Contribution of Headache on the Transition from Acute to Chronic Painful Temporomandibular Disorders (TMDs) and its Persistence: A Prospective Cohort Study

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DEDICATION

I would like to dedicate this work to my lovely parents, wife, and kids: Mr. Abdullah Amhmed and Mrs. Salma Ahmoudah, Dr. Wafaa Safour, Abdullah Elghaci Amhmed, Ali Amhmed for their support, patience, prayers and love throughout my postgraduate program.

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LIST OF ABBREVIATIONS

TMD	Temporomandibular Disorders
ACTION	Acute Chronic Transition
RDC/TMD	Research Diagnostic Criteria for Temporomandibular Disorders
DC/TMD	Diagnostic Criteria for Temporomandibular Disorders
M and F	Males and Females
B and G	Boys and Girls
AV	Ana Velly
MG	Mervyn Gornitsky
ZD	Zovinar Der Khatchadourian
JGH	Jewish General Hospital
OD	Oral Diagnosis
GCPS	Graded Chronic Pain Scale
CPI	Characteristic Pain Intensity
NRS	Numerical Rating Scale
IASP	International Association for the Study of Pain
PHQ-8	Patients Health Questionnaire-8
GAD-7	Generalized Anxiety Disorders-7
OR	Odds Ratio
CI	Confidence Interval
HR	Hazard ratio
IDR	Incidence Density Ratio
SCL-90	Symptom Checklist-90-R

IHCD-II	International classification of headache disorders second edition
TTH	Tension-type headache
HAD	Hospital Anxiety and Depression Scales
BSI	Brief Symptom Inventory
STAI	State-Trait Anxiety Inventory
PSS	Perceived Stress Scale
TMJ	Temporomandibular Joint

Abstract

Although most of TMD patients receive various kind of treatments, nearly one-third of these patients continue to suffer from moderate to severe levels of pain, psychological distress, disability, and lower quality of life. Therefore, it is crucial to prevent painful TMD from becoming chronic, which may be extremely hard to manage. Thus, TMD should be systematically assessed and adequately managed, which may require a multidisciplinary approach with a strong emphasis on factors that upgrade acute cases to become chronic or persistent chronic. The second project of our ACTION program suggested that headache should be considered as one of these factors, while the first project of ACTION program indicated that no study assessed headache as a risk factor for the transition from acute to chronic TMD or its persistence. The aim of this three-month cohort study was to determine whether headache is a risk factor for the transition from acute to chronic TMD and/or its persistence. This study included 186 patients who were followed for three months. TMD diagnosis was established according to the RDC/TMD; 56 and 130 patients were classified as acute and chronic painful TMD respectively. Our results show no significant association between headache and the transition from acute to chronic painful TMD. For persistence, the crude model revealed that headache duration (OR = 1.01 CI: 1.00 - 1.04), number of sites of headache (OR = 1.41, CI: 1.30 - 1.93), headache behind eyes or inside the head (OR = 4.15, CI: 1.34 - 12.81) were significantly associated with persistence of chronic painful TMD pain. The multivariable analysis showed that headache duration (OR = 1.01 CI: 1.00 - 1.02), and headache behind eyes or inside the head (OR = 4.22, CI: 1.16 - 15.41) remained significantly associated while the number of sites of headache was not.

Keywords:

TMD, headache, acute pain, chronic pain.

Abstrait

Bien que la plupart des patients avec DTM reçoivent différents types de traitements, près d'un tiers de ces patients continuent de souffrir de douleurs modérées à sévères, de détresse psychologique, d'incapacité et d'une qualité de vie inférieure. Par conséquent, il est essentiel d'éviter que le DTM douloureuse devient chronique, ce qui peut être extrêmement difficile à gérer. Ainsi, le DTM devrait être systématiquement évalué et géré de manière adéquate, ce qui pourrait nécessiter une approche pluridisciplinaire, en mettant fortement l'accent sur les facteurs qui améliorent les cas aigus pour devenir chroniques ou chroniques persistantes. Le deuxième projet de notre programme ACTION suggère que les maux de tête devraient être considérés comme l'un de ces facteurs, alors que le premier projet de programme ACTION indique qu'aucune étude a évalué les maux de tête comme facteurs de risque pour la transition de DTM aiguë ou chronique ou de sa persistance. Le but de cette étude de cohorte de trois mois était de déterminer si les maux de tête sont une facteur de risque pour la transition de DTM aiguë ou chronique et / ou de sa persistance. Cette étude comprenait 186 patients qui ont été suivis pendant trois mois. Le diagnostic de DTM a été établi selon le RDC / TMD; 56 et 130 patients ont été classés comme DGE douloureuse aiguë et chronique respectivement. Nos résultats ne montrent aucune association significative entre les maux de tête et la transition entre la DTM douloureuse aiguë et chronique. Pour la persistance, le modèle brut a révélé que la durée de la tête de tête (OR = 1.01 CI: 1.00 - 1.04), nombre de sites de céphalée (OR = 1.41, IC: 1.30 - 1.93), maux de tête derrière les yeux ou à l'intérieur de la tête (OR = 4.15, CI: 1.34 - 12.81) ont été significativement associés à la persistance de la douleur dorsale chronique douloureuse. L'analyse multivariable a montré que la durée des maux de tête (OR = 1.01 IC: 1.00 - 1.02) et des maux de tête derrière les yeux ou à l'intérieur de la tête (OR = 4.22, CI: 1.16 -15.41) sont restés significativement associés alors que le nombre de sites de céphalée ne l'était pas.

Mots clés: DTM, maux de tête, douleurs aiguës, douleurs chroniques.

PREFACE

This thesis has followed a manuscript based thesis style. As per McGill University standards, the manuscripts included in thesis should be logically-coherent and should have a unified theme. The manuscript in this thesis discusses a novel project on the contribution of headache on the transition from acute to chronic painful temporomandibular disorders and its persistence. Following a brief introduction of the topic in the first chapter, the second chapter provides previous and current knowledge in the field of painful temporomandibular disorders and headache. Chapter three include the objectives of the study. The methodology of the study was presented in chapter four and the manuscript in chapter five. Chapter six presents a comprehensive discussion including some methodological considerations. Finally, the last chapter presents a succinct conclusion of this work.

Multiple authors have contributed in the thesis' work; explicit appreciation of each author's contribution is mentioned in the following section.

CONTRIBUTION OF AUTHORS

Manuscript:

Contribution of Headache on the Transition from Acute to Chronic Painful Temporomandibular Disorders (TMDs) and its Persistence: A prospective cohort study.

Mohamed Amhmed, BDS, M.Sc. Candidate: Contributed to recruiting and following-up with patients, carrying out the statistical analysis, and writing the manuscript.

Mervyn Gornitsky, Professor Emeritus, McGill University, has clinical and research experience in orofacial pain and saliva studies and he supported this project by advising on the saliva analysis.

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Zovinar der Khatchadourian, is a Faculty Lecturer at the Faculty of Dentistry at McGill University. She collaborated by performing the clinical examination of the patients.

Ana Miriam Velly, Associate Professor, Faculty of Dentistry McGill University, Montreal, Quebec, Canada: She has a DDS degree, an MS in Neurological Sciences, a Ph.D. degree in Epidemiology, as well as post-doctoral training from the Randomized Clinical Trial Unit in the Dept. of Epidemiology at McGill University. She conceived this investigation, designed and supervised this study, carried out the statistical analysis, and contributed to manuscript writing.

CHAPTER 1. INTRODUCTION

Temporomandibular disorders (TMDs) are a group of conditions characterized by dysfunction and pain in the temporomandibular joints or muscles of mastication or both (1, 2). TMDs are the second most common musculoskeletal conditions after chronic lower back pain (2). TMds are important public health problems since they affect a significant portion of the general population. The prevalence of painful TMD has been reported to fall between 5 to 12% of the general population (2-4).

Research has indicated that there are many factors that predispose individuals to developing painful TMD. Most researchers focus on oral habits, trauma, psychological factors, gender, and comorbidities. Studies have found that oral habits (e.g. clenching) are positively associated with TMD-related pain (5-7). Other studies argued that patients who have an experience of surgical and non-surgical dental extraction of the third molar or other kinds of indirect traumas are more likely to develop painful TMD than individuals with no history of trauma (5, 8-10). Comparative studies results claimed that painful TMD was more prevalent in individuals with psychological disorders than healthy individuals (5, 11, 12). With respect to gender, females are more susceptible to this ailment than males (13, 14). In addition to the above-mentioned factors, there are many comorbidities shown an association with TMD, which include headache, neck pain, back pain and fibromyalgia (15-17). Of the aforementioned comorbidities, headache is the most prominent.

Furthermore, some of these factors, such as psychological disorders (5, 18-20) and comorbidities (5, 18-20), contribute to the persistence of painful TMD as well. Therefore, they may affect the treatment and could explain why 30% of TMD patients continue to suffer from

moderate to severe levels of pain, psychological distress, disability, and lower quality of life regardless of the various kinds of treatments received (21, 22).

Based on what precedes, it can be noted that both the assessment and the management of TMD may require a multidisciplinary approach with a strong emphasis on the factors that upgrade acute cases to become chronic (23). Understanding these factors would be helpful in developing a preventive intervention protocol in the early stages of this condition to prevent it from becoming chronic, a stage at which it is more difficult to manage. However, as stated by the National Institutes of Health (NIH) "we do not fully understand how acute progresses to chronic pain at any level, from molecular to behavioral" (24). This is the reason why, in 2015, the Acute to Chronic TMD Transition (ACTION) program was initiated by Dr. Ana Velly and her team. It was aimed at identifying the risk factors which contribute to the transition from acute to chronic painful TMD and its persistence. Results from the first step of this program (systematic review) showed that less than ten articles had been published regarding the differentiation between acute and chronic or transition from acute to chronic painful TMD (25) which supports the NIH's observation above. Furthermore, this systematic review revealed that myofascial pain and pain intensity contribute to the transition from acute to chronic painful TMD; but nothing is demonstrated about headache. However, due to the small number of cohort studies, and methodological weaknesses (e.g. misclassification, selection bias), there is insufficient evidence of risk factors implicated in the transition from acute to chronic painful TMD. Furthermore, results from the second project of ACTION program, aimed to differentiate acute from chronic painful TMD indicated that headache was more common among participants experiencing chronic (71.9%) than those experiencing acute painful TMD (54.6%) (26). These results suggest that headache should be considered as important risk factor implicated in the transition from acute to chronic painful TMD. Therefore,

this prospective cohort study which is the third project of ACTION program aimed at assessing whether headache contributes to the transition from acute to chronic TMD-related pain and its persistence.

CHAPTER 2. EPIDEMIOLOGY OF TEMPOROMANDIBULAR DISORDERS

2.1 Prevalence of Painful Temporomandibular Disorders

Prevalence is a general term referring to the frequency of a disease or condition, which occurs over a period of time (27). It is classified into three distinct types. The first type is period prevalence, which is the proportion of cases that have an event at any time within a particular period of time (28). The second type is lifetime prevalence, which is the proportion of a population, which has experienced the event or condition at any point in their lives (29). The third type is point prevalence, which is the proportion of people, who have the disease or the event at a specific point in time (the point of the assessment) (29).

Table 2.1.1 summarizes the prevalence of painful TMD including the content of nine studies which reflect several populations worldwide. Von Korff *et al*. surveyed subjects, assessing period prevalence using a self-administered questionnaire and telephone interview over a period of six months. A sample of 1,016 participants (80.3% participation rate), aged between 25 and 44 years, were recruited from Health Maintenance Organization in Seattle, USA. It was reported that the six-month prevalence of facial pain was 12% while lifetime prevalence was 34% for patients who live up to 70 years of age. In respect to gender, more females presented facial pain (15%) compared to males (8%), and more females (58.4%) sought treatment for painful TMD than males (41.6%) (3).

Another telephone survey conducted in households with one or more persons aged 18 years and older in the city of Toronto, Canada, targeted 1,002 individuals. About 677 subjects completed the interview (67.7% participation rate). Approximately 13% reported temporomandibular joint pain (TMJ) during jaw function or while at rest. Prevalence was higher among respondents aged

under 44 years than those aged 45 years or older (6.9% vs. 2.6%), and among females when compared to males (6.9% vs. 3.7%) (30).

A telephone survey carried out in Quebec, Canada, in 1995 (Goulet *et al.*) on 897 subjects (participation rate of 64%) who were aged 18 years and over, produced the following results. About 30% of the participants (400 males & 497 females) experienced pain in the jaw joints and/or muscles of mastication. The rate of the prevalence among females was almost twice as high as that of males (9% vs. 5%) (31).

In Iran, a cross-sectional study was conducted on 171 females (18-65 years) to assess the prevalence of myofascial pain where the diagnosis was established using RDC/TMD. Among the 151 participants who completed the study (95% response rate), 8.77% suffered from myofascial pain. Similar to some results from other studies which used RDC/TMD, the prevalence of myofascial pain was 9.93% (32).

A 2008 study based on the National Health Interview Survey in the USA assessed a three-month point prevalence of painful TMD. It showed that of the 30,978 participants (13,480 males and 17,498 females, ≥18 years), about 5% reported painful TMD. Additionally, more females reported painful TMD as compared to men (6.3% vs. 2.8%) (33).

Also in 2008, in the USA, a random telephone survey investigating a six-month period prevalence was conducted in NY metropolitan area. It was reported that from 19,586 females, who completed the survey, about 782 were examined using RDC/TMD. The participation rate was 60%. Overall, the results indicate a high level of similarity between the clinical examination and the telephone survey prevalence rates: 10.5% vs. 10.1%. This outcome validated the efficacy of these reports (34).

Table 2.1.1 Summary of Prevalence of Painful TMD									
Authors, Year	**Study Design**	**Study population**	**Gender**	**Age**	**Sample Size**	**Participation rate**	**Prevalence (%)**	**Condition**	**Assessment**
Von Korff *et al.*, 1988	Survey	Patients at Health Maintenance Organization in Seattle, USA	M & F	≥ 18	1,016	80%	12	Facial Pain	Symptoms Checklist
Locker *et al.*, 1988	Survey	Households within the city of Toronto	M & F	≥ 18	677	68%	12.9	TMJ Pain (function and rest)	Telephone Survey/ Questionnaire
Goulet et al., 1995	Survey	General population living in the Province of Quebec	M & F	≥ 18	897	64%	30	TMD Jaw Pain	Telephone Survey/ Questionnaire
Schmitter *et al., 2007*	Survey	Patients from Six health care bases in Mashhad, Iran	F	18 – 65	171	95%	9.93	Myofascial Pain	Questionnaire Examination RDC/TMD
Isong *et al.*, 2008	Survey	General population, USA	M & F	≥ 18	30,987	Not provided	4.6	TMD Pain	TMJMD-Type Pain Instrument
Janal *et al.*, 2008	Survey	Households, USA	F	18 – 75	782	60%	10.5	Myofascial TMD	Telephone Survey/ RDC/TMD/ Clinical Examination
Mobilio *et al.*, 2011	Survey	Households in Municipality of Ferrara, Italy	M & F	15 – 70	2,005	91%	5.1	Painful TMD	Questionnaire
Progiante et al., 2015	Survey	General population used the Brazilian Public Health System	M & F	20 – 65	1,643	93%	36.2	TMD Pain	Questionnaire Clinical Examination RDC/TMD
Gillborg *et al.*, 2017	Survey	Community population of southern Sweden	M & F	20 – 89	6,300	63%	11.0	TMD Pain	Questionnaire

A telephone survey conducted in Italy used a questionnaire adapted from RDC/TMD with a sample consisting of 2005 males and females aged between 15 and 70 years. The response rate was 91.3%, and 5.1% of those respondents (3.1% males and 6.4% females) reported having pain during the month preceding the survey (4).

A cross-sectional study, assessing the prevalence of TMD, surveyed 1,643 subjects (response rate 92.5%) aged 20 to 65, who used the Brazilian Public Health System. This study included both males and females and used RDC/TMD to assess for signs and symptoms of TMD Results indicated that around 36.2% of this population had painful TMD (35).

A recent survey conducted in Southern Sweden demonstrated that TMD prevalence was 11.0%. The sample group consisted of 6,300 (participation rate 63%) subjects aged between 20 and 89 years; the subjects who were contacted by mail were selected randomly. RDC/TMD was used to establish the TMD criteria. As already observed in other studies, age and gender influenced the rate of TMD occurrence. TMD was more likely to be present in patients younger than 50 years compared to the older ones (OR= 1.2; 95% CI: 1.0 -1.6) and in females compared to males (OR= 1.3; 95% CI: 1.0 - 1.6) (36).

2.2 Incidence of Painful Temporomandibular Disorders

Incidence is the proportion or rate of new cases of a disease that occurs in a population during a particular time interval (27). There are two types of incidence: the first type is cumulative incidence, which is characterized as the proportion of new events in a group that is initially free of disease and is observed over a specific period of time (37). The second type is incidence rate or density which is a measure of the instantaneous rate of development of disease in a population; it is expressed as the number of new cases per total number of person-years at risk (38). Compared

to the prevalence, the incidence of painful TMD has been reported in the literature with less range of difference. Table 2.2.1, summarizes results from some studies that assessed TMD incidence.

The incidence of painful TMD was estimated in a longitudinal study involving a sample population of 1,016 individuals aged between 18 and 65 years (participation rate 80.3%) The participants were recruited from the Health Maintenance Organization and interviewed three years after the baseline with a dropout rate of 15%. The results showed that the incidence of painful TMD was about 6.5% three years cumulative incidence. Results also showed that the incidence of TMD was higher in females than in males (7.7% vs. 4.8) (39).

A cohort study, done in Okayama, Japan, found that the cumulative incidence of TMD-related pain was 6.1% after a four-year follow-up. Among the 672 (304 males and 368 females) participants, only 367 (40% dropout rate) completed the subsequent questionnaire. The subjects were selected randomly from the voters' list of Okayama city with a mean age of 49.7 years (40).

In 2007, Nilsson *et al.* carried out a cohort study, looking at Swedish adolescents and the first onset of painful TMD. The 2,255 subjects (12-19 years old) who were recruited from Public Dental Service clinics were followed for three years with a 10% dropout rate. The resulting annual incidence was 2.9%. With respect to age and gender, older females were more susceptible to develop TMD than younger ones while, overall, girls were more at risk than boys (OR= 4.5, 95% CI: 3.9-5.3) (41).

The incidence of TMD-related pain among 2,737 US residents aged 18 to 44 years (16% dropout rate) was approximately 4%. The incidence increased significantly with age. While the incidence among younger participants aged 18 to 24 stood at 2.5%, it was higher, which amounted to 4.5% among the middle-aged participants (35 – 44 years). Interestingly, females had only slightly higher incidence than males (3.6 vs. 2.8) (42).

Table 2.2.1 Incidence of Painful TMD									
Authors, Year	**Study Design**	**Study population**	**Gender**	**Age**	**Sample Size**	**Dropout rate**	**Condition**	**Incidence (%)**	**Assessment**
Von Korff *et al.*,1993	Cohort	Enrollees of a large health maintenance organization, USA	M & F	18+	1,016	15%	Painful TMD	Cumulative (6.5)	Questionnaire
Kamisaka *et al.*,2000	Cohort	Population selected randomly from voter's list of Okayama city	M & F	20+	171	40%	TMD Pain	Cumulative (6.1)	Questionnaire
Nilsson *et al.*, 2007	Cohort	Individuals visited from Public Service clinics in Swedish	M & F	12-19	2,255	10%	Painful TMD	Annual (2.9)	Clinical Examination/ Questionnaire
Slade *et al.*, 2013	Cohort	Community-based volunteers from four different sites, USA	M & F	18-44	2,737	16%	Painful TMD	Annual (3.9)	Telephone Interview/ Clinical Examination (RDC/TMD)

2.3 Temporomandibular Disorders Evaluation

2.3.1 Temporomandibular Disorders Pain Screening Instrument

Many instruments have been developed for the TMD-pain screening; they include Nielsen and Terp (1990) (43), Gerstner *et al.* (1994) (44), Nilsson *et al.* (2006) (45), and Gonzalez *et al.* (2011) (46).

The most recent screening instrument was developed by Gonzalez *et al.* (2011) (Table 2.3.1.1) (46). Its two versions, a long version (six-item) and a short one (three-item), assess two core symptoms: (a) pain frequency and (b) pain by function. Both versions have an excellent sensitivity (99%), specificity (97%), and reliability.

Table 2.3.1.1 Instrument of Screening Temporomandibular Pain Disorder

1. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?	a. No pain
	b. From very brief to more than a week, but it does stop
	c. Continuous
2. In the last 30 days, have you had pain or stiffness in your jaw on awakening?	a. No
	b. Yes
3. 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 a. No b. Yes
	B. Opening your mouth or moving your jaw forward or to the side a. No b. Yes
	C. Jaw habits such as holding teeth together, clenching, grinding or chewing gum a. No b. Yes
	D. Other jaw activities such as talking, kissing or yawning a. No b. Yes
Note: Items 1 through 3A constitute the short-version of the screening instrument, and Items 1 through 3D constitute the long-version. An “a” response 0 points, a “b” response 1 point and a “c” response 2 points.	

2.3.2 Temporomandibular Disorders Diagnosis

Several diagnostic protocols, such as Helkimo's Index, Symptom Severity Index (SSI), Craniomandibular Index (CMI), Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), and Diagnostic criteria (DC/TMD), have been established for the diagnosis of TMD. The most recent ones, i.e. RDC/TMD and DC/TMD will be described in more details here.

2.3.2.1 Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD)

Dworkin *et al*. established RDC/TMD as a classification system to standardize TMD diagnoses. The method uses a twofold investigative process, called Axis I and II, to assure more consistency in findings. Axis I is the clinical examination which includes three subgroups, muscle disorder, disc displacement, and joint disease. Axis II, entails "the psychological assessment, pain-related disability, and TMD-pain and related parafunctional behaviors of the TMD subject." The first TMD subgroup, muscle disorder, has two subcategories of its own. Group I.a, which is myofascial pain, entails pain in the muscles of mastication or on palpation in minimally three places, one of which aligns with the reported pain. Similarly, group I.b, myofascial pain with a limited opening, refers to pain in the jaw area and/or muscles of mastication that limits jaw function, such as pain-free unassisted opening of less than 40 mm. Disc displacement, which is the second subgroup, categorizes three types of abnormal mandibular function. In disc displacement with reduction, type I, the TMJ is pain-free, emitting a clicking noise on vertical activity (opening or closing), but not on thrusting or forward motion. Type II, which is displacement without reduction with a limited opening, is also pain-free up to a degree of $\leq$ 35mm during unassisted opening. Unlike type I, the articular disc produces no detectable sound during function. Finally, type III, disc displacement without reduction without limited opening, pain only occurs once the mouth has reached a width of 35mm or more during unassisted opening. The third group is also

characterized by other joint diseases, such as a) arthralgia (pain in the joints without crepitus), b) osteoarthritis, which constitutes of pain and crepitus in the joint, and lastly c) osteoarthrosis characterized by pain-free with crepitus (47-49)

2.3.2.2 Diagnostic Criteria for Temporomandibular Disorder (DC/TMD)

DC/TMD classification is quite similar to RDC/TMD; however, some new criteria such as headache were introduced to this protocol. It also has two Axes with a slight difference. Axis I is for physical examination, and it includes three group of disorders, I) Muscle disorders, II) TMJ disorders, and III) Headache. I) Muscle disorders are divided into four subtypes, myalgia, tendonitis, myositis, and spasm. Myalgia includes three subcategories, local myalgia, myofascial pain, and myofascial pain with referral. II) TMJ disorders include arthralgia, disc displacement with reduction, disc displacement with reduction with intermediate locking, disc displacement without reduction with a limited opening, disc displacement without reduction without limited opening, osteoarthritis, osteoarthrosis, luxation, and subluxation. III) Headache includes headache attributed to TMD. Axis II includes evaluating pain behavior, psychological status, and psychosocial functioning (50).

2.4 Risk Factors for Temporomandibular Disorder

Risk factor refers to any exposure or characteristic which modifies the risk or the likelihood of developing a condition or disease. Putative risk factors leading to TMD include both direct and indirect trauma, oral habits, such as clenching and grinding, psychological factors, and gender. The following paragraphs present the above factors and give an overview of some resulting studies.

2.4.1 Bruxism

Bruxism, which is defined as a repetitive jaw-muscle activity, is characterized by grinding or clenching the teeth or by thrusting or bracing of the mandible, or both (51). The incidence of

bruxism is 4.5% in the general population (52) while the prevalence ranges from 8% to 31.4%, and it has two manifestations: it occurs during wakefulness (awake bruxism) or sleep (sleep bruxism) (51, 53-56). The following case-control studies point to some results which tend to confirm the association between TMD and bruxism.

A large case-control study including 469 participants aged 18-82 years (response rate 80%) was conducted. Participants were grouped according to RDC/TMD as follows: 157 with both myofascial pain and arthralgia, 97 with only myofascial pain, 20 with only arthralgia and 195 controls. The results showed that clenching was more prominent among groups with simple myofascial pain (OR = 4.8; 95% CI: 2.4 - 9.8) and myofascial pain with arthralgia (OR = 3.3; 95% CI: 1.8-5.8) when compared to controls. Moreover, those with myofascial pain (OR = 4.2, 95% CI= 2.0, 8.6) or myofascial pain with arthralgia (OR = 4.7, 95% CI= 2.4, 8.9) were more likely to be females than males (57).

One year later, a case-control study with a participation rate of 86% was conducted including 83 patients with myofascial pain and 100 controls. Of the 183 subjects, 72 % were females, and the mean age was 32.7 years. The study found that clenching (OR = 2.54; 95% CI: 1.10 – 5.58) and clenching-grinding (OR = 8.40; 95% CI: 2.74 - 25.73) were more likely to be presented by patients with myofascial compared to the group with grinding only and controls. This shows a strong association between clenching-grinding and chronic myofascial pain which was diagnosed based on RDC/TMD. The methodology of this study was unique where the effect of bruxism was measured separately for each type: clenching only, grinding only, and both clenching-grinding together. Furthermore, it took into account how the effect of clenching and clenching grinding could be modified depending on how the patient was notified about these habits (5).

A similar association was also found in a cross-sectional study which used RDC/TMD and another clinical diagnosis criteria which were proposed by American Academy of Sleep Medicine to diagnose TMD and sleep bruxism respectively. The study enrolled 272 subjects who sought care between March 2007 and March 2009 at Orofacial Pain Clinic of a University-based specialty clinic, Brazil. The mean age for these participants was 37.1 years, and 87.5% of them were females. The results showed that patients with painful TMD (OR = 5.93, 95% CI: 3.19 – 11.02) and arthralgia (OR = 2.3; 95% CI:1.58–3.46) were more likely to present bruxism than those without TMD. Unfortunately, no participation rate was provided (6).

Bruxism was associated with painful TMD in another cross-sectional study, including 1,220 TMD patients (1020 females & 190 males > 18 years) from the Orofacial Pain Unit of the Dental Medicine Section of the Cordoba Health District. The RDC/TMD was used to diagnose those patients. The results indicated that participants with TMD were more likely to present bruxism compared to those without TMD (OR = 2.5 95% CI: 1.1 - 5.5). Also, bruxism (clenching or grinding) was presented almost two times more by females than males (OR= 1.95; 95% CI, 1.42 - 2.67) (58).

A more recent case-control study with a sample consisting of 733 TMD patients according to RDC/TMD (82% females; mean age 41.4), and 890 controls (57% females; mean age 40.4), studied the relationship between TMD and sleep and/or awake bruxism. The result showed that sleep bruxism (49.4 versus 23.5%: P< 0.001) and awake bruxism (33.9 versus 11.2%; P< 0.001) were higher among patients with TMD compared to controls. Also, it was shown that subjects with TMD were three times as likely to report both sleep and awake bruxism (clenching or grinding) than subjects without TMD (OR = 3.0; 95% CI: 1.6 - 5.4). Both sleep and awake bruxism were assessed through self-report questioners (59).

A nested case-control study studied 185 painful TMD cases and 1,633 controls (83% response rate) aged 18 - 44 years. Females were 59.4% of the total sample, and RDC/TMD was used to diagnose TMD cases. The results demonstrated that painful TMD patients were more likely to report parafunctional behavior such as clenching the teeth or bracing the jaw (OR = 16.8; 95% CI: 8.6, 32.9) compared to controls (99)

These results align with a cohort study which involved 2,737 individuals (59.6% females). This cohort study showed that individuals who reported higher score of parafunctional behavior were more likely to develop painful TMD than those with lower score (HR = 1.75, CI = 1.28 - 2.39). Those participants were aged 18-44 years and were followed over a median of 2.8 follow-up year period with 16% of dropout rate. Furthermore, the response rate was 83%, and the diagnosis was established based on RDC/TMD (7).

2.4.2 Trauma

Trauma is defined as any force that exceeds the limit of the normal functional load. Such force is classed as direct or indirect. Direct trauma is isolated force involved in the structure, such as dental extraction and overstretching. On the contrary, indirect trauma is a sudden blow with no contact to the structure, but affecting it (i.e. neck & strain injury) (60).

Some studies concluded that both direct and indirect trauma are risk factors for painful TMD. These studies reported a significant relationship between trauma and TMD-related pain (5, 8-10).

Huang *et al.* (2002) study (described in details in the previous section), showed that trauma (e.g. hard blow or bang to the jaw) was more common among 97 patients with simple myofascial pain (OR = 2.0; 95% CI: 1.1-3.8) and 157 with myofascial pain with arthralgia (OR = 2.1; 95% CI: 1.2-3.6) when compared to controls (57).

The aforementioned Velly *et al*. (2003) study also demonstrated that among 183 subjects included in their study, 83 patients with TMD myofascial pain were more likely to have a history of head or neck trauma compared to 100 controls (OR = 2.26; 95% CI: 1.23 - 4.13) (5).

A retrospective cohort study with 34,491 participants (49% females) who were 15 years old and followed for five years, found that the subjects with a history of third molar extraction were almost twice as likely to develop painful TMD compared to those with no history of extraction (Relative Risk (RR) = 1.6; 95% CI: 1.3 to 2.0). The data used was gotten from electronic dental insurance records, and 2.7% of the subjects were excluded due to missing sex data (8).

A six-month prospective cohort study done in Denmark looked at two subject groups: 72 of whom underwent surgical third molar extraction (62.5% females; mean age 25) and 25 of whom did not (60% females; mean age 26). The subjects were tracked for one week, one month, and six months. The results showed that 21% of the participants with surgical third molar extraction and 16 % without third molar extraction developed TMD. Indeed, the results did not show statistically significant increase in the incidence of TMD among patients who underwent third molar surgery after a six-month follow-up. RDC/TMD was used for the clinical examination during the baseline and follow-up visits (9).

Another prospective cohort study, which enrolled 60 participants who experienced whiplash injury (mean age 33; females 63%) and 53 who did not (mean age 36; females 60%) with a participation rate of 98.4%, found an association between trauma and TMD. Fifty-seven patients with the injury and 50 without were interviewed after 1 and 15 years (5% dropout rate). The results indicated that presence of TMD among participants with whiplash injury was significantly higher than those without this injury (44% vs. 20%, P = 0.0055) (10).

2.4.3 Psychological Factors

Many studies indicated that individuals, who experienced painful TMD, usually demonstrate at least one psychological disorder, such as anxiety, stress, or depression (5, 19, 61 - 64). The following paragraphs discuss some of these studies.

The aforementioned Velly *et al*. case-control study, reported that patients with myofascial pain were more likely to have depression (OR= 2.76; 95% CI: 1.40 - 5.50), somatization (OR = 3.56; 95% CI: 1.80 - 7.02), anxiety (OR= 3.48; 95% CI:1.69 - 7.15), and hostility (OR = 2.39; 95% CI:1.0 - 6.72) as compared to controls. The Symptom Checklist-90-R (SCL-90) was used for assessing these factors (5).

A cross-sectional study was conducted to investigate the co-occurrence of syndromes that are frequently unexplained and to determine whether they have common associated factors, such as chronic orofacial pain. The chronic orofacial pain was defined as pain in the face, mouth, or jaws that had been existing for three months or more. The study included 2,299 subjects aged 18 to 75 years. The results showed that individuals with orofacial pain were more likely to report higher levels of somatization (OR = 4.3; 95% CI: 2.9 - 6.4), anxiety (OR = 3.5; 95% CI: 2.4 - 5.1), and depression (OR = 4.6; 95% CI: 2.9-7.2) than subjects without orofacial pain. Among these enrollees, 61.5% were females with a participation rate of 72 %. Psychological disorders were measured using hospital anxiety and depression scales (HAD) (65).

A three-year cohort study, in which Brief Symptom Inventory (BSI), State-Trait Anxiety Inventory (STAI), and Perceived Stress Scale (PSS) were used to assess psychological disorders, showed that, of the 171 subjects (18-34 years), those with perceived stress [Incidence density ratio (IDR) = 2.6; 95% CI: 1.5 – 5.5] and depression [Incidence density ratio (IDR) = 3.2; 95% CI: 1.5 – 6.7] were more likely to develop painful TMD compared to healthy individuals. Only females,

who were examined with RDC/TMD, were included in this study, and the dropout rate was 32% (66).

Furthermore, results from a two-year cohort study, having 1,329 participants (response rate 87%) and using Health Anxiety Questionnaire and HAD to assess psychological disorders, found that subjects with higher levels of anxiety were almost three times as likely to develop chronic orofacial pain than those with lower to no levels of anxiety (OR = 2.5, 95% CI: 1.3 - 4.6). Moreover, depression was shown to be significantly associated with orofacial pain (OR = 3.1, 95% CI: 1.3 - 7.5; $P< 0.05$). About 52% of those subjects were females, aged 18 - 175 years, and were followed for two years with a dropout rate of 14% (11).

A nested case-control study, which recruited 185 painful TMD cases and 1,633 controls (18 - 44 years) with an 83% response rate, determined that painful TMD patients were more likely to report stress (OR = 1.5; 95% CI: 1.3, 1.8), anxiety (OR = 1.5; 95% CI: 1.3, 1.7), and depression (OR = 1.6; 95% CI: 1.4, 1.8) than controls. This particular analysis employed (STAI), SCL-90R, and (PSS) to measure psychological disorders and RDC/TMD to diagnose TMD (19).

These results align with a cohort study which involved 2,737 individuals (59.6% females) and which used SLC-90R, PSS, and STAI to assess psychological comorbidities. This cohort study reported that individuals who experienced some psychological comorbidities, such as somatization [Hazard ratio (HR) = 1.38; 95% CI: 1.27 - 1.49; P<0.001], depression [Hazard ratio (HR) = 1.31; 95% CI: 1.19 – 1.42; P<0.001], and anxiety [Hazard ratio (HR) = 1.29; 95% CI: 1.19 - 1.39; P<0.001] were more likely to develop painful TMD than those with no psychological comorbidities. Those participants were aged 18-44 years and were followed over a median of 2.8 follow-up year period with 16% of dropout rate. Furthermore, the response rate was 83%, and the diagnosis was established based on RDC/TMD (12).

2.4.4 Gender

Several studies suggest that painful TMD affects more females than males (13, 14, 67). This gender-related difference is still not clearly explained. Nevertheless, some studies speculate that a possible justification is the females' tendency to seek medical care over males (68). In 1996, Wanman *et al*. theorized that males' recovery process tends to be shorter than that of females, which could account for the distinction between the two and the reason why females visit the doctor more (69). Other speculations include the link between the pathogenesis of TMD and female sexual hormones, and the link between pain modulation and TMD because females are more sensitive than males (13, 70 - 72).

This gender-related difference was also noted in Huang *et al*. (2002) study. The results indicated that females were more likely to have myofascial pain (OR = 4.2; 95% CI: 2.0 - 8.6) and myofascial pain with arthralgia (OR = 4.7; 95% CI: 2.4 - 8.9) as compared to males (57).

Similar results were found by Velly et al. (2002) who demonstrated that females were more likely to have myofascial pain compared to males (OR= 2.36; 95% CI: 1.19 - 4.66) (5).

A three-year cohort study which included 1,996 participants aged 11 years (response rate 49%), also indicated that adolescent females were more likely to develop TMD-related pain compared to males (OR = 2.0, 95% CI = 1.2 - 3.3). Among these subjects, 1310 (51% females) provided follow-up data, which were examined based on RDC/TMD with a dropout rate of 34% (14).

These results support other results from a cross-sectional study conducted by Sander *et al*. The study included 3,954 subjects (71.8% participation rate; 62% females) who were aged 18 - 91 years. This study concluded that TMD-related pain was significantly higher among females (12.6%) than in males (7.5%) (OR = 1.8; 95% CI: 1.2 - 2.7) (73).

A 2013 cross-sectional study, which enrolled 404 females (mean age 40 years) and 98 males (mean age 41 years) with TMD, indicated that more females presented TMD than males (P = 0.004). This study also showed that females suffered from a higher degree of restricted mouth opening compared to males (P<0.001) (67).

Three years later, another cross-sectional study was carried out and included 1,000 individuals (mean age 33) with TMD and divided into two groups: females (n = 823) and males (n = 177). The results demonstrated that TMD-related pain was more likely to be present in females than in males (OR = 2.31; 95% CI: 1.62 - 3.29) (13).

Similarly, a very recent mail survey conducted by Gillborg *et al.* which enrolled 3,480 females and 2,643 males aged 20 to 89 years with a response rate of 63%, found that TMD-related pain was almost 1.4 more common in females than in males (OR = 1.32; 95% CI: 1.07 - 1.65) (36).

2.5 Comorbidities

In addition to the TMDs symptoms, TMDs patients usually complain about other kinds of pains, such as headache, neck pain, back pain, and fibromyalgia. These other pain conditions are referred to as comorbidities. Comorbidities are defined as co-occurrence of two or more medically diagnosed conditions or diseases in the same patient (74).

Even though the mechanism of this co-occurrence is not clear, there are many pieces of evidence that these comorbidities contribute to the onset (11, 14, 64), and the persistence of chronic TMD (22, 75-77), and may significantly complicate diagnosis and treatment effectiveness (22, 78). The most common of these comorbid conditions is headache which will be described in detail in the following paragraphs.

2.5.1 Headache

The International classification of headache disorders defines headache as a recurrent episodic disorder manifesting in attacks lasting 4 - 72 hours with at least two of five features. The latter are unilateral location, pulsating pain, moderate or severe intensity, aggravation by routine physical activity, and association with nausea and/or photophobia (79). The one-year prevalence of headache in the general population, using International classification of headache disorders second edition (IHCD-II), for tension-type headache (TTH) ranges from 36 to 86.5% and from 10.2 to 23.6% for migraine (80-94).

2.5.2 Association between Headache and TMD

The relationship between headache and TMD is unclear, and many studies have claimed comorbidity between TMD and headache (95, 96). The majority of adult and adolescents TMD patients reported headache; and they were up to 8.8 times more likely to have headache compared to subjects without painful TMD (15, 61, 93, 97-101). The prevalence of headache among painful TMD patients ranges from 30% to 94% in adolescents (14, 17, 102) and 9% to 97% among adults (15, 61, 93, 95, 99-101, 103).

A nested case-control study studied 185 painful TMD cases and 1,633 controls (83% response rate) aged 18 - 44 years. Females were 59.4% of the total sample, and RDC/TMD was used to diagnose TMD cases. The results demonstrated that painful TMD patients were more likely to report headache and headaches types (OR = 8.8; 95% CI: 3.8, 20.1) compared to controls (99).

Another case-control study was conducted to investigate the relationship between headache and TMD subtypes as well as its severity. The study recruited 247 subjects with TMD and 53 without TMD (82.7% females) with a mean age of 37.4 years for females and 39.8 for males. It was found that patients who reported headache and higher frequency of headache were more likely

to have TMD (OR = 2.5; 95% CI: 1.7, 3.5, P = 0.0034) and higher intensity of painful TMD (OR = 6.6; 95% CI: 3.1, 14.0, P< 0.001). The ICDH-II and RDC/TMD were used to diagnose headache and TMD subsequently (101).

A matched case-control study was conducted (participation rate 54%) in Denmark including 58 subjects with TTH (mean age 34.5 years) and 58 healthy controls (male/female 13/45) with a mean age of 39.5 years. RDC/TMD was used for diagnosing TMD and ICHD-II for TTH. This study found that TTH patients had a higher prevalence of jaw pain/stiffness (67% vs. 9%, P <0.001) and limitation of jaw function (14% vs. 3%, P <0.01) compared to controls. Furthermore, according to Caspersen (2013), more than half of the headache patients from tertiary headache center (Denmark) also had TMD diagnosis based on RDC/TMD and ICHD-II (104).

Another cross-sectional study conducted in Denmark included 99 patients (mean age of 44.8 years); it demonstrated that out of 99 patients (76.6% females) who had headache, 82 (82.8% reported TMD-related pain according to RDC/TMD axis II. In addition, among 98 (participation rate 99%) patients who were clinically examined based on RDC/TMD, 56.1% of them had TMD-related pain. ICHD-II was also used in this study for headache diagnosis (93).

A large cross-sectional study recruited 544 subjects who were classified into three groups: 309 individuals had TMD-related pain with temple headache; 86 had painful TMD and no headache, 149 subjects did not have headache or TMD. The results of this study showed that there is a significant association of increased TMD pain intensity and increased frequency of clinical TMD signs with more frequent temple headache (P <0.001). The ICDH-II and RDC/TMD were used for diagnosing headache and TMD subsequently (95).

A cross-sectional study conducted in Capela Nova, Brazil (participation rate 98.42%) recruited 92 patients with chronic daily headache from headache centers (mean age 42 years) and

57 (mean age 43.3 years) from the general community. Chronic daily headache (CDH) included three types: chronic tension-type headache, chronic migraine, and headache attributed to excessive use of medication, and it was diagnosed according to ICHD-II while TMD was diagnosed by using RDC/TMD. About 58.1% of the patients recruited from the general community presented TMD while the number of those recruited from headache center who presented TMD amounted to 80%. As for TMD subtype, myofascial-TMD was presented by 55.3% of the patients from the headache center as opposed to 30.2% from the community (OR= -25; 95% CI: -40.8% to -9.4%) (105).

A case-control study used RDC/TMD and enrolled 285 TMD patients (77.2% girls) and 302 controls (22.5% boys) with a mean age of 16 years. The results pointed to differences between groups and headache was reported in 69.5% of painful TMD cases as opposed to 6.2% of controls. Patients with painful TMD were more likely to present headache compared to controls (OR = 4.4; 95% CI: 3.1 - 18.1). The study also found a higher association between painful TMD and headache in the subgroup where headache came before painful TMD (OR = 9.4; 95% CI: 4.8 - 7.07) (17).

2.5.3 Headache as a Risk Factor for First Onset of TMD

Although there are many studies which have been examining the relationship between headache and TMD, this relationship is still not well known. One of the most important questions which have arisen is: Are people who experience headache more likely to develop painful TMD? Based on the results from the following studies, the answer to this question is yes.

LeResche *et al.* conducted a three-year cohort study including 1,996 participants aged 11 years old with a response rate of 49%. The study measured the presence of headache and indicated that participants with headache were more likely to develop painful TMD compared to the group of subjects who did not report headache (OR = 2.6; 95% CI: 1.6 - 4.4). Among those subjects,

1310 (51% females) provided follow-up data which were examined based on RDC/TMD with a dropout rate of 34% (14).

A twenty-year cohort study recruited 337 subjects (56% females) aged between 30-31 years (participation rate of 74.1%); it demonstrated that participants with frequent headache were at a greater risk of developing orofacial pain compared to those without headache (OR = 3.7; 95%CI: 1.6-8.4) (64).

A three-year prospective cohort study (dropout rate 29%) included 266 females aged between 18 and 34 years and followed them yearly. It showed that subjects who developed TMD reported significantly more headache (P = 0.0006) than participants who did not develop. In this study, RDC/TMD was used to assess TMD while ICDH-II was used to assess headache (106).

These results support a cohort study conducted on a total sample of 2,722 participants (59.6% females). The response rate was 83%, and the diagnosis was established based on RDC/TMD. This study found that individuals who experienced headache were more likely to develop painful TMD than those without headache. More specifically, among the 206 subjects with tension-type headache at the baseline were 1.69 times as likely to develop TMD (HR = 1.69; 95% CL: 1.12, 2.53). These participants were aged 18-44 years and were followed over a median of 2.8 follow-up year period with a 16% of dropout rate (107).

A recent nested case-control study which is a part of OPPERA included 248 TMD patients (64.9% females) and 191 TMD-free control (63.9 females) aged between 18-44 years. It showed that the incident TMD cases reported significantly higher frequency of headache before the TMD onset (P < 0.0002). In other words, patients who developed TMD were twice as likely to report headache before the onset of TMD compared to the control group (OR = 2.1 95% CI: 1.3-3.5). ICHD-II and RDC-TMD were used for the assessment of headache and TMD respectively (94).

Tchivileva et al. also demonstrated that migraine (HR = 1.67, 95%CI: 1.06-2.62) and mixed headache (HR= 4.11, 95% CI: 1.47-11.46) were significant predictors for developing TMD in a prospective cohort study including 2410 subjects (59.9% females). Those participants were aged between 18-44 years and were followed for a median of 2.8 years per person with a dropout rate of 16%. Headache was assessed using ICHD-II, and TMD incident cases diagnosed based on RDC/TMD (94).

2.5.4 Headache as Risk Factor for the Transition from Acute to Chronic TMD and/or its Persistence

Based on the aforementioned systematic review (25), myofascial pain and pain intensity are potential predictors for the transition from acute to chronic painful TMD. However, due to the small number and limitations of the performed cohort studies, there is insufficient evidence of risk factors implicated in the transition from acute to chronic painful TMD. Moreover, this review showed that there is no study which has assessed headache as a risk factor for this transition and/or the persistence of the chronic painful TMD.

Additionally, results from the second project of ACTION program demonstrated that headache was more common among participants experiencing chronic painful TMD (71.9%) compared to acute painful TMD (54.6%). The results also showed that participants with chronic painful TMD were more likely to report headache located behind the eyes or inside the head (OR = 4.14, $P = 0.02$). These results suggested that headache should be considered as important risk factors implicated in the transition from acute to chronic painful TMD (25).

Based on the literature review and results presented above, the relationship between headache and TMD is still not fully understood, and there are many questions which have not been answered yet. For example, is headache a risk factor to the transition from acute to chronic TMD

and/or its persistence? Unfortunately, to the best of our knowledge, there are no studies which have addressed this question.

CHAPTER 3. STUDY OBJECTIVES AND HYPOTHESES

This 3-month cohort analysis is the third step of the ACTION project. The overall aim of this current study was to identify whether headache is a risk factor for the transition from acute to chronic painful TMD and/or its persistence.

More specifically, the aims and hypotheses are:

Primary Aims

1. To identify whether headache at baseline increases the risk related to the transition from acute to chronic painful TMD at three months follow-up.

Hypothesis 1. Participants with headache are more likely to have the transition from acute to chronic painful TMD at three months follow-up than those without headache.

2. To identify whether headache at baseline increases the risk related to the persistence of painful TMD at three months follow-up.

Hypothesis 2. Participants with headache are more likely to have the persistence of painful TMD at three months follow-up than those without headache.

Secondary Aims

1. To identify whether specific sites of headache (e.g. headache in temple area) at baseline increase the risk related to the transition from acute to chronic painful TMD at three months follow-up.

Hypothesis 1. Participants with specific sites of headache are more likely to have the transition from acute to chronic painful TMD at three months follow-up.

2. To identify whether specific sites of headache increase the risk related to the persistence of painful TMD at three months follow-up.

Hypothesis 2. Participants with specific sites of headache are more likely to have the persistence of painful TMD at three months follow-up.

CHAPTER 4. METHODOLOGY

In this section, the methodology of the current cohort study is described. It includes the following elements: ethics, study design, study population, data collection, and statistical analyses.

4.1 Ethics

The ACTION program was approved by the McGill Institutional Review Board in Montreal, Canada (approval number: A12-M113-14A) and by the Dental Specialists Group in Ottawa, Ontario (approval number: 240-400). All participants agreed to participate in this study and signed the consent form.

4.2 Study Design

This is a pilot prospective cohort study that followed acute and chronic TMD-related pain patients for three months. All the participants were recruited between August 2015 and March 2017. Enrollment in this ACTION prospective cohort study continued after March 2017 and is still going on, and the new data will be analyzed for future publications.

4.3 Study Population

Participants who met the eligibility criteria and who had acute or chronic painful TMD were recruited from the Jewish General Hospital (JGH) general dental clinic, the Faculty of Dentistry of McGill University oral diagnosis (OD) clinic, Montreal General Hospital, and the Dental Specialists Group TMD-specialized clinic. Participants with painful TMD were eligible to participate if they were aged between 18 and 80 years and were diagnosed with painful TMD (muscle and/or joint pain) according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). Patients were excluded, however, if they had another orofacial pain, had no access to a telephone, did not speak English or French, or were unable to provide informed consent.

4.4 Assessment of Headache at Baseline

Headache was assessed using the DC/TMD instrument. The DC/TMD included several questions assessing headache and some headaches characteristics, such as duration of headache, sites of headache, and intensity of headache (mild-moderate or moderate-severe).

4.5 Assessment of Study Outcome at the Three-Month Follow-up

At the first appointment, we informed patients about the follow-up which should be done three months later. Patients who failed to respond to the interview on the time of the follow-up received a call one or two days later and were rescheduled for another interview. The time needed to complete the interview ranged between 5 to 10 minutes. In this interview, we assessed two main outcomes which are the transition from acute to chronic TMD-related pain for acute cases (acute cohort) and the persistence among chronic patients (chronic cohort) using Numerical Rating Scale (0-10 NRS). At the follow-up interview, we also assessed TMD-related pain treatment using Brief Pain Inventory (BPI) (110).

4.6. Confounder Variables

Confounding is a distortion of the exposure-outcome association due to its mutual association with another factor (111). This distortion can lead to either overestimation or underestimation of the true association between exposure and outcome. In our study, the possible confounders were age, gender, anxiety, depression, pain intensity, and treatment.

For the assessment of potential confounders, pain intensity was also assessed using DC-TMD (50) which involves questions based on Graded Chronic Pain Scale (GCPS) (108). CPI was calculated as the mean of the patient's report of current pain, worst pain in the last three months and mean pain in the last three months, multiplied by 100 (109). Generalized Anxiety Disorders (GAD-7) and Patient Health Questionnaire (PHQ-8) were used to measure anxiety and depression,

respectively. The scoring cut-offs for the GAD-7 and PHQ-8 questionnaires assessing anxiety and depression respectively were: 0-4 indicates that a person is not anxious or depressed, 5-9 indicates mild, 10-14 moderate, 15–27 indicates severe anxious or depressed. Furthermore, the following two sociodemographic factors were investigated in this study: age and gender.

4.7. Statistical Analyses

Descriptive analyses were performed to assess the characteristics of acute and chronic TMD cohorts. Student's t-test, and ANOVA were used to compare the continuous variables (e.g. age) between study groups. Chi-square test was used to compare the categorical or binary variables between groups (e.g. gender).

Rather than just limiting our analysis to the relationship between presence or absence of headache and the transition from acute to chronic TMD-related pain, we decided to further include headache duration, headache intensity, and number of sites of headache (e.g. headache in temple area, headache in the top of head, and headache behind eyes) in the analyses.

The dependent variable in both acute cohort and chronic cohort was binary: chronic vs. nonchronic and persistent chronic vs. non-persistent chronic. Univariate and multivariable logistic regression analyses were used to determine if headache and headaches characteristics were associated with increased risk of transition from acute to chronic painful TMD and its persistence, regardless potential confounders: age, gender, anxiety, depression, pain intensity, and treatment. All the analyses tested a null hypothesis of no statistical relationship between the independent and dependent variables of interest at $\alpha = 0.05$ significance. The odds ratio (OR) and 95% confidence intervals (CI) for each factor were estimated. All the analyses were performed using the statistical software package SAS (version 9.4; SAS Institute Inc., Cary, NC, USA), with the significance level for type I error set at the 0.05 level.

The logistic regression equation used can be written as:

$$\ln\left(\frac{p}{1-p}\right) = \beta_0 + \sum_{i=1}^{k} \beta_i * X_i$$

Where,

p is the probability of Y = 1, or the probability of the outcome

X_i is the i^{th} predictor variable, i = 1,2,3…k;

β_o is the log odds of probability of outcome when predictor variables have a value of zero

β_i is the regression parameter associated with the i^{th} predictor variables such that odds ratio associated with an increase in one unit of the i^{th} variables, when other variables are constant, is

$$OR_i = e^{\beta_i}$$

Secondary Analysis

We also performed a secondary analysis to assess the effect of each site of headache separately (e.g. headache in the temple area, headache in the top of the head, and headache behind eyes) on the transition from acute to chronic painful TMD and/or its persistence. Univariate and multivariable logistic regression analyses were also applied to both acute and chronic cohorts.

CHAPTER 5. MANUSCRIPT

Contribution of Headache on the Transition from Acute to Chronic Painful Temporomandibular Disorders (TMDs) and its Persistence: A Prospective Cohort Study

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Introduction

Temporomandibular disorders (TMDs) are a group of conditions characterized by dysfunction and pain in the temporomandibular joints or muscles of mastication or both (1, 2). TMDs are the second most common musculoskeletal conditions after chronic lower back pain (2). TMds are important public health problems since it affects a significant portion of the general population; the prevalence of painful TMD has been reported to fall between 5 to 12% of the general population (2-4).

There are many factors that predispose individuals to develop painful TMD. Most researchers focus on oral habits, trauma, psychological factors, gender, and comorbidities. Studies have found that oral habits (e.g. clenching) are positively associated with TMD-related pain (5-7). Other studies argued that patients who underwent surgical and non-surgical dental extraction of the third molar or were exposed to other kinds of indirect traumas are more likely to develop painful TMD than individuals with no history of trauma (5, 8-10). Comparative study results claimed that painful TMD was more prevalent in individuals with psychological disorders than healthy individuals (5, 11, 12). With respect to gender, females are more susceptible to this ailment than males (13, 14). In addition to above-mentioned factors, there are many comorbidities shown an association with TMD, such as headache, neck pain, back pain and fibromyalgia (15-17). Of the aforementioned comorbidities, headache is the most prominent one.

Furthermore, some of these factors, such as psychological disorders (5, 18-20) and comorbidities (5, 18-20) contribute to the persistence of painful TMD, as well. Therefore, they may affect the treatment and could be the reason why 30% of TMD patients continue to suffer from moderate to severe levels of pain, psychological distress, disability, and lower quality of life regardless of the various kind of treatments received (21, 22).

Based on preceding facts, both the assessment and the management of TMD may require a multidisciplinary approach with a strong emphasis on the factors that upgrade acute cases to become chronic (23). Understanding these factors would be helpful in developing a preventive intervention protocol in the early stages of this condition to prevent it from becoming chronic which is more difficult to manage. However, as stated by the National Institutes of Health (NIH) "we do not fully understand how acute progresses to chronic pain at any level, from molecular to behavioral" (24). This is why in 2015 the Acute to Chronic TMD Transition (ACTION) program with the goal of identifying the risk factors contribute to the transition from acute to chronic painful TMD and its persistence was initiated. Results from the first step of this program (systematic review) showed that less than ten articles had been published in regards to the differentiating between acute and chronic or transition from acute to chronic painful TMD (25) which shows an agreement with the aforementioned statement from the NIH. Based on this systematic review, myofascial pain and pain intensity contribute to the transition from acute to chronic painful TMD where nothing demonstrated about headache. However, due to the small number of cohort studies, and methodological weaknesses, there is insufficient evidence of risk factors implicated in the transition from acute to chronic painful TMD. Furthermore, results from the second project of ACTION program, aimed to differentiate acute from chronic painful TMD indicated that headache was more common among participants experiencing chronic (71.9%) than acute painful TMD (54.6%). These results suggest that headache should be considered as important risk factors implicated in the transition from acute to chronic painful TMD. Therefore, this prospective cohort study which is the third project of ACTION program aimed at assessing whether headache contributes to the transition from acute to chronic TMD-related pain and its persistence.

Methods

Study Population

This three-month cohort study is the third study from the ACTION program which was approved by the McGill Institutional Review Board in Montreal, Canada (approval number: A12-M113-14A) and by the Dental Specialists Group in Ottawa, Ontario (approval number: 240-400).

Participants who met the eligibility criteria and who had acute or chronic painful TMD were recruited from the Jewish General Hospital (JGH) general dental clinic, the Faculty of Dentistry of McGill University oral diagnosis (OD) clinic, Montreal General Hospital, and the Dental Specialists Group TMD-specialized clinic. Participants with painful TMD were eligible to participate if they were aged between 18 and 80 years and were diagnosed with painful TMD (muscle and/or joint pain) according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). Patients were excluded, however, if they had another orofacial pain, had no access to a telephone, did not speak English or French, or were unable to provide informed consent.

Our decision to classify acute and chronic painful TMD is supported by the International Association for the Study of Pain (IASP) which defined chronic pain as "pain without apparent biological value that has persisted beyond normal tissue healing time, which in the absence of other criteria, is taken to be three months" (112, 113). Referring to the three-month period, Croft *et al*. (2010) contended that "this time reflects the most widely accepted time period"(114).

Assessment of Headache and Potential risk factors

Headache was assessed using the DC/TMD instrument. The DC/TMD included several questions assessing headache and some headaches characteristics, such as duration of headache

(when patients start getting headache), sites of headache, and intensity of headache (mild-moderate or moderate-severe).

For potential confounders, pain intensity was also assessed using DC-TMD (50) which involves questions based on Graded Chronic Pain Scale (GCPS) (108). CPI was calculated as the mean of the patient's report of current pain, worst pain in the last three months and mean pain in the last three months, multiplied by 100 (109). Generalized Anxiety Disorders (GAD-7) and Patient Health Questionnaire (PHQ-8) were used to measure anxiety and depression, respectively. The scoring cut-offs for the GAD-7 and PHQ-8 questionnaires assessing anxiety and depression respectively were: 0-4 indicates that a person is not anxious or depressed, 5-9 indicates mild, 10-14 moderate, 15-27 indicates severe anxious or depressed. Furthermore, the following two sociodemographic factors were investigated in this study: age and gender.

TMD Pain Screening Instrument

In this current study, the presence of TMD pain among the acute and chronic painful TMD cases was evaluated by using a TMD screening instrument. This instrument was developed by Gonzalez *et al.* (2011) (46) and reported an excellent sensitivity (99%) and specificity (97%).

Assessment of Study Outcome at the Three-Month Follow-up

At the first appointment, we informed patients about the follow-up which should be done three months later. Patients who failed to respond to the interview on the time of the follow-up received a call one or two days later and were rescheduled for another interview. The time needed to complete the interview ranged between 5 to 10 minutes. In this interview, we assessed two main outcomes: 1) the transition from acute to chronic TMD-related pain among acute cases (acute cohort) and 2) the persistence of chronic TMD pain in chronic patients (chronic cohort) using

Numerical Rating Scale (0-10 NRS). At the follow-up interview, we also assessed TMD-related pain treatment using Brief Pain Inventory (BPI) (110).

Statistical Analyses

Descriptive analyses were performed to assess the characteristics of acute and chronic TMD cohorts. Student's t-test, and ANOVA were used to compare the continuous variables (e.g. age) between study groups. Chi-square test was used to compare the categorical or binary variables between groups (e.g. gender).

Rather than just limiting our analysis to the relationship between presence or absence of headache and the transition from acute to chronic TMD-related pain, we decided to further include headaches duration, headaches intensity, and number of sites of headache (e.g. headache in temple area, headache in the top of head, and headache behind eyes) in the analyses.

The dependent variable in both acute cohort and chronic cohort was binary: chronic vs. nonchronic and persistent chronic vs. non-persistent chronic. Univariate and multivariable logistic regression analyses were used to determine if headache and headaches characteristics were associated with increased risk of transition from acute to chronic painful TMD and its persistence, regardless potential confounders: age, gender, anxiety, depression, pain intensity, and treatment. All the analyses tested a null hypothesis of no statistical relationship between the independent and dependent variables of interest at $\alpha = 0.05$ significance. The odds ratio (OR) and 95% confidence intervals (CI) for each factor were estimated. All the analyses were performed using the statistical software package SAS (version 9.4; SAS Institute Inc., Cary, NC, USA), with the significance level for type I error set at the 0.05 level.

Secondary Analysis

We also performed a secondary analysis to assess the effect of each site of headache separately

(e.g. headache in temple area, headache in the top of head, and headache behind eyes) on the transition from acute to chronic painful TMD and/or its persistence. Univariate and multivariable logistic regression analyses were also applied to both acute and chronic cohorts.

Results

Description of Population at Baseline

A total of 254 patients were invited to participate in the study, but nine refused (96.46% participation rate). Lack of time, distress, and lack of interest were the main reasons given for non-participation. Of the 245 patients, 47 were excluded from the study mostly because they had no pain or had orofacial pain other than TMD (e.g. pain of dental origin). Only a few of these excluded patients (8) were excluded for other reasons; 4 were over 80 years old, one was less than 18 years old while three were not able to communicate in French or English. Out of the 198 participants who were eligible, 60 (30.30%) had acute painful TMD for less than 3 months while 138 (69.70%) presented TMD-related pain for at least 3 months, and thus chronic cases.

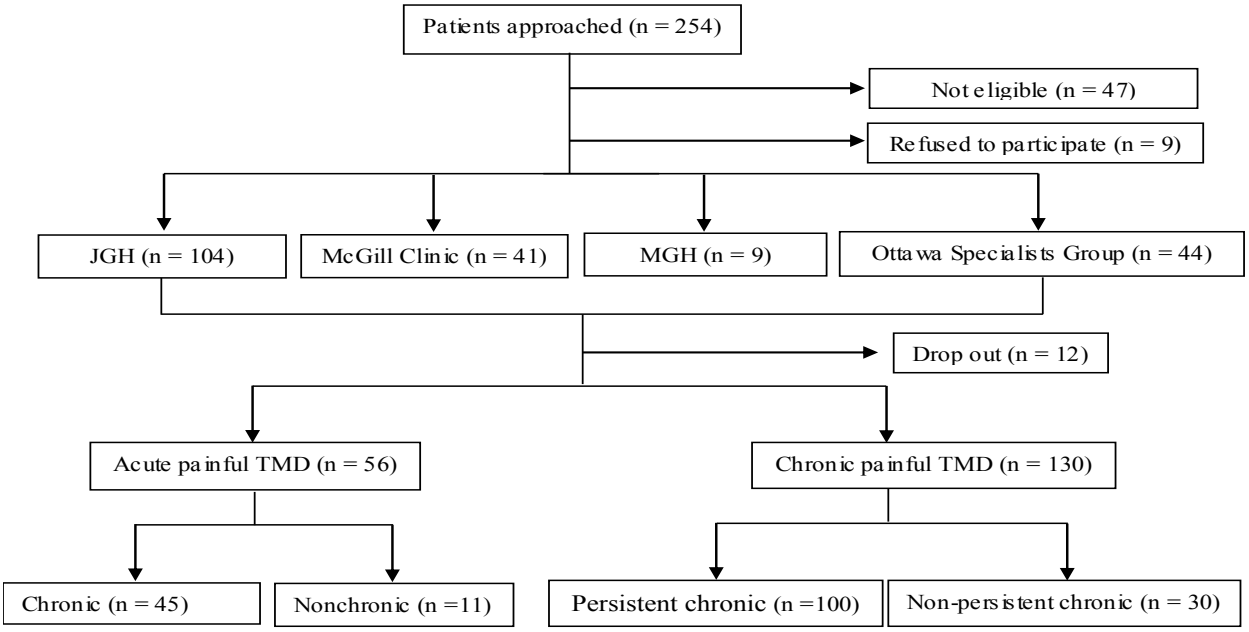
Among the 60 acute cases, 46 were females (76.67%); the number of females was 105 (76.64%; P = 0.93) among the chronic cases. The mean age for acute group was 43.85 (SD = 16.71) years; it was 42.14 (SD = 16.28) (P = 0.50) for the chronic group. Regarding recruitment, 104 (52.53%) patients were recruited from JGH, 9 (4.55%) from the MGH, 41 (20.71%) from McGill, and 44 (22.22%) from Ottawa Dental Specialist group (Figure 5.1.1). Most of the participants received a primary diagnosis of myofascial pain (80.41%), and 137 (69.19%) of them reported

headache. Among the acute patients, 37 (61.67%) reported headache versus 100 (72.46%) among the chronic group (P = 0.13).

Dropout

From the 198 participants who recruited at the baseline, 186 of them completed the three-month follow-up; 12 dropped out of the study (dropout rate = 6.06%). The characteristics of the dropout patients were similar to those of the ones who remained in the study except for the gender. The dropout rate was higher in men (n = 6; 13.04%) than in females (n = 6; 3.97%) (P = 0.02). The mean age of the patients who dropped out of the study was 41.33 (SD = 17.49) years versus 42.74 (SD = 16.36) years for those who remained (P = 0.77) in it. Furthermore, the number of dropouts was 6 (6.67%) for the acute group and 6 (5.80%) for the chronic group (P = 0.75). Regarding headache, 8 patients (66.67%) who had headache dropped out while 129 (69.35%) remained in the study (P = 0.84).

Figure 5.1.1 Enrolment flowchart



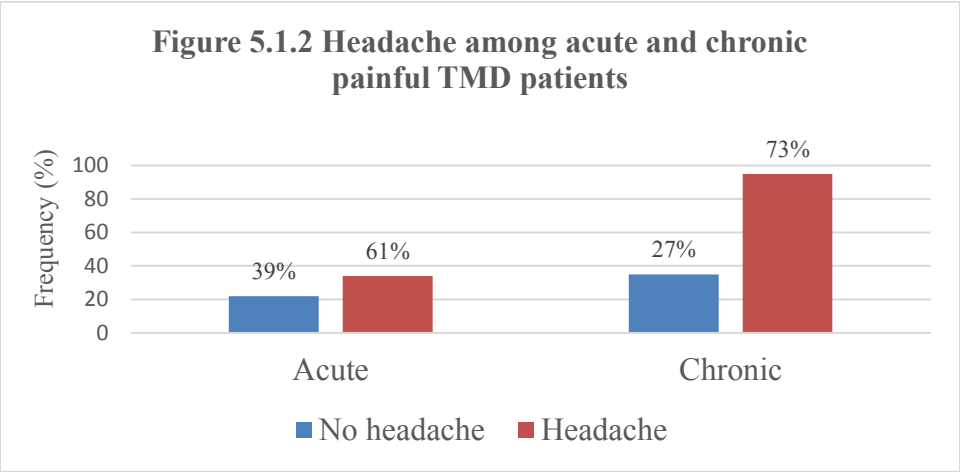
Description of acute and chronic cohorts at baseline

Of the 186 participants who completed the 3-month follow up, 56 were acute patients while 130 were chronic. Among the 56 acute patients, 44 were females (78.57%) versus 101 (78.29%) among the chronic group (P = 0.96). The mean age of acute patients was 43.71 years (SD = 16.87) versus 42.33 (SD = 16.18) for the chronic (P = 0.59). The mean of pain intensity in the acute group was 55.35 (SD = 20.01) while it was 57.79 (SD = 22.57) in the chronic group (P = 0.48). Thirty acute patients (60.71%) had anxiety compared to 54 patients (54.62%) in chronic patients (P = 0.44). For depression, 32 patients (57.14%) presented depression among acute group; they were 67 (51.54%) among the chronic group (P = 0.48). Moreover, 42 patients (75.0%) from the acute group received treatment versus 110 (84.62%) from the chronic group (P = 0.11).

Figure 5.1.2 shows that chronic patients (n = 95, 73.08%) reported headache more frequently than acute patients (n = 34, 60.71% (P = 0.09). The mean of the number of sites of headache among acute participants was 1.54 (SD = 1.5), while the corresponding mean for the chronic participants was 1.72 (SD = 1.49). Nineteen patients (34.55%) in the acute group presented moderate to severe headache intensity versus 45 (34.62%) in the chronic group (P = 0.13). Headache duration was longer among acute patients than chronic with a mean of 54.30 months (SD = 108.59) versus 49.86 months (SD = 101.86).

No statistically significant difference was found in frequency of different headaches sites between acute and chronic TMD group. Twenty-four patients (42.86%) from the acute group had temple headache versus 67 (51.54%) in the chronic patients (P = 0.27). About headache in the front of the head, it was presented by 20 patients (35.71%) in the acute group and 49 (37.69%) in the chronic (P = 0.79). Twelve patients (21.43%) reported headache in the top of the head compared to 29 (22.31%) in the chronic (P = 0.89). Headache in the back of the head was reported

by 10 (17.86%) of the acute patients, while 36 patients (27.69%) from the chronic group presented the same site of headache (P = 0.15). Headache behind eyes was presented by 21 patients (37.50%) in the acute group and 43 patients (33.08%) in the chronic group (P = 0.56).



Association between Headache and Acute to Chronic Painful TMD Transition (Acute cohort)

Among the 56 acute patients, 45 of them (80.36%) were classified as chronic cases since they still had pain at the three-month follow-up. Table 5.1.1 shows the demographic and clinical characteristics of participants who developed chronic TMD pain and those who did not at three-month follow-up from the acute cohort. There was no gender difference between the nonchronic and chronic groups (81.82% vs. 77.7%, P = 1.00), however the nonchronic group tended to be older (47.81 ± 16.84 vs. 42.71 ± 17.09 years, P = 0.37), although the difference was not significant. Higher frequencies of headache (62.22% vs 54.55%, P = 0.73), anxiety (62.22% vs 54.55%, P = 0.73), and depression (60.0% vs 45.45% P = 0.50) were observed in the chronic group compared to the non-chronic group, although these differences were not significant. The number of sites of headache, intensity of headache and duration of headache tended to be greater in the chronic group, however, none of these headache severity parameters were significantly different when compared to the non-chronic group.

Table 5.1.1 Crude and multivariable logistic regression analyses OR and 95% CI assessing headache and number of sites of headache as predictors of the transition from acute to chronic painful TMD (acute cohort)								
Risk factors and covariates at baseline	**Category**		**Chronic n = 45**	**Nonchronic n = 11**	**P value**	**OR (95% CI)**		
						Crude [a]	**Multivariable** [b]	**Multivariable** [c]
Headache	No	n (%)	17 (37.78)	5 (45.45)	0.73	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	28 (62.22)	6 (54.55)		1.37 (0.36 - 5.19)	1.06 (0.15 – 7.17)	Not included
Number of sites of headache	Mean	(SD)	1.60 (1.58)	1.36 (1.43)	0.65	1.10 (0.71 – 1.72)	Not included	0.99 (0.51 – 1.90)
Headache intensity	Mild-moderate	n (%)	10 (22.73)	4 (36.64)	0.40	*Not included*		*Not included*
	Moderate-severe	n (%)	17 (38.64)	2 (18.18)		*Not included*		*Not included*
Headache duration (months)	Mean	(SD)	57.80 (115.23)	40.00 (78.46)	0.63	1.002 (0.99 - 1.009)	1.00 (0.99 – 1.008)	1.00 (0.99 – 1.009)
Age (years)	Mean	(SD)	42.71 (17.09)	47.81 (16.05)	0.37	0.98 (0.94 -1.02)	0.98 (0.94 – 1.036)	0.98 (0.94 – 1.033)
Gender	Male	n (%)	10 (22.22)	2 (18.18)	1.00	1 (reference)	1 (reference)	1 (reference)
	Female	n (%)	35 (77.7)	9 (81.82)		0.77 (0.14 – 4.19)	0.68 (0.10 – 4.37)	0.69 (0.11 – 4.35)
Anxiety	No	n (%)	17 (37.78)	5 (45.45)	0.73	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	28 (62.22)	6 (54.55)		1.37 (0.36 – 5.19)	0.96 (0.19 – 4.74)	0.95 (0.19 – 4.79)
Depression	No	n (%)	18 (40.00)	6 (45.55)	0.50	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	27 (60.00)	5 (45.45)		1.80 (0.47 – 6.79)	1.85 (0.38 – 8.83)	1.86 (0.38 – 9.00)
Pain intensity	Mean	(SD)	55.70 (20.02)	53.93 (20.91)	0.79	1.00 (0.97 – 1.03)	0.99 (0.95 – 1.03)	0.99 (0.95 – 1.03)
Treatment	No	n (%)	9 (20.00)	5 (45.45)	0.11	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	36 (80.00)	6 (54.55)		3.33 (0.82 – 13.43)	3.48 (0.68 – 17.62)	3.45 (0.69 – 17.24)

[a] Simple logistic regression analysis, [b] Multivariable including presence of headache, duration of headache, age, gender, anxiety, depression, pain intensity, and treatment, [c] Multivariable model including number of sites of headache, duration of headache, age, gender, anxiety, depression, pain intensity, and treatment.
OR = Odds Ratio, CI = Confidence Interval

We conducted crude and multivariable unconditional logistic regression analyses assessing the association between various headaches characteristics and transition from acute to chronic painful TMD at 3 months follow-up (Table 5.1.1). The crude models revealed no significant predictors. Accounting for additional information in the adjusted models did not reveal any masked effects. Given the available data, we cannot conclude any association between headache and acute to chronic TMD transition.

We decided to check whether number of sites of headache influences this transition. To identify that, we conducted crude, and another multivariable regression analysis (Multivariable [c]) including number of sites of headache instead headache itself and adjusted for all other potential confounders (Table 5.1.1). Interestingly, these models revealed that the odds ratio of the number of sites of headache was similar to the odds ratio of headache itself with no significance in both models.

Sites of Headache and the Transition from Acute to Chronic painful TMD (Acute Cohort)

Headache at the baseline tended to be more common among participants with chronic painful TMD compared to acute painful TMD (73.08% vs. 60.71%, P = 0.09). Moreover, participants who developed chronic painful TMD at the three months follow-up presented more headache compared to patients who did not (62.22% vs. 54.55% P = 0.73), however the crude and multivariable logistic analysis which done previously did not show any contributions of headache to the transition from acute to chronic TMD. Therefore, we decided to assess whether the sites of headache was associated with the transition from acute to chronic TMD. There are five sites of headache that were considered in our analysis, including headache in the (i) temple area, (ii) front of the head, (iii) top of the head, (iv) back of the head and (v) behind eyes or inside the head.

Table 5.1.2 Crude and multivariable logistic regression analyses, odds ratio (OR) and 95% confidence interval (CI), assessing sites of headache as predictors of the transition from acute to chronic painful TMD (acute cohort)								
Risk factors and covariates at baseline	**Category**		**Chronic n = 45**	**Nonchronic n = 11**	**OR (95% CI)**			
					Crude [a]	**P value**	**Multivariable** [b]	**P value**
Headache in temple area	No	n (%)	26 (57.78)	6 (54.55)	1 (reference)	0.84	1 (reference)	0.57
	Yes	n (%)	19 (42.22)	5 (45.45)	0.87 (0.23-3.30)		0.57 (0.08-3.94)	
Headache in front of the head	No	n (%)	29 (64.44)	7 (63.64)	1 (reference)	0.96	1 (reference)	0.81
	Yes	n (%)	16 (35.56)	4 (36.36)	0.96 (0.24-3.80)		1.22 (0.22-6.72)	
Headache on top of the head	No	n (%)	34 (75.56)	10 (90.91)	*Not included*		*Not included*	
	Yes	n (%)	11 (24.44)	1 (9.09)				
Headache on back of the head	No	n (%)	36 (80.0)	10 (90.91)	*Not included*		*Not included*	
	Yes	n (%)	9 (20.0)	1 (9.09)				
Headache behind eyes or inside the head	No	n (%)	28 (62.22)	7 (63.64)	1 (reference)	0.93	1 (reference)	0.77
	Yes	n (%)	17 (37.78)	4 (36.36)	1.06 (0.27-4.17)		0.78 (0.15-4.06)	
Age (years)	Mean	(SD)	42.71 (17.09)	47.81 (16.05)	0.98 (0.94 -1.02)	0.37	0.98 (0.94-1.03)	0.51
Gender	Male	n (%)	10 (22.22)	2 (18.18)	1 (reference)	1.00	1 (reference)	0.76
	Female	n (%)	35 (77.7)	9 (81.82)	0.77 (0.14 – 4.19)		0.75 (0.11-4.86)	
Anxiety	No	n (%)	17 (37.78)	5 (45.45)	1 (reference)	0.73	1 (reference)	0.89
	Yes	n (%)	28 (62.22)	6 (54.55)	1.37 (0.36 – 5.19)		0.90 (0.18-4.51)	
Depression	No	n (%)	18 (40.00)	6 (45.55)	1 (reference)	0.50	1 (reference)	0.38
	Yes	n (%)	27 (60.00)	5 (45.45)	1.80 (0.47 – 6.79)		0.99 (0.42-9.31)	
Pain intensity	Mean	(SD)	55.70 (20.02)	53.93 (20.91)	1.00 (0.97 – 1.03)	0.79	1.00 (0.96-1.04)	0.90
Treatment	No	n (%)	9 (20.00)	5 (45.45)	1 (reference)	0.11	1 (reference)	0.11
	Yes	n (%)	36 (80.00)	6 (54.55)	3.33 (0.82 – 13.43)		3.89 (0.73-20.73)	

Headache in the top (n = 12) and the back (n = 10) of the head were excluded from the analysis due to an insufficiently large sample size.

We conducted crude and multivariable logistic regressions (Table 5.1.2) to determine whether an association between headache sites and acute to chronic transition existed. In the multivariable model, each headache site was adjusted for potential confounders, including age gender, anxiety, depression, pain intensity, and treatment. Both the crude and multivariable showed no significant association with any specific site of headache with the transition from acute to chronic painful TMD. The small sample size of acute cases might be the reason for not finding any association. Nonetheless, based on this dataset, we cannot conclude that any specific site of headache is a significant risk factor of acute to chronic painful TMD transition.

Association between Headache and Persistence of Chronic Painful TMD (Chronic Cohort)

Among the 130 patients who had chronic pain at the baseline, 100 patients (76.92%) continued to have TMD pain at three-month follow-up (persistent chronic) versus 30 (23.08%) who did not have it any longer (non-persistent chronic). The demographic and clinical characteristics of participants that have or have not developed persistent painful TMD were assessed (Table 5.1.3). Females developed persistent painful TMD more frequently than males (82.00% vs. 18.00%, P = 0.06), while the age different between the persistent and non-persistent group was negligible (42.69 ± 16.53 vs. 41.13 ± 15.16 years, P = 0.64).

The frequency of headache among participants that have developed persistent TMD was higher compared to participants who do not have pain anymore (75.00% vs. 66.67%, P = 0.36), but there was no significant difference between the groups. Nevertheless, the number of sites of headache (1.88 ± 1.56 vs. 1.20 ± 1.12, P = 0.03) and duration of headache (60.19 ± 113.0 vs. 15.45 ± 30.35, P = 0.03) were significantly higher in individuals that have developed persistent TMD

when compared to those that have not, respectively. Anxiety and depression presented slightly more among individuals who developed persistent painful TMD, however this difference was not statistically significance (P = 0.87 and P = 0.54, respectively) (Table 5.1.3).

To assess the association between headache and the persistence of chronic painful TMD, we conducted a crude and multivariable logistic regression analyses. Table 5.1.3 shows the crude model which revealed that headache itself was not significant predictor of chronic TMD pain persistence (OR = 1.50, CI: 0.62 - 3.63), however headache duration (OR = 1.01, CI: 1.00 - 1.04) and number of sites of headache (OR = 1.41, CI: 1.03 - 1.93) were significantly associated with persistence at three months follow-up. To ensure that the results found in the crude model were not confounded by other variables, two multivariable logistic regression models were constructed to adjust for potential confounders, such as age, gender, anxiety, and depression, pain intensity, and treatment. The first model excluded the number of sites of headache as a predictor (Multivariable [b]), while the second excluded the presence of headache as a predictor (Multivariable [c]). In both multivariable models, accounting for the confounding factors unmasked a significant association between pain intensity and TMD persistence (OR = 1.03, CI: 1.01 - 1.06). Furthermore, the second model (Multivariable [c]) revealed that the significant association that was identified between number of sites of headache and persistence in the crude model was lost after adjusting for confounding factors (OR = 1.82, CI: 0.73 - 1.58), despite the odds ratio increasing from 1.41 to 1.82. Taken together, our results suggest that there may be an association between number of sites of headache and painful TMD persistence, however further research in this direction is required. Pain intensity was found to be a relatively weak but significant predictor of persistence at three months follow-up.

Table 5.1.3 Crude and multivariable logistic regression analyses OR and 95% CI assessing headache and number of sites of headache as predictors of the persistence of chronic painful TMD (chronic cohort)								
Risk factors and covariates at baseline	**Category**		**Persistent chronic n = 100**	**Non-persistent chronic n = 30**	**P value**	**OR (95% CI)**		
						Crude [a]	**Multivariable** [b]	**Multivariable** [c]
Headache	No	n (%)	25 (25.00)	10 (33.33)	0.36	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	75 (75.00)	20 (66.67)		1.50 (0.62 – 3.63)	0.62 (0.20 – 1.91)	*Not included*
Number of sites of headache	Mean	(SD)	1.88 (1.56)	1.20 (1.12)	0.02	1.41 (1.03 – 1.93)	*Not included*	1.82 (0.73 – 1.58)
Headache duration (months)	Mean	(SD)	60.19 (113.06)	15.45 (30.35)	0.03	1.01 (1.00 - 1.02)	1.01 (1.00 – 1.02)	1.01 (0.99 – 1.02)
Age (years)	Mean	(SD)	42.69 (16.53)	41.13 (15.16)	0.64	0.98 (0.94 -1.02)	0.99 (0.96 – 1.02)	0.99 (0.97 – 1.02)
Gender	Male	n (%)	18 (18.00)	10 (34.48)	0.06	1 (reference)	1 (reference)	1 (reference)
	Female	n (%)	82 (82.00)	19 (65.52)		2.39 (0.95 – 6.07)	2.20 (0.76 – 6.37)	1.93 (0.67 – 5.50)
Anxiety	No	n (%)	45 (45.00)	14 (46.67)	0.87	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	55 (55.00)	16 (53.33)		1.06 (0.47 – 2.42)	0.90 (0.31 – 2.57)	0.87 (0.30 – 2.48)
Depression	No	n (%)	47 (47.00)	16 (53.33)	0.54	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	53 (53.00)	14 (46.67)		1.28 (0.56 – 2.91)	1.15 (0.41 – 3.21)	1.14 (0.40 – 3.19)
Pain intensity	Mean	(SD)	60.66 (19.95)	48.22 (28.00)	0.007	1.02 (1.00 – 1.04)	1.03 (1.01 – 1.06)	1.03 (1.01 – 1.06)
Treatment	No	n (%)	16 (16.00)	4 (13.33)	0.72	1 (reference)	1 (reference)	1 (reference)
	Yes	n (%)	84 (84.00)	26 (86.67)		0.80 (0.24 – 2.63)	0.63 (0.17 – 2.30)	0.55 (0.14 – 2.04)

[a] Simple logistic regression analysis, [b] Multivariable including presence of headache, headache intensity, duration of headache, age, gender, anxiety, depression, pain intensity, and treatment, [c] Multivariable model including number of sites of headache, headache intensity, duration of headache, age, gender, anxiety, depression, pain intensity, and treatment.
OR = Odds Ratio, CI = Confidence Interval

Sites of Headache and the Persistence of Chronic TMD Pain (Chronic Cohort)

The percentage of each site of headache was found to be higher among patients who developed persistent chronic TMD compared to the participants who did not (ranging from 24% - 76% for chronic group vs. 13.33% - 46.67% for the non-chronic group). We conducted crude and multivariable logistic regression to determine whether an association between headache sites and persistence of chronic TMD pain exists. Crude analysis showed that there was no association between headaches in the temple, front or top of the head and persistent painful TMD, while showed a borderline association between headache in the back of the head and the persistence (OR = 3.05 CI: 0.98 - 9.50, P = 0.05). Patients who developed persistent painful TMD were more likely to report headache behind eyes or inside the head (OR = 4.15 CI: 1.34 - 12.81) than patients who did develop the persistence. The associations between headache behind eyes or inside the head persistence of painful TMD remained strongly independent of participants age and gender, and the other clinical and psychological characteristics (OR = 4.22 CI: 1.16 - 15.41), however, the borderline association of headache in the back of the head was lost (OR = 2.11, CI: 0.55 - 8.09) (Table 5.1.4).

Discussion:

This study is the first prospective cohort study which was done to determine whether headache and some headaches characteristics are risk factors associated with the transition from acute to chronic painful TMD and/or its persistence. Our results showed no significant association between headache itself or headaches characteristics and transition from acute to chronic painful TMD.

The results from chronic cohort also showed no association between headache itself and the persistence of painful TMD at three months follow-up, however the study demonstrated

Table 5.1.4 Crude and multivariable logistic regression analyses, odds ratio (OR) and 95% confidence interval (CI), assessing sites of headache as predictors of the persistence of chronic painful TMD (chronic cohort)								
Risk factors and covariates at baseline	**Category**		**Persistent chronic n = 100**	**Non-persistent chronic n = 30**	**OR (95% CI)**			
					Crude [a]	**P value**	**Multivariable** [b]	**P value**
Headache in temple area	No	n (%)	47 (47.00)	16 (53.33)	1 (reference)	0.54	1 (reference)	0.45
	Yes	n (%)	53 (53.00)	14 (46.67)	1.28 (0.56 -2.91)		0.67 (0.23-1.91)	
Headache in front of the head	No	n (%)	60 (60.00)	21 (70.00)	1 (reference)	0.32	1 (reference)	0.57
	Yes	n (%)	40 (40.00)	9 (30.00)	1.55 (0.64-3.74)		1.41 (0.42-4.73)	
Headache on top of the head	No	n (%)	76 (76.00)	25 (83.33)	1 (reference)	0.40	1 (reference)	0.44
	Yes	n (%)	24 (24.00)	5 (16.67)	1.57 (0.54-4.57)		0.58 (0.14-2.32)	
Headache on back of the head	No	n (%)	68 (68.00)	26 (86.67)	1 (reference)	0.05	1 (reference)	0.27
	Yes	n (%)	32 (32.00)	4 (13.33)	3.05 (0.98-9.50)		2.11 (0.55-8.09)	
Headache behind eyes or inside the head	No	n (%)	61 (61.00)	26 (86.67)	1 (reference)	0.01	1 (reference)	0.03
	Yes	n (%)	39 (39.00)	4 (13.33)	4.15 (1.34-12.81)		4.22 (1.16-15.41)	
Age (years)	Mean	(SD)	42.69 (16.53)	41.13 (15.16)	1.00 (0.98 - 1.03)	0.64	0.99 (0.97-1.02)	0.94
Gender	Male	n (%)	18 (18.00)	10 (34.48)	1 (reference)	0.06	1 (reference)	0.18
	Female	n (%)	82 (82.00)	19 (65.52)	2.39 (0.95 - 6.01)		2.04 (0.70-5.92)	
Anxiety	No	n (%)	45 (45.00)	14 (46.67)	1 (reference)	0.87	1 (reference)	0.55
	Yes	n (%)	55 (55.00)	16 (53.33)	1.06 (0.47 - 2.42)		0.72 (0.25-2.10)	
Depression	No	n (%)	47 (47.00)	16 (53.33)	1 (reference)	0.54	1 (reference)	0.78
	Yes	n (%)	53 (53.00)	14 (46.67)	1.28 (0.56 - 2.91)		1.15 (0.41-3.21)	
Pain intensity	Mean	(SD)	60.66 (19.95)	48.22 (28.00)	1.02 (1.00 - 1.04)	0.009	1.03 (1.01-1.06)	0.004
Treatment	No	n (%)	9 (20.00)	5 (45.45)	1 (reference)	0.72	1 (reference)	0.36
	Yes	n (%)	36 (80.00)	6 (54.55)	1.23 (0.38 - 4.03)		0.53 (0.13 - 2.10)	

significant association between some characteristics of headache and the persistence of TMD at three months follow-up in contrary to the acute cohort. The crude model showed that headaches duration, number of sites of headache, and headache behind eyes or inside the head were significantly associated with persistence of chronic TMD pain. Headache duration and headache behind eyes or inside the head remained highly associated with persistence of painful TMD after adjusting for age, gender, anxiety, depression, pain intensity, and treatment, while the number of sites of headache did not. These results suggest that headache behind the eyes or inside the head is the most significant site of headache associated with the persistence of chronic painful TMD.

The sample size of acute cases (n = 56) may not be large enough to provide the statistical power required to identify the associations of interest in the acute cohort. Many of the factors (i.e. presence of a headache, number of sites of headache, gender, presence of anxiety or depression and treatment) were assessed show weak odds ratios as well as wide confidence intervals, suggesting high variability which may be addressed by a larger sample size in future studies. The positive results found in the chronic cohort (n = 130) support the suggestion that a bigger acute sample size is needed in the acute cohort to adequately assess the transition from acute to chronic painful TMD. A larger study on the transition from acute to chronic painful TMD may reveal similar associations. It is important to note that this is an ongoing project and more patients have been recruited since the time this analysis was performed. It is therefore hoped that this limitation is going to be addressed in the future.

Additional possible explanation for this lack of a positive association between headache or headaches characteristics and the transition from acute to chronic TMD may be a misclassification since we used a self-report method to collect information from patients, however validated questionnaires were used which should help in managing this type of bias. Since our study is a

prospective cohort study, the kind of misclassification which might be involved during the baseline and/or the three-month follow-up is nondifferential which is likely to weaken estimates of association.

Another misclassification could be involved in studies of this nature because of the way acute and chronic TMD were defined. To avoid this kind of misclassification, we decided to adopt IASP's definition of chronic pain (three months or more) and classify our TMD patients accordingly (112, 113). Our previous cross-sectional study (second project of ACTION program) showed that the magnitude of the odds ratio from persistent (≥ 6 months) and subchronic painful TMD (≥ 3 months and < 6 months) analyses were close, suggesting that our decision to follow IASP recommendation to place the cut-off at 3 months is appropriate (25).

In addition to some of the limitations mentioned above (small acute sample size and using self-report method), there is one more limitation in our study. Numerical Rating Scale (NRS) was not used for assessing headache intensity, and patients were given two choices, mild to moderate or moderate to severe, however this character was not included in the analyses.

Using validated questionnaires to collect the data and following IASP definition to classify our acute and chronic patients, were intended to address the above limitations. It should also be noted that our study has other strengths. First, we used a prospective cohort study design which should be the best design to achieve such kind of aims. Secondly, the participation rate was very high with a very low dropout rate. Thirdly, there was no significant difference between patients who dropped out and those who remained in the study especially in regards of headache. Next, potential confounders were adjusted in multivariable logistic regression analyses. Then, a full clinical examination was performed by a TMD specialist where the treatment was provided as well. Also, subjects were recruited from four different sites to minimize the chance of selection

bias which may lead to a positive association as a result of a referral pattern. Finally, we used DC/TMD which has established recently and included headache as one of the diagnostic criteria of TMD (50).

Summary

This study included 56 acute and 130 chronic patients who were followed over a three-month period. Our study revealed that headache did not contribute to the transition from acute to chronic painful TMD at three months follow-up. Headache duration, number of sites of headache, headache behind eyes or inside the head were all significantly associated with persistence of chronic TMD pain regardless of age, gender, anxiety, depression pain intensity, depression with the exception of number of sites of headache which disappeared when adjusted for these factors. Understanding the relationship between headache and transition or persistence of painful TMD may provide novel insights regarding the etiology of TMD as well as novel risk factors that may be used to further awareness amongst health-care providers and patients.

CHAPTER 6. DISCUSSION

Some methodological considerations, strengths, and limitations of this study will be discussed in this section.

6.1 Summary of the Results

This study is the first prospective cohort study which was done to determine whether headache and some headaches characteristics are risk factors associated with the transition from acute to chronic painful TMD and/or its persistence. Our results showed no significant association between headache itself or headaches characteristics and transition from acute to chronic painful TMD.

The results from chronic cohort also showed no association between headache itself and the persistence of painful TMD at three months follow-up, however the study demonstrated a significant association between some characteristics of headache and the persistence of TMD at three months follow-up in contrary to the acute cohort. The crude model showed that headaches duration, number of sites of headache, and headache behind eyes or inside the head were significantly associated with persistence of chronic TMD pain. Headache duration and headache behind eyes or inside the head remained highly associated with persistence of painful TMD after adjusting for age, gender, anxiety, depression, pain intensity, and treatment, while the number of sites of headache did not. These results suggest that headache behind the eyes or inside the head is the most significant site of headache associated with the persistence of chronic painful TMD.

6.4 Methodological Considerations

6.4.1 Bias

Bias is a systematic error which could occur in any epidemiological study, and lead to incorrect observations regarding the association between exposure and outcome. To ensure that a study has internal validity, selecting participants, measuring potential predictors, confounders, and outcomes as well as performing the statistical analyses need to be carefully considered. In the following paragraphs, we discuss some types of biases that might occur in studies of this nature.

6.4.1.1 Selection Bias

Selection bias means any error that arises during the process of identifying and recruiting participants (27). In this cohort study, subjects were recruited from four different sites to minimize the chance of selection bias which may lead to a positive association as a result of a referral pattern. The dropout rate is very important in cohort designs, and it is great that our study has a very low

dropout rate. Even though, there was no significant difference between patients who dropped out and those who remained in the study especially in regards of headache.

6.4.1.2 Information Bias

Information bias is a systematic error which may also occur during the classification of participants or measurement of the exposures or outcomes (27). In this cohort study, validated questionnaires were used to collect information from participants which helped in managing or controlling this kind of bias.

Misclassification might occur in this type of studies because of the way acute and chronic TMD was defined. To avoid this kind of misclassification, we decided to adopt IASP's definition of chronic pain (3 months or more) to classify our TMD patients. IASP chronic pain definition is: "pain without apparent biological value that has persisted beyond normal tissue healing time, which in the absence of other criteria, is taken to be 3 months" (112, 113). Our previous cross-sectional study (second step of ACTION program) showed that the magnitude of the odds ratio from persistent (≥ 6 months) and subchronic painful TMD (≥ 3 months and < 6 months) analyses were close, suggesting that our decision to follow IASP recommendation to place the cut-off at 3 months is appropriate.

6.4.2 Effect of Confounders

Confounding is the mixing of effects between an exposure, outcome, and another extraneous variable (confounder) which leads to incorrect observations or results since the relationship (111). In this study, pain intensity, treatment, demographic factors such as age and gender, and psychological factors, such as depression and anxiety, were considered as confounders. To control such potential confounders, we adjusted for them during the analytic stage of the study by using multivariable regression analyses.

6.5 Strengths

First of all, we used a prospective cohort study design which should be the best design to achieve such aims. Secondly, the participation rate was very high with a very low dropout rate. Thirdly, there was no significant difference between patients who dropped out and those who remained in the study especially in regards of headache. Next, potential confounders were adjusted in multivariable logistic regression analyses. Then, a full clinical examination was performed by TMD specialists where the treatment was provided as well. Finally, we used DC/TMD which has established recently and included headache as one of the diagnostic criteria of TMD (50).

6.6 Limitations

It is important to bear in mind that even though this study has several strengths, it also has some limitations. First, the classification of acute and chronic painful TMD has been used differently among researchers. To avoid misclassification, we followed the IASP to classify chronic pain, which suggested 3-month or more. Secondly, Numerical Rating Scale (NRS) was not used for assessing headache intensity, and patients were given two choices, mild to moderate or moderate to severe. Thirdly, a self-report method was used to collect data. This method might have some disadvantages, such as misunderstanding, exaggeration, and/or not remembering some details. Fourthly, the acute cases sample size was not large enough to adequately study the transition from acute to chronic painful TMD. This project is still going on and more patients have been recruited since the time this analysis was performed. It is therefore hoped that these limitations will be addressed in the future.

CHAPTER 7. CONCLUSION

The following conclusions can be drawn from the results of my thesis:

1) It was alarming to find that 80.36% developed chronic painful TMD, and 76.92% developed persistence of chronic painful TMD. Sixty percent of patients reported headache among the acute group versus 73.08% in the chronic group.

2) Our results revealed that a weak to no association was found between headache and transition from acute to chronic painful TMD. Our findings also showed that participants with longer headache duration, number of sites of headache, headache behind eyes or inside the head were more likely to develop persistent chronic painful TMD than patients without. These associations were not modified by aforementioned potential confounders with the exception of the association found between number of sites of headache and the persistence of painful TMD which disappeared. These findings suggest that these factors are relevant risk factors implicated in the persistence of chronic painful TMD but no the transition from acute to chronic painful TMD. Understanding the relationship between headache and transition or persistence of painful TMD may provide novel insights regarding the etiology of TMD as well as novel risk factors that may be used to further awareness amongst health-care providers and patients.

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CHAPTER 9. APPENDIX

(Questionnaires and Consent Forms)

ACTION PROGRAM BASELINE QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

Hospital			Patient Number	Initials	
Day	**Month**	**Year**			

Please answer the following questions:

1. How old are you? _____ *years old*

2. Do you have pain in temple, face, jaw joint, or jaws once a week or more often?

☐ Yes ☐ No

3. Do you have pain when you open your month wide or chew, once a week or more often?

☐ Yes ☐ No

4. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?

☐ No pain

☐ From very brief to more than a week, but it does stop

☐ Continuous

5. In the last 30 days, did you have pain or stiffness in your jaw on wakening?

☐ Yes ☐ No

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

A. Chewing hard or tough food. ☐ Yes ☐ No

B. Opening your mouth, or moving your jaw forward or to the side. ☐ Yes ☐ No

C. Jaw habits such as holding teeth together or chewing gum. ☐ Yes ☐ No

D. Other jaw activities such as talking, kissing, or yawning. ☐ Yes ☐ No

7. Have you ever had pain in your jaw, temple, in the ear, or in front of the ear on either side?

☐ Yes ☐ No

8. How many years or months ago did your pain in the jaw, temple, in the ear, or in front of the ear first begin?

   ____ Year(s) ____ Month(s)

9. How would you rate your facial pain right now?
   Please rate your pain by circling the number that tells how much pain you have right now.

   No pain — Pain as bad as it could be
   0 1 2 3 4 5 6 7 8 9 10

10. In the last 30 days, how would you rate your worst facial pain?
    Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be".

    No pain — Pain as bad as it could be
    0 1 2 3 4 5 6 7 8 9 10

11. In the last 30 days, on average, how would you rate your facial pain?
    Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be".
    (That is, your usual pain at times you were in pain)

    No pain — Pain as bad as it could be
    0 1 2 3 4 5 6 7 8 9 10

12. In the last 30 days, how many days did your facial pain keep you from doing your usual activities like work, school, or housework? *(every day = 30 days)*

    ____ Days

13. In the last 30 days, how much has facial pain interfered with your daily activities? Use a scale where 0 is "no interference" and 10 is "unable to carry on any activities".

    No interference — Unable to carry on any activities
    0 1 2 3 4 5 6 7 8 9 10

14. In the last 30 days, how much has facial pain interfered with your recreational, social and family activities? Use the same scale where 0 is "no interference" and 10 is "unable to carry on any activities".

    No interference — Unable to carry on any activities
    0 1 2 3 4 5 6 7 8 9 10

15. In the last 30 days, how much has facial pain interfered with your ability to work, including housework? Use the same scale where 0 is "no interference" and 10 is "unable to carry on any activities".

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

16. How would you describe the duration of this pain in your jaw, temple, ear, or in front of the ear since it first began? *(Select ONE response)*

- ☐ Persistent – continuous pain since initial onset
- ☐ Recurrent – more than one bout of pain, with periods of no pain
- ☐ One time – a prior episode of pain that has ended

17. In the last 30 days, which of the following best describes any pain in your jaw, temple, in the ear, or in front of the ear on either side? (Select ONE response)

- ☐ No pain
- ☐ Pain comes and goes
- ☐ Pain is always present

18. In the last 30 days, how many days per month have you had this pain in your jaw, temple, in the ear, or in front of the ear? *(Select ONE response)*

- ☐ Less than 1 day
- ☐ 1 day or more, but less than 15 days
- ☐ 15 days or more, but not continuous
- ☐ Continuous

19. On average, how long does a single episode of this pain in your jaw, temple, in the ear, or in front of the ear last? *(Select ONE response)*

- ☐ Less than 30 minutes per episode
- ☐ 30 minutes to less than 2 hours per episode
- ☐ 2 hours to less than 4 hours per episode
- ☐ 4 hours to 72 hours (3 days) per episode
- ☐ More than 3 days to 7 days per episode
- ☐ More than 7 days of continuous pain per episode

20. In the last 30 days, have you had any headaches?

☐ Yes ☐ No

If you answered NO to question 20, skip to Question 24.

21. How many years or months ago did your headache first begin?

☐ Year(s) ☐ Month(s)

22. In the last 30 days, rate the intensity, on average, of your headache? *(Select ONE response)*

- ☐ Mild to moderate
- ☐ Moderate to severe

23. Where is the headache located? *(Mark ALL that apply)*

- ☐ Temple
- ☐ Front of head
- ☐ Top of head
- ☐ Back of head
- ☐ Behind the eyes or inside the head

24. In the last 30 days, have you had any jaw joint noise(s) when you moved or used your jaw?

☐ Yes ☐ No

25. Have you ever had your jaw lock or catch, even for a moment, so that it would not open ALL THE WAY?

☐ Yes ☐ No

If you answered NO to question 25, skip to question 29.

26. Was your jaw locked or caught severely enough to limit your jaw opening and interfere with your ability to eat?

☐ Yes ☐ N

27. Is your jaw currently locked or limited so that your jaw will not open ALL THE WAY?

☐ Yes ☐ N

28. At any time in your life, when you opened your mouth wide, did your jaw lock or catch even for a moment such that you could not close it from this wide open position?

☐ Yes ☐ N

29. What treatments did you receive for your pain?

☐ Dental extraction

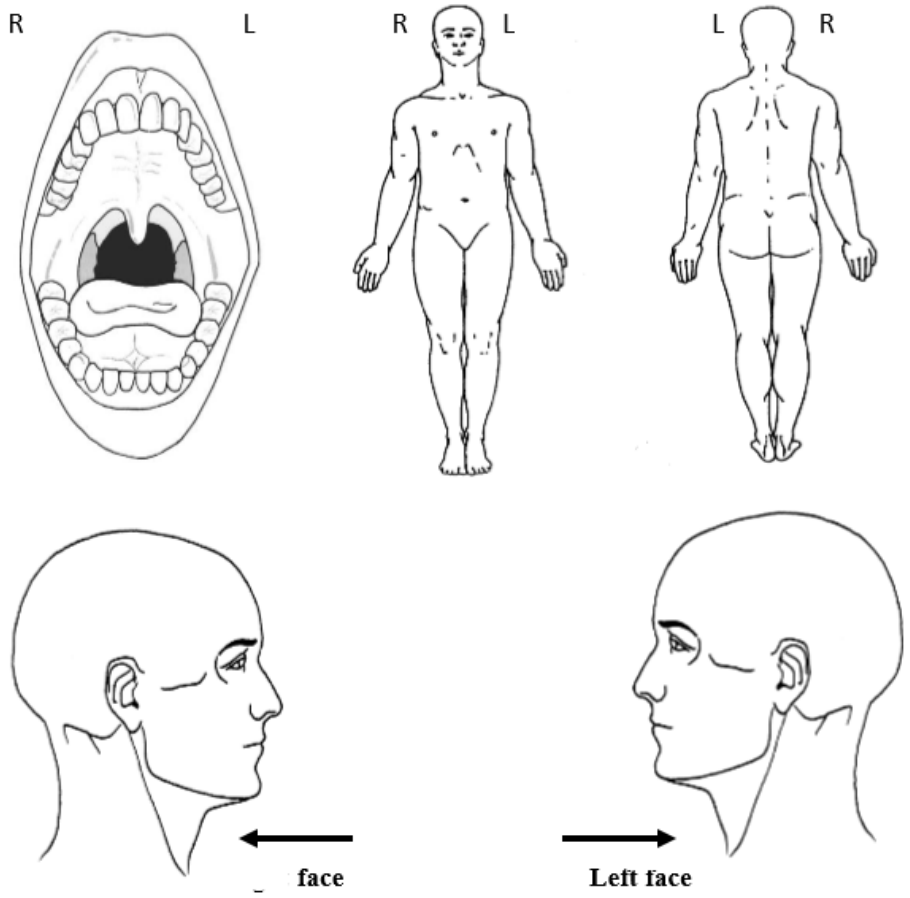
☐ Orthodontics treatment

30. Do you have:

Condition	*Yes*	*No*	*Medication for condition*
a. Diabetes	☐	☐	
b. Allergies (Penicillin/Medication)	☐	☐	
c. Thyroid problem	☐	☐	
d. Rheumatic fever	☐	☐	
e. High blood pressure	☐	☐	
f. Low blood pressure	☐	☐	
g. Smoking (per day)	☐	☐	
h. Asthma	☐	☐	
i. Heart problems	☐	☐	
j. Pain in arms	☐	☐	
k. Pain in legs	☐	☐	
l. Pain in chest	☐	☐	
m. Pain in neck	☐	☐	
n. Pain in back	☐	☐	
o. Pain in abdomen	☐	☐	

31. Pain Diagram

Indicate the location of ALL of your different pains by shading in the area, using the diagrams that are most relevant. If there is an exact spot where the pain is located, indicate the pain with a solid dot (●). If your pain moves from one location to another, use arrows to show the path.



32. On which side of the face is the pain more severe?

☐ Left side ☐ Right side ☐ Both sides equally

33. Using the scale below, please indicate the degree to which you have these feelings.

ACTION PROGRAM BASELINE QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
A. Feeling nervous, anxious or on edge	0	1	2	3
B. Not being able to stop or control worrying	0	1	2	3
C. Worrying too much about different things	0	1	2	3
D. Trouble relaxing	0	1	2	3
E. Being so restless that is hard to sit still	0	1	2	3
F. Becoming easily annoyed or irritable	0	1	2	3
G. Feeling afraid as if something might happen	0	1	2	3

34. Using the scale below, please indicate the degree to which you have these feelings.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
A. Little interest or pleasure in doing things.	0	1	2	3
B. Feeling down, depressed, or hopeless.	0	1	2	3
C. Trouble falling or staying asleep, or sleeping too much.	0	1	2	3
D. Feeling tired or having little energy.	0	1	2	3
E. Poor appetite or overeating.	0	1	2	3
F. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	0	1	2	3
G. Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
H. Moving or speaking so slowly that other people could have noticed or the opposite - being so fidgety or restless that you have been moving around a lot more than usual.	0	1	2	3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

35. Please answer the following questions about yourself by indicating the extent of your agreement:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
A. In uncertain times, I usually expect the best.					
B. It's easy for me to relax					
C. If something can go wrong for me, it will.					
D. I'm always optimistic about my future.					
E. I enjoy my friends a lot.					
F. It's important for me to keep busy.					
G. I hardly ever expect things to go my way.					
H. I don't get upset too easily.					
I. I rarely count on good things happening to me.					
J. Overall, I expect more good things to happen to me than bad.					

36. Have you undergone any tooth extraction?

☐ Yes ☐ No

If you answered "Yes", for what reason?

☐ Because of pain ☐ Do not remember ☐ Not because of pain

37. Have you received any orthodontics treatment?

☐ Yes ☐ No

If you answered "Yes", for what reason?

☐ Because of pain ☐ Do not remember ☐ Not because of pain

38. Write down the number corresponding to your choice in the right-hand column.

Included : ☐ **Yes** ☐ **No**

0 = No chance of dozing
1 = Slight chance of dozing
2 = Moderate chance of dozing
3 = High chance of dozing

Situation	Chance of dozing
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g. a theather or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in traffic	

39. Write your response (*Yes* or *No*) in the right hand column.

Questions	Yes or No
S- Snoring: Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?	
T- Tired: Do you feel tired, fatigued, or sleepy during daytime?	
O- Observed: Has anyone observed you stop breathing during sleep?	
P- Blood Pressure: Do you have or are you being treated for high blood pressure?	
B- BMI: Body mass index > 35	
A- Age: Age over 50 years old?	
N- Neck: Neck circumference or collar size > 40 cm?	
G- Gender: Male gender?	

40. The Fatigue Severity Scale (FSS) is a method of evaluating the impact of fatigue on you.

This tool allows assessing the impact of fatigue on you. This is a short questionnaire that asks you to rate your level of fatigue. It contains nine statements that rate the severity of your fatigue symptoms.

Read each statement and circle a number from 1 to 7, based on how accurately it reflects your condition during the past week and the extent to which you agree or disagree that the statement applies to you.

A low value (e.g., 1) indicates strong disagreement with the statement, whereas a high value (e.g., 7) indicates strong agreement. It is important to surround a number (1-7) for each question.

During the past week, I have found that:	**Disagree ⟷ Agree**						
My motivation is lower when I am fatigued.	1	2	3	4	5	6	7
Exercise brings on my fatigue.	1	2	3	4	5	6	7
I am easily fatigued.	1	2	3	4	5	6	7
Fatigue interferes with my physical functioning	1	2	3	4	5	6	7
Fatigue causes frequent problems for me.	1	2	3	4	5	6	7
My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7
Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3	4	5	6	7
Fatigue is among my three most disabling symptoms.	1	2	3	4	5	6	7
Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7
				Total :			

41. The Insomnia Severity Index has seven questions. For each question:

Please CIRCLE the number that best describes your answer.

ACTION PROGRAM BASELINE QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1) Difficulty falling asleep	0	1	2	3	4
2) Difficulty staying asleep	0	1	2	3	4
3) Problems waking up too early	0	1	2	3	4

4) How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very satisfied	Satisfied	Moderately satisfied	Dissatisfied	Very Dissatisfied
0	1	2	3	4

5) How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

6) How WORRIED/STRESSED are you about your current sleep problem?

Not at all Worried	A Little	Somewhat	Much	Very Much Worried
0	1	2	3	4

7) To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, etc.) CURRENTLY?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

ACTION PROGRAM BASELINE QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

To be completed by researcher only

Diagnosis: _____-

__

_____

_____

_____

Treatment received during baseline appointment: _____

_____

_____

_____

Additional notes: _____

_____

_____

_____

_____

_____

_____

_____

PROGRAMME ACTION QUESTIONS DE RÉFÉRENCE POUR LES DÉSORDRES TEMPOROMANDIBULAIRES

Hôpital			No. Patient	Initiales	
Jour	**Mois**	**Année**			

S'il-vous-plaît répondez aux questions suivantes:

1. Quel âge avez-vous? _____ *ans*

2. Avez-vous mal à la tempe, au visage, aux mâchoires, ou aux articulations des mâchoires, une fois par semaine ou plus souvent?

   ☐ Oui ☐ Non

3. Avez-vous des douleurs lorsque vous ouvrez votre bouche ou mâcher, une fois par semaine ou plus souvent?

   ☐ Oui ☐ Non

4. Au cours des 30 derniers jours, quelle était la durée de la douleur que vous avez peut-être ressentie dans la/les mâchoire/s ou au niveau de la/des tempe/s?

   ☐ Pas de douleur

   ☐ De très brève durée à plus d'une semaine, mais ça s'arrête

   ☐ Continue

5. Ces 30 derniers jours, avez-vous eu de la douleur ou rigidité dans votre mâchoire au réveil?

   ☐ Oui ☐ No

6. Ces 30 derniers jours, est-ce-que les activités suivantes ont changé la douleur (c'est-à-dire, s'est améliorée, s'est empirée) à la mâchoire, à la tempe, à l'oreille, ou devant l'oreille des deux côtés?

A. Mâcher de la nourriture dure.	☐ Oui	☐ Non
B. Ouvrir la bouche, ou bouger la mâchoire en avant en avant ou sur le côté.	☐ Oui	☐ Non
C. Des habitudes de fonction telles que maintenir les dents serrées, ou mâcher de la gomme.	☐ Oui	☐ Non
D. D'autres activités telles que parler, embrasser ou bailler.	☐ Oui	☐ Non

7. Avez-vous déjà eu de la douleur à la mâchoire, la tempe, dans l'oreille ou en avant de l'oreille d'un côté ou de l'autre?

   ☐ Oui ☐ Non

8. Il y a combien d'années ou de mois qu'a débuté, pour la première fois, votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille?

   ___ Année(s) ___ Mois

9. Veuillez encercler le numéro qui décrit le mieux le niveau de douleur faciale que vous ressentez en ce moment.
   Utilisez une échelle de 0 à 10, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

10. Quel est le chiffre qui décrit la plus forte douleur faciale que vous avez ressentie au cours des 30 derniers jours.
    Utilisez la même échelle, où 0 indique « aucune douleur » et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

11. Quel est le chiffre qui décrit le niveau de douleur faciale que vous avez ressenti en général au cours des 30 derniers jours.
    Utilisez la même échelle, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

12. Ces 30 derniers jours, combien de jours avez-vous été empêché(e) de faire vos activités habituelles tel que emploi, école/cours, ou travaux ménagers par votre douleur faciale? (*tous les jours = 30 jours*)

    ___ Jours

13. Jusqu'à quel point votre douleur faciale a interféré avec vos activités quotidiennes des 30 derniers jours. *Utilisez une échelle de 0 à 10, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».*

Aucune interférence — Incapable d'exécuter les activités quotidiennes

0 1 2 3 4 5 6 7 8 9 10

14. Jusqu'à quel point votre douleur faciale vous a empêché de prendre part à des activités sociales, familiales et récréatives au cours des 30 derniers jours. *Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».*

Aucune interférence — Incapable d'exécuter les activités quotidiennes

0 1 2 3 4 5 6 7 8 9 10

15. Jusqu'à quel point votre douleur faciale vous a empêché de faire votre travail au cours des 30 derniers jours (incluant les taches domestique)? *Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».*

Aucune interférence — Incapable d'exécuter les activités quotidiennes

0 1 2 3 4 5 6 7 8 9 10

16. Quel énoncé s'applique à la durée de cette douleur à la mâchoire, tempe, oreille, ou en avant de l'oreille depuis son apparition? (Choisir une seule réponse)

- ☐ Persistante - une douleur continue depuis le début
- ☐ Récurrente - plus d'un épisode de douleur, avec des périodes sans douleur
- ☐ Une fois - un épisode de douleur qui s'est terminé

17. Au cours des 30 derniers jours, laquelle des propositions suivantes décrit le mieux votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille d'un côté ou de l'autre? (Choisir une seule réponse?

- ☐ Aucune douleur
- ☐ La douleur qui vient et disparaît
- ☐ La douleur est toujours présente

18. Au cours des 30 derniers jours, combien de jours avez-vous eu votre douleur à la mâchoire, tempe, dans l'oreille ou en avant de l'oreille? (Choisir une seule réponse)

- ☐ Moins de 1 jour
- ☐ Un jour et plus, mais moins de 15 jours
- ☐ 15 jours et plus, mais pas continuellement
- ☐ Continuellement

19. En moyenne, combien de temps dure un seul épisode de votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille ? (Choisir une seule réponse)

- ☐ Moins de 30 minutes par épisode
- ☐ 30 minutes à moins de 2 heures par épisode
- ☐ 2 heures à moins de 4 heures par épisode
- ☐ 4 heures à 72 heures (3 jours) par épisode
- ☐ Plus de 3 jours à to 7 par épisode
- ☐ Plus de 7 jours à continuellement par épisode

20. Au cours des 30 derniers jours, avez-vous eu des maux de tête?

☐ Oui ☐ Non

Si vous avez répondu NON à la question 20, passez à la question 24.

21. Il y a combien d'années ou de mois que votre mal de tête débuté pour la première fois?

☐ Année(s) ☐ Mois

22. Au cours des 30 derniers jours, évaluez l'intensité en moyenne de votre mal de tête à la tempe. (Choisir une seule réponse)

- ☐ Légère à modérée
- ☐ Modérée à sévère

23. Où est le mal de tête situé? *(Cochez TOUT ce qui s'applique)*

- ☐ Tempe
- ☐ Front
- ☐ Dessus de la tête
- ☐ Arrière de la tête
- ☐ Derrière les yeux ou à l'intérieur de la tête

24. Au cours des 30 derniers jours, avez-vous eu des bruits dans l'articulation de la mâchoire lorsque vous bougez ou utilisez votre mâchoire??

☐ Oui ☐ Non

25. Avez-vous déjà eu la mâchoire bloquée ou coincée au point de ne pouvoir l'ouvrir COMPLÈTEMENT?

☐ Oui ☐ Non

Si vous avez répondu NON à la question 25, passez à la question 29.

26. Est-ce-que le blocage ou coincement de votre mâchoire était suffisamment sévère pour limiter son ouverture et interférer avec votre capacité à manger?

☐ Oui ☐ Non

27. Est-ce que votre mâchoire est actuellement bloquée ou limitée au point de ne pouvoir l'ouvrir COMPLÈTEMENT?

☐ Oui ☐ Non

28. À n'importe quel moment de votre vie lorsque vous avez ouvert la bouche grande, avez-vous déjà eu la mâchoire bloquée ou coincée, même pour un instant, au point de ne pouvoir la fermer de cette position grande ouverte?

☐ Oui ☐ Non

29. Quels traitements avez-vouz reçus contre la douleur?

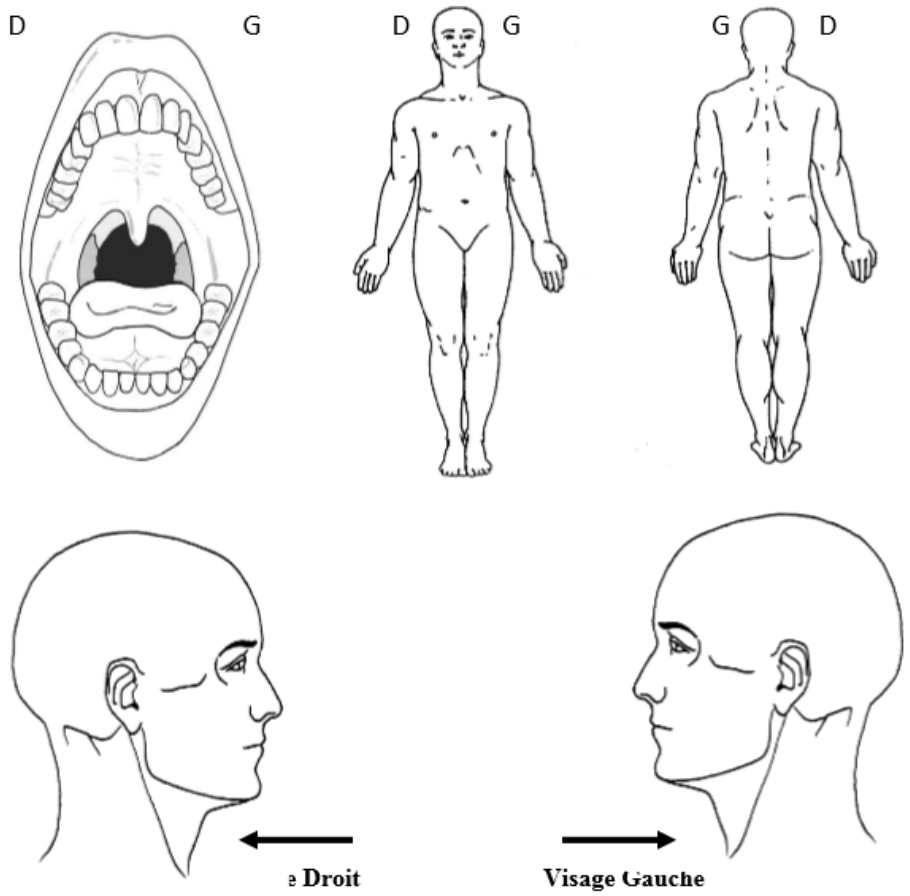
- ☐ Extraction dentaire
- ☐ Traitement orthodontique

30. Avez-vous ces conditions suivantes?

Condition	*Oui*	*Non*	*Médicament(s) pour la condition*
a. Diabète	☐	☐	
b. Allergies (Pénicilline/Médicaments)	☐	☐	
c. Problème de thyroïde	☐	☐	
d. Fièvre rhumatismale	☐	☐	
e. Haute pression sanguine	☐	☐	
f. Basse pression sanguine	☐	☐	
g. Fumez-vous? (nombre par jour)	☐	☐	
h. Asthme	☐	☐	
i. Problème cardiaque	☐	☐	
j. Douleur aux bras	☐	☐	
k. Douleur aux jambes	☐	☐	
l. Douleur à la poitrine	☐	☐	
m. Douleur au cou	☐	☐	
n. Douleur au dos	☐	☐	
o. Douleur à l'abdomène	☐	☐	

31. Diagramme de douleur

Indiquez l'emplacement de TOUTES vos douleurs différentes en colorant la zone, sur les illustrations appropriées. S'il y a un endroit précis où la douleur est localisée, indiquer la douleur avec un point solide (●). Si votre douleur bouge d'un endroit à un autre, utilisez des flèches pour indiquer la trajectoire.



32. De quel côté du visage la douleur est-elle plus sévère?

☐ Côté gauche ☐ Côté droit ☐ Les deux côtés également

33. En utilisant l'échelle ci-dessous, s'il-vous-plaît indiquez la mesure dans laquelle vous avez ces sentiments.

PROGRAMME ACTION QUESTIONS DE RÉFÉRENCE POUR LES DÉSORDRES TEMPOROMANDIBULAIRES

Au cours des 14 derniers jours, à quelle fréquence avez-vous été dérangé(e) par les problèmes suivants?	Jamais	Plusieurs jours	Plus de la moitié des jours	Presque tous les jours
A. Sentiment de nervosité, d'anxiété ou de tension.	0	1	2	3
B. Incapable d'arrêter de vous inquiéter ou de contrôler vos inquiétudes.	0	1	2	3
C. Inquiétudes excessive à propos de tout et de rien.	0	1	2	3
D. Difficulté à se détendre.	0	1	2	3
E. Agitation telle qu'il est difficile de rester tranquille.	0	1	2	3
F. Devenir facilement Contrarie(e) ou irritable.	0	1	2	3
G. Avoir peur que quelque chose d'épouvantable puisse arriver.	0	1	2	3

34. En utilisant l'échelle ci-dessous, s'il-vous-plaît indiquez la mesure dans laquelle vous avez ces sentiments.

Au cours des 14 derniers jours, à quelle fréquence avez-vous été dérangé(e) par les problèmes ou états suivants?	Jamais	Plusieurs jours	Plus de 7 jours	Presque tous les jours
A. Peu d'intérêt ou de plaisir à faire des choses	0	1	2	3
B. Se sentir triste, déprimé(e) ou désespéré(e)	0	1	2	3
C. Difficultés à s'endormir ou à rester endormi(e), ou trop dormir	0	1	2	3
D. Se sentir fatigué(e) ou avoir peu d'énergie	0	1	2	3
E. Peu d'appétit ou trop manger	0	1	2	3
F. Mauvaise perception de vous-même – ou vous pensez que vous êtes un perdant ou que vous n'avez pas satisfaits vos propres attentes ou celles de votre famille	0	1	2	3
G. Difficultés à se concentrer sur des choses tel que lire le journal ou regarder la télévision	0	1	2	3
H. Vous bougez ou parlez si lentement que les autres personnes ont pu le remarquer. Ou au contraire – vous êtes si agité(e) que vous bougez beaucoup plus que d'habitude	0	1	2	3

Si vous avez cochez au moins un des problèmes nommés dans ce questionnaire, répondez a la question suivante : Dans quelle mesure ce(s) problème(s) a-t-il (ont-ils) rendu difficile votre travail, vos taches à la maison ou votre capacité a bien vous entendre avec les autre?

☐ Pas du tout difficile ☐ Plutôt difficile ☐ Très difficile ☐ Extrêmement difficile

35. S'il-vous-plaît répondez aux questions suivantes sur vous-même en indiquant la mesure de votre accord :

	Totalement en désaccord	Plutôt en désaccord	Neutre	Plutôt d'accord	Totalement d'accord
A. Dans les moments d'incertitude, je m'attends habituellement au mieux					
B. J'ai de la facilité à me relaxer					
C. S'il y a des chances que ça aille mal pour moi, ça ira mal					
D. Je suis toujours optimiste face à mon avenir					
E. J'apprécie beaucoup mes amis(e)s					
F. C'est important pour moi de me tenir occupé(e)					
G. Je ne m'attends presque jamais à ce que les choses aillent comme je le souhaite					
H. Je ne me fâche pas très facilement					
I. Je m'attends rarement à ce que de bonnes choses m'arrivent					
J. Dans l'ensemble, je m'attends à ce qu'il m'arrive plus de bonnes choses que de mauvaises					

36. Avez-vous déjà subi une extraction dentaire?

☐ Oui ☐ Non

Si vous avez répondu « Oui », pour quelle raison?

☐ Parce que j'avais mal ☐ Je ne m'en souviens pas ☐ Pas à cause de la douleur

37. Avez-vous déjà eu un traitement orthodontique?

☐ Oui ☐ Non

Si vous avez répondu « Oui », pour quelle raison?

☐ Parce que j'avais mal ☐ Je ne m'en souviens pas ☐ Pas à cause de la douleur

38. Écrivez le numéro correspondant à votre choix dans la colonne de droite.

Inclu: ☐ Oui ☐ Non

0 = Aucun risque de m'assoupir ou de m'endormir
1 = Faible risque de m'assoupir ou de m'endormir
2 = Risque modéré de m'assoupir ou de m'endormir
3 = Risque élevé de m'assoupir ou de m'endormir

Situations	Scores (0, 1, 2 ou 3)
Lire en position assise	
Regarder la télévision	
Être assis(e) inactif(ve) dans un lieu public (par exemple théâtre, réunion etc.)	
Être assis(e) en tant que passager(ère) dans un véhicule pour une période d'une heure sans arrêt	
Être étendu(e) l'après-midi lorsque les circonstances le permettent	
Être assis(e) en parlant avec quelqu'un	
Être assis(e) tranquille après un repas sans boisson alcoolique	
Dans une voiture arrêtée quelques minutes a un feu de circulation ou dans la circulation	

39. Inscrivez votre réponse (*Oui* ou *Non*) dans la colonne de droite.

PROGRAMME ACTION QUESTIONS DE RÉFÉRENCE POUR LES DÉSORDRES TEMPOROMANDIBULAIRES

Questions	Oui ou Non
Ronflements **Ronflez**-vous **fort** (suffisamment fort pour qu'on vous entende à travers une porte fermée ou pour que votre partenaire vous donne des coups de coude parce que vous ronflez) ?	
Fatigue Vous sentez-vous souvent **fatigué(e)**, **épuisé(e)** ou **somnolent(e)** pendant la journée (comme par exemple s'endormir au volant) ?	
Observation Quelqu'un a-t-il **observé** que vous **arrêtiez de respirer** ou que **vous vous étouffiez/suffoquiez** pendant votre sommeil ?	
Tension Êtes-vous atteint(e) d'**hypertension artérielle** ou êtes-vous traité(e) pour ce problème ?	
Indice de Masse Corporelle supérieur à 35 kg/m^2 ?	
Âge supérieur à 50 ans?	
Tour de cou important (mesuré au niveau de la pomme d'Adam) Pour les hommes, votre tour de cou est-il supérieur ou égal à 43 cm ? Pour les femmes, votre tour de cou est-il supérieur ou égal à 41 cm ?	
Sexe = Masculin?	

40. Fatigue Severity Scale (FSS) des troubles du sommeil.

Cet outil permet d'évaluer l'impact de la fatigue sur vous. Il s'agit d'un court questionnaire qui vous demande de mesurer votre niveau de fatigue. Il contient neuf affirmations qui mesurent la sévérité des symptômes de votre fatigue.

Lisez chaque affirmation et entourez un nombre de 1 à 7 qui semble correspondre à votre état de fatigue durant la semaine dernière.

• Une valeur basse (1) indique que vous n'êtes pas d'accord avec l'affirmation, tandis qu'une valeur haute (7) indique que vous êtes d'accord avec l'affirmation proposée.

• Il est important d'entourer un nombre (1 à 7) pour chaque question.

Durant la semaine passée, j'ai trouvé que :	**Pas d'accord → D'accord**						
Ma motivation est plus basse quand je suis fatigué (e)	1	2	3	4	5	6	7
Les exercices me demandent des efforts	1	2	3	4	5	6	7
Je suis facilement fatigué(e)	1	2	3	4	5	6	7
La fatigue interfère avec mes fonctions physiques	1	2	3	4	5	6	7
La fatigue me cause souvent des problèmes	1	2	3	4	5	6	7
Ma fatigue empêche certaines fonctions physiques	1	2	3	4	5	6	7
La fatigue m'empêche de mener à bien certaines obligations et responsabilités	1	2	3	4	5	6	7
La fatigue est parmi mes 3 symptômes les plus handicapants	1	2	3	4	5	6	7
La fatigue interfère avec mon travail, ma famille ou ma vie sociale	1	2	3	4	5	6	7
				Total :			

41. L'Indice de gravité Insomnia a sept questions. Pour chaque question:

PROGRAMME ACTION QUESTIONS DE RÉFÉRENCE POUR LES DÉSORDRES TEMPOROMANDIBULAIRES

S'il-vous-plaît encerclez le numéro qui décrit le mieux votre réponse. Veuillez noter la SÉVÉRITÉ COURANTE (à savoir, 2 dernières semaines) de votre problème d'insomnie .

Problème d'insomnie	Aucune	Légère	Moyenne	Élevée	Extrême
1) Difficulté à s'endormir	0	1	2	3	4
2) Difficulté à rester endormi(e)	0	1	2	3	4
3) Problème de réveil trop tôt le matin	0	1	2	3	4

4) À quel point êtes-vous SATISFAIT(E) / INSATISFAIT(E) de votre sommeil actuel ?

Très satisfait(e)	Satisfait(e)	Neutre	Insatisfait(e)	Très insatisfait(e)
0	1	2	3	4

5) À quel point considérez-vous que vos difficultés de sommeil sont APPARENTES pour les autres en termes de détérioration de la qualité de vie ?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

6) À quel point êtes-vous INQUIET(ÈTE) / PRÉOCCUPÉ(E) à propos de vos difficultés de sommeil actuelles ?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

7) À quel point considérez-vous que vos difficultés de sommeil PERTURBENT votre fonctionnement quotidien (ex. : fatigue, concentration, mémoire, humeur) ACTUELLE?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

À compléter par le/la chercheur/e

Diagnosis: _____-

__

_____

_____

_____

Treatment received during baseline appointment: _____

_____

_____

_____

Additional notes: _____

_____

_____

_____

_____

_____

_____

_____

ACTION PROGRAM 3 AND 6 MONTHS QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

Hospital			Patient Number	Initials	
Day	**Month**	**Year**			

Please answer the following questions:

1. On how many days in the last month have you had facial pain? ____ Days

2. In the last 30 days, which of the following best describes any pain in your jaw, temple, in the ear, or in front of the ear on either side? *(Select ONE response)*

   ☐ No pain

   ☐ Pain comes and goes

   ☐ Pain is always present

3. Do you have pain in temple, face, jaw joint, or jaws once a week or more often?

   ☐ Yes ☐ No

4. Do you have pain when you open your month wide or chew, once a week or more often?

   ☐ Yes ☐ No

5. Do you have pain in the temples once a week or more often?

   ☐ Yes ☐ No

ACTION PROGRAM 3 AND 6 MONTHS QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

6. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last? *(Select ONE response)*

   ☐ No pain

   ☐ From very brief to more than a week, but it does stop

   ☐ Continuous

7. In the last 30 days, did you have pain or stiffness in your jaw on awakening?

   ☐ Yes ☐ No

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

A. Chewing hard or tough food.	☐ Yes	☐ No
B. Opening your mouth, or moving your jaw forward or to the side.	☐ Yes	☐ No
C. Jaw habits such as holding teeth together or chewing gum.	☐ Yes	☐ No
D. Other jaw activities such as talking, kissing, or yawning.	☐ Yes	☐ No

9. How would you rate your facial pain right now?
   Please rate your pain by circling the number that tells how much pain you have right now.

No pain — Pain as bad as it could be

0 1 2 3 4 5 6 7 8 9 10

10. In the last 30 days, how would you rate your worst facial pain?
    Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be".

No pain — Pain as bad as it could be

0 1 2 3 4 5 6 7 8 9 10

11. In the last 30 days, on average, how would you rate your facial pain?
Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be".
(That is, your usual pain at times you were in pain)

No pain — Pain as bad as it could be

0 1 2 3 4 5 6 7 8 9 10

12. In the last 30 days, how many days did your facial pain keep you from doing your usual activities like work, school, or housework? *(every day = 30 days)*

___ Days

13. In the last 30 days, how much has facial pain interfered with your daily activities? Use a scale where 0 is "no interference" and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

14. In the last 30 days, how much has facial pain interfered with your recreational, social and family activities? Use the same scale where 0 is "no interference" and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

15. In the last 30 days, how much has facial pain interfered with your ability to work, including housework? Use the same scale where 0 is "no interference" and 10 is "unable to carry on any activities".

No interference — Unable to carry on any activities

0 1 2 3 4 5 6 7 8 9 10

16. What treatments did you receive for your pain?

_____

_____

PROGRAMME ACTION QUESTIONS DE SUIVI DE 3 & 6 MOIS POUR LES DÉSORDRES TEMPOROMANDIBULAIRES

Hôpital			No. Patient	Initiales	
Jour	**Mois**	**Année**			

S'il-vous-plaît répondez aux questions suivantes:

1. Pendant combien de jours au cours des 3 derniers mois avez-vous eu des douleurs faciales?

   ____ Jours

2. Au cours des 30 derniers jours, laquelle des propositions suivantes décrit le mieux votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille d'un côté ou de l'autre? (Choisir une seule réponse)

   ☐ Pas de douleur

   ☐ La douleur qui vient et disparaît

   ☐ La douleur est toujours présente

3. Avez-vous mal à la tempe, au visage, aux mâchoires, ou aux articulations des mâchoires, une fois par semaine ou plus souvent?

   ☐ Oui ☐ Non

4. Avez-vous des douleurs lorsque vous ouvrez votre bouche ou mâcher, une fois par semaine ou plus souvent?

   ☐ Oui ☐ Non

5. Avez-vous des douleurs aux tempes une fois par semaine ou plus souvent?

   ☐ Oui ☐ Non

6. Au cours des 30 derniers jours, quelle était la durée de la douleur que vous avez peut-être ressentie dans la/les mâchoire/s ou au niveau de la/des tempe/s?

   ☐ Pas de douleur

   ☐ De très brève durée à plus d'une semaine, mais ça s'arrête

   ☐ Continue

7. Ces 30 derniers jours, avez-vous eu de la douleur ou rigidité dans votre mâchoire au réveil?

   ☐ Oui ☐ Non

8. Ces 30 derniers jours, est-ce-que les activités suivantes ont changé la douleur (c'est-à-dire, s'est améliorée, s'est empirée) à la mâchoire, à la tempe, à l'oreille, ou devant l'oreille des deux côtés?

A. Mâcher de la nourriture dure.	☐ Oui	☐ Non
B. Ouvrir la bouche, ou bouger la mâchoire en avant en avant ou sur le côté.	☐ Oui	☐ Non
C. Des habitudes de fonction telles que maintenir les dents serrées, ou mâcher de la gomme.	☐ Oui	☐ Non
D. D'autres activités telles que parler, embrasser ou bailler.	☐ Oui	☐ Non

9. Veuillez encercler le numéro qui décrit le mieux le niveau de douleur faciale que vous ressentez en ce moment.
   Utilisez une échelle de 0 à 10, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

10. Quel est le chiffre qui décrit la plus forte douleur faciale que vous avez ressentie au cours des 30 derniers jours.

Utilisez la même échelle, où 0 indique « aucune douleur » et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

11. Quel est le chiffre qui décrit le niveau de douleur faciale que vous avez ressenti en général au cours des 30 derniers jours.
Utilisez la même échelle, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

Aucune douleur										La pire douleur possible
0	1	2	3	4	5	6	7	8	9	10

12. Ces 30 derniers jours, combien de jours avez-vous été empêché(e) de faire vos activités habituelles tel que emploi, école/cours, ou travaux ménagers par votre douleur faciale? (*tous les jours = 30 jours*)

___ Jours

13. Jusqu'à quel point votre douleur faciale a interféré avec vos activités quotidiennes des 30 derniers jours.
Utilisez une échelle de 0 à 10, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».

Aucune interférence										Incapable d'exécuter les activités quotidiennes
0	1	2	3	4	5	6	7	8	9	10

14. Jusqu'à quel point votre douleur faciale vous a empêché de prendre part à des activités sociales, familiales et récréatives au cours des 30 derniers jours.
Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».

Aucune interférence — Incapable d'exécuter les activités quotidiennes

0 1 2 3 4 5 6 7 8 9 10

15. Jusqu'à quel point votre douleur faciale vous a empêché de faire votre travail au cours des 30 derniers jours (incluant les taches domestique)?
Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».

Aucune interférence — Incapable d'exécuter les activités quotidiennes

0 1 2 3 4 5 6 7 8 9 10

16. Quels médicaments prenez-vous contre la douleur?

_____

_____

Centre universitaire de santé McGill | McGill University Health Centre

Hôpital général juif
Jewish General Hospital

McGill

Consent Form

Transition from acute to chronic painful temporomandibular disorders: A prospective cohort study

You are being invited to participate in a study regarding transition from acute to chronic Temporomandibular Disorder 'called TMD', a type of facial pain. You have been selected as we are interested in understanding what may predict health wellbeing associated with facial pain. You have the right to know about the purposes and procedures that are be used in this study and to be informed about its potential benefits, risks and any discomfort that may occur. There is no compensation for your participation. Before you agree to take part in this study, it is important that you read the information in this consent form. You should ask as many questions as you need to in order to understand what you will be asked to do. Your participation is voluntary.

Purpose of this study:

The purpose of this study is to identify the possibilities of having a TMD-related pain and determine the factors associated with this facial pain.

Procedures:

If you agree to participate in our study, you will be asked to do the following:

- You will be invited to complete a questionnaire on the day of your dental appointment (today), and at 3 and 6 months after this first interview. If you cannot do so, we will ask you to complete it at a later time and mail it back to us in a postage-paid envelope that will be provided to you. If you cannot return this questionnaire, a telephone interview will then be conducted by the research assistant. The completion of the questionnaire may take on average 10 to 20 minutes.
- Allow us to collect saliva (5-10 ml) on the day of the first interview. To collect the saliva, the research assistant will ask you to spit into a sterilized centrifuge tube. No hospitalization is required for this purpose. The duration of saliva collection will take a maximum of 10 minutes. Saliva samples will be used to assess if the composition of the saliva is related to TMD-related pain.
- The research team will ask you about your general health using a brief questionnaire. We will see if you have high blood pressure, diabetes, thyroid problem, allergy, and asthma. We will do that to see if these factors may predict health wellbeing associated with facial pain.
- The questions which are going to be asked in the study will help to identify the individuals with TMD, as well as to measure the level of pain and disability related to this condition. Other questions will evaluate the level of general health and psychological characteristics (e.g., anxiety and depression).

Risks, Disadvantages and Side-Effects:
You will be interviewed by the research assistant. If you feel uncomfortable to answer any of the questions, you are free to stop or skip that question and move on to the next one. This interview will take a maximum of 20 minutes of your time.

Benefits:
There is no direct benefit to participate in this study. However, this study will provide the medical and dental community with more definitive evidence of factors that may increase the chance of this type of facial pain. The results of this study may contribute to the development of personalized programs to improve TMD pain management.

Voluntary participation / withdrawal:
Your participation in this study is voluntary. Whether you accept or decline to participate in this study, your future dental care and your patient-doctor relationship will not be affected in any way. You may choose to participate now and decide to stop your participation at any time. If you decide to withdraw from the study, all information obtained about you up to the point of your withdrawal will be kept to preserve the scientific integrity of the study. Upon your withdrawal, you can request to have your saliva samples destroyed.

Confidentiality:
While you take part in this research study, the researcher in charge and study staff will collect and store personal identifiable information about you in a file for the purpose of the research study. Only information necessary for the research study will be collected.

All information and saliva sample obtained about you during this study will be treated confidentially within the limits of the law. Thus, to protect your identity, your name and identifying information will be replaced with a code (numbers). The link between the code and your identity as well as the study file will be kept under the responsibility of Dr. Velly and will be held in a locked drawer in Dr. Velly's office at the Dental Department of the Jewish General Hospital. No information that discloses your identity will be allowed to leave the institution.

The saliva sample will be stored in the saliva freezer at the Lady Davis Institute of the Jewish General Hospital under the responsibility of Drs. Gornitsky, Schipper and Velly. Your sample will be stored until the saliva is used for study analysis. The remaining saliva sample will be destroyed in the laboratory of Dr. Hyman Schipper at the Lady Davis Institute, 10 years after the completion of the study. The sample will only be used for the purposes described in this consent form. The Lady Davis Institute requires a pass for entry, the door to the lab is locked and the results of the samples will be kept in a locked drawer with information being codified. Computer information is restricted by a password.

The result of the analysis will be kept confidential and will not be placed anywhere in your file. Also, you will not be identified in any published report. A copy of this consent form will not be placed in your medical record file and a copy will be given to you.

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For the purpose of monitoring this research, your research study file as well as your medical records identifying you could be checked by a person authorized by the Research Ethics Committee of the Jewish General Hospital or the Institutional Review Board of McGill University. This person is obliged to respect your privacy.

For safety purposes, and in order to communicate information that is required in order to protect your well-being, Dr. Velly, the principal researcher of this study will keep your personal information including your name, contact information, the date when your participation in the study began and when it ended separate from the research documents.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, as long as the study researcher or the institution keeps this information.

Contact information:
If you have any question about this study, please contact Dr. Ana Velly: 514-340-8222 ext 2932, 3755 Cote St. Catherine Road, room A-017, Montreal, Quebec H3T 1E2. For any question regarding your rights as a research participant, please contact Rosemary Steinberg (Jewish General Hospital), local commissioner of complaints and quality of service, at 514-340-8222 ext. 5833 or Pascale Valois (Montreal General Hospital), local commissioner of complaints and quality of service, at 514-934-1934 ext. 44285

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Statement of Consent:

I have read the previous information and my questions were answered to my satisfaction. A copy of this signed consent form will be given to me. My participation is voluntary and I can withdraw from the study at any time without giving reasons. It will not affect my dental care now or later. I do not give up any of my legal rights by participating in this study. I understand that I will be contacted by the research assistant at the first appointment and after three and six months.

I agree to participate in this study.

_____
Printed name of participant

_____ _____
Signature of Subject Date

_____
Printed name of person obtaining consent

_____ _____
Signature of Person Obtaining Consent Date

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Formulaire de consentement

Transition de la douleur aiguë à la douleur chronique liée aux désordres temporomandibulaires: Une étude de cohorte prospective

Vous êtes invité à participer à une étude concernant la transition de la douleur aigue à la douleur chronique liée aux désordres temporomandibulaires, nommés « DAM », un type de douleur au visage. Vous avez été sélectionné car nous sommes intéressés à comprendre ce qui peut prédire le bien-être en santé lié à la douleur faciale. Vous avez le droit de connaître le but et les procédures de cette étude, et d'être informé sur ses potentiels avantages et risques, ainsi que tout inconfort qui peuvent être encourus. Il n'y a aucune rémunération pour participer à cette étude.

Avant d'accepter de prendre part à cette étude, il est important que vous lisiez l'information dans ce formulaire de consentement. Vous devriez poser autant de questions nécessaires afin de comprendre ce que vous serez invité à faire. Votre participation est volontaire.

But de l'étude:
L'objectif de cette étude est de déterminer les possibilités d'avoir de la douleur liée aux désordres temporomandibulaires et de déterminer les facteurs associés à cette douleur au visage.

Procédures:
Si vous acceptez de participer à notre étude, vous serez demandé de faire ce qui suit:

- Vous serez invité à compléter un questionnaire le jour de votre rendez-vous (aujourd'hui), 3 et 6 mois après ce premier entretien. Si vous ne pouvez pas le compléter, nous vous demanderons de le faire ultérieurement et de nous renvoyer le questionnaire dans une enveloppe prépayée que nous vous fournirons. Si vous ne pouvez pas nous retourner ce questionnaire, une entrevue téléphonique sera alors effectuée par l'assistant de recherche. L'achèvement du questionnaire peut prendre en moyenne de 10 à 20 minutes.
- Permettez-nous de recueillir de la salive (5-10 ml) le jour de la première entrevue. Afin de collecter la salive, l'assistant de recherche vous demandera de cracher dans une éprouvette stérilisée. Aucune hospitalisation ne sera nécessaire à ces fins. La durée de la collecte de salive prendra un maximum de 10 minutes. Les échantillons de salive seront utilisés afin d'évaluer si la composition de la salive est liée à cette douleur.
- L'équipe de recherché vous posera des questions sur vos la santé en général en utilisant un bref questionnaire. Nous vérifierons si vous avez de l'hypertension, le diabète, des problèmes de thyroïde, des allergies ou de l'asthme. Nous ferons cela afin de voir si ces facteurs peuvent prédire le bien-être en santé associé à la douleur au visage.
- Les questions qui seront posées lors de cette étude aideront à l'identification des individus atteints de DAM, ainsi que de mesurer le niveau de douleur et

d'incapacité lié à cette condition. D'autres questions évalueront le niveau de la santé en général et les caractéristiques psychologiques (ex. anxiété et dépression).

Les risques, inconforts et effets secondaires:
Vous aurez des entrevues avec l'assistant de recherche. Si vous n'êtes pas confortable à répondre à certaines questions en particulier, vous êtes libres d'arrêter ou de sauter la question et de passer à la suivante. Cette entrevue prendra un maximum de 20 minutes de votre temps.

Avantages:
Il n'y a aucun avantage direct à participer à cette étude. Cependant, cette étude fournira à la communauté médicale et dentaire des preuves plus définitives sur les facteurs qui peuvent augmenter les chances de cette douleur au visage. Ces résultats peuvent contribuer au développement de programmes personnalisés pour améliorer la gestion de la douleur liée aux désordres temporomandibulaires.

Participation volontaire / retrait:
Votre participation à cette étude est volontaire. Indépendamment de si vous accepter ou refuser de participer à cette étude, vos futurs soins dentaire et votre relation dentiste-patient ne seront affectés en aucune façon. Vous pouvez choisir de participer maintenant et d'arrêter à tout moment. Si vous décidez de vous retirer de cette étude, toutes informations recueillies jusqu'au moment de votre retrait seront gardées afin de protéger l'intégrité scientifique de l'étude. Après votre retrait, vous pouvez demander à ce que vos échantillons de salive soient détruits.

Confidentialité:
Durant votre participation à cette étude, le chercheur responsable et le personnel impliqué dans l'étude collecteront et conserveront des informations personnelles pouvant vous identifier dans un dossier aux fins de l'étude. Seules les informations nécessaires à l'étude de recherche seront recueillies.

Toutes les informations et échantillons de salive obtenus de vous au cours de cette étude seront traités confidentiellement dans les limites de la loi. Ainsi, afin de protéger votre identité, votre nom et informations d'identification seront remplacés par un code (chiffres). Le lien entre le code et votre identité ainsi que le dossier d'étude seront maintenus sous la responsabilité du Dr. Velly, et seront conservés dans un tiroir verrouillé dans le bureau du Dr. Velly au département dentaire de l'Hôpital général juif. Aucune information révélant votre identité ne sera autorisé à quitter l'établissement.

L'échantillon de salive sera conservé dans un congélateur contenant des échantillons de salive à l'Institut Lady Davis de l'Hôpital général juif, sous la responsabilité des Drs. Gornitsky, Schipper et Velly. Votre échantillon sera conservé jusqu'à ce que la salive soit utilisée pour des analyses. Le reste de l'échantillon de salive sera détruit dans le laboratoire du Dr. Hyman Schipper à l'Institut Lady Davis, 10 ans après la fin de l'étude. L'échantillon de salive sera utilisé uniquement aux fins des objectifs décrits dans ce formulaire de consentement. L'Institut Lady Davis nécessite un laissez-passer pour y accéder, la porte du laboratoire est verrouillée, et les

résultats des échantillons seront conservés dans un tiroir fermé à clé avec les informations codifiées. Les informations sur l'ordinateur sont limitées par un mot de passe.

Le résultat de l'analyse sera maintenu confidentiel et ne sera pas placé dans votre dossier. En outre, vous ne serez identifié dans aucun rapport publié. Une copie de ce formulaire de consentement ne sera pas placée dans votre dossier médical, et un exemplaire vous sera remis.

Aux fins de surveillance de cette étude, votre dossier de recherche ainsi que vos dossiers médicaux vous identifiant peuvent être vérifiés par une personne autorisée par le comité d'éthique de l'Hôpital général juif ou le comité d'examen institutionnel de l'Université McGill. Cette personne est tenue de respecter votre vie privée.

Pour des raisons de sécurité, et afin de communiquer des informations qui sont nécessaires pour protéger vos données, Dr. Velly, chercheur principal de cette étude, gardera vos informations personnelles, y compris votre nom, vos coordonnées, les dates auxquelles votre participation à l'étude a commencé et a fini séparées des documents de recherche.

Vous avez le droit de consulter votre dossier d'étude afin de vérifier les informations recueillies sur vous et de les corrigées, si nécessaire, tant que le chercheur ou l'institution conserve ces renseignements.

Contacts :

Si vous avez des questions au sujet de cette étude, s'il vous plaît contacter Dr. Ana Velly: 514-340-8222 poste 2932, 3755 Côte Ste. Catherine Road, room A 017, Montréal, Québec H3T 1E2. Pour toute information concernant vos droits à titre de participant à une étude de recherche, veuillez contacter Rosemary Steinberg (Hôpital général juif), commissaire locale aux plaintes et à la qualité du service, au 514-340-8222 poste 5833 ou Pascale Valois (Hôpital général de Montréal), commissaire locale aux plaintes et à la qualité du service, au 514-934-1934 poste 44285.

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Déclaration de consentement:

J'ai lu les informations et mes questions ont été répondues à ma satisfaction. Une copie de ce formulaire de consentement signé me sera remise. Ma participation est volontaire et je peux me retirer de l'étude à tout moment sans donner de raisons, sans que cela affecte mes soins médicaux maintenant ou plus tard. Je ne renonce à aucun de mes droits légaux en participant à cette étude. Je comprends que je serai contacté par l'assistante de recherche au premier rendez-vous et après trois et six mois.

Je suis d'accord pour participer à cette étude.

_____

Nom du participant

_____ _____

Signature du participant Date

_____

Nom de la personne obtenant le consentement

_____ _____

Signature de la personne obtenant le consentement Date