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Migraine co-existing tension-type headache and neck pain: Validation of questionnaires

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HIGHLIGHTS

- "Impact of migraine, tension-type headache and neck pain" is a new questionnaire.
- This is the first questionnaire to cover migraine and its co-morbidities.
- The questionnaire showed acceptable face validity and excellent content validity.
- The questionnaire may be useful for evaluating the effect of treatment.

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ABSTRACT

Background and aim: Migraine often includes co-existing tension-type headache (TTH) and neck pain (NP). Multiple headache questionnaires assessing headache impact have been described previously; however, none of the existing questionnaires have been designed to cover migraine with co-existing TTH and NP. Therefore a new questionnaire was developed to measure these co-morbidities. The aim was to determine face and content validity of the newly developed questionnaire, "Impact of Migraine, Tension-Type Headache and Neck Pain" (impact M-TTH-NP) and to determine face and content validity of the International Physical Activity Questionnaire (IPAQ short form), Migraine-Specific Quality of Life Questionnaire (MSQ v. 2.1), WHO-Five Well-Being Index (WHO-5), Major Depression Inventory (MDI) and Neck Disability Index (NDI) not yet validated in this target population.

Material and methods: The new multi-dimensional questionnaire "Impact M-TTH-NP" cover pain, triggers, psychosocial, socioeconomic and work related aspects, based on a four-week recall period. The items are rated on an 11-point numeric rating scale with the end points 0 = no impact and 10 = most imaginable impact. Face validity was assessed by migraine patients with co-existing TTH and NP. They were recruited between September 2012 and March 2013 from a tertiary referral headache centre. Nine women with a mean age of 38 years participated in group interviews. The questionnaires were reviewed for relevance and meaningfulness. Content validity was assessed by 13 headache experts. They had worked with headache diseases for an average of 9 (range, 2–38) years. Experts were recruited between August 2012 and October 2012. Nine medical doctors, two physical therapists, one headache nurse and one psychologist (eight women and five men, mean age of 42 years) participated. The experts rated each item of the questionnaires using a four-point Likert scale with the end points 1 = not relevant and 4 = highly relevant.

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Abbreviations: Impact M-TTH-NP, Impact of Migraine, Tension-Type Headache and Neck Pain; TTH, tension-type headache; NP, neck pain; CVI, content validity index; I-CVI, item-level content validity index; S-CVI/Ave, scale-level content validity index average; AD index, average deviation index; IPAQ, International Physical Activity Questionnaire; MSQ v. 2.1, Migraine-Specific Quality of Life Questionnaire version 2.1; WHO-5, WHO-Five Well-Being Index; MDI, Mayor depression inventory; NDI, Neck Disability Index; ICHD-3 beta, The International Classification of Headache Disorders 3rd edition (beta version).

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The quantitative measurement of content validity was calculated by the item-level content validity index (I-CVI) and the scale-level content validity average method (S-CVI/Ave). The average deviation (AD) index was used as a measure of interrater agreement.

Results: Impact M-TTH-NP showed acceptable face validity. Of 78 items twelve were revised and one was added based on group interviews and expert review. Seventy-two items (92%) obtained I-CVI ≥ 0.78 (range 0.78–1.00) indicating excellent content validity, 71 items (91%) obtained acceptable AD index. Nine items did not meet either the limit for excellent I-CVI and/or acceptable AD index. The overall S-CVI/Ave was 0.92 indicating an excellent content validity. In addition, four of the five additional questionnaires showed acceptable face validity (MSQ, WHO-5, MDI and NDI) and three showed excellent content validity (WHO-5, MDI and NDI) for patients suffering from migraine and co-existing TTH and NP.

Conclusions and implications: The impact M-TTH-NP questionnaire showed acceptable face validity and excellent content validity and may be useful when evaluating treatment effect in this target group. The new impact M-TTH-NP questionnaire in combination with the additional questionnaires that together assess pain, triggers, psychosocial and socioeconomic aspects may provide a deeper understanding of the complexity of migraine with co-existing TTH and NP.

1. Introduction

The prevalence of migraine in Europe is 15% [1] and is more common among young adults [2]. Furthermore, 94% of migraineurs suffered from co-existing TTH [3], and 89.3% of this sample suffered from co-existing neck pain [4]. However, as existing headache questionnaires do not include migraine with co-existing TTH and NP, a new questionnaire was therefore developed in order to measure the impact of these combined conditions for use in clinical studies and as assessment of clinical treatment.

Migraine is defined by attacks lasting between 4–72 h, a moderate to severe pain intensity, pulsating quality, unilateral localisation, aggravated by physical activity and accompanied by either nausea, photophobia or phonophobia. TTH appears in attacks with a pressing quality, bilateral localisation, mild to moderate pain intensity, typically not aggravated by physical activity and without accompanying symptoms [5]. NP is defined as pain located to the anatomic region of the neck with or without radiation to the head, trunk, and upper limbs grade I–II [6].

Multiple headache questionnaires assessing headache impact have been described previously [7,8]. In addition, the EUROLIGHT questionnaire has been developed to assess the impact of primary headache disorders including co-morbidities, management of the disease and quality of life [9]. These questionnaires cover migraine or headache in general. However, a large part of the migraine population also suffers from co-existing tension-type headache (TTH) and neck pain (NP). The new questionnaire was designed to cover all these three conditions combined in order to present a detailed and clinically valid assessment.

The aim of this study was (a) to determine face and content validity of a newly developed questionnaire named Impact of Migraine, Tension-Type Headache and Neck Pain (Impact M-TTH-NP) and (b) to determine face and content validity of the International Physical Activity Questionnaire (IPAQ short form) [10], Migraine-Specific Quality of Life Questionnaire (MSQ v. 2.1) [11], WHO-Five Well-Being Index (WHO-5) [12], Major Depression Inventory (MDI) [13] and Neck Disability Index (NDI) [14] not yet validated in patients with migraine and co-existing TTH and NP.

2. Material and methods

The multi-dimensional questionnaire impact M-TTH-NP is a revised version of two questionnaires used in an earlier study [3], the revision was based on clinical observations. Impact M-TTH-NP consisted of 78 items covering pain, triggers, psychosocial, socioeconomic and work related aspects, based on a four-week recall period in most items. It was divided into six parts covering (1) sleep and stress, (2) migraine, (3) TTH, (4) NP, (5) extent of perceived degree of discomfort between migraine, TTH and NP and socioeconomic consequences and (6) self-rated health, work ability [15] and physical activity. In most items an 11-point numeric rating scale was applied with the end points 0 = no impact and 10 = most imaginable impact as applied in other studies [16,17]. Furthermore, five existing questionnaires were included in the study, IPAQ short form, MSQ v. 2.1, WHO-5, MDI and NDI (Table 1). None of these have previously been validated in patients suffering from migraine and co-existing TTH and NP.

2.1. Participants

Patients with migraine and co-existing TTH and NP were recruited between September 2012 and March 2013 from a tertiary referral headache centre. Exclusion criteria were whiplash injury, significant neck trauma (*significant neck trauma was defined as a history of trauma to the neck, fracture, distortion and violent attack that have caused the current NP*), nerve root compression of the cervical spine, post traumatic headache, medication overuse headache, cluster headache, trigeminal neuralgia, pregnancy and breastfeeding, severe physical and/or mental diseases, abuse of alcohol and drugs, and inability to speak and understand Danish. Fourteen were eligible, five declined participation, two due to time constraint, one due to illness and two did not state any explanation. The nine participants were women with a mean age of 38 (range, 28–50) years. Four were employed, three on sick leave, one unemployed and one was a student. Their symptoms were characterized by an average headache history of 17 (range, 6–24) years and an average frequency of 22 days per month for migraine and co-existing TTH and an average NP frequency of 23 days per month.

Thirteen headache experts were recruited between August 2012 and October 2012. Nine medical doctors, two physical therapists, one headache nurse and one psychologist (eight women and five men) with a mean age of 42 (range, 27–71) years participated. They had worked with headache diseases for an average of 9 (range, 2–38) years, and had research experience for an average of 8 (range, 1–40) years.

2.2. Ethics

The participants received oral and written information. All signed the informed consent form. The study was approved by the local ethical committee of the Capital region, protocol no H-1-2011-090.

2.3. Procedure

The six questionnaires were sent out to the patients with migraine and co-existing TTH and NP with instructions regarding

Table 1
Characteristics of the questionnaires representing different aspects of the impact of migraine with co-existing tension-type headache and neck pain, references in brackets refer to validation of the questionnaires.

Questionnaire	Generic/condition specific	Target area	No of items	Recall period
Impact of Migraine, Tension-Type Headache and Neck Pain (Impact M-TTH-NP)	Condition specific and generic	Pain, triggers, psychosocial, socioeconomic and work related aspects	78	Past 4 weeks (in most items)
International physical activity questionnaire (IPAQ short form) [10]	Generic	Level of vigorous, moderate and sedentary physical activity	7	Past 7 days
Migraine-Specific Quality of Life Questionnaire (MSQ v. 2.1)[11]	Condition specific	Quality of life	14	Past 4 weeks
WHO-Five Well-Being Index (WHO-5)[12]	Generic	Psychological well-being	5	Past 2 weeks
Major Depression Inventory (MDI)[13]	Generic	Depression	12	Past 2 weeks
Neck Disability Index (NDI)[14]	Condition specific	Neck pain disability	10	Present

what to prepare before the group interview, and separate paper sheets for notes. Three group interviews were then conducted with four, three and two participants, respectively, and each lasted for 1–1½ h. The participants were introduced to the background, purpose and procedure of the group interview and the questionnaires were reviewed for clarity, understanding, relevance and meaningfulness. All were encouraged to take part in the discussion. Finally the participants were asked if any items/topics needed to be added. The moderator (LSK) guided the sessions and the assistant (TFL) took notes. After each group interview the moderator and the assistant reviewed all comments and revised accordingly.

The experts were sent a cover letter explaining the purpose and background of the questionnaires, the six questionnaires, detailed instructions, separate paper sheets for comments and a questionnaire for their demographic data and work experience. They were asked to rate each item using a four-point Likert scale 1 = not relevant and 4 = highly relevant [18] and to provide written comments on perceived relevance/irrelevance, ambiguity, wording and whether additional items were needed.

2.4. Analyses

The quantitative measurement of content validity was calculated by the item-level content validity index (I-CVI), and the scale-level content validity index average method (S-CVI/Ave) [19]. The average deviation (AD) index was used as a measure of inter-rater agreement [20].

The experts rated the degree of relevance of each item in the questionnaires. Then the scale was dichotomized into not relevant (rating 1 or 2) and relevant (rating 3 or 4). The I-CVI was the proportion of experts giving a rating of 3 or 4 [19]. An item with an I-CVI of 0.78 or higher was considered as having excellent content validity [21]. Next, the S-CVI/Ave was used as an average calculation across the I-CVI for each item in order to assess the degree of relevance of the entire questionnaire. A questionnaire with a S-CVI/Ave of 0.90 or higher was considered as having excellent content validity [21].

The AD index for Likert-type scales was used to measure inter-rater agreement [20]. The AD index measures the dispersion of responses about the median. This was calculated as the sum of differences from the median in absolute values divided by the number of experts. At 5% level of significance the cut-off limit was 0.65 for 13 raters. Values below 0.65 indicated acceptable and statistically significant agreement [20]. Data were analysed using IBM SPSS (version 19).

3. Results

The face validation of the impact M-TTH-NP questionnaire ascertained that no items needed to be removed. One item concerning the total amount of sleep at night was added to the questionnaire. In addition, twelve items needed revision and were rephrased (Table 2). The item concerning cost of health care consultations was rephrased, and the recall period was changed from a four-week recall to a three-month recall period, as the likelihood of capturing various health care consultations was higher with the latter. All revised items were perceived as relevant and meaningful by most patients. However, some patients would have liked the opportunity to describe their ability to perform daily tasks despite headache and NP e.g. "*who else is supposed to pick up my kids from kindergarten?" and "things must be done*. . .".

The content validation of the Impact M-TTH-NP showed that 72/78 (92%) obtained I-CVI ≥ 0.78 (range 0.78–1.00) indicating excellent content validity, 71/78 (91%) obtained AD index below 0.65 (range 0–0.62). In all, 9/78 items did not meet either the limit for excellent I-CVI and/or acceptable AD index. These nine items represented sleep quality, difficulty falling asleep, lack of rest and work at a moderate intensity as triggers for migraine, work at moderate intensity as a trigger for NP, reduced productivity at work measured in hours, current and future job and physical activity. The S-CVI/Ave for the entire Impact M-TTH-NP questionnaire was 0.92 indicating excellent content validity. The S-CVI/Ave of the six parts of the questionnaire showed that part 1 and 6 obtained S-CVI/Ave of 0.89 and 0.77 respectively below the cut-off limit and parts 2 to 5 obtained S-CVI/Ave ranging from 0.90–0.94 (Table 3).

The face validation of the additional five questionnaires (Table 4) showed that some patients perceived calculating the activity into minutes (IPAQ), as difficult and not meaningful. Experts also had critical comments about this questionnaire. Most patients perceived the MSQ v. 2.1 as relevant, whereas some experts reported that this questionnaire was redundant as most of the items were covered by the Impact M-TTH-NP questionnaire. Some patients pointed out the recall period of two weeks in the WHO-5 as being too short, but the items were relevant and meaningful. One expert wrote, "*Very general questions; which conclusions may be drawn from them?*" The patients perceived the items of the MDI as relevant and meaningful. One expert wrote, "*Important to screen for depression, but many questions are repeated in the other questionnaires*". Although relevant, the items concerning personal care and lifting, in the NDI, were considered difficult to answer by some patients. The response categories were considered too vague and open for interpretation by one expert.

The content validation of the additional five questionnaires showed that the items concerning walking and sitting (IPAQ); reduced work, concentration, prevented from working, need for help, and need for breaks (MSQ v. 2.1) obtained I-CVI < 0.78 and AD index > 0.65. Items concerning personal care and driving car (NDI) obtained I-CVI < 0.78 but AD index < 0.65. The items concerning fear of failing other (MSQ v 2.1) and daily life filled with interesting things (WHO-5) obtained I-CVI of 0.85 but AD index > 0.65. In the MDI all items obtained excellent I-CVI and AD index < 0.65 (Table 5).

WHO-5, MDI and NDI obtained S-CVI/Ave > 0.90 (range 0.92–0.95) indicating excellent content validity. IPAQ short form

Table 2
Specific comments on the Impact of Migraine, Tension-Type Headache and Neck Pain questionnaire from migraine patients with co-existing tension-type headache and neck pain ($n = 9$) and from experts in headache diseases ($n = 13$); together with the revised items.

Item	Migraine patients with co-existing tension-type headache (TTH) and neck pain (NP)	Experts (comments between brackets equals to one comment)	Revision
Number 1.2 "*Over the past 4 weeks, how many consecutive hours did you sleep on average at night?*"	In general the item was understood as average sleep at night and not only consecutive hours, otherwise relevant and meaningful	The need to know the total amount of hours of sleep at night was requested by some experts	*"Over the past 4 weeks, how many hours did you sleep in all, on average, at night?"* (Item number 1.1)
Number 2.6.11, 3.5.11, 4.5.11"*Over the past 4 weeks, to what extent have you experienced the following as triggers for your migraine, TTH and NP?" Examples*. . . . . "*Other work as a trigger for migraine, TTH and NP?" Please write which*:	"Other work" as a trigger was generally misunderstood, otherwise relevant and meaningful	No written comments	*"Over the past 4 weeks, to what extent have you experienced the following as triggers for your migraine, TTH and NP?" Examples*. . . . . *"Other **task/work** position at your job as a trigger for migraine, TTH and NP?" Please write which*:
Number 5.1 "*In general to what extent does your migraine, TTH and NP affect you? All three diagnoses must add up to 100%*"	Difficult to answer by several patients, otherwise relevant and meaningful	"will probably be difficult to answer", "it might be difficult to make proper statistics"	No revision
Number 6.1, 6.2, 6.3 "*Over the past 4 week, how many sick days, days with reduced productivity, hours with reduced productivity have you had (on days when you had to work/study) because of migraine, TTH, NP and other illness? If you have not had any absences, please tick the box: No absence/no reduced productivity, unemployed or studying, please tick in the box: Is currently unemployed, on maternity leave, retirement or similar*	"Not studying" and "on sick leave" were requested in the box to tic. These items concerning absenteeism and productivity were in general relevant but especially reduced productivity measured in hours was a difficult question to answer for several patients	"Absenteeism and productivity are relevant, but difficult to answer and the risk of recall bias is large", "absenteeism measured in hours depends very much on the person and the job"	"*If you for the time being are unemployed or study, please tick in the box: Is currently unemployed, **not studying**, **on sick leave**, on maternity leave, retirement or similar*"
Number 7.1 "*Over the past 4 weeks, how much have you, in total, spent on prescription drugs, over the counter drugs and herbal remedies for migraine, TTH, NP and other illness, respectively?*"	Difficult to remember for some patients as reimbursement of prescription drugs changes from month to month, otherwise relevant and meaningful	No written comments	*"Over the past 4 weeks, which kind of medication have you used and how much on prescription drugs, over the counter drugs, and herbal remedies for M, TTH, NP and other illness*?"
Number 8.1 "*Over the past 4 week, have you been in contact with examples..... due to migraine, TTH, NP and other illness?*"	A recall period of three months was more appropriate for several patients, otherwise relevant and meaningful	"add psychologist to the cost table"	*"Over the **past 3 months**, have you been in contact with examples..... due to migraine, TTH, NP and other illness?"* "Psychologist" was added
Number 9.2, 9.3, 9.4, 9.5 "*How would you rate your current work ability, work ability related to physical demands, related to mental demands and future work expectations?*"	A box to tic with the text: "*Is currently unemployed, on sick leave, on maternity leave, retirement or similar*" were requested. Otherwise relevant and meaningful		"*Is currently unemployed, on sick leave, on maternity leave, retirement or similar*" were added
Number 9.5 "*Do you believe that, from the standpoint of your health, you will be able to do your current job two years from now?*"	For some patients, this item was difficult to answer. Otherwise relevant and meaningful	"Difficult to answer for the patients", "it is very intrusive for the patients", "the patients are not able to predict the future", "why exactly two years?", and "it depends on the job and the person"	No revision
General comments	Some patients would have liked the opportunity to describe their ability to perform the daily tasks despite headache and NP	"A lot of questions increase the risk of error", "the Impact of Migraine, TTH and NP questionnaire could replace Migraine-Specific Quality of Life Questionnaire (MSQ)"	

and MSQ v. 2.1 obtained S-CVI/Ave < 0.90 (0.87 and 0.84 respectively) (Table 5).

4. Discussion

Most items of the Impact M-TTH-NP were well understood, clear, and perceived as relevant and meaningful by the patients. Several patients perceived the items concerning sick leave and reduced productivity at work/school, measured in hours, as difficult to answer but relevant and meaningful. The participants also found it difficult to foresee the ability to do the current job two years from now. One explanation may be that they had suffered from headache and NP for several years and consequently was unable to predict their future symptoms. Another explanation may be that a typical coping strategy among people with chronic headache involves avoidance behaviour and endurance strategies [22].

A key issue pointed out by several patients was the difficulty of rating the impact of headache and NP. Even though they suffered from headache and NP they had become capable of ignoring pain, i.e. they performed their daily tasks despite pain, and such compensatory mechanisms were not covered in the instruments. This

Table 3
Content validity of impact of migraine, tension-type headache and neck pain (impact M-TTH-NP) using item-level content validity index (I-CVI), average deviation (AD) index as a measure of interrater agreement, and scale-level content validity index average method (S-CVI/Ave).

Impact M-TTH-NP Part 1–6	I-CVI ≥ 0.78[a] (number of items)	AD index < 0.65[b] (number of items)	S-CVI/Ave[c]
Part 1. Sleep and stress (*n* = 5 items)	3	4	0.89
Part 2. M (*n* = 21 items)	21	19	0.93
Part 3. TTH (*n* = 20 items)	20	20	0.94
Part 4. NP (*n* = 20 items)	20	19	0.94
Part 5. Perceived degree of discomfort between M, TTH, and NP, and socio-economic consequences (*n* = 6 items)	5	5	0.90
Part 6. Self-rated health, work ability and physical activity (*n* = 6 items)	3	4	0.77

[a] I-CVI the cut-off limit for excellent content validity = 0.78.
[b] AD index < 0.65 = interrater agreement.
[c] S-CVI/Ave the cuff-off limit for excellent content validity = 0.90.

Table 4
Specific comments on five additional questionnaires from migraine patients with co-existing tension-type headache and neck pain (*n* = 9) and from experts in headache diseases (*n* = 13).

Questionnaires	Migraine patients with co-existing tension-type headache (TTH) and neck pain (NP)	Experts (comments between brackets equals to one comment)
IPAQ short form[a] All items	Calculating the activity into minutes was too difficult and not meaningful for some patients	"The activities are too difficult to remember", "it is confusing to count both days and hours", "time spent on sitting is very difficult to calculate unless the daily life is characterized by routines", "standing for a long time is also important to consider"
MSQ v. 2.1[b] All items	The response categories were somewhat problematic to answer for some patients owing to the ability to ignore pain and to perform the daily tasks despite of the headache, otherwise relevant and meaningful for most patients	"This questionnaire is covered in the impact of migraine, TTH and NP questionnaire", "the items are close to impact of migraine, TTH and NP questionnaire", "this questionnaire covers only migraine, and differentiating can be difficult owing to co-existing TTH and NP"
WHO-5[c] All items	Relevant and meaningful for all patients. The recall period of two weeks was mentioned as being too short for some patients	"Very general questions what conclusions may be drawn from them?"
MDI[d] All items	Relevant and meaningful for all patients	"Important to screen for depression but many questions are repeated in the other questionnaires", "difficult to distinguish depression because of migraine or regular depression"
NDI[e] Item no 2, 3, 5, 8 and 9	Some patients did not have any experience with personal care and lifting due to NP and could therefore not answer these items. Some patients did not have a drivers licence and therefore could not answer this item, otherwise relevant and meaningful for all patients	"maybe more relevant for neck pain than for migraine and TTH patients", response categories are too vague and open for interpretation", "the item concerning headache covers both frequency and intensity in the same response category", "it is confusing to use first disturbed sleep and then quantify insomnia in parenthesis in the response categories"

[a] International Physical Activity Questionnaire.
[b] Migraine-Specific Quality of Life Questionnaire.
[c] WHO-Five Well-Being Index.
[d] Mayor Depression Inventory.
[e] Neck Disability Index.

Table 5
Content validity of five additional questionnaires using item-level content validity index (I-CVI), average deviation (AD) index as a measure of interrater agreement, and scale-level content validity index average method (S-CVI/Ave).

Questionnaire	I-CVI ≥ 0.78[a] (number of items)	AD index < 0.65[b] (number of items)	S-CVI/Ave[c]
IPAQ short form[d] Items *n* = 7	5	5	0.87
MSQ v. 2.1[e] Items *n* = 14	9	8	0.84
WHO-5[f] Items *n* = 5	5	4	0.94
MDI[g] Items *n* = 12	12	12	0.95
NDI[h] Items *n* = 10	8	10	0.92

[a] I-CVI the cut-off limit for excellent content validity = 0.78.
[b] AD index < 0.65 = interrater agreement.
[c] S-CVI/Ave the cuff-off limit for excellent content validity = 0.90.
[d] International Physical Activity Questionnaire.
[e] Migraine-Specific Quality of Life Questionnaire.
[f] WHO-Five Well-Being Index.
[g] Mayor Depression Inventory.
[h] Neck Disability Index.

ability to ignore pain may have an important implication for the quantification of the effect of future treatment modalities, as many headache patients have lived with pain for many years and may underreport disability simply because they have become accustomed to it.

The overall S-CVI/Ave showed an excellent content validity of the new Impact M-TTH-NP questionnaire. The nine items that did not reach the cut off levels for either excellent I-CVI and/or acceptable AD index assess clinically relevant aspects and are therefore difficult to remove completely as they are addressing disease-specific qualities. Consequently, further revision and analyses of the usefulness of these items are needed.

The results suggest that the Impact M-TTH-NP questionnaire can be applied in a clinical setting for assessing migraine patients with co-existing TTH and NP. Andrée et al. have recently developed a large multi-dimensional questionnaire "The EUROLIGHT Questionnaire" to estimate the burden of headache disorders [9]. The questionnaire was also tested for face and content validity and has obtained acceptable construct validity in line with our results. The EUROLIGHT Questionnaire and our questionnaire cover some similar items e.g. the use of healthcare services, medication intake, headache impact, absenteeism and reduced productivity. However, The EUROLIGHT Questionnaire does not differentiate between migraine and TTH and it does not contain items about NP and physical activity. The items of The EUROLIGHT Questionnaire are also based on different recall-periods.

Some important aspects were not included in the Impact M-TTH-NP, and therefore existing questionnaires covering quality of life, psychological well-being, level of physical activity, depression and NP were assessed.

The IPAQ short form has shown a fair to moderate criterion validity and in a patient population a weak concurrent validity [10,23,24]. The weak validity was in line with our findings. The two items concerning walking and sitting obtained an I-CVI just below the cut-off level, but the S-CVI/Ave did not meet the limit for excellent content validity. The results stemming from IPAQ have previously been reported to overestimate time spent on physical activity [24,25], which may have been caused by social desirability bias or simply because it was too difficult to remember how much time has been spent on different activities. This might also have been the case among our participants.

In a prior study the MSQ v. 1.0 has been validated in collaboration with migraine patient and migraine specialists [26], the construct validity and ability to detect change of MSQ v. 2.1 has been confirmed [11,27]. Although the patients in our study found the items relevant and meaningful, the scores did not meet the limit for excellent content validity. One explanation may be that this questionnaire was deemed redundant by some experts. Another explanation may be that the MSQ does not include co-existing TTH and NP also pointed out by some experts. MSQ could be a good choice as a single measurement tool of the quality of life in migraine patients who do not have co-existing TTH and NP. This indicates that the Impact M-TTH-NP covers sufficiently the quality of life of migraine patients suffering from co-existing TTH and NP.

WHO-5 has shown good convergent and discriminative validity [28] and a review has also reported an excellent validity [29], which is in line with our results. WHO-5 measures psychological well-being and has a high sensitivity and specificity as a screening instrument for depression [29], and may therefore represent central aspects of the impact of migraine with co-existing TTH and NP.

In addition, MDI, like WHO-5, was perceived as relevant and meaningful by all patients and obtained excellent S-CVI/Ave. Previously, MDI has been found to be a useful tool to diagnose and monitoring depression among depressive patients with the highest coefficients values in relation to Beck Depression Inventory and Hamilton Depression Scale [30].

The NDI has shown adequate measurement properties [31], and a strong convergent and divergent validity with other instruments used to evaluate patients with NP [32]. In contrast to the present study, NDI obtained poor content validity, in a recent study of NP-patients [33] because of unclear definition of the construct, evaluated by 10 NP-patients and 11 experts. Some of our patients' comments were in line with this recent study, as they did not have any experience with impaired personal care and lifting due to NP, however, these items were perceived as relevant.

4.1. Methodological considerations

This study represents a careful evaluation and testing of a new developed and comprehensive questionnaire along with selected existing questionnaires. All experts have a high expertise and were recruited from the same tertiary referral headache centre, which is specialized within the field of headache. This, however, could result in selection bias, although none of the experts were involved in the development of the new questionnaire.

All patients were classified according to The International Classification of Headache Disorders (ICHD-3 beta) [5]. They suffered from a high frequency of migraine with co-existing TTH and NP. Patients with less frequent headache and NP may evaluate the questionnaires differently. The patients were all recruited from a tertiary referral headache centre, and the results may therefore not be representative for the general population.

The impact of headache and NP is a comprehensive topic. In this study six questionnaires were used to capture as many aspects of the impact of headache and NP as possible. The face and content validity of these questionnaires were assessed at the same time. The patients and experts may have felt overloaded by the task. Thereby, the questionnaires may have been rated differently compared to a separate analysis of each questionnaire at different time points.

We were aware that a patient's opinion might be affected by the others participating in a group interview. All participants were therefore encouraged to be actively involved in the discussions.

To measure content validity at scale level the S-CVI average approach was used as recommended [19,21] as it represents information about each item compared to the universal agreement approach, which is considered to be too stringent as the chance of universal agreement decreases with the increasing number of experts [19,21]. The I-CVI does not account for chance agreement among raters, and the analysis of the collapsed response categories may lead to loss of information [34]. The AD index was therefore applied as used in an earlier study [35]. This index provided information of all four response categories as opposed to I-CVI which collapsed the response categories into relevant and not relevant.

5. Conclusions

Based on patients' evaluation and experts' review the new Impact M-TTH-NP questionnaire showed acceptable face validity in terms of relevance and an excellent content validity. In addition, four of the five additional questionnaires have shown acceptable face validity (MSQ, WHO-5, MDI and NDI) and three showed excellent content validity (WHO-5, MDI and NDI).

6. Implications

Applying the new Impact M-TTH-NP questionnaire in combination with the additional questionnaires that together assess pain, triggers, psychosocial and socioeconomic aspects may lead to a deeper understanding of the complexity of migraine with

co-existing TTH and NP. The impact M-TTH-NP may be used in clinical settings to assess treatment effect on patients suffering from a high frequent of migraine and co-existing TTH and NP.

Conflict of interest

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