

Study Information Email Script

This research study is about regulating mood and sleep with morning light exposure.

The purpose of this Human Research study is to examine whether morning light exposure using light emitting glasses can improve mood through circadian rhythm realignment. Information gained from this study will support the relationship between the effects of light exposure on circadian rhythms and treating the symptoms that result from circadian misalignment. Results from this study will be used to address the pervasive issue of sleep disruption and circadian misalignment and potentially improve the quality of life for members of the military. This information could be generalized to populations that deal with circadian misalignment like night-shift workers, as well as provide overall insight to other symptoms of low light exposure in the general population such as Seasonal Affective Disorder (SAD).

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

To be eligible for participation, you must be a service member of any Armed Forces branch, including Active Duty, Reserve, or National Guard or a recently separated veteran (discharged within the last 5 years). You must be between 18 and 60 years of age and score within the moderate-severe range on the Patient Health Questionnaire. You must be able to provide written informed consent and score at least 80% on a quiz of the study information presented in the consent form. If you do not obtain 80% on the quiz you will be given the opportunity to review the protocol information and retake the quiz once.

For your own safety, you might be excluded from participating if you have ever had any of the following: a history of psychotic disorder or manic episodes, history of bipolar disorder, diseases of the eye, history of light-sensitive migraine headaches, sleep-related breathing disorders, self-reported plan to engage in nightshift work during the 6-week course of the study, or have a sleep schedule outside of normal day and night circadian sleep cycle. Women must not be breast-feeding, lactating, or actively trying to conceive.

Military personnel may advise their supervisors of their participation in this study if they wish. Participants should complete study tasks in a way that does not interfere with their work. Participation in this study will take no longer than 30 minutes a day apart from the initial screening and enrollment process which may be slightly longer.

This study involves five parts:

The first part consists of an online screening on REDCap to determine eligibility for the study.

- You will complete a screening questionnaire and one other assessment to determine eligibility based on inclusion/exclusion criteria.
- You will be asked to read and sign the informed consent form.
- You will complete a comprehension assessment based on the informed consent form.
- You will then provide contact and shipping information, after which we will be in contact with you via email to proceed with enrollment.

The second part of this study will continue if you are qualified to participate based on the screening. You will be emailed with instructions to complete a demographics survey on REDCap to confirm your commitment to participate. After you have completed this, we will follow up with you about the details and active expectations of the study.

- After completing the demographics survey, you will be shipped a package with all equipment needed for the study.
- You will be contacted by email to verify that you have received all necessary equipment and understand the expectations of your participation. Pairing devices and setting up login IDs may take longer than 30 minutes to complete.
- During this communication you can also clarify any questions about compensation that you may have.
- After this communication you will be prompted to start your 6 weeks of online assessments.

For the third part, you will begin your first set of online assessments. Day one will consist of Pre-Assessment 1 where you will complete online surveys that morning.

- During Pre-Assessment 1 you will begin to wear the Fitbit Charge 6 for the entire study.
- The next day, you will start your 2-week Daily Assessment online surveys that must be completed in the time window of **6 am to 11 am**. This involves wearing the first set of designated glasses between 6 am and 11 am and the Fitbit Charge 6 daily. At the end of the 2 weeks, you will be asked to complete Post-Assessment 1, which consists of the same surveys as Pre-Assessment 1.

For the fourth part, you will complete a 2-week washout period.

- During this entire time, you will **NOT** wear a pair of glasses.
- You will continue to wear the Fitbit Charge 6 throughout the study.
- During the washout, you will continue completing online surveys every morning between **6 am and 11 am**. These are the same Daily Assessments as the week before.

For the fifth part, you will complete Pre-Assessment 2, prior to beginning the second assessment period. You will not wear glasses for this day, but you will wear the Fitbit Charge 6 at all times.

- The following day, you will begin Daily Assessment 2 taking online surveys every morning within the time window of **6 am to 11 am**.

- During this 2-week period, you will wear the second set of designated glasses between 6 am and 11 am, and the Fitbit Charge 6 as usual.
- The next day following the 2 weeks, you will need to complete Post-Assessment 2 as your final set of surveys.

If you complete all parts of the study, you will be compensated up to \$500.00 in the form of a gift card of your choosing, along with the Fitbit Charge 6, totaling a value of \$695 for successful completion of the study.

You can change your mind about participating at any time. If at any point you need to contact the study staff, please call (480) 420-4937 or email us at BrightLightStudy@arizona.edu.