

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

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## **STATEMENT OF COMPLIANCE**

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects' protection training.

## SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigator or Clinical Site Investigator:

Signed:



Date: 1/30/2015

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## TABLE OF CONTENTS

	PAGE
STATEMENT OF COMPLIANCE .....	I
SIGNATURE PAGE .....	II
TABLE OF CONTENTS .....	III
PROTOCOL SUMMARY .....	VI
1 KEY ROLES AND CONTACT INFORMATION.....	1
2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE.....	3
2.1 Background Information .....	3
2.2 Rationale .....	4
2.3 Potential Risks and Benefits.....	5
2.3.1 Potential Risks .....	5
2.3.2 Potential Benefits .....	5
3 OBJECTIVES AND OUTCOME MEASURES.....	6
3.1 Study Objectives .....	6
3.1.1 Objective 1 .....	6
3.1.2 Objective 2 .....	6
3.1.3 Objective 3 .....	6
3.2 Study Outcome Measures .....	7
3.2.1 Objective 1 Outcome Measures .....	7
3.2.2 Objective 2 Outcome Measures .....	11
3.2.3 Objective 3 Outcome Measures .....	11
4 STUDY DESIGN .....	14
5 STUDY ENROLLMENT AND WITHDRAWAL .....	15
5.1 Subject Inclusion Criteria.....	15
5.2 Subject Exclusion Criteria.....	15
5.3 Strategies for Recruitment and Retention .....	16
5.4 Treatment Assignment Procedures .....	17
5.4.1 Randomization Procedures .....	17
5.4.2 Masking Procedures.....	17
5.5 Subject Withdrawal.....	18
5.5.1 Reasons for Withdrawal .....	18
5.5.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention .....	18
5.6 Premature Termination or Suspension of Study .....	18
5.7 Study Behavioral or Social Intervention(s) Description	
5.7.1 PACT Program	
5.7.2 Control Group	
5.8 Administration of Intervention	
5.9 Procedures for Training Interventionists and Monitoring Intervention Fidelity	
5.10 Assessment of Subject Compliance with Study Intervention	

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5.11	Concomitant Medications/Treatments	
6	STUDY SCHEDULE.....	22
6.1	Screening (Week -1 Pre-Intervention) .....	22
6.2	Enrollment/Baseline Visit (Website Visit 1, Week 0) .....	22
6.3	Intermediate Visits (8 weekly website visits during weeks 1 to 8) .....	22
6.4	Final Study Visits (Final Visits, Weeks 8 and 16).....	23
6.5	Withdrawal Visit.....	24
6.6	Unscheduled Visit.....	24
7	STUDY PROCEDURES/EVALUATIONS .....	25
7.1	Outcome Measure Questionnaires .....	25
7.2	Hypothesis Mediators.....	26
7.3	Evaluation and Qualitative Interview.....	26
8	ASSESSMENT OF SAFETY .....	27
8.1	Specification of Safety Parameters.....	27
8.1.1	Unanticipated Problems .....	27
8.1.2	Adverse Events .....	27
8.1.3	Serious Adverse Events .....	27
8.2	Events Qualifying as an Adverse Event or Serious Adverse Event for the Purpose of this Protocol.....	28
8.3	Characteristics of an Adverse Event.....	28
8.3.1	Relationship to Study Intervention .....	28
8.3.2	Expectedness of SAEs.....	<b>Error! Bookmark not defined.</b> 29
8.3.3	Severity of Event .....	<b>Error! Bookmark not defined.</b> 29
8.4	Time Period and Frequency for Event Assessment and Follow-Up .....	29
8.5	Reporting Procedures.....	29
8.5.1	Adverse Events .....	29
8.5.2	Unanticipated Problem Reporting to IRB and NIDCR .....	29
8.5.3	Serious Adverse Event Reporting to NIDCR.....	30
8.5.4	Reporting of SAEs and AEs to FDA .....	31
8.5.5	Reporting of Pregnancy.....	31
8.6	Halting Rules.....	31
9.	STUDY OVERSIGHT .....	33
10.	CLINICAL SITE MONITORING .....	34
11.	STATISTICAL CONSIDERATIONS.....	35
12.1	Study Hypotheses .....	35
12.2	Sample Size Considerations.....	35
12.3	Interim Safety Review.....	35
12.4	Final Analysis Plan .....	35
12.	SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS .....	37
13.	QUALITY CONTROL AND QUALITY ASSURANCE .....	38
14.	ETHICS/PROTECTION OF HUMAN SUBJECTS .....	39
15.1	Ethical Standard.....	39
15.2	Institutional Review Board .....	39

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15.3	Informed Consent Process .....	39
15.4	Exclusion of Women, Minorities, and Children (Special Populations) .....	39
15.5	Subject Confidentiality .....	39
15.6	Future Use of Stored Specimens and Other Identifiable Data.....	40
15	DATA HANDLING AND RECORD KEEPING.....	41
16.1	Data Management Responsibilities .....	41
16.2	Data Capture Methods .....	41
16.3	Types of Data .....	41
16.4	Schedule and Content of Reports.....	41
16.5	Study Records Retention.....	41
16.6	Protocol Deviations .....	41
16	PUBLICATION/DATA SHARING POLICY .....	43
17	REFERENCES.....	44
	APPENDICES .....	50-128
	APPENDIX A – J .....	
	A: Scheule of Events	
	B: PACT Content and Text for Introductory Video	
	C: Traditional Self-Care Protocol	
	D: Health Coach Phone Protocol for PACT Arm	
	E: Telephone Screen	
	F: Sample Consent Form	
	G: Data Collection Forms at Baseline and Follow up	
	H: Qualitative Interview	
	I: Barriers to use of Consumer Health Information Technology (CHIT)	
	J: Data Management and Safety Plan	

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## PROTOCOL SUMMARY

- Title:** Tailored Self-Management of TMD Pain using Health Information Technology
- Short Title** TMD Self-Care Study
- Précis:** This protocol describes activities to determine the feasibility and acceptability of proposed methods for a subsequent clinical trial of a tailored self-management program (PACT) designed to decrease pain in participants with temporomandibular disorders (TMD). The PACT program is a personalized program of exercise and behavioral changes implemented through a web-based program supported by a health coach. For this feasibility and acceptability study, 80 adults with TMD pain will be randomized either to the PACT program or to traditional self-care. This sample size was determined as the number needed to evaluate feasibility and acceptability of the primary intervention and determine the utility of the outcomes measures that will be collected at baseline, 8-week and 16-week follow-ups.
- Objectives:**
- Objective 1:** To evaluate the feasibility and acceptability of methods to conduct a full-scale multi-site randomized clinical trial comparing PACT self-management with traditional self-care for TMD. Methods to be tested are:
- a. Participant recruitment, consent, enrollment, and retention;
  - b. Participant adherence to the study;
  - c. Completion of study questionnaires at 8-week and 16-week follow-up;
  - d. Participant perceptions of the online website functionality and acceptability;
  - e. Participant perception of health coaches in the PACT program.
- Objective 2:** To demonstrate ability to accurately capture outcome measures to be used in the multi-site study.
- Objective 3:** To demonstrate ability to accurately capture potential mediators/moderators of specific behavioral and psychosocial factors on the PACT program's observed effects on pain and functioning outcomes through self-report. Hypothesized mediators are self-efficacy, participant activation exercise frequency and sleep quality. Hypothesized

moderators are disability status, catastrophizing, depression, repetitive strain from oral habits, perceived stress, and social support.

**Population:** The study will recruit 80 adults with TMD pain more than once a week from the HealthPartners Dental Group and selected dental clinics within the HealthPartners research network will be randomized. Ten participants will provide feedback on the online program during the development phase.

**Phase:** Pilot

**Number of Sites:** 1 – HealthPartners Institute (HPI)

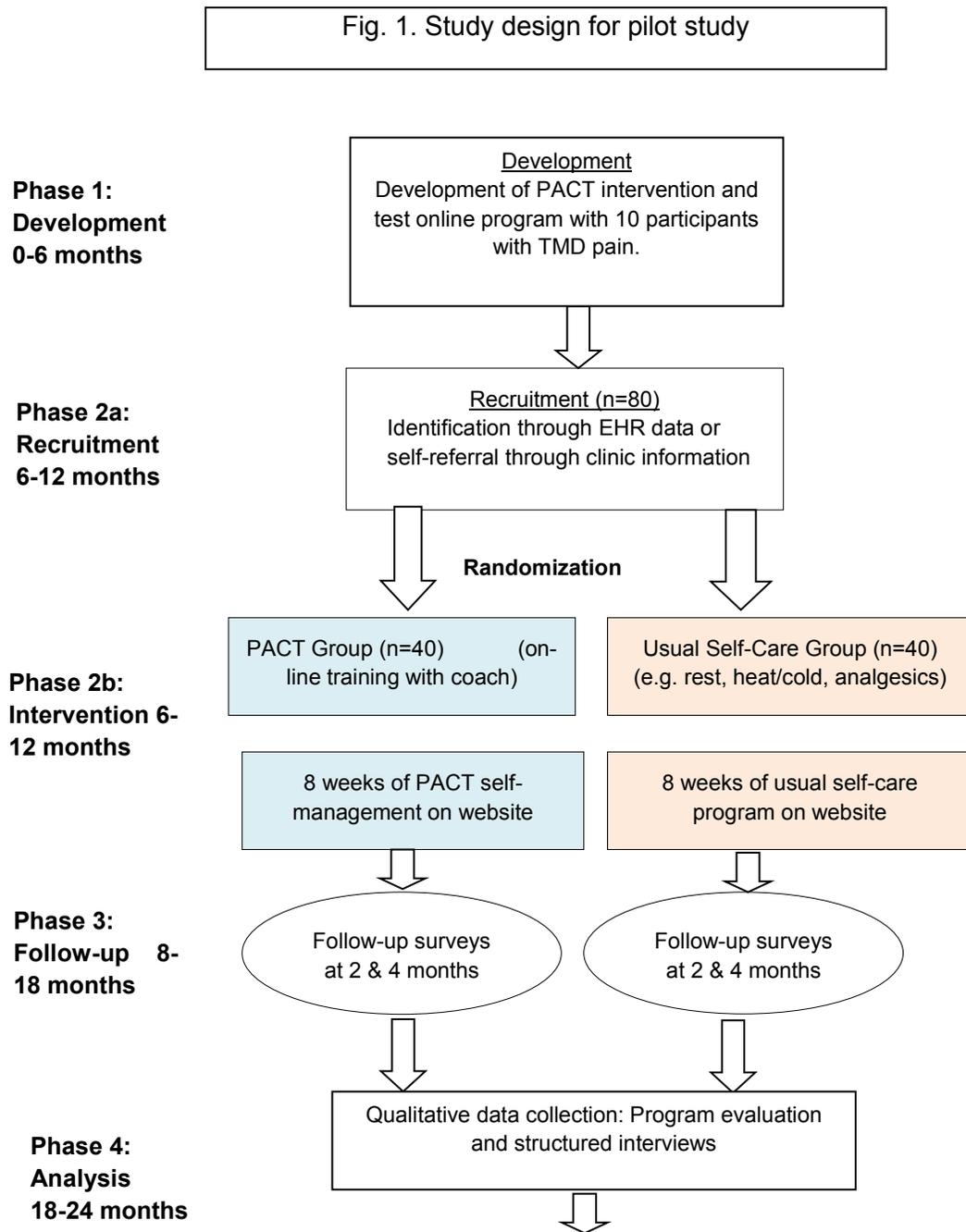
**Description of Intervention:** Personalized Activated Care and Training (PACT) is a personalized 8-week progressive program with a health coach to enhance understanding, compliance, and success in self-management of TMD pain.

**Study Duration:** 12-18 months

**Subject Participation Duration:** 4 months

**Estimated Time to Complete Enrollment:** 8 months

### SCHEMATIC OF STUDY DESIGN:



## 1 KEY ROLES AND CONTACT INFORMATION

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## 2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

### 2.1 Background Information

**Health problem.** Temporomandibular disorders (TMD) are the second most common musculoskeletal pain condition, affecting about 10% of the general population.<sup>1,6-8</sup> In 2011, the Institute of Medicine (IOM) made research on pain conditions such as temporomandibular disorders (TMD), among the highest priorities because of its high prevalence, functional limitations, missed work, opioid dependency, and high health care cost.<sup>1-12</sup> More than 100 million U.S. adults are affected by chronic pain conditions, costing between \$560 and \$635 billion annually in medical care and lost productivity.<sup>1-6</sup> TMDs are the second most common musculoskeletal pain condition, affecting about 10% of the general population.<sup>1,9-11</sup>

**Interventions.** Self-management programs provide a convenient mechanism for health care professionals to improve the management of pain conditions at an earlier point in their development, when it is easier to prevent chronic pain. The study will employ a self-management program, entitled Personalized Activated Care and Training (PACT) that is a tailored 8-week progressive web-based training program supported by a health coach to enhance understanding, compliance, and success in improving TMD pain. The program provides 8 weeks of structured didactic and experiential training on exercises and cognitive-behavioral training to reduce risk factors that contribute to delayed recovery and enhance protective factors that have evidence of improving TMD pain.

**Relevant research and scientific justification.** Chronic pain in the jaw, head, and face are caused by conditions such as joint disk disorders, myofascial pain, and osteoarthritis. These conditions may begin with an injury or strain, but often persist due to the presence of risk factors such as repetitive strain, depression, poor sleep, stress, maladaptive postures, depression, catastrophizing, and others factors that can delay recovery, increase peripheral and central sensitization, and, ultimately cause the persistence of chronic pain.<sup>5-11</sup> When an acute TMD pain becomes chronic it often results in severe jaw pain, headaches, missed work, disability, opioid dependency and higher cost of care.<sup>9-15</sup> Half of the persons seeking care for TMD still have pain 5 years later, and 15% to 20% of them have long-term disability.<sup>15-19</sup> The care for these patients often escalates to high-cost and higher-risk passive interventions such as opioid analgesics, polypharmacy, high-tech imaging, and surgery.<sup>8-12</sup> Yet, clinical trials and systematic reviews have not found the outcomes of passive therapies to be any better than self-management strategies that activate the patient through exercise and cognitive and behavioral changes.<sup>32-43</sup> The Institute of Medicine states the clinicians' primary role in caring for chronic pain requires guiding, coaching, and assisting patients with day-to-day self-management in addition to evidence-based medical treatments.<sup>1</sup> However, most health professionals lack the time and training to perform this role, and find little support and reimbursement for doing so. As the Institute of Medicine simply stated, we need a revolution in health care to replace our current passive model of *doctor-centered* care with patient-centered care that integrates robust self-management with evidence-based treatments.<sup>1</sup> Clinical trials have found that patients who are engaged in self-management have significantly more successful outcomes than passive biomedical treatments alone.<sup>12-14</sup> Thus, the use of on-line self-management programs provides a convenient and cost-effective mechanism for health professionals to improve the management of pain conditions at an earlier point in their development, when it is easier to prevent chronic pain.<sup>20-31</sup> While training patient in self-management is a laudable goal, the implementation as part of routine care is a challenge that

most health professionals do not embrace due to time and training, and reimbursement. The use of Consumer Health Information Technology (CHIT) to empower and engage consumers to better manage their health is becoming an acceptable alternative to in-person training session for self-management.<sup>63-66</sup> The use of CHIT has distinct advantages of being flexible, personalized, scalable, clinically effective, and cost-effective, and can help transform the health care system by allow most health professional to use with patients. The Center for Information Technology Leadership (2008), a nonprofit research center, concluded that CHIT could save \$19 billion annually by focusing on prevention, early intervention, self-management, and evidence-based care using CHIT.<sup>21</sup> Partner's Center for Connected Health also concluded that health care will not be reformed without consumer engagement.<sup>22</sup> However, these goals will not become reality unless research such as this study demonstrates efficacy. This project uses CHIT to engage patients, enhance understanding, adherence, and document outcomes.

## 2.2 Rationale

While several distinct pathophysiological mechanisms may occur in TMD pain conditions, it is important to understand and address the complex interaction of diverse factors that can initiate, perpetuate, delay recovery, or even protect patients from increasing severity of pain due to changes to peripheral and central sensitization.<sup>44-60</sup> Maixner, et al (2011) have identified biopsychosocial and genetic risk factors that contribute to the onset and persistence of painful TMD in the OPPERA Study.<sup>46-47</sup> Their conceptual model describes the changes that can occur in human biology, behaviors, and relationships when a person develops a chronic pain condition. This model suggests the need to address the "whole" patient by addressing multiple inter-related risk factors that play a role in the progression of the pain and can be influenced to prevent progression.<sup>48-49</sup> Addressing these factors can lead to tailored treatment strategies with more predictable outcomes in reducing pain, peripheral, and central pain sensitization by influencing the underlying causes. *Risk factors* such as behavioral factors (e.g., repetitive strain, muscle tension, postural habits), emotional risk factors (e.g., anxiety, depression), comorbid conditions (e.g., fibromyalgia), and cognitive factors (e.g., poor understanding of etiology, unrealistic expectations, somatization, coping strategies, catastrophizing) have been found to be important in the progression to chronic persistent pain.<sup>50-60</sup> For example, our studies found depression, somatization, fibromyalgia, and premorbid perceived stress to be significant risk factors that increase central sensitization and play a key role in predicting poor outcomes in TMD pain patients.<sup>58-60</sup> By reducing these factors, they will encourage healing and lessen pain. On the other hand, *protective factors* can reduce delayed recovery and also improve normal healing, and prevent chronic pain. Factors such as level of coping, self-efficacy, patient beliefs (e.g., perceived control over pain), and social support can lead to more positive outcomes.<sup>51-57</sup> Each of these factors are integrated into the PACT program.

The PACT program provides structured education, exercises, and cognitive-behavioral training that have evidence of improving TMD pain by changing these risk factors and enhancing protective factors.<sup>26-42</sup> The program is based on clinical guidelines, clinical experience, clinical trial research, research on risk factors, protective factors, and systematic reviews of self-management efficacy of pain. The educational content is based on an existing on-line training course on preventing chronic pain and has been adapted for the PACT program.<sup>67</sup>

## **2.3 Potential Risks and Benefits**

### **2.3.1 Potential Risks**

Potential risks include:

- 1) Although the program includes simple exercises and behavioral changes, participant conditions may not improve or may have their pain aggravated. This is minimized by providing personalized experiential instruction on the exercises and behavioral changes and cautioning participants to seek additional care if their condition does not improve or worsens. Participants will be screened by TMD diagnostic criteria to ensure their condition is appropriate for the study.
- 2) There is some risk associated with the release of personal health information (PHI) from health records. The investigators will protect subjects' records so their name, address, phone number, and clinical information is kept private and will not be released without participants' specific written permission. All data will be stored in a de-identified format without reference to participant identity.

### **2.3.2 Potential Benefits**

Potential benefits include:

- 1) While this study is not designed to test the efficacy of the PACT program, participants may derive benefit from participation in the study with a reduction of pain, improvement in daily activities, and engagement in self-management strategies. In addition, the improved knowledge from use of PACT will enhance the participants' own understanding of their condition and how to self-manage it. The information and knowledge gained from the study may be valuable in improving care and management of TMD pain and implementation of evidence-based care with providers.
- 2) The importance of knowledge gained. This research may provide information for the development of new, more effective strategies to predict, prevent, and manage TMD pain in participants of all racial and ethnic groups, as well as improve understanding and development of efficacious, cost-effective treatments that contribute to better outcomes for participants.

### 3 OBJECTIVES AND OUTCOME MEASURES

#### 3.1 Study Objectives

##### 3.1.1 Objective 1

**Objective 1** is to evaluate the feasibility and acceptability of methods to conduct a full-scale multi-site randomized clinical trial comparing PACT self-management with traditional self-care for TMD.

- Participants will find the PACT program acceptable as an intervention to help improve TMD pain and the study will successfully recruit participants to test the intervention.
- The study will reach recruitment, randomization, and retention goals
- The study will satisfactory collect study data (screening, baseline, follow up, qualitative) for evaluation purposes

Methods to be tested are:

- a. Participant recruitment, consent, enrollment, and retention;
- b. Participant adherence to the study;
- c. Completion of study questionnaires at 8-week and 16-week follow-up;
- d. Participant perceptions of the online website functionality and acceptability;
- e. Participant perception of health coaches in the PACT program.

##### 3.1.2 Objective 2

**Objective 2** is to demonstrate ability to accurately capture outcome measures to be used in the multi-site study.

- The PACT study will accurately define and capture accurate primary and secondary outcomes measures (jaw functioning, pain severity and pain interference) to be used in a larger multisite study

##### 3.1.3 Objective 3

**Objective 3** is to demonstrate ability to accurately capture potential mediators/moderators of specific behavioral and psychosocial factors on the PACT program's observed effects on pain and functioning outcomes through self-report. Hypothesized mediators are self-efficacy, participant activation exercise frequency and sleep quality. Hypothesized moderators are disability status, catastrophizing, depression, repetitive strain from oral habits, perceived stress, and social support.

- The PACT study will accurately define and capture hypothesized mediators including self-efficacy, participant activation exercise frequency and sleep quality
- The PACT study will accurately define and capture hypothesized moderators including disability status, catastrophizing, depression, repetitive strain from oral habits, perceived stress, and social support.

### 3.2 Study Outcome Measures

#### 3.2.1 Objective 1 Outcome Measures

Four study methods will be tested, each with specific measures to evaluate feasibility and acceptability. The methods to be tested and their associated measures are as follows:

- a. Participant recruitment, consent, enrollment, and retention: Feasibility of participant recruitment will be measured by demonstrating the ability to meet the enrollment target for the study (N=80). Milestones toward meeting target enrollment are: the ability to identify an adequate number of individuals that meet eligibility criteria, and number (%) of individuals consenting to participate compared with the total number contacted.

Objective	Constructs	Target outcomes
Recruitment (identify)	<ol style="list-style-type: none"> <li>1. Identification of TMD patients using HPDG electronic records (EHRs)</li> <li>2. Percentage of participants recruited by both electronic health records (EHR) and self-referral</li> </ol>	<ol style="list-style-type: none"> <li>1. Generate a list of new TMD patients for possible enrollment in the study during the 6 months of recruitment</li> <li>2. Participants will be recruited from both the search of the EHR and self-referral using brochures in the clinics</li> </ol>
Recruitment (enroll and consent)	<ol style="list-style-type: none"> <li>1. Percentage of contacting participants who meet eligibility criteria</li> <li>2. Percentage of contacted participants who consent to enroll in study</li> </ol>	<ol style="list-style-type: none"> <li>1. 80% of participants who talk with staff meet eligibility criteria for study</li> <li>2. 30% of eligible participants contacted enroll in the study</li> </ol>
Recruitment (retention)	<ol style="list-style-type: none"> <li>1. Percentage of participants who start program after randomization</li> </ol>	<ol style="list-style-type: none"> <li>1. 95% participants recruited for each arm start program after randomization</li> </ol>

- b. Participant adherence will be measured by accessing the website at each of the follow-up periods. Participant adherence to the study will also be measured by number of participants completing all 8 on-line modules (with a goal of 80%).

Objective	Constructs	Target outcomes
Intervention (adherence/compliance)	<ol style="list-style-type: none"> <li>1. Number of participants accessing all online lessons</li> <li>2. Use of health coaches (PACT arm)</li> <li>3. Pain and risk assessment instruments within the PACT program (PACT arm)</li> <li>4. Time spent in online program per week (PACT arm)</li> </ol>	<ol style="list-style-type: none"> <li>1. 80% of enrolled participants access all lessons as measured by Web site hits</li> <li>2. 90% of participants in PACT have at least 3 phone meetings with the health coach (PACT arm)</li> <li>3. Completion of all pain and risk assessment instruments within the PACT program (PACT arm)</li> <li>4. Time spent in each module of online program per week (PACT arm)</li> </ol>

- c. Completion of questionnaires at 8-week and 16-week follow-ups, and program evaluation. Completion of questionnaires will be measured by the percent of participants who complete the 8-week and 16-week follow-up questionnaires and, the program evaluation. We expect that at least 80% of participants will complete all questionnaires.

Objective	Constructs	Target outcomes
Evaluation (adherence/compliance)	<ol style="list-style-type: none"> <li>1. Number of participants completing 8-week and 16-week follow-up questionnaires</li> <li>2. Number of participants completing the program evaluation survey questions (PACT arm)</li> </ol>	<ol style="list-style-type: none"> <li>1. 80% complete both 8- and 16-week follow-up questionnaires</li> <li>2. 80% of participants in PACT group complete the program evaluation form</li> </ol>
Evaluation (instrument performance)	<ol style="list-style-type: none"> <li>1. Responsiveness to constructs in subscales of the survey.</li> <li>2. Inter-correlations between scales</li> <li>3. Participant burden is measured by time to complete.</li> </ol>	<ol style="list-style-type: none"> <li>1. Outcome variables show changes in the expected direction</li> <li>2. Outcome variables are associated with mediator/moderator factors in the expected direction</li> <li>3. 90% of participants complete all surveys in estimated time</li> </ol>

- d. Participant perceptions of the online website functionality and acceptability will be measured by participant reports of problems and ease of use reported at the program

evaluation. These reports will come from the number of phone calls/questions received about web-site issues, and from the qualitative interview.

<b>Objective</b>	<b>Constructs</b>	<b>Target outcomes for both arms</b>
Web-Site functionality	<ol style="list-style-type: none"> <li>1. Heuristic evaluation of functionality of the Web-based platform</li> <li>2. Mode of administration acceptance</li> </ol>	<ol style="list-style-type: none"> <li>1. Less than 10% of participants note problems with website via comments section in each module or during program evaluation</li> <li>2. 90% of participants rate web-site accessibility for learning the concepts as very good to excellent</li> </ol>
Intervention (acceptability)	<ol style="list-style-type: none"> <li>1. Identification of self-reported barriers for improvement</li> <li>2. Pace in which participants complete the program</li> </ol>	<ol style="list-style-type: none"> <li>1. 80% of participants identify at least one self-report barrier for improvement</li> <li>2. 60% of participants follow the timeline on the Web site to complete in 8 weeks</li> </ol>
Participant perceptions of program	<ol style="list-style-type: none"> <li>1. Qualitative interviews of participants</li> </ol>	<ol style="list-style-type: none"> <li>1. At least ten randomly selected participants will agree to be interviewed to provide their perceptions about the content of the program and at least 90% report that it is acceptable.</li> </ol>

- e. Participant perception of health coaches in the PACT program will be evaluated by qualitative interviews of both health coaches and participants

<b>Objective</b>	<b>Constructs</b>	<b>Target outcomes for both arms</b>
Participant perceptions of health coach	<ol style="list-style-type: none"> <li>1. Qualitative interviews of participants about health coaches</li> </ol>	<ol style="list-style-type: none"> <li>1. At least ten randomly selected participants will agree to be interviewed to provide their perceptions about the content of the program. Of at least 10 participants interviewed, 90% will report that they found the health coaches to be helpful.</li> </ol>

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Health coach perception of program	1. Qualitative interviews of participants	1. Health coaches will provide their perceptions on the program and areas for development
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### 3.2.2 Objective 2 Outcome Measures

Outcome measures to be used are listed in the table below. Of the 80 patients participating in the study, we believe that 90% will complete the outcome measures at baseline and all follow-up periods and report the burden of completing these is acceptable.

Outcome Domain	Measure
<b>Primary</b>	
Pain severity	Graded Chronic Pain Scale (GCPS) with mean intensity ratings for reported current, worst, and average pain. <sup>68-69</sup>
Jaw Functioning	Jaw Functional Limitation Scale (JFLS-8) identifies daily activities interfered with by jaw pain. <sup>40</sup>
<b>Secondary</b>	
Pain interference	Graded Chronic Pain Scale
Pain timing	Symptom Severity Index

### 3.2.3 Objective 3 Outcome Measures

#### 3.2.3.1 Hypothesized mediators

Of the 80 patients participating in the study, we believe that 90% will complete the mediator questionnaire at baseline and all follow-up periods and report the burden of completing these is acceptable. Specific measures of self-efficacy, participant activation, exercise frequency, and sleep quality will be made by questionnaires, as described in section 8.1.1.

#### 3.2.3.2 Hypothesized moderators

Of the 80 patients participating in the study, we believe that 90% will complete the moderator measures at baseline and all follow-up periods and report the burden of completing these is acceptable. Specific measures of disability status, catastrophizing, depression, oral habits, perceived stress, and social support will be made by questionnaires, as described in section 8.1.1.

Outcome Measures including Data Constructs, Scales, Sources and intervals.								
	Construct	Scale/ Variable	Data Source	Target	Baseline	Intervention	Weeks from baseline	Weeks from baseline
<b>Timing (weeks)</b>					At Enrollment	0-8 wks.	8 wks.	16 wks.
Screening	Eligibility	DC-TMD Pain Screener and self-report criteria	Phone Screen	Potential participants screened	X			
	Demo-graphics	Age, marital status, education, employment,	Phone screen	Potential participants screened	X			

<b>Outcome Measures including Data Constructs, Scales, Sources and intervals.</b>								
	<b>Construct</b>	<b>Scale/ Variable</b>	<b>Data Source</b>	<b>Target</b>	<b>Baseline</b>	<b>Intervention</b>	<b>Weeks from baseline</b>	<b>Weeks from baseline</b>
<b>Timing (weeks)</b>					At Enrollment	0-8 wks.	8 wks.	16 wks.
Other Descriptive Information	Prior Medical Conditions	Prior Medical Conditions	On-line survey	Participants	X			
Objective 1 Process Evaluation	Recruitment	Contact/consent	Survey Center logs	Participants	X			
	Compliance/adherence	Self-report of intervention practice	On-line Survey	Participants		X		
	Compliance/adherence	Program evaluation form	On-line survey	Participants			X	
	Acceptability	Heuristic evaluation of ease of use and functionality	Web hits Survey	Participants			X	
	Participant experience	Barriers and facilitators to adherence	Qualitative interview	Participants		X	X	X
Objective 2 Primary Outcomes	Pain Severity	Graded Chronic Pain Scale-severity (7 items; of 10)	On-line survey	Participants	X	X	X	X
	Jaw Function	Jaw Functional Limitation Scale (JFLS-8; items; short version)	On-line survey	Participants	X	X	X	X
Objective 2 Secondary Pain Outcomes	Pain interference	Graded Chronic Pain Scale-intensity (3 items of 10)	On-line survey	Participants	X	X	X	X
Objective 3 Mediators	Self-efficacy	Chronic Pain Self-efficacy Questionnaire (5 item Self-efficacy for Pain management (PSE) scale)	On-line survey	Participants	X	X	X	X

<b>Outcome Measures including Data Constructs, Scales, Sources and intervals.</b>								
	<b>Construct</b>	<b>Scale/ Variable</b>	<b>Data Source</b>	<b>Target</b>	<b>Baseline</b>	<b>Intervention</b>	<b>Weeks from baseline</b>	<b>Weeks from baseline</b>
<b>Timing (weeks)</b>					At Enrollment	0-8 wks.	8 wks.	16 wks.
	Participant Activation	Patient Activation Measure (PAM; 7-items)	On-line survey	Participants	X	X	X	X
	Exercise	Global Physical Activity Questionnaire (2 questions)	On-line survey	Participants	X	X	X	X
	Sleep quality	WHO World Health Survey (4 questions)	On-line survey	Participants	X	X	X	X
Objective 3: Moderators	Catastrophizing	Pain Catastrophizing Scale (PCS; 14 items)	On-line survey	Participants	X			
	Depression	Patient Health Questionnaire (PHQ8; 8 items)	On-line survey	Participants	X			
	Oral habits	DC/TMD Oral Behavioral Checklist (15 items)	On-line survey	Participants	X			
	Stress	Perceived Stress Scale (PSS; 10 items)	On-line survey	Participants	X			
	Social Support	Social Support Questionnaire (SSQ; 6 items)	On-line survey	Participants	X			

#### **4 STUDY DESIGN**

The pilot study design is a 2-arm randomized clinical trial to test the methods that will be used in a future proposal for a full-scale multi-site clinical trial.

Eighty participants with TMD will be recruited through 2 recruitment protocols (1-Inbound recruitment or self-referral and 2-outbound recruitment or ICD-9/ICD-10 code identification) and randomized in a 1:1 ratio to the PACT program or Traditional self-care. Participants will be aged 18 or older because significant adjustments would need to be made to the program to take into consideration the differing cognitive status and developmental age, and limited to English-speakers because one of the primary outcome instruments is only validated in English.

The study should be completed in 12-18 months, with enrollment occurring for 8 months.

Participants will be evaluated for eligibility over the telephone following verbal consent for screening, and information including demographics and eligibility criteria. Eligible participants will be consented over the telephone and will sign the consent electronically. Following consent participants will complete the baseline questionnaire and be randomized to PACT (intervention) or self-care (control). Weeks 1-8 (intermediate visits) will consist of weekly website visits. Participants in the self-care arm will be provided with traditional self-care material. Participants in the PACT arm will complete initial assessments for weekly lessons, and based on the assessment will be provided personalized lessons. Participants in the PACT arm will also receive weekly coaching sessions by phone. All participants will participate in usual care from their dentist and will be asked to limit concomitant medications to NSAIDs. Participants in both arms will complete follow-up measures at 8 and 16 weeks post-intervention. Following the 8-week follow-up participants will be asked to complete a program evaluation, and at least 10 randomly-selected subjects will complete a qualitative interview.

Data analysis will evaluate feasibility and acceptability of the primary intervention and determine the utility of the outcomes measures that will be collected at baseline, 8-week and 16-week follow-ups.

## **5 STUDY ENROLLMENT AND WITHDRAWAL**

### **5.1 Subject Inclusion Criteria**

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Age 18 or older
- Able and willing to access the internet on a regular basis
- Able and willing to participate in weekly phone coaching calls
- Able to read and speak English\*\*
- Willing and able to comply with all study procedures and be available for the duration of the study:
- Has a diagnosis of TMD pain using a self-report screener, specifically:
  1. Reporting pain in the jaw or temple area (on either side) in the last 30 days.
  2. Reporting pain or stiffness in the jaw on awakening in the last 30 days.
  3. Reporting changes in pain (either better or worse) in the jaw or temple area (on either side) in the last 30 days, after the following activities: chewing hard or tough food, opening the mouth or moving the jaw forward or to the side, jaw habits such as holding teeth together, clenching/grinding, or chewing gum, or other jaw activities such as talking, kissing, or yawning
- Has a frequency of TMD pain more than once a week with pain in the past 6 months
- Provides an electronically signed and dated informed consent form.

### **5.2 Subject Exclusion Criteria**

An individual who meets any of the following criteria will be excluded from participation in this study:

- Currently participating in any other TMD/TMJ related studies
- Has major disc disorder requiring opioids or is scheduled to have surgery for TMD pain
- Has any serious medical condition that might interfere with or prohibit participation in an online program
- Is pregnant
- Has been treated for a mental health disorder or substance abuse in the past six months

\*\* Note: This project is limited to subjects with the ability to read and speak English since one of the primary outcome instruments (Jaw Functional Limitation Scale) is only validated in English.

### 5.3 Strategies for Recruitment and Retention

Participants will be recruited using two recruitment protocols, which may run in the same clinics:

- A. Recruitment Protocol 1 relies on the participant proactively calling the Survey Research Center (SRC) following receiving information about the study from their dental clinic;
- B. Protocol 2 relies on the SRC initiating contact by sending a letter and making subsequent outbound telephone calls.

All recruitment materials will be submitted to the Institutional Review Boards (IRBs) for review and approval prior to their use.

#### **Recruitment Protocol 1: *Inbound recruitment – Self referral through clinic information***

Pre-implementation:

- A. Clinics will be identified for initial participant recruitment. Clinical directors/ and or managers will be contacted for participation in the study and process of recruitment.
- B. Clinicians at sites will be informed about the study and asked to refer patients with diagnosed TMD to the study, or direct patients to clinic brochures.

Implementation:

- A. Brochures will be placed in clinic waiting rooms or other places staff deemed appropriate
- B. Dentist or hygienist will discuss the study or encourage patients to review the study brochure.
- C. Potential study participant interested in the study will contact the SRC at HPI. The SRC will describe the study and proceed to the phone screening.

#### **Recruitment Protocol 2: *ICD-9/ICD-10 code identification***

Pre-implementation:

- A. Clinics will be identified for initial participant direct recruitment. Clinic medical directors/ and or managers will be contacted to discuss the study and recruitment.
- B. Dental providers will be asked to review recruitment letter that will be sent to their patients identified using ICD-9/ICD-10 codes as having TMD, and to provide approval of use of their signature on the letter.

Implementation:

- A. The study programmer will use the ICD-9/ICD-10 codes for TMD diagnosis (within specified timeframe) to identify all patients in HPDG from [DATE] thru [DATE] eligible for study recruitment. ICD10 codes are M26.6x, G44.209 and M79.x. We will cross check these codes with ICD-9 codes from the past including 524.6x and 729.x
- B. Once a potential participant is identified using ICD-9 / ICD-10 codes for TMD their contact information will be accessed. A weekly list will be generated from a search of the HealthPartners claims data.

- C. Name, address, and primary dental provider will be used to generate recruitment letter with primary dental provider signature.
- D. The potential participants would then be sent an introductory letter signed by the provider and study PI and study brochure inviting participation. The letter will also contain a telephone number to call to decline to participate in, or be contacted about the study.
- E. Participants not declining participation within 1 week of initial recruitment letter will be contacted by the SRC regarding participation in the study.
- F. If after hearing a brief description of the study the potential participant is interested; the SRC will proceed with the phone screen.

### **Compensation:**

Participants will be compensated for their participation in the study in an amount stated in the informed consent.

## **5.4 Assignment Procedures**

### **5.4.1 Randomization Procedures**

Participants will be assigned to a study arm through a computer-generated randomization procedure completed within the programming of the TMD Pain Study website. The ratio between intervention and control arms will be 1:1. Randomization scheme will be prepared by the statistician using a permuted block design. The maintenance of trial randomization scheme will occur within the database of the TMD Pain Study website and reviewed periodically by study coordinator to ensure that concealment has been maintained.

Randomization process will be prepared by the statistician, a member of the Research Methodology Group at Health Partners Institute. The maintenance of trial randomization scheme will occur within the database of the TMD Pain Study website. To ensure that the allocation cannot be predicted by researchers, the algorithm will be based on permuted blocks design of 4 and 2 with a 1:1 allocation ratio. Assignment will be accessed directly through the on-line PACT portal after a participant has completed the consent and baseline survey. The use of the online portal will assure allocation concealment, immediate notification of the assignment to the participants, and access to the assigned program.

### **5.4.2 Masking Procedures**

Since the control and intervention arms of the study are significantly different due to the more extensive training and health coaching in the PACT program, it may be apparent to patients which group they are in. As a result, it is probable that neither the intervention group nor the control group will be completely masked to the group they are in. However, both groups will complete all outcome measures through the web-based system.

The following procedures will be used for blinding and protection from bias. Baseline data are collected prior to randomization. Participants and researchers are not blinded to allocation because of the nature of the study. Participants may share this information with their dental care team. Baseline and follow up data are collected through the online program and transferred to a database format with group assignment indicated,. All reports reviewed by the

PI.

## **5.5 Subject Withdrawal**

Participants may withdraw voluntarily from the study at any time or the investigator may terminate participation for any of the following reasons:

- Participant reports that the TMD self-care practices result in:
  - sustained increased pain,
  - the jaw locks,
  - or if the participant appears to display serious emotional difficulties, dissatisfaction or confusion with care during the lessons.
- Participant refuses to participate in any of the PACT program activities after enrollment.
- Continued participation deemed to be not in the participant's best interest.
- Investigator discretion.

Participants withdrawn after randomization will not be replaced.

### **5.5.1 Reasons for Withdrawal**

Study staff will record reasons for withdrawal or discontinuation when possible. If the participant withdraws consent, no further evaluations will be performed, and no attempts will be made to collect additional data.

### **5.5.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention**

Study staff will contact each participant who is withdrawing or discontinuation to discuss and document the reasons for withdrawal or discontinuation. All information will be documented in a log of participant completion of study activities.

Any participant discontinued due to TMD self-care practices resulting in sustained increased pain, the jaw locking, or displaying serious emotional difficulties, dissatisfaction or confusion with care during the lessons will be referred to their HealthPartners Dental Provider for further evaluation and follow-up.

## **5.6 Premature Termination or Suspension of Study**

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PI or NIDCR. If the study is prematurely terminated or suspended, the principal investigator will promptly inform the IRB and will provide the reason(s) for the termination or suspension. The study will also inform participating clinics. Since this is a self-management behavioral study with minimal risks, there are few possible reasons for termination or suspension of the study.

This study will be stopped prior to its completion if:

- The intervention is associated with adverse effects that call into question the safety of the intervention;
- Difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints;

- Any new information becomes available during the trial that necessitates stopping the trial; or
- Other situations occur that might warrant stopping the trial.

## 5.7 Study Behavioral or Social Intervention(s) Description

### 5.7.1 PACT Program

The Personalized Activated Care and Training (PACT) program is a self-management program designed to help participants with TMD pain understand the “big picture” of their condition, how to reduce risk factors and enhance protective factors using a cognitive-behavioral training approach. Eight lessons are delivered over 8-weeks. The program is designed to improve participant engagement, understanding, and compliance. Activities in each module will include improving understanding of TMD, its causes and the role of self-care in healing. Activities are designed to teach concepts on how to reduce risk factors, improve protective factors, encourage healing, restore range of motion, reduce pain, and improve the healthy use of the jaw in everyday life. Risk factors include: behavioral factors (e.g., repetitive strain, muscle tension, postural habits, chemical use, diet), emotional factors (e.g., anxiety, depression), cognitive factors (e.g., poor understanding, poor coping strategies, catastrophizing), social factors (e.g., stress, conflict, abuse), and environmental factors (e.g. environmental risk and injury) that can lead to delayed recovery. Protective factors include: exercise, relaxation, coping, self-efficacy, participant beliefs (e.g., perceived control over pain), and social support that can lead to more positive outcomes.<sup>58-61</sup> **APPENDIX B: CONTENT AND TEXT FOR INTRODUCTORY VIDEO** provides more detailed information about each lesson.

Questionnaires to assess risk factors briefly in each realm for each patient in the PACT program will also be administered online. Training patients on risk and protective factors are integrated to provide more personalized self-management training plan for the participant and supported by the coach.

The PACT program will be compared to a usual self-care focused on traditional strategies implemented with a written handout at the initial visit to encourage healing and recovery. This information will be used as the content for usual self-care in the study. The format of usual self-care materials will match the format of the PACT program. Both the PACT program and the written handout will available through the web-based platform to encourage participant retention and to track the access of usual self-care training materials.

### 5.7.2 Control Group

The control group will be able to download usual self-care pdfs from the website. Usual self-care strategy in pdf form will include rest, heat/ cold, soft diet, palatal tongue posture, reduce gum chewing, and avoid strain during opening the jaw. A summary of self-care materials for TMD that is used in the HPDG clinics is presented in **APPENDIX C: TRADITIONAL SELF-CARE PROTOCOL**.

## 5.8 Administration of Intervention

Course material will be administered through an on-line website program. The focus will be on both didactic knowledge and interactive content. The use of a health coach is also integrated into the online intervention and will be conducted through telephone calls with study participants on a regular basis determined by the coach and participant at the start of

the intervention period (see Appendix D for Health Coach Phone Protocol).

*Health Coach.* The self-management program will also be supported by 3 three health coaches who have specialized training in health coaching with additional training in TMD and chronic pain. Health coaches are already employed within HealthPartners to engage patients with several chronic illnesses. Three of these trained coaches will provide the coaching services for the study. An agreement or pact with the participant is implemented by the health coach to ensure understanding of self-management program and the importance of each step. An initial phone call is held with the participant to ensure that they understand the basics on the self-management training program and how to use the information technology. Phone support is provided on a weekly basis to answer questions and encourage understanding and adherence to the self-management program. A minimum phone contact of 3 calls including the initial call, touch base call, and final call is required. If a participant is very engaged in the health coaching, a maximum phone contact will be two times per week for three months. The average length of calls is intended to be initial call of 30-60 min. as needed with follow-up calls of 30 min. Audio recordings of the telehealth visits will not be completed since the analysis of the coaching model itself is not the focus of study outcomes and it may interfere with coaching. Fidelity of the health coaching component of the PACT program will be assessed by review of the coaching logs, including the number of contacts and adherence to the coaching model with discussion of goals, barriers, understanding, and motivation. Discussions will be held with health coaches to assess their experience and how they perceive it contributes to the overall the PACT program.

## **5.9 Procedures for Training Interventionists and Monitoring Intervention Fidelity**

The study intervention is a self-administered online self-management program supported by a health coach, in this context the interventionists for the PACT program are health coaches.

*Training.* The study coordinator and health coaches will receive training on the study protocol, PACT manual, and the care of temporomandibular disorders including self-management. This includes participating in IRB training, study protocol training, as well as an on-line MOOC course on preventing chronic pain ([www.coursera.org/learn/chronic\\_pain](http://www.coursera.org/learn/chronic_pain)). Study staff are required to pass examinations after completing this online course in order to serve as health coaches for this study. Study staff will also participate in the on-line PACT training program themselves as if they were participants. Then, 3 one hour or more discussion groups and training sessions with the health coaches will occur before, during and after the study. The health coaches will be supervised by the Principal Investigator, Dr. James Friction, and Dr. Brad Rindal as well as our consultant Dr. Karen Lawson, Director of the Health Coaching training program at the University of Minnesota. These investigators will meet with health coaches each month to review their discussions with patients, their barriers, and implementation of the program. Their notes about the health coaching experiences will be discussed also.

In this study, Health Coaching is considered a relationship-centered, client-driven process designed to facilitate and empower a client to achieve self-determined goals related to health and overall well-being. While the participant's primary goal in this study is to improve their TMD pain and function, the coaching model includes the selection of goals and exploration on how to achieve them based on the participants' preferences. Individuals may be just beginning to consider life change, may be exploring aspects of preparing for a change, or may be ready to implement actual actions. In a safe and consistent space, participants can explore their thoughts, emotions, and actions, in a way that allows them to recognize the power of their own

choices to impact their pain and well-being. Health Coaching is a methodology that is different from but supported by the on-line health education in the PACT program and the counseling or therapy received by health professionals such as the dental provider and physical therapist. It is designed to work well in combination with those care strategies. By applying clearly defined knowledge and skills, they support individuals or groups in mobilizing their internal strengths and external resources to achieve sustainable changes in beliefs or behaviors. Health Coaching has the potential to help individuals, families, and groups achieve improved health and wellbeing.

*Fidelity of Health Coaching.* Fidelity to the coaching model will be assessed by analysis of the interviews and review of the coaching documentation with a focus on: 1) development a positive supportive health coaching relationship, 2) clarification of goals, 3) identifying strengths/resources/barriers, 4) monitoring completion of weekly modules, 5) inquiring about usefulness of information.

*Monitoring Protocols and Interventions.* Once the participant has enrolled in the TMD Pain Study and been randomized to the PACT program or the control arm, the study coordinator will monitor compliance and adherence to the study protocol. The study coordinator will do this by monitoring completion of the baseline and follow-up questionnaires answer questions and the SRC will send reminders to participants, as needed. Compliance and adherence will be assessed by the number of on-line sessions that the study participants in both arms participate, data that will be collected each week by monitoring on-line access and health coaching reports.

## **5.10 Assessment of Subject Compliance with Study Intervention**

The assessment of subject compliance with study intervention corresponds to one of our feasibility aims (see section 3.2.b) Compliance and adherence to the study intervention will be assessed by the number of on-line sessions (or self-care materials accessed online by control arm) that the study participants in both arms participate in and self-reported program activities (PACT arm only), Information about the on-line sessions will be collected each week by monitoring on-line access.

## **5.11 Concomitant Medications/Treatments**

The study will allow the concomitant use of other TMD treatments such as medication, splints, and physical therapy. The use of these treatments will be monitored during study implementation. This will allow us to determine the likely extent of concomitant use of medication, splints, and physical therapy during the PACT program and, in the larger study, account for their effects in final analyses.

## 6 STUDY SCHEDULE

The Schedule of Events table, found in APPENDIX A, provides an overview of initial, intermediate, and final study visits (including all contacts with participants; e.g., telephone, website, screening, and other contacts) Two weeks is the acceptable time windows for each of the activities. If each phase is not completed within this 2 week window after consenting, the project manager will call the patient to remind them and determine if there are barriers to completion.

### 6.1 Screening (Week -1 Pre-Intervention)

After obtaining verbal consent, the TMD screener form (APPENDIX E) will be administered specific points of medical history, eligibility criteria, and contact information will be recorded. Screening will occur by telephone and the contact will be documented on the screening form. Inclusion and exclusion criteria will be reviewed and documented including the TMD screener form and exclusions such as serious co-morbid conditions or medical history that contributing to pain or prevent participation e.g. pregnancy, psychiatric disorder, or systemic pain disorder.

All potential participants will be given a verbal explanation of the study, and will be screened by phone to ensure eligibility. If they meet eligibility criteria, a packet of study materials (including an overview of the study, consent, and HIPAA privacy information) will be emailed to the potential participant, and their contact information will be added to the coordinator contact list.

### 6.2 Enrollment/Baseline Visit (Website Visit 1, Week 0)

1. The SRC will contact the participant to review the consent form, HIPAA privacy information, study information, and the risk and benefits for participation including the cost and compensation and will confirm understanding of the study information. If subject remains interested, a username and password to log into the study website will be emailed and the subject will be asked to read and electronically sign the informed consent within 1 week of the phone contact.
2. Following consent participants will be directed to complete the baseline questionnaire (APPENDIX G) electronically within 1 week of contact. This timeline is not required for study participation, if the subject completes the consent form and/or baseline questionnaires beyond the 1-week limit, they will still be enrolled in the study.
  - If the consent and baseline questionnaire are not completed within 1 week, SRC will call the participant to confirm their interest in enrolling and encourage participation.
  - Criteria in the baseline questionnaire must be negative prior to randomization.
3. When the consent is electronically signed and baseline questionnaire is completed and randomization will occur electronically through the website.

### 6.3 Intermediate Visits (8 weekly website visits during weeks 1 to 8)

Once enrolled in the study participants will be randomized to one of two arms.

1. *Traditional Self- Care*: control arm
2. *PACT*: Intervention arm

### **A. Traditional Self-Care Control Arm**

1. Participants randomized to the Traditional Self-Care arm will be electronically directed to the traditional self-care website landing page.
2. Traditional self-care material will be available for the participant to review via the website. This material is equivalent to what is typically given to patients in the dental clinic. Traditional self-care includes focusing on rest and healing through changes in chewing, diet, heat/cold, over the counter analgesics, and reducing strain from oral and sleeping habits.
3. Participant will also continue participate in usual care from their dentist such as a splint or anti-inflammatory medications as needed. Some patients may be under care of another healthcare provider, such as a physical therapist.
4. Adverse events will be recorded through the website assessments.

### **B. PACT Experimental Arm**

1. Participants randomized to the PACT care arm will be electronically directed to the PACT website landing page which explains each step of the process. Participants will complete the initial PACT assessment for each lesson. Based on the assessment, the PACT website will provide personalized training lessons for each participant.
2. Participants will also participate in weekly phone coach sessions.
3. Participants will complete each lesson on a weekly basis in order to focus on, understand, and implement the steps in each lesson. New material will only be made available to participants every 7 days.
  - a. If participants fail to complete a lesson, they will be prohibited from accessing all future materials until the missed lesson is completed, even if it takes more than one week.
  - b. Participants who fail to complete each lesson within a month will be called by the study coordinator to identify if problem exists and may result in study withdrawal.
4. Participant will also continue participate in usual care from their dentist such as a splint or anti-inflammatory medications as needed. Some patients may be under care of another healthcare provider such as a physical therapist.
5. Adverse events will be recorded through the website assessments.

## **6.4 Final Study Visits (Final Visits, Weeks 8 and 16)**

All participants will be asked to complete the final follow-up outcomes evaluation at 8 weeks from the beginning of the intervention and at 16-weeks (2 months after program end). This includes questions about any adverse events and outcomes as reported by the participants during or after the lessons.

Participants will receive weekly email reminders from the web-system to complete the post-intervention questionnaires. There is a 2-week window in the completion of questionnaires at the 8-week and 16-week post-intervention time periods. If the questionnaire has not been completed at the 2-week period, participants will receive up to 3 reminder calls from the study coordinator to identify the barrier to completing the questionnaires and facilitate its completion.

If after two more weeks of time have passed without completion, the questionnaire will be not evaluable, and therefore, considered missing data.

At the end of the 8 week outcome questionnaire, participants will complete several program evaluation questions. In addition, at least ten randomly-selected subjects will complete a semi-structured qualitative interview about their experience in the program.

### **6.5 Withdrawal Visit**

If a participant is discontinued before study completion, prior to withdrawal of consent and with the participant's permission, an Early Termination visit will occur. Each of the procedures described for the Final Study Visit will be performed at (specify timeframe).

### **6.6 Unscheduled Visit**

Study participants are encouraged to work with the health coach on a regular basis, and may contact the Study Coordinator (SC) during the study. All contacts with the SC will be documented in the study records. PACT subjects will be able to make unscheduled calls to the health coach to have questions answered; however, they will be scheduled for future telehealth visits.

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## 7 STUDY PROCEDURES/EVALUATIONS

### 7.1 Study Procedures/Evaluations

#### 7.1.1 Outcome Measure Questionnaires

The questionnaires that will be utilized are briefly described below. Copies of the questionnaires are reproduced in the appendix. All of the questionnaires are self-administered except for the qualitative interview which is conducted via phone by the study coordinator. For outcome measure questionnaires, responses will be recorded electronically through the study website.

Telephone Screen. This is a method used to screen for TMD pain. This questionnaire will be completed baseline and repeated at the final study visits.

Pain severity and Pain Interference. The Graded Chronic Pain Scale (GCPS) assesses 2 dimensions of pain: pain intensity and pain-related disability with mean intensity ratings for reported current, worst, and average pain.<sup>68-69</sup>

Jaw Functioning. Jaw Functional Limitation Scale (JFLS-8) identifies daily activities interfered with by jaw pain.<sup>40</sup> This 20-item instrument measures limitations across 3 domains: mastication (6 items), vertical jaw mobility (4 items), and verbal and emotional expression (8 items). Two items are not scored as part of these 3 subscales. A degree of limitation is rated on a 0-10 scale from 0 ("no limitation") to 10 ("severe limitation").

#### Hypothesized mediators

Self-efficacy. The Chronic Pain Self-efficacy Scale<sup>70</sup> is a 22-item instrument that measures a person's beliefs in their capabilities to produce a given outcome, particularly regarding compliance and adherence with self-care in reducing pain. For the pilot study, we will be using the 5-item Self-efficacy for Pain management (PSE) subscale of the Chronic Pain Self-efficacy Scale.

Participant activation. The Patient Activation Measure (PAM) is a 7-item instrument that gauges the knowledge, skills, and confidence essential to managing one's own health and health care.<sup>71</sup> PAM segments consumers into 1 of 4 progressively higher activation levels, including disengaged, becoming aware, taking action, and maintaining behaviors.

Exercise frequency. Type and frequency of conditioning exercises are measured using two questions from the Global Physical Activity Questionnaire. The questions measure exercise habits.<sup>78</sup>

Sleep quality. Quality of sleep is measured using four questions from the World Health Survey (WHO).<sup>77</sup>

Catastrophizing. The Pain Catastrophizing Scale is a 14-item instrument that will be measured at baseline.<sup>73</sup> Participants who cope poorly due to catastrophizing often have

negative outcomes.

Depression. The Patient Health Questionnaire (PHQ9) is a widely-used 9-item depression screen with questions covering the core DSM V screening criteria for diagnosing depression.  
74

Oral habits. The DC/TMD Oral Parafunctional Habits Scale measures frequency and duration of oral parafunctional habits that place repetitive strain on the jaw. 40

Perceived Stress Scale (PSS). This questionnaire assesses 10 sources of stress and produces an overall perceived stress rating and has been used to measure stress associated with chronic disease.<sup>75-76</sup>

Social support. The Social Support Questionnaire (shortened version) is a 6-item questionnaire designed to measure perceptions of social support and satisfaction with that social support. 72

## **7.1.2 Program Evaluation and Qualitative Interview**

### **7.1.2.1 Program Evaluation**

As part of the 8-week follow up survey, the program evaluation involves 7 close-ended questions to assess participant experience with the overall program and an additional 11 close ended questions for participants involved in the PACT program to assess satisfaction and perceptions of the program.

### **7.1.2.2 Qualitative Interview of Participants**

At least 10 randomly selected participants will be asked to complete the qualitative interview. The qualitative interview involves 9 open-ended questions to assess participants' satisfaction and perceptions of the program.

### **7.1.2.3 Website issues**

Phone calls and questions received about web-site issues will be documented throughout the study to assess functionality of the website.

## 8 ASSESSMENT OF SAFETY

We will implement a meaningful safety system for the study by considering the risks of the study intervention, study procedures as well as the characteristics of the study population (individuals with TMD pain). There are no risks to other individuals in the study such as health coaches.

Specifications of Safety Parameters that will be recorded by the Study Coordinator for each participant in their research record include;

- The study coordinator will be in frequent contact with the health coaches to identify any potential participant concerns with study staff.
- The participants also have the phone number for the study coordinator to call if a concern related to the study program arises.

### 8.1 Specification of Safety Parameters

#### 8.1.1 *Unanticipated Problems*

It is believed that risks to participants in the present study are minimal. Both traditional and PACT self-care is currently used by many TMD clinicians in the U.S. and abroad. It has been used with a wide variety of people, including adults with TMD and has been used in previous research with no reported risks to the research participants. The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- The research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

#### 8.1.2 *Adverse Events*

An **adverse event (AE)** is generally defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen. Adverse events are to be recorded regardless of their relationship to the study intervention.

#### 8.1.3 *Serious Adverse Events*

A **serious adverse event (SAE)** is generally defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.

The study intervention is a patient-centered self-management program for TMD pain. Potential participants with serious medical or psychiatric conditions are excluded from the study at initial screening. If study participants develop an increase in pain or other health concerns during the course of the study whether or not related to the study intervention would be considered an adverse event. The PACT program is a web-based, tailored 8-week program supported by a health coach to help enhance understanding, compliance, and success in self-management for TMD pain. There are self-report assessments at the end of each week throughout the entire program to monitor progress, compliance, adverse events, risk factors, and protective factors. If study subjects develop an aggravation of the pain or a new symptom that the subject attributes to the study intervention this would be considered an adverse event. This will be monitored by both self-report within the PACT program weekly assessments as well as by the dental professional who is caring for the patient. Adverse events will be reported to the Study Coordinator, the PI and the PO.

If participants screen for depression, we will provide a list of mental health providers who they can consult with to ensure their safety.

## **8.2 Events Qualifying as an Adverse Event or Serious Adverse Event for the Purpose of this Protocol**

Only those events considered to be related to the study intervention will be reported. A clinically significant change from the baseline in a pre-existing condition documented as screening will be reported as an AE if the change is considered at least possibly related to study intervention.

## **8.3 Characteristics of an Adverse Event**

### **8.3.1 Relationship to Study Intervention**

All adverse events will have their relationship to study intervention assessed and documented in the participant research record and will be included in summary reporting to the IRB and the PI. Evaluation of relatedness will consider etiologies such as natural history of the underlying disease, concurrent illness, concomitant therapy, study-related procedures, accidents, and other external factors. In a clinical trial, the study intervention must always be suspect. AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled for this study as:

1. (Definitely unrelated, definitely related, probably related or possibly related to the study intervention)
  - a. The event is known to occur with the study intervention.
  - b. There is a temporal relationship between the intervention and event onset.
  - c. The event abates when the intervention is discontinued.
  - d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
  - a. There is no temporal relationship between the intervention and event onset.
  - b. An alternate etiology has been established.

### **8.3.2 Expectedness of SAEs**

The risk information to assess expectedness will be obtained from preclinical studies, the investigator's brochure, published medical literature, the protocol, or the informed consent document. If an SAE occurs, the Safety Monitor, the NIDCR Medical Monitor and the Study PI will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention. This will be recorded in the participant research record and in summary reports of the study.

### **8.3.3 Severity of Event**

AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed "mild" if it does not have an impact on the patient, "moderate" if it causes the patient some minor impact and inconvenience and "severe" if it causes a substantial disruption to the patient's well-being.

This will be recorded in the participant research record and in summary reports of the study.

## **8.4 Time Period and Frequency for Event Assessment and Follow-Up**

The investigator will report all study intervention-related SAEs and related unexpected AEs with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit (or since the first procedure at the first active phase visit). The investigator will also review all source documentation related to study procedures for evidence of related AEs. Events will be followed for outcome information until they return to baseline or stabilize. Study intervention-related AEs will be followed until resolution or stabilization of the AE, after which the subject will be referred to a qualified clinician(s) for care and follow-up.

## **8.5 Reporting Procedures**

### **8.5.1 Adverse Events**

Study intervention-related AEs will be monitored throughout this study and recorded on a case report form at each visit. These events will be reported and reviewed by the PI as they occur, and reported to the IRB. DSM forms will be completed on a quarterly time frame for reporting and include summary reports of adverse events and others relevant to summary data will be reported to the DSM.

### **8.5.2 Unanticipated Problem Reporting to IRB and NIDCR**

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. This will follow the OHRP recommendations to include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;

- A detailed description of the adverse event, incident, experience, or outcome;
- An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will also be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: [rho\\_productsafety@rho-world.com](mailto:rho_productsafety@rho-world.com)

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231
- International: 919-595-6486

### **8.5.3 Serious Adverse Event Reporting to NIDCR**

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IRB, and NIDCR in accordance with requirements. Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NIDCR Program Officer within 7 days. Other serious and unexpected AEs related to the intervention will be reported to the NIDCR Program Official within 15 days. Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the IRB, and NIDCR in accordance with their requirements. In the annual AE summary, the PI will state that they have reviewed all AE reports.

SAE Reporting Contact Information:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998

- Product Safety Email: [rho\\_productsafety@rhoworld.com](mailto:rho_productsafety@rhoworld.com)

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231
- International: 919-595-6486

The study clinician will complete a Serious Adverse Event Form and submit via fax or email within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and submitted to Product Safety within 24 hours of site awareness.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by fax within 72 hours of site awareness.

All SAEs will be followed until resolution or stabilization.

The study coordinator will be responsible for compiling the data and producing the necessary reports, as well as assuring that all parties obtain copies of these reports. Adverse events will be reported and reviewed by Dr. Friction as they occur and reported to the IRB. The number of days by which a serious adverse event or unanticipated problem would be reported is 2 days. Summary reports of adverse events and others relevant to summary data will be reported to the PO at NIDCR. Reports will include description of study progress, subject recruitment, subject demographic data, subject status, and inclusion/exclusion criteria. These reports will be reviewed by the Principal Investigator and study team prior to presenting to NIDCR.

#### **8.5.4 Reporting of SAEs and AEs to FDA**

The study coordinator will be responsible for compiling the data and producing the necessary reports, as well as assuring that all parties obtain copies of these reports. Adverse events will be reported and reviewed by Dr. Friction as they occur and reported to the IRB. A serious adverse event or unanticipated problem will be reported in 2 days. These reports will be reviewed by the Principal Investigator and study team.

#### **8.5.5 Reporting of Pregnancy**

This study will exclude potential participants who are pregnant. If pregnancy occurs during the course of the study, we will follow the participant and make appropriate modifications to study procedures including discontinuation of self-care, if warranted by the treating dental provider or medical provider. We will also continue to conduct safety follow-up, by requesting permission from any pregnant women to pregnancy outcome.

### **8.6 Halting Rules**

Any SAE related to study intervention that results from the self-care protocols will be evaluated by the SMB to determine its' relationship to the protocols. If the safety finding is serious and directly related, this would prompt temporary suspension of enrollment and/or study interventions until a safety review is convened (either routine or ad hoc). The objective of the safety review is to decide whether the study (or intervention for an individual or study cohort)

should continue per protocol, proceed with caution, be further investigated, be discontinued, or be modified and then proceed. Suspension of enrollment is a potential outcome of a safety review.

Subsequent review of serious, unexpected, and related AEs by the Medical Monitor, IRB, the sponsor(s), or relevant local regulatory authorities may also result in suspension of further trial interventions/administration of study product at a site. The study sponsor(s) retain the authority to suspend additional enrollment and study interventions for the entire study, as applicable.

## **9 STUDY OVERSIGHT**

This study has been designated by the NIDCR as appropriate for standard oversight, which means that the Principal Investigators and the grantee institution take full responsibility for the conduct of the study, and will report progress annually during the grant period, using the usual format required for NIH progress reports.

The investigator will be responsible for monitoring safety and ensuring that the study is conducted according to the protocol and ensuring data integrity. The PI will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

## **10 CLINICAL SITE MONITORING**

Independent clinical site monitoring is not planned for this study however; the NIDCR reserves the right to conduct independent audits or clinical monitoring as necessary.

## **11 STATISTICAL CONSIDERATIONS**

### **11.1 Study Hypotheses**

The study hypotheses for this project are included as part of Objective 1, 2 and 3 in section 3 of the protocol.

### **11.2 Sample Size Considerations**

This is a pilot randomized clinical trial of the PACT program for TMD pain to determine feasibility and acceptability of methods and preliminary outcomes to power a multisite randomized clinical trial of its efficacy. The study is not powered to detect statistically significant intervention effects. For this study a sample size of 80 participants has been selected. This will provide an adequate sample for feasibility assessments and is in line with the constraints of available study resources and timing considerations related to the funding mechanism of the study. Comparisons done as part of the feasibility analyses of patient characteristics in each stage will serve as an alert to potential sources of bias in the study and will be used to inform refinement of the protocol for a larger study. Results from the pilot study, in conjunction with previous findings of behavioral interventions will be used to estimate the parameters needed for the study trial.

Our final target sample size for the pilot study will be a total of 80 consenting participants, with 40 in each arm. A 2014 query of patient populations from selected HPDG TMD providers using ICD codes (524.6x and 729.x) during a 6-month period identified 550 new patients with TMD pain who may qualify for participation. We anticipate that a minimum of 40% of participants will meet eligibility criteria for the TMD pain study and that a minimum of 40% of eligible participants who talk with recruitment staff will enroll and complete the entire study, leaving a total final sample size for the 2 arms of 110 to achieve the final sample size of 60 participants.

### **11.3 Interim Safety Review**

We do not expect any safety events because this is a minimal risk self-care intervention. However, the safety review plan will include quarterly reports of participant accrual, enrollment, adherences to the intervention and adverse events.

Study progress and safety will be reviewed following each recruitment and intervention phase – every 6 months. Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the PI and PO following each of the reviews. An Annual Report will be compiled and will include a list and summary of AEs. In addition, the Annual Report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The Annual Report will be sent to the PO and will be forwarded to the IRB and NIDCR. The IRB will review progress of this study on an annual basis.

### **11.4 Final Analysis Plan**

We will perform the following analysis and present results in preparation of the full study. The Primary outcomes for this study are acceptability and feasibility of the methods. The study is not sufficiently powered to test for mean changes from baseline to follow-up. Thus, we will conduct the following descriptive analysis at noted in the outcome measures:

- Number of participants, baseline characteristics and outcomes at baseline will be summarized descriptively
- Summary measures will include mean values (standard deviation SD) for continuous variables and frequency distribution for categorical variables.
- Outcome measures will be analyzed for departure of normality, and standard transformations will be applied.
- Percent of participants completing the measures for outcomes, mediating and moderating factors at baseline and each follow-up periods

The acceptability of the outcomes, mediating and moderating measures at baseline and follow-up periods

## **12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS**

There are five main data instruments:

1. TMD phone Screening Form
2. Baseline questionnaire
3. 8-week Post-intervention questionnaire with program evaluation questions
4. 16-week Post-intervention questionnaire
5. Semi-Structured Interview (subgroup)

Data collection will occur at multiple points across the study period, including eligibility screening, the baseline questionnaire prior to the start of the intervention, 1st post-intervention questionnaire (week 8), and 2nd post-interventional questionnaire (week 16). Data will be collected electronically in both arms.

Web-based activity will be tracked in several ways using hits on the web-site pages including:

1. accessing each module within the web-site
2. accessing each self-report risk assessments
3. each weekly pain and function assessments
4. accessing the interactive components of the website including benefit balloons and barrier bricks

Audio-recorded, transcribed, and coded coaching sessions will be used to assess fidelity to the PACT intervention.

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of participants. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

### 13 QUALITY CONTROL AND QUALITY ASSURANCE

Quality control is the ongoing, concurrent review of data collection forms for completion and logic. Quality assurance is a comprehensive, retrospective review of all components of research records to assess adherence to protocol, standard operation procedures, and regulations and to evaluate the accuracy of the records. Quality management is the process of assessing the quality of processes within a system and encompasses quality assurance and quality control.

The quality management program will include, but will not be limited to, the following:

- Dr. Brad Rindal will closely evaluate study processes and documentation based on NIDCR standards and the International Conference on Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP).
- Training of staff on the protocol, study procedures, and use of the data collection forms and systems
- Documentation and tracking of training for each staff member
- A Quality Management Plan that details the responsibility, scope, and frequency of quality management activities, including QM tools to facilitate the quality review of data, study essential documents, and other study-wide documents

Quality of data and data handling is described in section 16.

**Quality Assurance.** Staff for this study has a long history of experience with similar or larger research studies at HPI. Both the study coordinator and the staff within the HPI SRC have excellent history of quality data collection and have worked with Dr. Friction on other similar studies.

**Quality Control Committee.** The SRC has a manual of protocols and procedures that assure quality control of data collected by the Center.

**Metrics.** All data will be reviewed for completeness. Since assessment data is all entered electronically within the PACT website, accuracy and completeness of the data is maximize through alerts and pop-ups if the data is inconsistent or not entered.

**Protocol Deviations.** All deviations from protocol will be captured, documented, reviewed and addressed on an ongoing basis to insure integrity of the data.

**Monitoring Quality Assurance.** Dr. Friction will meet weekly with study staff to discuss study progress and problem-solve. The purpose of these meetings is to focus on the day-to-day operations of the project and to assure that all necessary tasks are completed in a timely fashion and strictly according to study protocol. Biweekly meetings will include all co-investigators and will address scientific issues, including refinement of conceptual models, strategies to streamline and deploy the interventions efficiently and effectively, and strategies to maximize both recruitment and retention of study participants, as well as methods to assure uniformity and fidelity to intervention protocols and data collection.

## **14 ETHICS/PROTECTION OF HUMAN SUBJECTS**

### **14.1 Ethical Standard**

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

### **14.2 Institutional Review Board**

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

### **14.3 Informed Consent Process**

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to potential participants. A consent form describing in detail the study procedures and risks will be provided via email to the potential participant. Consent forms will be IRB-approved, and the potential participant is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the potential participant and answer any questions that may arise.

The potential participant will sign the informed consent document electronically prior to any study-related assessments or procedures. Potential participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be emailed to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. The consent process will be documented in the research record.

### **14.4 Exclusion of Women, Minorities, and Children (Special Populations)**

Adult individuals of any gender or racial/ethnic group may participate if they meet the study inclusion and exclusion criteria. The study does not intend to enroll children, pregnant women, prisoners, or other vulnerable populations. Pregnancies may interfere with retention and study participation if the participant delivers during study participation and thus, pregnant women will be excluded. Teens (and children) are excluded due to the design of the PACT program. We will also conform to NIH policy on inclusion of women and minorities.

### **14.5 Subject Confidentiality**

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents. This confidentiality is extended to cover any study information relating to participants. The study protocol, documentation, data, and all other information

generated by the TMD Pain Study will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

If needed, study monitors and other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Confidentiality of study data will be ensured by assigning an arbitrary and unique participant identification number to each participant. All data collected in the study will be identified by participant identification number only. These data will be entered by identification number into the HPI computer database to which only the researchers directly involved in the study will have access. No protected health information (PHI) data will be included in the analytical dataset. No participant data will be individually identified or released to anyone other than the study investigators without specific written permission from the study participant.

Data will be stored within a secure folder on the research server with limited access to project team members. A file containing a link between the study ID and individually identifying information will be maintained at HPI by HPI members of the study team. All electronic study data will be maintained in a computerized database residing on a username and password protected file- server to which only the researchers involved in the study will have access. All study related paper documents containing individually identifiable information will be maintained in locked file cabinets within HPI

#### **14.6 Future Use of Stored Specimens and Other Identifiable Data**

De-identified study ID and no protected health information (PHI) data will be included in the analytical dataset. Data will be stored within a secure folder on the research server with limited access to project team members for the required timeframe. This study does not involve genetic testing or collection of specimens.

## **15 DATA HANDLING AND RECORD KEEPING**

The investigators in the TMD Pain Study will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Since most of the data collected will be through the secure PACT website, accuracy and completeness of the data is maximize through alerts and pop-ups if the data is inconsistent or not entered. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. We will also maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation. See a comprehensive Data Management Plan located in the Manual of Operations and a Data Management and Safety and Monitoring Plan in **APPENDIX J** below.

### **15.1 Data Management Responsibilities**

Data collection and accurate documentation will be the responsibility of all TMD Self-Care Study staff under the supervision of the PI. A programmer from HPI will develop our initial contact tracking database using REDCap (Electronic Data Capture) software to track all phone calls, contacts, and information for participants. All source documents and assessment reports will be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events will be reviewed by the investigator or designee.

### **15.2 Data Capture Methods**

Since assessment data is all entered electronically within the TMD Pain Study website, accuracy and completeness of the data is maximize through alerts and pop-ups if the data is inconsistent, out of range, or not entered. The database is centrally located with ongoing processing. The data entry procedures include a secure intra-net log-in that is password protected and data entry will have data quality checks with the electronic data system.

### **15.3 Types of Data**

Self-report assessment and outcome measure data that involve questionnaire responses are collected in the secure TMD Pain Study Website. Safety data are collected in a separate database related to each participant.

### **15.4 Schedule and Content of Reports**

Reports to monitor enrollment rate, will be generated each week by the data from REDCap Software and the TMD Pain Study website. These reports will be discussed at the weekly investigator meeting.

### **15.5 Study Records Retention**

Study records will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the NIH. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

### **15.6 Protocol Deviations**

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the

participant, the investigator, or study staff. As a result of deviations, corrective actions that address the non-compliance issue have been developed by the study staff and will be implemented promptly. These practices are consistent with investigator and sponsor obligations in ICH E6:

- Compliance with Protocol, Sections 4.5.1, 4.5.2, 4.5.3, and 4.5.4.
- Quality Assurance and Quality Control, Section 5.1.1
- Noncompliance, Sections 5.20.1 and 5.20.2.

All deviations from the protocol will be addressed in study participant source documents and promptly reported to NIDCR and the local IRB, according to their requirements.

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## 16 PUBLICATION/DATA SHARING POLICY

This study will comply with the [NIH Public Access Policy](#), which ensures that the public has access to the published results of NIH funded research. We will submit all final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](#) upon acceptance for publication.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

The ICMJE policy requires that all clinical trials be registered in a public trials registry such as [ClinicalTrials.gov](#), which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIDCR grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish. [U.S. Public Law 110-85](#) (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials:" *NIH grantees must take specific steps to ensure compliance with NIH implementation of FDAAA. These steps include;*

1. Determine if the competing application or funded grant supports an applicable clinical trial that is required under FDAAA to be registered in ClinicalTrials.gov
2. Include a certification of compliance in the competing grant application and progress report.
3. If the grant supports an applicable clinical trial, then determine which entity or individual is the responsible party
4. If the grantee is not the sponsor and therefore not the responsible party, contact the responsible party to ensure that the responsible party registers the trial and reports results as appropriate.
5. If the grantee is not the sponsor and therefore not the responsible party, contact the responsible party to ensure that the responsible party registers the trial and reports results as appropriate
6. The responsible party must regularly update information in the applicable clinical trial record.
7. If required, the responsible party must report summary results (including adverse event information) not later than 1 year after the trial completion date

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## SUPPLEMENTAL MATERIALS AND APPENDICES

- Appendix A. Schedule of Events*
- Appendix B. PACT Content and Text for Introductory Video*
- Appendix C. Traditional Self-Care Protocol*
- Appendix D. Health Coach Phone Protocol for PACT Arm*
- Appendix E. Telephone screen*
- Appendix F. Sample Consent Form*
- Appendix G. Data Collection Surveys at Baseline, 8 and 16 Week Post Intervention*
- Appendix H. Qualitative Interview*
- Appendix I. Barriers to use of Consumer Health Information Technology (CHIT)*
- Appendix J. Data Management and Safety Plan*

### APPENDIX A: SCHEDULE OF EVENTS

Below is a schedule of events that include initial, intermediate, and final study visits, and all contacts with participants, e.g., telephone, website, screening, and other contacts includes the permissible time windows for study visits, For each visit, the purpose and description of what will occur at the visit.

Contacts with participant	Identification Phase	Telephone Screening Phase	Consent Phase	Intervention Phase	1 <sup>st</sup> Post-Intervention Phase	2 <sup>nd</sup> Post-intervention Phase	Interview Phase
Time Period (weeks)	Week 1 Pre-	Week 0 Pre-	Week 0 Pre-	Week 1-8 Intervention	Week 8 Post-	Week 16 Post-	Week 16 Post-
EMR List of TMD patients	X						
Demographics information	X	X					
Inclusion/ Exclusion Criteria		X					
Recruitment			X	X			
Consent/ HIPPA Form			X	X			
Baseline Questionnaire			X	X			
Intervention Compliance/ adherence				X			
Coach support				X			
Outcomes Compliance/ adherence					X	X	
8 week Questionnaire					X		
16 week Questionnaire						X	
Qualitative interviews							X
Adverse Event Reporting				X	X		

## APPENDIX B: PACT CONTENT AND TEXT FOR INTRODUCTORY VIDEO

**Description.** The PACT program is an innovative self-management training program of care that focuses on integrating robust self-management training with a health coach to engage, empower and educate participants to reduce risk factors and enhance protective factors for the condition. In 2011, the Institute of Medicine (IOM) stated that health professional’s primary role for chronic pain should be guiding, coaching, and assisting participants with day-to-day self-management of chronic pain and established research involving self-management as one of the highest priority topics.

To support self-management, the use of web-based on-line programs has been applied to train participants in self-management for many chronic conditions, but has not yet been applied to participants with pain conditions such as TMD. The use of on-line training with health coaches have distinct advantages that require minimal change in work-flow and time commitment of busy health professionals while making the innovative care model affordable, rapidly deployed, scalable, and transferable to other settings and conditions.

**A. Background to the PACT program.** Humans are complex, multi-dimensional, and dynamic beings and live within an ever-changing physical and social environment that contributes to the balance between health and illness. Yet, our traditional biomedical model is based on a scientific paradigm that is uni-dimensional, reductionistic, and inflexible that is based primarily on understanding the underlying pathophysiology. Health care professionals tend to see what they treat and treat what they see. If they see only the pathophysiology, they do not recognize and understand the complex risk and protective factors that interact and play a powerful role in the onset, perpetuation, and progression of any illness. As a result, success of treatment is often compromised by limited approaches that only address part of the problem. When treatment approaches are limited, outcomes are limited. This explains why systematic reviews of efficacy of nearly every biomedical treatment for chronic illnesses have shown that even with the most efficacious treatments, they improve outcomes by only slightly above placebo. Patients have more influence over the outcomes of their illness than any treatment provided by clinicians. Thus, when evidence-based biomedical treatments are combined with robust self-management training, they have transformed the patient from one of illness to health and wellness– thus, the development of a transformative care model. The clinical paradigms associated with the PACT program are described in Table 1. This is the basis for the PACT program and its 8 lessons.

<b>New paradigm</b>	<b>Description and presenting concept</b>
Understand the whole patient	We need to identify all diagnoses, risk factors, and protective factors in the 7 realms of life (body, mind, spirit, lifestyle, emotion, social, and physical environment) to shift the balance from illness to health.
Each patient is complex	There are usually multiple conditions and interrelated contributing factors may initiate, result from, increase risk, or decrease risk of illness. Each need to be addressed as part of comprehensive management strategy.
Self-responsibility is	You have more influence on the problem than any treatment

key to recovery	provided. Will you take ownership and control of the condition?
Self-care	You will need to make daily changes in order to improve your condition. Will you be willing to take the time to do this?
Education and training	We will teach you how to make these changes.
Long-term change	Change only occurs over time and it may take months for the changes to have a large impact on reducing pain and symptoms.
Strong provider-patient partnerships	We, as health professionals, will support you as you make the changes. We can be an agent to help you change.
Personal motivation	Will you be able to make the changes needed?
Social support	You may need help to make these changes.
Change process	Change will occur incrementally over time.
Fluctuation of progress	Expect ups and downs during the recovery process.

**B. Components of the PACT program.** The total commitment time by patient to participate in the PACT program is about 1 hour of on-line education per week and 1 hour of activity per day for healthy habits and calming practice. In addition, there are several PAUSES during the day to pay attention to what is happening without judging in each of the 7 realms: Body, Lifestyle, Mind, Emotion, Spirit, Social life, and Environment (Table 2). The program includes the following components;

- ***PACT with the Patient.*** All patients make a commitment to the program by signing a PACT agreement with the health professional and the health coach. This highlights the patient's responsibility in complying with the self-management.
- ***Personalized Risk and Protective Factor Assessment.*** A self-assessment of the condition and its contributing factors is administered online or on paper, at home or in the office. The results are reviewed by the HCC to provide a personalized action plan to engage the patient in self-management, lifestyle changes and shared decision-making.
- ***PACT On-line training.*** Based on the assessment, experiential lessons are generated to recommend exercises and lifestyle changes to improve the condition, reduce risk factors for delayed recovery, and enhance protective factors that encourage healing. The PACT program for pain conditions consists for 8 Lessons designed for an 8-week program. Each lesson includes about 4 to 5 ten-minute video sessions for a total of about 50 minutes per week. They start with a brief self-assessment to personalize the recommendations followed with recommended video sessions based on the risk factors present and protective factors that are weak. The program includes both print handouts on the content and experiential daily changes that are recommended. A diary is provided to track daily practice and achievement in goals. The lessons are focused on understanding the big picture of their condition, how it can be improved by the balance between risk and protective factors in a person's life.

- **Animated Characters.** On-line training programs need to be brief, to the point, and engaging to have participants maintain interest over the 8 weeks of the program. One of the important elements is the animated characters that present the content. In PACT, we



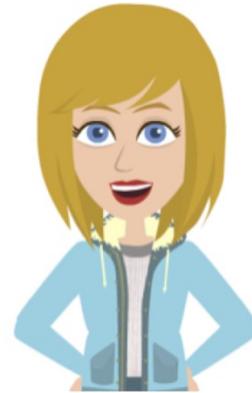
Professor Payne



Action Annie



Barrier Bob



Calming Kate

have 4 diverse characters with distinct positive personalities that present the content. Professor James Payne is a distinguished professor, researcher, and pain specialist who presents the lessons but also tells stories of the many patients he has managed over the years. Action Annie is a perky plain-speaking trainer whose main job is to help the participant implement their action plan within their lifestyle. Calming Kate is an experienced health professional who teaches mindfulness-based stress reduction with a calm voice, enlightening dialogue, and guided imagery. Barrier Bob is a no-nonsense barrier buster who helps participants identify and change barriers that may be confronted on the way to changing a person's health and life.

- **TeleHealth Coach (THC).** THCs are well-trained and certified health professionals who review assessments and provide self-management training to patients to facilitate their knowledge and skills necessary for self-management of chronic conditions. The process incorporates the needs, goals and life experiences of the patients and is guided by evidence-based interventions for the target condition.
- **Reminders.** Reminders can be sent through on-line platform on an opt-in basis for participants to schedule health coach visits, track progress, identify adverse events, or personalize self-management protocols. Participants have the choice of electronic options such as email, social media, and phone messaging.
- **Outcomes Dashboard.** The PACT website will provide updates of participant's progress and change in assessments as part of the PACT program.
- **Action Plan.** The action plan that is generated for each patient includes 3 components: Healthy habits, daily PAUSEs, and calming practice. Healthy habits means taking dedicated time each day to work on enhancing protective factors in order to decrease risk factors. PAUSE now means taking a time-out pause to check-in on what you are doing right now in a non-judgmental way. This is essential to living a life that is in the present and mindful of each protective factor to enhance health and well-being. P-pause, A-assess, U-understand, S-Start fresh, and E-energize with protective actions to achieve a long now.
- **Calming practice** includes spending a few minutes each day doing a brief relaxation technique allows many benefits. These include meditation to calm the mind, relaxing the muscles and nerves, contemplation about your life, prayer to ask for help, and reflection

on how you will move forward.

- **Support team.** Having friend or family team member who can support you and encourage you along your journey will help you be successful. If you haven't already, you will get another chance to sign up a teammate before you start Lesson 2, or can add one at any time using the team of your dashboard.

**Table 2. Description of the 7 realms in human systems approach to preventing chronic pain**

Realm	Description	Protective Factors	Risk Factors
<b>B</b> ody	Physical and physiologic aspects of the body	Balanced relaxed posture, stretching, strengthening, and conditioning exercise	Genetic risk, comorbid conditions, poor posture, tight weak muscles, hypo- or hypermobile joints, poor conditioning, and injury
<b>L</b> ifestyle	Lifestyles and behaviors that we do regularly	Protective diet, steady pacing, being active, regular sleep, low risk behaviors, high energy, and compliance with protective actions	Poor diet, sedentary life, prolonged sitting, poor sleep, hurrying/rushed, repetitive strain, high risk behaviors, chemical use, low energy
<b>E</b> motions	Positive and negative feelings we experience	Sustained positive emotions, such as joy, excitement, confidence, optimism, happiness, and contentment	Prolonged negative emotional experiences, anger, anxiety, sadness, fear, and depression
<b>S</b> ocial Life	Social relationships with the people around us	Positive relationships, social support, helping others, reward for recovery, eg, family, friends, colleagues, community, society	Poor relationships, conflict, abuse, posttraumatic stress, low social support, isolation, secondary and tertiary gain
<b>S</b> pirit	Higher beliefs and purposes that drive us	Purpose, direction, beliefs, faith, hope, self-compassion, and self-esteem	Stress, burnout, disbelief, cynicism, doubt, helpless, and hopelessness
<b>M</b> ind	Thoughts and attitudes	Whole understanding, resilience, self-efficacy, self-control, accepting responsibility, realistic expectations, and engaging in active coping	Ignorance of problem, low resilience, low self-efficacy/control, refuse responsibility, poor compliance, unrealistic expectations, and passive coping
<b>E</b> nvironment	Physical environment that surrounds us	Clean, organized, safe environment, and an approach that is protective, cautious, and careful	Living within an unclean, chaotic, and disorganized environment with activities that are negligent, dangerous, risky, and increase risk of injury, accident, and trauma

### C. Lesson Content

#### Lesson 1. Understanding Pain: The balance between health and illness.

“The good physician treats the disease; the great physician treats the patient who has the disease.”- Sir William Osler. This lesson helps patients understanding their big picture of their health and illness and how risk factor and protective factors in each realm of our life can play a role. Several concepts are explained in simple ways for patients to understand and are integrated into the PACT program and explained in this first lesson in a simple format.

- *Human System's Theory (HST)* explains the importance of understanding the whole person who has chronic pain and all risk and protective factors that contribute to their health or illness and not simply the physical and pathophysiologic. The whole becomes greater than the sum of its parts. Seven realms of our lives include the mind, body, and spirit that interact with the social and physical environment through behavioral and emotional processes.
- *Cybernetics* explains how specific factors can generate a change which leads to either positive or negative feedback to the whole system. Thus, each realm of our lives are connected to the others and influences whether we maintain health or develop an illness.
- *Chaos Theory* explains how small differences in initial conditions of the dynamic human system will often yield widely diverging outcomes. This suggests that the "little things" we do every day of our lives matter significantly over time to determine if we maintain health or develop chronic pain or illness. When applied to of multiple risk and protective factors have a large chronic illness. However, when these factors are combined they will accelerate the condition dramatically.
- *Behavioral medicine theories* suggests that many chronic diseases have a behavioral component and these illnesses can be significantly and directly modified by behavior to supplement pharmacological or surgical treatments.
- *Cognitive-behavioral therapy (CBT)* has been shown to be very effective for changing lifestyle factors that lead to chronic pain. *The principles of Positive Psychology* are also presented in these lessons suggesting that it is as effective to enhance protective factors through cultivating positive behaviors and virtues as it is with weakness and vices. Therapy is directed at improving the positive aspects of lives of normal people such as happiness, health, and wellness as much as healing illness, pain, and dysfunction.

The sessions include;

1. Introduction: How the program works. Understanding chronic pain: why it is such a problem for people, and how to best manage it. Understanding your pain by taking the self-assessment
2. Understanding ourselves: The big picture of health and illness and the pain cycles and balance that occur between risk factors and protective factors. How little changes can have a big impact. Assess your risk and protective factors and the goals of how we want to be.
3. Conditions: a summary of musculoskeletal, neuropathic, and neurovascular pain disorders
4. Treatments: A review of pain treatments including medications and opioids, how to use them, their relative efficacy from systematic reviews in a simple easy to understand format. Preventing medical and dental treatment risks and chronic pain
5. Causes: Review of the most common onset and perpetuating factors for chronic pain conditions
6. Self-management: Training on self-management to be integrated with treatments to ensure pain problems are optimally managed. Using trigger point massage.
7. Self-care for pain conditions
8. Action Annie: Taking action with healthy habits, daily pauses, and calming practice

9. Barrier Bob: Identifying barriers with solutions to ensure long-term compliance
10. Calming Kate: Reviewing the principles and strategies for calming practice to calm the brain, relax the body, and gain insight into their lives.

### Lesson 2 Body: Exercise, posture, and reducing strain.

This lesson focuses on the physical and pathophysiologic aspects of the body. Protective factors include balanced posture, relaxation exercise, stretching exercise, strengthening exercise, conditioning exercise, and genetic factors. Risk factors include poor posture, tense tight muscles, hypo- or hyper-mobile joints, weak muscles, and poor conditioning.

The sessions include;

1. Introduction to Your Body
2. Assessment of physical risk and protective factors
3. Stretch and strengthen: Feeling good each day
4. Reducing strain: Preventing Pain
5. Posture and Relaxation
6. Fitness for Relief
7. Case illustration
8. Action Annie: action plan for stretching, strengthening, and fitness. Taking pauses to scan for posture and strain
9. Barrier Bob to overcome barriers to exercise with specific solutions
10. Calming Kate for relaxing the body

### Lesson 3 Lifestyle: Diet, sleep, and energy.

This lesson focuses behaviors and actions that we do on a daily basis that play a role in chronic pain. Protective factors including diet, activity level, sleep, pacing, variation in lifestyle, low risk behaviors, and how dietary supplements can be used. Risk factors include poor diet, inactivity, prolonged sitting, poor sleep, hurrying/ rushed, repetitive strain, high-risk behaviors, and adverse events from chemical use. Sessions include

1. Introduction to your lifestyle and lifestyle cycles
2. Assessment of your lifestyle risk and protective factors
3. Active Lifestyle: Maximizing the lifestyle treadmill
4. Pain-free Diet: Diet, nutrition, weight, and eating disorders in chronic pain
5. Restful Sleep to Prevent Chronic Pain
6. Substance Use and Abuse: Preventive use of substances, smoking, and illicit drug use
7. Case illustration
8. Action Annie: action plan for diet and sleep. Taking pauses to check-in on substance use and pacing.
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

### Lesson 4 Mind: Improve understanding, self-efficacy, and resilience

This lesson focuses on the thoughts and attitudes that we experience and how they impact chronic pain, health, and well-being. Protective factors include understanding whole problem, resilience and ability to rebound, self-efficacy and self-control, accepting responsibility, compliance, realistic expectations, and active coping. Risk factors include ignorance of

problem, low resilience, low self-efficacy/ control, denying responsibility, poor compliance, unrealistic expectations, and passive coping.

Sessions include;

1. Introduction to your Mind and your mind cycles
2. Assessment of cognitive risk and protective factors
3. Resilience & Coping: bouncing back from adversity
4. Everyday Optimism: Change your mind: Change your pain
5. Self-Efficacy: You can do it.
6. Realistic Expectations:
7. Case illustration
8. Action Annie: Steps to boost understanding, self-efficacy, and resilience. Taking pauses to check-in on automatic thoughts, understanding, expectations
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

#### Lesson 5 Emotions: Managing emotional challenges and pain.

This lesson focuses on the personal expressions of feelings that we experience and how they play a role in chronic pain. Protective factors include emotional experiences such as feeling joy, confidence, calm, happiness, contentment, and optimism. Risk factors include anger, anxiety, nervousness, sadness, and depression. Emotions can fluctuate daily and even hourly depending on the situation. Like pain in different areas of the body, it is important to recognize and talk about emotions, both positive and negative, and the reasons we have them. When do we feel happiness, contentment, calmness, excitement, passion or other emotions? On the other hand, when do we feel sadness, anxiety, depression, anger, or fear? This module allows us to focus on the activities and relationships that bring more positive emotions, which reduces chronic pain, than negative emotions that increase pain. In addition, pay attention to and ask about emotions in other people. "How do you feel?" Sessions include;

1. Introduction to your emotions: the volume control on chronic pain,
2. Assessment of emotional risk and protective factors,
3. Lifting Depression & Sadness,
4. Calming Anxiety & Fear,
5. Resolving Anger & Frustration
6. Overcoming Guilt & Shame
7. Case illustration
8. Action Annie: Harnessing positive psychology, creativity, and emotions for healing. Taking pauses to check-in on emotions.
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

#### Lesson 6 Spirit: Purpose, passion, and pain

This lesson focuses on how purpose, beliefs, and passions that drive our health and wellness and how this can either drive stress, burn-out, and chronic pain or protect us from it. Protective factors include self-compassion, self-esteem, purpose and direction in life, beliefs, faith, hope, and optimism about the future. Risk factors include stress and burnout, disbelief/ cynicism, doubt, hopelessness, pessimism, feeling lost, meaningless in life, hate, loathing, and low self-esteem. Sessions include;

1. Introduction to Your Spirit and Brain neuroplasticity

2. Assessment of spirit risk and protective factors
3. Healing Power of Purpose and Passion
4. Self-Compassion: Coming back to yourself and the efficacy of self-compassion
5. Finding Hope & Faith in recovery
6. Grit & Determination
7. Case illustration
8. Action Annie: Harnessing positive psychology, creativity, and emotions for healing. Taking pauses to check-in on emotions.
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

### Lesson 7 Social Life: Social support for recovery

This lesson focuses on the people that surround us on a daily basis and how this social environment can impact chronic pain, health, and well-being. Protective factors include helping others, creating harmony and peace, social support and it's characteristics such as being tolerant, flexible, and treated as a healthy and well person even when illness to avoid secondary gain. Risk factors include being self-centered, conflict, abuse, post-traumatic stress, lack of support, secondary and tertiary gain, being intolerant and demanding. Sessions include;

1. Introduction to your Social life and impact of social relationships on the brain,
2. Assessment of social risk and protective factors,
3. Social Support and its healing potential
4. Love & Belonging
5. Work Well-being: Disability, secondary gain, and the socioeconomics of pain
6. Releasing Social Stress: Abuse, conflict, Post-traumatic Stress as Pain Amplifiers
7. Case illustration
8. Action Annie: Getting and giving the social support we need. Taking pauses to check-in on relationships.
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

### Lesson 8 Environment: Creating a safe and protective environment

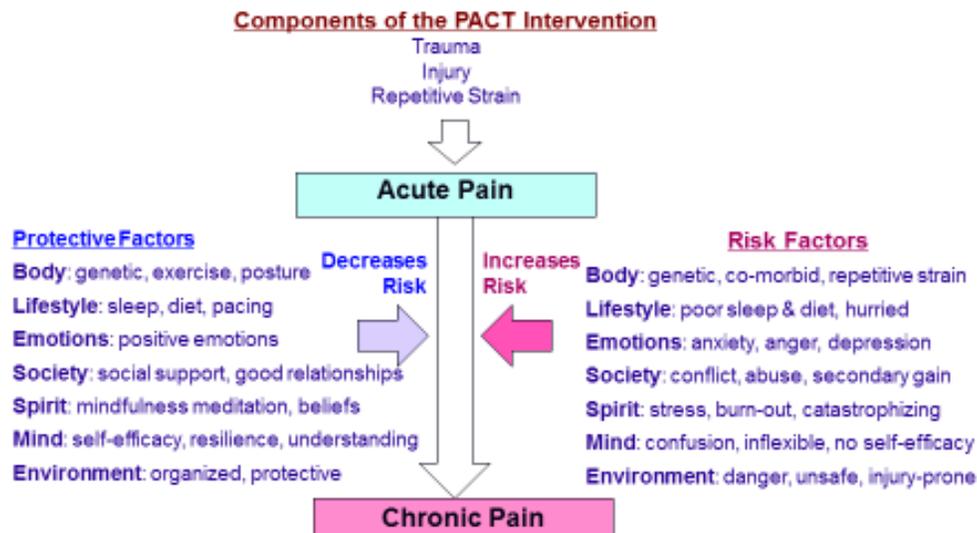
This lesson focuses on factors in the physical environment that surrounds us and interact with every day. It can be both natural and man-made and can have a large impact on chronic pain as well as our health and well-being. Protective factors include how to create a clean, organized, and safe surrounding that is protective and careful of our health and well-being and not lead to injury and pain. Risk factors include living within an infectious, unclean, negligent, and chaotic physical environment that can be dangerous, threatening, accident- and injury-prone that may injure us and cause chronic pain to persist.

Sessions include;

1. Introduction to Your Environment
2. Assessment of environmental risks and their impact on chronic pain
3. Safe Living: Preventing accidents and chronic pain
4. Decluttering Your Life
5. Clean & Healthy: Preventing infection with cleanliness
6. Living Pollution Free
7. Case illustration

8. Action Annie: Protect yourself: conduct an environmental scan of risk factors. Taking pauses to check-in on your environment for safety
9. Barrier Bob to overcome barriers to lifestyle problems with specific solutions
10. Calming Kate for maximizing your lifestyle

## Protective and Risk Factors of the PACT Intervention



### The PACT program website

The goal of the PACT TMD web application is to provide a smooth, easy to navigate and rich user interface to the participants enrolled in the TMD Pain Study and to the health coaches, study coordinators and investigator.

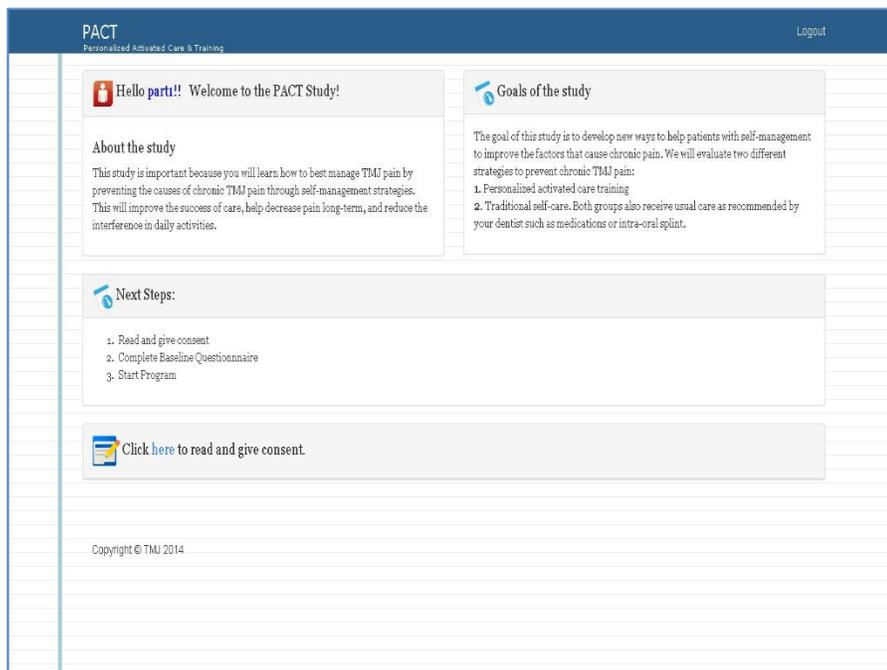
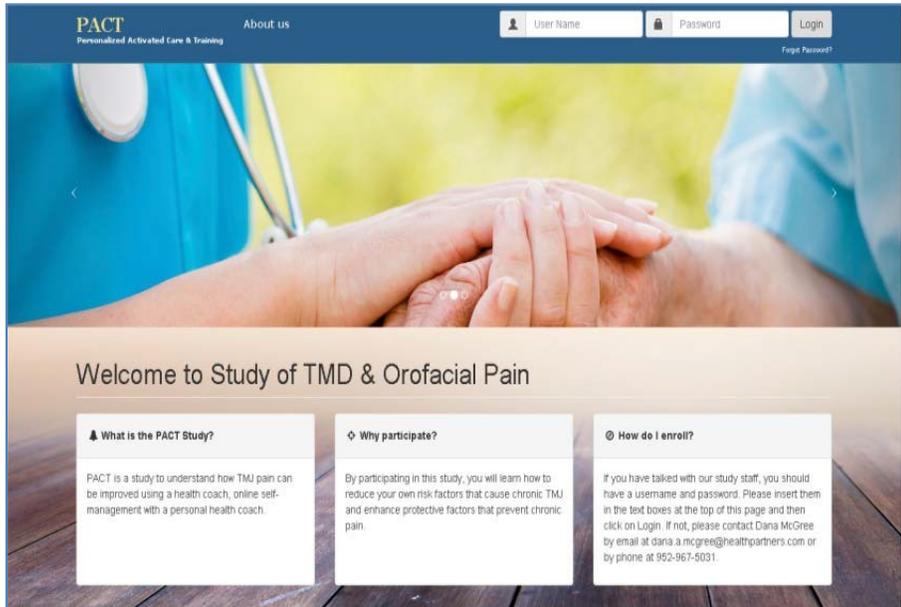
*System Architecture/Infrastructure:* This application provides secure anywhere/anytime remote access to all stakeholders. It is compatible with portable devices such as tablets and smart phones. This application uses 3-tier architecture standards with browser based front end thin client, Apache Tomcat application server as middleware and Oracle relational database as the backend platforms. Java, J2EE constitutes application's knowledge base. Application utilizes the J2EE based MVC (Model View Control) architecture to handle the application request-response workflow and supports JSP. Application is compatible with OSGi based J2EE containers to ensure security, modularity and services. Application strongly adheres to the OO (Object Oriented) Design principles and uses J2EE design patterns. Application interfaces with REDCap system to pull the user information. Application uses Single Sign-on (SSO) capabilities for easy login using unique username and password. It uses Spring Security framework for User Management and Role based access. Application uses jQuery, Bootstrap framework, Ajax, JavaScript to create visually appealing GUI (Graphical User Interface). Application provides reports on user behavior and user progress on the study modules. Reports can be generated using standard reporting tools and analytics such as Oracle SQL/PL SQL and jFree chart for visual representation of reports. Application is scalable to accommodate additional utilization or load, users and additional local/remote sites. Application's majority tools and technologies are open source and it follows agile methodology for the development. Application implements Log4j framework to log critical application activities. Application uses JUnit framework for unit testing. Application evaluation is done using Functional, Usability, Interface, Compatibility, Performance and Security testing strategies. Before application goes live, it will go through UAT (User Acceptance Test) phase

to address any issues. Application can be monitored via alerting and monitoring tools that send notification to the system administrator whenever the application becomes inaccessible. Application uses open source version control system like SVN for source code version maintenance.

Application development uses the following tools/technologies/languages: Java, J2EE, JSP, Spring MVC Framework, Spring Security Framework, J2EE design patterns, jQuery, AJAX, Bootstrap framework, JavaScript, Oracle SQL/PLSQL, Log4j, jFree chart, JUnit, Apache Tomcat V7.0, Shell script, SVN, REDCap.

*Control Flow:* User log-in to the system using their unique user-id and password. For study participants after login, system presents a brief intro of study along with consent form. User gives his/her consent which is stored in the system data base; system then navigates to initial baseline survey form. Upon successful completion of the survey the survey results are stored in the database and based on pre-identified criteria system randomly assigns user to Usual-self-care arm or PACT arm; system takes user to their respective arm's program page. In the program page user has the opportunity to learn through the study modules. Based on user arm type, study modules present self-management lessons in the form of videos or slides. Once user completes the modules, then system prompts user to complete periodic (2month, 4month) surveys. The survey responses are stored in database and analyzed later to understand how the program has helped participants in improving TMD pain. Users of the application can use the contact information provided in the consent form to contact study coordinator in case of any navigation issues or application accessibility issues. Users can get new password/reset one using "forgot password" links.

## Screen shots of the PACT website

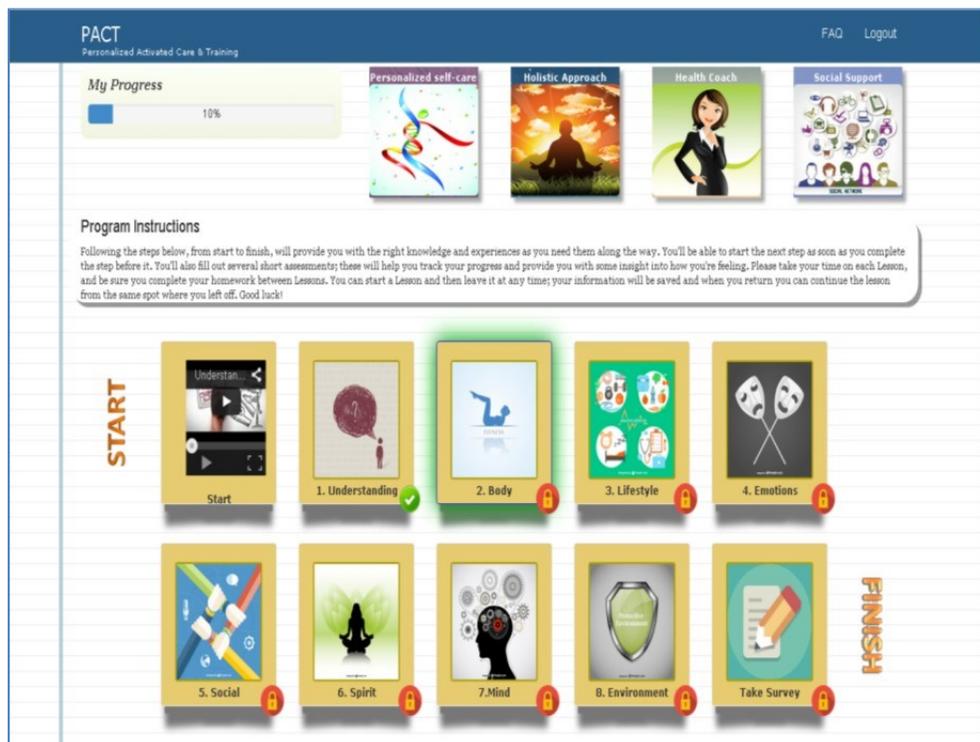
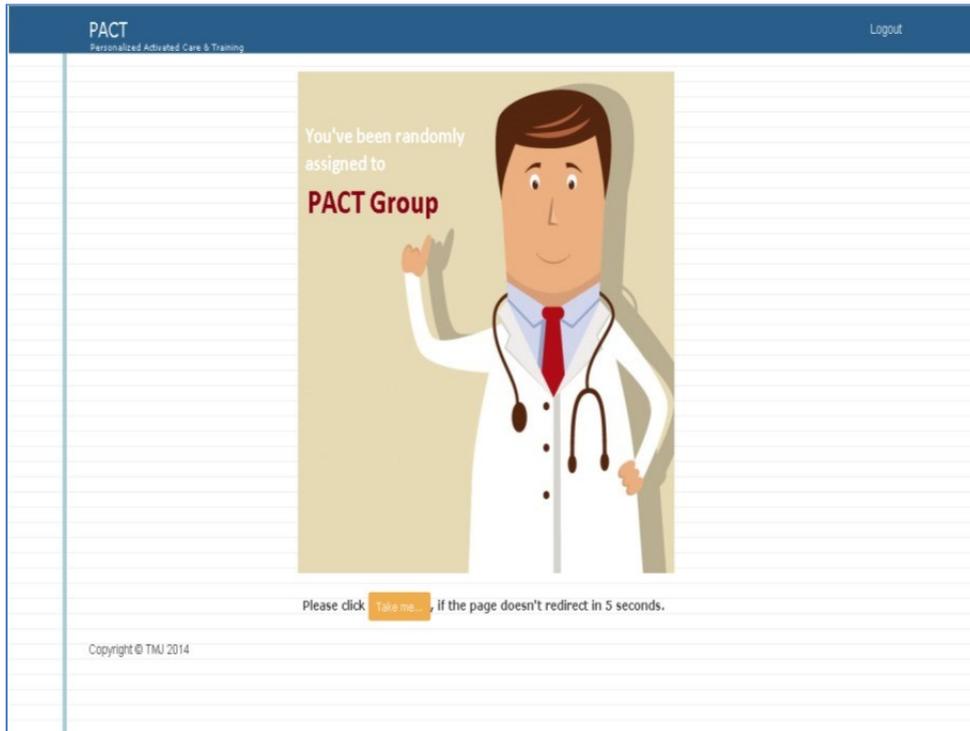


The screenshot shows the PACT web application interface. At the top, there is a blue header with the PACT logo and a 'Logout' link. Below the header, a navigation bar contains a 'Start Program' button. The main content area features a link to read and give consent, followed by the title 'ELECTRONIC CONSENT FORM' and the subtitle 'Self-management training for temporomandibular disorders'. The text of the consent form includes an invitation to participate, a description of the study, the study purpose, and the study procedures. At the bottom of the page, there is a copyright notice for TMJ 2014. The footer of the application includes the PACT logo, the text 'Personalized Activated Care & Training', and 'Start Program' and 'Logout' links.

## Frequently Asked Questions

The screenshot shows a 'Frequently Asked Questions' section. The first question is 'What's up with chronic pain?'. The answer states that chronic pain conditions are the 'big elephant in the room' of health care and lists several facts: they are the most prevalent chronic conditions; they are the primary driver of health care, costing more than diabetes, cancer, and heart disease combined; with at least 120 million U.S. adults suffering from chronic pain, it has become the primary reason for seeking health care; half of all visits are attributed to some type of chronic pain; it costs society an estimated \$800 billion in health care and lost work; and this is equivalent to about 25% of the total cost of health care and nearly 5% of the total U.S. gross national product (GNP). A photograph of a large elephant in a room is included. Below this are several other questions with expandable answers: 'How can chronic pain impact our lives?', 'What can we do to solve this?', 'What are temporomandibular disorders (TMD)?', 'What causes chronic TMD pain?', and 'Why do some patients fail to get better with treatment?'.

### Sample screen shots of the PACT Program Arm.



PACT Personalized Activated Care & Training Logout

You've been randomly assigned to  
**Usual Self-Care Group**



Please click [Take me...](#) if the page doesn't redirect in 5 seconds.

Copyright © TMJ 2014

PACT Personalized Activated Care & Training FAQ Logout

**Program Instructions**

Following the steps below, from start to finish, will provide you with the right knowledge and experiences as you need them along the way. Please take your time on each Lesson. You can start a Lesson and then leave it at any time and when you return you can continue the lesson from the same spot where you left off. Good luck!

**START**

- Start
- 1. Rest
- 2. Heat/Cold
- 3. Analgesics
- 4. Jaw Position
- 5. Habits
- 6. Exercise
- 7. Sleep
- 8. Diet
- Take Survey

**FINISH**

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[www.youtube.com/PACT introductory video](http://www.youtube.com/PACT_introduutory_video)

Slide	Text
1. Intro	Welcome to the PACT study and thank you for participating. Hi My name is James Friction and I am the principal investigator and a pain specialist who cares for and about patients with pain conditions.
2. PACT	PACT stands for Personalized Activated Care and Training. This study is about determining the best ways to help people prevent chronic pain from temporomandibular disorders or TMD.
3. face	The study is funded by the national Institutes of Dental and Craniofacial Research of the National Institutes of Health
4. Big Elephant	Chronic pain is the big elephant in the room of health care. It is the #1 cost driver of health care costs...costing more the diabetes, cancer, and heart disease combined.
5. #1	And it impacts nearly every person's life. It has become # 1 chronic condition, the #1 reason for going to the doctor, and the #1 cause of disability, work loss, addiction and overdosages.
6. TMD pic	TMD is one of the most complex pain disorders. The number of different symptoms are not surprising knowing that there are more nerves per area than any other area of the body.
7. \$	Billions of dollars are spent on chronic pain, but the majority of those with pain over 1 month, still have pain 5 years later, despite the most innovative, extensive and expensive treatments.
8.	What does the PACT study help improve this?
9. Root	Research has shown that success in treating chronic pain is most successful if we change the root cause of the problem.
10.	This means reducing the risk factors that cause chronic pain while also enhancing the protective factors that improve recovery from pain
11.	It's about changing the little things in our lives that cause chronic pain such as habits, stress, and posture.
12.	Thus, we designed the PACT program to help people prevent chronic pain through self-management. This study is designed to evaluate how different versions of self- management work.
13.	How do we do this? Well, it starts with you. The person with pain.
14.	We do this with engaging each participant in self-care
15.	Educating to know what to do to relieve the pain
16.	Empowering the participant: They have more control than any passive treatment
17.	Reducing the strain
18.	Healing the tissues
19.	And relieving the pain
20.	Thank you for participating

## APPENDIX C: TRADITIONAL SELF-CARE PROTOCOL



### Self-care tips for helping temporomandibular disorders (TMD)

Jaw pain and difficulty with jaw movement are common signs of problems with the temporomandibular joint (TMJ) or jaw muscles. These problems as a group are called temporomandibular disorders or TMD. You can often improve these problems with some basic home care.

1. **Try moist heat:** Moist heat can be especially helpful for sore muscles. Apply heat to the painful area of the jaw for 15 to 20 minutes, three to four times a day. Try using a wet towel over a hot water bottle, a gel-type heat pack, or a wet washcloth heated in a microwave. *Take care to avoid burning your skin.*
2. **Try ice:** Ice treatment is often helpful if you have a sore jaw joint. Place an ice cube directly over your jaw joint in front of your ear. Move the ice cube over the jaw joint for four to five minutes. *Take care to avoid frosting your skin.*
3. **Eat a soft diet:** A simple rule of thumb is to avoid chewing foods that make the pain worse or cause your jaw to “click.” Cook foods to a soft consistency and cut into smaller bites. Try to avoid biting off pieces of food with your front teeth. Place smaller pieces of food directly in the back of your mouth and chew on both sides to avoid overloading one side.
4. **Avoid chewing gum:** Do *not* chew gum. Chewing gum puts a lot of pressure on your jaw joints for long periods of time.
5. **Practice good jaw position:** The normal resting position of your jaw is to have your teeth slightly separated, and the tip of your tongue in the roof of your mouth behind your front teeth. This is a *relaxed* position with no tense jaw muscles. Your teeth should only touch when you chew or swallow. Check your jaw position several times during the day to make sure you are *not* clenching your teeth.
6. **Practice good jaw habits:** Do you have any habits that may make your jaw problem worse? Ask your family or friends to let you know if they see you doing any of the following: clenching or grinding your teeth, biting your lip or your cheek, biting your fingernails or a pen, or thrusting your jaw forward and bracing your jaw, even with your teeth apart.
7. **Talk to your dentist at appointments:** Tell your dentist or hygienist if you have been having problems with your jaw. Avoid holding your mouth open for long periods during the exam.
8. **Avoid caffeine:** Avoid drinking a lot of caffeinated beverages, such as coffee or colas. They can contribute to jaw muscle tension and pain. Aim for two or less caffeinated beverages a day.
9. **Try a new sleeping position:** Try *not* to sleep on your stomach, as this can put pressure on your jaw.
10. **Use medications as necessary:** Over-the-counter medications such as ibuprofen, aspirin or Tylenol<sup>®</sup> can be helpful in reducing your jaw pain. Take these medications as prescribed on the product instructions.

## Soft diet for temporomandibular joint pain

Good nutrition is very important for good health and well-being. If you are having jaw pain or difficulty chewing, you will need to modify the texture of your diet while maintaining an adequate nutrient (carbohydrate, protein, vitamins, minerals) and caloric intake.

Daily *minimum* food group requirements for adults include:

- 4 servings from the grains group
- 4 servings from the vegetable and fruit group
- 2 servings from the meat and protein group
- 2 servings from the milk group (4 servings for teenagers and young adults)

The following chart is designed to help you make healthy food choices.\*

<b>Food Group</b>	<b>Allowed</b>	<b>Avoid</b>
<b>Grains</b> (at least 4 servings/day) <b>Bread or rolls</b>	All plain, easy to chew.	Bread or rolls made with hard crust, seeds or nuts. Bagels.
<b>Crackers</b>	All plain, easy to chew.	Seeds or nuts.
<b>Cereals</b>	Cooked cereals: cream of wheat, cream of rice, Malt-O-Meal™, oatmeal. Dry cereals: corn, rice,	Granola or cereals that are advertised as “high fiber.”
<b>Potatoes/Pasta/Rice</b>	Mashed, baked (without skin), and creamed potatoes. Macaroni, pasta, rice, hominy.	Potato skins, wild rice, popcorn
<b>Vegetables</b> (at least 2 servings/day)	Cooked, tender vegetables; tomato and vegetable juice. Tender lettuce, tomatoes.	Raw vegetables.
<b>Fruit</b> (at least 2 servings/day)	All fruit juices. Raw fruits: soft, peeled such as banana, orange, peach, apricot or nectarine. Canned or cooked fruits without tough skins or membranes.	All other fresh fruit. Dried fruit.

*\*This material has been adapted from the Twin City District Dietetic Association manual.*

*Continued*

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## APPENDIX D: HEALTH COACH PHONE PROTOCOL FOR PACT ARM

The Health Coach will assist patients who are participating in the PACT program by assessing, educating, and supporting patients in self-management to prevent chronic pain. The Coach will interact with patients through an on-line video conferencing, by phone, or through the Integrated Resource Information System (IRIS). Patients will be trained in reducing risk factors and enhancing protective factors for their pain condition. The Coach will be responsible for developing a health coaching relationship with them and assisting the patient through the process of care by actively working towards better health by providing support, encouragement, and education.

Health Coaching is relationship-centered, client-driven process designed to facilitate and empower a client to achieve self-determined goals related to health and overall well-being. While these goals may be informed by or suggested by others, such as an individual's physician or other health provider, the selection of the goal and exploration where one is relationship to the goal is up to the client. Individuals may be just beginning to consider a change, may be exploring aspects of preparing for a change, or may be ready to implement actual actions. In a safe and consistent space, clients can explore their thoughts, emotions, and actions, in a way that allows them to recognize the power of their own choices to impact their wellness.

Health Coaching is a methodology that differs from health education or counseling or therapy, though it can work well in combination with those other practices. Health Coaches assume that people have strong intrinsic resources and strengths, can access the self-motivation needed to function autonomously and competently, and are able to realize positive change within a safe and confidential alliance, where they are inspired, respected, and supported. By applying clearly defined knowledge and skills, they support individuals or groups in mobilizing their internal strengths and external resources to achieve sustainable changes in beliefs or behaviors. Health Coaching has the potential to help individuals, families, and groups achieve improved health and wellbeing.

### **Important Components of Health Coaching include;**

*Building a relationship.* Health coaching is relationship-centered, client-driven process designed to facilitate and empower a client to make changes that will help them achieve self-determined goals related to health and overall well-being. Health Coaching is a methodology that differs from health education, counseling or therapy, though it can work well in combination with those other practices. Health coaches facilitate the following;

*Setting goals.* While a person's goals may be informed by the condition, such as to reduce the pain, or suggested by others, such as a health professional or the on-line training such as to exercise, the health coach will help with selection of the goal and exploration where one is relationship to the goal is up to the client.

*Facilitating Change.* Individuals may be just beginning to consider a change, may be exploring aspects of preparing for a change, or may be ready to implement actual actions. In a safe, consistent, non-judgemental, and supportive space, clients can explore their thoughts, emotions, and actions, in a way that allows them to recognize the power of their own choices to impact their wellness.

*Empowering people.* Health coaches assume that people have strong intrinsic resources and strengths and can access the self-motivation and energy needed to accomplish their goals.

*Engaging responsibly.* Health coaches assume that people will function autonomously and competently, and are able to realize positive change within a safe and confidential alliance with the health coach. The coach relationship is one of inspiration, respect, and non-judgmental support.

*Achieving goals.* By applying clearly defined knowledge and skills, the health coach can support individuals or groups in mobilizing their internal strengths and external resources to achieve sustainable changes in thoughts, emotions, and behaviors. Health Coaching has the potential to help individuals, families, and groups achieve their goal of improved health and wellbeing.

*Coach Protocol.* Once the participant has enrolled in the PACT Study and been randomized to the PACT program, the phone coach will contact participant by telephone at varying intervals (see table 1). The role of the coach is to help the participant clarify their goals and identify strengths, resources, and barriers related to behavioral changes using motivational interviewing techniques. Coaches may also encourage completion of weekly educational module content and to inquire about the usefulness of the information, but that is a secondary focus.

## **RESPONSIBILITIES**

(include but are not limited to): The 4 basic responsibilities would be to 1) facilitate the patient's process of tapering the opioid medications and use of alternative medical management, 2) enhance understanding and compliance in self-management training for their condition address risk factors, and strengthen protective factors, 3) ensure patient is following up with health care provider for medical management, and 4) improve follow-up, outcomes, and quality of care. Thus, a health coach would also be working directly with the patients to help with the following;

- 1) Call the patient for an initial consult using video conferencing such as Skype, if available. An in-person meeting can be arranged also as needed
- 2) Understand the process of tapering opioids and replacing with alternative medical management interventions.
- 3) Understand addiction medicine and the patient-centered barriers and problems associated tapering from opioids and help address each one during the process.
- 4) Explain how the PACT program works and how to complete each training module and assessment instrument.
- 5) Answers questions that many patients still have about their problem and how it will be addressed with treatment plan.
- 6) Complete the assessment of risk and protective factors through the PACT program
- 7) Call the patient biweekly by video-conferencing to reinforce compliance and understanding and ensure follow-up with each team member.
- 8) Facilitate review of on-line modules for self-management training to reinforce the doctor's information.
- 9) Explain health education materials to patient, when questions arise
- 10) Provides the patient with a pain diary to document progress with changing pain, functional status, identify triggers, risk factors, protective factors and barriers to success. They will work with the team to improve outcomes.

## **KNOWLEDGE AND SKILL**

Bachelor's degree or higher in health promotion, health education, nursing, athletic training, nutrition, psychology, social work, or other health related field or counseling and training certificate in health coaching. Knowledge of specific disease and lifestyle related topics such as pain management, smoking cessation, weight management, nutrition, pre-post natal care, stress reduction and chronic conditions and certification from an accredited professional health coach training program preferred.

**PROTOCOL:** Once the participant has enrolled in the PACT Study and been randomized to the PACT program, the phone coach will contact participant by telephone at varying intervals (see table 1). The role of the coach is to help the participant clarify their goals and identify strengths, resources, and barriers related to behavioral changes using motivational interviewing techniques. Coaches may also encourage completion of weekly educational module content and to inquire about the usefulness of the information, but that is a secondary focus.

### Contact, duration, and frequency

- Minimum phone contact: Initial call, touch base call, and final call
- Maximum phone contact: Two times per week for three months
- The intention is for an initial call of 30-60 min (as needed) followed by 30 minute follow-ups
- Documentation will occur at all calls to collect time and focus of the session and self-identified goals (yes?)

### During the initial phone call, the phone coach will be responsible for:

- 1) Explanation of coaching – how it works, expectations
- 2) Set ground rules and determine interaction frequency
  - At minimum the participant needs to have an initial call, a touch base call, and a final call
- 3) Determination of participant needs, goals, and barriers. What do they want to work on?
  - Example questions that may be asked: What is important? What strengths have led to success? Types of barriers to success? What steps have you taken to achieve your goal? Pattern of thoughts getting in your way?
- 4) Foster motivation and help participant to prioritize and address goals and barriers, applying collaborative communication techniques supporting the client's power to direct their own agenda

During program calls, the phone coaches' responsibility will be to:

- 1) Touch base on where the participant is at with their goals
- 2) Help participant clarify goals and identify and address resources and barriers
- 3) Check-in about online training program progression and impact
- 4) Base discussion on current happenings in participant's life and client's agenda in the moment

During the final phone call, the phone coach will be responsible for:

- 1) Final determination of where the participant is at in achieving or moving toward their goal(s)
- 2) Mention that the participant may be eligible, based on their insurance coverage, to have access to coaching services. If this is something of interest, direct them to member services at their health plan

<i>Table 1: Frequency of Phone Calls for Health Coaches</i>		
<b>Time Period</b>	<b>Frequency of Contact</b>	<b>Content</b>
Study Month 1	At most 2 times/week	1) Touch base on where the participant is at with their goal(s) 2) Help participant clarify goals and identify and address resources and barriers 3) Check-in about online training program progression and impact 4) Base discussion on current happenings in participant's life and client's agenda in the moment
Study Month 2	Same as above	Same as the above
Study Month 3	Last call	1) Final determination of where the participant is at in achieving their goal(s) 2) Mention that the participant may be eligible, based on their insurance coverage, to have access to coaching services. If this is something of interest, direct them to member services at their health plan

**Forms and Supplies Needed**

- Participant's home phone number and email address.
- PACT program website access
- Weekly Log

<b>Chart on Preventing Chronic Pain in the Seven Realms</b>			
	<b>Triggers pain flares</b>	<b>Risk Factors to avoid</b>	<b>Protective actions to follow</b>
<b>B Body</b>	Poor posture Tensing, strain to muscle Over-vigorous exercise, strenuous labor Acute injury Menstrual cycle, thyroid, hormonal changes	Tense and poor postures Repetitive muscle strain Poor conditioning Weak muscles Illness, obesity, hypermobile joints	Balanced relaxed posture during day Conditioning exercises Strengthening exercise Avoid physical risks to avoid injury
<b>L Lifestyle</b>	Diet triggers* (see below) Dehydration Poor sleep/ oversleeping Chemical, caffeine, tobacco products Stress-too busy, shift work hours	Poor diet and sleep Inactivity/ prolonged sitting Hurrying, feeling rushed Extreme sports/activity Chemical and tobacco use Irregular lifestyle, shift work	Healthy diet daily(see handout) Diet supplements Staying active all day Follow good sleep routine Pace through-out the day Take actions to be safe daily
<b>E Emotion</b>	Anxious/ crisis situation Prolonged depression or sadness Prolonged anger	Anger Anxiety Nervousness Sadness Depression	Be creative: cooking, art, music, writing Deep breathing exercise Practice relaxation to calm muscles, nerves Practice positive psychology: Identify blessings Identify, discover, express your emotions
<b>S Society</b>	Stress- family Stress- people at work Stress- new/changing job Stress- loss of job Stress- financial PTSD	Self-centered and ego-centric Conflict and abuse Lack of social support Feeling lonely and isolated Secondary gain Intolerant/ Unforgiving	Cultivate positive relationships Help others daily Be courteous and respectful Provide social support to those around you Create win-win in resolving conflicts

<p>S Spirit</p>	<p>Feeling lost                  Burned-out                  Hate and dislikes in life                  Self-abuse</p>	<p>Stress and burnout                  Hate and loathing                  Low self esteem                  Lost and meaningless life                  Disbelief/ cynicism/ doubt                  Hopelessness and pessimism</p>	<p>Mindfulness meditation and prayer                  Find meaning in life                  Maintain love and passion in life                  Explore dreams, hopes, and aspirations</p>
<p>M Mind</p>	<p>Stress- confusion, being ill-prepared                  Stress- dishonest, cheating                  Stress- fail to meet expectations                  Stress- out of control situations                  Stress- poor resilience</p>	<p>Ignorance of whole problem                  Low resilience and coping                  Low self-efficacy/ control                  Deny responsibility                  Poor compliance                  Unrealistic expectations</p>	<p>Learn about condition/risk/ protective factors                  humor, balance, flexible, tough, centered                  Self-motivated, growth, responsible write positive affirmations                  Practice adapt to new situations                  Learn realistic outcomes</p>
<p>E Environment</p>	<p>Air pollution/ allergens                  Weather changes                  Noise                  Vibration                  High altitudes and environmental triggers</p>	<p>Infection prone and unclean                  Chaotic environment                  Dangerous surroundings                  Accident prone                  Negligent</p>	<p>Clean and organize the home                  Reduce air pollution, allergens, vibrations                  Follow food safety plan create safe home and work environment                  Reduce risks and drive defensively</p>

## APPENDIX E: TELEPHONE SCREEN

### Initial Phone Contact

#### Incoming call (Protocol 1 HP Member or Non-HP Member contacts SRC)

- ❖ Thank you for calling the TMD Self-Care Study. Before I describe the study I would like to start by asking how you heard about the TMD Self-Care Study.

1) How did you hear about the study? (*Do not read list— let the participant tell you, okay to check more than one if volunteered*)

- a) Brochure describe what brochure, where from, etc.: \_\_\_\_\_
- b) Clinic describe which clinic, etc.: \_\_\_\_\_
- c) Health Professional describe who, where, etc.: \_\_\_\_\_
- d) Friend describe: \_\_\_\_\_
- e) Recruitment letter describe: \_\_\_\_\_
- f) Other describe: \_\_\_\_\_
- g) Do not remember

#### Outgoing call (Protocol 2)

- ❖ Hello. May I please speak with [full name of potential participant]?  
*If respondent is not available, schedule a call back and end call.*  
*If respondent is on the phone, continue.*
- ❖ This is [INSERT FIRST NAME] from the HealthPartners Institute. I'm following up to a letter we recently sent you about a study that you may be able to participate in called the TMD Self-Care Study. Is now a good time to tell you more about this study?
- ❖ If no: When is a better time to reach you? (schedule a call back if possible, or thank them and end call)
- ❖ If Yes: Great! I'll need to ask you some question to determine your eligibility. But first, I would like to ask a few questions about you. This helps us understand who may or may not be interested in studies like the TMD Self-Care Study. We ask these questions of everyone before determining if they are eligible. These questions are not used to determine if you are eligible. **(Go to question 2)**

#### Messages

- ❖ Initial message: (Protocol 2)

Hello. This message is for [full name of respondent]. This is [INSERT FIRST NAME] from the HealthPartners Institute. I'm calling about a letter we recently sent about an exciting new research study. Please call us at 952-967-5696 to learn more. If you reach our voicemail,

please leave your full name, phone number and the best time to reach you. If we don't hear back, we'll try you again later. Thank you!

❖ Second (final) message:

Hello. This message is for [full name of respondent]. This is [INSERT FIRST NAME] from the HealthPartners Institute following up on a letter recently sent inviting you to participate in an exciting new research study. Sorry we missed you again. Please call us at 952-967-5696 if you are interested. We will not call you again unless we hear from you. Thank you!

- 2) How do you describe yourself? (check one)
  - a) Male
  - b) Female
  - c) Transgender
  - d) Do not identify as female, male, or transgender
- 3) What is your age? \_\_\_\_\_ (if less than 18 years old; not eligible)
- 4) Do you consider yourself to be Hispanic or Latino?
  - a) No, not Hispanic/Latino
  - b) Yes, Hispanic/Latino
- 5) Which of the following do you consider yourself (mark all that apply)?
  - a) White
  - b) American Indian/Alaskan Native
  - c) Asian
  - d) Native Hawaiian or Pacific Islander
  - e) Black or African American
  - f) Other (describe): \_\_\_\_\_
  - g) Don't know/refuse [do not read]

Thank you for answering these questions. Now I'll tell you more about the study.

**Study description:**

HealthPartners Institute is conducting a new study called TMD Self-Care Study that is funded by the National Institute of Health. The study is looking at a new way of helping people manage chronic pain from TMJ or temporomandibular muscle and joint pain, which is pain in the face and jaw.

The study will be randomizing people into one of two self-management online programs, the Personalized Activated Care and Training (PACT) program or the traditional care program. In the PACT program people will move through an eight week online course that includes audio, video and written materials along with phone coaching. In the traditional care program people will receive information about self-care of TMJ using video and written materials. Both groups will be asked to complete three surveys and will receive up to \$100 in Target gift cards for participation. This includes a \$20 gift card for completion of the initial survey, \$35 gift card for completing the survey at two months and \$45 gift card for completing the survey at four months.

6) Are you interested in seeing if you are eligible for this study?

a) No: Thank and end call.

b) Yes: continue

Great, I'll need to ask you some questions to determine your eligibility.

### Phone Screen for Study Eligibility

If at any time the caller **does not meet eligibility criteria** stop the screening, thank them for their interest, and refer to section “B” at the end of the screen. *Mark disposition as ineligible.*

7) Are you able and willing to access to the internet on a regular basis?

- a) NO ***If NO, go to section B***
- b) YES

***If asked, program is mobile responsive and can be accessed using cell phone or tablet.***

8) Are you able to read and speak in English?

- a) NO ***If NO, go to section B***
- b) YES

9) Will you be reachable by phone and able to participate in phone coaching calls if you are assigned to the PACT program?

- a) NO ***If NO, go to section B***
- b) YES

***These next questions are related to your TMD symptoms.***

10) Has a health professional ever told you that you have TMD/TMJ?

- a) NO ***If NO, go to section B***
- b) YES

11) In the last 30 days, which of the following best describes any pain in your jaw or temple area on either side?

- a) No pain (0 points)
- b) From very brief to more than once a week, but it does stop (1 point)
- c) Continuous (2 points)

12) In the last 30 days, have you had pain or stiffness in your jaw on awakening?

- a) No (0 points)
- b) Yes (1 point)

13) In the last 30 days, did the following activities change any pain (that is, make it better or make it worse) in your jaw or temple area on either side?

- a) Chewing hard or tough food
  - 1) No (0 points)
  - 2) Yes (1 point)
- b) Opening your mouth or moving your jaw forward or to the side

- 1) No
- 2) Yes
- c) Jaw habits such as holding teeth together, clenching/grinding, or chewing gum
  - 1) No
  - 2) Yes
- d) Other jaw activities such as talking, kissing, or yawning
  - 1) No
  - 2) Yes

14) How long have you experienced jaw or temple pain? (Check one)

- Less than 1 month
- 1 month or more but less than 3 months
- 3 months or more but less than 6 months
- 6 months or more but less than 1 year
- 1 year or more but less than 3 years
- 3 years or more

15) In the last 30 days, where did you have any jaw or temple pain? (Check yes or no for each)

Left jaw area	<input type="checkbox"/> Yes <input type="checkbox"/> No	Right jaw area	<input type="checkbox"/> Yes <input type="checkbox"/> No
Left temple area	<input type="checkbox"/> Yes <input type="checkbox"/> No	Right temple area	<input type="checkbox"/> Yes <input type="checkbox"/> No

[INSERT scoring information]

16) Are you currently participating in any other TMD/TMJ related studies?

- e) No
- f) Yes ***If YES, go to section B.***

17) Are you scheduled to have surgery for your TMD/TMJ disorder?

- g) No
- h) Yes ***If YES, go to section B.***

***Now I need to ask you a few additional medical questions.***

18) Do you have any serious medical conditions that might interfere with or prohibit you from participating in an online self-care program or currently pregnant?

- i) No

j) Yes ***If YES, go to section B.***

19) Have you received treatment for a mental health disorder or substance abuse in the past six months?

k) No

l) Yes ***If YES, go to section B.***

20)

#### **End Phone Screen – determine eligibility**

**If Questions 11, 12 and 13a = 2 or more then participant is eligible.**

**If Questions 11, 12 and 13a = less than 2 then participant is NOT eligible.**

**Yes/ No Eligible**

#### **A. Eligible**

Based on your responses, you are eligible for study participation. The next step would be for me to send you information about the study by email, including a study brochure and consent form. I will also send you instructions including a link to the study website with log-in information. You will then be directed to the study website to complete the consent form to enroll you in the study.

Would you like me to send study information to you so you can get started?

#### **Yes:**

**Incoming calls:** Great, I will need to collect your contact information so I can email you study materials. If you have a few minutes, I would like to briefly review the study with you and answer any additional questions you may have while we are on the phone. Once you receive the email you can enter the website, review the consent form online, and get started.

**Outgoing calls:** Great, I will need to confirm the contact information we have for you. I will briefly review the study with you now while we are on the phone and answer any additional questions that might come up. In addition I will email you instructions for participation in the study including a study brochure, a link to the study website and your username/password to access the study website so you can complete the consent form to enroll into the study.

#### **No:**

I'm sorry to hear that. Would you mind telling me why? \_\_\_\_\_

#### **Thinking about it:**

Collect patient name only below to identify if they call back.

**Contact Information (auto-populated for outgoing calls)**

21) What is your full name? \_\_\_\_\_

22) What is your mailing address?

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

23) What is your preferred method of contact, phone or email? If phone also obtain preferred time of day to contact:

a) Home phone ( ) \_\_\_\_\_

b) Work phone ( ) \_\_\_\_\_

c) Cell phone ( ) \_\_\_\_\_

d) Email address \_\_\_\_\_

24) Can we leave message at:

a) Home **YES NO**

b) Work **YES NO**

c) Cell **YES NO**

25) Are you able and willing to receive text messages?

a) **YES** (standards rates would apply; just know you won't be able to text us back)

b) **NO**

26) (If yes to any item in 25) May we call ourselves TMD Self-care Study when we call?

a) **YES**

b) **NO**

If NO: OK, is there any other name you would like us to use? \_\_\_\_\_

**B. Ineligible**

I'm sorry, but you are not eligible for this study.

We thank you for your interest and your willingness to go through our phone screen. We appreciate your time and consideration.

**If the potential participant pushes for why this makes them not eligible:**

You know, I can't speak specifically to why the study has chosen the eligibility criteria it did, that would be a question for the study coordinator, but I do know they have specific reasons for each criterion. Would you like to discuss further with the study coordinator, Liz Grossman at 952-XXX-XXXX?

## APPENDIX F: SAMPLE 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 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 – XXX-XXXX. You may also contact the study investigator Jim Friction at: 952 – XXX-XXXX. If you have questions about your rights as a research subject, you may contact the HealthPartners Office of Research Subjects at (651) 254-4757

**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: \_\_\_\_\_

**APPENDIX G: DATA COLLECTION SURVEYS AT BASELINE, 8 WEEK and  
 16 WEEK POST-INTERVENTION**

**Baseline Survey**

**Thank you for participating in the TMD Self-Care Study. The following questions are about your experiences with this study and should take about 5-10 minutes to answer. The first questions are about your jaw and temple pain. Please answer all the questions as best as you can.**

**Graded Chronic Pain**

1. On how many days in the last 30 days have you had jaw or temple pain? \_\_\_\_\_ Number of Days

2. How would you rate your jaw or temple pain RIGHT NOW?

<b>No Pain</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Pain as bad as could be</b>
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3. In the **last 30 days**, how would you rate your **WORST** jaw or temple pain?

<b>No Pain</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Pain as bad as could be</b>
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4. In the **last 30 days**, **ON AVERAGE**, how would you rate your jaw or temple pain?  
 That is, *your usual pain* at times you were in pain.

<b>No Pain</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Pain as bad as could be</b>
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5. In the **last 30 days**, how many days did your jaw or temple pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework?

\_\_\_\_\_ Number of Days

6. In the **last 30 days**, how much has jaw and temple pain interfered with your **DAILY ACTIVITIES**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference	0	1	2	3	4	5	6	7	8	9	10	Unable to carry on any activities
	<input type="checkbox"/>											

7. In the **last 30 days**, how much has jaw and temple pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**, rated on a scale of 0-10 where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference	0	1	2	3	4	5	6	7	8	9	10	Unable to carry on any activities
	<input type="checkbox"/>											

8. In the **last 30 days**, how much has jaw and temple pain interfered with your **ABILITY TO WORK, INCLUDING HOUSEWORK**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

No interference	0	1	2	3	4	5	6	7	8	9	10	Unable to carry on any activities
	<input type="checkbox"/>											

### Jaw Functioning

9. For each of the items below, please indicate the level of limitation during the **last 30 days**. If the activity has been completely avoided because it is too difficult, then fill in "10". If you avoid an activity for reasons other than pain or difficulty fill in the "not applicable" (N/A).

In the <b>LAST 30 days</b> :	N/A	No Limitation										Severe Limitation	
		0	1	2	3	4	5	6	7	8	9	10	
a. Chew tough food	<input type="checkbox"/>												
b. Chew chicken (e.g. prepared in oven)	<input type="checkbox"/>												

c. Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food)	<input type="checkbox"/>											
d. Open wide enough to drink from cup	<input type="checkbox"/>											
e. Swallow	<input type="checkbox"/>											
f. Yawn	<input type="checkbox"/>											
g. Talk	<input type="checkbox"/>											
h. Smile	<input type="checkbox"/>											

**Chronic Pain Self-Efficacy**

We would like to know about how you manage your pain. For each of the following questions, please choose the number that best indicates how certain or uncertain you are.

	Very Uncertain										Very Certain
10. How certain are you that you can decrease your pain quite a bit?	1	2	3	4	5	6	7	8	9	10	
11. How certain are you that you can continue most of your daily activities?	1	2	3	4	5	6	7	8	9	10	
12. How certain you that you can keep your pain from interfering with your sleep?	1	2	3	4	5	6	7	8	9	10	

13. How certain are you that you can make a small-to-moderate reduction in your pain by using methods other than taking extra medications?      1      2      3      4      5      6      7      8      9      10

14. How certain are you that you can make a large reduction in your pain by using methods other than taking extra medications?      1      2      3      4      5      6      7      8      9      10

**The following questions are about how you manage your own health and healthcare.**

**PAM 7**

15. How much do you agree or disagree with the following statements?

	Disagree Strongly	Disagree	Agree	Agree Strongly
a. Taking an active role in my own health care is the most important factor in determining my health and ability to function.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I know the lifestyle changes like diet and exercise that are recommended for my health condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I am confident that I can follow through on medical recommendations my health care provider makes such as changing my diet or doing regular exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I am confident that I can find trustworthy sources of information about my health condition and my health choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I know how to prevent further problems with my health condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I am able to handle symptoms of my health condition on my own at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

g. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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**The next questions are about your sleep and exercise habits.**

16. **Overall in the last 30 days**, how much of a problem did you have with sleeping, such as falling asleep, waking up frequently during the night or waking up too early in the morning?

- a. None
- b. Mild
- c. Moderate
- d. Severe
- e. Extreme

17. **In the last 30 days**, how much of a problem did you have due to not feeling rested and refreshed during the day (e.g. feeling tired, not having energy)?

- a. None
- b. Mild
- c. Moderate
- d. Severe
- e. Extreme

19. **In a typical week**, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate (such as running, aerobics, soccer) for at least 10 minutes continuously?

\_\_\_ days

20. **On a typical day** that you do vigorous-intensity sports, fitness or recreational activities, how much time do you spend doing them?

\_\_\_ minutes

20. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate (such as brisk walking, cycling, swimming, volleyball) for at least 10 minutes continuously? \_\_\_days

21. On a typical day that you do moderate-intensity sports, fitness or recreational (leisure) activities, how much time do you spend doing them?

\_\_\_minutes

**Overall Program Evaluation**

**The following questions are about your experience with the TMD Self-Care Programs.**

22. Please indicate how much you agree or disagree with the following statements about the TMD Self-Care program.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
a. I was satisfied with the information I received in the program	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I received the right amount of information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The information was relevant and applicable to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I found the online learning information and materials to be clear and understandable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I found the information presented valuable in managing my TMD pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I have a better understanding of how to manage my TMD pain as a result of participating in the program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I found the online program easy to access and navigate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Thank you for participating in this study and completing this survey. We will be mailing you a \$35 dollar Target gift card as a thank you for completing this survey.**

## TMD Self-Care Study Follow up Survey (8-week follow-up Survey including Program Evaluation Questions)

**Thank you for participating in the TMD Self-Care Study. The following questions are about your experiences with this study and should take about 5-10 minutes to answer. The first questions are about your jaw and temple pain. Please answer all the questions as best as you can.**

### Graded Chronic Pain

1. On how many days in the last 30 days have you had jaw or temple pain? \_\_\_\_\_ Number of Days

2. How would you rate your jaw or temple pain **RIGHT NOW**?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
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3. In the **last 30 days**, how would you rate your **WORST** jaw or temple pain?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

4. In the **last 30 days**, **ON AVERAGE**, how would you rate your jaw or temple pain? That is, *your usual pain* at times you were in pain.

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

5. In the **last 30 days**, how many days did your jaw or temple pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework?

\_\_\_\_\_ Number of Days

6. In the **last 30 days**, how much has jaw and temple pain interfered with your **DAILY ACTIVITIES**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Unable to carry on any activities</b>
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	<input type="checkbox"/>											
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7. **In the last 30 days**, how much has jaw and temple pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**, rated on a scale of 0-10 where 0 is “no interference” and 10 is “unable to carry on any activities”?

No interference	0	1	2	3	4	5	6	7	8	9	10	Unable to carry on any activities
	<input type="checkbox"/>											

8. **In the last 30 days**, how much has jaw and temple pain interfered with your **ABILITY TO WORK, INCLUDING HOUSEWORK**, rated on a scale of 0-10, where 0 is “no interference” and 10 is “unable to carry on any activities”?

No interference	0	1	2	3	4	5	6	7	8	9	10	Unable to carry on any activities
	<input type="checkbox"/>											

**Jaw Functioning**

9. For each of the items below, please indicate the level of limitation during **the last 30 days**. If the activity has been completely avoided because it is too difficult, then fill in “10”. If you avoid an activity for reasons other than pain or difficulty fill in the “not applicable” (N/A).

In the <b>LAST 30 days</b> :	N/A	<b>No Limitation</b>										<b>Severe Limitation</b>	
		0	1	2	3	4	5	6	7	8	9	10	
a. Chew tough food	<input type="checkbox"/>												
b. Chew chicken (e.g. prepared in oven)	<input type="checkbox"/>												
c. Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food)	<input type="checkbox"/>												
d. Open wide enough to drink from cup	<input type="checkbox"/>												

e. Swallow	<input type="checkbox"/>											
f. Yawn	<input type="checkbox"/>											
g. Talk	<input type="checkbox"/>											
h. Smile	<input type="checkbox"/>											

**Chronic Pain Self-Efficacy**

We would like to know about how you manage your pain. For each of the following questions, please choose the number that best indicates how certain or uncertain you are.

	Very Uncertain										Very Certain
10. How certain are you that you can decrease your pain quite a bit?	1	2	3	4	5	6	7	8	9	10	
11. How certain are you that you can continue most of your daily activities?	1	2	3	4	5	6	7	8	9	10	
12. How certain you that you can keep your pain from interfering with your sleep?	1	2	3	4	5	6	7	8	9	10	
13. How certain are you that you can make a small-to-moderate reduction in your pain by using methods other than taking extra medications?	1	2	3	4	5	6	7	8	9	10	
14. How certain are you that you can make a large reduction in your pain by using methods other than taking extra medications?	1	2	3	4	5	6	7	8	9	10	

**The following questions are about how you manage your own health and healthcare.**

**PAM 7**

15. How much do you agree or disagree with the following statements?

	Disagree Strongly	Disagree	Agree	Agree Strongly
a. Taking an active role in my own health care is the most important factor in determining my health and ability to function.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I know the lifestyle changes like diet and exercise that are recommended for my health condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I am confident that I can follow through on medical recommendations my health care provider makes such as changing my diet or doing regular exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I am confident that I can find trustworthy sources of information about my health condition and my health choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I know how to prevent further problems with my health condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I am able to handle symptoms of my health condition on my own at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**The next questions are about your sleep and exercise habits.**

16. **Overall in the last 30 days**, how much of a problem did you have with sleeping, such as falling asleep, waking up frequently during the night or waking up too early in the morning?

- f. None
- g. Mild
- h. Moderate
- i. Severe
- j. Extreme

17. **In the last 30 days**, how much of a problem did you have due to not feeling rested and refreshed during the day (e.g. feeling tired, not having energy)?

- f. None
- g. Mild
- h. Moderate
- i. Severe
- j. Extreme

19. **In a typical week**, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate (such as running, aerobics, soccer) for at least 10 minutes continuously?

\_\_\_ days

20. **On a typical day** that you do vigorous-intensity sports, fitness or recreational activities, how much time do you spend doing them?

\_\_\_ minutes

20. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate (such as brisk walking, cycling, swimming, volleyball) for at least 10 minutes continuously?

\_\_\_ days

21. On a typical day that you do moderate-intensity sports, fitness or recreational (leisure) activities, how much time do you spend doing them?

\_\_\_ minutes

### **Overall Program Evaluation**

**The following questions are about your experience with the TMD Self-Care Programs.**

22. Please indicate how much you agree or disagree with the following statements about the TMD Self-Care program.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
a. I was satisfied with the information I received in the program	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I received the right amount of information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The information was relevant and applicable to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I found the online learning information and materials to be clear and understandable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I found the information presented valuable in managing my TMD pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I have a better understanding of how to manage my TMD pain as a result of participating in the program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I found the online program easy to access and navigate					

**Thank you for participating in this study and completing this survey.  
 We will be mailing you a \$35 dollar Target gift card as a thank you for  
 completing this survey.**

## 8-week follow-up Survey including Program Evaluation Questions (PACT ONLY)

**Thank you for participating in the TMD Self-Care Study. The following questions are about your experiences with this study and should take about 5-10 minutes to answer. The first questions are about your jaw and temple pain. Please answer all the questions as best as you can.**

### Graded Chronic Pain

1. On how many days in the last 30 days have you had jaw or temple pain? \_\_\_\_\_ Number of Days

2. How would you rate your jaw or temple pain RIGHT NOW?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

3. In the **last 30 days**, how would you rate your **WORST** jaw or temple pain?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

4. In the **last 30 days**, **ON AVERAGE**, how would you rate your jaw or temple pain?  
 That is, *your usual pain* at times you were in pain.

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

5. In the **last 30 days**, how many days did your jaw or temple pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework?

\_\_\_\_\_ Number of Days

6. In the **last 30 days**, how much has jaw and temple pain interfered with your **DAILY ACTIVITIES**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Unable to carry on any</b>
------------------------	---	---	---	---	---	---	---	---	---	---	----	-------------------------------

													<b>activities</b>
	<input type="checkbox"/>												

7. **In the last 30 days**, how much has jaw and temple pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**, rated on a scale of 0-10 where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Unable to carry on any activities</b>
	<input type="checkbox"/>											

8. **In the last 30 days**, how much has jaw and temple pain interfered with your **ABILITY TO WORK, INCLUDING HOUSEWORK**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Unable to carry on any activities</b>
	<input type="checkbox"/>											

**Jaw Functioning**

9. For each of the items below, please indicate the level of limitation during **the last 30 days**. If the activity has been completely avoided because it is too difficult, then fill in "10". If you avoid an activity for reasons other than pain or difficulty fill in the "not applicable" (N/A).

In the <b>LAST 30 days</b> :	N/A	<b>No Limitation</b>										<b>Severe Limitation</b>	
		<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	
a. Chew tough food	<input type="checkbox"/>												
b. Chew chicken (e.g. prepared in oven)	<input type="checkbox"/>												
c. Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food)	<input type="checkbox"/>												

d. Open wide enough to drink from cup	<input type="checkbox"/>											
e. Swallow	<input type="checkbox"/>											
f. Yawn	<input type="checkbox"/>											
g. Talk	<input type="checkbox"/>											
h. Smile	<input type="checkbox"/>											

**Chronic Pain Self-Efficacy**

We would like to know about how you manage your pain. For each of the following questions, please choose the number that best indicates how certain or uncertain you are.

	Very Uncertain										Very Certain
10. How certain are you that you can decrease your pain quite a bit?	1	2	3	4	5	6	7	8	9	10	
11. How certain are you that you can continue most of your daily activities?	1	2	3	4	5	6	7	8	9	10	
12. How certain you that you can keep your pain from interfering with your sleep?	1	2	3	4	5	6	7	8	9	10	
13. How certain are you that you can make a small-to-moderate reduction in your pain by using methods other than taking extra medications?	1	2	3	4	5	6	7	8	9	10	

14. How certain are you that you can make a large reduction in your pain by using methods other than taking extra medications?

1      2      3      4      5      6      7      8      9      10

**The following questions are about how you manage your own health and healthcare.**

**PAM 7**

15. How much do you agree or disagree with the following statements?

	Disagree Strongly	Disagree	Agree	Agree Strongly
a. Taking an active role in my own health care is the most important factor in determining my health and ability to function.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I know the lifestyle changes like diet and exercise that are recommended for my health condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I am confident that I can follow through on medical recommendations my health care provider makes such as changing my diet or doing regular exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I am confident that I can find trustworthy sources of information about my health condition and my health choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I know how to prevent further problems with my health condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I am able to handle symptoms of my health condition on my own at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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**The next questions are about your sleep and exercise habits.**

16. **Overall in the last 30 days**, how much of a problem did you have with sleeping, such as falling asleep, waking up frequently during the night or waking up too early in the morning?

- k. None
- a. Mild
- b. Moderate
- c. Severe
- d. Extreme

17. **In the last 30 days**, how much of a problem did you have due to not feeling rested and refreshed during the day (e.g. feeling tired, not having energy)?

- a. None
- b. Mild
- c. Moderate
- d. Severe
- e. Extreme

19. **In a typical week**, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate (such as running, aerobics, soccer) for at least 10 minutes continuously?

\_\_\_ days

20. **On a typical day** that you do vigorous-intensity sports, fitness or recreational activities, how much time do you spend doing them?

\_\_\_ minutes

20. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate (such as brisk walking, cycling, swimming, volleyball) for at least 10 minutes continuously?

\_\_\_days

21. On a typical day that you do moderate-intensity sports, fitness or recreational (leisure) activities, how much time do you spend doing them?

\_\_\_minutes

## Overall Program Evaluation

The following questions are about your experience with the TMD Self-Care Programs.

22. Please indicate how much you agree or disagree with the following statements about the TMD Self-Care program.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
a. I was satisfied with the information I received in the program	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I received the right amount of information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The information was relevant and applicable to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I found the online learning information and materials to be clear and understandable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I found the information presented valuable in managing my TMD pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I have a better understanding of how to manage my TMD pain as a result of participating in the program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I found the online program easy to access and navigate					

## PACT Program Evaluation

23. The next questions are about your participation in the PACT Self-Care program. To what extent do you agree or disagree with the following statements.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
a. I was interested and engaged by the PACT learning modules.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I found the subject matter relevant and interesting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The amount of learning material presented in each module was about right.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I have a better understanding of how to prevent and relieve pain as a result of the program.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I have a better understanding of how to use different self-care strategies to manage my TMD pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I found the recommended "action plan" activities from each learning module helpful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I found the individual self-assessments at within the program helpful in my learning.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. The time commitment for the program was about right.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. The program held my interest over the 8 weeks.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. I found it easy to move through the online modules and lessons.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. I would recommend the PACT program to others who have TMD pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. To what degree did was each of the following features/components of the PACT Self-Care program helpful in contributing to your learning?

	Not at all Helpful	Somewhat Helpful	Helpful	Very Helpful	Extremely Helpful	NA
a. Video lessons	<input type="checkbox"/>					
b. Narrated PowerPoint presentations	<input type="checkbox"/>					
c. Graphic Illustrations	<input type="checkbox"/>					
d. Presentations by Professor James	<input type="checkbox"/>					
e. Self-assessments at the end of each module	<input type="checkbox"/>					
f. Online animated characters used to support learning	<input type="checkbox"/>					
g. Recommended exercises and activities in each module.	<input type="checkbox"/>					

25. To what degree did the follow three aspects of the PACT Self-Care program help you in your learning?

	Not at all Helpful	Somewhat Helpful	Helpful	Very Helpful	Extremely Helpful	NA
a. Daily pauses	<input type="checkbox"/>					
b. Calming activities	<input type="checkbox"/>					
c. Helpful habits	<input type="checkbox"/>					

26. What did you like most about the program?

27. What suggestions do you have for improving the online PACT Self-Care program?

28. In addition to the 8 week survey, some participants will be selected for a more in-depth interview about their experience in the TMD Self-Care Study. The phone interview would take 20-30 minutes and would be scheduled at a time that was convenient for you. All feedback would be confidential and you would receive a \$25 Target gift card as a thank you for your time. If you are selected, would you be interested in participating in this conversation?

Yes I would be interested.

Preferred contact phone number \_\_\_\_\_

**Thank you for participating in this study and completing this survey.  
We will be mailing you a \$35 dollar Target gift card as a thank you for  
completing this survey.**

## TMD Self-Care Study 16 Week Follow up Survey

**Thank you for participating in the TMD Self-Care Study. The following questions are about your experiences with this study and should take about 5-10 minutes to answer. The first questions are about your jaw and temple pain. Please answer all the questions as best as you can.**

### Graded Chronic Pain

1. On how many days in the last 30 days have you had jaw or temple pain? \_\_\_\_\_ Number of Days

2. How would you rate your jaw or temple pain RIGHT NOW?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

3. In the **last 30 days**, how would you rate your **WORST** jaw or temple pain?

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

4. In the **last 30 days**, **ON AVERAGE**, how would you rate your jaw or temple pain?  
 That is, *your usual pain* at times you were in pain.

<b>No Pain</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Pain as bad as could be</b>
----------------	---	---	---	---	---	---	---	---	---	---	----	--------------------------------

5. In the **last 30 days**, how many days did your jaw or temple pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework?

\_\_\_\_\_ Number of Days

6. In the **last 30 days**, how much has jaw and temple pain interfered with your **DAILY ACTIVITIES**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	0	1	2	3	4	5	6	7	8	9	10	<b>Unable to carry on any activities</b>
	<input type="checkbox"/>											

7. **In the last 30 days**, how much has jaw and temple pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**, rated on a scale of 0-10 where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Unable to carry on any activities</b>
	<input type="checkbox"/>											

8. **In the last 30 days**, how much has jaw and temple pain interfered with your **ABILITY TO WORK, INCLUDING HOUSEWORK**, rated on a scale of 0-10, where 0 is "no interference" and 10 is "unable to carry on any activities"?

<b>No interference</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>Unable to carry on any activities</b>
	<input type="checkbox"/>											

**Jaw Functioning**

9. For each of the items below, please indicate the level of limitation during **the last 30 days**. If the activity has been completely avoided because it is too difficult, then fill in "10". If you avoid an activity for reasons other than pain or difficulty fill in the "not applicable" (N/A).

In the <b>LAST 30 days</b> :	N/A	<b>No Limitation</b>										<b>Severe Limitation</b>	
		<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	
a. Chew tough food	<input type="checkbox"/>												
b. Chew chicken (e.g. prepared in oven)	<input type="checkbox"/>												
c. Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food)	<input type="checkbox"/>												
d. Open wide enough to drink from cup	<input type="checkbox"/>												

e. Swallow	<input type="checkbox"/>											
f. Yawn	<input type="checkbox"/>											
g. Talk	<input type="checkbox"/>											
h. Smile	<input type="checkbox"/>											

**Chronic Pain Self-Efficacy**

We would like to know about how you manage your pain. For each of the following questions, please choose the number that best indicates how certain or uncertain you are.

	Very Uncertain										Very Certain
10. How certain are you that you can decrease your pain quite a bit?	1	2	3	4	5	6	7	8	9	10	
11. How certain are you that you can continue most of your daily activities?	1	2	3	4	5	6	7	8	9	10	
12. How certain you that you can keep your pain from interfering with your sleep?	1	2	3	4	5	6	7	8	9	10	
13. How certain are you that you can make a small-to-moderate reduction in your pain by using methods other than taking extra medications?	1	2	3	4	5	6	7	8	9	10	
14. How certain are you that you can make a large reduction in your pain by using methods other than taking extra medications?	1	2	3	4	5	6	7	8	9	10	

**The following questions are about how you manage your own health and healthcare.**

**PAM 7**

15. How much do you agree or disagree with the following statements?

	Disagree Strongly	Disagree	Agree	Agree Strongly
a. Taking an active role in my own health care is the most important factor in determining my health and ability to function.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. I know the lifestyle changes like diet and exercise that are recommended for my health condition.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I am confident that I can follow through on medical recommendations my health care provider makes such as changing my diet or doing regular exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I am confident that I can find trustworthy sources of information about my health condition and my health choices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. I know how to prevent further problems with my health condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. I am able to handle symptoms of my health condition on my own at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**The next questions are about your sleep and exercise habits.**

16. **Overall in the last 30 days**, how much of a problem did you have with sleeping, such as falling asleep, waking up frequently during the night or waking up too early in the morning?

- a. None

- b. Mild
- c. Moderate
- d. Severe
- e. Extreme

17. **In the last 30 days**, how much of a problem did you have due to not feeling rested and refreshed during the day (e.g. feeling tired, not having energy)?

- a. None
- b. Mild
- c. Moderate
- d. Severe
- e. Extreme

18. **In a typical week**, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate (such as running, aerobics, soccer) for at least 10 minutes continuously?

\_\_\_ days

29. **On a typical day** that you do vigorous-intensity sports, fitness or recreational activities, how much time do you spend doing them?

\_\_\_ minutes

20. In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate (such as brisk walking, cycling, swimming, volleyball) for at least 10 minutes continuously?

\_\_\_ days

21. On a typical day that you do moderate-intensity sports, fitness or recreational (leisure) activities, how much time do you spend doing them?

\_\_\_ minutes

**Thank you for participating in this study and completing this survey.**

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**We will be mailing you a \$45 dollar Target gift card as a thank you for completing this survey.**

**APPENDIX H. QUALITATIVE INTERVIEW  
(FOR PACT STUDY INTERVENTION PARTICIPANTS)**

Thank you for agreeing to take the time to talk with me about your participation in the TMD Self-Care Study. We are particularly interested in your perceptions about the PACT Program as we continue to work on developing and improving the program. This interview will take approximately 20-30 minutes. All feedback you provide will be confidential and you will receive a \$25 Target gift card as a thank you for your time.

1. I would like to start by asking you to tell me about your overall thoughts about the PACT Program? What did you think about it?
2. How has the PACT program affected the way you think about your TMD pain
3. How has the PACT program affected how you manage your TMD pain?
4. What did you learn from the PACT program that was new to you?
5. Have you made any changes in your life as a result of your participation in the PACT program? If yes, please tell me about them.
6. What did you learn in the PACT program that continues to be helpful to you in managing your TMD pain?

PROBE: Are there specific ways you take care of yourself now based on what you learned from the PACT program?

7. Considering your life in general, what do you think has changed for you as a result of your participation in the PACT program?
8. Has your reaction to stressful situations changed as a result of participating in the PACT program?
9. Please tell me about your experience with your health coach.

PROBES:

- a. What was the most helpful part of having a phone coach?
- b. How frequently did you meet with the coach?

- c. What did you find difficult about working with the health coach?
  - d. Do you think your opinion of the PACT program would change if the health coach was not a part of the program?
10. Considering your participation in the PACT program what were the least helpful parts of the program?
11. What parts of the program were the most helpful for you?
12. If you could make a change to the PACT program what would it be?
13. Of the seven main modules, which were the most effective for you?  
PROBES: to remind you the 7 modules are Body, Lifestyle, Mind, Emotions, Spirit, Social Life and Environment
14. What parts of your **Action Plan** were most helpful? (Health habits, daily pauses, and calming practice were the 3 main components of the action plan).
15. What did you think about the amount of information that was conveyed in each module?
16. What did you think about the use of animation and graphics in the program?
17. Did you find the assessments at the end of each module helpful?
18. Is there anything else about your experience with PACT Program or the study you think it would be helpful for us to know?

**Thank you for your feedback.**

**We will be mailing you a \$25 dollar Target gift card as a thank you for completing this interview**

## APPENDIX I: BARRIERS TO CONSUMER HEALTH INFORMATION TECHNOLOGY (CHIT)

The use of *consumer health information technology (CHIT)* as part of health professional care, particularly, in small primary care practices, has the potential to transform their role from a passive recipient of care to taking an active role in improving their health. CHIT is a secure set of online tools that provides e-tools to help them manage their health, health care, wellness, and their associated costs.<sup>1-3</sup> CHIT are simple, inexpensive, and an easy-to-use method to facilitate patient engagement aspects in this study and can include many features such as calendar and alerts, health records, communication, health education, incentives, and cost management tools (Fig.2). The *Center for Information Technology Leadership (CITL, 2008)*, a nonprofit research center, released findings on the value of personal health records (PHRs), concluding that CHIT could save \$19 billion annually on a national level by focusing on prevention, early intervention, self-management, and evidence-based care.<sup>2</sup> In January, the non-profit *Partners Center for Connected Health* released a report concluding that EMRs will not reform health care without consumer engagement, stating: "True healthcare reform will require a more patient-centered approach and a broader policy palette, including incentives for providers to adopt more population health management tools and for patients and consumers to take more ownership of their health."<sup>34</sup> Furthermore, *Institute for Medicine (2008)*<sup>35</sup> also states that many of the goals suggested in using HIT to improve health care requires a consumer focus.

However, *many barriers* exist in the use of CHIT, particularly with health disparity populations. Even when research results of health IT in an ambulatory setting are available, its scalability and generalizability to broader settings and with people of different cultures are often limited due to many issues including lack of awareness of its functionality, insufficient training of users, inadequate considerations of workflow issues such as integration to existing workflow and coordination between settings or staff, concerns regarding security of the data in the system, cost considerations, and other challenges. Jimison et al (2008)<sup>19</sup> conducted a review of barriers to the use of consumer HIT for the elderly, chronically ill, or underserved populations and found that the most common barriers were the lack of perceived benefit by consumers, its inconvenience of manual data entry, and lack of integration into the user's daily routine. However, they also found that several types of interactive consumer health IT were usable and effective in multiple settings in these populations. There was a more positive effect when the systems provided a complete feedback loop that included: (a) monitoring of current patient status, (b) interpretation of the data in comparison to individualized, treatment goals, (c) adjustment of the management plan as needed, (d) communication back to the patient with tailored recommendations or advice, and (e) repetition of this cycle at appropriate intervals.

Despite the promise of CHIT, their implementation, adoption, and the meaningful use of them has been disappointing. We need more knowledge about what tools within the CHIT both engage patients to be more active in their health maintenance and health care and encourage health care providers to be more patient-centered in their care and employing evidence-based shared decision-making. Jimison et al (2008), CITL, and the IOM suggest features for CHIT in order to engage both patients and health care providers. These include:

- Access to integrated health information with health information exchange (HIE) to allow a person to transfer medical records into one location to improve security and privacy

and easier direct access by the consumer.

- Integration of non-biased evidence-based health information that can be integrated into a personalized “learning” health care system that analyzes ongoing patient experience as relevant to the care process.
- Empowerment of patients and their families in health care decisions and their implementation, timely and focused communication with professional health care providers, and care that is integrated into daily activities including calendar with reminders of health events.
- Tracking patient biometrics such as weight, body mass, exercise, blood pressure, blood sugar, and other biometrics at home with CHIT connected-devices. Participants can store data automatically with wireless connections, document recordings, and graph data over time and allow doctors to view progress.
- Privacy and security standards to ensure confidential and secure health information with adequate authentication, encryption, and access controls.
- Shared vocabulary, data elements, data models, use of data standards for data exchange with EHRs.
- Universally accessible content that patients of diverse health literacy, skill levels, backgrounds, languages, and capabilities including intuitive interfaces to organize and present complex health information.
- Customizable to allow both simple and complex features to be included based on user preference with clear and easy training programs.

## APPENDIX J: DATA MANAGEMENT AND SAFETY MONITORING PLAN



### ❖ Tailored Self-Management of TMD Pain using Health Information Technology

1U01 DE025609-01 (PI: Friction)

The Data and Safety Monitoring Plan (DSMP) outlined below will adhere to the protocol approved by The HealthPartners Institutional Review Board and the recommendations of the National Institute for Dental and Craniofacial Research at <http://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm>.

#### I. Confidentiality

##### A. Protection of Subject Privacy

During this study, limited medical information will be obtained including patient self-report data. All of the materials collected are for research purposes only, and data will be kept in strict confidence. No information will be given to anyone without permission from the subject.

Confidentiality of study data will be ensured by assigning an arbitrary and unique subject identification number to each participant in the study. All data collected in the study will be identified by subject identification number only. These data will be entered by identification number into a computer database to which only the researchers directly involved in the study will have access. No participant data will be individually identified or released to anyone other than the study investigators without specific written permission from the study participant.

##### B. Database Protection

The database will be secured with password protection. A file containing a link between the study ID and individually identifying information will be maintained at HPRF by HPRF members of the study team. All electronic study data will be maintained in a computerized database residing on a username and password protected file-server to which only the researchers involved in the study will have access. All study related paper documents containing individually identifiable information will be maintained in locked file cabinets within HPRF.

##### C. Confidentiality During Adverse Event (AE) Reporting

AE reports and annual summaries will not include subject or group-identifiable material. Each report will only include the identification code.

#### II. Adverse Event Information

##### A. Definition

An **adverse event (AE)** is generally defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to

worsen. Adverse events are to be recorded regardless of their relationship to the study intervention.

A **serious adverse event (SAE)** is generally defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly.

If participants screen for depression and/or suicidal ideation, we will provide a list of mental health providers who they can consult with to ensure their safety.

The study intervention is a patient-centered self-management program for TMD pain. The PACT program is a web-based, tailored 8-week program supported by a health coach to help enhance understanding, compliance, and success in self-management for TMD pain. There are self-report assessments at the end of each week throughout the entire program to monitor progress, compliance, adverse events, risk factors, and protective factors. If study subjects develop an aggravation of the pain or a new symptom that the subject attributes to the study intervention this would be considered an adverse event. This will be monitored by both self-report within the PACT program weekly assessments as well as by the dental professional who is caring for the patient. In both cases, this will be reported to the PI and PO.

#### **B. Classification of AE Severity**

AEs will be labeled according to severity, which is based on their impact on the patient. An AE will be termed “mild” if it does not have an impact on the patient, “moderate” if it causes the patient some minor impact and inconvenience and “severe” if it causes a substantial disruption to the patient’s well-being.

#### **C. AE Attribution Scale**

AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled definitely unrelated, definitely related, probably related, or possibly related to the study intervention.

#### **D. Expected Risks**

It is believed that risks to subjects in the present study are minimal. The PACT program uses well-tested cognitive-behavioral strategies to help patients reduce lifestyle risk factors and enhance protective factors to prevent chronic pain. Study risks are considered to be minimal and are addressed in the protocol and consent form.

#### **E. AE Reporting and Follow-Up**

The study coordinator will be responsible for compiling the data and producing the necessary reports, as well as assuring that all parties obtain copies of these reports. Adverse events will be reported and reviewed by Dr. Friction as they occur and reported to the IRB. The number of days by which a serious adverse event or unanticipated problem would be reported is 2 days. Summary reports of adverse events and others relevant to summary data will be reported to the PI and the PO at NIDCR. Reports will include

description of study progress, subject recruitment, subject demographic data, subject status, and inclusion/exclusion criteria. These reports will be reviewed by the Principal Investigator and study team prior to being presented to NIDCR.

#### **F. SAE Reporting**

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to the IRB and NIDCR in accordance with requirements.

- Unexpected fatal or life-threatening AEs related to the intervention will be reported to the NIDCR Program Officer within 7 days. Other serious and unexpected AEs related to the intervention will be reported to the NIDCR Program Official within 15 days.
- Anticipated or unrelated SAEs will be handled in a less urgent manner but will be reported to the IRB and NIDCR in accordance with their requirements. In the annual AE summary, the PI will state that he has reviewed all AE reports.

### **III. Data Quality and Safety Review Board and Monitoring**

The study coordinator will submit data to the PI and they will evaluate the timeliness, completeness, and accuracy of the data to ensure an adequate evaluation of the safety and welfare of study participants. This will include a review of:

- Data for evidence of study-related adverse events from the self-report and clinical data;
- Data for evidence of efficacy according to pre-established statistical guidelines;
- Data quality, completeness, and timeliness;
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;
- Adherence to the protocol;
- Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol violations, unmasking, etc.); and,
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

The PI will also provide recommendations to NIDCR as to whether the study should continue without change, be modified, or terminated. Recommendations regarding modification of the design and conduct of the study could include:

- Modifications of the study protocol based upon the review of the safety data;
- Suspension or early termination of the study or of one or more study arms because of serious concerns about subjects' safety, inadequate performance or rate of enrollment;
- Suspension or early termination of the study or of one or more study arms because study objectives have been obtained according to pre-established statistical guidelines;
- Optional approaches for NIDCR and investigators to consider when the PI determines that the incidence of primary study outcomes is substantially less than expected such as

- recommendations to increase the number of trial centers or extend the recruitment period;  
 and,
- Corrective actions regarding a study center whose performance appears unsatisfactory or suspicious.
  - Confidentiality must always be maintained during all phases of Study Coordinator, PI review and deliberations.

**A. Data Quality and Management**

Description of Plan for Data Quality and Management—The study coordinator and study staff will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance.

- The study coordinator will review all surveys and the Activity logs submitted for completeness at the time of completion by the study participant.
- Semi-structured interview data will be reviewed by the study PI on an ongoing basis as interviews are completed.
- Weekly study participation will be reviewed by the study coordinator on an ongoing basis during the intervention. The study coordinator will also assure the program evaluation is completed.

Frequency of Data Review for this Study— The frequency of data review for this study differs according to the type of data and is summarized as follow:

<b>Data type</b>	<b>Frequency of review</b>	<b>Reviewer</b>
Subject accrual (including compliance with protocol enrollment criteria)	Quarterly	Study Coordinator and PI
Status of all enrolled subjects, as of date of reporting	Quarterly	Study Coordinator and PI
Adherence data regarding study intervention	Quarterly	Study Coordinator and PI
AEs and rates )	Quarterly	Study Coordinator and PI
SAEs	Per occurrence	Study Coordinator and PI and

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		NIDCR
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## **B. Subject Accrual and Compliance**

Measurement and Reporting of Subject Accrual, Compliance with Inclusion/Exclusion Criteria— Review of rate of subject accrual and compliance with inclusion exclusion criteria will occur during each recruitment phase to ensure that a sufficient number of participants are being enrolled and that they meet the study criteria;

### Measurement and Reporting of Participant Adherence to Treatment Protocol

Adherence will be assessed by the number of participants, using health coach (PACT only), and number of online modules completed.

## **C. Justification of Sample Size**

This is a pilot randomized clinical trial of the PACT program for TMD pain to determine feasibility and acceptability of methods and preliminary outcomes to power a multisite randomized clinical trial of its efficacy. The study is not powered to detect statistically significant intervention effects. For this study we have selected a sample size of 80 participants. This will provide an adequate sample for feasibility assessments and is in line with the constraints of available study resources and timing considerations related to the funding mechanism of the study. Comparisons done as part of the feasibility analyses of patient characteristics in each stage will serve as an alert to potential sources of bias in the study and will be used to inform refinement of the protocol for a larger study. Results from the pilot study, in conjunction with previous findings of behavioral interventions will be used to estimate the parameters needed for the study trial.

## **D. Stopping Rules**

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

## **E. Designation of PI/PO in the Role of Data Safety Monitor**

The PI, Dr. James Friction will provide data safety monitoring oversight for the study.

## **F. Safety Review Plan**

Study progress and safety will be reviewed following each recruitment and intervention phase – every 6 months by the Study Coordinator in collaboration with the PI. Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the PI following each of the reviews. An Annual Report will be compiled and will include a list and summary of AEs. In addition, the Annual Report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The Annual Report will be sent to the IRB and NIDCR. The IRB will review progress of this study on an annual basis.

### **G. Study Report Outline for the Interim or Annual Reports**

The study coordinator and statistician will prepare a study safety report which begins with a brief introduction section describing the study status, issues, and procedures that produced the report (e.g., data obtained by specific date). A study description with a current timetable and study schedule will be included. Data are presented that describe the administrative status of the study, including recruitment and forms handling. The study data report will describe demographic, baseline characteristics, subject status, and safety assessment.

#### *Study Report Outline*

- I. Table of Contents
- II. Introduction
  - a. Summary of Study Status and Issues or Problems
  - b. Report Preparation Procedures
- III. Study Description
  - a. Project Organization Chart, Personnel
  - b. Brief Statement of Purpose of Trial
  - c. Projected Timetable and Schedule
  - d. List of Any Resource Centers
- IV. Study Administration
  - a. Recruitment Status
    - i. Enrollment by Month for 6 months of enrollment
    - ii. Comparison of Targeted to Actual Enrollment
  - b. Retention Status
    - i. Overall Subject Status

- ii. Individual Subject Status
- V. Study Data Reports/Tables or Figures
- a. General Information
    - i. Enrollment (see Appendix A, Table 1)
    - ii. Demographic/Baseline Data (see Appendix A, Table 2)
    - iii. Subject Status (see Appendix A, Table 3)
  - b. Safety Assessment
    - i. Treatment Duration for All Subjects (see Appendix A, Table 3)
    - ii. AE Data
      - 1. Overall Listing (see Appendix A, Table 4)
      - 2. Specific Symptom Listing (see Appendix A, Table 5)
      - 3. Out-of-Range Values (see Appendix A, Table 6)
      - 4. SAE Listing (see Appendix A, Table 7)
      - 5. Subject Deaths (see Appendix A, Table 8)

#### **IV. Informed Consent**

A structured enrollment screening process will be implemented to assure that all subjects obtain complete information about the study and appropriate questions are asked to insure their understanding about the project prior to and during the consent process.

The SRC will contact all study participants completing the initial phone screen who are eligible and still express interest in the study. The SRC staff member will first provide a complete overview of the study and detail the requirements of study participation as specified in the consent form. The SRC will then ask whether the potential participant is still interested in study participation. If yes, they will describe the benefits and risks of study participation and discuss issues of confidentiality. Following this the SRC staff member will again ask about continued interest in the study and elicit questions from the potential participant. The participant will then be asked if they still wish to proceed. If the subject wishes to proceed, the SRC will then email the participant the study consent and HIPPA form along with a link to the website with log-in information (username and password). Subjects will be asked to visit the study website and log-in to complete the consent form electronically before continuing on in the study.

#### **V. Reporting Changes in Study Status**

During the funding of this study, any action by an IRB or one of the study investigators that results in a temporary or permanent suspension of the study will be reported to the NIDCR Program Official within 1 business day of notification.



**Data Safety and Monitoring Plan**

**Appendix A**

**Table 1. Enrollment by Month of Study**

Week #	# Expected (400 )	# Screened	# Enrolled	# Withdrawn	# Actual (#Enrolled - #Withdrawn)	# Cumulative

**Table 2. Demographics**

Characteristics	N	N%
Gender		
Female		
Male		
Ethnicity		
Hispanic or Latino		
Not Hispanic or Latino		
Unknown		
Age		
Mean (SE)		
Median (min, max)		
Race		
Asian		
Nat Hawaiian/Other Pac Islander		

Black or African American		
White		
Other		
More than one race		
Unknown		

**Table 3. Subject Status**

Pt Identifier	Date Enrolled	Date Completed Study	Study Status	Reason for Withdrawal	% Adherence to Intervention (# of Modules completed)	Intervention Duration (Weeks)

Status:

A = Active

C = Completed

W = Withdrew

L = Lost to Follow Up

% Adherence to Intervention:

(# Modules completed/total #)\*100

or

**Table 4. Adverse Events**

Pt Identifier	AE Onset	AE End	AE Description	Severity	SAE? (Y/N)	Relatedness	Action Taken	Outcome	Comments

Severity of AE:

- 1 = Mild
- 2 = Moderate
- 3 = Severe

Relatedness to Intervention:

- 1 = Definitely Unrelated
- 2 = Possibly Related
- 3 = Probably Related
- 4 = Definitely Related

Action Taken:

- 0 = None
- 1 = Dose modification
- 2 = Medical intervention  
- (specify in comments)
- 3 = Hospitalization
- 4 = Intervention discontinued
- 5 = Other

Outcome:

- 1 = Resolved
- 2 = Recovered with minor sequelae
- 3 = Recovered with major sequelae
- 4 = Continuing treatment
- 5 = Condition worsening
- 6 = Patient death\*\*

\*\*Provide further details regarding all reported serious AEs and deaths in the SAE and Subject Deaths tables listed at the end of this section.

**Table 5. Frequency of Specific Symptoms**

Symptoms	Description of AE	N%
Jaw Fatigue		
Jaw pain		
Jaw joint clicking		
Jaw joint locking		
Difficulty chewing		

**Table 6. Serious Adverse Events**

Pt Identifier	Age	Treatment Date	SAE	SAE Date	Related to Intervention	Description of Actions and Outcomes (e.g., hospitalization, withdrawn from study)
Subj001						
Subj002						
Subj003						