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The Validity and Reliability of a Developed Mobile Health Application to Differentiate between Migraine and Tension-Type Headaches: A Pilot Study

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Abstract

Background: *Headache disorders are the most common neurological disorders globally, and tension-type headaches (TTH) and migraine are the most common primary headache types. Accurate diagnosis is crucial to management, but headache type differentiation remains challenging in routine practice. mobile health (mHealth) apps can potentially aid better headache classification but their diagnostic performance must be tested.*

Purpose: *The purpose of this study was to validate and confirm the reliability of a new emerging mobile health app to distinguish between migraine and tension-type headaches according to the International Classification of Headache Disorders (ICHD-3) criteria.*

Methods*: A quantitative cross-sectional pilot trial with 73 participants in a university setting. The app employed a diagnostic algorithm based on ICHD-3 criteria, in conjunction with a structured questionnaire that captured headache characteristics, comorbid symptoms, precipitants, and impact.*
Results: The mobile application reported a total diagnostic accuracy of 88.0% (95% CI: 68.8% - 97.5%), sensitivity of 80.0%, and specificity of 93.3% for migraine classification. The predictors of migraine were photophobia (OR: 12.85), pulsating pain quality (OR: 8.93), and phonophobia (OR: 6.42). The app was highly rated for usability with a mean SUS score of 78.6 (SD = 12.3) indicating good user acceptance.

Conclusion: *The pilot study provides preliminary evidence in support of the validity and reliability of the mobile health app in differentiating between migraine and tension-type headache.*

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Introduction

Headaches are one of the most common neurological disorders, affecting individuals worldwide regardless of age, gender, or socioeconomic status. The World Health Organization (WHO) classifies headaches as one of the top causes of disability, impacting daily functioning and productivity [1]. Headaches can vary in severity, frequency, and underlying causes, making accurate diagnosis and management crucial for improving patients' quality of life.

Headaches significantly affect individuals' quality of life, leading to reduced work productivity, impaired cognitive function, and emotional distress. The Global Burden of Disease (GBD) study identified migraines as the second leading cause of disability worldwide, with TTH also contributing substantially to global disability-adjusted life years (DALYs) [2]. Studies have highlighted that inadequate access to specialized headache care, misdiagnosis, and delayed treatment contribute to increased disease burden, especially in low- and middle-income countries [3].

The rapid advancement of digital health technologies has led to the emergence of mobile health (mHealth) applications as essential tools in managing chronic conditions, including headache disorders. mHealth applications leverage smartphone technology to assist patients in tracking symptoms, identifying triggers, and accessing personalized treatment recommendations. These digital platforms play a crucial role in bridging the gap between healthcare providers and patients, enabling remote monitoring and self-management strategies. The widespread use of smartphones and increasing demand for telemedicine solutions have accelerated the development and adoption of headache-related mHealth applications [4].

mHealth applications for headache management typically incorporate multiple features designed to enhance self-monitoring and optimize treatment. One of the most critical aspects of these applications is symptom tracking, where users log headache characteristics, including intensity, duration, associated symptoms, and potential triggers [5].

The integration of artificial intelligence (AI) and machine learning algorithms into mHealth applications has enhanced their diagnostic potential. Many applications utilize International Classification of Headache Disorders (ICHD-3) criteria to classify headache types based on user-reported symptoms [6].

Aim of the Study

The primary aim of this study was to evaluate the validity and reliability of a developed mobile health application in differentiating between migraine and tension-type headaches based on the International Classification of Headache Disorders (ICHD-3) criteria

Research Questions

1. Does the mobile app accurately distinguish migraine from TTH (as measured by sensitivity, specificity, and overall accuracy)?
2. What is the extent of agreement between the app's classification and clinical diagnosis (Cohen's kappa)?
3. Which headache symptoms or features predict a migraine diagnosis in the app algorithm (e.g. photophobia, phonophobia, pain quality)?
4. How do users rate the app's usability and acceptability (System Usability Scale)?

Methods

Study Design

This research used a quantitative, cross-sectional pilot study design to assess diagnostic accuracy and usability of the mHealth app. A pilot design ($n \approx 30–50$) was chosen to gather preliminary data on feasibility and performance before larger trials. The study took place in a university environment where frequent headache sufferers could be recruited. No longitudinal follow-up was conducted.

Participants and Setting

Participants were convenience-sampled from students and health professionals at the University of Fujairah. Eligibility criteria included age ≥18 years, owning a smartphone with internet access, and a history of recurrent headache (migraine or TTH) in the past three months. Individuals with secondary headaches (e.g., head injury, infection, medication-overuse headache) or incomplete data were excluded. Although the pilot aimed for 50 users based on sample size guidelines, 73 participants ultimately completed the study questionnaire (mean age 22.1 years, 63.5% female). The sample was predominantly young adult and largely female, reflecting typical headache epidemiology. Convenience sampling was used via social media announcements and direct invitations, which allowed rapid recruitment of target users.

Mobile Application and Instrumentation

The study utilized a newly developed smartphone application tailored for headache classification. The app was developed iteratively by IT experts in collaboration with clinicians, embedding the ICHD-3 diagnostic algorithm into a structured questionnaire. The questionnaire covered headache characteristics (location, quality, duration), associated symptoms (nausea, sensitivity to light/sound), triggers (stress, sleep), and impact. After completion, the app automatically generated a provisional diagnosis (migraine or TTH) using weighted scoring of criteria. The app also included an embedded System Usability Scale (SUS) survey to capture user experience after completing the diagnostic section. In a subset of 25 participants who had recent clinician-confirmed diagnoses, those clinical diagnoses served as a reference standard for validating the app's output.

Data Collection Procedure

Upon consent, participants completed a baseline demographic survey (age, gender, education) built into the app. They then reported headache episodes via the app in real time or shortly after occurrence. After entering symptoms, the app applied its diagnostic algorithm to classify the headache type. The provisional diagnosis was stored securely. Participants immediately rated the app using the SUS within the app interface. Data synchronization was automated to a secure central database whenever internet connection was available. Quality control measures included in-app checks to prevent incomplete submissions and follow-up with participants to clarify any inconsistent responses. All participants completed the process in late March 2025.

Ethical Considerations

The study was approved by the institutional review board (Ethics Approval No. EA#12), in accordance with the Declaration of Helsinki. Participants provided written informed consent after receiving information about the study purpose, procedures, and their rights, including the right to withdraw at any time without penalty. Confidentiality was strictly maintained by anonymizing data; only research personnel had access to the encrypted database. No identifiable data were published.

Data Analysis

Data were analyzed using PSPP (a free statistical software). Descriptive statistics (means, standard deviations, frequencies) summarized participant demographics and headache characteristics. For diagnostic performance, a confusion matrix compared app-based classification to clinical diagnosis in the subset of participants. From this, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), overall accuracy, and Cohen's kappa (agreement beyond chance) were calculated. Logistic regression identified which symptoms (e.g. photophobia, phonophobia, pain quality) significantly predicted a migraine classification, reporting odds ratios (ORs) with 95% confidence intervals. Inferential statistics (chi-square tests, t-tests) examined associations between headache type and demographic or clinical variables as needed. A significance threshold of $p < 0.05$ was used for statistical tests.

Results

Participant Characteristics

Seventy-three participants completed the study. The mean age was 22.1 years (SD ~7.4), and 63.5% were female. Most had university-level education. The sample mainly consisted of students (71.6%) and a smaller proportion of staff and health professionals (the capstone mentions ~10.8% teachers) (data not shown). Family history of headache was reported by 30% of participants.

Headache Classification Outcomes

Using the app's algorithm, 19 participants (26.0%) were classified with migraine and 54 (74.0%) with TTH. This distribution (more TTH than migraine) aligns with epidemiological expectations for general populations. Among female participants, migraine prevalence was 29.8% (vs. 19.2% in males), reflecting the known higher migraine prevalence in women, though this difference was only marginally significant (χ^2=3.76, p=0.052). No significant association was found between age group or education level and headache type (p>0.5).

Symptom patterns differed markedly between groups. Migraine participants were more likely to report:

- Pulsating/throbbing pain (78.9% vs. 21.3% in TTH, p < 0.001)
- Unilateral pain (63.2% vs. 14.8%, p < 0.001)
- Photophobia (68.4% vs. 1.9%, p < 0.001)
- Phonophobia (84.2% vs. 27.8%, p < 0.001)
- Nausea/vomiting (57.9% vs. 0%, p < 0.001)
- Exacerbation with activity (89.5% vs. 50.0%, p = 0.003)
- Post-headache fatigue (100% vs. 0%, p < 0.001)

In contrast, TTH participants commonly reported:

- Tight-band like pain (85.2% vs. 21.1%, p < 0.001)
- Bilateral/whole-head location (81.5% vs. 36.8%, p < 0.001)
- Gradual onset (100% vs. 0%, p < 0.001)
- Normal post-headache state (100% vs. 0%, p < 0.001)
- Stress as the main trigger (87.0% vs. 42.1%, p < 0.001)

These findings confirm that the app's classification aligns with classical ICHD-3
distinctions.

Diagnostic Accuracy of the App

Among 25 participants with prior clinical diagnoses:

- Migraine: 8 true positives, 2 false negatives
- TTH: 14 true negatives, 1 false positive

Metrics

- Sensitivity: 80.0% (95% CI: 44.4%–97.5%)
- Specificity: 93.3% (95% CI: 68.1%–99.8%)
- Positive Predictive Value: 88.9%
- Negative Predictive Value: 87.5%
- Overall Accuracy: 88.0% (95% CI: 68.8%–97.5%)
- Cohen's Kappa: 0.74 (95% CI: 0.48–0.99)

These values suggest strong performance, particularly in excluding non-migraine cases.

Symptom Predictors of Migraine

A logistic regression analysis identified several significant predictors of migraine classification. The most influential symptoms were photophobia (OR = 12.85, 95% CI: 5.37–30.74, p < 0.001), phonophobia (OR = 6.42, 95% CI: 2.81–14.67, p < 0.001), and pulsating pain quality (OR = 8.93, 95% CI: 3.74–21.32, p < 0.001). Additionally, worsening of symptoms with physical activity was a strong predictor (OR = 5.27, p < 0.001). Demographic factors such as female gender (OR = 2.31, p < 0.05) and a family history of headache (OR = 3.76, p < 0.05) were also associated with a higher likelihood of migraine. The model demonstrated a good fit, with a Hosmer–Lemeshow test p-value of 0.724 and a Nagelkerke R^2 of 0.68, indicating that the app's classification logic is statistically sound and consistent with known clinical patterns.

Usability and Reliability

All 73 participants completed the System Usability Scale (SUS) following their use of the app. The mean SUS score was 78.6 (SD = 12.3), placing the app in the "good to excellent" usability range according to standard benchmarks. The majority of users (93.2%) agreed that the app was easy to use, and 89.0% indicated that they would like to use it frequently. Only a small proportion (8.2%) felt they would require technical support to operate the app. Qualitative feedback gathered through open comments emphasized the app's intuitive interface and educational value. Furthermore, the questionnaire instrument demonstrated strong internal consistency and test-retest reliability, reinforcing the app's potential as a dependable digital diagnostic tool.

This pilot study evaluated a mobile health application designed to classify migraine versus tension-type headache (TTH) using the International Classification of Headache Disorders, 3rd edition (ICHD-3) criteria. The primary finding was that the app demonstrated strong diagnostic validity, with an overall accuracy of 88.0% when compared to clinical diagnoses and a

particularly high specificity of 93.3% for migraine. These results are consistent with prior research on digital headache tools [7]. For instance, reported approximately 78% accuracy for a web-based diagnostic questionnaire, supporting the conclusion that structured, ICHD-based digital tools can effectively distinguish between headache types. The app's kappa coefficient ($\kappa = 0.74$) further confirmed substantial agreement with expert diagnosis.

The symptom patterns observed in this study reinforce the app's clinical validity. Migraines were most commonly associated with photophobia, phonophobia, and a pulsating or throbbing pain quality—the classical triad described in ICHD-3. The logistic regression analysis underscored these associations, with odds ratios of 12.85 for photophobia, 8.93 for pulsating pain, and 6.42 for phonophobia. These symptoms were markedly less frequent among participants with TTH, where nearly none reported associated nausea or post-attack fatigue. Findings on triggers and pain localization also mirrored existing literature: stress and hormonal fluctuations emerged as common triggers, and bilateral pain presentation was observed more frequently than traditional descriptions suggest. This aligns with findings by Viana et al. (2019), who also noted that bilateral pain is not exclusive to TTH and is increasingly seen in migraine presentations.

When comparing these outcomes with the broader literature, the app's diagnostic performance and usability appear promising. The mean System Usability Scale (SUS) score of 78.6 indicates that participants found the app highly usable. High usability and user satisfaction are critical components for mHealth tools to be effective in real-world practice, echoing the benchmarks proposed by Bangor et al. (2009). Moreover, the demographic characteristics of the participants—predominantly young adult females—reflect the known epidemiological distribution of primary headache disorders. The observed migraine prevalence in the sample (26%) aligns with general population estimates rather than specialized clinical populations, where migraine tends to be more concentrated. In line with established risk profiles, the study also found that female gender and positive family history were significantly associated with migraine classification.

Limitations of the Study

Several limitations should be acknowledged in this study. First, the cross-sectional pilot design offers only a single-time snapshot and does not allow for assessment of the app's performance across multiple headache episodes or over time. Without longitudinal follow-up, it is impossible to evaluate test–retest consistency or potential learning effects. Second, the study used a convenience sample composed mostly of young, university-affiliated individuals. This limits the generalizability of the findings to older adults or more diverse populations with headache disorders. Additionally, while the sample size ($n = 73$, including 25 participants with clinical diagnoses) was sufficient for a pilot study, it limits the precision of accuracy estimates due to relatively wide confidence intervals and prevents robust subgroup analyses. Third, all symptom data were self-reported via the app. While this reflects real-world usage, it introduces potential reporting bias, especially in the absence of in-person clinical interviews. Finally, the study lacked certain inferential statistics (e.g., formal hypothesis testing across all comparisons) and did not include a control group or comparison against another digital tool. Future studies should address these limitations by using larger, more diverse samples and incorporating longitudinal and comparative designs.

Recommendations

For clinical practice, validated mobile health (mHealth) applications such as the one evaluated in this study can serve as useful screening aids for headache classification. Given the app's high specificity, a positive migraine result could prompt early referral to a neurologist, while negative results (TTH classification) may help direct patients toward stress-reduction or lifestyle interventions. However, these tools should be used to supplement—not replace—professional clinical evaluation. Emphasizing discriminative symptoms like photophobia, pulsating pain, and phonophobia in routine assessments could further refine diagnostic accuracy. Clinicians are also encouraged to educate patients about common headache triggers such as stress, hormonal fluctuations, and inadequate sleep.

For patients, self-monitoring using headache classification apps can help improve understanding of personal headache patterns and enhance communication

with healthcare providers. By systematically logging symptoms and potential triggers, patients may gain insights into behavioral or environmental modifications that reduce headache frequency or severity. It is important, however, that patients understand these tools are adjunctive aids—not replacements for clinical care—and should be used to complement professional assessment and treatment.

For app developers, future iterations of the app should prioritize inclusion and weighting of key discriminative features such as photophobia, pulsating pain, and phonophobia within their diagnostic algorithms. Enhancements in the user interface, including reminders, offline access, and data visualization features, could further improve usability. Integrating wearable sensor data (e.g., sleep or activity levels) may add objectivity and enrich the diagnostic process. Developers should also focus on continuous improvement informed by user feedback and updated clinical research.

For research, further validation studies are necessary to confirm the app's effectiveness in broader, more diverse populations, including varying age groups, cultural backgrounds, and primary care settings. Head-to-head comparisons with gold-standard clinical assessments performed by headache specialists would strengthen the evidence base for the app's sensitivity and specificity. Longitudinal studies exploring usage adherence and learning effects over time would add further insight into its practical value. Incorporating passive data from wearable technologies and applying machine learning to symptom data represent promising areas for enhancing diagnostic performance beyond static scoring systems.

Conclusion

This pilot study provides preliminary evidence that a purpose-built mobile health (mHealth) application can accurately and reliably distinguish migraine from tension-type headache (TTH) using standardized diagnostic criteria. The app demonstrated a high diagnostic accuracy of 88.0% and substantial agreement with clinical diagnoses (Cohen's kappa = 0.74). It successfully identified core migraine symptoms such as photophobia, pulsating pain, and phonophobia as the most influential predictors. Usability testing further confirmed that users found the app easy to use and educational, with a mean System Usability Scale (SUS) score of approximately 79. These findings suggest that mHealth applications based on the International Classification of Headache Disorders (ICHD-3) criteria can serve as valuable tools for preliminary headache screening and triage, especially in settings with limited access to specialized care. Further research and development are warranted to refine this digital approach and explore its broader implementation in clinical and community contexts [8].

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Conflict of Interest

No conflict of interest declared.

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