

**Tailored Self-Management of TMD Pain using Health  
Information Technology**

**NIDCR Protocol Number: 16-054-E**

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**Principal Investigator: James Friction, DDS, MS**

**Date: 4-17-2017**

## TMD Self-Care Study **CONSENT FORM**

You are invited to participate in a research study called TMD Self-Care using PACT - Personalized Activated Care and Training for the self-management for temporomandibular disorder (TMD) pain. This study is being conducted by Dr. James Friction at HealthPartners Institute. It is funded by the National Institutes of Health, National Institute of Dental and Craniofacial Research. You were selected as a possible participant because you have TMD pain and are interested in self-management. We ask that you read this form and ask any questions you may have before agreeing to participate in the study.

### **Purpose:**

The purpose of the study is to examine new ways to help people with the self-management of their TMD pain. We will be looking at a new online self-management program and comparing it with traditional self-management for TMD pain. We will be enrolling a total of 80 people.

### **Procedures:**

If you are eligible to participate you will be randomized to one of two programs. Randomization is similar to the toss of a coin; you will have an equal chance of being in either program. Participants in both programs will continue with their usual care for TMD pain (such as splints or medications). The two programs are:

**The PACT Program** which consists of an 8 week online educational program based on reducing lifestyle and other risk factors that lead to increased TMD pain, and enhancing protective factors that lead to decreased TMD pain. The program is completed at the participants own pace. Participants in the program complete brief weekly assessments, receive online materials in video, audio and written format, and receive weekly phone coaching. Participants will be linked to a phone coach that will help clarify goals and identify strengths, resources, and barriers related to behavioral changes. Coaches are an integral part of the PACT program. They will be involved in the program, review your progress, and they may also encourage participants to review and complete weekly module content. At minimum, this involves an initial call, a touch base call, and a final call near the end of the program with a limit of two calls per week during the course of the program. Access to the internet is required for this program.

**Traditional TMD Care** which consists of self-care materials provided by dentists and oral pain specialists that focus on self-care education including diet, oral habits and use of heat to reduce pain. The materials will be provided in an online program using video and audio materials. Access to the internet is required for this program.

### **Participants in both programs will also need to:**

- Complete 3 surveys: before starting their program, at 2 months and at 4 months
- Complete a program evaluation and in some cases, structured interview
- Participate in and complete their self-care program materials

### **Risk and Benefits of Being in the Study**

There are minimal psychological or physical risks from participating in this study. You may skip any survey questions you don't want to answer. You may benefit from learning new strategies and techniques for managing your TMD pain through an online program that others have found interesting.

**Research Related Injury:** If you think you have suffered any type of research-related injury, let the study Project Manager know as soon as possible. Neither the study sponsor nor the HealthPartners Institute would be responsible for any payment. If you do begin to experience increased health concerns during the study the study team will refer you to your regular healthcare providers.

**Costs and Compensation:** There are no costs to participating in the study; all materials are provided free of charge. Participants will also be paid up to \$100.00 in Target gift cards for participation in the study. This includes a \$20.00 gift card for completion of the initial survey, a \$35.00 gift card for completing the survey at 2 months and \$45.00 gift card for completing the survey at 4 months. You may be invited to participate in a

qualitative phone interview about your experience in the study. Those participating in the interview will be offered a \$25.00 Target gift card for their participation.

### **Confidentiality**

Your records from the study will be kept private. Research records will be kept on secure password protected servers and only study team members will have access to the information. We will not include any information that will make it possible to identify individual subjects in any reports that we might publish.

### **Voluntary Nature of the Study**

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with HealthPartners or the HealthPartners Institute. You are free to withdraw from the study at any time. The investigators can also decide to end your participation in the study if you are not able to complete the tasks or no longer have internet access required by the study.

### **Contacts and Questions**

You may ask any questions you have now; if you have questions later you can contact the study coordinator, at: **(952) 967-5787**. You may also contact the study investigator Jim Friction at: **(612) 619-1678**. If you have questions about your rights as a research subject, you may contact the HealthPartners Office of Research Subjects at **(952) 967-5025**.

**Subject name:** \_\_\_\_\_

By checking the box below, I acknowledge that:

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form. A copy will be put in my study record.
- I am not giving up any of my legal rights by signing this form.

O Agreed      Date: \_\_\_\_\_