Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: **Addressing Mental Health in Orthopedic Care** NCT05194722

Principal Investigator: **Abby Cheng, MD**

Research Team Contact: **Melissa Armbrecht, 618-719-1773 or armbrechtm@wustl.edu**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Abby Cheng which addresses how mental health affects orthopedic patients. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to participate in an informal interview to discuss your thoughts regarding how mental health can and should be addressed in an orthopedic clinic setting. You will also be asked to compete a baseline survey, and then you will be given one month of free access to an online app which has tools to address stress, sleep, pain, and/or mental health issues you may be dealing with. One month later, you will be asked to complete one more survey about your current level of health and functioning. You will need to have access to a smartphone or other mobile device to be able to complete this study. You will not be required to come into the office for any research procedures, unless you prefer to. The main risk to you if you participate is boredom while filling out surveys or using the app.

This study may not benefit you directly, but it will help us understand how we can improve care for orthopedic patients by addressing how mental health can affect pain and physical function. By volunteering, you may help someone else in the future. There is no cost to you and you will be paid a total of $60 in gift cards between the initial survey and follow up survey for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are coming into the Washington University Department of Orthopaedic Surgery for treatment of a spine condition.

The main purpose of this research is to determine how mental health can and should be addressed in an orthopedic clinic setting in order to most effectively improve patients' musculoskeletal conditions. A second purpose is to understand whether a pain-specific customized version of a smartphone app (Wysa©) can help patients with musculoskeletal pain to improve their overall wellness within one month. We invite you to participate in this research study because you are an adult patient in the Washington University Department of Orthopaedic Surgery and are being treated for a spine condition which has caused pain for at least three months.

The Wysa app is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

After agreeing to participate, patient participants will continue their participation in their orthopedic care plan, as directed by their healthcare provider. If you choose to enroll, we will also ask you to complete a 5-10 minute survey which asks about how you describe yourself and your overall health. Next, you will participate in a 45-60 minute informal interview that will be recorded via a handheld recorder and/or recorded on zoom meeting. We will ask your thoughts regarding whether and how mental health should be addressed during an orthopedic clinic visit, and we would like to hear your thoughts on two potential mental health resources. One is a smartphone app (Wysa), and the other is a printed resource guide. We will ask you to rate how helpful you feel each of these resources is.

Next, if you agree, we will help you download the Wysa app to your smartphone or other mobile device. Through the Wysa app, you can access research-based techniques to help with sleep, reduce the impact of pain on quality of life, and manage stress. Wysa provides access to research-based wellness tools such as supportive listening, deep breathing techniques, guided meditation, journaling, yoga, and more. Wysa users can communicate with a digital chatbot, and/or they can use text messaging to communicate with a human well-being coach who is certified in counseling. The intended use of the Wysa app is to encourage mental well-being as an early intervention tool in a self-help context. The Wysa app is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration. Participants will have access to the Wysa app services for one month, and they can use any or all of the services as much or as little as they find useful. No one on the Washington University study team or from Wysa will read your chats to the Wysa chatbot or human coaches. Your data shared with the Wysa app will be de-identified and will remain in the USA. We will only receive information from Wysa regarding whether participants used the Wysa app and which types of tools were accessed and/or reported to be helpful.

Finally, one month after enrollment, participants will be e-mailed one more short, 5-10 minute survey. The survey will ask about any updates in your current health and will ask you to rate the usefulness of Wysa for you. Participants are free to not answer any of the questions on the survey.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio recordings of you. We would like to audio record your interview to be able to transcribe, or listen to and type out, your exact responses in order to be able to do a qualitative analysis of your responses to the interview questions. We will keep these audio recordings in a password protected file that is only be able to be accessed by study team members.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your voice recording. After the interview, the recording will then be reviewed by a study team member, and all personal identifiers will be removed prior to being uploaded into Rev.com to be transcribed into text for qualitative analysis.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding how to address mental health in our orthopaedic patients. Future research may also include studies to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We may share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories, only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for one month.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

One risk of participating in this study is boredom due to filling out surveys. You are free to skip any questions that you do not feel comfortable answering.

The Wysa app's artificial intelligence chatbot may not recognize an issue that you describe to it. It is not a human. Hence, it may be restricted in its responses to you, and it will not offer advice on issues it does not recognize. If this happens, we encourage you to address your issue with a human Wysa well-being coach.
Another risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

Finally, the Wysa app is not designed to be a replacement for receiving in-person psychological counseling. It is also not designed to assist with crises such as abuse, severe mental health conditions that may cause feelings of suicide or self-harm, or any other medical emergencies. Wysa cannot and will not offer medical or clinical advice. It can only suggest that users seek advanced and professional medical help. If you are experiencing these or other distressing symptoms, please let your healthcare provider know.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. However, by participating, you will receive one month of access to the Wysa app, which provides research-based tools to help with sleep, reduce the impact of pain on quality of life, and manage stress.

Additionally, we hope that in the future, other people might benefit from what we learn in this study. We hope to learn how to address mental health for orthopedic patients in a way that can improve pain and dysfunction caused by orthopedic problems. We also hope to learn whether the Wysa app can be an effective tool for orthopedic patients.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

You can choose not to participate in the study. Whether or not you participate, your orthopedic treatment plan will continue, as you discussed with your healthcare provider.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number

(SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number for this purpose. Because your social security number is obtained for payment purposes only, it will not be retained for research purposes.

All participants who complete the baseline survey and interview will receive a $40 gift card, either handed to you, mailed to you, or sent to your e-mail address, whichever you prefer.

In some circumstances, we can also subsidize transportation-related costs that are related to the study, such as parking validation. The study team will work with you to understand your costs and how we can reimburse you.

Participants will also get 1 month of free access to pain-specific, customized version of the Wysa app. If you wish to continue using the Wysa app after completion of this study, you will be responsible for charges after your month of free access.

When you complete the 1-month follow-up survey, you will receive another $20 gift card, either handed to you, mailed to you, or sent to your e-mail address.

WHO IS FUNDING THIS STUDY?

The National Institute of Mental Health (NIMH) is funding this research study. This means that Washington University is receiving payments from NIMH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIMH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator via Melissa Armbrecht at armbrechtm@wustl.edu and/or the Human Research Protection Office at 1-(800)-438-0445.

The sponsor will reimburse your reasonable and necessary medical costs for treatment for a research-related illness or injury through Washington University in St. Louis if the injury or illness:

- is a direct result of the device (app) being studied or the properly performed study procedures
- is not a medical condition that you had when you started the study;
- is not the direct result of a failure to follow the study plan; and
- is not the direct result of proven negligence of Washington University in St. Louis.

The sponsor does not plan to provide any other form of compensation to you for any illness or injury resulting from this study. Washington University in St. Louis does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institute of Mental Health (NIMH)
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will keep your information in a password protected database that only the research team has access to.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA. Study team members will remove all personal identifiers prior to sharing any data outside of the approved research study team.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you by removing any personal identifiers (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and text?

We would like to contact you by email and text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Emailing you links to complete the surveys, as described above
- Texting you links to complete the surveys, as described above. Texting may also be used as needed to remind you to complete your one-month follow-up survey.

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish

us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ **Yes** _____ **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

If you withdraw from the study we will ask your permission to continue to use the data you have already

provided, but we will stop any further contact to you regarding this study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Melissa Armbrecht at armbrechtm@wustl.edu. If you experience a research-related injury, please contact: Melissa Armbrecht at the above number.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/09/24.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)