UNIVERSITY of WASHINGTON
Department of Psychiatry & Behavioral Sciences
Division of Population Health / AIMS Center

CHAMP Patient FAQs

Q - WHO IS DOING THIS EVALUATION ?

A. The study is being done at our clinic in collaboration with investigators at the University of Washington.

Q - WHAT IS THE PURPOSE OF THIS STUDY?

A. The purpose of this study is to evaluate different approaches to helping primary care patients stop their unhealthy use of opioids.

Q – WHO FUNDED THIS STUDY?

A. This study is being funded by National Institutes of Health.

Q – WHO HAS REVIEWED AND APPROVED THIS EVALUATION?

A. The National Institutes of Health have reviewed and approved the scientific importance of this study. The Institutional Review Board, Advarra, has reviewed the study procedures and determined that it presents minimal risk to participants.

Q - HOW MANY PEOPLE WILL BE IN THE STUDY?

A. We plan to enroll about 1200 people in the study.

Q - HOW CAN I BE SURE THIS IS LEGITIMATE?

A. You call Dr. John Fortney at (206) 686-6955 and discuss the study with him. The name of the study is CHAMP which stands for Collaborating to Heal Addiction and Mental Health in Primary care.

Q - HOW DID I GET CHOSEN FOR THE STUDY?

A. You were invited to participate in the study because you reported that opioids are causing problems for you.

Q – DO I HAVE AN OPIOID USE DISORDER OR MENTAL HEALTH DISORDER

A. You should discuss this with your family doctor or other health care provider during your appointment.

Q – HOW LONG WILL THIS STUDY LAST?

A. You would participate in the study for 6 months. You can drop out of the study at any time.

Q – WILL THIS RESEARCH HELP IN UNDERSTANDING MY CONDITION? IF SO HOW?

A. This study should help identify ways to improve the treatment of opioid use disorder and mental health symptoms. If you participate in this study, you will be able to receive treatment from your family doctor and behavioral health care manager who may help you understand opioid use disorder and how to manage your symptoms better.

Q – WHAT COULD HAPPEN TO ME, GOOD OR BAD, IF I TAKE PART IN THE STUDY?

A. Although the study is designed to improve the quality of care you receive, we cannot promise any clinical benefits of participating. If your doctor prescribes you a medication for your symptoms, it is likely that you may experience side effects like headaches, nausea or insomnia. If you receive counseling, that can sometimes be upsetting.

Q – COULD MY CONDITION GET WORSE DURING THE STUDY? WHAT WILL HAPPEN IF IT DOES?

A. Your symptoms could get worse during the study. If they do, you should contact your family doctor and let him/her know. If you tell the person conducting the research survey that your symptoms have become so bad that you are having current thoughts of harming yourself, they will facilitate developing a safety plan for you. We will offer you five options. The first option is to be transferred to a trained staff member at the National Suicide Prevention Lifeline. The second option is to call a local Crisis Center. The third option is to call or go to your Community Health Center. The fourth option is to go to the nearest emergency room. If none of these options are acceptable to you, we will call your local emergency responder to come check on you. An emergency responder would be someone like the County Sheriff.

Q – WHO WILL BE IN CHARGE OF MY CARE? WILL I BE ABLE TO CONTINUE TO SEE MY OWN DOCTOR?

A. Your family doctor will be in charge of your medical care. The behavioral health care manager and a consulting psychiatrist will help your family doctor manage your opioid use and treat your mental health symptoms. Your medical records will only be maintained at your clinic.

Q – IF I DECIDE TO PARTICIPATE IN THIS STUDY, HOW WILL IT AFFECT MY DAILY LIFE?

A. You will be asked to complete three surveys, which can last up to an hour each.

Your behavioral health care manager in coordination with your family doctor in consultation with a psychiatrist will help you better manage your use of opioids and mental health symptoms.

Q - IS THIS CONFIDENTIAL? WHAT DO YOU DO WITH MY ANSWERS?

A. Yes, it is absolutely confidential. As the survey is completed, the answers are put into a computer database. Nothing is recorded on paper, and no information that could be used to identify you is stored in the same database containing the responses you give. All information we report will be in an aggregate format. For example, we will report the percentage of people who responded "yes" or "no" to a particular question.

Q – WHAT TESTS OR PROCEDURES WILL BE DONE?

A. Participating in the research evaluation does not involve any medical tests or procedures of any kind. Participating in this research evaluation does not involve drawing blood or collecting urine or salvia samples. However, some medications for opioid use disorder and mental health disorders do require some routine tests that require drawing blood or collecting urine samples. If you are prescribed one of those medications, your family doctor may ask you do one of these routine tests. Also, if you might get pregnant, your doctor will typically order a pregnancy test for you before prescribing some medications. These tests would be recommended or required even if you were not participating in the research evaluation.

Q – WILL I RECEIVE AN EXPERIMENTAL TREATMENT?

A. No experimental medications will be prescribed. No experimental devises or therapies will be involved. All treatments offered to you have been proven effective and/or are routine using in clinical care.

Q – IS IT POSSIBLE THAT I WILL RECEIVE A PLACEBO (INACTIVE SUBSTANCE)?

A. No

Q – WHAT WILL HAPPEN TO ANY SPECIMENS THAT I GIVE?

A. You will not be asked to provide any specimens for the research evaluation.

Q – WILL YOU BE LOOKING AT MY MEDICAL RECORDS?

A. Yes.

Q – WHAT WILL HAPPEN TO ME AT THE END OF THE STUDY?

A. You will be thanked for participating and mailed a $50 check for completing the last follow-up survey. You may be discharged back to your family doctor (without support from the behavioral health care manager and consulting psychiatrist) at the end of the study.

Q – WILL I BE CHARGED ANYTHING OR PAID ANYTHING TO BE IN THE STUDY?

A. You will be compensated $50 for the first survey, $50 for the second survey and $50 for the third and last survey. If you complete all three surveys, you will receive $150. You will not incur any expenses related to participating in this study. If you normally have to make co-payments when you receive care at our clinic, you may be asked to make the same payments when you come here for care of your mental health symptoms. Likewise, if you normally have to make co-payments for your medications, you will be asked to make the same payments for any medications prescribed for your personal or emotional problems.

Q – WILL I BE TOLD THE RESULTS OF THE STUDY?

A. If you request it, we will mail you the results.

Q – HOW DO I END MY PARTICIPATING IN THIS STUDY IF I CHANGE MY MIND?

A. You can tell your clinic and call John Fortney, listed on the consent form, or just refuse to complete the survey.

Q – WHAT OTHER OPTIONS OR CHOICES DO I HAVE IF I DECIDE NOT TO TAKE PART IN THIS EVALUATION?

A. You may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. You would also be free to withdraw from the study at any time. If you decide not to participate in the study, you can still receive any treatments offered by your clinic, including support from a behavioral health care manager and a consulting psychiatrist

Q – WHOM DO I CONTACT FOR QUESTIONS AND INFORMATION ABOUT THE STUDY?

A. You can call the principal investigator, John Fortney at (206) 685-6955

You can also read about the study at https://champ.psychiatry.uw.edu/