Baylor University
Psychology and Neuroscience

Consent Form for Research

PROTOCOL TITLE: **Self-Administered Hypnosis Treatment for the Management of Hot Flashes in Women: A Randomized Clinical Trial**

PRINCIPAL INVESTIGATOR: Gary Elkins, Ph.D.

SUPPORTED BY: **National Center for Complementary and Integrative Health &**
Baylor University

Introduction

Please read this form carefully. The purpose of this form is to provide you with important information about taking part in a research study. If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions. You have the right to discuss this study with another person who is not part of the research team before making your decision whether to be in the study.

Taking part in this research study is up to you. If you decide to take part in this research study, we will ask you to sign this form. If you are completing this form in person, we will give you a copy of the signed form. If you are mailing in your completed form, we will mail you a copy of the signed form. If you are completing this form electronically, you will be able to print or save a copy of the signed consent form that you can keep for your records.

The person in charge of this study is Gary Elkins, Ph.D. We will refer to this person as the "researcher" throughout this form.

Why is this study being done?

Hot flashes can disrupt one's quality of life and medications to relieve hot flashes can have unwanted side effects. Previous studies have found hypnosis delivered by a therapist to be effective in reducing hot flashes. Finding a hypnotherapist may not be possible. It may be possible to use a type of hypnosis you can do by yourself. The purpose of this study is to find out whether self-administered mind-body interventions with the use of audio recordings are effective in treating hot flashes and related symptoms.

We are asking you to take part in this study because you are 18 years or older, are postmenopausal, who's experienced at least four (4) hot flashes/day or 28 in a week. If you've had a history of breast cancer, you may take part in the study. You may not participate if you are on other treatments for hot flashes, have a diagnosed mental illness, have Stage IV breast cancer, or are currently using hypnosis for any reason.

This study aims to randomize 232 women, 116 of them from Baylor University.

How long will I take part in this research study?

We expect that you will be in this research study for 13 weeks. During this time, we will ask you to participate in two (2) visits with a member of the Mind-Body Medicine Research Lab team at Baylor University. During COVID-19 restrictions, these visits will be held via telephone, video conference, or in-person. These visits will be called the baseline visit and the randomization/education visit. These visits will take approximately 1.5 hours. In addition, each week you will be asked to listen to your assigned recording which lasts about 20 minutes. You will be asked to do this daily each week for six (6) weeks. Further communications and data

collection will be via phone calls and mailings, no more often than about every 7-10 days. The phone calls will not last more than 10 minutes.

What will happen if I take part in this research study?

Once you have consented to participate (by signing this form) and completed baseline measures, you will be randomly assigned to one of two groups, both of which will include self-administered hypnosis programs (i.e., instruction for a state of focused attention and reduced peripheral awareness). You will receive audio-recordings and instruction booklets which will guide you through your participation in this study. After providing consent, a baseline appointment will be scheduled. During the COVID-19 restrictions, this baseline appointment will be via telephone, video conference, or in-person.

Prior to Baseline Visit

Before participating in the baseline visit via telephone or video conference, you will receive a copy of the consent form as well as a packet of questionnaires. These materials will be sent via mail or through an online platform. The online platform that will be utilized for this study will be DocuSign. If you are participating the baseline visit in person, these materials will be provided to you during the baseline visit.

Baseline Visit

This appointment is expected to last approximately 1.5 hours. At this appointment, you will review the baseline week materials that have been provided to you. These materials include a hot flash daily diary and a packet of questionnaires. This may also include a salivette kit to collect saliva samples and a device that looks similar to a watch (Polar V800) to measure heart rate variability (HRV). A research assistant will provide detailed instructions on how to complete the hot flash daily diary and collect the heart rate and saliva data. During the COVID-19 restrictions, the cortisol and HRV collections will be optional.

During the baseline week, you will keep track of your hot flashes every day in a hot flash diary. After completing the baseline week data collection, you will return the materials via mail and/or DocuSign.

If you are completing the cortisol and HRV collections for this study, you will do so during the baseline week. During your baseline week, you will collect your saliva and wear the Polar V800 to measure HRV on 2 days during the week. The saliva will be collected at three times during each of two days. The saliva will be collected as soon as you wake up, (before getting out of bed), 30 minutes later and at bed time. The saliva is being used to measure cortisol, which is one way to evaluate stress levels. The Polar V800 is a small device you wear on your wrist, similar to a watch, with a strap across your chest. It measures activity related to your nervous system in terms of excitement versus being in a more relaxed state. The heart rate monitor will

be worn for two 6- minute periods while lying down on one of the days you are collecting your saliva, and one 24- hour period on the other day you are collecting saliva. The HRV monitor and saliva will be mailed back to the study team at the end of the week using pre-paid and addressed mailers you will be given.

Randomization Visit

After completing the baseline week data collection and returning the baseline materials via mail and/or DocuSign, you will have a second visit scheduled to learn about your assigned treatment and how to implement it. During COVID-19 restrictions, this visit will be held via telephone, video conference, or in-person. You will visit with a research assistant to review the materials that have been provided to you (booklets and audio recordings) that you will be using as part of your treatment. The research assistant will provide education regarding the treatment and how to incorporate the treatment into your weekly schedule. You may also be given a hypnotizability scale, which measures how hypnotizable you are.

Weeks 1 to 6

You will use the self-management materials (hot flash daily diaries, hypnosis practice log, booklets, and audio recordings) for 6 weeks. You will be asked to the read the weekly booklet at the beginning of each week and listen to the accompanying audio recordings daily. You will also be asked to keep track of your hot flashes in the hot flash daily diary and write the frequency of home self-hypnosis practice on a log for these 6 weeks. You will receive phone contacts approximately every 10 days (for a total of 5 phone calls), from a research assistant during these 6 weeks to encourage your practice and answer questions.

During week 5, you will be mailed a second kit to collect saliva and the Polar V800 (HRV watch). During week 6, you will collect your saliva and wear the Polar V800 to measure HRV on 2 days, using the exact same procedures you used during the baseline week. At the end of week 6, you will return all completed hot flash daily diaries, questionnaires on sleep quality, hot flash related daily interference in daily activities, stress, anxiety, perception of benefit, saliva samples, and the HRV watch. These items will be returned in two pre-paid mailers, one for the questionnaires and one for the HRV watch and saliva kit. During the COVID-19 restrictions, the cortisol and HRV collections will be optional.

Week 12

During week 11, you will receive a phone call reminding you about the week 12 data collection. In your toolkit will be a hot flash daily diary and a questionnaire booklet on sleep quality, hot flash related daily inference in daily activities, stress and anxiety. These questionnaires will be filled out at the end of week 12. Once they are done, you will return the completed hot flash daily diary and questionnaire booklet using a pre-paid mailer.

The Schedule of Activities (Table 1) provides an outline of the measures and when they will be administered for the duration of the study.

Table 1: *Schedule of Activities*		**Treatment and Follow-up**						
	BL	**1**	**2**	**3**	**4**	**5**	**6**	**12**
Hot flash daily diary	D	D	D	D	D	D	D	D
Hot Flash Related Daily Interference Scale	X						X	X
PROMIS Emotional Distress- Anxiety Scale	X						X	X
Pittsburgh Sleep Quality Index	X						X	X
Global Impression of change							X	X
Saliva collection for diurnal cortisol**	X						X	
HRV through Polar V800**	X						X	
Perceived Stress Scale	X						X	X
Elkins Hypnotizability Scale (EHS-CF)**	X							
Frequency of home practice		D	D	D	D	D	D	D
Check In Phone Calls		X	X	X	X	X		
*Note: BL – Baseline; D - daily completion over the course of the entire study through week 6, then again during week 12; **These data collections will be optional during COVID-19 restrictions*								

What are the risks of taking part in this research study?

Risk and discomfort, both physical and emotional, are rare with the mind-body interventions being used in this study. The known or possible risks are agitation or anxiety while listening to the audio-recordings. It also may be found to not be helpful and to take up too much time.

Hypnotic relaxation is nothing like what is portrayed in the entertainment industry. You will not be controlled into doing things of which you are not aware, nor will you lose control to make decisions and continue your usual daily activities.

The HRV recording device consists of a band around the wrist (like a wrist watch) and a band around the chest. There could be skin irritation caused by these bands. There are no other known potential toxicities from the HRV recording device.

Questionnaire/Survey Risks

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

Loss of Confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The researcher plans to protect your confidentiality. Their plans for keeping your information private are described later in this consent form.

As with any research study, there may be additional risks that are unknown or unexpected. The researchers will try to minimize these risks by:

- Your protected health information will not be disclosed to anyone outside of the study team and only then if absolutely needed for the conduct of the study. Any information linked to you will be kept in a locked cabinet in a locked office that only study personnel can access. All questionnaires will be coded with a research number and will not contain any identifiable information about you.
- If you feel overly anxious, you can seek care from your usual doctor or be referred to a mental health specialist.

The Mind-Body Medicine Research Lab has made every effort to make your interactions private by ensuring the use of secure, HIPAA-compliant platforms to help keep your information private. However, the nature of electronic communications technologies is such that we cannot guarantee that your communications will be kept confidential or that other people may not gain access to your communications. There is a risk that your electronic communications may be compromised, unsecured, or accessed by others.

You should also take reasonable steps to ensure the security of communication (for example, avoid using open networks and have passwords to protect the device you use). If you are participating in visits via telephone or video conference, it is important for you to participate in visits only while in a room or area where other people are not present and cannot overhear the conversation. It is recommended that you take steps to ensure your privacy including use of earphones, shielding your screen from view, etc.

Are there any benefits from being in this research study?

Possible Benefits to the Participant: You may not receive any personal benefit from being in this study. The possible benefit you may experience from the intervention described in this research includes reductions in frequency and/or intensity of hot flashes, reductions in interference due to hot flashes, improved sleep, a decrease in perceived stress and anxiety. However, there is no guarantee that you will benefit from being in this research.

Possible Benefits to Others: The results of this research may guide the future treatment of hot flashes without the use of hormonal therapy.

How Will You Keep My Study Records Confidential?

We will keep the records of this study confidential by keeping your records in a secured area in a locked file cabinet within a locked file room. Secure, HIPAA-compliant platforms will be used during the study as well. The saliva samples collected for research purposes will be labeled with a code number and securely stored in a temperature-controlled freezer. HRV (heart rate variability) data will be saved to encrypted files and secured in locked storage. In the event of any publication or presentation resulting from the research, no personal identifiable information will be shared. We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of his research team
- Authorized members of Baylor University who may need to see your information, such as administrative staff members from the Office of the Vice Provost for Research and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research (such as the HHS Office of Human Research Protection or the Food and Drug Administration)

The results of this study may also be used for teaching, publications, or presentations at professional meetings. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

Study Participation and Early Withdrawal

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You cannot withdraw information collected prior to your withdrawal.

The researcher may take you out of this study without your permission. This may happen because:

- The researcher thinks it is in your best interest
- You can't make the required study visits
- Other administrative reasons

Will I get paid for taking part in this research study?

If you are selected to be part of the study, you may receive up to $125.00 for compensation for time and effort expanded in study participation which will be pro-rated as follows: completion of Week 1-Week 6 = $75; Week 1-12 = $125. These payments will be provided by gift card or check. An email address may be required to enable payment. Research participants who receive compensation for research are required by Baylor University's accounting department to provide their name, address, social security number, payment amount, and related information for tax reporting purposes. If you do not want to provide this information, you may still participate in the study, but you will not be compensated.

What will it cost me to take part in this research study?

There are no costs to you for taking part in this research study.

What if I have any questions or concerns about this research study?

You can call us with any concerns or questions about the research. Our telephone numbers are listed below:

PI: Gary Elkins, Ph.D.
254- 296-0643
Study Coordinator: Whitney Williams, M.S.
254-296-0824

Study staff still will be available Monday-Friday 8am – 5pm (excluding holidays).

If you want to speak with someone **not** directly involved in this research study, you may contact the Baylor University IRB through the Office of the Vice Provost for Research at 254-710-1438. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Future Contact

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Baylor University.

Do you agree to let us contact you in the future?

_____YES _____NO _____INITIALS

Statement of Consent

PARTICIPANT: I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

Participant's Printed Name:

_____

_____

Signature of Participant Date Time

PERSON EXPLAINING THE RESEARCH: Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research, and that the participant has printed, signed, dated and written in the time above.

Printed Name:

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Signature of person who explained this research Date Time