Assent

Approval Date: September 20, 2022

Study Title: Treating sleep disruption in teens with millisecond light exposure during sleep

Official title: Passive Phototherapy to Improve Sleep in Teens
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1. **What will happen to me in this study?**
   We are examining whether a novel pattern of light exposure during sleep is able to change the timing of your sleep, which would enable you to go to sleep at an earlier hour. There will be two segments of the study. In the first 10-week segment, we ask that you complete some online questionnaires at baseline and again at the end of the segment, that ask about your mood, nighttime sleep, and daytime sleepiness. Wealso ask that you complete a brief sleep log in the morning via text when you wake up, and that you wear a watch-like device to monitor your sleep patterns throughout this segment. Within the first 2 weeks, a special light will be installed in your bedroom, either by a member of the study team or it will be sent to you with instructions on where to place it. Every night, you will be exposed to the experimental light while you are asleep. Once the light has been installed, we will ask that you attend four weeks of behavioral therapy on sleep. This therapy will be delivered in either a "1:1" or a "Video" format. The "1:1" format consists of four weekly 50-minute behavioral sessions with a licensed Psychologist or supervised trainee over Stanford Zoom. The "Video" format consists of watching a series of brief videos over the course of four weeks. In either version of the therapy, you will learn about sleep and how to improve your sleep. You will also be asked to try exercises at home before bed or in the morning, and you may be asked to make changes to your sleep schedule. At the end of the sessions or the videos, you may also be asked to answer some brief questionnaires and carry out homework in between. There are two groups in this study – an 'active' group and a 'placebo' group. You will be randomly assigned to one of these groups. Both groups will get light during sleep but we have designed the sequence of light to be ineffective in the 'placebo' group. As this is a "double-blind" study, neither you nor the investigator will know into which study group you are placed. Lastly, at baseline and again at the end of the segment, you will be asked to come to the Sleep Center in Redwood City for six hours, from approximately 8:30pm to 2:30am, along with some other participants. During this time, you will be attended by study staff and asked to provide a saliva sample every 30 minutes.
   During the second 10-week segment, you will be asked to complete the same online questionnaires at the beginning and again at the end, and will only continue with the nightly light exposure.

   We would like your permission to videotape the 1:1 treatment sessions, so that a member of the study team can go back and double-check that we covered all of the materials we set out to cover in each session. We will permanently destroy the files once we have double-checked it. You can still participate in the intervention even if you don't want to be taped.

   Do you give consent to be videotaped?

   Please initial your choice: ___Yes ___No

2. **Can anything bad happen to me?**
   There are very few risks associated with participating in this study. The behavioral interventions to improve sleep may require you to rearrange your schedule, which may take

getting used to at first. It is unlikely, though possible, that your mood or daytime sleepiness might worsen during the study. We will be monitoring this with the weekly questionnaires and therapy sessions. If either were to get much worse, we would refer you to an independent pediatric sleep specialist who is overseeing this study. This clinician would then be able to recommend an appropriate course of action. Sometimes, talking about sleep may be distressing, and you are free to not answer any question that makes you uncomfortable. If you are uncomfortable due to any aspect of participating, you should inform both your parents and the study team as soon as possible.

3. **Can anything good happen to me?**
   It is possible that this therapy will be effective and you will find it easier to go to sleep at an earlier time. This might also result in a decrease in daytime sleepiness and an improvement in mood. If this therapy were to be effective, it would provide a simple way to help hundreds of thousands of teens who struggle with going to bed at an early enough time.

4. **Do I have other choices?**
   You have two main choices. Firstly, you can choose not to participate in this study. Second, you can make an appointment with a sleep specialist who then would likely be able to prescribe the standard behavioral intervention that requires you to wake up several hours earlier than your target waketime and be exposed to light while awake.

5. **Will anyone know I am in the study?**
   Your participation in this study will be kept completely confidential as allowed by law. We may have to reveal your identity to the study sponsor, the National Institutes of Health (NIH). All of the data we collect from you will be anonymous in any publication or presentation.

6. **What happens if I get hurt?**
   Your parents/legal guardians have been given information on what to do if you are injured during the study.

7. **Who can I talk to about the study?**
   If you have any questions about the study or any problems to do with the study you can contact the Protocol Director, Dr. Jamie Zeitzer. You can call him at 650-255-7559. You can also call Dr. Rafael Pelayo at 650-723-6601.

   If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Stanford Institutional Review Board (IRB) at 650-723-5244 or toll free at 1-866-680-2906.

8. **What if I do not want to do this?**
   Your participation in this study is completely voluntary. You may withdraw your consent at any time without getting into trouble. Your own personal physician can continue any necessary available treatments.

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SIGNATURE

If you agree to be in this study, please sign here:

_____ _____

Signature of Child Date

_____

Printed name of Child