Cognitive Behavioral Therapy for Insomnia for Gulf War Illness

NCT02782780

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Study Protocol

I. Hypothesis: We hypothesize that telephone delivered cognitive behavioral therapy for insomnia (CBTi) will reduce insomnia and non-sleep Gulf War Illness (GWI) symptoms in Gulf War veterans with GWI. Specifically:

1. Effect sizes will suggest that 8-weeks of telephone CBTi improves measures of insomnia severity, subjective sleep quality, and sleep diary measures of total sleep time, sleep onset latency (i.e., the time it takes to fall asleep), and sleep efficiency.
2. Effect sizes will suggest that 8-weeks of telephone CBTi improves measures of non-sleep GWI symptoms, as assessed by the "symptom" portion of the Kansas Gulf War Military History and Health Questionnaire, and measures of fatigue, pain, cognitive dysfunction, and depression and anxiety.
3. In subjects randomized to the treatment arm of the trial, post-CBTi improvements in measures of insomnia and GWI symptoms will be maintained at the 6-month follow-up.

II. Aims:

1. Estimate effect size of telephone-delivered CBTi on insomnia and sleep quality in veterans with Gulf War Illness (GWI) and insomnia (i.e., have Insomnia Severity Index (ISI) scores $\geq$ 14).
2. Estimate effect size of telephone-delivered CBTi on GWI symptoms in veterans with GWI and ISI scores $\geq$ 14.
3. Examine maintenance of telephone-delivered CBTi effects at 6-month follow-up.

III. Study Design: The project will test the efficacy of telephone-delivered CBTi for sleep and non-sleep symptoms associated with GWI by performing a randomized, parallel-group trial with GW Veterans who meet both the Centers for Disease Control and Prevention (CDC) case definition for Chronic Multisymptom Illness (CMI)[4], the Kansas case definition for Gulf War Illness (GWI)[5], and who have insomnia, operationalized as having ISI scores $\geq$ 14.

The study's goal is to randomize 80 eligible participants to get 64 participants who complete the trial. Half of the participants will be randomly assigned to receive telephone CBTi (TX). The other half will be randomized to a Monitor Only (MO) control group. Participants randomized to the TX group will receive 8 weekly sessions of CBTi via telephone with the study therapist. Participants randomized to the MO group will be monitored for 8 weeks (i.e., they will be advised to continue doing whatever they were doing to manage their GWI and insomnia symptoms without change dosage or frequency of treatment).

Prior to randomization, all subjects will be monitored for 1 week with sleep diary. Sleep diary data will also be acquired continuously throughout the 8 study-weeks in both groups. Outcomes will be assessed in all study participants at baseline (i.e., before randomization), mid- and post-treatment. In subjects randomized to TX, outcomes will be assessed once more, 6 months after treatment with Qualtrics online surveys or with traditional pen-and-pencil surveys.

Subjects randomized to the MO condition will be offered telephone-CBTi, at no cost to them, after 8 weeks of monitoring and upon completion of thepost-treatment assessments.

Prior to the initiation of the study, we will conduct a test run of the study procedures in 2-6 GW vetearans. To preserve our pool of eligible GW veterans for the CBT-I trial proper, for the test run, we will recruit GW veterans who have Insomnia Severity Index (ISI) scores > 12, and/or who screen positive for obstructive sleep apnea, and/or who do not meet the criteria for Kansas Gulf War Illness because of an exclusionary medical condition (e.g., seizures or heart disease).

IV. Procedures:

A. Subject Evaluations:

1. Screening for Inclusion: Once subjects have initiated contact, they will be given more information about the study by telephone or by US mail. An initial pre-screen will be performed over the telephone by a study staff member after subjects have given their verbal consent to determine inclusion/exclusion criteria.

2. Clinical Screening: If subjects pass the initial pre-screening for inclusion, they will participate in a clinical screening interview with an experienced clinical interviewer under the supervision of a licensed clinical psychologist. The clinical interviewer will be kept blind to treatment assignment. The following instruments will be used in the clinical screening interview:

a. The Structured Clinical Interview for DSM-V (SCID-5[15]) will be used to assess DSM-V diagnostic criteria for Axis I disorders.
b. Clinician Administered PTSD Scale (CAPS[56]) will be administered to all study participants to assess posttraumatic stress disorder (PTSD) status at baseline.
c. Addiction Severity Index-Lite (ASI-Lite) questionnaire will be used to obtaining data on the participant's history of alcohol consumption and substance use.
d. Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID[69]) This is a standardized procedure to elicit the lifetime history of TBI for an individual. The instrument is based on CDC; National Center for Injury Prevention and Control (2003) case definitions and recommendations for TBI surveillance
e. Subjects will be screened with the Berlin Questionnaire to assess the likelihood of obstructive sleep apnea (OSA).
f. Subjects will be screened with restless legs syndrome screening questionnaire (RLSSQ)[75] to assess the likelihood of restless legs syndrome (RLS). An RLSSQ score $\geq$ 7,[75] identifies patients with RLS with 97.9% sensitivity and 96.2% specificity, will be dropped from the study.

If data from the clinical evaluation suggests that a subject is eligible for the study, the subject will be asked to keep a sleep diary for one week. Following that, the subject will be randomized to the CBT-I (TX) group or the Monitor Only (MO) group

B. STUDY ASSESSMENTS: The following assessments wil be performed at baseline (i.e., before randomization), mid- and post-treatment in all participants. For participants randomized to TX, the assessments will be performed again 6-months after treatment.

1) The **Insomnia Severity Index (ISI[76])** is a 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia in the last month. The dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item (e.g., 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28.[76]

2) The **Pittsburgh Sleep Quality Index (PSQI[77])** is a self-report measure that provides a subjective assessment of sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sedative-hypnotics, and daytime energy.

3) The symptom portion of the **Kansas Gulf War Military History and Health Questionnaire**,[7] which includes 32 questions about fatigue/sleep problems, somatic pain, skin abnormalities, gastrointestinal symptoms, respiratory symptoms, and neurologic/cognitive/mood symptoms, based on the Kansas and Centers for Disease Control and Prevention (CDC) GWI case definition, will be used to assess Gulf War Illness (GWI) symptoms. To assess **current** GWI symptoms, we ask participants about the absence, presence, and severity of the symptoms over the past **2 weeks** instead of over the past 6-months. A **GWI Symptom Severity score** will be derived by summing the answers to 30 of the GWI symptom questions. A higher score will indicate more symptoms and symptoms of greater severity.

4) The **Fatigue Severity Scale (FSS)** is a 9-item questionnaire reflecting the consequences of fatigue. It gives a single score (range 0–7, high scores represent high levels of fatigue). A score of 4 has been described as the cutoff for clinical fatigue.[78]

5) The **Brief Pain Inventory (BPI)[79]** is a 17-item self-rating scale assessing demographic data, use of medications, as well as sensory, and reactive components of pain. The BPI includes items that address components of sensory pain including severity, location (identified with a body map as a measure of pain distribution), chronicity, degree of relief

due to therapy, and reactive pain (e.g., depression, suffering, and perceived availability of relief).

6) The **Multiple Abilities Self-Report Questionnaire (MASQ)**[80] is a 38-item self-report measure of cognitive function compared to same age peers across 5 domains (i.e., verbal memory, attention, language, visual memory, visuo-perceptual ability)

7) The **Hospital Anxiety and Depression Scale (HADS)**[81] will be used to assess **anxiety and depressive** symptoms.

8) The **PCL-5**,[82] a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD, will be used to monitor PTSD symptom change in subjects with PTSD.

9) **Sleep Diary:** All subjects will fill out an online (or paper) sleep diary for 1 week prior to randomization and continuously during the 6-week study period. During CBT-I, the sleep diaries will be a part of treatment and will be examined by the study therapist to monitor adherence, treatment progress, and to inform interventions or sleep restriction titration. Sleep diaries are daily self-monitoring forms that allow the self-recording of various sleep-related measures such as time in bed (TIB), total sleep time (TST), wake after sleep onset (WASO), sleep onset latency (SOL, the time it takes to fall asleep). Participant will also be asked to log the nature and dose of all medications in their sleep diaries. This information will be used to examine whether there are group differences in baseline rates of medication use, mean weekly rates of use during treatment, or change in rates of use throughout the study.

10) **Epworth Sleepiness Scale** will be used to help case formulation and to individualize administration of CBTi.

11) **Morningness-Eveningness Scale** will be used to help case formulation and to individualize administration of CBTi.

All of the self-report assessments and sleep diary data will be obtained online via the Qualtrics survey tool. If participants do not have access to a personal computer and/or would prefer to fill out the self-report assessments and sleep diary via pencil-and-paper, they will be allowed to do so and will be provided a stamped envelope with which to mail the assessments and sleep diary back to us.

We will template and write brief notes about the CBTi treatment in the VA's computerized patient record system (CPRS) as is expected with treatment studies.

Subjects randomized to the MO group will be offered the opportunity to receive CBTi, by telephone, upon completion of all study procedures. However, we will allow these

subjects more flexibility in the duration of CBTi. In practice, there is no "magic number" of sessions. Some patients get better quickly, and some take longer. Therefore we would like to allow subjects randomized to the MO group who elect to receive CBTi by telephone after completing all study procedures the opportunity to receive CBTi for 6-8 weeks. We will ***not*** give subjects originally randomized to the MO group ***more*** sessions of CBTi than subjects randomized to the treatment group, but we will not mandate that they be in therapy for 8 weeks if they and the CBTi therapist does not deem it necessary, especially since these subjects have already been in the study 8 weeks prior to starting CBTi filing out sleep diaries and other study questionnaires.

Some subjects find that, after a few sessions, CBTi is not for them. In practice, we find that these are the subjects who become non-compliant with the therapy (e.g., do not follow the therapist's recommendations and prescriptions). Therefore, we will allow subjects originally randomized to the MO group who elect to receive CBTi after the study but are non-compliant with CBTi the opportunity to stop therapy if both they and the therapist agree that it is not in their best interest at the present time to continue with CBTi.

We will request participants refrain from having elective surgery, starting, stopping, and/or changing their medication or medication dose within 1 month of starting CBTi and during CBTi. We will also ask participants refrain from missing more than 2 CBTi sessions.

V. Assessment Instruments:

- Research version of the Structured Clinical Interview for DSM-V (SCID-5[15]), will be administered to assess DSM-V diagnostic criteria for Axis I disorders.
- Clinician Administered PTSD Scale (CAPS[56]) will be administered to all study participants to assess PTSD status at baseline.
- Addiction Severity Index-Lite (ASI-Lite) questionnaire will be used to obtaining data on the participants' alcohol consumption and substance use.
- Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID[69]) This is a standardized procedure to elicit the lifetime history of TBI for an individual. The instrument is based on CDC; National Center for Injury Prevention and Control (2003) case definitions and recommendations for TBI surveillance.
- Berlin Questionnaire will be used to assess the likelihood of obstructive sleep apnea (OSA).
- Restless legs syndrome screening questionnaire (RLSSQ)[75] will be used to assess the likelihood of RLS.
- Insomnia Severity Index (ISI[76]) is a 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia in the last month. The dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item

(e.g., 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28.

- Pittsburgh Sleep Quality Index (PSQI[77]) is a self-report measure that provides a subjective assessment of sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sedative-hypnotics, and daytime energy.
- Kansas Gulf War Military History and Health Questionnaire[7] includes 32 questions about fatigue/sleep problems, somatic pain, skin abnormalities, gastrointestinal symptoms, respiratory symptoms, and neurologic/cognitive/mood symptoms, based on the Kansas and CDC GWI case definition. We will use the symptom portion of the questionnaire to assess GWI symptoms, excluding the 2 questions about sleep difficulties to assess GWI symptoms.
- Fatigue Severity Scale (FSS) is a 9-item questionnaire reflecting the consequences of fatigue. It gives a single score (range 0–7, high scores represent high levels of fatigue). A score of 4 has been described as the cutoff for clinical fatigue.[78]
- Brief Pain Inventory (BPI)[79] is a 17-item self-rating scale assessing demographic data, use of medications, as well as sensory, and reactive components of pain. The BPI includes items that address components of sensory pain including severity, location (identified with a body map as a measure of pain distribution), chronicity, degree of relief due to therapy, and reactive pain (e.g., depression, suffering, and perceived availability of relief).
- Multiple Abilities Self-Report Questionnaire (MASQ)[80] is a 38-item self-report measure of cognitive function compared to same age peers across 5 domains (i.e., verbal memory, attention, language, visual memory, visuo-perceptual ability)
- Hospital Anxiety and Depression Scale (HADS)[81] will be used to assess anxiety and depressive symptoms.
- PCL-5,[82] a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD, will be used to monitor PTSD symptom change in subjects with PTSD.
- Sleep diaries will be used to allow the self-recording of various sleep-related measures such as time in bed (TIB), total sleep time (TST), wake after sleep onset (WASO), sleep onset latency (SOL, the time it takes to fall asleep).In addition, participant will be asked to log the nature and dose of all medications in their sleep diaries.

VI. Intervention:

A. Cognitive Behavioral Therapy for Insomnia (CBTi) will be administered via telephone by therapists at the San Francisco VA Medical Center to participants for 8 weekly sessions.

B. CBTi will consist of several sessions of sleep restriction, stimulus control and cognitive restructuring related to sleep concerns. The CBTi therapists will all have prior training in CBTi and will be supervised by study co-investigator Dr. Shira Maguen, a licensed clinical psychologist with over ten years of experience in behavioral sleep medicine treatment and research.

C. Monitor Only Waitlist Control condition will consist of continuous monitoring of sleep with diary and data collection at baseline, weeks 4 and 9.

D. Waitlist participants will receive weekly telephone or email check-ins from the study coordinator and will be offered CBTi following completion of the research protocol.

VII. Statistical Analysis:

- Linear mixed models with random effects for subjects will be used to analyze all available data for the intent-to-treat analysis. Because sex will be used as a stratification variable in the randomization procedure, it will not be included as a covariate the analyses.
- Treatment effects will be estimated from post-treatment group differences using mixed models adjusting for baseline scores on each outcome. Standardized effect sizes will be calculated by dividing the treatment effect on each outcome variable by the pooled standard deviation of the variable at baseline.
- To compare baseline data to 6-month follow-up data in the CBTi group, planned contrasts following the mixed models will be used. Statistical analyses will be carried out using R (version 4.0.1). Mixed models will be fitted using the lme4 package (version 1.1-23) and significance tests will be based on Kenward-Roger degrees of freedom estimate provided by the pbkrtest package (version 3.1-2).

Department of VeteransAffairs	**INFORMED CONSENTFORM**
Subject Name:	**Date:**
Title of Study: Pilot Test of Telephone-Delivered Cognitive Behavioral Therapy for Insomnia for Veterans with Gulf War Illness	
Principal Investigator: Linda Chao,PhD	**San Francisco VAMC**

Why is the name of this research study?

- Pilot Test of Telephone-Delivered Cognitive Behavioral Therapy for Insomnia for Veterans with Gulf War Illness

Who is the Principal Investigator?

- Linda Chao, PhD

Who is paying for this study?

The Department of Veterans Affairs

Why is this research study being done?

- To find out if a type of behavioral sleep treatment called cognitive behavioral therapy for insomnia (CBTi), delivered by telephone, can help alleviate sleep and non-sleep symptoms associated with Gulf War Illness (GWI) in Gulf War veterans.

Why am I being asked to take part in this research study?

- You are a Gulf War (GW) veteran with symptoms of GWI and insomnia (i.e., difficulty with falling or staying asleep).

How many people will take part in this study?

- 64 GW veterans.

What will happen if I take part in this research study?

- A study staff member will describe the study to you so you can decide whether or not you want to participate.
- If you decide to participate, there will be a telephone clinical interview with a research mental health clinician to determine your psychiatric and medical history and the type and severity of your sleep problems. This interview will last approximately 2 to 4 hours and will be audio taped.
- If the clinical interview shows that you can continue to be part of the study, and you choose to take part, you will be asked to complete the following baseline monitoring and assessments:

  - You will be asked to keep a sleep diary for 7 days to monitor your sleep and wake schedule. You will fill out the sleep diary every evening to record how much, if any, caffeine, alcohol and/or medications you took as well as how fatigued you felt that day. Each morning you will record your estimated sleep time and the number of times you woke up during the night. The sleep diary will take approximately 5 minutes total to complete each day.
  - You will be asked to complete some self-report questionnaires about your health, mood, sleeping patterns, and GWI symptoms. These questionnaires will take about 50 minutes to complete. You will be asked to mail the questionnaires back to us in a pre-addressed, pre-stamped envelope.

- You will be randomly assigned (i.e., randomized) to one of two groups. One group will undergo CBTi by telephone once a week for 8 weeks. The other group will be asked keep doing their usual activities for 8 weeks. You have a 50-50 chance of being in either group (like flipping a coin). You will not be able to choose the group to which you are assigned.

What will happen if I am assigned to the CBTi group?

- Participants in the CBTi group will undergo 8 weekly CBTi sessions with a sleep coach (i.e., Masters or Doctoral level mental health professional). Each session will last approximately 30 – 90 minutes.
- During the CBTi sessions the sleep coach will give you information about the science of sleep as well as instructions and strategies that may help you resolve your problems of falling and staying asleep and/or improve the quality of your sleep.
- During the 8 weeks of CBTi you will continue to fill out the Sleep Diary each evening and morning.
- On week 4 of CBTi and after completing CBTi, you will be asked to fill out some more self-report questionnaires (on paper to be mailed back to us in a pre-stamped, self-addressed envelope).
- Six months after finishing CBTi, you will again be asked to keep a Sleep Diary for 1 week and to fill out some self-report questionnaires (to be mailed back to us in a pre-stamped, self-addressed envelope).

What will happen if I am assigned to the Usual Activities group?

- The purpose of the Usual Activities group is to allow us to compare the effects of those of receiving CBTi by telephone with those who have not yet received CBTi. For this reason, participants in the Usual Activities group will be asked to maintain their normal daily routine for 8 weeks and to fill out a Sleep Diary during this time
- On week 4, you will be asked to fill out some self-report questionnaires (which you will mail back to us in a pre-stamped, self-addressed envelope).

- On week 9, you will again be asked to fill out some self -report questionnaires (which you will mail back to us in a pre-stamped, self-addressed envelope). After we receive your self-report questionnaires, you will be offered the opportunity to begin 8 weeks of telephone delivered CBTi, described above.

What will happen after the 8 weeks of CBTi or Usual Activities?

- You will be asked to complete some self-report questionnaires about your health, mood, sleeping patterns, and GWI symptoms (which you will mail back to us in a pre-stamped, pre-addressed envelope).
- If you were assigned to the CBTi group,6 months later you will be asked to keep a Sleep Diary for one week and to complete some self-report questionnaires about your health, mood, sleeping patterns, and GWI symptoms (which you will mail back to us in a pre-stamped, pre-addressed envelope).
- If you were assigned to the Usual Activities group, you will have the option to begin 8-weeks of CBTi with our sleep coach at no cost to you.

Where will the study take place?

- Although the study staff (e.g., recruiter, clinical interviewer, and sleep coach) are located at the San Francisco VA Medical center, all the study procedures will be conducted over the telephone or by mail. Therefore, you do not have to come to San Francisco to participate. You can participate from nearly anywhere (such as your home).
- The self-report questionnaires can be completed anywhere, and you will be asked mail it back to us in a pre-stamped, pre-addressed envelope.

How long will I be in this study?

- All participants will be in the study for at least 10 weeks. This includes:
    - 1 week of monitoring sleep habits by keeping a sleep diary and filling out some self-report questionnaires before randomization
    - 8 weeks of telephone delivered CBTi or 8 weeks of keeping a sleep diary and doing your usual activities.
    - 1 week of monitoring sleep habits with a sleep diary and filling out some self-report questionnaires.
- Participants assigned to the CBTi group will be asked to repeat the post-treatment assessments 6 months after finishing CBTi to help us determine the long-term effects of telephone delivered CBTi.
- Participants assigned to the Usual Activities group will have the opportunity to undergo 8 weeks of telephone delivered CBTi after the post-study assessments are complete.

Can I continue with other treatments while I am in the study?

- Yes, you may continue any other treatments you are receiving for GWI during the study. However, you will be asked to provide information about any changes in these other treatments that take place during this study.

Are there any risks with being in the study?

- You may experience some discomforts while participating in the study: During the course of CBTi, some fatigue and/or sleepiness, and/or memory and concentration difficulties may occur, although they are usually limited to the first 1-2 weeks of treatment. If the side effects become too bothersome or are uncontrollable, you are free to discontinue CBTi and withdraw from the study or the study researcher may recommend that you withdraw from the study.
- Everyone taking part in the study will be watched carefully for any side effects. However, there may be side effects that the doctors/sleep coaches do not know about. Therefore, you should talk to your sleep coach about any side effects or discomforts you experience while taking part in the study. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.
- To ensure that you have access to immediate attention over the course of the study, **all** study participants will be provided with the telephone numbers of the study researchers.
- The clinical interview and/or self-report questionnaires may be distressing to some participants. You are free to decline to answer any questions or to stop the interviews at any time. The interviewer will be available to immediately assist with any problems that arise in the interview and will make a referral if required.
- The clinical interviews will be audio taped for quality control purposes. The audio taping may make you somewhat more uncomfortable than you would otherwise be if the interview were not taped. Only research personnel will use the recordings to calibrate the clinicians' ratings on the standardized interview format. The audio tapes will be maintained under secured conditions (the tapes will be protected with a pass-code, and stored and accessed via a secure server), and will be identified only by a unique ID number. The audio recordings will NOT be disclosed outside VA.
- The CBTi sessions will also be audio taped. This taping may make you somewhat more uncomfortable than you would otherwise be without the taping. These recordings will only be reviewed by research staff for the purposes of assessing the quality of the CBTI that you receive. The recordings will be identified by a unique ID number and will be stored under secure conditions (the recordings will be protected with a pass code and stored on a secure server). The audio recordings will NOT be disclosed outside VA.

- You have a 50% chance of being assigned to the Usual Activities group, which will delay the start of telephone delivered CBTI for approximately 9 weeks.

Can I stop being in the study?

- Yes, you can decide to stop at any time. Just tell a study staff member that you are thinking about stopping or if you have decided to stop. S/He will tell you how to stop your participation safely.
- It is important to tell the sleep coach if you are thinking about stopping CBTi so she can evaluate any risks from the treatment, and discuss what alternative follow-up care could be most helpful for you.
- The study researcher may stop you from taking part in this study at any time if s/he believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

Are there benefits to taking part in the study?

- Taking part in this study may or may not make your non-sleep GWI symptoms better or improve your sleep. While researchers hope that CBTi will be effective in treating your sleep problems associated with GWI symptoms, there is no proof of this yet.

What other choices do I have if I do not take part in this study?

- Your other choices may include not getting treatment or getting standard treatment for your condition without being in a study. You may also seek medical treatment for insomnia, including a sleep aid such as trazodone, or you may take part in another study.
- If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from the VA the way you usually do.
- Please talk to your doctor about your choices before deciding whether or not you will participate in this study.

Will information about me be kept private?

- We will do our best to make sure the personal information gathered for this study is kept private. However, we cannot guarantee total privacy.
- Data collected for this study may be stored in electronic research databases at the San Francisco VA.
- Your personal information may be given out if required by law. For instance, this would occur if it were learned through the clinical interview or study that you were a danger to yourself or others, that a child had been abused or neglected, or that an elder or dependent had been abused. Should this happen, the appropriate authorities would be notified, as required by law.

- Your personal information may be seen or copied by people who are checking to make sure we are doing a good job, including UCSF's Institutional Review Board, Department of Veterans Affairs, or other study auditors.
- If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If you opt to receive text and/or email reminders during this study regarding appointment times or study materials, we will not put any personal information in the body of the text.

What are the costs of taking part in this study?

- You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

- **All subjects** will receive **$60** for the clinical assessment interview.
- **All subjects** will receive **$30** for the baseline assessment (e.g., self-report questionnaires and 1 week of sleep diary).
- Subjects assigned to the **CBTi group** will receive **$60** for the mid-treatment assessment, **$60** for the post-treatment assessment (e.g., self-report questionnaires), and **$70** for the 6-month follow-up assessments (e.g., self-report questionnaires and 1 week of sleep diary, see Table 1).
- Subjects assigned to the **Usual Activities group** will receive **$10 a week** for keeping a sleep diary for 9 weeks (**$90** for 9 weeks), **$50** for the mid-treatment assessment and **$50** for the post-treatment assessment (e.g., self-report questionnaires, see Table 1).
- **All subjects** who complete the study will receive a **completion bonus of $75**.
- Payments will be through Electronic Fund Transfer (EFT) and will be received within 20-30 business days of completing the assessment.
- We will need the following information from you in order to process the EFT: your name and address, your social security number, your bank's name and address, your bank account and routing transit numbers.

Table 1. Payment schedule for both groups

Group	Pre-treatment		Treatment			Post-treatment		Completion Bonus
	screening	baseline	Wk 1-3	Wk 4	Wk 5-8	Wk 9	Month 6	
CBTi	$60	$30[a,b]		$60[a]		$60[a]	$70[a,b]	**$75**
Usual Activities	$60	$30[a,b]	$30[b]	$60[a,b]	$40[b]	$60[a]		**$75**

[a]Self-report questionnaires
[b]Sleep diary

What happens if I am injured because I took part in this study?

- It is important that you tell the principle investigator, Linda Chao, if you feel that

you have been injured because of taking part in this study. You can call Dr. Chao at (415) 221-4810, ext. 24386.

- If you are injured as a result of being in this study, VA will ensure that treatment is made available at a VA medical facility. If you are eligible for veteran's benefits, the costs of such treatment will be covered by the Department of Veterans Affairs. If you are not eligible for veteran's benefits, the costs of treatment may be billed to you or your insurer just like any other medical costs, or covered by the Department of Veterans' Affairs or the University of California or the study sponsor [sponsor name], depending on a number of factors. The Department of Veterans Affairs, the University and the sponsor do not normally provide any other form of compensation for injury. For furtherinformation about this, call the VA Regional Counsel at (415) 750-2288 or the office of the UCSF Committee on Human Research at (415) 476-1814.

What are my rights if I take part in this study?

- Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You will still be able to get medical care from the VA.
- We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.
- In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

What will happen to my information once the study is over?

- Research records will be retained in accordance with the VHA Records Control Schedule.
- Other researchers may request permission to use data from this study to answer other research questions. However, your personally identifying information (such as your name or contact information) will **not** be shared.

Can I find out the results of the study?

- We will let all study participants know the overall results of the study at the end of the study.
- However, you will not be given your personal results.

Who can answer my questions about the study?

- You can talk to the researchers about any questions, concerns, or complains you may have about the study. Dr. Linda Chao, the Principal Investigator, may be contacted at 415-221-4810, ext. 24386.
- If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any

problems or concerns you may have about the study, please call the Office of the Committee on Human Research at UCSF, which is a group of people who review the research to protect your rights.

- Phone: 415-476-1848 (8am to 5 pm, Monday through Friday)
- Address: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143

CONSENT:

- You will be given a copy of this consent form to keep.
- You will be given the Experimental Subjects Bill of Rights.
- You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about yourself.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

CONSENT FOR FUTURE CONTACT

We would like to contact you in the future to follow up and/or to tell you about other studies. However, you have the option to opt out if you do not want to be contacted. Please check the appropriate box below:

☐ I DO NOT AGREE to be contacted in the future.

☐ I AGREE to be contacted in the future about THIS RESEARCH STUDY.

☐ I AGREE to be contacted in the future about OTHER RESEARCH STUDIES.

If you are willing to be contacted, please sign below.

_____

Date Participant's Signature for Consent

VETERANS ADMINISTRATION MEDICAL CENTER, SAN FRANCISCO AND
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out,
2. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5. To be told of the other choices I have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7. To be told what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.Call 476-1814 for information in translations.