ^a				
Source	Numerator df	Denominator df	F	Sig.
Intercept	1	84.869	4.475	.037
TXGRP	1	90.271	4.666	.033
VISIT	3	144.281	4.718	.004
AGE	1	85.340	1.125	.292
SEX	1	91.790	.173	.679
EDUC	1	88.065	.061	.805
TXGRP * VISIT	3	144.255	1.761	.157

25

Survival Analysis: Suicidal Ideation



DBT 50% w/o ideation @ 18 months
TAU 46% w/o ideation @ 18 months

27

ADDITIONAL ANALYSIS- SURVIVAL ANALYSES

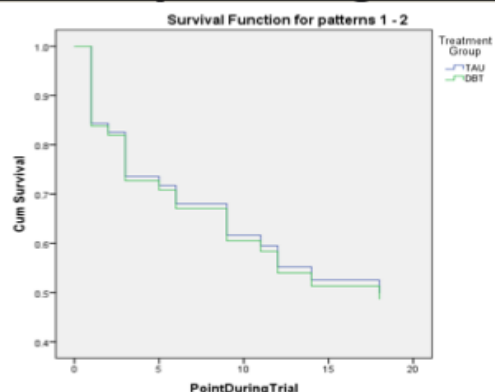
Aim 2- FIGURES 6 and 7:

Survival Analysis – Suicide Ideation

Survival Analysis- Re-Hospitalizations

** Note almost identical survival curves between the two treatment groups. Note very high rate of re-hospitalization.

Survival Analysis: Hospitalizations



Both treatment groups @ about 51% w/o hospitalizations.

30

Progress Pertaining to Aim #3

There were no significant differences found between treatment groups in the domains of interpersonal functioning nor resiliency.

Problems Accomplishing Tasks

With Hurricane Sandy this past year, the Manhattan VA hospital was closed for upwards of 5 months. This led to disruptions of care at our facility, as Manhattan patients sought treatment temporarily at our hospital. This complicated RCT recruitment efforts as pts were less likely to enroll in a longitudinal study that would require changing the location of their outpatient care beyond the expected time of Manhattan VA's closure.

SUPPLEMENT:

In addition to our three aims for the parent study, we have three additional aims for the supplemental study:

Supplement Aim 1 is to conduct a nonverbal and objective psychophysiological assessment of emotion processing using the affective startle paradigm to test whether it might serve as a potential biomarker for differentiating levels of suicidality. This will be accomplished under the leadership of Drs. Marianne Goodman and Erin Hazlett, James J. Peters VAMC, Bronx NY 10468

Aim 1. To examine the magnitude, time course, and rate of habituation of the startle eyeblink response during unpleasant, neutral, and pleasant pictures in 150 veterans with varying levels of suicidality; 60 veterans with a recent suicide attempt (during past 3 months), 60 veterans with suicidal ideation but no history of attempts, and 30 healthy veteran controls (i.e. no current psychiatric diagnosis).

This aim will be accomplished by adding the affective startle modulation paradigm to our current assessment battery of high- and low-risk suicidal subjects. Eligible subjects enrolled in the DoD funded parent project will participate in a 1-hour psychophysiology session at the MIRECC psychophysiology laboratory where we will record our primary variable of interest, namely the affective startle eyeblink response at baseline and 6 months for those enrolled in the DoD treatment trial. During this session, participants will view an intermixed series of unpleasant, neutral, and pleasant pictures from a standardized picture set. For each of the 3 picture conditions, we will examine three measures related to affective startle eyeblink modulation which is our psychophysiological measure of emotion processing: (1) the *amplitude* of the startle eyeblink response; (2) the *time course* of emotion processing by presenting the startle probes at different times during and post-picture processing; and (3) the rate of *habituation* of the startle eyeblink response.

Supplement Aim 2 is to compare startle variables across suicide groups (ideators, attempters) by presence or absence of borderline personality disorder to clarify if differences in affective startle modulation extend beyond personality disorder diagnosis. Thirty suicide attempters with BPD (SABPD+) will be compared with 30 suicide attempters without BPD (SABPD-) and 30 suicide ideators with BPD (SIBPD+) will be compared to 30 ideators without BPD (SIBPD-) across startle variables. This will be accomplished under the leadership of Drs. Marianne Goodman and Erin Hazlett, James J. Peters VAMC, Bronx NY 10468

Aim 2 investigates the relationship of Axis II diagnosis, suicidality and affective startle. The collected data for Aim 2 will be used to explore this question.

Supplement Aim 3 (No-Cost Extension) is to explore gender differences between male and female veterans regarding affective startle modulation and using lifetime number of suicide attempts as a continuous variable of interest. Fifty female veterans will be compared with fifty male veterans for this analysis. This will be accomplished under the leadership of Drs. Marianne Goodman and Erin Hazlett, James J. Peters VAMC, Bronx NY 10468

Aim 3 investigates the relationship of gender, suicidality and affective startle. We will investigate potential differences in affective startle response across gender and suicide status.

Supplement Promised Work:

	Supplement: Startle assessments: Pt Pt HC HC Baseline 6mo Baseline 6mo			
Months 13-18	Obtain IRB approval			
Months 19-24	45	-----	12	----
Months 25-30	50	23 *	12	10
Months 31-36	25	22 *	6	11
Months 37-42	----	5 *	----	4
Months 43-48				

The project was awarded funding on 9/24/2011. In its first 12 months, the research team was incredibly effective in mobilizing resources and enrolling and testing **94** subjects at baseline and completing **1** 6-month follow-up. Over the next 12-month period (10/1/12 → 9/30/13), the team was similarly effective with recruitment, testing an additional **55** subjects at baseline and **13** at 6-months following the treatment trial. In the most recent 12-month period (10/1/13 → 9/30/14), we have tested additional **19** subjects at baseline and **9** at 6-months. The vast majority of these new participants were female (18/19), as we redoubled efforts to recruit from this population at the JJPVAMC. These figures bring the cumulative total of baseline and 6-month numbers to **168** subjects and **23** subjects respectively. We therefore have completed baseline affective startle recruitment, but continue to recruit female participants for **Supplement Aim 3** (see above).

Progress Pertaining to Supplement Aim #1

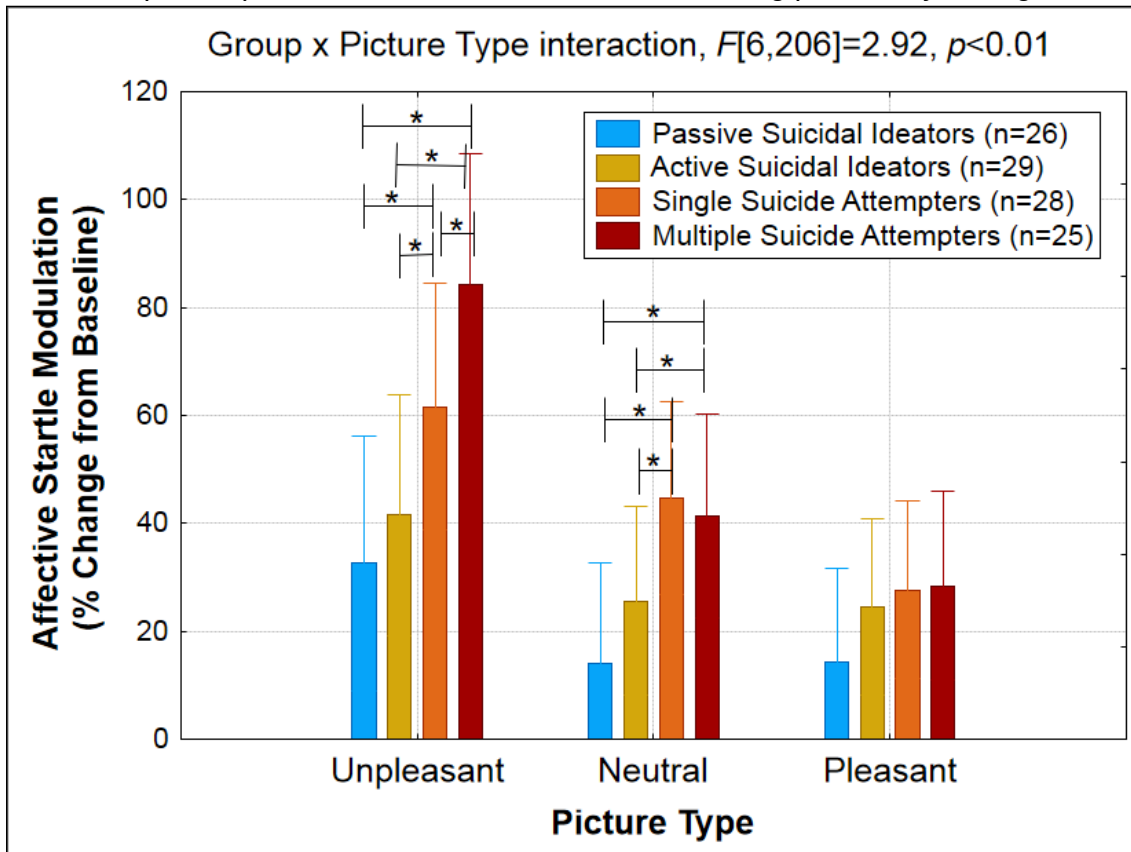
Since receiving funding, we have run **168** patients at baseline and have done **23** 6-month follow-ups and therefore have met our recruitment goals for supplement Aim #1. The overall and 12-month breakdowns are as follows:

Group	Recruitment - Total	Recruitment – Last 12-Months
Controls	34 (5F/29M)	2 (2F)
Ideators	44 (12F/32M)	10 (10F)
Single Attemptors	42 (12F/26M)	4 (4F)
Multiple Attemptors	49* (23F/26M)	3 (2F/1M)
6-Month Follow-Up	23 (6F/17M)	9 (3F/6M)

*Four patients reclassified as a Single Attemptors

Preliminary analyses on the first **108** subjects demonstrated a significant interaction between affective startle and suicide risk. (see **Supplement figure 1**). Multiple ideators, in the unpleasant picture condition, had significantly elevated affective startle % change values as compare to single attemptors and ideators (both

active and passive). We await confirmation of these exciting preliminary findings with the full data set.



Supplement/Figure 1- Affective Startle and Suicide Risk in veterans with passive ideation, active ideation, and a history of single and multiple suicide attempts (preliminary data, n=108)

Progress Pertaining to Supplement Aim # 2

See information pertaining to Aim #1.

Progress Pertaining to Supplement Aim # 3 (NCE)

This is a newly added Aim for our recently approved No-Cost Extension and we will continue to gather data from female participants.

Problems Accomplishing Tasks

We are not experiencing any difficulty recruiting for this project and are in fact ahead of schedule. We expect to increase the number of baseline assessments on females in the coming year.

Key Research Accomplishments for both Parent and Supplement Projects

We have just completed year 5 of the parent study and now approved for a no-cost extension for the affective startle supplement.

- Since DoD IRB approval (4/27/10): parent subject recruitment has been brisk. **384** Veteran subjects have signed consent.
- **340** (out of promised 300) subjects completed baseline assessments.
- **93** HR patients were randomized to the treatment trial,

- **53** HR patients have completed the 6-month treatment trial,.
- **168** subjects have completed baseline affective startle
- **Treatment trial results suggest that DBT is no more effective than enhanced treatment as usual for suicidal Veterans.**

**** however both groups had significant drop out rates and difficulty with engagement.**

Future directions for research suggest alternative modalities for early engagement post hospitalization.

Reportable Outcomes 2013-2014:

Presentations:

- 1) **American Psychiatric Association, May 2013**
- 2) **Society for Psychophysiology Research, September 2014**
- 3) **North American Society Personality Disorders, April 2014 - two presentations and 1 poster**
- 4) **Veterans Integrated Service Network VISN 3 Annual meeting- May 2013**
- 5) **International Society of Psychophysiology Research, Sept 2013**
- 6) **Biological Psychiatry, May 2014 (poster)**

Conclusion:

Our preliminary baseline data highlights the importance of Axis II psychopathology, in particular, borderline personality disorder as a risk factor for high-risk suicidal behavior. This is relevant as the disorder is often under recognized in VA settings and not even listed in the Uniform Services Package, the document listing required services for Veterans.

Enhanced Treatment as Usual and DBT are both effective treatments for suicidal veterans, however there is no significant difference between treatments and DBT results in enhanced treatment delivery needs. Future directions for research should be targeted to better engagement of high risk suicidal veterans, who do not follow up with outpatient psychotherapy treatments as both groups had high drops out in this subset. These individuals were primarily male, homeless and abusing substances.

Regarding our supplemental funding for affective startle, a psychophysiological assessment tool, there does appear to be a significant relationship between the affective startle response to negative picture probes and number of suicide attempts. These results suggest that the processing of negative emotion is a critical element of suicide attempt history. Future studies using affective startle include whether this measure can predict those at suicide risk prospectively. We are currently piloting a portable version of the affective startle assessment which will allow us to assess individuals in different setting (e.g. emergency room, inpatient unit, off campus locations).

We hope to report on gender differences in our last progress report next year after our no-cost extension for the supplement.

References:

Alvarez, V (2009). Suicides of Soldiers Reach High of Nearly 3 Decades New York Timescom. New York, New York Times.

Appendices: none included

Supporting Data: none included