Practical Experience with the Use of Electronic Headache Diaries and Video Consultations in Migraine Care from a Longitudinal Cohort Study

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Abstract

Background: *Telemedicine offers a promising solution to enhance the delivery and personalization of headache care. Integrating electronic (e-)tools enables the objective monitoring of migraine.*

Objectives: *This study aims to demonstrate the relevance of e-tools for personalized headache care, assess patient and caregiver compliance and satisfaction, and present their use in enhancing care.*

Methods: *Firstly, a systematic review was performed to validate the diagnostic accuracy of e-diaries for diagnosing migraine. Secondly, we collected e-diary data prospectively from diagnosed adult migraine patients at the Leiden Headache Center. Finally, questionnaires were sent to evaluate satisfaction of patients and health care providers with the Leiden e-headache diary and video consultations.*

Results: *In the systematic review, the Leiden Headache Center's e-diary was the only validated tool. Patients (*n *= 1,009) were followed for a median of 181 days (interquartile range [IQR] 84–240). Compliance was 96.4% (IQR 85.2 – 99.1%), with 10.8% of days missing. Factors positively associated with compliance were older age (*p *< 0.001), female sex (*p *< 0.001), higher e-diary grade (*p *< 0.001), and clinical use (*p *= 0.04). The e-diary received a median score of 8/10 and was well-liked by patients (*n *= 535) and providers (*n *= 23). Video consultations were a good alternative for physical visits according to 76.9% of patients and 84.6% of providers.*

Conclusion: *Validated e-headache diaries and video consultations in telemedicine enhance headache care accessibility, providing convenient care at preferred times and locations.*

Keywords: *migraine, headache, telemedicine, e-health, remote consultation, e-diary*

Introduction

Telemedicine presents a hopeful prospect for improving the provision and customization of headache treatment. It has the potential to improve access to health care services especially for those who live in underserved areas, have mobility limitations, or face other barriers to in-person care. It can enhance cost-effectiveness of health care delivery by reducing travel time and expenses, minimizing waiting times, and optimizing health care resources. Patients diagnosed with headache such as migraine are excellent candidates for the use of telemedicine as monitoring of treatment may take place trough collection of diary data on headache frequency. In addition, patient-reported outcomes may be collected. Through this approach, medical professionals can remotely provide assistance to a patient, taking into consideration their lifestyle and medication regimen, while simultaneously ensuring adherence to prescribed medication(s) and monitoring its impact on the headache.

In both clinical practice and research, there is often a need to quantify the frequency of migraine by determining the

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number of monthly migraine days (MMD), monthly headache days (MHD), and monthly acute medication days (MAMD). In an earlier study of our research group, we clearly demonstrated a recall bias between self-reported and actual-recorded MMD.[1,2] This emphasizes the necessity for a validated and easy-to-use daily headache diary in headache care. If an e-headache diary is not validated, there is a risk that the data collected may be unreliable, incomplete, or inaccurate, which could potentially lead to incorrect decision making and ineffective treatment strategies. This could have negative consequences for patient health outcomes.

The Leiden e-headache diary is time-locked and based on validated algorithms to determine whether a day is a (non)headache day, a migraine day, and/or an acute medication day.[1,3] In 2011, the Leiden Headache Center started web-based recruitment of participants with migraine using e-questionnaires.[4] Nowadays, the Leiden Headache e-tools include validated screening and extensive headache, and comorbidity questionnaires, and a daily e-headache diary, with the possibility to incorporate all e-tools in the same application that can be downloaded on a smartphone (Patient Journey App).[1,4] Although various commercial headache diaries have entered the market, it is concerning that many lack a robust scientific foundation and expertise.[5,6] The onset of the COVID-19 pandemic highlighted the utility of these e-tools ensuring the continuation of migraine care.[7] However, an exploration of their practical utility and acceptance in patient care remains unaddressed, which is an important aspect to evaluate when considering the incorporation of e-tools into routine patient care.

In this study, we will also outline current availability of validated e-tools. Our aim is to assess compliance to our e-headache diary and evaluate patients' and caregivers' satisfaction concerning telemedicine at our headache center.

Methods

As part of the Dutch headache treatment guideline for neurologists, a systematic review of the literature was performed in July 2022. The following question was assessed: What is the diagnostic accuracy of using e-diaries compared with a medical consultation in diagnosing migraine in patients?[8] The literature search was done on Medline and Embase. Search terms included migraine, diary, and intermethod comparison or sensitivity and specificity. The exact search terms can be found in Supplementary file S1. To be eligible for inclusion in this review, studies had to meet three criteria: (1) full text in English, (2) enrollment of ≥20 patients, and (3) address the following PICO: P: patients suspected of migraine; I: use of (validated) e-headache diaries; C: usual care/no use of e-diaries; O: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) on diagnosing migraine.

The Medical Ethics committee of the Leiden University Medical Center judged this study as not being associated with ethical concerns. Therefore, participants did not have to provide additional informed consent. We collected data from two sources: (1) patients diagnosed with migraine who received care at the Leiden Headache Center and were aged 18 years or older and (2) health care providers who treated headache patients at the Leiden Headache Center during the period from April 2022 to March 2023.[4] There were no other inclusion criteria. Patients had to use the e-headache diary imbedded in the Patient Journey App for a follow-up period of at least 2 weeks, after which they were invited to fill out a questionnaire on satisfactory with the e-diary and video consultations.[1,9] Patients could be using this e-diary for research or health care purposes or a combination of both. As part of their care for patients with headaches, health care providers utilized the e-diary and video consultation and were subsequently invited to complete a satisfaction questionnaire. All data were analyzed in a fully anonymized setting.

E-QUESTIONNAIRES AND E-DIARY DATA

Patients were followed prospectively between April 6, 2022 and March 12, 2023 with the previously validated e-questionnaires (screening questionnaire and additional more detailed migraine questionnaire) and the e-headache diary during ≥2 weeks (see *Fig. 1*).[1] Patients provided daily information about the presence of headache and its characteristics and accompanying symptoms, aura symptoms, and the use of acute (pain) medication. An underlying algorithm verified for each day whether it was a migraine day, a headache day, or a nonheadache day.[3,10] The e-diary was embedded in the Patient Journey App, and patients were encouraged to provide daily information via in-app notifications at 8 am and, if they have not responded, yet at 6 pm as well. An automated email was sent at 8 pm if the e-headache diary was not filled out yet. Patients could also opt for automated emails. The e-diary was time-locked, becoming inaccessible after 48 h. The information provided by patients was used to generate a visual overview, providing insight into the migraine course. The company that has developed the app used in our study is ISO27001 (information security) and ISO9001 (quality management) certified. In addition, they are NEN7510 certified (processing of medical data). The company and the app undergo privacy audits every 3 months, to ensure compliance with the European data protection regulations (GRPR). Access to personal data is role-based and only for health care professionals; researchers can only access the data after they are anonymized. Data were transported and stored encrypted in certified data centers, and access to patient data was role-

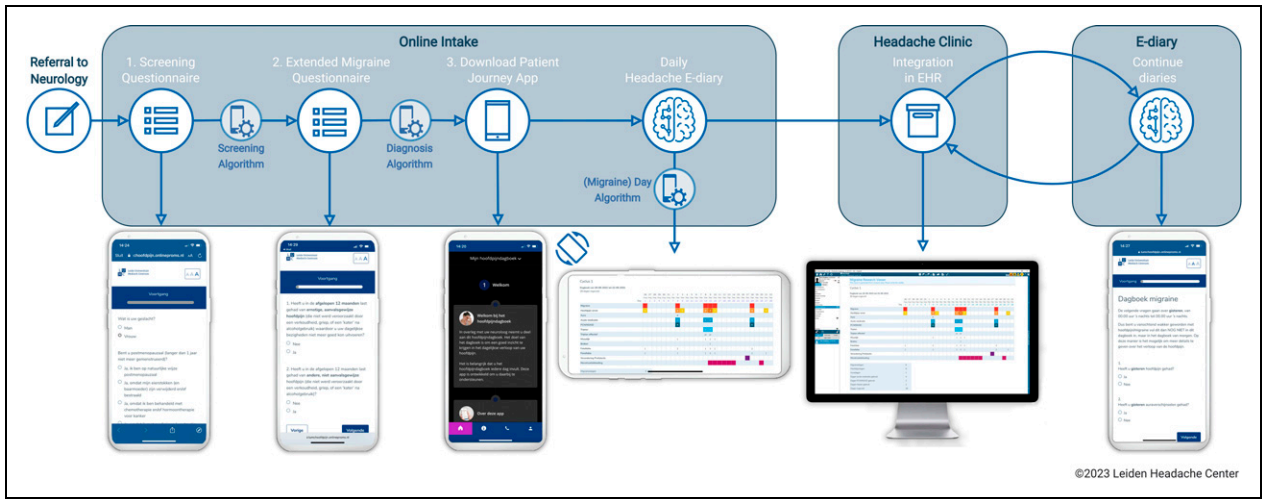

Fig. 1. Overview of telemedicine use after referral to the Leiden Headache Center. e-Diary, electronic diary; EHR, electronic health record.

based and for health care professionals only. Patients could access the app via a unique, personal code, and could enable an additional code or biometric access. The workflow that is used at the Leiden Headache Center is presented in *Fig. 1*.

PREDICTORS OF E-DIARY COMPLIANCE

We assessed the compliance of all patients using the e-diary and conducted a linear regression analysis to identify factors associated with compliance. Compliance, in this context, is quantified as the percentage of e-diary days completed by each individual, calculated as the ratio of completed days to the total days. Our predictors included age, sex, chronic migraine, e-diary grade, and purpose of e-diary use (clinical or research). According to the International Classification of Headache Disorders-3 criteria, chronic migraine requires three consecutive months of recorded migraine and headache days. However, for this linear regression analysis with compliance as the outcome, relying solely on e-diary data for chronic migraine diagnosis is not possible owing to potential missing days in the data. To address this, we used a retrospective report from an extended migraine questionnaire to gather self-reported information on migraine and headache days over 3 months. Self-reported data may be less reliable than daily e-diary recordings, but retrospective reports are commonly used in clinical settings when consecutive monthly data are not available.

PATIENT SATISFACTION

After 2 weeks of using the e-headache diary, patients with migraine received a questionnaire in the Patient Journey App to evaluate their experiences and satisfaction with the app. Patients were asked to grade the headache diary on a scale from 0 to 10 based on their overall experience (e-diary grade). The amount of information in the app was questioned by a labeled multiple-choice question with three options: not enough, exactly enough, and too much. A sliding scale (VAS 0–100) was used to evaluate to what extent the app helped to follow instructions by their physician, their satisfaction with the application, and the applications' user-friendliness.

HEALTH CARE PROVIDER SATISFACTION

In March 2023, a questionnaire was sent out to health care providers that regularly use(d) the e-headache diary for patient care at the Leiden Headache Center between April 2022 and March 2023. Health care providers completed the questionnaire on paper to ensure they were fully anonymized. The health care providers included neurologists, residents, and headache-nurses who had been working with telemedicine and the e-diary. Their experiences were evaluated in order to determine the benefit of an e-headache diary and video consultation in patient care. The same questions were used for patients to grade the e-headache diary, the amount of information in the e-diary, and the use of video consultation. However, the question regarding satisfaction applies to patient satisfaction. We asked health care providers how satisfied they think patients are with the headache diary. We used a five-point categorical scale to evaluate the effectiveness of the e-headache diary in providing instructions to patients, as well as their assessment of patients' satisfaction with the e-diary and the perceived user-friendliness of the e-diary.

SATISFACTION QUESTIONNAIRE ON VIDEO CONSULTATION

For this aspect of the study, patients who used the e-diary during the COVID-19 pandemic, between February 2020 and August 2022, were identified and included if they had a conformed diagnosis of migraine, aged 18 years or older and filled out the e-diary for at least 3 months with at least 80% compliance per month.[11] In July 2022, we administered a video consultation questionnaire to this cohort. This approach was used to ensure a good representation of patients at the Leiden Headache Center. The questionnaire aimed to assess experiences with video consultations as a substitute for physical visits. Specifically, patients were asked about their satisfaction with video consultation and whether they felt video consultation was a good alternative to physical visits. The same questions were included in the questionnaire that was sent out to health care providers.

DATA ANALYSIS

Baseline characteristics were described using descriptive statistics. For each characteristic, the mean and standard deviation (SD) was calculated for normally distributed variables, otherwise the median and interquartile range (IQR) was determined. In order to make all data comparable, data gathered by a sliding scale (0–100) in the one-time questionnaires were transformed to a five-point categorical scale.

We performed a chi-square test to analyze the frequency of e-diary completions on each weekday. Values of $p < 0.05$ were considered statistically significant. All analyses were performed in R version 4.2.1.

Results

The only validated study found in the literature search, which provided both PPV and NPV for an e-headache diary, was conducted on the e-diary created by the Leiden Headache Group.[1] The migraine screening approach consisting of the combination of the e-screening headache questionnaire and the e-diary has a sensitivity of 98%, specificity of 17%, PPV of 84%, and NPV of 68% for migraine. The approach including the combination of the e-screening questionnaire, the e-diary, and the e-extended migraine questionnaire had a sensitivity of 79%, specificity of 69%, PPV of 92%, and NPV of 43% for migraine (Supplementary Table S1). Similar screening approaches were used to assess reliability of aura diagnoses. Combining e-screening questionnaire and e-diary resulted in a sensitivity of 60%, specificity of 78%, PPV of 58%, and NPV of 80%. Combining it with the e-migraine extensive questionnaire as well led to a sensitivity of 39%, specificity of 98%, PPV of 84%, and NPV of 83% (Supplementary Table S2). For some other e-diaries, the psychometric construct of the diary was assessed (Supplementary Table S1).[8,12–14]

STUDY POPULATION

We identified 1,009 patients with migraine that were followed from April 2022 until March 2023. Patients used the e-diary as embedded in the Patient Journey App (Interactive Studios, The Netherlands). A total of 433 patients accessed the app through an Android device (42.9%) and 573 used an Apple device (57.1%). Of these 1,009 patients, 55 (5%) were excluded owing to a follow-up time of <2 weeks, leaving a representative group of 954 patients to which a one-time patient satisfaction questionnaire was sent. The response rate for this satisfaction questionnaire was 56% (535/954), resulting in a subgroup of 535 patients.

We randomly selected a representative sample of 54 patients who had undergone video consultations at the Leiden Headache Center. Among them, 52 out of 54 patients (96%) completed a satisfaction questionnaire regarding their recent video consultation experience. Baseline characteristics of the (sub)groups are shown in *Table 1*.

PREDICTORS OF E-DIARY COMPLIANCE

Median patient follow-up time was 181 (IQR 84–240) days in a total follow-up period of 340 days. Of the total 162,846 registered days, 10.8% were missing days. Median compliance was 96.4% (IQR 85.2–99.1%), visualized in *Fig. 2*. Of all patients, 755 (79.1%) achieved a compliance rate of ≥80%. Linear regression analysis showed that older age ($\beta = 0.20$, $p < 0.001$), female sex ($\beta = 2.61$, $p = 0.005$), a higher reported e-diary grade ($\beta = 2.62$, $p < 0.001$), and filling out the e-diary for clinical purposes ($\beta = 1.67$, $p = 0.04$) were all positively associated with compliance. A probable diagnosis of chronic migraine was not correlated with compliance ($p = 0.40$, Supplementary Table S2. Finally, the weekday of completion of the e-diary was similar across all days ($p = 1.00$).

PATIENT SATISFACTION

Among the 535 patients with migraine who responded to the patient questionnaire on satisfaction with the e-diary, 12 individuals (2.2%) did not complete this specific questionnaire and 3 patients (0.6%) were excluded as they had not yet started to use the e-diary. The remaining 520 patients rated their satisfaction with the e-diary with an overall median grade of 8 (IQR 7–8), as shown in *Fig. 3A*. In accordance, *Fig. 3B* shows that 66.7% (347/520) of patients reported being (very) satisfied with the e-diary. As for usefulness in helping patients follow their physicians' instructions, the majority of patients (68.8%, 358/520) rated the app neutral to (very) useful for

Table 1. Baseline Characteristics of the Study Population

	E-DIARY PATIENTS (TOTAL)	E-DIARY PATIENT QUESTIONNAIRE (SUBGROUP)	VIDEO CONSULTATION QUESTIONNAIRE	HEALTH CARE PROVIDERS
Number of participants, *n*	954	532	52	23
Years of age, mean ± SD	46 ± 13.0	49 ± 12.3	45 ± 13.6	[a]
Female sex, *n* (%)	760 (81.0)	418 (79.0)	46 (85.2)	[a]
Probable CM, *n* (%)	835 (42.9)	542 (44.5)	NA	NA
e-Diary compliance (%), median [IQR]	97 [90–99]	97 [89–99]	NA	NA
Clinical patients[b], *n* (%)	740 (78.7)	410 (77.4)	52 (100.0)	NA

[a]For all health care providers, questionnaire data were collected fully anonymously.

[b]Clinical patients are those who attended the outpatient headache clinic; the other patients participated in research of the Leiden Headache Center.

IQR, interquartile range; SD, standard deviation.

following up instructions (*Fig. 3C*). The general user-friendliness of the app is shown in *Fig. 3D*, with 85.0% (442/520) of patients reporting a (very) high user-friendliness. The majority of patients (75.2%, 391/520) found that the e-diary provided an adequate amount of information (*Fig. 3E*). The amount of push notifications was found to be adequate by 84.4% (439/520) (*Fig. 3F*).

HEALTH CARE PROVIDER SATISFACTION

The health care provider questionnaire was completed by 23/23 (100%) treating physicians and nurses who were involved in the care for headache patients at the Leiden University Medical Center. The 23 health care providers rated their satisfaction with the e-diary with an overall median grade of 8 (IQR 8–9) as shown in *Fig. 4A*. In accordance, *Fig. 4B* shows that all health care providers expected patients to be satisfied or very satisfied with the e-diary (satisfied: 19/23, 83%; very satisfied: 4/23, 17%). As for the app's usefulness in helping health care providers to give instructions to their patients, all health care providers found it (very) useful (high usefulness: 14/23, 61%; very high usefulness 9/23, 39%; *Fig. 4C*). The user-friendliness of the app is shown in *Fig. 4D*, with all health care providers reporting a (very) high user-friendliness (high user-friendliness: 12/23, 52%; very high user-friendliness: 11/23, 48%). The majority of health care providers (96%, 22/23) found that the e-diary provided an adequate amount of information (*Fig. 4E*).

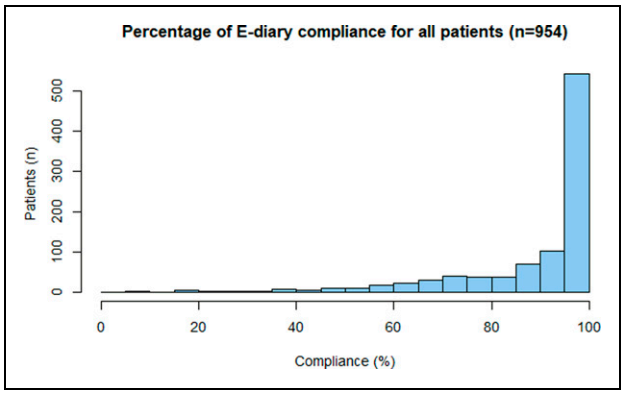

Fig. 2. The percentage of e-diary compliance for all patients with a minimum follow-up of 2 weeks ($n = 954$).

SATISFACTION QUESTIONNAIRE ON VIDEO CONSULTATION

Out of the 547 patients initially meeting the inclusion criteria, 336 patients (61.4%) responded to this questionnaire. Among the respondents, 52 patients (15%) reported having experience with video consultations during the specified period. *Fig. 5A* shows the satisfaction of the patients that used video consultation. Of all patients that completed this questionnaire, 76.9% (40/52) considered video consultation a good replacement for physical visits (*Fig. 5B*).

In total, 13/23 health care providers indicated to have experience with video consultation. *Fig. 5C* shows the satisfaction of health care providers who used video consultation, with 84.6% (11/13) considering it a good replacement for physical visits (*Fig. 5D*).

Discussion

We assessed compliance to our e-headache diary and evaluated patients' and caregivers' satisfaction concerning telemedicine. The e-diary is highly valued by patients and health care providers, with a score of 8/10 in both groups. The high median

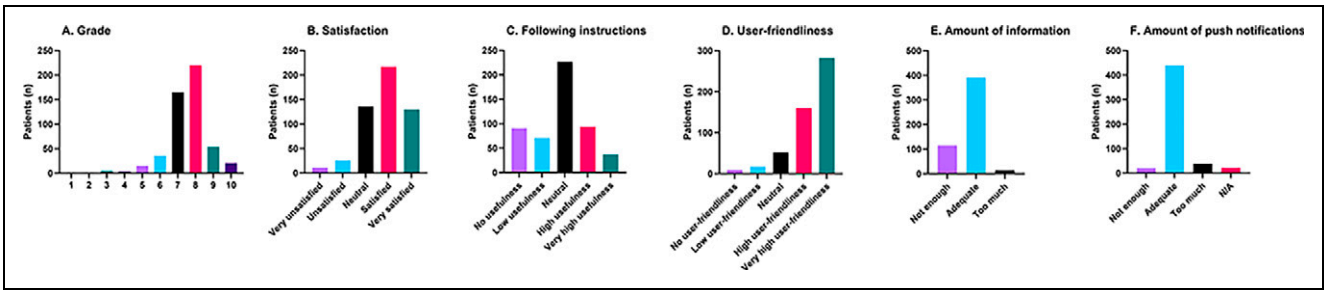

Fig. 3. Results of the patient satisfaction questionnaire on the e-headache diary (n = 520 patients).

compliance rate of 96.4% suggests that the e-diary is very well usable. In addition, it is a reliable tool as it reduces recall bias owing to the 48-hour time-lock. Notably, patients were equally committed to completing the e-diary throughout the week. The positive association between e-diary compliance and its usage in a clinical setting indicates that patients receiving care are more motivated. For patients who filled out the e-diary for research purposes, the inclusion of additional research-related questions may have resulted in an increased burden and lower compliance. Moreover, the integration of the app with treatment advice for patients renders greater advantages for e-diary compliance as compared with research participants. The majority of patients and health care providers found video consultations to be a good substitute for physical visits.

It is important to note that, like other digital care tools, an e-diary needs to undergo adequate validation to ensure its reliability and accuracy. We have found that the combination of questionnaires and e-diary has a high sensitivity and specificity for diagnosing migraine.[1] However, the sensitivity for aura diagnoses was only 39%, suggesting that for aura diagnoses, clinical assessment remains important. The flow at our clinic facilitates this by including final assessment by the treating neurologist or resident-in-neurology under supervision of a headache specialist.

This study might have a limitation related to potential selection bias, as patients in an academic headache center might be more motivated to participate in research and telemedicine than those in nonacademic centers. Through collaboration with other nonacademic Dutch hospitals that have successfully implemented the e-diary, we obtained firsthand knowledge about similar compliance and satisfaction rates (unpublished data), suggesting that this potential bias may not be of significant concern. Including all patients aged 18 years or older who received care at the Leiden Headache Center, our study adopted a broad inclusion criterion to ensure a good representation of the total population. As such, there were no additional selection criteria, minimizing potential sources of selection bias.

However, an observation worth noting is the slight disparity in compliance levels between responders and nonresponders to the satisfaction questionnaire, as indicated in *Table 1*. Respondents showed a slightly higher level of compliance with the e-diary, indicating a possible selection bias against patients who were more actively involved in using this electronic tool. It is essential to recognize that respondents may span a spectrum of motivations, making it challenging to definitively determine the impact of this bias on research results. Patients who expressed concerns, sought improvements, or expressed dissatisfaction may also have been more likely to participate in the questionnaire. Another limitation can be the relatively small population in the video consultation questionnaire, because many responders did not use this

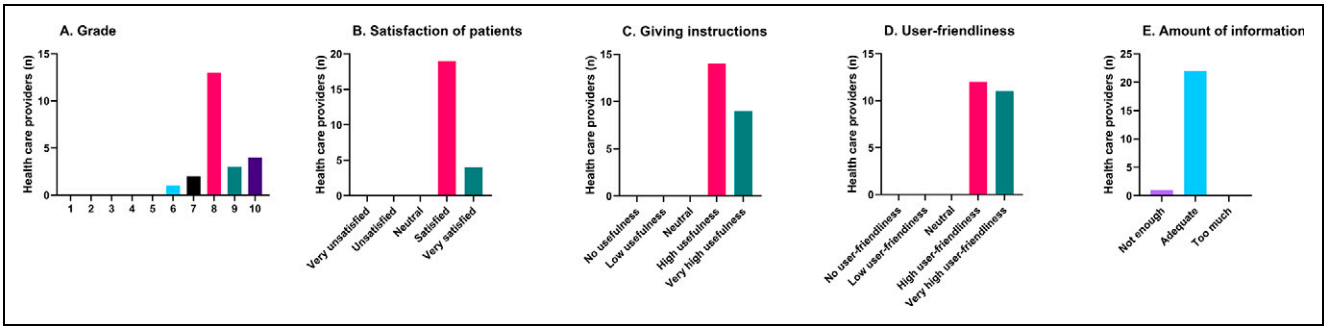

Fig. 4. Results of the health care provider satisfaction questionnaire on the e-headache diary (n = 23 health care providers).

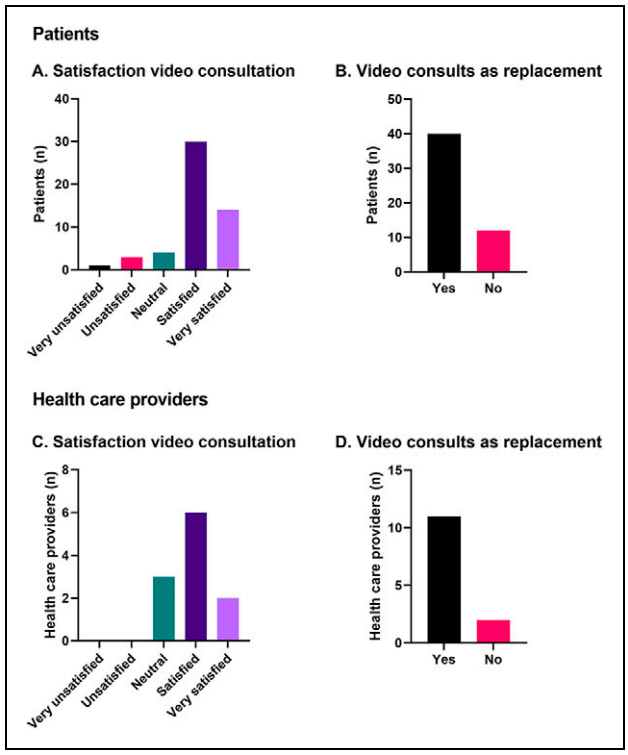

Fig. 5. Results of the video consultation questionnaire for health care providers and patients with migraine.

e-tool and, therefore, could not evaluate their satisfaction. A limitation of the e-diary is that it is currently only suitable for tension-type headache, migraine, and medication overuse headache, but not for trigeminal autonomic cephalalgias (TACs). However, this limitation can be addressed in future developments for e-diaries specifically designed for very short lasting and high frequent attacks such as cluster headache and other TACs.

This study also has several strengths, including the use of a large, well-defined migraine patient population. Moreover, the validated e-diary has demonstrated to be useful for monitoring sex-specific aspects of migraine and new therapeutic options for migraine, such as calcitonin gene-related peptide receptor monoclonal antibodies which are expensive and require adequate monitoring.[2,15–18] By using an e-headache diary, patients and health care providers can gain reliable insights into the effectiveness of these treatments, preventing the continuation of ineffective medication and thereby potentially reducing costs.[19] In this process, the e-diary also increases shared decision making. Thus, the e-diary represents a critical telemedicine tool for advancing health care and achieving financial benefits in new therapies.

Video consultations are increasingly used especially when in-person visits are not feasible. Both patients and health care providers valued video consultation, which is in line with previous research.[20] The most critical aspect of a consultation is the headache history, which can be obtained accurately through telemedicine.[21] Patients are able to monitor their symptoms and communicate specific concerns or questions during e-consultations and video consultations. We advise conducting an initial in-person consultation for a physical and neurological assessment.

It has been suggested that patients with greater disability might prefer care provided by a neurologist in person.[22,23] We did not find a difference in preference for chronic migraine patients in literature. Telemedicine can also be particularly beneficial for patients in rural areas, as it can improve cost and time efficiency.[24] The typical patients who benefit from telemedicine resembles patients with migraine: young, well-educated women.[23,25,26] Additionally, telemedicine can be especially useful when in-person visits are not possible owing to factors such as topography or a pandemic.[21]

Telemedicine with e-diaries can improve access to headache care and make it more convenient for patients to receive the care they need, when and where they need it. Its implementation in clinical practice is still limited owing to various barriers that physicians face that may include unfamiliarity, costs, and technical issues.[27] Academic centers should lead the way by setting an example and establishing the foundation for the rest of the field. Future research should establish whether telemedicine improves outcomes in routine clinical care, and further underpin its merits both as intervention and outcome in research settings.

Authors' Contributions

B.W.H.v.d.A., L.J.H., I.E.V., and G.M.T. contributed to conception and design of the study. B.W.H.v.d.A. and L.J.H. contributed to acquisition and analysis of data. B.W.H.v.d.A., L.J.H., and G.M.T. contributed to drafting a significant portion of the article. All authors contributed to the critical review of the article.

Disclosure Statement

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author, G.M.T., upon reasonable request.

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Supplementary Material

Supplementary file S1
Supplementary Table S1
Supplementary Table S2

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