



INFORMED CONSENT

PRINCIPAL INVESTIGATOR: Robert J. Gatchel, Ph.D.

TITLE OF PROJECT: An Implementation and Biobehavioral Study of TMJMD

SPONSOR: National Institute of Dental and Craniofacial Research of the National Institutes of Health

This Informed Consent will explain about being a research subject in a clinical research study. It is important that you read this material carefully and then decide if you wish to be a volunteer.

PURPOSE

Temporomandibular joint and muscle disorder (TMJMD) pain refers to pain in the jaw or muscles surrounding the jaw. It is a very common type of pain in the general population, and has traditionally been associated with high costs for treatment (which was sometimes surgical treatment). Fortunately, however, now there are non-surgical treatment techniques to effectively manage jaw pain. Also, clinical research has demonstrated that if jaw pain is treated early on when it first appears, then the success of these new non-surgical treatment techniques are greatly increased. These non-surgical treatment techniques include methods such as biofeedback, stress management and self-management coping skills training. On the basis of past clinical research that we have conducted, we are now at a point to provide this early intervention for patients who have recently developed jaw pain. These methods were initially developed in a University research setting. We now want to evaluate whether we can produce the same positive results in a community setting such as the one where you are today. Therefore, the major goals of the present study are to evaluate whether our early non-surgical intervention method reduces your jaw pain or discomfort during treatment, just after treatment, as well as long term (when we evaluate you one year and two years after treatment). We also want to evaluate whether such treatment reduces the overall financial costs of jaw pain.

DURATION

We plan to recruit a total of 675 patients from 5 community dental clinics in Dallas. You will be seen for four separate assessment sessions: just before the start of treatment, immediately following treatment, as well as at one- and two-year follow-up periods. Each of these assessment sessions will last approximately 2.5 hours. At your very first visit, you will be paid \$20 to complete a brief questionnaire, as well as to read and sign an Informed Consent document. This should take approximately 20 minutes to complete. You will be paid \$50 for

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each subsequent assessment session (one of which will be today). You will also be administered 6 treatment sessions during the first one-two months of the study. Each of these sessions will last approximately one hour. There will be absolutely no cost to you for any of these sessions. Finally, after completion of treatment, we will also follow up by telephone at three-month intervals. The telephone follow-up will be brief, and will essentially involve your telling us about the status of your jaw pain/discomfort, whether it is interfering with your life, as well as any additional treatment you have sought as a result of your pain.

### PROCEDURES

**Intake Phase:** Before you see the study clinician today, you will be asked to complete a brief questionnaire about your jaw pain as well as signing an Informed Consent for participation in this study. Right after these forms are completed, the study clinician will ask you questions about your health, medications you take for any health problems, any surgical procedures you have had, and your overall coping style. All of this information will be collected via the following: A patient information form; a few brief questions about your pain and health care utilization related and unrelated to your jaw pain/discomfort; an oral facial exam, that involves taking physical measurements from your head and face area; a chewing performance evaluation, in which you chew an artificial food substance and then spit it out; a diagnostic interview; and completion of five questionnaires. The diagnostic interview will look at potential emotional difficulties and life experiences that you may or may not have had. You do not have to answer any questions that make you feel uncomfortable. The questionnaires will ask questions about your pain experience, as well as how you generally handle life events that may be related to your pain/discomfort experience. The entire evaluation will take approximately 2.5 hours.

**Treatment Phase:** If the study clinician believes that you qualify to participate in this clinical research, you will be offered one of two treatments to help manage your jaw pain/discomfort (you will have a 50% chance of being assigned to either of these two groups): either an early intervention self-care treatment program or an early biobehavioral treatment program. This early intervention consists of six one-hour sessions with the study clinician, in which you will be instructed in a means of reducing your jaw pain and discomfort. It does not have risks associated with it. Despite this, you will, of course, have the right to refuse such treatment after it is explained to you.

**Costs of Dental-Related Difficulties:** As noted earlier, we also are interested in evaluating the overall financial costs of jaw pain/discomfort. Therefore, we will want to gather such cost information. From time to time, health, family, transportation, and financial difficulties may make it difficult for some patients to obtain the dental/medical care they need. In order to gain a better understanding of how you access health care and the cost involved, we will need to obtain information on the care you received from all health care providers you have seen for the *past*

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*year*, and from all health care providers you will see for the *next two* years. This means that we may look at the services you used for one year prior to today's date, and for the next two years, or a total period not to exceed three years. This information will be collected from your physicians, with your consent, after you have signed the following release form. The information collected will include the date and place of services, medical procedures done, diagnoses, and billing charges if any. All attempts will be made to maintain your confidentiality, and your name will be removed from all information collected. The information is being collected for verification purposes only, and will not be used in any way not described in this consent.

#### POSSIBLE RISKS/DISCOMFORTS

All patients participating in this research program will be at minimal risk physically and/or psychologically. There are presently no known risks or side effects involved in participating in either the assessment or treatment parts of this study. The only inconvenience may be the amount of time that is required. However, that inconvenience is offset by the fact that this comprehensive program will cost you nothing. Finally, it should be noted that in all of our past clinical research projects in this area, we have never encountered any significant physical or psychological problem, or the need for any type of emergency care.

#### POSSIBLE BENEFITS

The possible benefits of your participation are the following: a significant decrease in any jaw pain or discomfort; an improvement in your ability to chew food more effectively, as well as in opening and closing your jaw/mouth more efficiently; the ability to more effectively cope with any pain or stress caused by any possible "flare-up" of jaw pain/discomfort. It should also be noted that this clinical research will not only help you by reducing your jaw pain and discomfort, but also result in a major contribution to society in general because these interventions can then be used as a general dental treatment method in all clinics and practices.

#### ALTERNATIVE PROCEDURES / TREATMENTS

The alternative procedures/treatments available to you if you elect not to participate in this study are to continue the usual dental care that you have received in the past, or to decide not to seek any additional dental care for your jaw pain and discomfort. The major risk of these alternatives is that your jaw pain or discomfort may not be reduced.

#### CONFIDENTIALITY

Every attempt will be made to see that your study results are kept confidential. A copy of the records from this study will be stored in Department of Psychology at The University of Texas at

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Arlington for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Although your rights and privacy will be maintained, the Secretary of the Department of Health and Human Services, the UT Arlington IRB, the FDA (if applicable), and personnel particular to this research (individual or department) have access to the study records. Your medical records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as noted above.

**FINANCIAL COSTS**

As noted earlier, there will be absolutely no financial cost to you for participating in this research study. In fact, as noted earlier, you will be compensated for the time spent during the four separate assessment sessions involved in your participation.

**CONTACT FOR QUESTIONS**

Name	Role on Project	Contact Phone Number
Robert J. Gatchel, Ph.D.	Principal Investigator, UTA	817-272-2541
Robbie Haggard, M.S.	Program Coordinator, UTA	214-645-8749
Margaret Perish, MACL	Post-Treatment Evaluator	214-645-8741
Cassandra Reid, M.S.	Intervention/Assessment Clinician, UTA	817-675-3075
Jacqueline Rosckes, M.S.	Intervention/Assessment Clinician, UTA	214-962-9096
Christina Thomas, M.S.	Intervention/Assessment Clinician, UTA	214-962-9086
Jane Williamson, L.M.S. W.	Intervention/Assessment Clinician, UTA	214-537-1729

If you have any questions, problems or research-related medical problems at any time, you may call any of the persons listed above. You may call the Chairman of the Institutional Review Board of The University of Texas at Arlington at 817/272-3723 for any questions you may have about your rights as a research subject.

**VOLUNTARY PARTICIPATION**

Participation in this research experiment is voluntary. You may refuse to participate or quit at any time. If you quit or refuse to participate, the benefits (or treatment) to which you are otherwise entitled will not be affected. You may quit by calling any of the persons listed above. You will be told immediately if any of the results of the study should reasonably be expected to make you change your mind about staying in the study.

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\_\_\_\_\_ Subject Initials

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By signing below, you confirm that you have read or had this document read to you. You will be given a signed copy of this informed consent document. You have been and will continue to be given the chance to ask questions and to discuss your participation with the investigator.

You freely and voluntarily choose to be in this research project.

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PRINCIPAL INVESTIGATOR \_\_\_\_\_ DATE \_\_\_\_\_

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SIGNATURE OF VOLUNTEER \_\_\_\_\_ DATE \_\_\_\_\_

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SIGNATURE OF PATIENT/LEGAL GUARDIAN (if applicable) \_\_\_\_\_ DATE \_\_\_\_\_

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SIGNATURE OF WITNESS (if applicable) \_\_\_\_\_ DATE \_\_\_\_\_

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