Remotely-Delivered Benefits Counseling for Service Connection Applicants

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Project Description

1. Principal Investigator
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2. Project Title
Remotely-Delivered Benefits Counseling for Service Connection Applicants

3. Purpose
The purpose of this study is to evaluate the utility of Remotely-Delivered Benefits Counseling in a 24-week clinical trial. This study will evaluate the effectiveness of Benefits Counseling on work and work-related outcomes with Veterans who are applying for service-connection. This study has the following specific aims and hypotheses:

Primary Aim 1: To estimate the effect of Remotely-Delivered Benefits Counseling on the slopes of paid work over time.

> *Hypothesis*: The slopes of hours of paid work over time will differ between the control and Benefits Counseling groups, as evidenced by a significant, positive treatment-by-time interaction effect.

Exploratory Aim One: To estimate the effect of Remotely-Delivered Benefits Counseling on other outcomes.

> *Hypothesis*: The slopes of hours of volunteer work; days attending school, days in vocational rehabilitation settings, days engaged in any one of the work-related activities; and income earned over time will differ between the control and Benefits Counseling groups.

Exploratory Aim Two: To conduct bivariate analyses of two of the components of mediation of Benefits Counseling's effects---correlation with the group assignment and with the outcome:

> *Hypothesis 2A*: Assignment to Benefits Counseling (vs. control) will be associated with one or more of the following: (i) more positive changes in ratings of work's importance, (ii) greater decreases in beliefs that working and service connection are linked, and (iii) more positive changes in number of weeks attending any mental health or vocational counseling.
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> *Hypothesis 2B*: Individual slopes in hours worked over time will be associated with one or more of the potential mediators (i, ii, iii) as above in Hypothesis 2A.

4. Background
In FY 2013, a total of 1,110,050 Veterans were being compensated for mental disorders. Of the 1.4 million new claims awarded for various conditions, 100,515 were for a mental disorder [8]. More than half of all OEF/OIF Veterans are expected to apply for some form of service connection [9]. The disability decision has far-reaching implications for Veterans' financial and work status [10]. Despite the predominantly salutary effects of disability payments [11, 12], Veterans [13, 14] and Social Security recipients [15] who receive disability payments are less

likely to work for pay, even after statistically adjusting for the fact that people awarded benefits are generally more disabled than those denied benefits. Working is associated with better quality of life and other benefits [9, 16], so underemployment is a problem. A strong argument for engagement of Veterans applying for service-connection in occupational rehabilitation was made by Sally Satel, a Yale-affiliated psychiatrist, in 2011 Congressional Hearings. In her testimony, titled "Bridging the Gap Between Care and Compensation for Veterans" [17] she cited our editorial on engaging Veterans in treatment when they apply for service-connection [18] in describing the need for rehabilitation at the time that Veterans apply for service-connection.

Benefits Counseling maximizes beneficiaries' time engaging in work-related activities in the following ways: 1) Providing information about how work might impact receipt of disability payments: One reason people who receive disability payments are disproportionately underemployed is the perception that beneficiaries who work will definitely lose their disability benefits [16, 19]. However, service-connection ratings are based primarily on the *average* impairment in earning capacity, and therefore an individual Veteran is not supposed to be penalized for overcoming a disability by working (38 CFR Section 4.15). There are some exceptions [20] but nevertheless, the best available data are that only about 6% of Veterans who are service connected for PTSD lose these benefits during a ten year period [21]. 2) Amplifying applicants' existing motivation to engage in work and related-activities, using a Motivational Interviewing approach: Motivation has been associated with success in rehabilitation [22, 23]. Benefits Counseling brings out motivation to work in a non-judgmental, individually-tailored way. 3) Guiding Veterans to available vocational rehabilitation, education, and job-finding services: Veterans applying for disability compensation can benefit from the extensive treatment, rehabilitation, and employment-related resources available to them. There is little in the current VA disability application process that informs patients of vocational rehabilitation opportunities. Results of the 2010 National Survey of Veterans suggested that rehabilitation benefits were underused [24]; only 14.8% of Veteran respondents who applied for disability compensation indicated that they had ever used vocational rehabilitation services. Many who applied for disability benefits but did not use any vocational rehabilitation services indicated reasons that were remediable such as not knowing how to apply and not knowing they were eligible for these services. 4) Encouraging Veterans to seek treatment for psychiatric disorders that are barriers to working. A substantial proportion of Veterans presenting for Compensation examinations have not received VA services before---75.3% in one published study [25]--- making this a valuable opportunity to engage Veterans in treatment and thus reduce health-related barriers to working.

Evidence of Benefits Counseling's Efficacy
Benefits Counseling was evaluated in an observational cohort study among Social Security recipients with psychiatric conditions who had expressed some interest in working [26]. Participants received an average of 8 hours of counseling. Remarkably, those beneficiaries who received this Benefits Counseling earned an average of $1,256 more per year than matched controls. Subsequently, a large, randomized controlled trial of Benefits Counseling as part of a multi-component bundled intervention found a large and significant effect; 61 percent of Benefits Counseling participants were working at follow-up compared to only 41 percent of control participants [27]. Our group's work extended these findings to Veterans applying for service-connection for psychiatric conditions. We developed a Veteran-specific manual based on published literature---primarily that of Robert Drake and colleagues [26] and Nina Sayer [28-30].

Vocational rehabilitation materials were developed with input from our VISN 1 MIRECC collaborators, primarily Charles Drebing and Lisa Mueller, and input from rehabilitation experts at VA Connecticut (Morris Bell, Joanna Fiszdon). The material was discussed with Veterans, Veterans' Service Organizations, and Veterans Benefits Administration stakeholders. It was then pilot tested and further refined. We demonstrated Benefits Counseling's efficacy among Veterans in a randomized clinical trial published in Psychiatric Services [31]. The study utilized many methodologies that are in the proposed study -recruitment of Veterans applying for service-connection for a psychiatric condition, use of a timeline followback calendar to assess daily amount of work done, and assessment 4, 12, and 24 weeks after randomization. The main outcome analysis found that Benefits Counseling was associated with a significantly greater slope in days worked for pay than the control condition (p=.01). The effect size for this difference was 0.69 (standardized mean difference in slope estimates between the Benefits Counseling and control groups), a large effect for a behavioral intervention.

The Development of Benefits Counseling in a Remotely-delivered Format in Addition to Face-to-Face. Motivational Interviewing interventions targeting complex behaviors have been effectively delivered by computerized programs. Computer-delivered treatments employing Motivational Interviewing have shown some efficacy for diverse conditions including self-management of epilepsy [32], reduction of drug and alcohol use [33], reduction of risky sexual behaviors [34], and quitting smoking [35]. Because of their economies of scale [36, 37], online therapies are often developed in addition to face-to-face, in order to expand access to treatment, a particularly relevant advantage in counseling Veterans who come from remote areas for one-time C&P evaluations. Our group developed the internet-based version of Benefits Counseling using methods described by Dilorio and colleagues [32]. They identified characteristics of a website that effectively delivers an intervention: simple layout; navigability to different modules, resources and links; aesthetic appeal (e.g video clips); graphics; and ease of use. Other investigators have made similar recommendations [38, 39].

5. Significance

Early intervention is particularly important for most psychiatric conditions affecting Veterans [40] that may become chronic [41]. Benefits Counseling can engage more Veterans in work and productive activity. Work has myriad health-related benefits, and can provide pride and a sense of purpose. A remotely-delivered Benefits Counseling intervention can be widely offered with a modest investment. There is considerable public pressure to integrate Veterans into the workforce, and to look at the Compensation and Pension process as a place to do it. In widely publicized testimony to the House Committee on Veterans Affairs, Linda Bilmes called for something like the proposed intervention: "VBA should shift its focus away from claims processing and onto rehabilitating and reintegration of Veterans" (*House Committee on Veterans Affairs*, 2007). Finally, the proposed study's findings among Veterans applying for service connection for mental health conditions may be generalizable to Veterans applying for service-connection for non-psychiatric, medical disabilities. The study results may hasten the day that a Compensation examination is routinely seen as an opportunity for both evaluation and rehabilitation for Veterans.

6. Research plan

A. Study Design Overview

Data collection will be conducted at the Northampton VA Medical Center and the West Haven VA Medical Center. Veterans will complete baseline evaluations, and then be given a user ID and instructions to log-on to a study website at home to receive their randomization assignment. Only those who do so will continue in the study and be asked to complete the telephone-delivered assessments on weeks 4, 12, and 24. This randomization after logging in restricts participation to people who demonstrate some motivation and ability to access a website.

Sequence of procedures for the clinical trial:

___ Potentially eligible Veterans scheduled for a Compensation examination are identified by reviewing Compensation clinic schedules and charts.

___ Potentially eligible Veteran receives letter explaining that a study recruitment telephone call will be coming, thus allowing the Veteran to opt out of receiving it (see Appendix). Veterans can also opt out by calling a toll-free phone provided in the letter.

___ Telephone call inviting participation. The Research Assistant calls and asks the Veteran questions to determine eligibility. Following a script (see Appendix), the Research Assistant describes the study to the Veteran and schedules an appointment for informed consent and data collection. Appointments will be scheduled before a Veteran's planned Compensation examination and up to 3 months after the exam. Veterans vary in how able they are to schedule appointments immediately before or after Compensation examinations. Flexible scheduling balances feasibility and experimental rigor.

___ Informed consent and baseline data collection by Research Assistant.

___ The Research Assistant gives the Veteran a user ID and password to log on to the study Website.

___ Veteran goes home, logs onto the website, and receives directions to log-on to either the Benefits Counseling or Control websites (i.e. the Veteran is randomized).

____ Veteran is called by the study therapist within two days of logging on and is counseled with the assigned treatment. If the Veteran has not logged on for randomization within a week, then the therapist will call and encourage the Veteran to log-on for randomization and continuation in the study. If after one more week the Veteran has not been randomized, that participant will be discontinued from the study.

___ Assessments by phone at weeks 4, 12, 24 (only of randomized Veterans).

<u>B. Remotely-Delivered Benefits Counseling</u>

1. Integration of Website Use and Therapist Phone Calls:

a. Purposes of Phone Calls: The purpose of the Benefits Counseling phone calls is to complement the web-based modules and to support the Veteran in applying the website content to his/her particular situation.

b. Introduction: The therapist explains that his/her role is to help the Veteran get as much as possible out of the Benefits Counseling website. The therapist plans the dates and times for phone calls and provides the Veteran with a phone number to call him/her for rescheduling or brief questions.

c. Timing and Content of Session Calls: The therapist tries to schedule calls soon after the Veteran has completed each of the first two modules. At each of the calls, the therapist makes general inquiries about the Veteran's experience using the site, the information covered, and any follow-up the Veteran plans. Based on these responses, the therapist

will follow-up with questions about the content of the module just completed (domains described below).

d. Timing and Content of Session-Three Call: Therapists will instruct Veterans to complete Module Three after receiving their service-connection decision and to call after completing it. If the Veteran has not called by week 12, the therapist will call the Veteran to determine the status of the C&P claim, and module completion. If the C&P decision has not been received, the therapist will call again at 16 and 20 weeks to review the decision and module, if the Veteran hasn't called first.

e. Overall Call Limit: Therapists will limit calls to no more than 30 minutes each, and no more than three therapy calls per Veteran; calls lasting fewer than five minutes (e.g. for scheduling or brief questions) will not count towards the three call limit.

2. Website

a. The VACHS IRB reviewed the website's content as part of protocol MR0031, IRB #01389, for preliminary use by Veterans. Screenshots of the website are attached as an Appendix.

The website can also be accessed by

Going to vabenefitseducation.org
Entering username marc
Password bluefish
Selecting go to cloned interview.

b. The Goals and Content of the Three Modules: In keeping with published literature and our pilot experience, we kept the intervention modules brief (about 20-30 minutes each).

Module	Module's Goals	Session Content in Brief
Session One: Your Benefits and Your Goals	To engage Veteran in the program, explain that Veterans can work and earn service-connection	-Instruction on how to use the website and its purpose -Review Veteran's experience applying for benefits -Inquire about Veteran's perception of relationship between disability benefits and work, explanation of relationship between disability benefits and work
Session Two: Your Options-Work and Otherwise	To enhance the Veteran's motivation to work. Based on goals, make an Action Plan.	-Elicit situation, feelings and attitudes towards employment -Motivational Interviewing exercises (e.g., Decisional Balance, Values Card Sort) -Review barriers to work including the disabling condition; consideration of treatment for disabling condition -Develop an action plan
Session Three: After Your Service Connection Decision	To review the goals and plans identified in the previous sessions in light of the award (or denial) of service-connection benefits	-Inquiries about Veteran's reaction to service-connection decision; provide information about how to appeal decision -Reconsider work and financial goals (from Session Two) in light of service-connection award (or denial) -Review action plan

		-Troubleshoot barriers, summary, and follow-up resources

c. The relationship between work and benefits is explained using graphics, and video testimonials from Veterans who are service-connected and work.

C. Control Condition:

1. *Description of the Control Condition and Rationale for Choosing this Specific Control Condition*: This control condition, involving referral to VA websites, represents enhanced treatment-as-usual. A Veteran who completes a Compensation examination ordinarily has no further treatment or referral as part of the Compensation examination. The information about benefits-related websites controls for having information available about benefits and receiving encouragement to pursue that information.

2. *Control Condition Content*: The control condition involves being urged to explore links to three VA websites with Compensation & Pension-related information:

a. The VBA website with links about VA disability compensation. The questions answered are: What is VA Disability Compensation?, Who Is Eligible?, How Much Does VA Pay?, How Can You Apply? And Upcoming Events.

b. The VBA site with fact sheets about the different types of benefits available to Veterans. The topics covered in these fact sheets are: General Benefit Information, Veterans with Service-Connected Disabilities, Veterans with Limited Income, Education and Training for Veterans, Home Loans, Dependents and Survivors' Benefits, Burial and Memorial Benefits, and Insurance.

c. The VBA websites for the local C&P office where issues pertaining to an individual Veteran's specific application are addressed. The site includes phone numbers to call with questions, e-mail contacts and directions to the VBA office.

3. *Role of Therapists in Control Condition: The therapists in the control condition will differ from the Benefits Counseling therapist as shown in the table below*

Control Therapist	**Benefits Counseling Therapist**
Initiate calls to Veterans at weeks 1 and 2	Initiate calls to Veteran at weeks 1 and 2 and around time of Module Three (or thereafter)
Up to three therapy calls of up to 30 minutes each	Up to three therapy calls of up to 30 minutes each
Convey information about Veterans Benefits	Convey information about Veterans Benefits AND vocational issues
Offer to elaborate on information on control websites	Inquiry about modules on Benefits Counseling website. Follow-up inquiries about domains covered on site.

Justification of Sample Size

We estimate that 190 Veterans will be enrolled and complete baseline assessments; 130 will log-in to the randomization site and be assigned to a treatment condition; 104 (52 per condition) will complete at least one follow-up assessment.

Precision Analysis

Consistent with the purpose of a pilot study, the sample size was selected to

estimate the standardized effect of treatment with reasonable precision, rather than to power for a statistically significant effect [50]; A **sample size of 52 per treatment condition** permits estimation of an expected standardized difference in slopes of hours worked between Benefits Counseling and control groups (e.g., (slopeBC-slopeCON)/SDslope) of δ=.40 with a 95% confidence interval of (.01, .79). This effect would reflect an average 6% increase in baseline number of hours worked per month, or a total increase of 43% by month 6. Assuming an average baseline event rate of 40 hours/28 days and no change in the control group, this effect is equivalent to approximately 17 additional hours (approximately 2 days) of work per month by month 6.

We planned our precision analysis around an effect size of 0.4 because (a) the effect size in our RCT of face-to-face Benefits Counseling was δ=.69 and (b) an effect size of 0.4 is clinically meaningful. An additional 2 days worked reflects earning a substantial amount of additional money for people with limited incomes, in addition to other benefits associated with working.

D. Experimental Participants

1. Inclusion and Exclusion Criteria

a. *Inclusion Criteria*: All enrolled participants will have difficulty working as evidenced by a "Yes" response to any sub-part of the question below (from the SF-36, [51]): "During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious): (a) Cut down on the amount of time you spent on work or other activities? (b) Accomplished less than you would like? (c) Didn't do work or other activities as carefully as usual?"

Participants will also meet the following inclusion criteria: (i) A Compensation and Pension evaluation by a psychiatrist or psychologist is scheduled; (ii) Does not have a service-connected physical disability rated over 30%; (iii) Is not service-connected for a psychiatric condition (0% service-connection is allowed, as Veterans with 0% service-connection have not received any benefit payments); (iv) Age 18-65; (v) Reports access to an internet-connected computer/tablet and a working telephone; (vi) Reports working no more than 24 hours per week for pay over the preceding 4 weeks; (vii) Self-reported ability to participate psychologically and physically, able to give informed consent and complete assessments; (viii)
Reports being able to read (this is necessary for understanding the website); (ix) Expressed interest in sampling whatever website is provided.

b. *Exclusion Criteria*: (i) Already receiving service-connection, SSI or SSDI; (ii) Has a conservator.

2. Feasibility of Randomizing 130 Veterans: A review of Compensation examinations conducted at Northampton over a 12 month period showed that 547 were conducted for psychiatric conditions. Of these, 348 were initial examinations, 190 were reviews, and 9 were for other reasons. We are estimating that approximately 60% of the 348 will be working fewer than two days per week and receiving less than 30% service-connection. In a chart review of Compensation examinations conducted at our MIRECC site in Bedford, approximately half (17 out of 38) of Veterans coming for new psychiatric Compensation evaluations were both not working ***at all*** and less than 30% service-connected. Some Veterans will be excluded for other reasons. Therefore, we estimate that 209 eligible Veterans will be approached in a year, which is enough to randomize 130 over two and a half years of recruitment.

3. Balancing the study groups: Participants will be randomized by the Project Director, with assignment delivered by the website, using an urn randomization procedure [52] that offers the benefits of balancing allocation of important prognostic variables in treatment groups, while still retaining other benefits of random assignment. The factors in the urn will be those potentially related to vocational outcomes in Veterans:

- Self-reported use of an illicit drug and/or risky alcohol use within the past 3 months (as measured by the ASSIST, using standard definitions [53,60,61,62]) within the last 28 days. Opioid use will qualify if the opioids were *not* prescribed to the Veteran.
- Current enrollment in VA psychiatric or substance abuse treatment (yes/no).
- Race (African American –yes/no) has been associated with responses to remotely-delivered behavioral messages [54].

Justification for Why Follow-up Data Collection after Baseline will be Done via Telephone:

Timeline followbacks have been administered by phone for substance abuse evaluation and are highly consistent with face-to- face assessments conducted in the same participants---in fact reports of substance use were numerically higher with the telephone assessment, suggesting a greater likelihood of truthful reporting of embarrassing information by phone [55]. The follow-up assessments are also relatively brief, taking 30 minutes or less per session. Veterans will have already completed these assessments at the face-to-face baseline visit so they will be familiar with them when they are re-administered by phone.

1. Separation of Therapies from Assessments: Veterans will be instructed not to tell the Research Assistant if they are receiving Benefits Counseling or not. To determine if the blind was maintained, we will ask the Research Assistant to rate the condition each Veteran was assigned to and the Research Assistant's certainty about the assignment on a 0-100 visual analogue scale.

2. Participant Tracking Procedures: After randomization, participants will schedule phone assessments with the Research Assistant. The Research Assistant will offer to place reminder calls or a text message/email reminder prior to the assessment call to help Veterans remember them. Within two days of an upcoming appointment, participants will receive a reminder call/email/text. (Sample text/email would read: "You have a follow-up phone call for the VA research study scheduled for [date] at [time]. Please call [Research Assistant's name] at [phone number] if you need to reschedule. Do not reply to this message as the account is not monitored. Thank you.") If a participant misses a scheduled assessment, the Research Assistant will place follow-up calls.

To the extent that participants are not able to be reached for either the phone assessments (or therapist telephone calls), participants' VA medical records will be accessed to obtain updated telephone numbers, in addition to updated resident addresses. This will allow us to call participants and send letters to participants using the most up to date information on file. We also will seek to obtain information from participants' VA records regarding upcoming appointments and additional locations where they can be located so as to re-establish contact. Participants will have the option to not allow this via an opt-out statement included in the consent form.

Through these proposed means we believe we will be able to increase participant retention and better track the outcome of participation in the current study.

3. Schedule of Assessments

Visit	Domain	Assessment
BL	Characterize Participants	Baseline Questionnaire, SF 36; Alcohol, Smoking and Substance Involvement Screening Test (ASSIST); Disability Application Appraisal Inventory; PTSD Checklist (DSM5 version); Brief Symptom Inventory
BL, 4, 12, 24	Baseline and Outcomes	Timeline Follow-Back Calendar: paid work, unpaid work, voc rehab, education; Income from different sources; Brief Symptom Inventory; PTSD Checklist-5
BL, 4, 12, 24	Potential Mediators	Work-Related Attitudes Scale: Work Importance and Confidence Ruler
Therapy Session	Process	Audio-recorded Phone Calls
Week 8, 24	Process	Satisfaction with Counseling and with Websites (mailed assessment)
End-of-Study	Process	Extent of Study Participation from Therapist Cell-Phone (# minutes on phone with Therapist) Extent of Benefits Counseling Website Use (# days logged on to website, # modules completed)
End-of-Study	Extract Data from C&P Exam and VA Database	Mental Health Diagnoses and service connection outcome and award determination from C&P Examination Reports and VBA databases and VA Mental Health Service Use from VA Databases

Justification for Schedule of Assessments: The initial 4-week assessment follow-up date was chosen because results of Motivational Interviewing interventions have been detectable this quickly in other studies [56]. In our randomized clinical trial of in-person Benefits Counseling, week 24 assessments allowed for detection of later emerging effects of Benefits Counseling.

Baseline Assessment Measures to Characterize Participants: The following measures will be administered by the Research Assistant in a face-to-face meeting prior to beginning the intervention:

1. Baseline Characteristics Questionnaire: A questionnaire to characterize study participants has been used in our recently-completed Benefits Counseling study. It covers the following domains: demographics, military history, psychiatric history, employment, legal status, and last 28 days of income by source. It also includes 10 items from the Attitudes toward Seeking Professional Psychological Help Scale-Short Form [57]. This widely-used scale consists of two factors, one reflecting openness to seeking treatment for emotional problems and the other reflecting value of seeking treatment and need for it. The Questionnaire also includes a four-question screen for TBI, a screen which is intended to be sensitive but not specific, when a single positive answer is interpreted as a positive screen [58]. Internet usage is measured using items derived from a clinical trial of an interactive voice response system [59]. Veterans are asked whether they own different technology types (e.g. a working cell phone), whether they make different uses of it (e-mail, text messaging, searching) and number of days engaged in activities such as sending e-mail.
2. The SF-36 will be used to measure self-rated quality of life. The SF-36 was derived from the Medical Outcomes Study to assess health-related quality of life [51]. Patients answer 36 questions about health related impairments in daily activities, impairments from illness, and psychological states.

3. Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): The ASSIST consists of eight questions concerning use of alcohol and or drugs, mostly within a three-month timeframe. It includes inquiries about amount of use, and incorporates questions that are somewhat indirect such as whether anyone else asked the Veteran to cut-down on use [60]. The ASSIST has excellent reliability [61] and validity [62].
4. The Disability Application Appraisal Inventory [28] was developed to better understand VA disability claimants' views of disability application and the role the beliefs play in clinical presentation. It is composed of 3 scales assessing (i) understanding of the claims process (Knowledge scale), (ii) expectations specific to the process (Negative Expectations scale), and (iii) the reasons becoming service connected is important to Veterans (Importance scale). The Disability Application Appraisal Inventory's test-retest reliability, internal consistency, factor structure and validation against selected MMPI subscales were tested and the measure has good reliability and construct validity [28].
5. The Post Traumatic Stress Disorder Checklist for DSM5 is a 20-item update [3] of the extensively validated earlier version [63], which had excellent agreement with comprehensive observer ratings [64, 65]. Veterans are asked to rate their agreement on a 5-point Likert scale with statements about how bothered the Veteran has been by each symptom in the past month, and the total score is the sum of the 20 item scores. The wording is general enough to rate PTSD symptoms related to Military Sexual Trauma as well as Combat Trauma and it has been sensitive to treatment effects in behavior therapy trials [66].

Outcomes Measured Repeatedly (Baseline, Weeks 4, 12, and 24)
1. Work and rehabilitative activities. A time-line-follow-back method will be used to determine whether and on what days the Veteran engaged in different work-related activities.
--- work for pay (in-kind compensation such as reduced rent is only counted when it is a formal arrangement)
---working without pay (includes formal volunteer work, and informal work such as babysitting, cleaning grounds for a neighbor, cleaning basements and attics, informal in-kind arrangements)
---participated in any kind of vocational rehabilitation (includes Compensated Work Therapy, Supported Employment)
---enrolled in classes, attended school
Additional coding is made for illicit work, and an "other" category for other work-related activities.
A calendar avoids information being collected twice for the same service, such as Compensated Work Therapy being counted as a paid job and as rehabilitation. Separate summary measures will be the number of hours and days the participant worked for pay; and days worked without pay, participated in any kind of vocational rehabilitation, and attended school. A secondary outcome will be the number of days out of 28 the Veteran engaged in any one of these activities (i.e. range of 0-28 with each day scored 0/1 for whether any of the above activities were engaged in). Income earned will be tabulated.

2. The Brief Symptom Inventory [4] is a 53-item self-report inventory of psychiatric symptoms that asks patients to rate items on a 5-point scale of distress. It yields nine primary symptom dimensions: anxiety, depression, hostility, interpersonal sensitivity, obsessive-compulsive, paranoia, phobic anxiety, psychoticism and somatization. Depression, most notably, has been strongly associated with function among the disabled [68].

Attitude Measures that Might Mediate Treatment Response
1. Work Importance and Confidence Ruler: One potential mediator of change that will be measured is "importance of work" and "confidence in ability to work" rated on a similar scale and asked in a similar way as used in Motivational Interviewing [69] and for many other behavioral measures [70]. Our VISN 1 MIRECC colleague Lisa Mueller used this scale to show that Veteran-rated importance of work was associated with engagement in Compensated Work Therapy among Veterans with vocational and psychiatric difficulties.

2. Work-Related Attitudes Scale. This instrument asks the Veteran to rate agreement with statements asserting an absolute connection between several work situations and receiving service-connection. The items were modified from those used in a completed study of Supported Employment at VA [71] and from those that showed range restriction in our study of in person Benefits Counseling.

Time Veterans Need to Complete Assessments: It is estimated that the assessments collected at the first face-to-face assessment will take approximately 90 minutes to complete and the assessments collected serially by phone at 4, 12, and 24 weeks will take an average of 25 minutes per call to complete.

During Therapy Session Audio Recordings

Counselors will attempt to audio record all telephone sessions. From these, a random sample of approximately 20 will be rated. Procedures for rating audio recordings and items will follow the format of the Yale Adherence and Competence Scale (YACS) [72] in that sessions will be rated for expected elements (review of work and compensation claim), proscribed elements (pressuring Veterans to work against their will) and general elements (therapist supportiveness).

Ratings will be conducted by the Project Director and an experienced clinician-rater. Only the independent rater's ratings will be analyzed; the Director's ratings will be for training and supervision only. The rater will be trained until adequate inter-rater reliability with the Project Director's ratings is achieved.

Process Measures (weeks 8 and 24):
a. Satisfaction with Counseling and Websites will be rated on Likert-scaled items. This form will be mailed to the Veteran at weeks 8 and 24 with instructions to complete it, place it in a sealed envelope, and mail it to the Project Director. The reason to administer this assessment by mail is to maintain the study blind, which would be compromised by having the Research Assistant obtain them. The initial portion of this scale asks for ratings of the counseling overall. The second portion, used in our "Think Aloud" study, asks participants to rate characteristics of the website they were randomized to (e.g. clarity of layout, usefulness of information, desirability compared to face-to-face presentation of same material).
b. Benefits Counseling Treatment Engagement. The hosting server will record the date and time of each log-in by study ID. We will track the number of separate days the Veteran logged on to each website module and responses for each participant. We will also track the number of completed modules (out of three possible). The main treatment participation measure will be number of days logged on to the website. Note that the program does not collect any PHI. It also

does not record how long was spent on the website because it cannot distinguish between when someone is using the program, has left the browser open, or has left the program without logging out. Study therapists will complete a contact log for each encounter. The contact log will document whether there was a scheduled contact that was not attended, the date and time of contact, and time spent in minutes.

End of Study Measures
1. The current diagnoses, service-connection outcome, and award determination will be obtained from the completed Compensation and Pension examination and VBA database. Diagnoses will be coded within DSM-V with specifiers for definite diagnoses and rule-outs.
2. VA Service Use Outcomes. Analyses will be conducted by Robert Rosenheck, a national authority on service use analyses. Episodes reflecting use of VA substance abuse, specialized PTSD and other mental health treatment will be collected from VA administrative records as described previously [73, 74]. Information will be accessed by an agreement between the MIRECC and the West Haven-sited Northeast Program Evaluation Center (NEPEC), which routinely accesses this information for VA reports. VA bed section codes indicate hospitalization on specialized units and VA clinic codes indicate outpatient treatment in specialized clinics. Mental Health service use data will be collected from 24 weeks before the Compensation examination (to allow analyses to control for baseline service use) until 24 weeks after claims adjudication.
3. Cost of Therapist Time Providing the Intervention: The direct costs of providing Remotely-Delivered Benefits Counseling will be calculated but a full cost-effectiveness analysis is beyond the scope of this proposal. The amount of time the therapist spends will be calculated by having therapists maintain logs of time spent on study-related activities including conducting telephone calls, scheduling phone calls, and reminding Veterans to access the study website. The product of the therapist's time spent and the average therapist cost will be used to calculate the labor cost. Therapist salaries will be calculated including fringe benefits but not the overhead rate of the VA facilities. We will not include research costs, facility costs, or the costs of developing the intervention.

Data Analysis
1. Determination of Study Outcomes: We list below the outcome measures whose scoring requires explication. Many of the scales' scoring is embedded in our earlier description of the measure.
a. Primary Outcome: The a priori definition of a primary outcome reduces the risk of Type I error. The number of hours paid work will be the primary treatment outcome. As noted previously, this includes work that is formal or under-the-table, and includes formal in-kind arrangements. It does not include days engaged in informal in-kind arrangements (housekeeping) or illegal activities such as gambling.
b. Secondary Outcomes: Secondary outcomes include each of the other work-related activities considered separately (unpaid work, attending school, engaging in vocational rehabilitation). Another secondary outcome is days engaged in any of the above work-related activities. This measure of work-related activities has a range of 0 to 28 in that each day is scored for whether any work-related activity was engaged in on that day as a dichotomous (0,1) value.

Dollars earned will be log-transformed (adding "1" to totals before transformation to allow calculation for veterans with no income) for outcome analyses if it is heavily skewed by outliers with high incomes.

c. Scoring of Clinical Measures.

i. Psychiatric Symptomatology: The Global Severity Index from the Brief Symptom Inventory will be the main outcome from the BSI. The depression subscale will be scored too because of the association between depression and poor work function.

ii. The SF-36 will be scored to yield standardized Mental Health and Physical Health Component Scores, with a mean of 50 and population standard deviation of 10. As noted earlier, the PTSD Checklist items are summed to yield a single score.

iii. For the Work-Related Attitudes Scale, EFA will be conducted if it can be accomplished with the sample, i.e., if there is approximately a 10:1 participant:item ratio and item communalities are high [.6 or greater] after dropping any items with poor variability. If EFA is not feasible, we will analyze inter-item correlations and estimate internal consistency reliabilities to identify items that cluster together within a domain that reflect the perceived work-benefits relationship. A mean score of all items in this domain (or domains, if more than one is identified), will be generated.

iv. The ASSIST yields an overall substance use severity score.

d. Process Measures

i. Treatment engagement: This will be measured as number of days logging onto the website, number of modules completed, number of minutes spent in telephone calls with the Counselor.

ii. Treatment satisfaction will be assessed using mean score on subscales of the Likert-scaled Satisfaction questionnaire (with reverse scoring). Satisfaction with discrete elements of the websites will be considered as separate items.

iii. Number of weeks attending any VA substance abuse and/or mental health treatment will be derived from the service use data.

2. Approach to Missing Data: For analyses involving HLM, maximum likelihood estimation techniques permit missing data on the dependent variable. Valid parameters are estimated from all available data from all cases under the assumption that data are missing at random. To improve the plausibility of the missing-at-random assumption, we may include missing data correlates in the model. For normal models (ANOVA, Regression) requiring complete data, if data are not missing completely at random (MCAR), we will use NORM software to multiply impute missing values. We will first determine whether data are MCAR using Little's test [75]. If data are not MCAR, we will characterize study drop-outs in terms of differences in mean scores on relevant variables. Variables determined to be related to missingness or to the incomplete variables (missing data correlates) will be included in models to improve estimation [76]. In specifying the imputation model, we will follow guidelines of Rubin [77], Schafer [78, 79]) and Collins et al. [76], including all variables that will be included in the analytical models,

as well as all variables that are associated with the variable(s) with missing values, and with missingness itself. We will combine parameter estimates and estimate standard errors according to Rubin's rules [80]. To determine what observed variables are associated with missingness on a given variable, we will create dichotomous "missingness" indicators (missing or not missing; 1/0) and estimate logistic regression models. Variables that significantly predict missingness will be included in the imputation model.

3. Evaluation of Treatment Effects: For baseline values potentially related to outcome, evaluation of comparability of the two treatment groups will be conducted using chi-square tests for categorical variables and t-tests for continuous variables. If an unexpected difference is found and is related to the outcome, the potentially significant confounding variable will be added to the primary outcome analysis as a covariate.

The principal strategy for assessing the efficacy of the study treatment will be random effects regression, which will be used to determine the differences in slopes of outcomes between Veterans assigned to Benefits Counseling compared to Control. The model will include covariates described in the Introduction Section, time measured in weeks, and the contrasts of Benefits Counseling versus Control. A linear effect of time on outcome variables is being hypothesized but ancillary analyses will be conducted to determine if the effect of Benefits Counseling treatment is better explained by a quadratic function (as described in the Introduction section of this grant). Models will be specified to accommodate the observed distributions of outcomes (e.g., Poisson, normal, Bernoulli) and theory, model estimates, and fit indices will inform the specification of effects as fixed or random, and the structure of the variance-covariance matrix.

Our principal data analyses will be conducted on all randomized Veterans. We will attempt to follow all participants who are randomized for assessments regardless of their retention in treatment. Intention-to-treat analyses will be supplemented by analyses to describe the consistency of findings across different definitions of the sample: e.g., module-completers and treatment completers. Measures of engagement in Benefits Counseling will also be tested for their association with outcomes (number of days using the website, modules completed, minutes on phone with Benefits Counselor).

4. Evaluation of Processes that Might Mediate Treatment Response: This study is not powered for full mediation analyses but will allow for bivariate analyses of the components of mediation. Bivariate analyses will be conducted of the relationship between the slope of each potential mediator and (1) group assignment and (2) slope of hours worked per week. The partial correlation of group assignment with the slope of hours worked per week will be calculated, controlling in turn for each potential mediator's slope.

The general potential *mediators* of treatment response will include ratings of importance/confidence in ability to work, work-benefits attitudes (attitudes about one's personal situation, understanding of work-benefits relationship), service-connection award, and number of weeks engaged in any mental health and/or substance abuse treatment.

5. Evaluation of Process Measures: The Likert-scaled therapy process ratings and other measures reflecting single values (e.g. number of times logging into the study website) will be compared between groups using parametric or non-parametric group comparisons. Only the Benefits

Counseling group will have ratings of audiotaped therapy sessions and these will be tabulated for descriptive statistics.

6. Evaluation of Factors Associated with Effects of Study Treatments on Working (Moderators)
To determine what factors are associated with response to counseling, potential predictor variables will be serially entered into the primary outcome analyses as separate covariates, and as terms interacting with group-assignment. To avoid finding significant associations by chance, potential predictors will be screened for their intercorrelations with each other and redundant measures (e.g., $r>.7$; R2 $\geq .6$; VIF≥ 2.5) will be pared or
combined. Potential predictor variables include:
--Demographic variables (age, race, gender),
--Conditions that Make Working More Difficult: Substance use severity, baseline PTSD severity as measured by the PCL-5, overall psychological symptomatology as measured by the BSI, depression as measured by the BSI.
--Attitudes Toward Seeking Professional Psychological Help Scale-Short Form (two domains---openness to seeking treatment for emotional problems and value of seeking treatment).
---Veterans' rated reasons for seeking compensation as described by the Disability Application Appraisal and Inventory [28]: we hypothesize that Veterans who rate themselves higher in having applied for financial gain will be more likely to work in response to Benefits Counseling.

7. Evaluation of factors associated with progress through different steps of study participation
(i.e. going to the website for randomization vs. not doing so; using the Benefits Counseling website if assigned to it vs. not following the assignment). Potential predictors will be screened for their intercorrelations with each other and redundant measures will be pared or combined. We will then use bivariate analyses (t-test, chi-square) to identify factors that differentiate the groups of interest at a significance level of alpha = .10 or less. Identified factors will be entered into a logistic regression with group as the dependent variable (e.g. randomized vs. not). Factors to be considered include internet-associated factors (ease of internet access, extent of internet use), disability related factors (knowledge of disability process, desire to learn more about it), work-related factors (e.g. distress about not working), and demographic variables (age, gender, race, education status), and conditions that make internet use more difficult (e.g. BSI global severity).

Human Subjects
A. Consent Procedures
1. Recruitment: A waiver of informed consent and HIPPAA authorization will be obtained to review the Compensation and Pension materials and charts of Veterans scheduled for Compensation and Pension examinations to identify those who are not more than 30% service-connected for physical conditions and scheduled for examinations for a psychiatric condition. The waiver will allow for the collection of basic demographic information concerning Veterans screened for study participation to determine if Veterans who consent to study participation differ systematically from those who do not.

The recruitment strategy involved identifying Veterans who have submitted requests for mental health Compensation examinations. Potentially eligible Veterans will be Express Mailed a letter from the P.I. explaining the basics of the study and that unless the Veteran opts out, a member of the research team will call to further explain the study. The letter will include a phone

number to call to opt not to receive the research call. No phone calls will be made to Veterans calling to opt out.

At that call, the Research Assistant will explain the study and invite the Veteran for a face-to-face meeting with further screening, informed consent, and baseline assessments. A Waiver of written informed consent will be obtained to screen potential participants over the phone.

Justification for recruitment via mailed letter: The proposed letter recruitment strategy, which was used in several of Dr. Rosen's other approved studies including two SBIRT studies (projects which deliver SBIRT to Veterans applying for disability for painful musculoskeletal conditions or PTSD) and the QUERI study (a multi-site study of the Compensation and Pension process directed by Theodore Speroff), was effective. The main reason for recruitment by letter is that it would not be feasible to recruit Veterans at the time they come for their Compensation examination because Veterans may not have time to consider study participation when they are already at their Compensation examinations. Veterans at their Compensation and Pension evaluations may be nervous and rushed. They may be accompanied by other people who cannot or will not wait while the Veteran participates in an unplanned study. Additionally, assessments are designed to be collected before the Compensation examination.

A second mode of recruitment will involve having C&P clinic staff (but not the C&P examiner) give potentially eligible Veterans a study brochure and ask them if they are willing to discuss study participation with a member of the study staff. If they are, a member of the staff will contact them at the C&P office, if feasible, or by phone.

2. Consent: Voluntary informed consent will be obtained from all Veterans prior to participation. Consent will be obtained by one of the investigators or his/her designee after the research procedures and risks associated with participation have been explained to the candidate. A signed copy of the consent form will be provided to all potential Veterans.

Participants will be asked several questions to be certain they understand the risks associated with study participation. Only participants who correctly answer all the questions (with a second chance to answer questions if incorrectly answered the first time) will be enrolled. The questions will be the following:

a. What topics will you be asked about?

Answer should mention working.

b. Is it possible that someone will learn that you were at the study website?

The correct answer is "Yes."

c. Can you drop out of this study whenever you want? Yes.

B. Risks and Discomforts

Risks associated with participation in the study include risks associated with:

1. Completing questionnaires: Administration of study instruments may be boring, frustrating, or upsetting.

2. Becoming upset while discussing traumatic events*:* There is a risk that individual Veterans will become upset by discussing their traumatic events during assessments or counseling. In practice, study-related adverse events in clinical trials involving PTSD assessments among Veterans have been very rare. Research assistants will emphasize that answering questions is voluntary and will allow Veterans to answer questions at their own pace and without duress.

3. Information from the counseling being told to participants' clinicians at the VA or to someone who reviews their disability application. The counseling is unlikely to impact the Veteran's disability application. The therapist will not volunteer any non-emergent information in the Veterans' chart or to other clinicians, as this is contrary to the voluntary, Motivational Interviewing stance that is integral to Benefits Counseling. The therapist will write a note in the Veteran's VA chart after any phone counseling indicating that the participant was in this research study and spoke to the therapist.

Nevertheless, the therapist is going to convey information to other VA clinicians if the Veteran indicates information during the therapy that requires emergency intervention. If the Veteran indicates information suggesting imminent danger to the Veteran or to others, the Benefits Counseling therapist will share this information with other VA clinicians so they can take appropriate action. Therefore, Veterans will be told the risk that information that they tell the study therapist may be told to their VA clinicians and would then become available to someone who reviews their disability application. It is very unlikely that an emergency disclosure would prevent receipt of service-connected disability.

4. Potential effect of work on the benefits application process: Veterans compensated for physical or mental problems that developed during or were made worse by military service are not supposed to be penalized for coping well with these problems by working. However, the Veterans Benefits Administration reviews claims on a case-by-case basis, and it is unknown to what extent working will influence any individual Veteran's disability determination process. Veterans will be told this as part of the informed consent process.

5. Breach of Confidentiality: The website will not contain any PHI.

However, the Veterans' computer that accesses the website will leave a trace (in the history of browsed sites on the local computer).Therefore, if a subsequent user of a computer knows the specific Veteran who used an account, the user may infer that the Veteran has a Compensation claim and/or a psychiatric disorder.

Research Assistants and Therapists will clarify communication procedures with Veterans. They will ask the Veteran's preference in terms of whether or not the Veteran wants messages left on voicemail, and if so, if the Veteran wants the study therapist's phone number left on the voicemail. Therapists will establish that the Veteran is the person answering the phone by using personal identifiers drawn from a standard list of security questions (mother's maiden name, etc.) that the Veteran has supplied.

C. Protection of Participants

1. Confidentiality of Research Materials: All research information is considered confidential. All computers used by research staff are password protected. Limits to confidentiality include only disclosure of acute suicidality, homicidality, or abuse of a minor, as is standard in clinical practice. If a Veteran selects any value over 1 ("a little bit") on the Brief Symptom Inventory question about "thoughts about ending your own life," the Research Assistant will contact Dr. Kessler, his covering psychiatrist or, if neither is available, the clinician handling intakes to arrange for an evaluation of the Veteran.

All screening forms will have a study code number but no identifying information. Electronic files containing identifiable information will be kept on a secure VA server available only to research staff.

Research data will be identified by code number and will not include names, although enrollment records must also be kept and these records will include names. Our study forms have

been designed to avoid collecting identifiable information; no Protected Health Information (PHI) will be collected on study forms. We generally collect only protocol session dates. These dates are changed to 'number of sessions completed' when data sets are anonymized and released to other investigators. Research data, containing no PHI, will be uploaded to a secure VA server using SharePoint. SharePoint is a platform that allows users to create and share information, documents, and reports through a common secure VA intranet portal. Files containing audio-recorded sessions will be uploaded using SharePoint for rating at West Haven, after which they will be deleted. Data storage will use the HSR&D PRIME Center's data storage servers (support letter attached).

Personal identifiers will be retained to obtain VA service use data. After the service use data has been extracted, the identifiers will be removed to create files with de-identified data for subsequent analyses. Source documents (e.g. Compensation and Pension examinations) are stored on VA clinical servers behind a secure firewall, and will not be stored with research data. Other forms that contain PHI such as consent forms will be collected by the two site PIs and stored in locked file cabinets by the site PI's until seven years from the last study-regulated publication, unless VA regulations stipulate a different date and mode for their destruction.

All possible precautions will be taken to prevent a breach of confidentiality. Study IDs will be assigned at the time of recruitment and replace names and record numbers. Clinical enrollment records are kept separate from research data, and are not available without a Veteran's written consent. Participants' names will appear only on the consent form, HIPAA authorization form, and "key" form kept by the site P.I. All paper forms will be stored and secured in a locked file cabinet under the jurisdiction of the site P.I.

At the conclusion of the study, all locator data will be destroyed. The crosswalk file will be stored separately from all other study data on VA secure network computers. Data Security will be insured via the servers, which all reside completely behind the VA firewall. All systems utilize Secure Socket Layer (SSL) technology for internet protocol data transfer, which encrypts all network transmissions and transmits only within the VA network backbone. There is no public internet access. Another layer of protection for sensitive information is ascribed to the system by use of granular access privileges. Only site-specific authorized staff will have data access. The Study Coordinator will have the capability of granting access and read-write privileges to users. All systems undergo daily backup and 24-hour security.

The research records will be used to prepare reports that do not include patient identification. All research staff and therapists receive annual Good Clinical Practice, Human Subjects Protection, and HIPAA training through the Yale Department of Psychiatry. Our data collection and management procedures are fully compliant with HIPAA.

2. Confidentiality of Benefits Counseling Website:

Information to be collected via the internet-based Benefits Counseling program will include participants' responses to the questions, and dates and times that participants' logged on to the site. Participants will not be asked to provide any PHI in the course of their engagement in the internet-based Benefits Counseling intervention.

At the initial meeting for consenting and baseline assessment, participants will be provided with a personal user login ID and a temporary password. The participant will be required to change the password at initial logon to the website to a personal one that s/he will recall. Only the participant and the study staff will have the authority to access the participant's responses to the components of the intervention. If the participant forgets or loses his/her

password, s/he will be issued a new temporary password and will again be prompted to change it upon the next logon to the program. The information collected via the internet-based program will be captured in a database (again, containing no PHI, only the participant's user ID, which will not be linked to his/her identifying information or study number in that database).

Google Analytics and other server software allows for tracking the IP address and/or the address of the router via which the Benefits Counseling website was accessed. Thus, there is a risk that someone accessing the server hosting the web site could learn that a computer at a particular network address accessed the Benefits Counseling site. However, host sites (i.e. Heroku) have security policies and procedures to prevent the unauthorized accessing and use of this information.

Patients will be warned that if they use their computers or tablets to access the study website, it is possible that someone else who uses the computer or tablet later will be able to tell that their computer or phone accessed the Benefits Counseling web site.

3. Confidentiality of Audio recordings (Recording phone calls between Veterans and counselors): To assure the confidentiality and protection of participants with respect to audio recording, the following steps will be taken:

- Participants will provide informed consent for audio recording. Participants will be allowed to participate in the study and refuse the audio recording. Participants who do consent to audio recording will be informed that they have the right to stop recording at any time.
- Audio recordings will be treated as confidential research records. The digital file, labeled with a unique study ID code will be uploaded to a secure network VA server, separate from other study data. The file name will use study ID codes.
- Access to audio files will be limited to members of the investigative team including trained research raters who will rate the tapes according to the therapist rating scales. A separate file will link the file code to the participant's unique identification code, the therapist name, and the date of the session.
- When the study is completed and the ratings have been properly coded, all audiotapes will be deleted according to VA regulations. Participants will be told about this process when they provide informed consent.
- Additional consent will be requested of a patient if that patient's audiotape may be added to materials that will be disseminated, such as a training tape.

4. Training of Study Therapists: The risk of angering or alienating Veterans is very small because of the non-confrontational nature of Benefits Counseling. The risk will be further minimized by hiring staff who have experience with the study population. Study therapists will be trained to adopt a collaborative approach. Study therapists will also be taught the phone numbers to call in case of an emergency during a telephone call with Veterans.

5. Training of Research Assistants: Research Assistants will also be taught where the emergency facilities are including the location of emergency rooms, VA and public police and crisis services. Research Assistants will also receive training in de-escalating agitated Veterans.

D. Data Safety Monitoring Plan:

1. Data Management Plan

Careful training of evaluators will precede study initiation. The main instrument on which training is needed is the baseline Work-Related Activities timeline-follow-back calendar. Training to conduct the Work-Related Activities Calendars will involve at least three supervised ratings.

Our research group will be using REDcap, a free, secure VA Web application that allows for the collection and entry of research data. In addition to enabling users to develop surveys and databases without additional software, REDcap helps researchers enter, store and manage project data. All data entries will have a study code number but no identifying information. Registration records including the signed consent form will be stored separately from these study records.

2. Safety Monitoring Plan: The risk to Veterans who do go on to be randomized to Benefits Counseling or Control is low (greater than minimal). Veterans presenting with PTSD symptoms and other psychiatric conditions for Compensation and Pension examinations have a high frequency of medical and psychiatric difficulties. Therefore, changes in medication regimen, the presence of medication side effects and symptom exacerbations are not untoward and do not constitute adverse events. Anticipated adverse events include complaints about the study procedures and the counseling, and any occurrence in which the patient attributes discomfort, harm or disability to the study procedures.

In the clinical trial, assessment for adverse events will be a routine part of every study and therapy visit. Any report that a patient required overnight treatment in any facility (emergency room, detoxification, and hospitalization) will constitute an SAE, as will any report of death or serious disability. Hospitalization or death of another individual due to direct action of patient will also be considered an SAE.

Any SAEs will be immediately reported to Dr. Rosen and, if he is unavailable, to Dr. Black. Reports to Dr. Rosen will include a description of the event and a summary of recent contacts with the patient. This summary will include any warning signs of the adverse event, the patient's general state and any information suggesting a causal link between study participation and the event. Dr. Rosen will report these to the IRB within 3 working days.

The New England MIRECC's D.S.M.B. will be the D.S.M.B. for this study. The D.S.M.B. will be contacted within 3 days about all significant study-related adverse events. The main risks of the study are frustration with the study procedures, frustration with the Benefits Counseling website, and someone learning about the Veteran accessing the Benefits Counseling website without the Veteran's permission. Because of the very low risk that either therapy would worsen outcomes, no a priori stopping criteria are proposed. Every year, Dr. Rosen and the D.S.M.B. will review study information on a standardized form. Board members will review recruitment, retention, and follow-up rates for the study-to-date, SAEs and AEs and other data as the D.S.M.B. deems necessary.

Based on this report, each DSMB member will complete a form making one of two recommendations: 1) continue recruitment as planned; or 2) schedule formal DSMB meeting immediately. If any DSMB member recommends a meeting, this will be scheduled within one week, minutes will be kept, the report will be reviewed with the PI, and the committee will vote on whether the study should: 1) continue recruitment unchanged; 2) continue with a protocol amendment; 3) stop recruiting pending further investigation. If, after this meeting, any DSMB member votes to stop recruitment or requests a protocol modification, the Yale IRB will be informed.

A written summary including this information will be provided to the IRB with the protocol renewal.

D. Potential Benefits

1. Benefits to the Participants: The potential benefits to participants is that they may improve their vocational functioning as a result of engaging in the Benefits Counseling or Control interventions.
2. Benefits to Society: The study will provide important information concerning the attitudinal and other factors that determine whether Veterans applying for Compensation engage in work and related activities. The study findings may suggest modifications to existing VA Compensation policies to facilitate engagement in vocational rehabilitation. The studies will contribute to the development of a novel format for implementing Benefits Counseling (i.e., an internet-based version) that may be appealing and accessible to Veterans applying for VA benefits.
3. Financial Compensation to Participants for Completing Assessments: It is our usual practice to compensate participants for studies like this one that require considerable time completing forms and ratings that are not a part of routine clinical care. Compensation offsets the inconvenience of these procedures. Participant payments will be $60 for the baseline evaluation and $30 for each of weeks 4, 12 and 24. This totals $150 per participant. These amounts were chosen to be sufficient reimbursement for participants who have competing, paid demands on their time, and who come for their initial Compensation Examinations from all over Connecticut, often despite no treatment relationship with the VA Healthcare System. In addition, participants will be reimbursed 57.5¢ per mile traveled to their residence and from the Compensation examination.

E. Risk/Benefit Ratio

The study has the potential to further the development of effective treatment for Veterans who have psychiatric and vocational problems. Consideration of the risks and benefits mentioned above suggests that potential benefits for both the participants and science outweigh the risk of minor harm associated with the study procedures.

F. Enrollment of Women and Minorities

Enrollment of women and minorities will reflect their proportions in the pool of Veterans presenting for Compensation and Pension evaluations for psychiatric conditions at the Northampton VA. As noted in the Feasibility Section, approximately 8% of recent Veterans evaluated were women, 4% were Hispanic, and 12% were African American. We anticipate approximately these proportions among the Veterans enrolled in this study.
Our group has a good record of enrolling representative proportions of women and minorities in C&P-based RCTs. In our completed study of face-to-face Benefits Counseling, 17% of Veterans were women, 13% were African American, and 17% were Hispanic.

References

1. Lord, S. *Development of an Efficacious Online STI/HIV Prevention Program for Young Adults*. in *College on the Problems of Drug Dependence*. 2012. Palm Springs, California.
2. Rounsaville, B.J., K.M. Carroll, and L.S. Onken, *A stage model of behavioral therapies research: Getting started and moving on from stage I.* Clinical Psychology: Science and Practice, 2001. **8**(2): p. 133-142.
3. Weathers, F.W., et al., *PTSD Checklist for DSM-5 (PCL-5)*, N.C.f. PTSD, Editor. 2013.
4. Derogatis, L.R., *Brief Symptom Inventory (BSI): Administration, scoring, and procedures manual.* 2nd ed. 1992, Baltimore, MD: Clinical Psychometric Research.
5. Murdoch, M., et al., *Regional variation and other correlates of department of veterans affairs disability awards for patients with posttraumatic stress disorder.* Medical Care, 2005. **43**(2): p. 112-121.
6. Jackson, J.C., et al., *Variation in practices and attitudes of clinicians assessing PTSD-related disability among veterans.* Journal of Traumatic Stress, 2011. **24**(5): p. 609-613.
7. Department of Veterans Affairs. *Disability Benefits Questionnaires (DBQs)*. [Online]. (2014) Cited October 16, 2014.
8. U.S. Department of Veterans Affairs, V.B.A., *ANNUAL BENEFITS REPORT, Fiscal Year 2011*. 2011.
9. Marchione, M. *U.S. vets' disability filings reach historic rate*. USA Today, 2012.
10. Murdoch, M., et al., *Long-term Outcomes of Disability Benefits in US Veterans With Posttraumatic Stress Disorder.* Arch Gen Psychiatry, 2011. **68**(10): p. 1072-1080.
11. Rosenheck, R.A., et al., *Outcomes after initial receipt of social security benefits among homeless veterans with mental illness.* Psychiatric Services, 2000. **51**(12): p. 1549-1554.
12. Murdoch, M., et al., *Mitigating effect of department of veterans affairs disability benefits for post-traumatic stress disorder on low income.* Military Medicine, 2005. **170**(2): p. 137-140.
13. Rosenheck, R., L. Frisman, and J. Sindelar, *Disability compensation and work among veterans with psychiatric and nonpsychiatric impairments.* Psychiatric Services, 1995. **46**(4): p. 359-365.
14. Drew, D., et al., *Effects of disability compensation on participation in and outcomes of vocational rehabilitation.* Psychiatric Services, 2001. **52**(11): p. 1479-1484.
15. Rosen, M.I., et al., *Effect of Social Security Payments on Substance Abuse in a Homeless Mentally Ill Cohort.* Health Services Research, 2006. **41**(1): p. 173-191.
16. Meshberg-Cohen, S., et al., *Veterans' attitudes toward work and disability compensation: Associations with substance abuse.* Addictive Behaviors, 2014. **39**(2): p. 445-448.
17. *Prepared Statement of Sally Satel, M.D., Resident Scholar, American Enterprise Institute*, in *House Committee on Veterans Affairs*. 2011: Washington DC.

18. Rosen, M.I., *Compensation examinations for PTSD--an opportunity for treatment?* Journal of Rehabilitation Research & Development, 2010. **47**(5): p. xv-xxii.
19. Tremblay, T., et al., *The impact of specialized benefits counseling services on social security administration disability beneficiaries in Vermont.* Journal of Rehabilitation, 2004. **70**(2): p. 5-11.
20. Council, C.o.V.C.f.P.S.D.I.o.M.a.N.R., *PTSD Compensation and Military Service*. 2007, Washington D.C.: The National Academies Press.
21. Sayer, N.A., et al., *Gender Differences in VA Disability Status for PTSD Over Time.* Psychiatr Serv, 2014.
22. Grahn, B., C. Ekdahl, and L. Borgquist, *Motivation as a predictor of changes in quality of life and working ability in multidisciplinary rehabilitation: A two-year follow-up of a prospective controlled study in patients with prolonged musculoskeletal disorders*, in *Disabil Rehabil*. 2000. p. 639-654.
23. Drebing, C.E., et al., *The impact of enhanced incentives on vocational rehabilitation outcomes for dually diagnosed veterans.* Journal of Applied Behavior Analysis, 2005. **38**(3): p. 359-72.
24. *Planning, and Preparedness Office National Survey of Veterans 2010 Final Report*. Office of Policy of the Department of Veterans Affairs Assistant Secretary for Policy.
25. Sayer, N.A., M. Spoont, and D.B. Nelson, *Disability Compensation for PTSD and Use of VA Mental Health Care.* Psychiatr Serv, 2004. **55**(5): p. 589.
26. Tremblay, T., et al., *Effect of benefits counseling services on employment outcomes for people with psychiatric disabilities.* Psychiatric Services, 2006. **57**(6): p. 816-821.
27. Frey , W.D., et al., *Mental Health Treatment Study Final Report July 2011*. 2011, Westat.
28. Sayer, N.A., et al., *Development and psychometric properties of the disability application appraisal inventory.* Psychological Assessment, 2004. **16**(2): p. 192-6.
29. Sayer, N.A., M. Spoont, and D.B. Nelson, *Post-traumatic stress disorder claims from the viewpoint of veterans service officers.* Military Medicine, 2005. **170**(10): p. 867-70.
30. Sayer, N., et al., *A qualitative study of determinants of PTSD treatment initiation in veterans.* Psychiatry, 2009. **72**(3): p. 238-255.
31. Rosen, M.I., et al., *Work Outcomes After Benefits Counseling Among Veterans Applying for Service Connection for a Psychiatric Condition.* Psychiatr Serv, 2014.
32. DiIorio, C., et al., *WebEase: development of a Web-based epilepsy self-management intervention.* Prev Chronic Dis, 2009. **6**(1): p. A28.
33. Hester, R.K., D.D. Squires, and H.D. Delaney, *The Drinker's Check-up: 12-month outcomes of a controlled clinical trial of a stand-alone software program for problem drinkers.* Journal of Substance Abuse Treatment, 2005. **28**(2): p. 159-169.
34. Kiene, S.M. and W.D. Barta, *A Brief Individualized Computer-Delivered Sexual Risk Reduction Intervention Increases HIV/AIDS Preventive Behavior.* Journal of Adolescent Health, 2006. **39**(3): p. 404-410.
35. Escoffery, C., L. McCormick, and K. Bateman, *Development and process evaluation of a web-based smoking cessation program for college smokers: innovative tool for education.* Patient Educ Couns, 2004. **53**(2): p. 217-25.
36. Kaltenthaler, E., et al., *The acceptability to patients of computerized cognitive behaviour therapy for depression: a systematic review.* Psychological Medicine, 2008. **38**(11): p. 1521-30.

37. Waller, R. and S. Gilbody, *Barriers to the uptake of computerized cognitive behavioural therapy: a systematic review of the quantitative and qualitative evidence.* Psychol Med, 2009. **39**(5): p. 705-12.
38. Ondersma, S.J., et al., *Computer-based brief motivational intervention for perinatal drug use.* J Subst Abuse Treat, 2005. **28**(4): p. 305-12.
39. Steele, R., K.W. Mummery, and T. Dwyer, *Development and process evaluation of an internet-based physical activity behaviour change program.* Patient Educ Couns, 2007. **67**(1-2): p. 127-36.
40. Seal, K.H., et al., *Bringing the war back home: Mental health disorders among 103 788 US veterans returning from Iraq and Afghanistan seen at Department of Veterans Affairs Facilities.* Archives of Internal Medicine, 2007. **167**(5): p. 476-482.
41. Bremner, J., et al., *Chronic PTSD in Vietnam combat veterans: course of illness and substance abuse.* Am J Psychiatry, 1996. **153**(3): p. 369-375.
42. *House Committee on Veterans' Affairs*. [Online]. (2007). Cited May 23, 2007.
43. Speroff, T., et al., *Impact of evidence-based standardized assessment on the disability clinical interview for diagnosis of service-connected PTSD: a cluster-randomized trial.* J Trauma Stress, 2012. **25**(6): p. 607-15.
44. Rosen, M.I., et al., *Racial differences in veterans' satisfaction with examination of disability from posttraumatic stress disorder.* Psychiatr Serv, 2013. **64**(4): p. 354-9.
45. Rosen, M., *Compensation examinations for PTSD--an opportunity for treatment?* Journal of Rehabilitation Research & Development, 2010. **47**(5): p. xv-xxii.
46. Serowik, K.L., et al., *Developing a benefits counseling website for Veterans using Motivational Interviewing techniques.* Computers in Human Behavior, 2014. **37**: p. 26-30.
47. Christensen, H., K.M. Griffiths, and L. Farrer, *Adherence in internet interventions for anxiety and depression.* Journal of Medical Internet Research, 2009. **11**(2): p. e13.
48. Mander, H., *The impact of additional initial face-to-face sessions on engagement within an Improving Access to Psychological Therapies service.* The Cognitive Behaviour Therapist, 2014. **7**: p. e1-e8.
49. Johansson, R. and G. Andersson, *Internet-based psychological treatments for depression.* Expert Rev Neurother, 2012. **12**(7): p. 861-9; quiz 870.
50. Julious, S.A. and S.D. Patterson, *Sample sizes for estimation in clinical research.* Pharmaceutical Statistics, 2004. **3**: p. 213-215.
51. Ware, J.E., Jr. and C.D. Sherbourne, *The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection.* Medical Care, 1992. **30**(6): p. 473-83.
52. Stout, R.L., et al., *Ensuring balanced distribution of prognostic factors in treatment outcome research.* Journal of Studies on Alcohol Supplement, 1994. **12**: p. 70-5.
53. Saitz, R., *Unhealthy Alcohol Use.* New England Journal of Medicine, 2005. **352**(6): p. 596-607.
54. Aronson, I.D. and T.C. Bania, *Race and emotion in computer-based HIV prevention videos for emergency department patients.* AIDS Education & Prevention, 2011. **23**(2): p. 91-104.
55. Pedersen, E.R., et al., *Concurrent validity of an online version of the Timeline Followback assessment.* Psychology of Addictive Behaviors, 2012. **26**(3): p. 672-677.

56. Burke, B.L., H. Arkowitz, and M. Menchola, *The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials.* Journal of Consulting & Clinical Psychology, 2003. **71**(5): p. 843-61.
57. Elhai, J.D., W. Schweinle, and S.M. Anderson, *Reliability and validity of the Attitudes Toward Seeking Professional Psychological Help Scale-Short Form.* Psychiatry Research, 2008. **159**(3): p. 320-329.
58. GAO, *Milld Traumatic Brain Injury Screening and Evaluation Implemented for OEF/OIF Veterans, but Challenges Remain*. 2008: Washington DC.
59. Moore, B.A., et al., *The Recovery Line: A pilot trial of automated, telephone-based treatment for continued drug use in methadone maintenance.* J Subst Abuse Treat, 2013. **45**(1): p. 63-9.
60. Ewing, J.A., *Detecting alcoholism. The CAGE questionnaire.* JAMA, 1984. **252**(14): p. 1905-7.
61. Group, W.A.W., *The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility.* Addiction, 2002. **97**(9): p. 1183-94.
62. Humeniuk, R., et al., *Validation of the Alcohol, Smoking And Substance Involvement Screening Test (ASSIST).* Addiction, 2008. **103**(6): p. 1039-47.
63. Blanchard, E.B., et al., *Psychometric properties of the PTSD Checklist (PCL).* Behaviour Research & Therapy, 1996. **34**(8): p. 669-73.
64. Forbes, D., M. Creamer, and D. Biddle, *The validity of the PTSD checklist as a measure of symptomatic change in combat-related PTSD.* Behaviour Research & Therapy, 2001. **39**(8): p. 977-86.
65. Monson, C.M., et al., *Change in posttraumatic stress disorder symptoms: do clinicians and patients agree?* Psychological Assessment, 2008. **20**(2): p. 131-8.
66. Monson, C.M., et al., *Cognitive processing therapy for veterans with military-related posttraumatic stress disorder.* Journal of Consulting & Clinical Psychology, 2006. **74**(5): p. 898-907.
67. Drake, R.E., et al., *Assisting Social Security Disability Insurance beneficiaries with schizophrenia, bipolar disorder, or major depression in returning to work.* Am J Psychiatry, 2013. **170**(12): p. 1433-41.
68. Cook, J.A., *Depression, disability, and rehabilitation services for women.* Psychology of Women Quarterly, 2003. **27**(2): p. 121-129.
69. Miller, W.R., et al., *Motivational Enhancement Therapy Manual: A Clinical Research Guide for Therapists Treating Individuals With Alcohol Abuse and Dependence*. Vol. 2. 1992: U.S. Department of Health and Human Services.
70. Williams, E.C., et al., *Do brief measures of readiness to change predict alcohol consumption and consequences in primary care patients with unhealthy alcohol use?* Alcoholism: Clinical & Experimental Research, 2007. **31**(3): p. 428-35.
71. Rosenheck, R.A. and A.S. Mares, *Implementation of supported employment for homeless veterans with psychiatric or addiction disorders: Two-year outcomes.* Psychiatric Services, 2007. **58**(3): p. 325-333.
72. Carroll, K.M., et al., *A general system for evaluating therapist adherence and competence in psychotherapy research in the addictions.* Drug & Alcohol Dependence, 2000. **57**(3): p. 225-38.
73. Desai, R.A., et al., *Suicide among discharged psychiatric inpatients in the Department of Veterans Affairs.* Military Medicine, 2008. **173**(8): p. 721-8.

74. Harpaz-Rotem, I., et al., *Tracing the flow of knowledge: geographic variability in the diffusion of prazosin use for the treatment of posttraumatic stress disorder nationally in the Department of Veterans Affairs.* Archives of General Psychiatry, 2009. **66**(4): p. 417-21.
75. Little, R.J.A., *A test for missing completely at random for multivariate data with missing values.* Journal of the American Statistical Association, 1988. **83**: p. 1198-1202.
76. LM, C., S. JL, and K. C, *A comparison of inclusive and restrictive strategies in modern missing data procedures.* Psychological Methods, 2001. **6**: p. 330-351.
77. Rubin, D.B., *Multiple imputation after 18+ years.* Journal of the American Statistical Association, 1996. **91**(434): p. 473-489.
78. Schafer, J.L. and M.K. Olsen, *Multiple imputation for multivariate missing-data problems: A data analyst's perspective.* Multivariate behavioral research, 1998. **33**(4): p. 545-571.
79. Schafer, J.L., *Analysis of incomplete multivariate data*. 2010: CRC press.
80. Schafer, J.L., *Analysis of incomplete multivariate data*. 1997, New York: Chapman & Hall.