Sleep Study CRU 3 Week Follow-Up Session
UAB Biobehavioral Pain Research Lab (BPRL)
Session One: Research Assistant Instructions and Information

Date ___/___/___

Brief Title: The Impact of Insomnia on Pain in HIV (the HIPPI study)

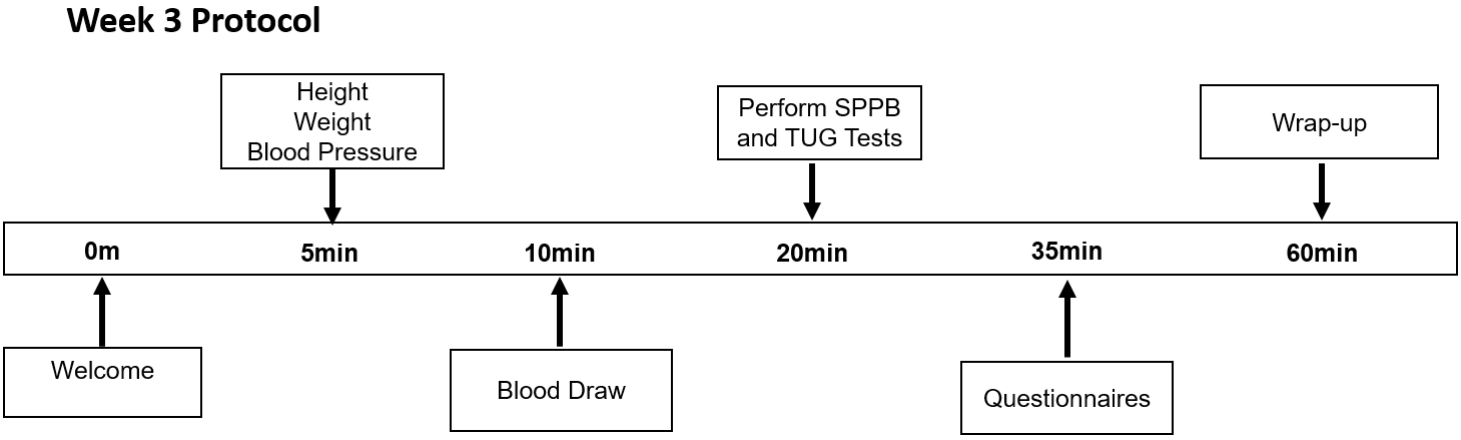
NCT Number: NCT04298658

Date: 7/31/2025

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Figure 3: Graphical depiction of the Week 3 protocol



Week 3 Protocol

Plan to be at the BPRL at least 45 minutes prior to the start of session one in order to complete the following:

- Call participant to ensure they are still able to make the session on time and answer any questions they may have pertaining to the session (directions, location, what to bring, etc.)
- Organize the subject packet (checklist, surveys & MD note)
- Collect the equipment (Laptop, clipboard, stop watch, checklist)

Plan to arrive at the CRU at least 30 minutes prior to the start of the session in order to complete the following:

- Confirm room and participant with the nurses for the study
  - Double check the name/PID on the tubes
- Ensure all the study material is set up within the room
- If subject is driving to the CRU for participation, you will need to be prepared to meet him/her in 6th Ave. Parking Deck if necessary. Make sure you have the laminated "Sleep Study" sign.
- If subject is being dropped off at street entrance (19th Street), you will need to be prepared to meet him/her at street level entrance. Make sure you have the laminated "Sleep Study" sign.

When Participant arrives:

6th Ave. Parking Deck *(instructions for participants and guiding RAs)**:***

- Enter the hospital on the 2nd floor entrance through the blue double doors.
- Follow Concourse D (Jefferson Towers) to the first elevator bank.
- Take elevator to the 15th Floor.
- Have the participant check in at the nurse's station then show them to their room.

19th Street South Entrance *(instructions for participants and guiding RAs)***:**

- Go up the steps and enter through the double doors.
- The elevators will be on your left. Take it up to the 15th floor.
- Have the participant check in at the nurse's station then show them to their room.

RA Note: Participant has already signed the consent for this part of the study. However, it has been approximately a week since their last visit so take some time now to briefly go through everything that will be performed during this current visit.

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Starting the Session

Before Blood Draw

- Assess subject readiness for session, ensure participant doesn't have any questions or concerns before starting. (e.g., using the restroom)
- Place the blood pressure cuff on the dominant arm. (Place cuff and position subject's arm for accurate blood pressure readings.) Ask subject to keep his/her arm in the same position. We will be taking blood pressure three separate times and the readings will be very different if the arm is moving or in a different position. If the readings are a little high, give the participant a couple minutes to adjust to the room, and then try again. **At least one reading should be below 150/95.**

Blood Draw: Butterfly (Nurse)

- During this session there will **only be one blood draw** at the beginning. As a nurse to assist in collecting the three samples at this time.
  - 1 – 10mL plain red tube
  - 1 – 6 mL plain red tube
  - 1 – 4 mL light blue tube (outreach)

Short Physical Performance Battery

1.) **BALANCE TESTS -** For each balance test, the experimenter will first describe the position that the subject will take. Ensure that the subject waits until the instructions are complete before moving into the balance position.



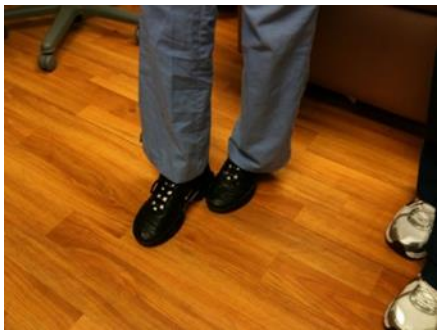
A. Side-by-Side Stand
RA Note: (Demonstrate the position) Ask the participant to stand with their feet together, side-by-side, for about 10 seconds.

The subject may use their arms, bend their knees, or move their body to maintain their balance, **BUT MUST TRY NOT TO MOVE THEIR FEET!**
He/she should hold this position until they hear the experimenter say, "Stop".

RA Note: Stand next to the participant to help him/her into the side-by-side position. Supply just enough support to the participant's arm to prevent loss of balance. When the participant has his/her feet together, ask "Are you ready?" Then let go and begin timing as you say, "Ready, begin."

Stop the stopwatch and say "Stop" after 10 seconds or when the participant steps out of position or grabs your arm.
If participant is unable to hold the position for 10 seconds, record result (duration of time position was held) and go to the gait speed test.

B. Semi-Tandem Stand



RA Note: (Demonstrate) Ask the participant to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. Explain to him/her that they may put either foot in front, whichever is more comfortable for you.

The subject may use their arms, bend their knees, or move their body to maintain their balance, but must try not to move their feet.

The subject must try to hold this position until the experimenter says "stop".

RA Note: Stand next to the participant to help him/her into the semi-tandem position

Supply just enough support to the participant's arm to prevent loss of balance. When the participant has his/her feet together, ask "Are you ready?" Then let go and begin timing as you say "Ready, begin."

Stop the stopwatch and say "Stop" after 10 seconds or when the participant steps out of position or grabs your arm.

If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

C. Tandem Stand



RA Note: (Demonstrate) Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.

The subject may use his/her arms, bend their knees, or move their body to maintain your balance, but try not to move their feet. Try to hold this position until I tell you to stop.

RA Note: Stand next to the participant to help him/her into the tandem position.
Supply just enough support to the participant's arm to prevent loss of balance.
When the participant has his/her feet together, ask "Are you ready?" Then let go and begin timing as you say, "Ready, begin."

Stop the stopwatch after 10 seconds or when the subject steps out of position and grabs your arm.

2.) **GAIT SPEED TEST** - During the Gait Speed Test the subject will walk a four-meter course twice. Two experimenters may run the gait speed test. Experimenter # 1 will stand with the subject at the starting point of the course and provide the instructions from the SBBP form, and walk the course with the subject. Experimenter #1or #2 will start a stopwatch and stop the stopwatch when the subject first crosses the finish point. Once the subject has finished walking the course for the first time, he/she will turn around and return to the beginning of the course. When everyone is back in position have the subject repeat the timed walk.

RA Note: Tell the participant, "Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it."

First Gait Speed Test

I want you to walk to the other end of the course at your usual speed, just as if you were walking down the

street to go to the store.

RA Note: Demonstrate the walk for the participant. Walk all the way past the other end of the tape before you stop. Tell the participant, "I will walk with you." Ask the participant, "Do you feel this would be safe?"

RA Note: Have the participant stand with both feet touching the starting line.

When I want you to start, I will say: "Ready, begin."

- When the participant acknowledges this instruction say: "Ready, begin."
- Press the start/stop button to start the stopwatch as the participant begins walking.
- Walk behind and to the side of the participant.
- Stop timing when one of the participant's feet is completely across the end line.

Second Gait Speed Test

Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.

RA Note: Have the participant stand with both feet touching the starting line.
When I want you to start, I will say: "Ready, begin."

- When the participant acknowledges this instruction say: "Ready, begin."
- Press the start/stop button to start the stopwatch as the participant begins walking.
- Walk behind and to the side of the participant.
- Stop timing when one of the participant's feet is completely across the end line.

3.) **CHAIR STAND TEST** - For the chair stand test, the subject will be asked to stand from a seated position with his/her arms folded across their chest. They will do this once, then five times sequentially. The single chair stand is used to assess the safety of the subject standing without using any support from their upper body. This portion of the test is not scored but is necessary to move on to the repeated chair stand. If the participant is unable to stand a single time without using his/her arms, they receive a zero for this portion of the test and should not proceed to the repeated chair stand test. If the subject completes the single chair stand test, he/she will proceed to the repeated chair stand test, be timed, and scored accordingly.

Single Chair Stand

RA Note: Tell the participant, "Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms? The next test measures the strength in your legs."

RA Note: (Demonstrate and explain)
Procedure: First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest. Please stand up keeping your arms folded across your chest. (Record result).

If participant cannot rise without using arms, say "Okay, try to stand up using your arms." This is the end of their test. Record result and go to the scoring page. If the participant is able to stand without using

his/her arms, move on to the repeated chair stands.

Repeated Chair Stands

RA Note: Ask the participant the following question: Do you think it would be safe for you to try to stand up from a chair five times without using your arms?

RA Note: (Demonstrate and explain)

- Procedure: Please stand up straight as QUICKLY as you can five times, without stopping in between.
- After standing up each time, sit down and then stand up again.
- Keep your arms folded across your chest. I'll be timing you with a stopwatch.

RA Note: When the participant is properly seated, say: "Ready? Stand" and begin timing.

- Count out loud as the participant arises each time, up to five times.
- Stop if participant becomes tired or short of breath during repeated chair stands.
- Stop the stopwatch when he/she has straightened up completely for the fifth time.

Also stop: • If participant uses his/her arms • After 1 minute, if participant has not completed rises • At your discretion, if concerned for participant's safety

RA Note: If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking "Can you continue?"
If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

RA Note: There will be a 2-minute break between the end of Short Physical Performance Battery and TUG assessment

(TUG) Timed Up and Go Task

The TUG measures the time that a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down. During the test, the person is expected to wear their regular footwear and use any mobility aids that they would normally require.

- **RA Note: Measure and mark a 3 meter (9.8) walkway and place a standard height chair (seat height 46 cm, arm height 67 cm) at the beginning of the walkway. Any assistive device used for walking should be nearby.**
- Instruct the subject to sit on the chair and place his/her back against the chair and rest his/her arms on the chair's arms.
- The upper extremities should not be on the assistive device (if used for walking), but it should be nearby.

- **RA NOTE: Demonstrate the test to subject**
- When subject is ready, say "Go'.
- The stopwatch should be start when you say go and should be stopped when the subject's buttocks touch the seat

RA Note: There will be a 2-minute break between the end of TUG assessment and questionnaires

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QUESTIONNAIRES

Ask subject to please answer the questions in the questionnaire packet. Tell him/her to answer every question – there is no right or wrong answers. Allow them to ask questions if needed and tell them to let the experimenter know when they are finished. **Questionnaires include the Lee Fatigue Scale.**

End of Study and Wrap Up

- Inform participant should see their payment on the card within 3 business days.
- Ensure all subject data is in the chart, as well as everything is signed and time stamped.
- Thank subject for their time and show them to the elevator or back to car if necessary.
- Wipe down equipment that contacted subject with washcloth.
- Put away testing items at the CRU and BPRL.