provided by Dépôt numérique de UQTR Houle, M., Marchand, A.-A., & Descarreaux, M. (2020). Can Headache Profile Predict Future Disability: A Cohort Study. The Clinical Journal of Pain, 36(8), 594-600. CC BY-NC http://dx.doi.org/10.1097/ajp.0000000000843

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27	Conflict of Interest Statement: There is no conflict of interest.
28	
29	Funding : This research received no specific grant from any funding agency in the public,
30	commercial, or not-for-profit sectors.
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35 Abstract:

36 Objectives:

The aim of this study was to determine if headache profile can predict future disability inpatients with TTH.

39 Methods

Eighty-three patients with TTH were recruited. To be included in the study participants 40 needed to fulfill the International Headache Society classification's criteria for episodic or 41 chronic TTH form and to be at least 18 years old. Baseline clinical outcomes (headache 42 and neck-related disability, kinesiophobia, self-efficacy and anxiety) and physical 43 outcomes (neck extensors muscles maximum voluntary contraction) were collected for all 44 patients. A prospective data collection of headache characteristics (intensity and frequency) 45 46 was conducted using daily SMS or e-mail over a 1-month period. Headache-related disability was assessed at the 3-month follow-up and was used as the disability criterion 47 for TTH. 48

49 **Results**

50 Correlations showed that the number of years with headache (r=.53 ; p<0.001 , self-51 reported neck pain intensity (r=.29 ; p=0.025), headache frequency (r=.60 ; p<0.001) and 52 intensity (r=.54 ; p<0.001), anxiety (r=.28 ; p=0.031) as well as neck-related disability 53 (r=.63 ; p<0.001) were correlated to headache-related disability assessed at 3 months. 54 Multiple regression showed that these determinants can be used to predict headache 55 disability (R^2 = 0.583). Headache frequency (β =0.284) was the best individual predictor.

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59 Results showed that TTH frequency and intensity and the presence of concomitant 60 infrequent migraine are predictors of future disability over a 3-month period. Further 61 studies are needed to evaluate the contribution of other potential physical outcomes on 62 headache-related disability.

- 63 Keys words: Tension-type headache; headache profile; neck pain; disability; strength
- 64 List of abbreviations
- 65 TTH: tension-type headache
- 66 IETTH: infrequent episodic tension-type headache
- 67 FETTH: frequent episodic tension-type headache
- 68 CTTH: chronic tension-type headache
- 69 IHS: International Headache Society
- 70 MVC: maximum voluntary contraction
- 71 HIT-6: 6-item headache impact test
- 72 NDI: neck disability index
- 73 VAS: visual analogue scale

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81 Can headache profile predict future disability: a cohort study.

82 **Introduction**

Tension-type headache (TTH) is the most common type of headache [1] with a lifetime prevalence in the general population that ranges between 30% to 78% [2-4]. The average age of TTH onset is estimated between 25 and 30 years old with the peak prevalence for both sexes occurring between 30 to 39 years of age, followed by a decline with increasing age [1, 5]. Women are more affected than men with female:male ratios ranging from 1.3:1 to 5:4 [1, 5, 6].

89 According to the International Headache Society (IHS), tension-type headache is classified 90 as a primary headache [3] and typically described by a bilateral, pressing, tightening and 91 non-pulsating pain. In addition, intensity of TTH is considered to be mild to moderate 92 without aggravation by routine physical activity such as climbing stairs or walking and is 93 not associated with nausea or vomiting except for mild nausea that can be present in chronic 94 TTH (CTTH) [5]. Furthermore, phonophobia or photophobia can occur during TTH 95 episodes, but both symptoms should not be present at the same time [3, 5]. TTH can be divided into two categories: episodic or chronic form. The episodic form is further divided 96 97 into two subcategories based on the frequency of episodes: infrequent episodic tensiontype headache (IETTH) or frequent episodic tension-type headache (FETTH) [3]. IETTH 98 99 is characterized by at least 10 episodes occurring less than one day per month (< 12 days 100 per years), FETTH is characterized by 1 to 14 days per month for at least 3 consecutive months (> 12 and < 180 days per year) and CTTH consists of fifteen days or more with 101 headaches per month (> 180 days per year) [1, 3]. In a Danish population-based study, the 102 103 one-year prevalence of each category at 40 years old was 48.2%, 33.8% and 2.3% respectively and the prevalence was higher in men for the infrequent episodic TTH than in
women but frequent episodic and chronic TTH was more frequent in women than in men
[7]. Tension-type headache and particularly CTTH are often associated with medical and
psychiatric conditions. Indeed, TTH has previously been linked to common comorbidities
such as temporomandibular disorders, depression, anxiety and panic disorders [5].

109 To date, only a few studies have evaluated risk factors for the development of TTH or risk 110 factors that leads to a transition from episodic to chronic forms [8-10]. In fact, environmental, genetic and peripheral factors such as tenderness in pericranial muscles, 111 112 muscle strain, muscle blood flow and other central factors have all been hypothesized as 113 possible contributors to the development of TTH [8]. Moreover, risk factors to transition from the episodic TTH form to the chronic TTH form are divided into two categories: non-114 modifiable risk factors and modifiable risk factors. On the one hand, non-modifiable risk 115 factors include increasing age, female sex, being Caucasian, previous history of head 116 trauma and low socioeconomic status [9]. On the other hand, modifiable risk factors 117 118 include sleep disturbances, medication overuse, obesity and the presence of psychological 119 comorbidities [9]. Depression and anxiety are common with TTH, especially in the chronic form [11]. However, there are only few studies with follow-ups that have been conducted 120 in adults with tension-type headache. A study by Lyngberg and colleagues showed that, in 121 adults randomly drawn from the general population, predictors of poor outcomes in patients 122 with tension-type headache were having frequent episodic or chronic tension-type 123 headache at baseline, having coexisting migraine, not being married and having sleep 124 problems. In their study, no association was found with respect to age, gender or 125 126 educational levels [12].

127 Frequency and intensity of tension-type headache are two factors frequently assessed in 128 studies but are also used to define inclusion criteria for TTH participants (IETTH, FETTH) or CTTH group). Moreover, Sauro et al. reported a positive correlation between intensity 129 130 and headache-related disability as evaluated by the 6-item headache impact test (HIT-6) questionnaire but failed to identify any correlations between frequency and headache-131 related disability [13] in patients with headache including patients with TTH. In the general 132 population, individuals with higher impact associated to TTH have a lower quality of life, 133 are more frequently absent from work and have lower work performance [14]. A Danish 134 population-based study reported that absence rates were higher in individuals with FTTH 135 than in healthy subjects [15]. Headache-related disability assessed by the HIT-6 136 questionnaire appear to be an important aspect to monitor in TTH patients to evaluate 137 138 changes over time and to guide futures clinical interventions. The aim of this study was to determine if headache profile can predict future disability in participants with tension-type 139 headache. 140

141

142 Materials and Methods

143 Study design

This cohort study was conducted at the Laboratory of motor control and neuromechanics located at the University of Québec in Trois-Rivières. Recruitment, testing and follow-up were conducted from August 2016 to November 2017. This study falls within the continuity of a study with controls and TTH participants (Marchand et al. in press in BMJ).

148

149 Participants' selection

150 Eighty-three participants with tension-type headache were recruited via social media 151 platforms and from the university community. To be included in the study, participants needed to fulfill the International Headache Society (IHS) classification criteria for IETTH, 152 153 FETTH or CTTH (see table 1). Participants with concomitant headache and neck pain were included only if neck pain was not the dominant pain perceived. For participants 154 experiencing other concomitant headache type, presentation and symptoms of TTH were 155 discussed at baseline and only patients for which tension-type headache was the main 156 headache type were included. Participants with concomitant migraine were included only 157 if their episodes were infrequent. Distinction between headaches types were clearly 158 highlighted at baseline as the goal of the study was to track only information related to 159 TTH over the study period. However, participants were asked to report when they were 160 161 affected by another headache type during the follow-up period. Exclusion criteria included having a recent history of cervical spine trauma, recent whiplash, neck fracture, surgery or 162 malignant lesion, infection, medication overuse, having a diagnosis of fibromyalgia and 163 164 having neurological deficits, spasmodic torticollis, presence of upper limb pain or lack of tension type headache episodes. Participants with neck, head or shoulder pain due to an 165 injury were excluded from this study as well as participants with all forms of pain whose 166 frequency and intensity could interfere with headaches. Participants were not allowed to 167 participate if they were under a course of treatment for headache tension-type headache or 168 for neck pain. Pregnant women were also excluded from the experimentation because of 169 170 the prone position adopted during the neck extension task.

172 <u>Table 1: International Headache Society (IHS) classification criteria for IETTH, FETTH</u>

173 <u>or CTTH</u>

Infrequent episodic tension-type	Frequent episodic tension-type	Chronic tension-type headache	
headache	headache		
A. At least 10 episodes of	A. At least 10 episodes of	A. Headache occurring on ≥ 15	
headache occurring on <1	headache occurring on 1-14 days	days per month on average for >3	
day/month on average (<12	per month on average for >3	months (≥ 180 days per year) and	
days/year) and fulfilling criteria	months (≥ 12 and < 180 days per	fulfilling criteria B-D	
B-D	year) and fulfilling criteria B-D		
B. Lasting from 30 minutes to 7 days	B . Lasting from 30 min to 7 days	B . Lasting hours to days, or unremitting	
C. At le	east two of the following four charact	eristics:	
1. bilateral location			
2. pressing or tightening (no	n-pulsating) quality		
3. mild or moderate intensity	ý		
4. not aggravated by routine	physical activity such as walking or	climbing stairs	
D. Both of the following:	D . Both of the following:	D . Both of the following:	
 no nausea or vomiting no more than one of photophobia or phonophobia 	 no nausea or vomiting no more than one of photophobia or phonophobia 	 no more than one of photophobia, phonophobia or mild nausea neither moderate or severe nausea nor vomiting 	

- 174 This study was approved by the University's Research Ethic Committee for human subjects
- 175 (CER-16-225-07.15). All participants provided informed written consent prior to their
- 176 participation in the study.
- 177
- 178 Procedures



179

180 Figure 1 : Timeline of clinical and physical outcomes

The first session began with a brief history taking to obtain demographic data as well as information regarding typical episodes of TTH and neck pain over the last month. Headache and neck pain maximum and mean intensities were measured using a 10 cm visual analogue scale (VAS). Participants were inquired about frequency of headache and neck pain episodes over the past month. All clinical and physical outcomes were obtained at baseline. In addition, headache frequency and intensity were monitored daily for 30 days and two self-reported questionnaires (6-item Headache Impact Test and Neck disability Index) were completed electronically using an online survey at the 1- and 3-month follow-ups (see figure 1).

190

191 *Clinical Outcomes*

192 <u>6-item Headache Impact Test</u>

The validated French version of HIT-6 questionnaire was used to assess disability related to headaches [16]. The HIT-6 is a 6-item, retrospective and self-reported questionnaire. This questionnaire addresses several quality of life components of such as pain, cognitive functioning, role functioning, vitality, social functioning and psychological distress [13, 17]. Participants were asked to complete the questionnaire based on the past four weeks [13]. The total score obtained was calculated by adding scores from each question for a maximum of 78 points [13]. Higher scores reveal greater headache-related disability.

200

201 <u>Neck Disability Index</u> (NDI)

The validated French version of NDI was used to evaluate disability related to neck pain [18]. This is a 10-item questionnaire related to cervical pain and the impact on everyday life as, for example, pain intensity, headache, concentration, reading, driving and work [19]. The total score obtained was calculated by adding scores from each question for a maximum of 50 points and higher scores reveal greater neck-related disability [18].

207

208 <u>Kinesiophobia, anxiety and self-efficacy</u>

At baseline, participants were asked to complete three other questionnaires related tokinesiophobia, anxiety and self-efficacy. Kinesiophobia was assessed using the validated

211 French version of the Tampa Scale of Kinesiophobia (TSK) a 17-items questionnaire which 212 allow to quantify fear of movement with higher score reflecting an increased level of kinesiophobia [20]. To assess anxiety, the validated French-Canadian version of the state 213 214 trait anxiety inventory (STAI-Y) was used [21]. This 20-item questionnaire allows to evaluate anxiety as a personality trait and anxiety as an emotional state related to a 215 particular situation [21]. Finally, self-efficacy was assessed by the validated French general 216 self-efficacy scale (GSE) which allows the evaluation of individuals perception to meet the 217 needs of tasks in different contexts [22, 23]. 218

219

220 <u>30-day data collection</u>

On a daily basis, participants were asked for 30 days about the presence and intensity of headaches within the last 24 hours. If any, they were invited to identify the type of headache they had (TTH or migraine for participants known to have concomitant types of headache). Based on participants' preferences, they were contacted by e-mails (5) or text messages (43) and some people (11) preferred to complete a headache diary.

226

227 *Physical Outcomes*

Maximum voluntary contraction (MVC) of neck-extensor muscles was tested in a prone position on a table with the participant's head and the neck past the edge of the table. To ensure minimal recruitment of thoracic and scapular muscles, the cervico-thoracic junction was stabilized with a strap (see figure 2). To evaluate the strength of the neck extensor muscles, another strap was disposed over the protuberancia occipitalis and was anchored to the floor. The head strap was adjusted to ensure that participants' head was stabilized in

neutral horizontal position throughout testing. Participants were then asked to perform 234 three neck extensors MCV while keeping the neutral horizontal position of the neck and 235 the head. To perform the neck extensors MVC, participants were asked to progressively 236 237 increase muscle contraction until maximum, hold the maximum for 3 to 5 seconds and then release. Maximum voluntary contractions were recorded using a force gauge (Model 238 IPM250; Futek Advanced Sensor Technology Inc, Irvine, CA, USA). The first trial was 239 240 performed to familiarized participants with the isometric extension contraction and a further two trials were conducted after the familiarization task. Each trial was followed by 241 a period of rest of one minute. 242

243



244

245 Figure 2: Participants position during the evaluation of neck extensor maximal isometric strength

246

247 Data and statistical analyses

248 Statistical analyses were performed using STATISTICA statistical package version 10

(Statsoft, Tulsa, OK), and the level of significance was set at p<.05. Because of the

250 asymmetrical data distribution (skewness) of several variables, data were normalized whenever it was deemed necessary using log-transformation. Self-reported headache 251 frequency and intensity were compared to the data obtained from the 30-day daily 252 253 monitoring using dependent t-tests to assess participants' ability to estimate their headache characteristics. Repeated ANOVA were performed for HIT-6 and NDI questionnaires to 254 assess the evolution of participants' headache and neck-related disabilities and Tukey post-255 hoc tests were performed to identify significant differences between baseline, the 1-month 256 and the 3-month follow-up for HIT-6 and NDI. Correlations between headache frequency, 257 headache intensity, neck pain frequency, neck pain intensity, kinesiophobia, anxiety, self-258 efficacy, neck-related disability and headache-related disability at the 3-month follow-up 259 were evaluated using the Pearson's correlation coefficient. Multiple regressions analysis 260 261 were conducted using the highest correlations value between all determinants and HIT-6 questionnaire at the 3-month follow-up to test if any variables predicted future headache-262 related disability over a 3-month period. Significant correlated determinants were added 263 264 into the stepwise regression model and determinants that significantly contributed to headache-related disability over a 3-month period were identify. 265

266

267 <u>Results</u>

Eighty-three participants were included at baseline. Twelve participants were lost at the 1month follow-up and 8 others were lost at the 3-month follow-up because participants did not return the questionnaires (see figure 3). Before excluding a participant, a reminder was sent on 3 different occasions to any participant who did not return their questionnaires. A

- total of 59 participants were included in the analysis. Three participants had concomitant
- 273 infrequent migraine.



274

275 Figure 3: Flowchart of TTH participants enrollment and reasons for exclusion of the

276 <u>analysis</u>

277 Baseline demographics

278 Means scores and standard deviations were calculated for all clinical and physical baseline

- outcomes (see table 2). Participants presented with low fear of movement (27.80±5.86) and
- anxiety (35.64 ± 9.47) mean scores and a high self-efficacy mean score (35.42 ± 3.24) . The
- mean score for headache-related disability indicated moderate headache impact (score \geq 50
- 282 points for the HIT-6 questionnaire).

283

284 <u>Table 2: Participant's baseline results for clinical and physical outcomes</u>

	Variables	Mean	SD
	Age (years)	27.88	9.41
	F:M	40:19	N/A
	Weight (kg)	67.72	14.12
ics	Height (m)	1.67	0.09
graph	BMI (kg/m ²)	24.18	4.10
Demo	Years with headache	6.22	6.55
1	Kinesiophobia (17-68)	27.80	5.86
	Self-efficacy scale (10-40)	35.42	3.24
	Anxiety (20-80)	35.64	9.47
	Self-reported frequency of	6.58	8.06
<i>b</i>)	headache (previous month)		
dache	Self-reported mean intensity	3.93	1.77
Hea	of headache (/10)		
	HIT-6 (36-78)	51.17	9.31
	Self-reported frequency of	5.97	8.15
2	neck pain (previous month)		
k pair	Self-reported mean intensity	2.58	1.89
Nec	of neck pain (/10)		
	NDI (/50)	5.52	4.99
Strength	MVC (N)	97.57	34.86

285	SD= standard deviation, F= female, M= male, BMI= body mass index, HIT-6= 6-item
286	headache impact test, NDI= neck disability index, MVC= maximum voluntary contraction.
287	

Table 3 : Participant's results regarding frequency and intensity of headache for the 30-day
 data collection

Variables	Mean	SD
Frequency of headache	7.75	6.84
(/30 days)		
Intensity (/10)	2.97	1.51

290

291

292 <u>Frequency and intensity of headache</u>

T-test for dependent samples comparing self-reported frequency (mean= 6.58; SD = 8.06) and frequency assess at 30 days (7.75; SD= 6.69) revealed no significant difference between self-reported headache frequency and 30 days data collection (p = 0.107). However, there was a significant difference (p < 0.001) between self-reported headache intensity (mean = 3.93; SD = 1.77) and headache intensity obtain from the 30-day data collection (mean = 2.97; SD = 1.51) (see table 2 for self-reported data and table 3 for 30day data collection).

300

301 <u>HIT-6 and NDI score evolution</u>

The ANOVA indicated a significant effect of time on headache-related disability (F(2, 116)=4.53, p=0.013) and a significant effect of time on neck-related disability (F(2,

116)=4.89, p=0.009). Tukey post-hoc test showed a significant decrease in headacherelated disability between baseline and the 1-month follow-up (p=0.036) and between baseline and the 3-month follow-up (p=0.021) (see figure 4) and showed a significant diminution in neck-related disability between baseline and the 3-month follow-up (p=0.007) (see figure 5).

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311



313 * : p= 0.025, ** : p= 0.017



317 * : p=0.007

318

319 <u>Table 4: Correlations between determinants and headache-related disability</u>

	Variables	HIT-6 (3-month)	
		Correlation coefficient	р
		(r)	
Baseline	MVC of neck extensors	-0.16	0.236
	Years with headache	0.53	< 0.001
	Self-reported headache	0.52	< 0.001
	frequency		

	Self-reported headache	0.61	< 0.001
	intensity		
	Self-reported neck pain	0.21	0.115
	frequency		
	Self reported neck pain	0.29	0.025
	intensity		
	Kinesiophobia	-0.009	0.945
	Anxiety	0.28	0.031
	Self-efficacy	-0.10	0.437
	HIT-6	0.72	< 0.001
	NDI	0.64	< 0.001
30 days	Headache frequency	0.60	< 0.001
data	Headache intensity	0.54	< 0.001
collection			
1 month	HIT-6	0.86	< 0.001
Follow-up	NDI	0.65	< 0.001
MVC = Maximal Voluntary Contraction, HIT-6 = 6-item Headache Impact Test, NDI =			

321 Neck Disability Index

322

320

323 <u>Table 5: Predictors of headache-related disability</u>

Variables	β value	р
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Years with headaches	0.087	0.460
Self-reported neck pain intensity	-0.073	0.508
Headache frequency in 30 days	0.284	0.032
Headache intensity in 30 days	0.253	0.024
Anxiety	0.100	0.304
NDI (baseline)	0.245	0.112
Presence of concomitant migraine	0.206	0.044
	Multiple regression: $R^2 = 0.583$	

324

325 <u>Predictors of headache-related disability at 3 months</u>

High correlations were found between self-reported headache frequency, self-reported 326 headache intensity and HIT-6 score at the 3-month follow-up. However, self-reported 327 headache frequency and intensity were excluded from the multiple regression because 328 frequency and intensity were also prospectively collected for 30 days and were considered 329 330 more specific than self-reported data estimated at baseline considering the past month. Selfreported neck pain frequency, kinesiophobia and self-efficacy were also excluded because 331 they did not correlate with HIT-6 at 3 months nor with any other outcome measures (see 332 333 table 5). Number of years with TTH (r=.53; p<0.001), self-reported neck pain intensity (r=.29; p=0.025), headache frequency (r=.60; p<0.001), headache intensity (r=.54; 334 p < 0.001), anxiety (r=.28 ;p=0.031) as well as neck-related disability at baseline (r=.64 ; 335 p<0.001) were included in the multiple regression model because of their high correlation 336 with the HIT-6 score at 3 months. Presence of concomitant infrequent migraine was added 337 as a covariable to the multiple regression model given that migraine is known to be a 338

339 predictor of poor outcome in TTH [12]. Number of years with TTH, self-reported neck 340 pain intensity, anxiety and neck-related disability at baseline were highly correlated with headache-related disability at 3-month. However, in the stepwise regression model, none 341 342 of them remained significantly associated with headache-related disability at 3-month (p values = 0.460, 0.508, 0.304 and 0.112 respectively). Results showed that headache 343 frequency, headache intensity and the presence of concomitant infrequent migraine were 344 good predictors of headache-related disability at 3 months. All together, predictors were 345 able to predict 58.3 % of the headache-related disability variance. Results of the regression 346 347 model are presented in table 5.

348

349 **Discussion**

The purpose of this study was to determine if headache profile can predict future disability in participants with TTH. Participants' mean age was 27.88±9.41 years which is consistent with the age group with the highest TTH prevalence in the literature (25-30 years old). The results showed that 30 days mean headache frequency and intensity as well as self-reported mean intensity of neck pain, years with TTH, neck-related disability and presence of concomitant infrequent migraine can predict future disability in patients with TTH.

356

357 <u>Headaches characteristics</u>

With regards to participants' headache characteristics, the results showed a high correlation between the number of years with TTH and headache-related disability and between number of TTH episodes in a month and headache-related disability as well as a moderate correlation between TTH intensity and headache-related disability. Mild to moderate pain 362 intensity represents the clinical criteria required in the diagnosis of TTH and based on the present results moderate intensity had a higher impact on headache-related disability. In 363 this study, multiple regressions showed that intensity is an important predictor of future 364 365 disability, but headache frequency was the most important predictive factor of headacherelated disability. These results are in accordance with a previous study which showed that 366 frequent headache categories (FETTH and CTTH) are associated with higher headache-367 related impact than the infrequent headache category [24]. Kim et al. (2015) also reported 368 an increased burden of headache-related disability associated to the chronic form compared 369 to infrequent and frequent episodic forms [25]. TTH patients seem to be more affected by 370 the number of headache episodes than by their intensity. Suffering from TTH on a regular 371 basis seems to influence psychological well being. In fact, frequent headache and disability 372 373 seem to impair quality of life [26, 27]. Headache intensity contributes to occasional 374 disability in a month or in a year while a higher number of headaches in a month can contribute to higher disability. A previous study showed the impact of ETTH and CTTH 375 376 and their contribution to absenteeism and presenteeism in TTH patients [28].

377

378 <u>Neck pain and neck extensor muscle strength</u>

In the current study, neck pain and neck extensor muscle MVC were assessed because neck pain has been traditionally linked with tension type headache [29, 30] and neck pain has been shown to be more prevalent in TTH patients than in individuals with no TTH [31]. Neck pain has previously been associated with decreased neck muscle strength [32, 33]. The present study did not reveal any correlation between neck extensor muscle strength and headache-related disability. In addition, neck muscle strength was not retained among 385 predictive factors of future headache-related disability. However, results showed that 386 concomitant neck pain was present in TTH patients with a self-reported mean of 5.97 days (SD = 8.15) which is consistent with the literature [31]. Results also showed that neck pain 387 388 intensity was correlated with a higher score in HIT-6 at the 3-month follow-up (r=0.29) and that it can be considered as a predictive determinant of future disability. Ashina et al. 389 (2015) found a correlation between neck pain frequency and the frequency of TTH and 390 suggested a possible shared pathophysiological mechanism between neck pain and primary 391 headache including tension-type headache [31]. Regarding neck extensor muscle strength, 392 previous studies showed a decrease in neck extensor muscle force production in TTH 393 patients compared to healthy controls [33, 34]. However, our results showed that MVC is 394 not a physical determinant of future disability as evaluated by the HIT-6 questionnaire. 395

396

397 <u>HIT-6 and NDI</u>

Findings of the present study indicated statistically significant decreases in headache-398 399 related disability and neck-related disability over the 3-month follow-up period but these differences were not clinically significant. To be considered clinically significant, the 400 minimally clinical important change in TTH related disability should reach 8 points on the 401 HIT-6 score [17]. The results of the present study showed a decrease of only 2.07 points 402 on the HIT-6 mean score between baseline and the 3-month follow-up. Regarding the neck 403 disability, a difference of 3.5 points on the NDI scale represents the minimally clinical 404 important change [35] and the present results indicated a decrease of 1.21 points between 405 the baseline and 3-month scores therefore not reaching the threshold for neck-related 406 407 disability minimally clinical important change. The decrease for HIT-6 and NDI scores found in the present study can be explained by the natural fluctuation of tension-type
headache over time. Indeed, prognostic factors of TTH recovery are less severe headache,
mild headache-related disability, not using medication, absence of anxiety, sleep problem,
depression or other pain [36].

412

413 <u>Kinesiophobia, anxiety and self-efficacy</u>

The results showed low levels of kinesiophobia and high self-efficacy scores and these scores were not correlated to any of the clinical or physical outcomes. The current results showed that anxiety was correlated with headache-related disability. Anxiety has been extensively explored in TTH and some studies found that anxiety seemed to be more dependent on the TTH frequency [37, 38] which means that CTTH patients would be more anxious than ETTH patients. Results of the present study are consistent with theses previous findings.

421

422 <u>Limitations</u>

This study is not without limitations. Indeed, baseline neck pain frequency and intensity 423 were self-reported by participants based on episodes over the past month, which could have 424 been influenced by recollection bias. Although the comparison between retrospective and 425 prospective self-reported data showed that participants were able to correctly estimate 426 headache frequency, they overestimated headache intensity which could also have been 427 overestimated in self-reported neck pain intensity. In addition, in the present study, TTH 428 participants results were analyzed without considering TTH categories (infrequent 429 430 episodic, frequent episodic and chronic), and it should be kept in mind that results could differ between the episodic forms and the chronic form. Another limitation is our smallnumber of participants, meaning that the results should be interpreted with caution.

433

434 Results of the present study showed that TTH frequency and intensity, and the presence of concomitant infrequent migraine are predictors of future disability over a 3-month period. 435 Results also showed that neck extensor muscles strength was not correlated with headache-436 related disability or with any other clinical outcomes and was not a good predictor of future 437 disability. Further studies are needed to evaluate the predictive value of other physical 438 outcomes on headache-related disability. Tension-type headache constitutes a major public 439 health problem and a better understanding of clinical and physical factors is needed. Health 440 professionals should consider clinical outcomes to evaluate and elaborate future treatment 441 strategies for patients with TTH. 442

443

444 **Declarations:**

Ethics approval and consent to participate: This study has been approved by the ethic
committee of human subjects of the Université du Québec à Trois-Rivières (CER-16-22507.15).

448 Availability of data and material : The datasets used and/or analysed during the current
449 study are available from the corresponding author on reasonable request.

450 **Competing interests :** None to declare.

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