Title: Bright Start Study Informed Consent Document for Research

NCT number: NCT05356130

Document date: June 9, 2022

Informed Consent Document for Research
Information Sheet

Study Title: Bright Start

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Hello! You are being invited to take part in a research study. This is a consent information sheet. It tells you important information about the Bright Start study to help you decide whether you would like to take part in this study. Please read this form carefully. A member of our study team will also talk to you about this study over the phone. Please ask questions about anything you don't understand before deciding whether to take part. For you to be in the study, you must provide your verbal consent over the phone. Please keep this consent information sheet for your future reference. If you are viewing this document electronically, please download and save a copy for your future reference.

1. What is the study about?

You are being asked to join a research study at the Center for Health Research (CHR) at Kaiser Permanente Northwest, funded by the National institute of Mental Health. We are interested in alternative and complimentary treatments for depression that are not used very often. This study will help us understand how to assist people to get the most benefit from a specific alternative treatment for depression: bright light therapy (BLT). This work is being done as a pilot, or a practice run, to plan a larger study we hope to do later.

If you are interested in being in this study, we will ask you to answer a few questions over the phone or with website questions to find out if you are eligible. If you are eligible and decide to join the study, we will ask you to complete a brief initial survey online or over the phone. You will then be assigned by chance (like flipping a coin) to one of three study groups, which are described in greater detail on page 3. Some of these study groups may receive different levels of assistance with starting and continuing bright light therapy.

You will be in the study for about six months. Over this time we will ask you to complete three 30-minute follow up surveys online. In addition, we will send you text messages up to three times per week containing a link to 1-minute online surveys, each with just a few questions. You will also be asked to wear an activity/sleep recording 'watch' for 10 days following the initial survey and after the 2-month follow up

Approved Date: June 9, 2022
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survey. To see if the study changes the type and amount of health care people get, we will also collect information about health care treatment from your KP medical record.

2. What are alternative therapies?

While depression is most commonly treated with prescription antidepressant medications, many people don't find medications successfully control their symptoms or they decide with their physician to delay treatment. Psychotherapy is another traditional depression treatment, but it is often costly and difficult to find a qualified therapist. Therefore, some people turn to alternative therapies like Tai Chi, meditation, exercise, diet, or bright light therapy.

3. Why is this study being done?

BLT is an effective treatment for both regular depression and 'winter depression' or Seasonal Affective Disorder (SAD). However, it is not used as often as it could be, and it isn't always used in the most effective way. This study will us help understand what type of support might assist people to get the most benefit from BLT.

4. Who is doing this research study?

The study is being done by the Center for Health Research (CHR), which is part of Kaiser Permanente Northwest (KPNW). The study is funded by the National Institute of Mental Health (NIMH).

5. Do I have to be in this research study?

No. You can choose whether you want to be a part of this study. If you choose not to be in the study, it will not affect the care you receive at KPNW or from any other medical provider. If you do take part in the study, you can quit at any time. You can also use any non-study treatments or services recommended by your doctor while you are in the study.

6. Will this study help me?

There is no guarantee that this study will help you. However, some people may find the information provided during this study helps them improve their well-being and mental health.

7. Will this study help others?

The benefits of this study may include a better understanding of how to help people get the most benefit from BLT, which has been shown to be an effective treatment for depression.

8. Who will take part in this study?

We are recruiting 90 to 100 KPNW members ages 18-69 who have recently been diagnosed with depression to take part in this study.

9. What will I be asked to do if I take part in this study?

If you are interested in being in this study, we will ask you to answer a few questions over the phone or online to find out if you are eligible. Some of the questions are on sensitive topics such as mental health treatment or thoughts of harming yourself. You don't have to answer any questions you don't want to. However, without your answers we won't know if you are eligible to join the study.

If you join the study, we will ask you to:

- **Take part in a baseline survey that will last about 30 minutes.** You will do the survey after you give your verbal consent to take part in the study. You can choose to complete the survey over the phone or online. The survey will include questions about your sleep, mood, activity level and overall mental health, as well as your use of treatments for depression. We will also ask about self-harm and thoughts about death or dying. You can skip any question you do not want to answer.
- **Be placed in one of three groups.** After you complete the baseline survey, we will randomly assign you (like a coin toss) to one of three study groups.
    - **Group 1** will continue treatment as usual through your Kaiser care team. You may also choose to use any treatment for depression.
    - **Group 2** will continue treatment as usual through your Kaiser care team, and you will receive written information on how to use the light box equipment for greatest benefit.
    - **Group 3** will continue treatment as usual through your Kaiser care team and will receive the same written light box information as Group 2. In addition, up to a few times per week you will receive a text, email, or phone call from a study phone coach to support using BLT. Phone calls with the study phone coach will be audio recorded, to make sure the phone coach is doing their job right.
- **Take part in three follow up surveys over the next six months.** We will email you a link to complete a survey online at 2 months, 4 months, and 6 months after you join the study. Each survey will take about 30 minutes. The survey will include questions about your sleep, mood, activity level and overall mental health, as well as your use of depression treatments, if any. We will also ask about self-harm and thoughts about death or dying. You can skip any question you do not want to answer.

- **Wear a sleep and activity recording device on your wrist (an "actiwatch") for up to 10 days after the baseline survey and after the 2-month follow up survey**. We will mail the device with instructions for use and a pre-paid return envelope to return it to us after you wear it for at least 10 days, or until the battery runs out.
- **Respond to a few brief questions online up to three times per week.** We will text you a link to these questions three times per week for the first month after you join the study, and two times per week for the following two months.
- About 16 people will also be asked to complete a **30-minute telephone interview** about their experiences in the study.
- **Let us collect some information from your medical record about health care provided to you for the past year and for 12 months after you join the study.** For research purposes only, study staff will run computer programs that scan your relevant medical records at KPNW for information about care for your mental health. Examples include: diagnoses for medical conditions, doctor visits for physical and emotional health, treatments you received, and medications you may be taking. We will also collect information about you, including your age and ethnic background. We will enter the information into a secure computer database. We will not be able to see all the information in your electronic medical record. We will use a computer program to find only the data that we need for the study.

  Giving access to your health information is voluntary. No matter what you decide, now or in the future, it will not affect your medical care. You can change your mind at any time in the future. However, if you choose not to give us access to your health information now, we will not be able to enroll you in the research study.

Your time in the study will last for about 6 months, if you decide to take part.

10. What are the possible risks of this study?

There are some possible risks or discomfort if you take part in this study. The services offered in this study have no greater risk than usual healthcare services.

Actiwatch Use
The following precautions should be considered while wearing the actiwatch:

- Discontinue use if skin reddening or inflammation appears.
- If the device becomes damaged, discontinue use and return it to the research team.
- Do not attempt to take the device apart. No user-serviceable parts are inside.

Light Therapy Side Effects
If you use light therapy, there is a small to moderate chance you could experience any of the following:

- Eyestrain
- Headache

- Nausea
- Irritability or agitation
- Mania, euphoria, hyperactivity or agitation associated with bipolar disorder

If side effects occur, they are usually mild and may go away on their own within a few days of starting light therapy. If you do experience any of the symptoms above, please share this information with our research team by phone (503) 335-6767 or email CHR_BrightStartStudy@kpchr.org.

Sensitive Subject Matter
It is possible that some of the questions we ask during surveys or contacts with phone coaches (if you are assigned to one) may make you feel uneasy or embarrassed. We may ask sensitive questions about thoughts of suicide, mental health and behavior, etc. You do not have to answer any questions that you don't want to. Study staff will make every effort to ask these questions in a sensitive and supportive manner.

If we think you are in danger or unsafe based on the information you provide, we will report this information to a licensed member of our study team and discuss possible responses. A research team member may contact your KP medical doctor and/or a KP mental health provider if we believe you are in danger. The recommendation might be to seek emergency services immediately, such as going to the nearest emergency room, contacting the local emergency response team for evaluation, and requesting supervision and monitoring. There is a small chance that these emergency situations could result in an evaluation, which could lead to more intensive care such as psychiatric hospitalization if necessary.

Electronic Communication
We will be in touch with you by phone, email, and text message to schedule or remind you about completing surveys and for phone coaching for those in Group 3 only. We will also ask that you complete the surveys online using a link we will email to you. Any confidential information sent through the Internet has a small risk of being read by someone other than the person it was sent to. We cannot completely protect against all computer or human errors, but we will do all we can to reduce the risk of your private information being seen by someone who is not part of our research team.

11. How will my confidentiality and personal health information be protected?

Kaiser Permanente is committed to protecting your personal health information. State and federal laws also require Kaiser Permanente to maintain the privacy and security of your information. Every reasonable effort will be made to keep your records confidential, such as storing your private information in a secure location where only authorized individuals will have access to it. To protect your confidentiality, all records, audio recorded phone coaching calls, and information about your participation in this study will be stored in locked

file cabinets, on a secure encrypted study website, or on password-protected computers issued by the Kaiser Permanente Center for Health Research. Neither your name nor your identity will be used for publication or publicity.

By law, we may have to share your private information with someone other than your health care provider in case of a medical emergency, child abuse, elder abuse, or serious threats of harm to you or others. Otherwise, we will keep your information private.

The audio-recorded phone coaching calls will be sent to our research partners at Ernst Training and Consultation, so they can assist us with our research. These recordings do not include your full name, only the study identification number. These researchers will rate how well the phone coaching calls were conducted by our staff. This helps us to improve our services. This information will be shared in a private and secure way using a secure file transfer site so that your personal information is protected. Kaiser Permanente has an agreement with Ernst Training and Consultation to protect your health information, and we have full confidence in their ability to do so. However, Kaiser Permanente cannot control what happens to your audio recordings and personal health information once they are at Ernst Training and Consultation.

By giving your consent, you agree to let us use and disclose your personal health information to our research partners at Ernst Training and Consultation. If you do not agree to this, we cannot include you in the study. This agreement will end when the study is finished. If you decide that you no longer want us to share your personal health information you must notify us in writing by sending an email to: Greg.Clarke@kpchr.org

After we get your email, we will not collect any new information about you. However, we will still use information that has already been looked at or shared.

This authorization will not expire.

Sharing Data with our Study Funder

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). The NDA stores deidentified study data from many NIH studies.

Deidentified study data means that personal information (such as name, address, birthdate, and phone number) is removed and replaced with a code number. We will have to collect personal information from you to make that code number, but the code number cannot be used to identify you. We will never send your personal information to NDA.

You might participate in more than one study that sends data to NDA. In that case, NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This helps researchers who use NDA data to count you only one time.

Once we send study data to the NDA, other researchers across the world can then request data for different research projects. Every researcher and institution requesting your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. The NIH reviews each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. There is a very small chance that your study data could be accidentally shared by an outside researcher with an unauthorized person who may attempt to learn your identity.

You will not benefit directly from allowing your study data to be shared with NDA, but the data may help researchers around the world learn more about brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you do not want your data submitted to NDA but still want to take part in this study, please tell us when we call to do the consent process over the phone. If you decide any time after the consent phone call that you do not want your data to be added to NDA, call the Bright Start research team at (503) 335-6767 or email us at CHR_BrightStartStudy@kpchr.org. Once your data is part of NDA, we cannot take back the study data that was shared before we were notified that you changed your mind. If you would like more information about NDA, it is available online at http://nda.nih.gov.

12. Are there any costs for being in the study?

Some people will be encouraged to buy and use a light box. We cannot purchase a light box for you, but if the study encourages you to buy a light box and you do so, we will provide a Fred Meyer gift card for the purchase price of your device up to $80. To receive this compensation, you would need to buy a light box that meets study requirements, complete a payment request form, and submit proof of purchase. Light boxes range anywhere from $50 to $200. You can buy any light box you want, although we recommend some devices toward the higher end of the price range that have larger screens (this helps with getting adequate light exposure). You will be responsible for any purchase price greater than $80. If you are encouraged by the study to buy and use a light box, you will receive further instructions on submitting a payment request form.

13. Will I receive any payment for being in the study?

In appreciation for your help in this study, we will give you Amazon gift cards in the following amounts for the surveys you finish:

- Baseline survey: $25
- 2-month survey: $25
- 4-month survey: $30
- 6-month survey: $40

If you are one of the 16 people asked to complete an extra interview about your experience in the study, you would receive a $20 gift card for completing this extra interview.

14. If I have questions or concerns about this research study, who can I call?

If you have questions about the study, you may call the research team at (503) 335-6767 or email CHR_BrightStartStudy@kpchr.org.

This research is being monitored by an Institutional Review Board ("IRB"), to make sure people taking part such as yourself are treated fairly and protected from risk as much as possible. You may talk to them at (503) 335-6725, CHR_Compliance@kpchr.org if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Please mention that you are calling about the Bright Start Study.

CONSENT TO TAKE PART IN THE BRIGHT START STUDY

Thank you for taking the time to consider being in our study and for reviewing the consent information sheet.

If, after reviewing the consent, you agree to take part in the study and agree to allow us to use the information we collect from you and your medical record for the conduct of this study, we will ask you to verbally consent to join the study.

If you have been in other studies, you may have been asked to sign a consent form and been provided a copy. For this study, we have been given permission to do the consent process over the phone. So, we will just ask you to verbally acknowledge that you have read this consent information sheet, had all of your questions answered, that you authorize the use of your health information as described in this sheet, and freely agree to take part in this research project.