Preventative treatment of depression in survivors of aneurysmal subarachnoid hemorrhage

Abbreviated Title: Depression in aSAH

Protocol Number: IRB# STUDY00002718

Amendment Date: March 4, 2024

Sponsor:
University of Washington
Harborview Medical Center
325 9th Ave
Seattle, WA 98104

Study Principal Investigator: Michael Levitt MD

Administrative information

Title	Preventative treatment of depression in survivors of aneurysmal subarachnoid hemorrhage
Trial registration	NCT03826875
Protocol version	March 4, 2024
Funding	Brain Aneurysm Foundation
Author details	Michale Levitt MD, Louis Kim MD, Cory Kelly, Keiko Prijoles, Do Lim
Name and contact information for the trial sponsor	Michael Levitt MD (PI) University of Washington Harborview Medical Center 325 9th Ave Seattle, WA 98104 206-744-9330
Role of sponsor	Study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication

Introduction

Background and rationale

Approximately 30,000-50,000 patients suffer from SAH every year in North America, and it accounts for 5% of all strokes in the USA. The grave nature of this disease results in an approximately 35-50% mortality rate. As medical technology and techniques have improved, more and more of these patients are surviving this devastating neurological injury. However, the increasing number of survivors faces many challenges in their recovery and return to a normal life.

A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot or bursts (or ruptures). When that happens, part of the brain cannot get the blood (and oxygen) it needs, so it and brain cells die. Stroke can be caused either by a clot obstructing the flow of blood to the brain (called an ischemic stroke) or by a blood vessel rupturing and preventing blood flow to the brain (called a hemorrhagic stroke). There are two types of hemorrhagic stroke: intracerebral hemorrhage (ICH) and subarachnoid hemorrhage (SAH). ICH stroke happens when a blood vessel inside the brain bursts and leaks blood into surrounding brain tissue. The bleeding causes brain cells to die and the affected part of the brain stops working correctly. SAH stroke involves bleeding in the area between the brain and the tissue covering the brain, known as the subarachnoid space. SAH stroke can be caused by malformation of the blood vessels, bleeding disorders, blood thinners, or most commonly by burst aneurysms. This type of stroke is called aneurysmal subarachnoid hemorrhage or aSAH.

Survivors of SAH often suffer from new depression disorders after recovery, resulting in a decreased quality of life and increased health care costs. Approximately 1/3 of all SAH patients without a previous history of mood disorder have signs or symptoms of depression at least one year after hospitalization. Multiple studies of patients who become depressed after any type of significant injury show that their treatment is at least twice the cost of patients who do not develop depression. This cost rises substantially with both age and depression severity.

Our goal with this study is twofold; first, to address the gap in knowledge of utility of prophylactic SSRI in the aSAH subpopulation of stroke patients, and second, to study the role of cortisol regulation in susceptibility to depression so that we might identify what patients would most benefit from SSRI prophylaxis. We hypothesize that placing aSAH patients on preventative anti-depressant medications at the time of stroke may both improve their lives and the lives of their families, while also decreasing post-injury health care costs.

Fluoxetine (an antidepressant commonly known as Prozac) is among a group of medications known as selective-serotonin reuptake inhibitors that work to maintain higher-than-normal levels of serotonin, a neurotransmitter popularly associated with contributions to well-being and happiness. Fluoxetine is a World Health Organization Essential Medicine and is considered a first-line treatment for depression by the American Psychiatric Association. In addition, fluoxetine has a fast treatment effects and is inexpensive. It is currently not standard to implement antidepressant medications after aneurysm rupture due to the lack of studies on their preventative benefits to aSAH patients.

The use of SSRIs has been studied in the general poststroke population, to include patients with aSAH. However, the aSAH population has not been evaluated as an independent experimental cohort. These studies demonstrated no difference in adverse events between the stroke population and general population. Furthermore, one arm of the ongoing poststroke depression triad trials (AFFINITY, FOCUS, and EFFECT) is also including aSAH patients, but again not looking at these patients as an independent experimental cohort. Meta-analyses have demonstrated “Poststroke depression has been shown in 6 double-blind controlled studies to be effectively treated with antidepressants, and 1 study has recently shown that PSD can be effectively prevented” (Robinson 2010). More granular studies evaluating SSRIs and hemorrhagic stroke also demonstrated adverse events to be no more frequent than controls as well as similar medical outcomes. Furthermore, in our current clinical practice, aSAH patients currently

on SSRIs at presentation are either continued on their SSRIs or restarted on their SSRIs following treatment, without increased clinical concern.

This trial will evaluate the effect of preventative treatment of depression in survivors of aSAH patients to development of depression. Eligible patients will be divided into three groups: a control group, which receives a placebo medication, and an intervention group, which will receive fluoxetine, Patients will be evaluated for depression and health care-related quality of life immediately after treatment of aSAH, and several times over the first year of recovery. We expect that the patients receiving antidepressant medications will show an improvement in depression incidence, depression severity, and quality of life when compared to those patients who receive a placebo. We anticipate that these patients will have reduced post-injury health care utilization costs and return to work more often than those receiving placebo. The control group that receives a placebo is necessary to prove that the difference between the two groups is based on the effects of fluoxetine, rather than a placebo effect.

Objectives

We propose a double-blinded placebo-controlled randomized trial to evaluate the effect of preventative treatment of depression in survivors of aneurysmal subarachnoid hemorrhage (aSAH), a type of stroke.

Trial design

This investigation is pragmatic, prospective, double-blinded, placebo-controlled randomized trial to evaluate the effect of preventative treatment of depression in survivors of aneurysmal SAH, a type of non-traumatic, hemorrhagic stroke. Over a one-year period, English speaking adults (18-85 years old) of all genders admitted to, treated at, and discharging from Harborview Medical Center for aneurysmal SAH will be randomly prescribed either an oral antidepressant (the SSRI fluoxetine, commonly known as Prozac) or placebo prior to discharge. The control group that receives a placebo is necessary to prove that the difference between the two groups is based on the effects of the antidepressant medication, rather than a placebo effect. Patients will

be evaluated for depression and health-related quality of life immediately after treatment of SAH over the course of a one year following discharge. Patients declining the randomized trial, will be recruited into an observational cohort to establish baseline rates of symptoms.

Methods: Participants, interventions and outcomes

Study setting

The University of Washington School of Medicine's Harborview Medical Center is the primary tertiary referral center for the Pacific Northwest and WWAMI region and a Certified Comprehensive Stroke Center, per the Joint Commission and American Heart Association/American Stroke Association. Each year over 200 patients are admitted to Harborview Medical Center for aneurysmal SAH. Harborview Medical Center maintains an Investigational Drug Service that manages medications used in clinical trials.

Eligibility criteria

1) Patients 18 years of age and older will be included.
2) Patients above 85 years of age will be excluded from the drug vs placebo cohort.
3) Patients admitted for subarachnoid hemorrhage from a ruptured cerebral aneurysm will be included.
4) Non-English speaking patients will be excluded.
5) Patients currently receiving therapy for depression or related mental health diagnoses before admission will be excluded.
6) Patients with medical contraindications to fluoxetine therapy will be excluded from the drug vs placebo arms
7) Pregnant patients or patients considering pregnancy during the trial period at the time of consent will be excluded from the drug vs placebo arms.
8) Patients with active psychosis will be excluded.
9) Patients who are incarcerated or in police custody will be excluded.
10) Patients with a comorbidity or cognitive impairment (as determined by a recruiter-administered Montreal Cognitive Assessment [MoCA]; Patients scoring >20 are considered of appropriate cognitive function for consent) that precludes informed

consent and participation in the research interviews will be excluded from the observational and drug vs placebo cohorts, but may be included in the biofluid cohort.

Who will take informed consent?

Potential patient-subjects will be identified by neurosurgeons on the treatment team. Patients will be recruited and screened for participation in the drug vs placebo or observational cohort by a member of the research team prior to discharge. Patient inclusion and exclusion will be determined by the medical record as well as in-person by the provider. The Montreal Cognitive Assessment will be administered prior to the consent to determine baseline cognitive state. We will also conduct screening to determine if the patient is currently receiving therapy for depression or related mental health diagnoses. Any recruiter who administers the MoCA completes MoCA training and certification. Patients scoring >20 on the MoCA are considered of appropriate cognitive function to participate in the study.

Patients recruited for the drug vs placebo cohort will be provided with a detailed explanation regarding the study protocol, occurrence of depression in aneurysmal subarachnoid hemorrhage and the potential treatment effects of fluoxetine. Patients will have an opportunity for questions before providing before consent. Decisional capacity will be determined by having participants confirm their understanding of the study purpose and procedure, and the risks, benefits and alternatives to participating in the study.

Interventions

Explanation for the choice of comparators

If a patient chooses to decline treatment with fluoxetine but is eligible for the observational cohort, they will be given the necessary study information. Patients can choose to provide consent anytime between approach and discharge. Patients may revoke their informed consent at any time by contacting the research team.

Intervention description

Patients deemed eligible for inclusion in the drugs vs. placebo or observational cohort will be approached for consent in the inpatient ward as they are nearing discharge after aSAH. After consent is obtained, patients will be randomized to either a placebo or fluoxetine-treatment group. Patients that decline participation in the drug vs placebo arm may be enrolled in the observational cohort.

For patients participating in the drug vs. placebo cohort, the study drug will be provided at no cost for the duration of the trial (1 year).

Patients randomized to the fluoxetine treatment group will be initially prescribed fluoxetine 20mg/day. The drug will be supplied to patients in 90-day supply. For patients in the drug/placebo cohort, if severe depression (as defined by a HAM-D score of >24 or a PHQ-9 score >20 or positive endorsement on the PHQ-9 suicide items 2 or 3) is persistent at any study time points, an additional fluoxetine dose of 20mg/day will be administered for 40mg total dose for fluoxetine group.

If severe depression is persistent at any study time points for patients randomized to the placebo group (as defined above), they will be prescribed 20 mg of fluoxetine.

The research assistant will administer an approximately 45-minute interview at up to five time points to all patient-subjects: upon enrollment (prior to hospital discharge) as a baseline assessment, and up to four follow-up visits within 18 months after discharge from the hospital.

The goal will be to do these assessments at the six-week, six-month, and one-year follow-up appointments, taking into consideration that the actual appointments frequently do not occur exactly on the intended timescale. The trial period will be for 12 months after discharge; however, should we need to speak with patients or if they miss their 12 month appointment, we will allow for another timepoint within 18 months.

The interview questionnaires will assess depression and health-related quality of life, medication compliance, drug side effects and pregnancy, either in person, over the phone, via email, or mail. If the participant endorses serious side effects, the event will immediately be reported to and reviewed by the study PI for its relatedness to the study and it will be reported to IRB in accordance with University of Washington IRB reportable event guidelines.

Depression will be assessed using the Hamilton Rating Scale for Depression (HAM-D) and the Patient Health Questionnaire (PHQ-9). Health-related quality of life will be assessed using the Medical Outcomes Short Form Health Survey (SF-36). All measures will be assessed at each time point.

For patients reaching the end of the study and choosing to discontinue the study drug, the two week weaning period will begin at the completion of the 12-month trial period. Patient education regarding continuation or discontinuation of SSRI treatment at the completion of the study will be provided 90 days prior to reaching the end of the study, regardless of treatment group. From time to time, members of the study team may contact the patient to ensure medication compliance and answer questions about medications and the study the subject may have.

If any patient, in the drug vs. placebo demonstrates severe depression (as defined by a HAM-D score of >24 or a PHQ-9 score >20 or positive endorsement on the PHQ-9 suicide items 2 or 3) is persistent at any study time points, patient will be immediately directed to their physician for further evaluation. If a patient endorses suicidal ideation, they will be immediately referred to the psychiatric service for further urgent mental health evaluation before a dosage increase is considered. If a patient is removed from the study, that data will be included in the subsequent data analysis.

After a final timepoint at approximately 1 year after hospitalization (but up to 18 months), the subjects' study enrollment will be complete.

Criteria for discontinuing or modifying allocated interventions

Patients may be withdrawn from the research without their consent if the patient is no longer able to participate in the research protocol. In any case that a patient-subject will be discontinuing the drug, we will taper over two weeks, halving the dose each week.

Outcome Measures

- For all subjects enrolled in the study, relevant clinical and demographic data, including PHI such as name, date of birth, dates related to hospital stay, medications, and medical record number.
- Montreal Cognitive Assessment (MoCA)- 30-item questionnaire to determine cognitive status.
- Patient Health Questionnaire 9 (PHQ9): 9-item questionnaire to treat and diagnosis depression.
- Hamilton Rating Scale for Depression (HAM-D: 30-item questionnaire to treat and diagnosis depression. This will be given if a patient exhibits depression based on the PHQ9 score.
- The Short Form (36) Health Survey (SF-36): 36-item questionnaire to assess health-related quality-of-life.
- Barthel Index: Scale used to determine functional status, measuring performance in activities of daily living.
- Hamilton Anxiety Rating Scale: Measures the severity of anxiety through looking at both psychic and somatic anxiety.
- Multidimensional Scale of Perceived Social Support: Scale to determine a patients social support system
- PROMIS: Sleep disturbance scale assess pure domain of sleep disturbance
- Health Care Utilization: Assess ER visits, outpatient visits, rehospitalization and mortality
- Fatigue Severity Scale: Measures the severity of fatigue and its effect on a person’s activities and lifestyle in patients exhibiting depression

Participant timeline

The research assistant will administer an approximately 45-minute interview at up to five time points to all patient-subjects: upon enrollment (prior to hospital discharge) as a baseline assessment, and at up to four follow-up visits within 18 months after discharge from the hospital.

The goal will be to do these assessments at the six-week, six-month, and one-year follow-up appointments, taking into consideration that the actual appointments frequently do not occur exactly on the intended timescale. The trial period will be for 12 months after discharge; however, should we need to speak with patients or if they miss their 12 month appointment, we will allow for another timepoint within 18 months.

For patients reaching the end of the study and choosing to discontinue the study drug, the two week weaning period will begin at the completion of the 12-month trial period. Patient education regarding continuation or discontinuation of SSRI treatment at the completion of the study will be provided 90 days prior to reaching the end of the study, regardless of treatment group. From time to time, members of the study team may contact the patient to ensure medication compliance and answer questions about medications and the study the subject may have.

Sample size

Based upon previous studies we anticipate the rate of depression in the treatment group to be 7.3% and the rate of depression in the placebo group to be 21.2%, as determined by the HAM-D score. It is estimated that 200 patients are eligible per year, however we have conservatively estimated enrolling 20 patients to account for recruitment and retention rates. Power calculations show a large-scale trial would require 224 total patients. We anticipate analysis at 1-year (as funded from this proposal) will demonstrate the feasibility of both the randomized administration of antidepressant medication to the post-SAH population, as well as prospectively define the rate of new depression and the effect of SAH on health-related quality of life.

Recruitment

Patients will be recruited and screened for participation by a member of the research team prior to discharge. Patient inclusion and exclusion will be determined by the medical record as well as in-person by the provider. The Montreal Cognitive Assessment will be administered prior to the consent to determine baseline cognitive state. We will also conduct screening to determine if the patient is currently recieveing therapy for depression or related mental health diagnoses. Any recruiter who administers the MoCA completes MoCA training and certification. Patients scoring >20 on the MoCA are considered of appropriate cognitive function to participate in the study.

Patients recruited for the drug vs placebo cohort will be provided with a detailed explanation regarding the study protocol, occurrence of depression in aneurysmal subarachnoid hemorrhage and the potential treatment effects of fluoxetine. Patients will have an opportunity for questions befor providing before consent. Decisional capacity will be determined by having participants confirm their understanding of the study purpose and procedure, and the risks, benefits and alternatives to participating in the study.

Relevant clinical and demographic data such as name, date of birth, dates related to hospital stay, medical record number, area of the ruptured aneurysm, Glasgow Coma Score, Fisher Grade, Hunt and Hess Grade, Medications, medical history, and comorbidity which will be maintained in a secure screening and recruitment log. Patients can choose to provide consent anytime between approach and discharge. Patients may revoke their informed consent at any time by contacting the research team.

Assignment of interventions: allocation

Sequence generation

Simple randomization schemes will be utilized for the drug cohort and placebo cohort. For each cohort, subjects will be randomized in a 1 to 1 ratio to receive either the SSRI antidepressant or placebo drugs. Randomization will be done after the participant or

LAR as signed the ICF. Randomization will be performed by the study pharmacist. Study team, study assessor, study investigator is blinded until the subject exits the study, need to unblind for medical intervention, or end of the study.

Assignment of interventions: Blinding

Who will be blinded

Trial participants, care providers, outcome assessors will stay blinded. Placebo vs study drug will be prepared and dispensed by local study pharmacist. Only the study pharmacy will know the designation of each participant until the clinical team request the information for health care purposes or when the participants exit the study.

Procedure for unblinding if needed

If an adverse event occurs in which the disclosure of the treatment arm is necessary for medical treatment, the disclosure will be provided to the patient and/or provider.

Data collection and management

Plans for assessment and collection of outcomes

Preventative treatment of poststroke depression in aneurysmal subarachnoid hemorrhage					
Activity	**Initial Screening**	**Baseline**	**6-week**	**6-month**	**12-month**
Eligiblility Screen	x				
*Montreal Cognitive Assessment (MoCA)**	x				
Enrollment	x				
Consent	x				
OnCore/EPIC Update	x	x	x	x	x
Pharmacy Prescription Fluoxetine (every 90 days)		x	x	x	
Patient Health Questionnaire (PHQ-9)		x	x	x	x

*Hamilton Rating Scale for Depression (HAM-D)***		x	x	x	x
36-Item Short Form Survey (SF-36)		x	x	x	x
Barthel Index		x	x	x	x
Hamilton Anxiety Rating Scale (HAM-A)		x	x	x	x
Multidimensional Scale of Perceived Social Support		x	x	x	x
Sleep Distrubance (PROMIS)		x	x	x	x
Self Report Health Service Utilization and Medication Use		x	x	x	x
Fatigue Severity Scale (FSS)		x	x	x	x
Disclosure of Interventional Cohort					x
*MoCA score must score more than 20 in order to be enrolled and consented into the study **HAM-D only conducted when pt scores greater than 4 on PHQ-9					

Confidentiality and Data management

All research data will be deidentified. A single-master key will be retained. All data will be stored on a secure research database or in a secure cabinet on a secure floor. Access to identifiers will be limited to the study team. Data will be classified as Level 4 risk. U1-U13, D1-D9 will apply to all data. S1-S20 will be utilized; local procedures will be utilized in addition to the protections afforded by utilizing the UW OneDrive. P1-P3 will be utilized for non-digital records. T1-T8 will be utilized for data transmission. We do not intend to utilize vendors, but if vendors are utilized we will adhere to V1.

Statistical methods

Statistical methods for primary and secondary outcomes

In addition to patient-level measures, relevant clinical and demographic data will be

obtained for the descriptive statistics of the cohort. For each time point we will determine the rate and severity of the outcome measures. We will utilize linear mixed models to determine to determine the treatment effect of preventative fluoxetine administration in patients surviving subarachnoid hemorrhage. Important confounders will be determined and adjusted for in the analysis. The primary outcome will be analyzed at the one-year time point. The intermediate time points will be obtained to determine the longitudinal progression of the mental health status and functional ability in this patient population.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

The PI (or approved co-investigator) will monitor the study with prompt reporting of adverse events and other study related information to the IRB and other agencies as appropriate. Non-serious adverse events and unrelated serious adverse events will be reported in the annual progress report. Serious adverse events that could be related to the study should be reported within 7 days of becoming aware of the event. At any time, if a patient presents suicidal ideations, the patient will be immediately referred to psychiatric service for further evaluation and the event reported. Team meetings by the PI and staff will be conducted on a routine basis to discuss any new adverse events or changes in the protocol. This plan will be revised and updated if the benefit-risk analysis changes.

Composition of the data monitoring committee, its role and reporting structure

An independent medical monitor, an appropriately qualified physician with no conflict of interest and meeting he NINDS recommendation of being otherwise unaffiliated with the study or an institution conducting the study, will perform safety-focused reviews considering adverse events at a minimum of 6 month intervals.

Adverse event reporting and harms

The PI (or approved co-investigator) will monitor the study with prompt reporting of adverse events and other study related information to the IRB and other agencies as

appropriate. Non-serious adverse events and unrelated serious adverse events will be reported in the annual progress report. Serious adverse events that could be related to the study should be reported within 7 days of becoming aware of the event. At any time, if a patient presents suicidal ideations, the patient will be immediately referred to psychiatric service for further evaluation and the event reported.

If an adverse event occurs in which the disclosure of the treatment arm is necessary for medical treatment, the disclosure will be provided to the patient and/or provider.

Frequency and plans for auditing trial conduct

Internal audit will be conducted routinely with study PI and the study team. An independent medical monitor, an appropriately qualified physician with no conflict of interest and meeting the NINDS recommendation of being otherwise unaffiliated with the study or an institution conducting the study, will perform safety-focused reviews considering adverse events at a minimum of 6 month intervals.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)

Team meetings by the PI and staff will be conducted on a routine basis to discuss any new adverse events or changes in the protocol. This plan will be revised and updated if the benefit-risk analysis changes.

Dissemination plans

A description of this clinical trial will be available on https://clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Patient Health Questionnaire Depression (PHQ-9) (Kroenke et al., 2001)

For this next section, the questions I'll be asking you will be in regards to your mood **in the past month, since your injury.**

Phq	**Since your injury**, how often have you been bothered by any of the following problems?	**Not at all**	**A little of the time**	**More than half the time**	**Nearly all the time**
1.	Little interest or pleasure in doing things	0	1	2	3
2.	Feeling down, depressed or hopeless	0	1	2	3
3.	Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4.	Feeling tired or having little energy	0	1	2	3
5.	Poor appetite or overeating	0	1	2	3
6.	Feeling bad about yourself- or that you are a failure or have let yourself or your family down	0	1	2	3
7.	Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9.	Thoughts that you would be better off dead or of hurting yourself in some way. **Note, if any endorsement, RA assess further and contact PI* [9a.] Do you currently have plans to harm yourself or take your own life? Yes No if no, proceed to next section [9b.] Have you attempted to carry out this plan in the past two weeks? Yes No	0	1	2	3
10.	*[If YES to **any** problems*] How **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people?	0 Not at all	1 A little bit	2 Moderately	3 Extremely

Total Score: _____

The Hamilton Rating Scale for Depression

1. **DEPRESSED MOOD** (Sadness, hopeless, helpless, worthless)

   0= Absent
   1= These feeling states indicated only on questioning
   2= These feeling states spontaneously reported verbally
   3= Communicates feeling states non-verbally—i.e.,through facial expression, posture, voice, and tendency to weep
   4= Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. **FEELINGS OF GUILT**

   0= Absent
   1= Self reproach, feels he has let people down
   2= Ideas of guilt or rumination over past errors or sinful deeds

   3= Present illness is a punishment. Delusions of guilt
   4= Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. **SUICIDE**

   0= Absent
   1= Feels life is not worth living
   2= Wishes he were dead or any thoughts of possible death to self

   3= Suicidal ideas or gesture
   4= Attempts at suicide (any serious attempt rates 4)

4. **INSOMNIA EARLY**

   0= No difficulty falling asleep
   1= Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour

   2= Complains of nightly difficulty falling asleep

5. **INSOMNIA MIDDLE**

   0= No difficulty
   1= Patient complains of being restless and disturbed during the night
   2= Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

6. **INSOMNIA LATE**

   0= No difficulty
   1= Waking in early hours of the morning but goes back to sleep

   2= Unable to fall asleep again if he gets out of bed

7. **WORK AND ACTIVITIES**

   0= No difficulty
   1= Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

2= Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

3= Decrease in actual time spent in activities or decrease in productivity

4= Stopped working because of present illness

8. **RETARDATION: PSYCHOMOTOR** (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

   0= Normal speech and thought
   1= Slight retardation at interview
   2= Obvious retardation at interview
   3= Interview difficult
   4= Complete stupor

9. **AGITATION**

   0= None
   1= Fidgetiness
   2= Playing with hands, hair, etc.

   3= Moving about, can't sit still
   4= Hand wringing, nail biting, hair-pulling, biting of lips

10. **ANXIETY (PSYCHOLOGICAL)**

    0= No difficulty
    1= Subjective tension and irritability

    2= Worrying about minor matters
    3= Apprehensive attitude apparent in face or speech

    4= Fears expressed without questioning

11. **ANXIETY SOMATIC:** Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

    0= Absent

    1= Mild
    2= Moderate

    3= Severe
    4= Incapacitating

12. **SOMATIC SYMPTOMS (GASTROINTESTINAL)**

    0= None
    1= Loss of appetite but eating without encouragement from others. Food intake about normal
    2= Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. **SOMATIC SYMPTOMS GENERAL**

    0= None
    1= Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability

    2= Any clear-cut symptom rates 2

14. **GENITAL SYMPTOMS** (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

    0= Absent

    1= Mild

    2= Severe

15. **HYPOCHONDRIASIS**

    0= Not present
    1= Self-absorption (bodily)
    2= Preoccupation with health
    3= Frequent complaints, requests for help, etc.
    4= Hypochondriacal delusions

16. **LOSS OF WEIGHT**

    A. When rating by history:
    0= No weight loss
    1= Probably weight loss associated with present illness
    2= Definite (according to patient) weight loss
    3= Not assessed

17. **INSIGHT**

    0= Acknowledges being depressed and ill
    1= Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
    2= Denies being ill at all

18. **DIURNAL VARIATION**

    A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none
    0= No variation
    1= Worse in A.M.
    2= Worse in P.M.
    B. When present, mark the severity of the variation. Mark “None” if NO variation
    0= None
    1= Mild
    2= Severe

19. **DEPERSONALIZATION AND DEREALIZATION** (Such as: Feelings of unreality; Nihilistic ideas)

    0= Absent
    1= Mild
    2= Moderate
    3= Severe
    4= Incapacitating

20. **PARANOID SYMPTOMS**

    0= None
    1= Suspicious
    2= Ideas of reference

3= Delusions of reference and persecution

21. OBSESSIONAL AND COMPULSIVE SYMPTOMS

0= Absent
1= Mild
2= Severe

Total Score: _____

36-Item Short Form Survey Instrument (SF-36)

1. In general, would you say your health is:

1= Excellent
2= Very good
3= Good
4= Fair
5= Poor

2. Compared to one year ago, how would you rate your health in general **now**?

1= Much better now than one year ago
2= Somewhat better now than one year ago
3= About the same
4= Somewhat worse now than one year ago
5= Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing **several** flights of stairs	1	2	3
7. Climbing **one** flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3
9. Walking **more than a mile**	1	2	3
10. Walking **several blocks**	1	2	3
11. Walking **one block**	1	2	3
12. Bathing or dressing yourself	1	2	3

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 your physical health**?

	Yes	**No**
13. Cut down the **amount of time** you spent on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

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)?

	Yes	**No**
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

1= Not at all
2= Slightly
3= Moderately
4= Quite a bit
5= Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

1= None
2= Very mild
3= Mild
4= Moderate
5= Severe
6= Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

1= Not at all
2= A little bit
3= Moderately
4= Quite a bit
5= Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

1= All of the time
2= Most of the time
3= Some of the time
4= A little of the time
5= None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

The Barthel Index

FEEDING
0= unable
5= needs help cutting, spreading butter, etc., or requires modified diet
10= independent

BATHING
0= dependent
5= independent (or in shower)

GROOMING
0= needs to help with personal care
5= independent face/hair/teeth/shaving (implements provided)

DRESSING
0= dependent
5= needs help but can do about half unaided
10= independent (including buttons, zips, laces, etc.)

BOWELS
0= incontinent (or needs to be given enemas)
5= occasional accident
10= continent

BLADDER
0= incontinent, or catheterized and unable to manage alone
5= occasional accident
10= continent

TOILET USE
0= dependent
5= needs some help, but can do something alone
10= independent (on and off, dressing, wiping)

TRANSFERS (BED TO CHAIR AND BACK)
0= unable, no sitting balance
5= major help (one or two people, physical), can sit
10= minor help (verbal or physical)
15= independent

MOBILITY (ON LEVEL SURFACES)
0= immobile or < 50 yards
5= wheelchair independent, including corners, > 50 yards
10= walks with help of one person (verbal or physical) > 50 yards
15= independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0= unable
5= needs help (verbal, physical, carrying aid)
10= independent

Total Score (0-100): _____

Hamilton Anxiety Rating Scale (HAM-A)

	Not present	Mild	Moderate	Severe	Very Severe
1.Anxious mood Worries, anticipation of the worst, fearful anticipation, irritability	0	1	2	3	4
2.Tension Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.	0	1	2	3	4
3.Fears Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.	0	1	2	3	4
4.Insomnia Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.	0	1	2	3	4
5.Intellectual Difficulty in concentration, poor memory.	0	1	2	3	4
6.Depressed mood Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.	0	1	2	3	4
7.Somatic (muscular) Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.	0	1	2	3	4
8.Somatic (sensory) Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.	0	1	2	3	4
9.Cardiovascular Symptoms Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.	0	1	2	3	4
10.Respiratory Symptoms Pressure or constriction in chest, choking feelings, sighing, dyspnea.	0	1	2	3	4

11.Gastrointestinal Symptoms Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.	0	1	2	3	4
12.Genitourinary Symptoms Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence	0	1	2	3	4
13.Autonomic Symptoms Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.	0	1	2	3	4
14.Behavior at interview Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.	0	1	2	3	4

Total Score: _____

Multidimensional Scale of Perceived Social Support (Zimet, Dahlem, Zimet & Farley, 1988)

	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree	
1. There is a special person who is around when I am in need.	1	2	3	4	5	6	7	SO
2. There is a special person with whom I can share my joys and sorrows.	1	2	3	4	5	6	7	SO
3. My family really tries to help me.	1	2	3	4	5	6	7	Fam
4. I get the emotional help and support I need from my family.	1	2	3	4	5	6	7	Fam
5. I have a special person who is a real source of comfort to me.	1	2	3	4	5	6	7	SO
6. My friends really try to help me.	1	2	3	4	5	6	7	Fri
7. I can count on my friends when things go wrong.	1	2	3	4	5	6	7	Fri
8. I can talk about my problems with my family.	1	2	3	4	5	6	7	Fam
9. I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7	Fri
10. There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7	SO
11. My family is willing to help me make decisions.	1	2	3	4	5	6	7	Fam
12. I can talk about my problems with my friends.	1	2	3	4	5	6	7	Fri

The items tended to divide into factor groups relating to the source of the social support, namely family (Fam), friends (Fri) or significant other (SO)

Total Score: _____

.

LEVEL 2—Sleep Disturbance—Adult*

*PROMIS—Sleep Disturbance—Short Form

If the measure is being completed by an informant, what is your relationship with the individual receiving care? _____

In a typical week, approximately how much time do you spend with the individual receiving care? _____ hours/week

In the past SEVEN (7) DAYS....					
	Not at all	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
1. My sleep was restless.	1	2	3	4	5
2. I was satisfied with my sleep.	5	4	3	2	1
3. My sleep was refreshing.	5	4	3	2	1
4. I had difficulty falling asleep.	1	2	3	4	5
In the past SEVEN (7) DAYS....					
	Never	**Rarely**	**Sometimes**	**Often**	**Always**
5. I had trouble staying asleep.	1	2	3	4	5
6. I had trouble sleeping.	1	2	3	4	5
7. I got enough sleep.	5	4	3	2	1
In the past SEVEN (7) DAYS....					
	Very Poor	**Poor**	**Fair**	**Good**	**Very good**
8. My sleep quality was...	5	4	3	2	1

Total/Partial Raw Score: _____
Prorated Total Raw Score: _____
T-Score: _____

Self-Report Health Service Utilization and Medication Use

INTERVIEWER: Did the patient respond to these questions at a previous interview?
If Yes, SKIP to section 3. If No, continue
Lifetime utilization questions should only be asked once during the 12 month follow-up period.

___ Yes (1) __No (0)

Now I am going to ask you a few questions about your health services utilization.

1.	Other than this hospitalization, how many times in **your lifetime, before this injury,** have you been hospitalized? _____ Times ___Patient Refused (-9)
2.	**In your lifetime**, **before this injury,** how many times have you visited an emergency department? _____ Times ___Patient Refused (-9)

1. **In your lifetime**, **before this injury,** had you ever had at least one outpatient visit with a psychiatrist, psychologist, social worker, psychiatric nurse, counselor or other similar professional about problems with your emotions, nerves, or use of substances? Have you seen a…		**Yes**	**No**	**Patient Refused**
3a.	Psychiatrist	1	0	-9
3b.	General practitioner or family doctor	1	0	-9
3c.	Any other medical doctor (GYN, urologist, etc.)	1	0	-9
3d.	Psychologist	1	0	-9
3e.	Social Worker	1	0	-9
3f.	Counselor	1	0	-9
3g .	Any kind of substance abuse or chemical dependency treatment, like AA, NA a sobering center, or detox	1	0	-9
3h.	Any other mental health professional	1	0	-9
3i.	Nurse, occupational therapist, or other health profession	1	0	-9
3j.	Religious or spiritual advisor like a minister, rabbi, or priest	1	0	-9
3k.	Any other healer, like an herbalist, chiropractor, or spiritualist	1	0	-9

4. During the year prior to your injury, did you have an outpatient visit with a psychiatrist, psychologist, social counselor or other similar professional about problems with your emotions or nerves, or use of alcohol? If yes, how many visits did you have with each of the following provider, and what were the visits for?	Yes (1)	No (0)	Patient Refused (-9)

4a.	Psychiatrist	**# visits**	**What for?**	
4b.	General practitioner or family doctor	**# visits**	**What for?**	
4c.	Any other medical doctor (GYN, urologist, etc.)	**# visits**	**What for?**	
4d.	Psychologist	**# visits**	**What for?**	
4e.	Social Worker	**# visits**	**What for?**	
4f.	Counselor	**# visits**	**What for?**	
4g.	Any kind of substance abuse or chemical dependency treatment, like AA, NA a sobering center, or detox	**# visits**	**What for?**	
4h.	Any other mental health professional	**# visits**	**What for?**	
4i.	Nurse, occupational therapist, or other health profession	**# visits**	**What for?**	
4j.	Religious or spiritual advisor like a minister, rabbi, or priest	**# visits**	**What for?**	
4k.	Any other healer, like an herbalist, chiropractor, or spiritualist	**# visits**	**What for?**	

5. Since your last study interview on ____/_____/_____ did you have an outpatient visit with a psychiatrist, psychologist, social worker, psychiatric nurse, counselor or other similar professional about problems with your emotions or nerves, or use of alcohol? If yes, how many visits did you have with each of the following provider, and what were the visits for?	Yes (1)	No (0)	Patient Refused (-9)

5a.	Psychiatrist	**# visits**	**What for?**	
5b.	General practitioner or family doctor	**# visits**	**What for?**	
5c.	Any other medical doctor (GYN, urologist, etc.)	**# visits**	**What for?**	

5d.	Psychologist	**# visits**	**What for?**	
5e.	Social Worker	**# visits**	**What for?**	
5f.	Counselor	**# visits**	**What for?**	
5g.	Any kind of substance abuse or chemical dependency treatment, like AA, NA a sobering center, or detox	**# visits**	**What for?**	
5h.	Any other mental health professional	**# visits**	**What for?**	
5i.	Nurse, occupational therapist, or other health profession	**# visits**	**What for?**	
5j.	Religious or spiritual advisor like a minister, rabbi, or priest	**# visits**	**What for?**	
5k.	Any other healer, like an herbalist, chiropractor, or spiritualist	**# visits**	**What for?**	

-

6a.	How many times **since your last study interview on _____/_____/_____,** have you been a patient over night or longer in a **hospital** for any reason? _____ # times		
6b.	If you can recall the first hospitalization since _____/_____/_____,, can you tell me:		
	[6b1.]	Where you were seen:	
	[6b2.]	What your primary complaint was:	
	[6b3.]	How many days you were in the hospital:	
	[6b4.]	Was this related to your original injury hospitalization?	
6c.	If you can recall the second hospitalization, can you tell me:		
	[6c1.]	Where you were seen:	
	[6c2.]	What your primary complaint was:	
	[6c3.]	How many days you were in the hospital:	
	[6c4.]	Was this related to your original injury hospitalization?	
6d.	If you can recall the third hospitalization, can you tell me:		
	[6d1.]	Where you were seen:	
	[6d2.]	What your primary complaint was:	

	[6d3.]	How many days you were in the hospital:	
	[6d4.]	Was this related to your original injury hospitalization?	

7a.	**Since your last study interview on _____/_____/_____,** how many visits did you make to an emergency room? _____ # visits		
7b.	*If you can recall the first visit since _____/_____/_____, can you tell me:*		
	[7b1.]	*What was the visit for?*	
	[7b2.]	*Where were you seen?*	
7c.	*If you can recall the second visit, can you tell me:*		
	[7c1.]	*What was the visit for?*	
	[7c2.]	*Where were you seen?*	
7d.	*If you can recall the third visit, can you tell me:*		
	[7d1.]	*What was the visit for?*	
	[7d2.]	*Where were you seen?*	

8a.	**Since your last study interview on _____/_____/_____**, how many visits did you make to a Skilled Nursing Facility or Rehabilitation Center? _____ # visits		
8b.	If you can recall the first visit since _____/_____/_____, can you tell me:		
	[8b1.]	Where you were seen:	
	[8b2.]	What your primary complaint was:	
	[8b3.]	How many days you were in the facility:	

	I will read a list of providers to you and I'd like you to tell me how many times **since your last stud interview on _____/_____/_____** you've seen each one. Please do not include visits to the emergency room, overnight stays in a hospital, nursing home, or other health care facility.	
9a.	Family Doctor	
9b.	Internal Medicine Doctor	
9c.	Nurse Practitioner	
9d.	Surgeon	
9e.	Neurologist or Pain Specialist	
9f.	Rehabilitation Medicine Doctor or Physical Therapist	
9g.	Obstetrician or Gynecologist *(if male, write N/A, data entry -7)*	
9h.	Lab tests and/or blood draws	
9i.	Any other healer, like an herbalist, chiropractor, or spiritualist	
9j.	Radiology (e.g. MRI, X-ray, Cat Scan)	
9k.	Other (specify other: _____)	

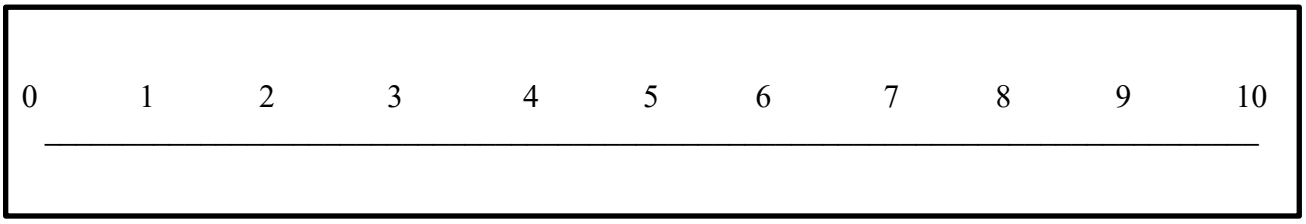
Total Score: _____

FATIGUE SEVERITY SCALE (FSS)

Read and circle a number.	**Strongly Disagree**			→		**Strongly Agree**	
1. My motivation is lower when I am fatigued**.**	1	2	3	4	5	6	7
2. Exercise brings on my fatigue.	1	2	3	4	5	6	7
3. I am easily fatigued.	1	2	3	4	5	6	7
4. Fatigue interferes with my physical functioning.	1	2	3	4	5	6	7
5. Fatigue causes frequent problems for **me.**	1	2	3	4	5	6	7
6. My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7
7. Fatigue interferes with carrying out **certain duties and responsibilities.**	1	2	3	4	5	6	7
8. Fatigue is among my most disabling symptoms.	1	2	3	4	5	6	7
9. Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7

VISUAL ANALOGUE FATIGUE SCALE (VAFS)

Please mark an “X” on the number line which describes your global fatigue with 0 being worst and 10 being normal.



Total Score: _____

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDANX01	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDDEP04	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
HI7	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
FATEXP41	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance

	In the past 7 days…	Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep20	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Ability to Participate in Social Roles and Activities

		Never	Rarely	Sometimes	Usually	Always
SRPPER11_CaPS	I have trouble doing all of my regular leisure activities with others.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER18_CaPS	I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER23_CaPS	I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER46_CaPS	I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Pain Interference

	In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ9	How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31	How much did pain interfere with your ability to participate in social activities? .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ34	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Intensity

In the past 7 days…

Global07	How would you rate your pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst imaginable pain**