Official title: Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease

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SleepTIGHT Study Protocol

(Sleep Therapeutics Intervention to improve coGnitive HealTh)

Full Study Title: Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease

Principal Investigator: Yue Leng, PhD

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Sponsor

National Institutes of Health

Title	Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease (SleepTIGHT)
Study Duration	Trial duration: 9 weeks + follow-up after 24 weeks
Study Center	UCSF Psychiatry department
Objective	Determine feasibility of online CBT-I in an older adult population (age 65+)
Number of Subjects	40
Diagnosis and Main Inclusion Criteria	**Inclusion Criteria** • 1) Age 65+, • 2) evidence of MCI, defined as: self-reported quick dementia rating system (QDRS) - derived global clinical dementia rating score of .5, • 3) adequate visual and auditory acquit to allow neuropsychological texting; • 4) evidence of subthreshold or clinical insomnia, defined as a score of 8 or more on the insomnia severity index, • 5) ability to speak understand and write in English, 6) study partner willing to participate, • 7) capacity to give written informed consent; and • 8) owns one or more smartphone or tablet devices that can be used to access the internet and to participate in video conferences. **Exclusion Criteria** • 1) Self-reported diagnosis by a physician of any major neurologic disease such as Alzheimer's disease, other dementia, Parkinson's disease, multiple sclerosis, epilepsy, Huntington's disease; • 2) History of brain tumor or significant head trauma (loss of consciousness >30 minutes); • 3) Evidence (CT or MRI scans within 12 months prior to screening) of brain infarction or other focal lesions; 4) Any comorbid psychiatric conditions or severe personality disorder within the past 2 years (by DSM-V), such as major depression, bipolar disorder, schizophrenia, and other psychotic features; • 5) Any uncontrolled medical conditions or systemic illness that might lead to difficulty complying with the study protocol; • 6) Any concomitant treatment that might confound the results (participants must be off all psychotropic medications, including hypnotic medications, and non-pharmacological treatments, for at least 30 days prior to screening); • 7) History of alcohol or substance abuse within the past 2 years; • 8) Shift workers; and • 9) Any inadequately treated primary or secondary sleep disorders

STUDY PERSONNEL AND ROLES

Yue Leng, PhD	Principal Investigator	Responsible for all study-related issues

Purpose

In order to address the hypothesis that CBT-I is feasible in patients with MCI, and could potentially improve their sleep quality, slow down cognitive decline, and improve quality of life of patients and caregivers, we will use a parallel-designed randomized controlled trial to pilot test the feasibility and effects of a digital CBT-I treatment program in those with MCI.

This study focuses on testing the validity of this CBT-I program while exploring its preliminary effects on sleep/cognition.

Duration of the Study

Screening + Intervention + post-study screening: 10 – 13 weeks
Post-treatment follow-up: After 24 weeks

Setting

The trial will take place remotely, with all activities and assessments done over phone or Zoom video call or app on smart device.

Description of the Intervention

We will randomize patients, using computer-generated random numbers, to one of two treatment arms:
a) an FDA-authorized prescription digital CBT-I therapeutic treatment
or
b) an interactive, attention-matched, internet-based placebo control program.

At the beginning of the intervention, study staff will give instructions on the use of the programs via zoom.

Throughout the intervention, study staff will call the participants weekly to give further clarifications and answer questions. Somryst is a 9-week program that delivers digital CBT-I therapeutic content, and can be used on a mobile device, such as a smartphone or tablet. CBT-I is a neurobehavioral treatment which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the cause of sleep problems. CBT-I can be conceptualized as six sessions or cores that deliver proven behavioral and cognitive treatment strategies.

Potential Benefits and Risks to Participants

There will be no direct benefit to the participants from taking part in this study. Taking part in this study may or may not make their health better. While doctors hope that cognitive training therapies will be beneficial, these trainings are still being studied.

Some of the most likely risks of participation in this study include:

- Risk of fatigue/distress: Finding study activities difficult, tiring, time-consuming, anxiety-provoking, frustrating, or boring. Participants are free to decline to answer any questions or to stop at any time. To reduce fatigue, breaks are scheduled during testing and training sessions. Additional breaks will be provided at the participant's request. If the participant appears to be under undue strain, the session will be discontinued.
- Risk of loss of privacy: Participation in research may involve a loss of privacy. Because training takes place in a small group setting, other research subjects within the group may become aware of information that participants would prefer to not be shared outside of the group. Researchers will ask all subjects to keep private all information learned about other group members and to not talk about this information outside of group sessions. However, absolute confidentiality cannot be guaranteed. The researchers will keep information about participants as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records. Other University of California personnel may also review or receive information about the participants. Study PI and research staff will retain the participant's research records indefinitely for research purposes. Personal identifiable information (PII) and protected health information (PHI) cannot be used for additional research without additional approval from either the participant or a review committee.
- Unknown risks: The experimental treatments may have risks or side effects that no one knows about yet. Members of the research team will inform participants about any new information that may impact their decision to remain in the study.

Recruitment Methods

Participants are recruited from MyChart patient records, screen in Computerized Patient Record System (CPRS), that meet inclusion criteria. Also, to be used: Research Match and social media recruitment via advertisement on relevant pages associated to CPBH, i.e., Memory and Aging Center.

Keywords checked in medical records:

- Mild Cognitive Impairment
- Age 65 or older
- History of Insomnia
- (Add final ICD-10 terms)

Reasons for Participant Withdrawal or Termination

Participants can decide to stop at any time. The study doctor may stop participants from taking part in this study at any time if the doctor believes it is in the participant's best interest, if the participant does not follow study rules, or if the study is stopped

Study Schedule & Procedure Summary
SCHEDULE OF EVALUATIONS

ASSESSMENT	Recruitment Pre-screening & Consent	Screening/ Assessment	Baseline Measures/ Start of Trial	9 Weeks/ End of Trial Follow-up
Inclusion/Exclusion Criteria	**X**			
Medical History	**X**	**X**		
Insomnia Severity Index	**X**	**X**		**X**
Pittsburg Sleep Quality Index		**X**		**X**
SF-36			**X**	**X**
Epworth Sleepiness Scale			**X**	**X**
Quality of Life			**X**	**X**
Cognitive function			**X**	**X**
Geriatric Depression Scale			**X**	
24-h Actigraphy (3 days)			**X**	**X**
Cognitive Assessment Battery			**X**	**X**

INITIAL CONTACT AND SCREENING

1. Participants, after being identified or reaching out to research team with interest, will be called with initial **contact phone script**, given introductory information about the study, asked to confirm their interest and given the option to fill **consent form** on same call or to schedule follow-up call for consent. IF participant it still interested, consent form is signed, then **ISI questionnaire** is given.

2. Followed by appointment for:
   - Baseline Cognitive Assessment Interview: 1 hour via Zoom.
   - Administer the following questionnaires:
     - **Pittsburg Sleep quality index**
     - **Epworth Sleepiness Scale**
     - **36-item short-form survey**

If continued interest, eligible, and consented

- Schedule meeting for briefing via Zoom on Somryst program or placebo condition materials
- Intervention **or** attention-matched placebo program (6 weeks) + Weekly meetings with research team for clarification or assistance with materials and content

A. INTERVENTION

Over six weeks, the research team will have scheduled meetings with participants to deliver content and instructions for use of the Somryst

The Somryst program is intended to deliver 6 treatment Cores, with the following specific CBT-I therapy content:

1. **Get Ready**: This Core sets the stage for the therapeutic experience. It lets the participant know what they will need to learn and do to improve sleep and sets goals for success.
2. **Sleep Window**: This Core focuses on the concept of sleep restriction and identifies a Sleep Window - a recommended Bedtime and Arising Time – the participant should follow.
3. **Behaviors**: This Core focuses on stimulus control and establishes guidelines for participants to follow while implementing their Sleep Window.
4. **Thoughts**: This Core explains how a participant's thinking can contribute to insomnia. The participant will learn to identify, and shift thought patterns.
5. **Education**: This Core helps the participant identify changes to be made in their lifestyle and environment that can promote better sleep.
6. **Looking Ahead**: This Core pulls together what the participant has learned, prepares the participant for the future, and teaches them what to do if they experience a relapse. Somryst also includes a daily Sleep Diary in which the participant records information about their sleep.

B. FOLLOW-UP MEASURES

Once intervention is completed,

- Feedback at the end of trial via survey and phone follow-up (if needed)
- Follow-up (3-day actigraphy & questionnaires + Cognitive Assessments)
- Follow-up at 24 weeks:
- Final follow-up actigraphy watch measurement
- Follow-up of cognitive assessment + questionnaires

OUTCOME MEASURES

Primary Outcomes

Feasibility

Proportion of eligible participants consented

- Proportion of participants randomized after baseline assessment
- Number of CBT-I sessions completed
- Adherence/compliance rates
- Follow-up rates
- Missing data (data completeness)
- Time needed to collect and analyze data

Acceptability

General study satisfaction

Acceptability of intervention

Barriers & Burden

Qualitative interview

Data Collection and Storage

Patient information is collected and stored in REDCap.

Once assessments are completed, they will be scored and recorded for later analysis.

Study Outline Graphic

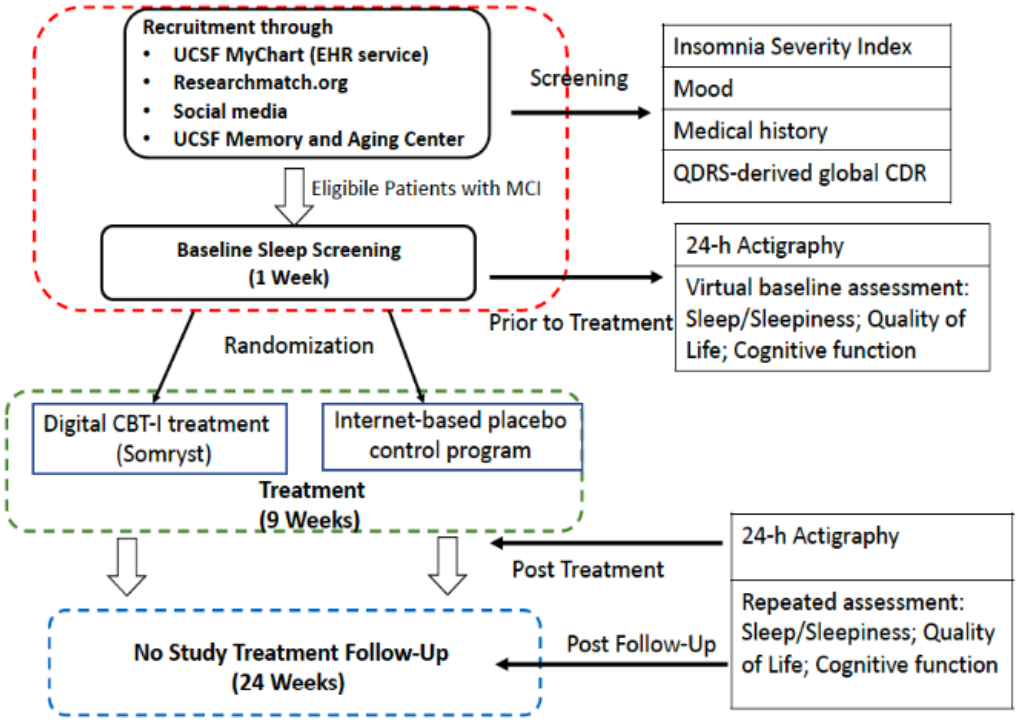

Figure 1 Outline of study visits and related measurements

APPENDIX A.

SLEEPTIGHT INITIAL CONTACT TELEPHONE SCREENER
Full study title - Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease

(For those who were pre-screened}

_____ Hello, my name is _____ and I am calling about a research study called SleepTIGHT being conducted at UCSF by Principal Investigator Yue Leng, PhD.

Is this a good time? Do you have time to talk for about five to seven minutes to learn briefly about our research study?

If no: what would be a good time to call you? (Specify follow-up) _____

If yes: Great! Broadly speaking, this research study is about digital therapeutics to treat sleep problems and improve cognition (Go to BRIEF STUDY OVERVIEW).

[For calling back individuals who asked for more information]

Hello, my name is _____. Thanks for expressing interest in our research study about sleep, insomnia, and cognitive decline. We appreciate you calling to learn more. The study is being conducted by researchers at the Department of Psychiatry and Behavioral Sciences at UCSF. We wanted to call today to tell you more about the study. Is this a good time? Do you have time to talk for about five to seven minutes to learn briefly about the study?

BRIEF STUDY OVERVIEW
Next, I'm going to give you a description of the study. Please stop me if you have any questions.

As mentioned earlier, SleepTIGHT is a study using a digital therapeutic treatment for improving sleep patterns in people with mild impairment in mental processing. This study is unique in that it requires no in-person visits, and the therapy is FDA-approved.

Participants will meet with researchers via phone and videoconference and undergo 6 weeks of (approx. 1 hour) sessions. You will be keeping a sleep diary to track progress and describe sleeping patterns over the course of the study. You will also complete questionnaires that ask about your experience in the program, your quality of life, sleeping habits and mental processing.

The primary goals with treatment are to improve sleep habits which may benefit your mental processing and slow or prevent risk for cognitive decline.

If you are interested in enrolling, you will take part in a few questionnaires and cognitive tests. These are necessary to make sure you are eligible to participate. The screening questions will ask about your quality of life, overall health, mood, and sleep. We also will ask about cognitive function. These questionnaires will take about 45 min – 1 hr. for you to complete.

After this, if you are interested and potentially eligible based on the screening, we will schedule a second appointment via videoconferencing to confirm your eligibility and complete necessary paperwork to begin the study.

Are you still interested in participating? Do you have any questions?

Would you like to do an initial screening for the study, or should I call back later? (it should take an additional 10-15 minutes)

*****Please note that you are free not to answer any questions you are uncomfortable with, and otherwise please answer as accurately as possible (to best determine your eligibility).**

APPENDIX B.

SleepTIGHT phone screening script

INTERVIEWER INSTRUCTIONS

Read **bolded** text verbatim. Answer any questions as needed. Record all contacts in the contact log.

If a STOP is reached at any point, say: **I'm sorry, but unfortunately you are not eligible to participate in this study.** [Explain why they are not eligible if appropriate and indicate reason for ineligibility].

☐ Not fluent in English ☐ No diagnosis ☐ No device to access content
☐ Age < 18 ☐ Medical condition ☐ Vision/hearing impairment
☐ Psychiatric condition ☐ Moderate/severe ☐ Low QDRS
☐ No study partner ☐ Research study ☐ Dementia medication change
☐ Other _____

INTRODUCTION

Hi, this is _____ from the SleepTIGHT study.

*Describe **how you got their name and phone number**. E.g., ____ is a UCSF patient who expressed interest in our program; you recently contacted us about the SleepTIGHT study. Clarify that the program may also be known as Napping, Sleep, and Risk of Alzheimer's Disease if necessary.*

Is this a good time for me to gather more information about your eligibility for the SleepTIGHT study? It should take about 20 minutes.

☐ Yes ☐ No

If NO or NOT AVAILABLE:
Schedule call-back
Date_____ Time:_____

If YES:
START HERE IF CONTINUING CALL

BACKGROUND INFORMATION

Great! Before we get started, can you please tell me your name? *[or confirm name if already known]*
_____

How did you learn about this study?
☐ UCSF email/letter (1) ☐ Facebook/Social Media (2) ☐ Physician Referral (3) ☐ Recruitment Partners (4) ☐ Other (99) _____

DEMOGRAPHIC INFORMATION

How old are you? _____ years (enter as current age in whole years; STOP if under 65)

Do you identify as male or female? ☐ Male (0) ☐ Female (1)
☐ Other (8) _____ Prefer not to answer (9)

Do you identify as Hispanic or Latino? ☐ Hispanic/Latino (1) ☐ Not Hispanic/Latino (0)
☒Other (7) _____ Prefer not to answer (8) Unknown/Not Reported (9) _____

What race or races do you consider yourself? (check all that apply)
☐ White (1) ☐ Asian (2) ☐ Black or African American (3) ☐ Native Hawaiian or Pacific Islander (4)
☐ American Indian or Alaska Native (5) ☐ Other (8) _____ ☐ Unknown or Not Reported (9)

How many years of school did you complete?
Elementary: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
High school: ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ GED
College: ☐ 13 ☐ 14 ☐ 15 ☐ 16
Post-graduate: ☐ 17 ☐ 18 ☐ 19 ☐ ≥20
☐ Not sure

ELIGIBILITY CRITERIA

Are you able to speak and understand English?
☐Yes (1) ☐ No (0)
If NO STOP

**** Do you have a diagnosis related to memory loss?** ☐ Alzheimer's disease (1)
☐ Vascular dementia (2) ☐ Dementia unspecified (3) ☐ Mixed dementia (4)
☐ Mild cognitive impairment (5)
☐ Not sure, but could ask doctor (6) ☐ Other (7) _____

Do you have history of brain tumor or significant head trauma (including for instance, loss of consciousness >30 minutes?)
☐Yes (1) ☐ No (0)
If YES STOP

Has a doctor ever diagnosed you with brain infarction?
☐Yes (1) ☐ No (0)
If YES STOP

Has a doctor ever diagnosed you with any severe psychiatric disorders in the past 2 years such as depression, bipolar disorder, schizophrenia or any others?

☐Yes (1) ☐ No (0)

If YES STOP

Specify which: _____

Has a doctor ever diagnosed you with any major neurological disease such as Parkinsons' multiple schlerosis, epilepsy, or Huntington's disease?

☐Yes (1) ☐ No (0)

If YES STOP

Specify which: _____

Has a doctor ever diagnosed you with Cognitive Impairment?

☐Yes (1) ☐ No (0)

Has a doctor ever diagnosed you with Insomnia?

☐Yes (1) ☐ No (0)

Have you been diagnosed with any sleep disorders (such as sleep apnea, sleep related movement disorders etc.) (yes or no) if yes (have they been treated?)

☐ No (0) ☐ Yes (1) If Yes, please describe: _____. If YES STOP

Are you currently taking any medications for memory loss or dementia?

☐Yes (1) ☐ No (0)

***If yes*, please indicate which one(s) (check all that apply):**

☐ **donepezil (Aricept)** ☐ **galantamine (Razadyne)** ☐ **rivastigmine (Exelon)**

☐ **memantine (Namenda)** ☐ **other _____**

Have you been on a steady dose for the past 3 months?

☐Yes (1) ☐ No (0) If NO STOP

Are any changes to these medications planned in the next 6 months?

☐Yes (1) ☐ No (0) If NO STOP

Have you been on any psychotropic or hypnotic medications within the past 30 days?

☐ No (0) ☐ Yes (1) If YES STOP

please describe: _____.

Do you have a history of alcohol or substance abuse within the past 2 years?

☐ No (0) ☐ Yes (1) If YES STOP

Are you employed as a shift-worker?

☐ No (0) ☐ Yes (1) If YES 

Do have vision or hearing impairment that could affect your ability to participate?

☐ No (0) ☐ Yes (1) If Yes, please describe: _____.

The next questions will ask about what devices you could use for the online material and assessments.

Do you have access to a device with a video camera that can connect to the internet? For example, an iPad, iPhone or other mobile device? *Ineligible if they do not have a mobile device or tablet - our platform will only support those devices.*

☐ Yes (1) ☐ No (0) If UNSURE, gather more information and continue.

☐ other (specify type: _____) Explain that camera access is only needed at certain times for cognitive testing and follow-up measures. Otherwise only a smartphone is needed.

Are you willing to participate in the SleepTIGHT material for about 35 minutes on a weekly basis over six weeks?

☐ Yes (1) ☐ No (0) 

Are you currently participating in another research study?

☐ No (0) ☐ Yes (1) If Yes, please describe: _____.

Great, it looks like so far you are eligible to proceed – though we will need to do a few more tests to decide if you are eligible for the participation in the study. The next step is to conduct a screening for insomnia, and we will get back to you with your final eligibility.

Subject's Initials ID# Date Time AM/PM

Please answer the following questions as accurately as possible.

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answersshould indicate the most accurate reply for the majority of days and nights in the past month.
Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may bedifferent than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

a) Cannot get to sleep within 30 minutes

Not during the last month _____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Wake up in the middle of the night or early morning

Not during the last month _____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Have to get up to use the bathroom

Not during the last month _____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Cannot breathe comfortably

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

e) Cough or snore loudly

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

f) Feel too hot

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

g) Had bad dreams

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

h) Have pain

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

i) Other reason(s), please describe

_____

_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or"over the counter")?

Not during the last month _____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eatingmeals, or engaging in social activity?

Not during the last month _____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or roommate?

No bed partner or roommate _____

Partner/roommate in other room _____

Partner in same room, but not in same bed _____

Partner in same bed _____

If you have a roommate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

b) Long pauses between breaths while asleep

Not during the Past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

c) Legs twitching or jerking while you sleep

Not during the Past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the Past month_____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

e) Other restlessness while you sleep; please describe

_____

Not during the last month _____ | Less than once a week_____ | Once or twice a week_____ | Three or more times a week_____

Insomnia Severity Index

The Insomnia Severity Index has seven questions. The seven answers are added up to get a total score. When you have your total score, look at the 'Guidelines for Scoring/Interpretation' below to see where your sleep difficulty fits.

For each question, please ~~CIRCLE the~~ (SAY WHICH choice) ~~number~~ that best describes your answer.

Please rate the CURRENT (i.e., LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty Falling Asleep	0	1	2	3	4
2. Difficulty Staying Asleep	0	1	2	3	4
3. Problems Waking up too early	0	1	2	3	4

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very Satisfied	Satisfied	Moderately Satisfied	Dissatisfied	Very Dissatisfied
0	1	2	3	4

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

6. How WORRIED/DISTRESSED are you about your current sleep problem?

Not at all Worried	A Little	Somewhat	Much	Very Much Worried
0	1	2	3	4

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, etc.) CURRENTLY?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

Guidelines for Scoring/Interpretation:

Add the scores for all seven items (questions 1 + 2 + 3 + 4 + 5 +6 + 7) = _____ your total score

Total score categories:
0–7 = No clinically significant insomnia
8–14 = Subthreshold insomnia
15–21 = Clinical insomnia (moderate severity) 22–28 = Clinical insomnia (severe)

Informed Consent Review [either continuation of above telephone conversation or in later call]
Note: the Informed Consent does not have to be read word-for-word over the telephone but major points need to be reviewed, including:

__ Subject Bill of Rights

__ Background and Purpose

__ Study Procedures/Plan

__ Responsibilities

__ Potential Benefits

__ Confidentiality

__ Participation is Voluntary

__ Medical Treatment and Compensation

__ Significant New Information

__ Time Requirements

__ Possible Risks and Discomforts

__ Alternatives to Participate

__ Costs and payments

__ Right of Investigator to Withdraw Subjects

Persons to Contact if Questions:

Contact Information: Dr. Yue Leng at 415-340-2708

For questions about your rights as a research participant, you can call the UCSF Institutional Review Board at 415-476-1814.

____ Would you be interested in being screened to see if you're eligible for this research? It will take about 30 minutes to go over these questions.

____ It's fine if you want to get back to us later about scheduling a telephone screening appointment. ____ [If potential subject wants to schedule phone appointment] When would be a good day and time?

Epworth Sleepiness Scale

Name:_____Today's date: _____

Your age (Yrs):_____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affectedyou.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation	**Chance of Dozing (0-3)**
Sitting and reading	___
Watching TV	___
Sitting, inactive in a public place (e.g. a theatre or a meeting)	___
As a passenger in a car for an hour without a break	___
Lying down to rest in the afternoon when circumstances permit	___
Sitting and talking to someone	___
Sitting quietly after a lunch without alcohol	___
In a car, while stopped for a few minutes in the traffic	

THANK YOU FOR YOUR COOPERATION

Medical Outcomes Study Questionnaire Short Form 36 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey! For each of the following questions, please (say which choice) ~~circle the number that~~ best describes your answer.

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. Compared to one year ago,	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. 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?
(Circle One Number on Each Line)

	Yes, Limited a Lot (1)	**Yes, Limiteda Little (2)**	**No, Not limited at All (3)**
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playinggolf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3

f. Bending, kneeling, or stooping	1	2	3

g. Walking **more than a mile**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. 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**?
(Circle One Number on Each Line)

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

5. 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)?
(Circle One Number on Each Line)

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

6. 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?	
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much bodily pain have you had during the past 4 weeks?	
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

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. **(Circle One Number on Each Line)**

9. 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**
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6

	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**
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. 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.)? (Circle One Number)	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you.(Circle One Number on Each Line)

	Definitely True	**Mostly True**	**Don't Know**	**Mostly False**	**Definitely False**
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

QUICK DEMENTIA RATING SYSTEM (QDRS)

These next questions are somewhat personal and will help us understand the severity of your symptoms. Please find a private space.

The following descriptions characterize changes in cognitive and functional abilities. Please compare yourself now to how you used to be—the key feature is change. Choose one answer for each category that best fits you. (Note – not all descriptions need to be present to choose an answer.) (for each category there are 5 levels of severity of change)

Which category best describes your:

1. Memory and recall	
No obvious memory loss or inconsistent forgetfulness that does not interfere with function in everyday activities	**0**
Consistent mild forgetfulness or partial recollection of events that may interfere with performing everyday activities; repeats questions/statements, misplaces items, forgets appointments	**0.5**
Mild to moderate memory loss; more noticeable for recent events; interferes with performing everyday activities	**1**
Moderate to severe memory loss; only highly learned information remembered; new information rapidly forgotten	**2**
Severe memory loss, almost impossible to recall new information; long-term memory may be affected	**3**
2. Orientation	
Fully oriented to person, place, and time nearly all the time	**0**
Slight difficulty in keeping track of time; may forget day or date more frequently than in the past	**0.5**
Mild to moderate difficulty in keeping track of time and sequence of events; forgets month or year; oriented to familiar places but gets confused outside familiar areas; gets lost or wanders	**1**
Moderate to severe difficulty, usually disoriented to time and place (familiar and unfamiliar); frequently dwells in past	**2**
Only oriented to their name, although may recognize family members	**3**
3. Decision-making and problem-solving abilities	
Solves everyday problems without difficulty; handles personal business and financial matters well; decision-making abilities consistent with past performance	**0**
Slight impairment or takes longer to solve problems; trouble with abstract concepts; decisions still sound	**0.5**
Moderate difficulty with handling problems and making decisions; defers many decisions to others; social judgment and behavior may be slightly impaired; loss of insight	**1**
Severely impaired in handling problems, making only simple personal decisions; social judgment and behavior often impaired; lacks insight	**2**
Unable to make decisions or solve problems; others make nearly all decisions for patient	**3**
4. Activities outside the home	
Independent in function at the usual level of performance in profession, shopping, community and religious activities, volunteering, or social groups	**0**
Slight impairment in these activities compared with previous performance; slight change in driving skills; still able to handle emergency situations	**0.5**
Unable to function independently but still may attend and be engaged; appears “normal” to others; notable changes in driving skills; concern about ability to handle emergency situations	**1**
No pretense of independent function outside the home; appears well enough to be taken to activities outside the family home but generally needs to be accompanied	**2**
No independent function or activities; appear too ill to be taken to activities outside the home	**3**

5. Function at home and hobby activities	
Chores at home, hobbies and personal interests are well maintained compared with past performance	**0**
Slight impairment or less interest in these activities; trouble operating appliances (particularly new purchases)	**0.5**
Mild but definite impairment in home and hobby function; more difficult chores or tasks abandoned; more complicated hobbies and interests given up	**1**
Only simple chores preserved, very restricted interest in hobbies which are poorly maintained	**2**
No meaningful function in household chores or with prior hobbies	**3**
6. Toiletting and personal hygiene	
Fully capable of self-care (dressing, grooming, washing, bathing, toileting)	**0**
Slight changes in abilities and attention to these activities	**0.5**
Needs prompting to complete these activities but may still complete independently	**1**
Requires some assistance in dressing, hygiene, keeping of personal items; occasionally incontinent	**2**
Requires significant help with personal care and hygiene; frequent incontinence	**3**
7. Behavior and personality changes	
Socially appropriate behavior in public and private; no changes in personality	**0**
Questionable or very mild changes in behavior, personality, emotional control, appropriateness of choices	**0.5**
Mild changes in behavior or personality	**1**
Moderate behavior or personality changes, affects interactions with others; may be avoided by friends, neighbors, or distant relatives	**2**
Severe behavior or personality changes; making interactions with others often unpleasant or avoided	**3**
8. Language and communication abilities	
No language difficulty or occasional word searching; reads and writes as in the past	**0**
Consistent mild word finding difficulties, using descriptive terms or takes longer to get point across, mild problems with comprehension, decreased conversation; may affect reading and writing	**0.5**
Moderate word finding difficulty in speech, cannot name objects, marked reduction in work production; reduced comprehension, conversation, writing, and/or reading	**1**
Moderate to severe impairments in speech production or comprehension; has difficulty in communicating thoughts to others; limited ability to read or write	**2**
Severe deficits in language and communication; little to no understandable speech is produced	**3**
9. Mood	
No changes in mood, interest, or motivation level	**0**
Occasional sadness, depression, anxiety, nervousness, or loss of interest/motivation	**0.5**
Daily mild issues with sadness, depression, anxiety, nervousness, or loss of interest/motivation	**1**
Moderate issues with sadness, depression, anxiety, nervousness, or loss of interest/motivation	**2**
Severe issues with sadness, depression, anxiety, nervousness, or loss of interest/motivation	**3**
10. Attention and concentration	
Normal attention, concentration, and interaction with his or her environment and surroundings	**0**
Mild problems with attention, concentration, and interaction with environment and surroundings, may appear drowsy during day	**0.5**
Moderate problems with attention and concentration, may have staring spells or spend time with eyes closed, increased daytime sleepiness	**1**
Significant portion of the day is spend sleeping, not paying attention to environment, when having a conversation may say things that are illogical or not consistent with topic	**2**
Limited to no ability to pay attention to external environment or surroundings	**3**

Total QDRS score: _____

- *0 to 1.5 = CDR 0 (normal)*

- *2.0 to 6.0 = CDR 0.5 (MCI) -- Eligible*
- *6.5 to 12.5 = CDR 1 (mild)-- Eligible*
- *13.0 to 17.5 = CDR 2 (moderate)*
- *≥18.0 = CDR 3 (severe)*

~~*If the QDRS score is 6.5 to 12.5, they are eligible. Otherwise: STOP]*~~

STOP-BANG Sleep Apnea Questionnaire

Name _____ Height _____ Weight _____
Age _____ Male / Female _____

STOP		
Do you **S**NORE loudly (louder than talking or loud (enough to be heard through closed doors)?	Yes	No
Do you often feel TIRED, fatigued, or sleepy during daytime?	Yes	No
Has anyone OBSERVED you stop breathing during your sleep?	Yes	No
Do you have or are you being treated for high blood PRESSURE?	Yes	No
BANG		
BMI more than 35kg/m2?	Yes	No
AGE over 50 years old?	Yes	No
NECK circumference > 16 inches (40cm)?	Yes	No
GENDER: Male?	Yes	No
TOTAL SCORE		

High risk of OSA: Yes 5 – 8

Intermediate risk of OSA: Yes 3 - 4

Low risk of OSA: Yes 0 - 2