

Chronic Sleep Deprivation Among the Poor: A Lab-in-the-field Approach

NCT03322358

December 18, 2018

SECTION P: PREAMBLE

P1. PID: |_|_|_|_|

P2. Interviewer

- | | |
|---|--|
| <input type="checkbox"/> 1. Alosias | <input type="checkbox"/> 8. Subashini. M |
| <input type="checkbox"/> 2. Anandan | <input type="checkbox"/> 9. Bhaskaran |
| <input type="checkbox"/> 3. Suganya | <input type="checkbox"/> 10. Nandhini. M |
| <input type="checkbox"/> 4. Clement | <input type="checkbox"/> 11. Gurulakshmi |
| <input type="checkbox"/> 5. Vimal Kumar | <input type="checkbox"/> 12. Shenbagavalli. |
| <input type="checkbox"/> 6. Praveen Kumar | <input type="checkbox"/> 998. Other, specify: _____. |
| <input type="checkbox"/> 7. Subhashini. R | |

P3. Date: |_|_|_|_|YYYY/|_|_|MM/|_|_|DD

P4. Interview Start Time: |_|_|:|_|_| 24HR

P5. **DO NOT READ:** Have you offered tea to the participant and shown them around the office?

0. No. → **Please offer tea to the participant before continuing.**
 1. Yes.

INTRODUCTION AND PURPOSE

Thank you for taking the time to talk with us about participating in this 31-day study. We would like to talk to you about the purpose of this study and ensure that you understand what we expect from you during these 31 days if you choose to participate.

We are a group of researchers, studying poverty and economics in Chennai. The goal of our studies here is to understand what difficulties underprivileged people in India face, and how these problems affect their lives. We hope that the results of our work can be used to improve the lives of people in Chennai, as well as other parts of India.

VOLUNTARY PARTICIPATION

Your participation is entirely voluntary and you can stop at any point if you do not wish to continue. You can also choose not to answer any of the questions you will be asked. If you do not participate, it will not affect your life in any other way. If you begin to participate but then wish to stop, that is also your choice. If you begin the study and then leave some time after the 8th day, you will not be eligible to participate in any future studies we may conduct. But, there are no other penalties for leaving the study at any time.

WHAT YOU WILL BE ASKED TO DO IF YOU PARTICIPATE

TIMING

Normal Working days:

Our office is open from 9:30 am to 8:00 pm from Monday to Saturday. You are free to come and go as you please. It would be helpful to us if you are at the office between 10:00 am and 5:30 pm daily. Further, we would also like to take a survey of around 20 minutes, before you leave the office every day. Hence, we would need you to tell us one hour before the time you intend to leave the office. We ask that you only enrol if you think you will be able to come to the study office consistently during the next 28 days, as well as one last time on the 31st day for only a few hours.

Shorter Days:

On some days, you will have shorter workdays and you will only be able to work from 11:00 am to 5:00 pm. For these days, we would ask you to be there at the office during that whole time slot. That means you should start typing at 11:00 am and cannot start typing before 11:00 am. You will be paid for your work.

DAILY ACTIVITIES

In the morning, we will ask you some questions about topics like your daily routine, sleep, earnings, pain level, alcohol consumption, and wellbeing. You will be asked to take alcohol test, and blood- pressure measurements. You will also be asked to work on different computer tasks. You will be paid for completing surveys and finishing the tasks. Payment for completing surveys is fixed, and does not depend on your answers in any way. You can refuse to answer any question you are not comfortable with, with no consequence for you. Payment for the computer based tasks will be based on how well you do. We will give you a lot of guidance and you can always ask us questions, if you are unsure about anything.

The typing task consists of typing the words you see on the computer screen with your keyboard. You will copy every character you see on the screen one by one. You will gain money for every correct character you will type and lose money for every mistake you will make. You don't need to have any previous knowledge of how to use a computer, we will teach you everything you need to know.

NAPS

In addition to responding to surveys and taking part in different tasks, some of the participants will also be asked to take a nap for 30 minutes during some afternoons. The participants who will nap are selected randomly by a computer. You cannot choose whether you will be asked to nap or not. If you are napping, you are provided with your own clean and comfortable bed.

If you are not taking a nap, then you will either spend those minutes waiting in the break room where you will be provided with Tamil newspapers and magazines or you will do regular typing work during that time. Whether you will be asked to type, take a nap, or take a break during this time, is determined randomly by a computer.

LOAN ITEMS

Participants in the study will be loaned certain items for the duration of the study. Some of the participants will be loaned sleep aids while others will receive household items. If you are selected to receive sleep aids,

you can choose which items (such as mattresses, pillow, fan etc.) you would like to take home for the duration of the study. Similarly, if you are selected to receive the household items, you can choose which items (such as clothes drying stand, mixer, toy statue and chair) you would like to take home for the duration of the study. There is no cost for the loan of these sleep aids and household items. However, they must be returned at the end of your time in the study or we will ask you to pay a fine. We will take a picture after dropping the sleep aids in your home. However, if you are a recipient of household items, you can either take home the items you have chosen by yourself and receive travel reimbursement, or we can drop it off in your house. The participants who will receive sleep aids and participants who will receive the household items will be chosen randomly by a computer. There is nothing you can do to increase your chances of receiving sleep aids or household items. Please remember that you will get either the opportunity to take home sleep aids OR the household items -- and not both.

SAVINGS

You will be paid your earnings from your work and the tasks every day when you leave the office. You have the choice to save or not some of this money by depositing it in your personal lock box, which we will provide and keep safe here in the office. If you end up facing a fine for unreturned sleep aids, the money you've saved in the office may be used to pay this fine. You may or may not receive interest on the money you save. We will explain this to you in detail later. You do not have to save any money in the lock box if you do not want to.

SLEEP WATCH

During the study you will be asked to wear a special watch that detects when you are sleeping and when you are not sleeping. It does not give us any further information. It does not send any signal, it only measures the amount of time you spend sleeping. We want you to wear the watch so that we can find out how much people sleep. When you come into the study office we will remove and clean the watch and give it back to you. This is very important for us and for the success of the study. For the watch to work properly, you need to wear it at all times other than when we remove it in the study office. You will receive a bonus for wearing the watch. At the beginning of the study Rs. 250 will be put into your personal account in the office. Every morning, we will check if you wore the sleep watch consistently the entire previous day. If you removed the watch at any point during that day, even for a few minutes, you will receive a warning the first time and the next time we will remove Rs. 50 from your account in the office. At the end of the study you will be given all the money that is left.

If you don't wear the watch for three days or more during the first 8 days, then you will be asked to discontinue this study.

In addition to the bonus for wearing the watch during the study, you will receive a Rs. 300 bonus for returning the sleep watch at the end of the study. If, for some reason, you leave the study earlier, you will still receive a bonus of Rs. 150 for returning the watch.

BDM

At the end of the study you will have the chance to buy one or more of the sleep aids (e.g. mattress, pillow, etc.). We will provide you with more information about the price and which item or items you will be able to purchase on the last day of the study.

OTHER TASKS

Other than the tasks described above, you will be asked to perform some additional tasks. On some days, you will be asked to make decisions regarding how much you would like to work, as well as how much money you would like to share with other participants anonymously. In addition, you will also be given the option to pedal on an indoor bike.

FOOD, BREAK & DRINK

If you decide to take part in the study, you will be provided with a lunch every day. You can bring lunch from your home but you will not be compensated any amount for that. You can help yourself to water whenever you want. You will also be provided with complimentary tea and biscuits once in the morning and once in the evening.

During the study, you can take breaks any time you want. There is a break room provided for you so that you have a comfortable place to rest during your break. However, as far as possible we encourage you avoid sleeping in the break room, as it might inconvenience others.

You are also allowed to go onto the balcony, smoke, and make phone calls during most of the day. However, we ask that you do not go outside or smoke during the nap as it may disturb others. We also ask that you do not leave the building without permission so that we know where all participants are during work hours.

PHOTO & ID

For internal purposes, we would like to keep a photo of you. This is so that our staff can recognize you better. Furthermore, we will give you an official ID card with your name and photo on it. We encourage you to wear it in the office. We will also provide you a second one to take home if you wish to. You may also leave your id here if you prefer. Once the study has finished, we will delete the photo.

Q1. Are you comfortable with us taking a photo of you?

0. No.

1. Yes. → ***Please take a photo of the participant.***

RISKS

The risk of wearing the watch and being surveyed is minimal. Sitting in a chair and looking at a computer screen for many hours a day may cause physical discomfort, body aches, and headaches. We encourage you to stretch during the breaks to alleviate back and neck pain or tension. We also encourage you to take regular breaks whenever you feel tired or have a headache.

CONFIDENTIALITY

We will take steps to make sure that the information you give us is kept private. To do this we will keep your name apart from the other information you give us. The data generated through surveys will be accessible only to our researchers. No other institutions will be given access to the data that we are

collecting now. In addition, we will destroy the list of names of people who were in the study when the study is over unless you would like us to keep your information in case there are future studies. We may keep and give others information about study participants as a group, e.g. summary information like how old the average participant is, but we will not provide any personally identifiable information about you to other persons or groups.

In short, we will take the necessary steps to keep your personal information confidential and securely stored and will not pass it on to anyone. We are conducting independent academic research. We will sign the form below so that you have this statement in writing from us.

BENEFITS AND COMPENSATION

- You will be paid for the computer tasks and for some of the surveys.
- Payment for the surveys is not linked in any way to the answers you give in the survey.
- Payment for the computer tasks is based on how well you do on these tasks.
- In addition, you get paid some amount for the time you are working on the computer no matter how well you do.
- Generally participants earn between Rs. 300 and Rs. 400 for each day they come to the office and stay the whole day. But some participants also earn more than Rs. 500 rupees per day.

BONUSES:

On the last day, you will receive bonuses

- depending on how many days you wore the watch (up to Rs. 310)
- if you return the watch (Rs. 300)

ABSENCE AND STUDY EXIT

If you are absent on the first eight days, which is called the baseline period, then you will be asked to repeat the day(s). If you take three days leave in the baseline period then you will be asked to discontinue from this study. Thus, please try to make sure you are present during the baseline period.

QUESTIONS

Q2. Do you have any questions?

[] 0. No.

[] 1. Yes. → ***Please answer any questions that the participant may have.***

SIGNATURE

The nature and purpose of this study have been explained to me. I understand this information and I agree to participate in the study. I also understand that I am free to leave the study at any time if I would like to, and that the investigator will gladly answer any questions that I have during the study.

Printed name of participant _____
Signature of participant |_|_|_|_|YYYY/|_|_|MM/|_|_|DD
Date

I have discussed with _____ the above procedures, explicitly pointing out potential risks or discomforts. I have asked whether any questions remain and have answered these questions to the best of my ability.

Printed name of surveyor _____
Signature of surveyor |_|_|_|_|YYYY/|_|_|MM/|_|_|DD
Date

CONTACT INFORMATION

If there are any issues with this research, please contact the investigator:

Gautam Rao c/o Alosias A.
Email: alosias.a@gmail.com
phone number: 044-42012032

To contact an administrator about your rights in this research, for questions, concerns, suggestions, or complaints that are not being addressed by the researcher, or research-related harm, please get in touch with the following institutions:

Institute for Financial Management and Research IRB,
c/o Sundar, 24 Kothari Rd., Nungambakam,
Chennai - 600 034.
Website:www.ifmr.ac.in

Committee on the Use of Human Subjects in Research at Harvard University,
1350 Massachusetts Avenue, Suite 395, Cambridge, MA 02138.
Phone number: +1 617-496-CUHS (2847)
Email: cuhs@harvard.edu

SECTION Z: PID - CHECK

Z1. **DO NOT READ:** PID check: Please re-enter the PID. |_|_|_|_|.

Z2. **DO NOT READ:** Is Z1 = P1?

0. No. → **Please re-check the PID and fix this.**

1. Yes.

Z3. **DO NOT READ:** Interview End Time: |_|_|:|_|_| 24HR