



Informed Consent to Participate in Research

Information to Consider Before Taking Part in this Research Study

Pro # 00025681

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study. We are asking you to take part in a research study that is called; Prospective cohort research study of Yoga and Mindfulness for Psychological and Physical Well-Being. The person who is in charge of this research study is Kevin E. Kip, Ph.D., FAHA. This person is called the Principal Investigator.

This study is sponsored by: Yoga for Men, LLC

Why are you being asked to take part?

This research study is being done to determine if an existing web-based online application of Yoga and Meditation through Yoga for Men's website is useful for US and non US active duty service members and veterans who may be experiencing a range of emotional, psychological, and behavioral challenges.

Purpose of the Study

The purpose of this research study is to evaluate an existing online self-help Yoga and Meditation program for active duty service members and veterans who may be struggling with a range of difficulties linked with service and coming back home, and those who may feel like they need some additional tools to help them move on with their lives.

- The online program that YfM has developed is being evaluated in this research based on a newer evidence-based approach to psychological health and wellness with Yoga and Meditation.
- Our intent is to offer this program to active duty service members and veterans as a way to help reduce or lessen psychological and emotional difficulties, and most importantly improve quality of life and ease the return back to civilian life.
- Thus, our purpose is to find out if a Yoga and Meditation online program is helpful in reducing the unique psychological, emotional, and behavioral challenges that active duty

and veterans may face coming home, while also improving quality of life. We are also interested to learn for whom the program is helpful, and in what ways it may be helpful.

- The existing program we are evaluating should not be considered a substitute for other forms of mental health care.

Study Procedures

If you take part in this study, you will be asked to:

This project has several parts. Here, we describe them in some detail.

- **Consent to Participate.** If you decide that you would like to participate in this study, you must click the appropriate box at the bottom of this consent form. This tells us that you are willing to participate. Once you click that link, you will be redirected to an online eligibility screening form.
- **Online Eligibility Screen.** This research is available to active duty service members and Veterans, but not everyone can or should participate in this study. Thus, after you consent, you must be willing to answer all questions on the online eligibility screening form. This screening is important and will be reviewed to determine if you meet eligibility requirements. If this is confirmed, the website will direct you to your personal study portal and will provide you with further instructions and a link that you will use to participate. If it is determined that you aren't eligible to participate, the YfM study website will inform you either way.
- The YfM website for the USF study site provides a safety disclaimer in regards to injury that could occur through practice of the online Yoga classes. All study participants are required to review and then click (accept) this disclaimer in order to proceed to the online YfM material.
- **If You Are Eligible to Participate.** The YfM study site will provide you with a link so that you can access your own secure personalized study portal. Your study portal will show you tasks that you have completed and those that are yet to be done. You will need to login to access your personalized study portal using the link you were given.
- **Initial Survey Battery.** Once logged in, your first task will be to complete the initial survey battery. This survey battery includes several questionnaires that ask you some basic background information about yourself, and then a series of questions about, your experience with anxiety, fears, depression, pain and sleep. This portion of the study will take you approximately 30 minutes.
 - You will be prompted to complete the Initial Survey Battery within 1-2 days following the eligibility screening.
 - You may complete the initial survey battery in one sitting, or if you chose to do so you may do it in two sittings, provided that you do that within 48 hours. The survey program we are using is hosted by a secure server and will save your work so that you can return to it and finish at a later time.
 - You will not be able to move on with the other aspects of the study until you complete this initial survey battery.
- **The Active YfM Online Intervention Yoga and Meditation**
 - You will be given access to the online intervention through your personal study portal. You will see that the online intervention consists of several modules of Yoga and Meditation, each Yoga taking about 30- 45 minutes to work through

and the Meditation about 10 minutes. The modules will include video, audio, and exercises to help reinforce key concepts and to help you learn new skills.

- You will be asked to work with the online intervention modules at your own pace over one month, however, this research study asks that you complete 2 Yoga sessions of your choice and 2 Meditation sessions a week. When you have finished one month, you will be asked to complete a 30 minute self-report assessment. Upon completion of the self-report assessment, your study number will be put into a raffle to win a free Yoga for Men Yoga mat. (\$135 value)
- The self-report assessment questionnaires will be repeated at 3 months, 6 months and again at 12months. Each time you complete them, your study number will be put into the raffle to win a free Yoga for Men Yoga mat.
- Each of the four assessments will be identical to the first one you did and ought to take no more than 30 minutes of your time. These assessments are really important so that we can figure out if active duty service members and veterans like you are being helped with the program and if you continue to be helped in the long-term (where it really counts).

Alternatives / Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer; you are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

If you decide not to take part in this study, that's okay. Instead of being in this research study you can choose not to participate. If you chose to not be in this research study you can still enroll and pay the conventional monthly membership fee of \$15 a month to YfM website for their program. We will provide other mental health and crisis information on the study website and encourage you to access these resources if you are facing psychological, emotional, or behavioral challenges related to your military service. Anxiety-related difficulties -- including depression, addictions, and anger -- are highly treatable with cognitive-behavior therapies alone and/or in combination with medications. Your local VA hospital or your primary care doctor may be good sources of information about other treatment options that may be available to you. You may continue to participate in this research while also receiving other forms of mental health care, but you should check in with your doctor to be sure that your participation in this research is OK.

Benefits and Risks

We cannot promise you will benefit by participating in this study. The tools and strategies contained in the YfM Yoga and Meditation Online program have been shown to help people suffering from many types of problems, and we hope to find out if YfM Yoga and Meditation online can do the same for you and active duty service members and veterans just like you. Everyone is unique. The strategies covered in the YfM Yoga and Meditation Online program are possibly different from most strategies that you have tried before. This is good in the sense that by doing something new, you risk getting a different outcome in your life. We don't know exactly what that might be for you, but our main goal is to learn something about how this program helps active duty service members and veterans, and hopefully something about how it is helpful.

The questionnaires may cause discomfort, there could be injury from Yoga and Breach of Confidentiality within the internet.

This research is considered to be minimal risk.

Compensation

There is no financial compensation for this study.

- Your study number will be entered into a raffle each time you complete the self-report assessments for a free Yoga for Men Yoga mat. This means if you do all four self-report assessments, your study number will be entered four times. If your study number is drawn, we will ask for your name and address to send it to you.

Costs

- YfM requires a monthly membership fee of \$15 to utilize the Yoga and Meditation online classes. If the US or non US service member is eligible for the study the \$15 monthly membership fee will be waived for the one year duration while you are in the study. There is no cost to be in the study.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential unless disclosure is required by law.

The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, and all other research staff associated with this project.
- Certain university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety. However, they will not be able to link you personally with any responses you provide.
- The University of South Florida (USF) Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, staff in the USF Office of Research and Innovation, USF Division of Research Integrity and Compliance, and other USF offices who oversee this research.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

It is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person's everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database

At the beginning of the study, you will be assigned a study number known only to the investigators. All the online questionnaires and chapter self-assessment questionnaires are anonymous and will never require you to input your name or other personal information.

Questionnaires are facilitated through a secure online questionnaire service. Completion of the self-report questionnaires will be possible through links online on the YfM website via your personalized study portal. These links and all information collected via study surveys will be secured by SSL encryption. SSL encryption is the same system used by banking and other commercial institutions and is considered to be the highest level or "gold standard" of online data protection. The data account with our online survey system is protected with a screen name and password known only to the investigators.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an adverse event or unanticipated problem, you may call or email the Principal Investigator for this study, Dr. Kevin E. Kip 412-974-2191, email: kkip@health.usf.edu or Sue Girling, Study Coordinator 813-974-9310, sgirling@health.usf.edu.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638.

Please print a copy of this document, so that you have on hand the contact information for the investigators and the Office of Research Compliance.

By checking the left most box appearing below, I acknowledge that I have read, or been informed of the information about this study. I hereby consent to participate in the study. By clicking the box to the right, you are indicating that you are not interested in participating. (Boxes will be provided on internet site and will not let subjects advance in the study unless they have checked at least one.)