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Chapter 3

Acceptance of preventive treatment in migraine patients: results of a survey

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ABSTRACT

Background
The number of migraine patients eligible for preventive treatment is considerably higher than the number of patients actually using it. This study explores reasons for this discrepancy.

Methods
An explorative survey among patients and their general practitioners (GPs) participating in a trial on preventive medication. Migraine patients who were eligible for preventive treatment (n=75) attended an evaluation consultation with their GP to optimize migraine treatment. GPs and patients who did not start preventive treatment were asked if they had discussed the possibility of preventive treatment and, if so, why they decided not to start it.

Results
Of the 32 GPs, 8 (25%) did not discuss the possibility of preventive treatment with their patients; in 4 because of perceived lack of effectiveness. Patients who did not start preventive treatment (n=43) used less triptans and had less psychological distress compared to those who did start (n=32). Main reasons for patients not starting were negative attitudes towards medication in general, fear of medication side-effects, previous unsuccessful attempts, attacks not being severe enough, and impact of migraine on daily life acceptable.

Conclusion
The decision of the individual patient and their GP to start preventive treatment is not only determined by attack frequency, but also depends on the impact of the headache attacks on their daily life and their negative attitude towards medication.
INTRODUCTION

Migraine is a common, disabling headache disorder with lifetime prevalence of 14%.\(^1\) In the Netherlands, 25% of women and 7.5% of men experience a migraine attack each year.\(^2\) Migraine leads to loss of quality of life and productivity both during and between attacks, causing a high socio-economic burden.\(^3,4\) In many guidelines on migraine treatment, a frequency of two or more attacks each month is an important starting point for discussing preventive treatment.\(^5-9\) Although over 5% of migraine patients suffer from two or more attacks each month and should be considered for preventive treatment, only 8-12% actually uses it.\(^2,4,10-12\) In the Netherlands, over 50% of migraine patients experiencing two or more attacks each month in general practice wishes to try preventive treatment, but have not discussed this with their general practitioner (GP).\(^12\) This study explores reasons for the discrepancy between the number of patients eligible for preventive treatment and the number of patients actually using it.

METHODS

Study group

The study group consisted of migraine patients who participated in the LIMIT study; details on this study are published elsewhere.\(^13\) Theoretically, participants may differ from patients in general. However, participants of the LIMIT study did not differ from non-participants in terms of age, sex, triptan use at baseline, triptans prescribed during the study period, consultations for headache in the previous year, HIT-6 score, EuroQol score and use of prophylactic medication at baseline or 12 months.\(^13\)

The study was approved by the Ethical Committee of the Leiden University Medical Centre. In this pragmatic randomized trial, a proactive approach to migraine patients by their GP was compared with usual care. GPs in the intervention group received two training sessions of three hours each from two specialized GPs. The protocol was based on the headache guideline of the Dutch College of General Practitioners.\(^5\) The GP training included diagnostic criteria for headache (migraine, tension-type headache, and medication-overuse headache), acute and prophylactic treatment, and treatment of medication-overuse headache. Patients in the intervention group were invited for an evaluation-consultation with their GP to optimize their migraine treatment according to the headache guideline of the Dutch College of General Practitioners. The guideline states that patients who experience two or more headache attacks per month should be offered preventive therapy.\(^5\) However, in the LIMIT study 43 (57%) participants, who experienced two or more headache attacks per month according to
their headache diary, did not start preventive therapy after this evaluation consultation (Figure 1).

**Characteristics of the study group**

The 43 patients who attended the evaluation consultation and reported two or more headache attacks per month, but did not start preventive treatment, were compared with the 32 patients who reported two or more headache attacks per month and did start preventive treatment. The following characteristics were compared: sex, age, impact of headache using the HIT-6 questionnaire, score range 36 (no headache) to 78 (very severe headache) (14); psychological distress using the K10 questionnaire, score range 10 (no distress) to 50 (severe distress) (15); number of headache attacks, number of headache days per month, hours of paid work per month, and absence from work (days per month).

Data on prescription of triptans and preventive medication, as well as consultation data, were collected from the electronic patient record.

**Outcome measures**

**Patients**

Patients were asked to complete a questionnaire about their reasons for not starting with preventive treatment (see Appendix 1). They were asked if they were aware of the possibility of preventive treatment, and if this option was discussed during the evaluation consultation, and who initiated this discussion (patient or GP). In case of not starting prophylaxis, they were asked why they decided not to raise the subject of preventive treatment, or not to start it after having discussed the subject.
GPs

GPs completed a questionnaire on each patient (see Appendix 1). They were asked if they had discussed preventive treatment during the evaluation consultation and who had initiated this discussion. When applicable, they indicated why they had decided not to raise the subject, or decided not to start preventive treatment after having discussed the subject with the patient.

Analyses

Statistical analyses were performed with the SPSS statistical package, using the independent sample t-test and the chi-square test in case of dichotomous data.

RESULTS

Starters versus non-starters

Table 1 presents data on patients starting and not starting preventive treatment. At baseline, patients who did not start preventive treatment used less triptans and had

<table>
<thead>
<tr>
<th>Evaluation consultation, but did not start preventive treatment (n=43)</th>
<th>Evaluation consultation and started preventive treatment (n=32)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (%)</td>
<td>88.1</td>
<td>93.8</td>
</tr>
<tr>
<td>Age in years</td>
<td>47.1 (10.4)</td>
<td>49.2 (11.3)</td>
</tr>
<tr>
<td>Number of triptans per month</td>
<td>3.6 (1.8)</td>
<td>6.8 (4.4)</td>
</tr>
<tr>
<td>Number of consultations for headache last year</td>
<td>0.43 (0.80)</td>
<td>0.45 (0.78)</td>
</tr>
<tr>
<td>HIT-6 score</td>
<td>61.2 (5.2)</td>
<td>62.8 (3.4)</td>
</tr>
<tr>
<td>K10 score</td>
<td>18.6 (5.8)</td>
<td>20.9 (6.3)</td>
</tr>
<tr>
<td>Number of attacks per month*</td>
<td>3.2 (1.3)</td>
<td>3.8 (1.6)</td>
</tr>
<tr>
<td>Headache days†</td>
<td>3.8 (2.1)</td>
<td>4.9 (4.4)</td>
</tr>
<tr>
<td>Paid work (hours per week)</td>
<td>21.4 (15.4)</td>
<td>18.0 (16.7)</td>
</tr>
<tr>
<td>Absence from work (days per month)</td>
<td>1.1 (0.6)</td>
<td>1.0 (1.4)</td>
</tr>
</tbody>
</table>

* Attacks of maximum 72 h, attacks recurring within 24 h are considered as a recurrence of the earlier attack
† Days with at least four hours of headache
a lower score on the K10 (indicating a lower level of psychological distress). No other differences were found.

Patients

The questionnaire was completed by 31 of 43 patients (72%) (Figure 2). Responders and non-responders did not differ regarding sex, age, HIT-6 score, K10 score, mean number of triptans prescribed per month during the last year, number of consultations for headache during the last year, number of headache attacks, and number of headache days (data not shown).

Of the 31 responders, 13 (42%) had discussed the possibility of preventive treatment with their GP. In all but one case, the GP initiated the conversation about preventive treatment. Of the 18 patients who did not discuss preventive treatment with their GP, 7 (39%) were aware of the option but did not raise the subject. The main reason for not raising the subject of preventive medication was that the patient had already tried this in the past (Table 2).

The main reasons for patients not starting preventive treatment after having discussed the issue with their GP were: a negative attitude against medication in general, fear of side-effects, migraine attacks not being severe enough, acceptable influence of migraine on their daily life, past usage of preventive treatment, and the desire to opt for different treatment first (Table 2).

Figure 2. Flowchart of the questionnaires completed by the patients
Table 2. Reasons given by patients (n=31) and general practitioners (GPs) (regarding 33 patients) for not discussing, or having discussed but not started, preventive treatment

<table>
<thead>
<tr>
<th>Reasons for both patient and GP</th>
<th>Patients</th>
<th>General practitioners</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not discussed</td>
<td>Not started</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td>n=18 (%)</td>
<td>n=13 (%)</td>
</tr>
<tr>
<td><strong>General practitioners</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not discussed</td>
<td>1 (5.3)</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Possible adverse effects</td>
<td>1 (5.4)</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Migraine attacks not severe enough</td>
<td>3 (15.8)</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Attack treatment could be improved</td>
<td>2 (10.5)</td>
<td>2 (5.7)</td>
</tr>
<tr>
<td>Influence of migraine on daily life acceptable</td>
<td>3 (15.8)</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Expected to forget to take preventive treatment</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Tried preventive treatment in the past</td>
<td>4 (21.1)*</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Did not expect effect of preventive treatment on severity or frequency of attacks</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Want to try other treatment first</td>
<td>2 (10.5)</td>
<td>5 (14.3)*</td>
</tr>
<tr>
<td>Otherwise, namely:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The attacks were not frequent enough</td>
<td>0 (0.0)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>Decline of attack frequency after menopause</td>
<td>2 (10.5)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td><strong>Reasons given only by patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not expect to be able to function better</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Makes me feel like I have a chronic illness</td>
<td>0 (0)</td>
<td>1 (2.9)</td>
</tr>
<tr>
<td>GP objected to preventive treatment</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>I thought the GP should raise the subject</td>
<td>1 (5.3)</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Reasons given only by GPs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I thought the patient should raise the subject</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Otherwise, namely:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient did not show up for consultation</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Patient was content with treatment</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Patient had objections about preventive therapy</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Patient had doubts about the diagnosis</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>19</td>
<td>35</td>
</tr>
</tbody>
</table>

Numbers between brackets indicate the percentage of respondents mentioning that particular reason. * Answers most frequently given.
The questionnaire was completed by 16 GPs with regard to 33 patients (Figure 3). In 8 cases (24%), preventive treatment was not discussed during the consultation. In all other 25 consultations, the physician raised the subject.

The main reason for not raising the subject was that the physician did not expect preventive treatment to have a positive effect on attack frequency or severity (Table 2). Other reasons were: attempt to optimize attack treatment first, try alternative treatment first (e.g. physiotherapy), and non-attendance at the follow-up consultation to start preventive treatment. The main reasons for not starting preventive treatment after having discussed the issue with the patient were that patients were content with their present treatment or were not sufficiently motivated for preventive treatment (Table 2).

In 4 cases the GP, after having checked the electronic patient record, reported that preventive treatment was discussed, whereas the patient reported that it was not discussed. This suggests recall bias among the patients. In 3 of these 4 cases, the GP reported not to have started preventive treatment because the patient did not want to use medication on a daily basis. In one case, the migraine attacks were not severe enough.

![Flowchart](https://example.com/flowchart.png)

**Figure 3.** Flowchart of questionnaires completed by the general practitioners (GPs) regarding 33 patients
DISCUSSION

Main results
Patients who did not start preventive treatment used less triptans per month compared with patients who started preventive treatment, whereas the two groups did not differ in HIT-6 score, attack frequency, and headache days per month. In addition, patients who did not start preventive treatment had a lower level of psychological distress, which may indicate that their coping with headaches was better and that their wellbeing was less influenced by headaches.
In almost 50% of patients with an indication for preventive treatment, this option was not discussed. When it was discussed, the decision to start actually preventive treatment was mainly influenced by patients’ attitudes towards medication in general, possible side-effects, and the impact of migraine on their daily life. The latter reason is noteworthy, because patients who did not start preventive treatment did not differ from patients who did in score on the HIT-6 questionnaire, attack frequency and headache days. Therefore, the decision regarding whether to start preventive treatment seems to depend more on how patients evaluate their condition than on objective measures.
The main reason for physicians not to discuss the option of preventive treatment was their low expectation of efficacy. When they did discuss preventive treatment, they were often confronted with barriers in the patients themselves.

Study limitations
First, the number of patients is relatively small because it was an explorative study within the setting of a trial. Therefore, we do not claim to give a complete overview of all issues that play a role in decisions on preventive medication. However, this is the first study to ask migraine patients about their reasons for not starting preventive treatment in a natural setting, rather than confronting them with a hypothetical situation.12,16
Second, the starting point for this pragmatic trial was the number of triptans used, rather than diagnosis of migraine headache. This could have led to the inclusion of participants that did not suffer from migraine headaches, or had a combination of different forms of headache for which preventive treatment was not appropriate.
Third, the results may be subject to recall bias. GPs and patients may have had difficulty in remembering the exact reasons for not starting preventive treatment.

Comparison with other studies
The present study shows that, in addition to migraine characteristics such as duration and frequency, and the impact of the migraine attacks on daily life, also fear of side-
effects and a negative attitude towards medication in general play a role in a patient’s decision about starting preventive treatment. This corresponds with earlier studies showing that important factors in the decision are effectiveness of an agent, general fear of new interventions on their health problem, fear of side-effects, drug dependency or fear of becoming a chronic patient, involvement in the decision-making process, and the physician taking the time to explain possible side-effects.\textsuperscript{17-20} Thus, the present study confirms earlier findings, but this time in a ‘real-life’ situation.

The main reason for physicians to discuss not even preventive treatment was their low expectation of efficacy. This corresponds with the findings in a focus group study with GPs that explored ideas, motives and expectations of GPs in relation to preventive treatment of migraine patients.\textsuperscript{21} In this study, the main reason for GPs not to start preventive treatment was barriers present in patients. Thus, the patient seems to play the main role in the decision to start or not to start. A study among patients at high risk for cardiovascular disease showed that their willingness to take preventive medication depended more on the mode of communication of treatment benefit than on their actual risk score or their level of concern about a future cardiovascular event.\textsuperscript{22}

**Implications for clinical practice**

In patients who seem good candidates for preventive treatment according to their attack frequency, the decision of the individual patient and their GP to start preventive treatment also depends on the impact of the headache attacks on their daily life and their negative attitude towards medication. However, in most guidelines on migraine treatment, as well as in (postgraduate) physician training and patient education, these aspects receive little attention. Therefore, these aspects should be addressed in order to rectify incorrect ideas and remove potential barriers, in both physicians and patients. In addition, as the decision seems to be influenced by the interaction with the GP, physicians should devote sufficient time to a shared decision-making process. Based on these results, we consider that GPs should pay more attention to exploring the attitudes of patients towards medication; providing adequate information about both positive and negative aspects may remove barriers and promote the option of possible effective preventive therapy.

**Conclusion**

The decision of the individual patient and their GP to start preventive treatment is not only determined by attack frequency, but also depends on the impact of the headache attacks on their daily life and their negative attitude towards medication.
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APPENDIX 1. PATIENT QUESTIONNAIRE

Question 1
Preventive therapy means that you take daily medication with the aim to reduce the number and/or severity of migraine attacks. Preventive therapy is not the medication you take when you have a migraine attack. Did you discuss the possibility of preventive therapy during the intervention consultation?
- Yes [to question 2]
- No [to question 3]

Question 2
Who initiated the discussion about preventive therapy?
- The patient (yourself) [to question 4]
- The general practitioner [to question 4]

Question 3
At the time of the consultation, were you familiar with the possibility of preventive therapy?
- Yes [to question 5]
- No [to question 6]

Question 4
You discussed the possibility of preventive therapy with your GP, but you did not start it. What was the reason(s) not to start? (multiple answers possible)
- Negative attitude towards drugs in general
- Possible adverse effects
- Migraine attacks not severe enough
- Attack treatment could be improved
- Influence of migraine on daily life acceptable
- Expected to forget to take preventive treatment
- Tried preventive treatment in the past
- Did not expect effect of preventive treatment on severity or frequency of attacks
- Did not expect to be able to function better
- Want to try other treatment first
- Makes me feel like I have a chronic illness
- GP objected to preventive treatment
- Otherwise, namely ....
Question 5
During the intervention consultation you did not ask after the possibility of preventive therapy, why did you decide not to bring up this subject? (multiple answers possible)
- Negative attitude towards drugs in general
- Possible adverse effects
- Migraine attacks not severe enough
- Attack treatment could be improved
- Influence of migraine on daily life acceptable
- Expected to forget to take preventive treatment
- Tried preventive treatment in the past
- Did not expect effect of preventive treatment on severity or frequency of attacks
- Did not expect to be able to function better
- Want to try other treatment first
- Makes me feel like I have a chronic illness
- I thought the GP should bring it up
- Otherwise, namely ….

Question 6
This is the end of the questionnaire. Do you have any other comments?
- Yes, namely ….
- No
APPENDIX 2. GP QUESTIONNAIRE

Question 1
Did you discuss the possibility of preventive therapy during the intervention consultation?
- Yes [to question 2]
- No [to question 4]

Question 2
Who initiated the discussion about preventive therapy?
- The GP (yourself)
- The patient

Question 3
You discussed the possibility of preventive therapy with the patient, but you did not start it. What was the reason(s) not to start? (multiple answers possible)
- Possible adverse effects
- Migraine attacks not severe enough
- Attack treatment could be improved
- Influence of migraine on daily life acceptable
- Expected the patient to forget to take preventive treatment
- Tried preventive treatment in the past
- Did not expect effect of preventive treatment on severity or frequency of attacks
- Did not expect the patient to be able to function better with preventive treatment
- I did not expect the patient to be willing to try preventive treatment
- I thought the patient should raise the subject of preventive treatment
- The patient had a contraindication for preventive treatment
- Otherwise, namely ….

Question 4
During the intervention consultation you did not ask after the possibility of preventive therapy, why did you decide not to bring up this subject? (multiple answers possible)
- Possible adverse effects
- Migraine attacks not severe enough
- Attack treatment could be improved
- Influence of migraine on daily life acceptable
- Expected the patient to forget to take preventive treatment
- Tried preventive treatment in the past
- Did not expect effect of preventive treatment on severity or frequency of attacks
- Did not expect the patient to be able to function better with preventive treatment
- The patient had a contraindication for preventive treatment
- Otherwise, namely ….

**Question 5**
This is the end of the questionnaire. Do you have any other comments?
- Yes, namely ….  
- No