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Does primary-care use of the HURT questionnaire aid the reduction of headache burden? Lessons for study design from an evaluation in primary care of the Arabic version

Ali M Al Khathaami¹⁻³, Danah Abo AlSamh³, Mohammed Al Jumah^{3,4}, Nasser Alotaibi¹⁻³, Suleiman Kojan¹⁻³, Altaf Khan² and Timothy J Steiner^{5,6*}

¹King Abdulaziz Medical City, Riyadh, Saudi Arabia

²King Abdullah International Medical Research Centre, Riyadh, Saudi Arabia

³King Saud Bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia

⁴Department of Neurosciences, King Fahad Medical City, MOH, Riyadh, Saudi Arabia

Department of Neuromedicine and Movement Science, NTNU Norwegian University of Science and Technology, Trondheim, Norway

⁶Division of Brain Sciences, Imperial College London, London, UK

Abstract

Background: The Headache Under-Response to Treatment (HURT) questionnaire is a self-administered outcome measure designed to assess and promote effectiveness of headache management in primary care. It links responses indicative of suboptimal treatment to specific clinical actions to improve outcomes. We aimed in this study to test whether integrating HURT into assessment and follow-up in primary care in Saudi Arabia improved headache management.

Methods: With IRB approval, primary-care physicians (PCPs) were recruited from two health-care centres in Riyadh. After basic training in headache care, they were randomly assigned to either of two groups: one, with further instruction on its use, incorporating HURT into their management of patients with headache (intervention group), the other applying standard care without HURT (control group). Patients were randomised on presentation to a PCP in one or other group, thereby randomly receiving care directed by HURT or not. The primary outcome measures, estimated using the Headache-Attributed Lost Time (HALT) index, were reductions in lost productivity from paid work and household chores after 3 and 5 months' follow-up.

Results: A total of 28 PCPs participated. The study was stopped early, because of slow recruitment, after enrolment of 171 patients (84 control, 87 intervention) of 420 planned. Baseline characteristics were well matched between the groups. Patients in both groups benefited from the care they received, with no significant difference in the primary endpoint between groups after 5 months (5.2 *versus* 5.7 days lost; p=0.4). Patients' understanding of their diagnosis reportedly improved in the intervention group during follow-up.

Conclusion: The study failed in its purpose but delivered useful lessons for future study design in a difficult field of enquiry. First, the training we gave all PCPs, in order to balance the treatment groups, may have rendered HURT largely redundant as a management aid intended for non-experts. Second, the study demonstrates again the difficulty of conducting experiments of this sort in primary care, where interest in headache and motivation to conduct headache research are largely lacking. The second is the more intractable problem.

Background

Among adults worldwide, more than 50% have an active headache disorder, experiencing at least one headache episode per year [1]. For many, there is attendant disability [2-4]. This high proportion with health-care need mandates the management of most patients in primary care [5]. Unfortunately, the ubiquity of headache disorders is coupled with widespread lack of knowledge about them among health-care providers (HCPs), especially those in primary care.

The Global Campaign against Headache is conducted by the UKregistered non-governmental organization *Lifting The Burden* (LTB) [6-8], in official relations with the World Health Organization [9]. LTB has recognized that non-specialist but competent management of headache by primary-care physicians (PCPs) would be helped not only by education but also by practical management aids [10]. One of these, developed through expert consensus and psychometric evaluation, is the Headache Under-Response to Treatment (HURT) questionnaire, a self-administered outcome measure. Used at base line and in follow-up, HURT was designed specifically for use in primary-care settings [11,12]. It is unique in that it not only assesses effectiveness of management but also links responses indicative of suboptimal treatment to specific clinical actions to improve outcomes [12].

*Correspondence to: TJ Steiner, Department of Neuromedicine and Movement Science, NTNU Norwegian University of Science and Technology, Trondheim, Norway, E-mail: t.steiner@imperial.ac.uk

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The eight items of HURT fall into three domains: a) Disease assessment (headache frequency and related disability), addressed by items 1-3; b) Use, efficacy and side effects of abortive medications, and patients' perceptions about the control of their headaches (items 4-7); and c) patients' understanding of their headache diagnoses (item 8) [12]. Items 1-7 each have five response options. Those concerning frequency (items 1-4) are arranged categorically from "none" to "highly frequent"; those addressing the likelihood of certain events (items 5-7) have verbal options between "always" and "never". Item 8 has dichotomous response options ("ves" or "no"). Responses are colour-coded to aid the physician's decision making: a gradient of white to dark grey indicates what clinical actions might best improve a patient's care. When all answers lie in the white zone, no clinical action is necessary. When there are responses within the grey zones, and more so the darker the grey, actions are recommended to achieve better headache control [12].

A key purpose in the development of HURT was to create an easyto-use instrument applicable not only across clinical settings but also across different cultures and languages [12]. In the Arabic-speaking world, as elsewhere, headache is a major contributor to public ill health: an estimated 60 million native Arabic speakers are affected by headache disorders [13]. In its Arabic version, HURT has undergone psychometric validation in a multicentre primary-care study in Saudi Arabia, with test-retest reliability, responsiveness and utility demonstrated in 342 Arabic-speaking patients [14]. Here we ascertain empirically whether integrating HURT into assessment and follow-up in primary health care in Saudi Arabia improves management.

Methods

Study design

This was a randomized controlled study conducted in two primary health-care centres (PHcCs) in Riyadh, Saudi Arabia (Comprehensive Specialized Clinic in Um Al Hammam, and King Abdulaziz Housing City Clinic in Yarmouk Iskan), from November 2011 to January 2014. Intervention was at PCP- rather than patient-level.

Ethics

The study protocol was approved by the Institutional Review Board (IRB) of the King Abdullah International Medical Research Centre (KAIMRC).

The study participants included both the treating PCPs and their patients presenting with headache. PCPs were recruited by a member of the research team while patients were approached by trained research nurses in the waiting areas of the PHcCs after confirming that headache was their main complaint. In both cases, full details of the study were explained verbally and by written letter, and willing participants gave signed consent.

Setting and participants

The two participating PHcCs were under the umbrella of National Guard Health Affairs and mostly served National Guard personnel and their dependents.

All PCPs in these PHcCs were eligible. Their baseline characteristics were recorded: age, gender, year of graduation, country of training, current career rank, years of clinical experience, Arabic fluency and estimated number of headache patients seen weekly. PCPs were asked to assess their level of comfort in managing headache patients on a 3-point verbal rating scale (VRS): "very comfortable", "somewhat

comfortable" or "not comfortable". To minimize inter-PCP variation in knowledge and skills, all PCPs attended a workshop on the basic principles of diagnosing and classifying headache disorders and their management according to the then-available European principles of management of common headache disorders in primary care [15].

In each PHcC, simple randomization at PCP level assigned PCPs by employee badge numbers into either the intervention arm (*ie*, using HURT for assessment and follow-up) or the control arm (providing standard care and follow-up without HURT). PCPs in the intervention group received further instruction, according to LTB guidance, on how to apply and interpret HURT and take the clinical actions indicated by HURT responses [12].

Patients attending either PHcC were eligible if they were over 18 years old, had presented with a main (but not necessarily sole) complaint of headache and were native Arabic speakers. Patients were excluded if they: a) were considered on initial evaluation to have a secondary headache disorder, headache as part of a somatization disorder or other psychiatric illness, cranial neuralgia or other central cause of facial pain; b) had significant comorbidity that would preclude the administration of HURT or prevent timely follow-up; c) showed evidence of dementia or cognitive impairment; or d) were illiterate. Eligible patients were randomized on arrival at the PHcC to an intervention PCP or a control PCP.

Assessment of patients, by a trained research nurse, captured baseline characteristics: age, gender, level of education, occupational status and a detailed headache history including medications they were taking to manage their headaches (abortive and preventative), their effectiveness and any side effects therefrom. Diagnoses were made by PCPs according to the International Classification of Headache Disorders (ICHD-II) [16]. Baseline assessment also included headache-attributed burden estimation using the Headache-Attributed Lost Time (HALT) index, which has five questions on lost productive or social time over the preceding 3 months [17].

Management and follow-up

From the first visit, all patients were managed by the PCPs according to the then current European principles of management of common headache disorders in primary care (standard care) [15]. In the intervention group, management was additionally informed and guided by patients' HURT responses at baseline and each followup visit. Each patient was followed by the PCP to whom he or she was initially assigned. Follow-up was planned after 3 months by clinic visit and again after 5 months by phone call, intervals chosen to provide an adequate trial of treatment and opportunity for effect measurement while minimizing learning bias arising from use of the same questionnaires more than once [18]. At the second visit, patients of both groups again completed HALT. Those in the intervention group also completed HURT, and continued treatment according to their HURT responses. Control patients were treated according to the best judgment of the treating PCPs. After 5 months, patients were contacted by a research coordinator blinded to group allocation, and again completed HALT.

Statistics and analyses

Outcome measures and sample size: Our primary outcome measures were reductions in headache burden at 3 and 5 months calculated, as a continuous measure (whole days lost), as the sum of responses to HALT items 1 to 4 (HALT score). These items estimated lost productivity from paid work and household chores. According

to accepted methodology [17], we equated "less than half achieved" to "nothing achieved" in a day, and counterbalanced this by equating "more than half" to "everything".

Power calculation was based on change in HALT score: a reduction from baseline of 30% days lost was regarded as indicative of successful management. With α =0.05 and power of 80%, we estimated that the required sample size was 420 participants (210 per group). We made no allowance for losses to follow up.

HALT also allowed grading based on summed responses to items 1-5, the last item relating to lost social occasions due to headache in the preceding 3 months [17]. HALT grades I-IV respectively indicated totals of 0-5, 6-10, 11-20 and >20 days lost. We used this as a secondary outcome measure. Other secondary measures were changes in frequency of headache attacks and use of abortive medication, and improved understanding of the headache diagnosis.

Group characteristics: Categorical data collected from PCPs and patients were analysed using descriptive statistics, and comparisons between groups used Pearson's chi-square test. Continuous variables were summarized by means and standard deviations (SDs) and compared using Student's t-test.

Analysis of outcomes: Statistical analyses were performed using SAS[™] software version 9.2.

The longitudinal study assigned three assessments to each patient (initial, and after 3 and 5 months), with, accordingly, two intervals for outcome measurement. To account for dependency between responses due to repeated assessments, we used the generalized estimating equation (GEE) for longitudinal response data. GEE is a statistical regression method estimating change in population average over the repeated measures [19]. We applied GEEs to HALT scores, change in headache frequency, change in proportion of abortive medication use and change in patients' understanding of their diagnoses over the duration of the study. GEE results were reported with standard deviations and 95% confidence intervals (CIs). Significance was declared when p<0.05.

Results

Baseline characteristics

All PCPs (N=28) from both PHcCs were included. Their characteristics are summarized in Table 1. More than half (57.1%) were male and most (70.8%) were general practitioners. All were native Arabic speakers, and most (82.1%) felt at least somewhat comfortable in managing patients with headache.

The two sites enrolled 171 patients before the study was terminated because of slow recruitment: 87 were assigned to intervention and 84 to standard care (control). None were lost to follow-up: all were included in the analyses at 3 and 5 months.

Baseline characteristics (Table 2) were well matched between the groups, except that those in the intervention group were somewhat better educated and more had sought medical help for headache in the preceding year. The control group registered fewer days lost at baseline (12.4 *versus* 14.8), but this difference was not significant.

Outcomes

Table 3 shows the primary outcome measure: mean reductions from baseline in productive days lost due to headache during followup. In both groups, these eventually exceeded 30%, the threshold adopted *a priori* as indicative of effective management. After 3 months, reductions were 2.7 days (22.4%) in the control group and 4.1 (27.8%) in the intervention group (p<0.0001) (Figure 1). After 5 months they were 7.2 days (58.1%) *versus* 9.1 (61.7%; p<0.0001) but with no significant difference in mean total lost days between control and intervention groups (5.2 versus 5.7 days; p=0.4) because of the baseline imbalance.

Secondary outcome measures are shown in Table 4. The proportions in HALT grade IV declined to zero in the control group and to 1.1% (one patient) in the intervention group. Again, this was indicative of effective management in both groups. However, there were no significant differences between groups in changes in the proportions of patients using abortive medications from baseline to the 3-month follow-up visit or from 3 months to the 5-month follow-up (p=0.840). Also, there were no differences between groups in change in the use of preventative medication over time (p=0.342) (data not shown).

Patients treated with HURT became more likely to report an understanding of their headache diagnoses over the follow-up period: from 71.4% responding "yes" at baseline (albeit with 17 missing responses) to 90.5% at 3 months (34 missing) and 98.8% (0 missing) at 5 months (p<0.0001).

Table 1. Characteristics of treating primary-care physicians

Characteristics	Values (N=28)		
Age (years) (mean ± SD)	40.3 ± 10.1		
Gender, n (%)			
male	16 (57.1)		
female	12 (42.9)		
Career rank, n (%)			
general practitioner (GP)	20 (71.4)		
board-certified family physician	5 (17.9)		
resident	3 (10.7)		
Country of training, n (%)			
Egypt	13 (46.4)		
Sudan	10 (35.8)		
Saudi Arabia	5 (17.9)		
Clinical experience (years) (mean \pm SD)	15.4 ± 9.5		
Arabic fluency, n (%)	28 (100)		
Headache patients per week (mean \pm SD)	6.8 ± 7.0		
Comfort level in managing headache, n (%)			
somewhat comfortable	16 (57.1)		
very comfortable	7 (25.0)		
did not disclose	5 (17.9)		

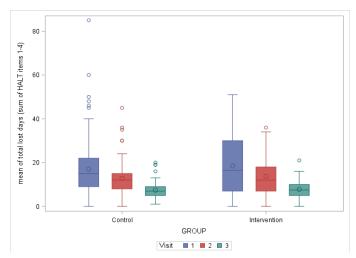


Figure 1. Change in mean total lost productive days (HALT items 1-4) over time by treatment group

Table 2. Baseline characteristics of	f participating	patients, by t	reatment group		
Characteristics	Overall Control I (N=171) (n=84)		Intervention (n=87)	р	
Age (years) (mean \pm SD)	36.8 ± 11.7	38.1 ± 11.5	35.6 ± 11.8	0.153	
Gender, n (%)					
Male	38 (22.2)	19 (20.7)	19 (20.0)	0.906	
Female	133 (77.8)	65 (79.3)	68 (80.0)	0.000	
Marital status, n (%)					
single	37 (21.9)	15 (18.3)	22 (25.3)	0.179	
married widowed	130 (76.9) 2 (1.2)	67 (81.7) 0	63 (72.4) 2 (2.3)	0.178	
Education level, n (%)	2 (112)	0	2 (213)		
less than primary school	27 (15.8)	13 (15.7)	14 (16.3)		
primary to high school	105 (62.1)	57 (68.7)	48 (55.8)	0.133	
university	37 (21.9)	13 (15.7)	24 (27.9)		
Education years (mean \pm SD)	8.7 ± 4.9	7.9 ± 4.4	9.4 ± 5.1	0.045	
Employment, n (%)					
unemployed/housewife	93 (55.7)	47 (57.3)	46 (54.1)		
full-time employment	28 (16.3)	14 (17.1)	13 (15.3)		
student	24(14.4)	7 (8.5)	17 (19.5)	0.249	
self-employed seeking work	16 (9.6) 5 (2.9)	10 (12.2) 3 (3.7)	6 (7.1) 2 (2.4)		
retired	2 (1.2)	1 (1.2)	1 (1.2)		
Sought medical help for headache in preceding year, n (%)	65 (38.0)	23 (27.4)	42 (50.0)	0.003	
Diagnosis, n (%)					
migraine	123 (74.1)	59 (72.8)	64 (75.3)	0.710	
tension-type headache	43 (25.9)	22 (27.2)	21 (24.7)	0.718	
Aware of diagnosis, n (%)	20 (19.6)	13 (25.0)	7 (14.0)	0.161	
Duration of headache since onset (months) (mean \pm SD)	15.3 ± 28.2	13.0 ± 18.7	17.7 ± 35.8	0.984	
Headache frequency per month $(mean \pm SD)$	5.2 ± 5.0	4.8 ± 4.4	5.7 ± 5.4	0.650	
Duration of headache attacks (hours) (mean ± SD)	1.0 ± 0.1	1.0 ± 0.0	1.0 ± 0.1	0.326	
Intensity (without treatment), n	(%)				
very bad	87 (51.2)	47 (56.0)	40 (46.5)		
somewhat bad	65 (38.2)	28 (33.3)	37 (43.0)	0.409	
not bad	18 (10.6)	9 (10.7)	9 (10.5)		
Effect on day-to-day activities, r					
able to do everything as usual	33 (19.4)	16 (19.0)	17 (19.8)	0.007	
cannot do certain activities cannot do anything	86 (50.6) 51 (30.0)	43 (51.2) 25 (29.8)	43 (50.0) 26 (30.2)	0.986	
Total days lost due to headache	51 (50.0)	25 (29.8)	20 (30.2)		
in preceding 3 months (mean \pm SD)	13.6 ± 12.0	12.4 ± 11.0	14.8±12.4	0.096	
HALT grades, n (%)					
I or II	59 (34.5)	28 (47.4)	31 (52.5)	0.96	
III or IV	112 (65.4)	56 (50.0)	56 (50.0)	0.70	
Usual treatment of attacks, n (%					
medication	159 (93.0)	81 (96.4)	78 (90.1)	0.083	
traditional therapies rest	1(0.6) 30(17.5)	1(1.2) 15(17.9)	0	0.491 0.915	
no therapeutic measures	30 (17.5) 2 (1.2)	15 (17.9) 1 (1.2)	15 (17.2) 1 (1.2)	1.000	
Frequency (days) of analgesic	()	()	()		
use during preceding month $(mean \pm SD)$	5.7 ± 7.1	3.7 ± 2.8	3.6 ± 2.4	0.722	
Use of prophylactic medication, n (%)	2 (1.2)	2 (2.4)	0		
Family history of migraine, n (%)	42 (25.5)	16 (19.5)	26 (31.3)	0.081	
Self-reported comorbidities, n (
depression	7 (4.1)	3 (3.6)	4 (4.6)	1.00	
bronchial asthma	6 (3.5)	3 (3.6)	3 (3.5)	1.00	
hypertension	15 (8.8)	9 (10.7)	6 (6.9)	0.377	
diabetes mellitus heart disease	11(6.4) 2(1.6)	6(7.1) 1(12)	5 (5.6)	0.710	
neaft disease	2 (1.6)	1 (1.2)	1 (1.6)	1.00	

Table 3. Outcome by treatment group (total days lost due to headache in the preceding 3 months, assessed by HALT)

Visit	Total days lost (mean±SD)			
	Control	Intervention		
Baseline	12.4 ± 11.0	14.8 ± 12.4		
After 3 months	9.7 ± 7.2	10.7 ± 7.6		
After 5 months	5.2 ± 2.8	5.7 ± 3.2		

Table 4. Outcome by treatment group assessed by secondary measures

Outcome measure	Control		Intervention				
	Baseline*	After 3 months**	After 5 months [†]	Baseline*	After 3 months**	After 5 months [†]	р‡
Reporting use of abortive medication n (%)	72 (85.7)	56 (66.7)	71 (84.5)	77 (88.5)	62 (71.3)	82 (94.3)	0.840
Change in H	ALT grade	s (%)					
I (0-5) II (6-10) III (11-20) IV (>20)	20.5 12.1 39.8 27.7	20.3 20.3 43.8 15.6	33.3 51.1 11.9 0	17.2 18.4 19.5 44.8	20.0 26.2 32.3 21.5	27.8 51.1 20.0 1.1	0.311

* From a total of 159 observations recorded at baseline (missing 12); ** from a total of 121 observations recorded at 3 months (missing 50); † from a total of 168 observations recorded at 5 months (missing 3); ‡ based on GEE comparing control and intervention groups for longitudinal change [19].

Discussion

In summary, we found improvement in both groups over 5 months of follow-up, consistent with effective (but not necessarily best) clinical management. This was reflected in the primary outcome measure and in reduction of HALT grades. All participating PCPs received training in the basic principles of diagnosing, classifying and managing headache disorders prior to study commencement, so any other finding would have been disappointing. However, against this background, any additional benefit from use of HURT (the specific intervention) was obscured.

Patients treated with HURT became significantly better able to understand their headache diagnoses over the follow-up period, replicating earlier findings [14]. The (English) wording of the question was "Do you feel you understand your diagnosis?", with response options "yes" or "no". Patients answering "no" (71% of those responding at baseline) ought, according to the guidance in HURT, then to be given an explanation by their PCP, repeated if indicated during follow-up, so that "no" would become "yes". This appeared to happen in all but one case, but this was an uncontrolled observation: in the control group, the question was, of course, not put.

There are two methodological lessons from this study that make it worth reporting.

First, the study design was misconceived. HURT was designed as an aid for non-expert HCPs, guiding them to better outcomes [10-12]. Its development foresaw a scenario in which primary-care management of headache disorders was greatly expanded, with many HCPs untrained in this role and, consequently, likely to benefit from such guidance [12]. The training we gave our PCPs, in order to balance the treatment groups, was not in keeping with this scenario, and probably rendered HURT largely redundant as a management aid. Any future attempt empirically to demonstrate benefit from introducing HURT into primary-care headache management would do better to avoid preconditioning in this way.

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Second, the study demonstrates again the difficulty of conducting experiments of this sort in primary care. The study was terminated because of slow recruitment, with only 40% of the target achieved. PCPs with no special interest in headache disorders have no reason to be highly motivated in any form of headache research. There is no easy solution to this. Offering incentives (should resources allow) would, in all probability, have a similar conditioning effect.

In conclusion, this study failed in its purpose, but delivered helpful lessons for future study design in a difficult field of enquiry.

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Authors' contributions

AMK contributed to project design, data analysis and interpretation and drafting the manuscript. DA contributed to data collection, analysis review and drafting the manuscript. MAJ contributed to project design. NA contributed to data collection and drafting the manuscript. AK contributed to data analysis. TJS contributed to project design, data analysis and interpretation and drafting the manuscript. All authors reviewed manuscript drafts and approved the final version.

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