The Development and Psychometric Properties of the MSQOL
A Migraine-Specific Quality-of-Life Instrument

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Summary

This paper describes the development and testing of the UK version of the Migraine-Specific Quality-of-Life instrument (MSQOL), a measure designed to assess the quality of life of migraineurs. The work was part of an international research study conducted in eight countries, with the initial development work conducted in the UK and the USA. In the UK, interviews were held with 30 patients with migraine, while in the USA, 25 individual interviews were conducted, along with one focus group with 5 participants. Transcripts were produced of the interviews/group discussion and these were used to determine the questionnaire items, which were then considered by an international translation panel. The panel considered the feasibility of translating the items into other European languages. The instrument was then assessed for reliability and validity. The UK version of the MSQOL was shown to have excellent test-retest reliability (0.93 over 2 weeks) and internal consistency (0.92 and 0.93 on the first and second administrations, respectively). Scores on the measure were also found to be related to a comparator measure of well-being and to perceived severity of migraine and disruption caused to patients by the disease. Findings for the other language versions of the MSQOL supported those from the UK, suggesting that the instrument may well be suitable for inclusion in clinical trials.

The term migraine is derived from hemicrania. The Greek physician Galen used it in the 2nd century to distinguish pain on only one side of the head from other forms of headache (cephalaea). He believed that headaches occurred when those with a head that was easily overfilled led an immoderate life.[1] Variations between symptoms of migraine attacks have made the diagnosis of migraine difficult in the past. However, the definition of the International Headache Society[2] is now generally accepted.

Incidence

Earlier inconsistency in definitions and individual differences in severity and experience have led to considerable discrepancies in the reported incidence of migraine and in the populations selected for research. Incidence rates reported in the UK range from 10% in males and 20% in females[3] to 4% in males and 7.7% in females.[4] Migraine is most prevalent in the age range 25 to 45 years, at about 10%, falling to around 3% over the age of 65

years. Thus, the condition is most common in people of working age.

The Effects of a Migraine Attack

The average migraineur is absent from work through migraine for between 3 and 4 days a year.[5] However, many of those who continue to work through an attack, or part of an attack, believe that they do not work effectively.[6] Most migraineurs will not qualify for sickness benefit because of the short duration of their absences.

In addition to physical concerns (severe pain, adverse effects of treatment or worry about the possible presence of a brain tumour) a number of anxieties provoked by migraine have been identified.[7] These include: fear of insanity and of loss of employment, interference with social activities and feelings of guilt. These fears are likely to lead to a disruption of the migraineur's life between attacks. Withdrawal from company combined with reluctance to make social arrangements could lead to increased social isolation. Consequently, the effective treatment of migraine would be expected to improve quality of life (QOL) not only at the time of an attack but also to increase QOL overall.

Several authors have looked at the relationship between migraine and personality and psychiatric disorders, but the results of the studies are far from clear. For example, Breslau and Andreski[8] showed that migraine was associated with neuroticism as measured by the Eysenck Personality Inventory (EPI). However, as Baskin[9] points out, many of the items in the EPI that are intended to assess neuroticism are also accepted symptoms of migraine. There does appear to be a link between migraine and major depression, and it is possible that the conditions have a shared aetiology.[10]

Quality of Life

The aim of QOL measurement is to quantify the impact of both clinical condition and treatment on the wider aspects of the patient's life, by going beyond the commonly used clinical indicators of the patient's progress.[11] In addition to symptomatology, clinical judgements of patients' response to treatment tend to be based on a return to optimal functioning such as ability to go to work. However, patients may consider quite different criteria to be important to their QOL. They may well be more concerned with their ability to enjoy themselves or to have the freedom to make plans for social outings.

Rather than concentrate on functioning, it is possible to conceive of QOL as the ability of an individual to satisfy his or her personal needs. This approach is not new, having been postulated by Thomas More in the 16th century.[12] He argued that human life quality was dependent on the satisfaction of certain basic needs, for example, those for health, mobility, adequate nutrition and shelter.

Major advances in needs theory in the 1940s and 1950s resulted from investigations into human motivation.[13,14] The relationship between needs and QOL continued to be explored with the advent of the social indicators movement in the 1970s.[15]

Early attempts to develop instruments based on needs fulfilment were largely unsuccessful. However, over the last 10 years several high quality needs-based instruments specific to a range of different diseases have been developed.[16-20] The model employed for these scales grew out of work in depression.[21] Recognising the importance of deriving the content of a QOL measure directly from relevant patients, the researchers began by interviewing patients about the impact of depression on their lives. They noticed that the interviewees described their experiences in terms of needs that were, or were not, being met rather than in functional terms.

A further advantage of concentrating on needs rather than the functions used to fulfil them is that needs are common to all respondents, making the content of measures highly relevant to respondents.

The needs-based model of QOL[21] was employed in the development of the Migraine-Specific Quality-of-Life instrument (MSQOL), which is described below. The model postulates that QOL is the extent to which an individual is able to meet his or her needs. This allows the development of disease-

specific instruments, as it is possible to focus on those needs influenced by the disease in question.

Instruments Employed in the Assessment of Health Status and QOL in Migraine

Few attempts have been made to assess QOL in migraine because of the absence of suitable instruments. However, measures of health status have been employed. Scores on the Nottingham Health Profile (NHP), a measure of perceived distress, indicated that migraineurs have relatively high levels of distress in the areas of energy level, sleep and emotional reactions.[22] Like the NHP, the Medical Outcomes Study Short Form (SF-36) assesses impairments and disability rather than QOL.[23] Scores on some sections of the SF-36 were found to improve following 6 to 9 months' treatment with sumatriptan, although the study did not employ a control group.[24]

Use of the Psychological General Well-Being Schedule indicated that migraineurs have impaired well-being between attacks, compared with an age- and gender-matched control group.[25]

An instrument was developed in France, intended to assess QOL in migraineurs.[26] However, the items in the measure were written by clinicians rather than being derived from relevant patients. Consequently, the instrument collects information that is of interest to clinicians rather than, necessarily, of relevance to the QOL of migraineurs.

The content of the questionnaire is problematic in that some items do not apply to all respondents. Items covering employment and sexual activity are not relevant to a proportion of the patient population. Other items involve more than one concept, making them difficult to answer and interpret. In general, the items are biased in favour of physical functioning and do not reflect any underlying model of QOL. The test-retest reliability coefficients of the subscales (0.65 to 0.82) are lower than that required of measures intended for use in a clinical trial.

Migraine Quality-of-Life Questionnaire

The Migraine Quality-of-Life Questionnaire (MQOLQ) was designed to assess the impact of a migraine headache over the 24 hours following its onset.[27] The authors argued that this was the most crucial period for assessment in a clinical trial, as it is the period over which medication would be likely to influence QOL. However, this argument is questionable. During a migraine headache the patient is more likely to be concerned about the severity of their symptoms than wider aspects of their QOL. Furthermore, effective medication would be expected to have a longer term benefit on QOL as a result of, for example, feelings of increased control over the headaches and reduced disruption of valued activities.

The authors defined QOL as 'health status related to patients' functioning'. However, the concepts of health status, functioning (disability) and QOL have recently been clearly distinguished in the literature.[11,28,29] The content of the MQOLQ was primarily derived from the literature and experts, although interviews were also conducted with 6 migraineurs in the item development stage. Item reduction also involved testing the instrument with migraineurs. The final instrument has 15 items, three for each of five sections: work functioning, social functioning, energy, headache symptoms and feelings/concerns. Thus, four of the sections assess impairments and disability rather than QOL.

Migraine-Specific Quality-of-Life Questionnaire

Several authors[30-32] report using the Migraine-Specific Quality-of-Life Questionnaire, a measure specific to migraineurs between attacks, in studies of the impact of sumatriptan versus normal treatment. Although the instrument is claimed to be particularly sensitive to changes in health-related QOL within the context of a clinical intervention, no formal description of the measurement's development or psychometric properties could be found in the literature. This makes it difficult to evaluate the value of the instrument.

A 'Generic QOL Scale'

Langeveld et al.[33] reported the development of the QLH-Y (Quality of Life Headache in Youth scale), a 'generic QOL scale' for adolescents aged between 12 and 18 years. Items for the measure

were generated predominantly from the literature or existing scales, with only five interviews conducted with migraine patients. The authors did not provide a model of QOL as a basis for the questionnaire content, which mostly concerns functioning.

The QLH-Y consists of 69 multi-choice items (which are claimed to form 13 subscales) and two visual analogue scales intended to assess satisfaction with health and with life in general. Unfortunately, the subscales have unacceptably low internal consistency and test-retest reliability, making the instrument unsuitable for use in a clinical trial. No other QOL instruments for use with migraineurs could be identified from Medline or Psyclit searches.

Given the impact of migraine on patients, its high prevalence and the development of new medications for its control, there was a clear need for a reliable and valid QOL instrument suitable for use in clinical trials and for monitoring the progress of individual patients.

Methods

Qualitative Interviews with Migraineurs

Table I shows the stages involved in the development of the MSQOL. 30 unstructured, qualitative interviews were conducted with migraineurs in both the UK and the USA. In the UK, 10 interviewees were employees of a pharmaceutical company, one responded to an advertisement in a local paper, two were recruited from general practitioners, and the remainder were members of the British Migraine Association, who responded to a request for volunteers to help with research. While it is recognised that these methods of recruitment could introduce bias, it was considered essential to include individuals with a range of severity of migraine rather than to recruit solely from clinical sources.

All interviewees had received a diagnosis of migraine from their general practitioner or another clinician. The pharmaceutical company employees were interviewed at their place of work. Most of the other participants were interviewed in their

Table I. Stages in the development of the Migraine-Specific Quality-of-Life instrument

Qualitative patient interviews in UK and focus groups in the USA
Content analysis of transcripts from interviews and focus groups
Development of item pool based on content analyses
International translation meeting
Field-test interviews with migraineurs to establish face and content validity
Postal survey to assess reliability and construct validity

homes, with three choosing to visit the researchers' offices. USA interviewees were recruited from headache/neurology clinics and by advertisement.

Interviewees were first asked to describe their most recent attack. The interviewer then enquired about the impact that migraine had on the participant's life overall and, in particular, about needs that were not being met as a result of their illness. The interviews were tape-recorded and transcribed. Content analyses were conducted on the transcripts to identify potential items for the QOL instrument. Similar analyses were conducted by the USA researchers. The results of the two sets of analyses were compared in order to develop a set of items that was relevant to both countries.

Translation Panel Meeting

Following identification of the item pool for the new instrument, a translation panel was convened. The panel consisted of researchers from the UK, USA, Germany and Italy. The purpose of the translation panel was to ensure that additional language versions of the measure could be developed in the future using the final set of items. The main difficulty with adapting measures for use in other European languages is the problem of obtaining conceptual equivalence of items. By considering potential items before a measure is finalised, such problems can be minimised. Other issues, such as the most appropriate response categories, can also be considered at this stage.

Ideally, the translation panel should have representatives from each country in which the measure will ultimately be used. However, the actual language

versions required were not known at this stage of the study. The inclusion of one expert from Northern Europe (Germany) and one from Southern Europe (Italy) was considered the minimum necessary (in addition to the UK and USA researchers).

In order to maintain the patient-based nature of the instrument the items were, as far as possible, presented in the actual words of respondents. The intention of the meeting was to maintain this wording unless a change proved essential. Each item was considered for translatability by the panel.

Following the international meeting it was decided that versions of the MSQOL were required for the UK, USA, France, Germany, Italy, Spain, Denmark and Sweden. The remaining stages of the project were run in parallel in the eight countries. This paper reports only on the work conducted in the UK, although changes to the measure were based on the results from all eight countries.[34]

Field-Testing for Face and Content Validity

Field-test interviews were conducted with 20 migraineurs, recruited from the membership of the Migraine Association. Interviewees were visited in their own homes and were asked to complete the questionnaire in the presence of an interviewer, who noted any difficulties with specific items. Respondents were then asked to comment on the relevance and acceptability of the items.

Testing Internal Consistency, Reliability and Construct Validity

Having tested the acceptability of the new instrument to respondents, it was necessary to establish its internal consistency, test-retest reliability and construct validity. This was done by means of a postal survey.

Internal consistency, in the form of Cronbach's alpha, is often used as an indication of the homogeneity of a scale. This has now been shown not to be the case, with alpha merely reflecting the extent to which the items in a scale are interrelated.[35] However, the statistic was calculated to allow comparison with the psychometric properties of other measures used to assess health status in migraine.

Test-retest reliability was assessed by applying the instrument on two occasions to the same sample of patients. Individuals completing an instrument with good reliability (reproducibility) would be expected to obtain the same score on each administration, assuming that there was no change in QOL between the administrations. The reliability is again expressed as a correlation between 0 and 1. Correlations of at least 0.85 are required where a measure is to be used in a clinical trial.[36]

Validity was tested by relating scores on the QOL measure to a comparator instrument, to self-perceived severity of the migraine, and to total amount of disruption caused by the migraine. The comparator instrument was the General Well-Being Index (GWBI), the British version of the Psychological General Well-Being Schedule.[37] The GWBI has 22 items designed to assess well-being. It was anticipated that there would be a low to moderate (0.4 to 0.7) correlation between scores on the MSQOL and the GWBI, given that they assess different but related constructs.

Volunteers from the British Migraine Association were sent a package consisting of a covering letter, a demographic questionnaire, the MSQOL and the GWBI. Respondents were asked to complete the measures and return them in the reply-paid envelope provided. All respondents who completed and returned these measures were sent a second package timed to arrive 2 weeks after the first questionnaires were completed. This package consisted of a covering letter, the migraine questionnaire and a reply-paid envelope. Again, they were asked to complete the questionnaire and return it to the researchers.

On each occasion, patients were asked to delay completing the questionnaires until fully recovered if they had just had a migraine headache.

Statistical Analyses

Cronbach's alpha was used to assess internal consistency. Nonparametric statistical analyses were applied in all other analyses. Test-retest reliability and the correlation between MSQOL and GWBI scores were assessed by Spearman rank correlation coefficients. Where two independent

groups were compared, a Mann-Whitney U-test was employed and for three groups, the Kruskal-Wallis 1-way analysis of variance was used. p-Values of 0.05 and below were considered statistically significant.

Results

In the following section, missing data have been excluded from the tables.

Patient Interviews

The interviews lasted between 20 minutes and 2.5 hours. The main issues raised by the interviewees were: time lost due to migraine, the need to keep to routines, care needed with selection of food and drinks, the need to limit the extent of their physical activity, difficulty with planning, dread, worry and guilt associated with the illness, the effects on other people, and denial of problems associated with the illness.

The interview transcripts were examined for phrases that might be suitable for inclusion in a QOL measure. Phrases were selected if they described the impact of migraine on the interviewees' ability to meet their needs. This is in accordance with the needs model of QOL.[21]

All possible phrases describing the impact of the condition were extracted from the transcripts, providing approximately 700 different phrases.

The measure was required to assess QOL between migraine attacks. Consequently, descriptions that referred only to impact during the attack itself (which were predominantly related to impairments and disabilities rather than QOL) were omitted, leaving a total of 224 phrases. These were loosely grouped and a panel of researchers who had conducted the interviews met to select the pool from which questionnaire items should be drawn.

As it was essential that all items in the measure were relevant to all respondents, phrases that were idiosyncratic or that made assumptions about the patients – for example, that they were married, in paid employment or drove a car – were removed. The researchers selected phrases that were ex-

pressed in the first person, were clear, and reflected the experience of several interviewees.

Occasionally, there were concepts that were commonly raised during the interviews that had not been expressed in an appropriate way by any of the interviewees. In these cases the researchers produced an item that reflected the experience of migraineurs and that fulfilled the above criteria. This process left a pool of 110 potential items.

The item pool was compared with that generated from the focus group discussions conducted by the USA researchers. There was a remarkable similarity in the items generated on each side of the Atlantic, providing evidence of the validity of the item pool. However, two major differences were found between the samples. In the USA, there was a commonly expressed concern about possible long-term health status; in particular, the increased likelihood of stroke. In the UK, there were many negative reports on treatments experienced and their associated adverse effects. Further items were removed from the UK pool because they were expressed in a way that was considered unacceptable to USA respondents. A new item pool was generated that included items that were common to both sets of interviews.

International Meeting

The discussion of the potential translatability of the item pool was prolonged and uncovered a number of differences between languages. Examples of these included problems with the meaning of the word 'resent' and the terms 'freedom', 'flexibility' and 'commitments'. No phrase could be found that was equivalent to *looking forward to* in Italian, or for *escape route* in either German or Italian. Problems were also found with distinguishing between the terms *close* and *personal* relationships. Where the item pool contained items with alternative wording for similar concepts, the most suitable for translation was selected.

In a few cases it was necessary to change the wording of items. For example, *I feel guilty about letting people down* was changed to *I worry about letting people down* and *I think that my migraine*

sometimes makes me intolerant was changed to *My migraine makes me impatient with other people*, due to problems with finding suitable translations for the concepts of guilt and intolerance in these contexts.

Items for which it proved impossible to achieve conceptual equivalence in all languages were rejected. These included *I prefer to stay away from places where I feel vulnerable* and *I am not as capable as people without migraine*. Following the international meeting the draft instrument had 33 items.

A four-point response format was adopted for the measure, in order to allow for variations in the level of QOL impairments experienced by potential respondents.

Field-Test Interviews

Interviewees took between 5 and 25 minutes to complete the measure, with a mean of 10 minutes. Problems were experienced with two items in the UK. *I am afraid of relaxing* was rejected for a number of reasons. Some respondents considered it irrelevant to migraine and others that it was offensive in suggesting that people with migraine were neurotic. Several others found the item difficult to answer. Some interviewees also considered that *I dislike having to rely on other people* was not relevant to them and it was also rejected. As a result of the field-test interviews in each of the countries a further six items were removed, leaving 27 items.

Postal Survey

Of the 90 people contacted, 87 completed and returned the questionnaires, representing a response rate of 96.7%. All 87 respondents also completed and returned the second set of questionnaires.

The sample was made up of 15 (17%) males and 72 (83%) females, aged between 22 and 92 years (mean 47.6 years). 81% of the respondents were married or living as married.

Self-perceived severity of migraine was selected as most relevant to QOL, as it allowed respondents to make a judgement on the impact of

Table II. Example items from the final version of the Migraine-Specific Quality-of-Life instrument

I'm reluctant to make plans because of my migraine
Yes, very much
Yes, quite a lot
Yes, a little
No, not at all
It is important for me to stay in familiar surroundings
Yes, it's very important
Yes, it's quite important
No, it's not very important
No, it's not important at all

both the frequency and severity of their headaches. Respondents were asked to rate the severity of their condition on a three-point scale. Nine (10%) rated their migraine mild, 30 (35%) moderate and 48 (55%) severe.

Item-total correlation coefficients were examined to determine the optimum set of items to include in the final measure. Items were removed that had either a very high (>0.8) or very low (<0.2) correlation with total score. As a result, seven items were removed. The results reported below are based on the final 20-item version of the measure. Table II shows example items from this version.

Scores on the Measure

Each item has four possible response categories, scored 1 to 4. This allows total scores to range from 20 to 80, with a high score indicating good QOL. Table III shows the scores on the MSQOL for the sample, by gender and age group. The differences in score for males and females failed to reach statistical significance, as did those for the three age groups.

Internal Consistency and Test-Retest Reliability

The internal consistency of the MSQOL was 0.92 on the first administration and 0.93 on the second. The test-retest reliability over 2 weeks was 0.93, indicating that the measure has high reliability and can be used on an individual patient basis.

Construct Validity

Rated Severity of Migraine and QOL

Relatively few respondents rated their condition mild and, consequently, the mild and moderate categories were collapsed for statistical analysis. The QOL scores for the two groups (mild to moderate, and severe) are shown in table IV. There was a clear relationship between QOL and perceived severity of condition, with respondents reporting their migraine as severe also having poor QOL.

Association Between QOL and Well-Being

The correlation between scores on the MSQOL and the GWBI was 0.38. This was lower than expected and reflects the fact that the QOL of migraineurs (as assessed by the MSQOL) is influenced by both physical and emotional factors, while the GWBI only assesses emotional well-being.

Disruption and QOL

Questions were included in the measure on the frequency of migraine attacks and the length of time the attacks lasted on average. By multiplying together the average number of attacks per month and their average length (in hours), an index of disruption (or hours of disruption per month) caused by migraine was generated. No attempt was made to include severity of symptoms in the calculation, as the emphasis was on time lost as a result

of migraine attacks. The sample was divided into three groups dependent on their level of disruption (i.e. low, moderate and high). Table V shows the MSQOL scores for the three groups.

The table shows a clear relationship between the amount of disruption caused by the migraine and QOL (Kruskal-Wallis 1-way analysis of variance; $p < 0.001$). The difference between groups represents about one standard deviation. Fletcher et al.[38] suggested that effects that are larger than a third of a standard deviation of the between-patient scores were detectable by patients. The present findings suggest that a treatment that reduces the amount of time lost through attacks might be expected to lead to an improvement in QOL as measured by the MSQOL. However, no causal relationship can be claimed from these data.

Discussion

A number of authors have reported that at least half of the people who experience migraine do not consult a doctor with their symptoms.[39-41] It is now generally recognised that the utilisation of health services is more closely linked to how people feel than to their clinical condition.[21,42] Guyatt et al.[43] commented that 2 patients sharing identical clinical criteria can have dramatically different responses to their condition.

Table III. Migraine-Specific Quality-of-Life instrument (final version) scores by gender and age group

	No.	Mean	Standard deviation	Median	Range
Females	69	46.3	12.2	44.0	21-73
Males	15	53.1	12.5	52.0	33-78
Age < 42y	26	46.6	12.4	47.5	27-73
Age ≥ 43 < 51y	28	48.3	12.7	47.0	28-69
Age ≥ 51y	29	47.3	12.7	44.0	21-78
Total	**84**	47.5	**12.5**	**46.5**	**21-78**

Table IV. Migraine-Specific Quality-of-Life instrument scores by rated severity of migraine

Severity rating	No.	Mean	Standard deviation	Median	Range	Probability
Mild to moderate	39	52.6	12.7	54	27-78	<0.001*
Severe	45	43.1	10.5	42	21-68	
* Mann-Whitney U test.						

Table V. Quality of life by disruption caused by migraine

Disruption group (hours per month)	No.	Mean	Standard deviation	Median	Range
Low: < 48	28	54.9	9.8	56.0	36-78
Moderate: ≥ 48 < 96	26	47.1	13.3	43.5	28-73
High: ≥ 96	29	41.1	10.3	41.0	21-64

Whether or not individuals seek medical attention is less dependent on the 'objective' presence of symptoms than on their response to these or to their general perception that something is amiss.[44] Such differences in perception affect utilisation of health services to the degree that one individual may seek medical advice while another may not. Compliance with treatment regimens is also largely dependent on the patient's perception of their effectiveness and on how the treatment affects his or her well-being and QOL.[21,45] Thus, it can be argued that QOL is a crucial variable at all stages of the migraineur's contact with the health services.

The availability of a reliable and valid migraine-specific QOL measure, such as the MSQOL, will allow more detailed exploration of the relative importance to the patient of headache type, intensity and frequency. Furthermore, it will provide clearer evidence of the long-term benefits of interventions to the patient.

The MSQOL was developed specifically for assessing the effects of migraine on QOL between attacks. The experience of a migraine headache is so unpleasant for migraineurs that their major concern at that time is for symptom control. However, the impact of the condition continues beyond the actual attack and can seriously affect QOL. The unpredictable nature of attacks means that it is difficult to plan social activities, and work and family responsibilities may be disrupted at any time. A preventive treatment or one that allowed headaches to be controlled quickly would be expected to give migraineurs greater control over their lives and to improve QOL.

By deriving the content of the MSQOL from interviews with migraineurs, it was possible to identify those QOL issues that are influenced specifically by the disease. Maximising the relevance of the questionnaire to patients in this way increases the likely responsiveness of the measure, by ensuring that irrelevant items are omitted. Furthermore, as the items were derived from patients, the acceptability of the instrument to respondents and completion rates in the postal survey were very high.

As the MSQOL is based on a coherent model of QOL, all items contribute to an index rather than to a profile of scores. Profiles are more difficult to interpret and analyse than an index. Further work is being conducted on the unidimensionality of the MSQOL, through the application of Rasch analysis.

The psychometric properties of the new measure were excellent. Internal consistency and reliability were well above the minimum requirements for an instrument to be used in a clinical trial or for monitoring patients on an individual basis. Similar results were found for the other language versions, suggesting that the instrument will be suitable for inclusion in international clinical trials of new and existing interventions for migraine. The cultural validity of the measure was maximised by producing the additional language versions in parallel with the UK measure. This will facilitate the development of further versions of the instrument, by minimising potential cultural differences.

The clear relationship between disruption caused by migraine and scores on the MSQOL also suggests that the instrument will be sensitive to QOL differences associated with disease severity. However, the relationship between severity/frequency of headaches and QOL is far from clear. A prerequisite of sensitivity and responsiveness is

good reliability, as exhibited by the MSQOL, as this indicates relatively low levels of random measurement error.[46] Further tests of the instrument's validity are underway and it has been included in an international clinical trial. The results of the trial will provide evidence of the MSQOL's responsiveness.

Conclusions

The MSQOL was developed from interviews with migraineurs in the UK and USA and employs the needs-based model of QOL. The psychometric properties of the measure have been shown to be excellent, allowing its use in clinical trials and for monitoring individual patients in clinical practice. Versions of the measure are currently available for the UK, USA, Germany, France, Spain, Italy, Denmark and Sweden. The availability of a migraine-specific QOL measure with such high levels of reliability will maximise the chances of detecting QOL changes associated with the effective treatment of the illness.

Acknowledgements

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