RESEARCH PAPER

Impact of a Mobile Health Application on Patient-Centered Outcomes in Migraine: A Comparative Study

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ABSTRACT

Background: Migraine is a common and disabling neurological disorder that significantly affects quality of life and daily functioning. Traditional headache diaries have limitations in accurate documentation and long-term monitoring. Mobile health (mHealth) applications offer a potential solution by enabling real-time tracking, improving patient engagement, and supporting clinical decision-making. The MIGRAINEMASTER application was developed as a digital tool to enhance migraine monitoring and management.

Aim: To evaluate the effectiveness of the MIGRAINEMASTER mobile application as an adjunct to standard prophylactic therapy in reducing migraine-related disability.

Methods: This study included 100 patients diagnosed with migraine, who were divided into two groups: an intervention group using the MIGRAINEMASTER application along with standard prophylactic therapy, and a control group receiving standard therapy alone. Baseline demographic and clinical characteristics were comparable between groups. Outcomes assessed over a period of 3 months included headache frequency, pain severity (VAS), migraine-related disability (MIDAS), headache impact (HIT-6), medication adherence, trigger identification, quality of life, patient satisfaction, and hospitalization. Statistical analysis was performed using independent t-test and Chi-square test, with a p-value <0.05 considered statistically significant.

Results: There was no statistically significant difference between the intervention and control groups in headache frequency ($p = 0.880$), mean pain scores (VAS) ($p = 0.311$), or migraine-related disability (MIDAS) ($p = 0.526$). However, significant improvements were observed in headache impact as measured by HIT-6 ($p < 0.05$), trigger identification ($p = 0.016$), medication adherence ($p < 0.001$), quality of life ($p < 0.001$), patient satisfaction ($p = 0.005$), and reduction in hospitalization ($p = 0.041$) in the intervention group compared to the control group.

Conclusion: The MIGRAINEMASTER application did not result in a statistically significant reduction in migraine-related disability, headache frequency, or mean pain scores over a 3-month period. However, it significantly improved patient adherence, trigger identification, quality of life, patient satisfaction, and headache impact, indicating its role as an effective supportive tool in migraine management. Further studies with longer follow-up and incorporation of standardized assessment tools are required to evaluate long-term clinical benefits.

Keywords: Migraine, Mobile health, mHealth, MIGRAINEMASTER, Headache impact, Medication adherence, Quality of life, Patient satisfaction

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INTRODUCTION

Migraine is a common primary headache disorder characterized by recurrent episodes of moderate to severe headache, often associated with nausea, vomiting, photophobia, and phonophobia. It is a major cause of neurological disability worldwide.

According to the International Classification of Headache Disorders, 3rd edition (ICHD-3), migraine presents as recurrent attacks lasting 4–72 hours, typically unilateral, pulsatile, and aggravated by routine physical activity. It may occur with or without aura, and attack frequency varies from occasional episodes to chronic migraine, defined as headache occurring on more than 15 days per month. Migraine affects approximately 12–15% of the population and is more common in women. It predominantly affects individuals during their productive years, leading to reduced quality of life and impaired daily functioning.

The clinical presentation varies among individuals. Some patients experience prodromal symptoms such as fatigue, mood changes, and neck discomfort, while others may develop aura, consisting of transient visual, sensory, or speech disturbances.

Accurate monitoring of migraine is essential for effective management. Patients are often advised to

maintain a headache diary to record details of headache episodes, associated symptoms, medication use, and triggering factors. Common triggers include stress, sleep disturbances, hormonal changes, dietary factors, and environmental stimuli. Traditional paper-based diaries have limitations such as recall bias and poor compliance. Digital tools offer improved accuracy and ease of use for real-time data recording.

The "MIGRAINEMASTER" application is designed to facilitate systematic recording of migraine episodes, including headache characteristics, trigger identification, and treatment response using the MIDAS score, thereby aiding in better clinical management.

METHODOLOGY

STUDY DESIGN: This study was a hospital-based, single-centre, prospective, randomized parallel-group comparative study conducted to evaluate the effectiveness of the "MIGRAINEMASTER" mobile application in improving migraine monitoring, identification of triggers, treatment adherence, and assessment of migraine-related disability among patients with migraine.

The study also compared clinical outcomes, frequency of migraine episodes, and disability scores between patients using the MIGRAINEMASTER mobile application and those receiving conventional follow-up care.

STUDY SETTING: The hospital-based study was conducted in the Department of General Medicine/Neurology at Saveetha Medical College and Hospital, SIMATS, Chennai, Tamil Nadu, India.

STUDY POPULATION: The study population comprised patients diagnosed with migraine and initiated on prophylaxis with Propranolol 10 mg twice daily attending the outpatient and inpatient services of the Department of General Medicine/Neurology who satisfied the inclusion criteria and provided informed written consent.

Inclusion criteria:

1. Age 18–60 years
2. Confirmed diagnosis of migraine (as per clinical criteria)
3. Candidates for prophylactic therapy
4. Willing to provide informed consent
5. Owning a smartphone compatible with the application
6. Ability to read and understand the language of the application – To ensure accurate symptom recording.

Exclusion criteria:

1. Serious comorbid medical or psychiatric conditions that could interfere with follow-up or study outcomes.
2. Pregnancy or lactation
3. Patients already using another structured migraine tracking application
4. Unwilling for follow-up

STUDY PERIOD: The study was carried out after obtaining approval from IRB (Ethical and Scientific Clearance).

- Period of data collection: 3 months
- Follow-up duration per participant: 3 months
- Period for data analysis and interpretation: 2 months

Each participant was followed up for 3 months to monitor migraine episodes, treatment adherence, trigger identification, and changes in migraine-related disability.

SAMPLE SIZE: The final sample size for the present study was 100 patients, divided into two groups:

- 50 patients using the "MIGRAINEMASTER" mobile application and Standard prophylaxis (Intervention group)
- 50 patients receiving conventional Standard prophylaxis alone (Control group) Intervention

Participants in the intervention group used the MIGRAINEMASTER mobile application as part of their routine migraine care.

The application was developed to assist patients in systematic recording of migraine episodes, identification of triggers, monitoring treatment response, and assessment of migraine-related disability.

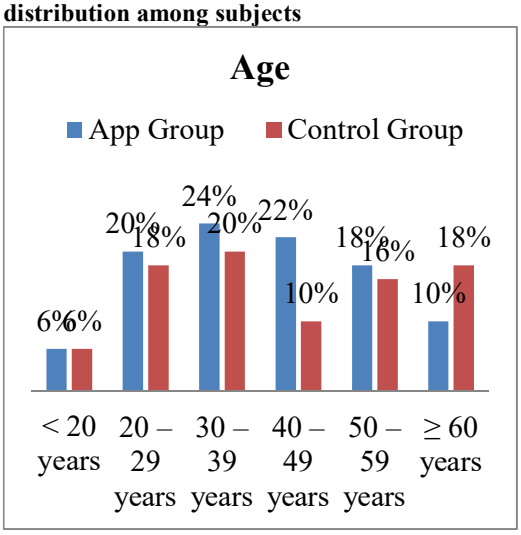
RESULTS

The present study included a total of 100 patients with migraine, who were divided equally into two groups: the intervention group using the MIGRAINEMASTER mobile application along with standard prophylactic therapy, and the control group receiving standard prophylactic therapy alone. Baseline demographic and clinical characteristics, including age, gender, migraine type, duration of illness, headache frequency, pain severity, and disability scores, were analyzed to ensure comparability between the two groups. The outcomes assessed included changes in headache frequency, pain intensity, migraine-related disability (MIDAS and HIT-6 scores), treatment adherence, quality of life, trigger identification, patient satisfaction, and healthcare utilization. Statistical analysis was performed to compare these parameters between the two groups, and a p-value of less than 0.05 was considered statistically significant.

Table 1: Distribution of subjects according to age

Age	App Group n (%)	Control Group n (%)	Total n (%)
< 20 years	3 (6%)	3 (6%)	**6 (6%)**
20 – 29 years	10 (20%)	9 (18%)	**19 (19%)**
30 – 39 years	12 (24%)	10 (20%)	**22 (22%)**
40 – 49 years	11 (22%)	11 (10%)	**22 (22%)**
50 – 59 years	9 (18%)	8 (16%)	**17 (17%)**
≥ 60 years	5 (10%)	9 (18%)	**14 (14%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	1.436	**p-value**	0.920
Mean age(years)	**40.1 ± 13.28**	**41.6 ± 14.77**	**40.9 ± 13.99**
t-value	-0.527	**p-value**	0.599

Figure 1: Columndiagram showing age distribution among subjects



The age distribution of study participants was comparable between the intervention (app) group and the control group. The majority of participants in both groups were in the 30–39 years and 40–49 years age categories, indicating that migraine was more prevalent in the middle-aged population.

The proportion of participants across different age groups did not differ significantly between the two groups. The Chi-square test ($\chi^2 = 1.436$, $p = 0.920$) showed that there was no statistically significant association between age distribution and study group, suggesting that both groups were well matched in terms of age.

The mean age in the app group was 40.1 ± 13.28 years, while in the control group it was 41.6 ± 14.77 years. The difference in mean age between the two groups was not statistically significant ($t = -0.527$, $p = 0.599$).

These findings indicate that the two groups were comparable with respect to age, and age is unlikely to have influenced the study outcomes. This baseline similarity enhances the validity of comparisons made between the intervention and control groups in subsequent analyses.

Table 2: Distribution of subjects according to gender

Gender	App Group n (%)	Control Group n (%)	Total n (%)
Males	32 (64%)	24 (48%)	**56 (56%)**
Females	18 (36%)	26 (52%)	**44 (44%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	2.597	**p-value**	0.107

Figure 2: Column diagram showing gender distribution among subjects

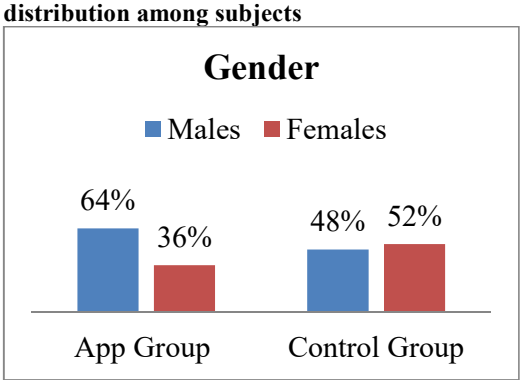


Table 2 shows the distribution of study participants according to gender in the App group and Control group. In the present study, a total of 100 patients were included, among whom 56% were males and 44% were females, indicating a slight male predominance in the study population.

In the App group, males constituted 64%, while females accounted for 36%. In contrast, in the Control group, males comprised 48% and females 52%. Although there appears to be a higher proportion of males in the App group and females in the Control group, the overall gender distribution between the two groups was relatively comparable.

The Chi-square test revealed no statistically significant association between gender distribution and study groups ($\chi^2 = 2.597$, $p = 0.107$), indicating that the observed difference was not statistically significant.

These findings suggest that both groups were comparable in terms of gender at baseline, and gender is unlikely to act as a confounding factor in the assessment of study outcomes.

Overall, the gender distribution reflects a reasonably balanced representation of both sexes. The comparability between groups enhances the internal validity of the study and supports an unbiased comparison of outcomes between the intervention and control groups.

Table 3: Distribution of subjects according to Migraine type

Migraine type	App Group n (%)	Control Group n (%)	Total n (%)

With aura	24 (48%)	25 (50%)	**49 (49%)**
Without aura	26 (52%)	25 (50%)	**51 (51%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	0.040	**p-value**	0.841

Figure 3: Bardiagram showing migraine type distribution among subjects

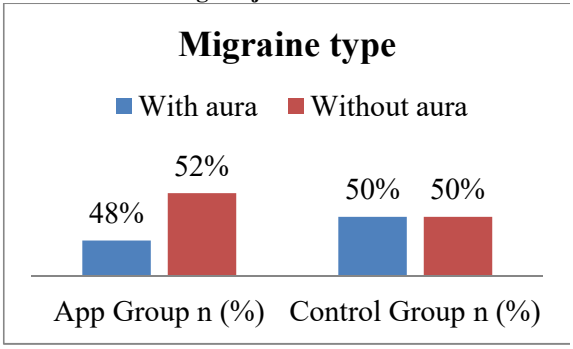


Table 3 shows the distribution of study participants according to migraine type in the App group and Control group. In the present study, a total of 100 patients were included, among whom 49% had migraine with aura and 51% had migraine without aura, indicating a nearly equal distribution of migraine types in the study population. In the App group, 48% of patients had migraine with aura, while 52% had migraine without aura. Similarly, in the Control group, 50% had migraine with aura and 50% had migraine without aura. The distribution of migraine types between the two groups was therefore almost identical. The Chi-square test revealed no statistically significant association between migraine type and study groups ($\chi^2 = 0.040$, $p = 0.841$), indicating that the difference observed between the groups was not statistically significant. These findings suggest that both groups were comparable in terms of migraine type at baseline, and migraine subtype is unlikely to act as a confounding factor in the assessment of study outcomes. Overall, the balanced distribution of migraine types between the two groups enhances the internal validity of the study.

Table 4: Distribution of subjects according to durationofmigraine

Duration ofmigraine (years)	**App Group n (%)**	**Control Group n (%)**	**Total n (%)**
≤ 5	17 (34%)	10 (20%)	**27 (27%)**
6 to 10	19 (38%)	16 (32%)	**35 (35%)**
11 to 15	14 (28%)	24 (48%)	**38 (38%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**

χ^2 value	4.704	**p-value**	0.095
Mean (years)	**7.4 ± 3.74**	**9.1 ± 4.02**	**8.3 ± 3.95**
t-value	-2.152	**p-value**	0.056

Figure 4: Column diagram showing duration of migraine distribution among subjects

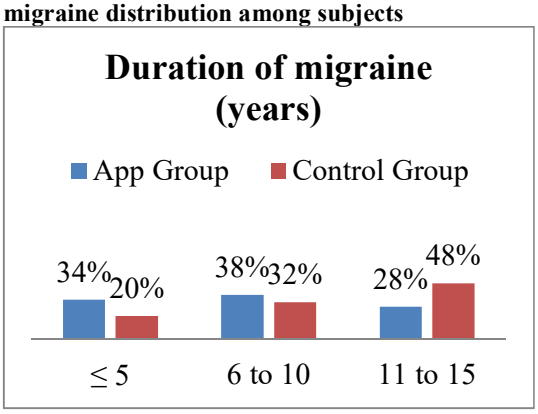


Table 4 shows the distribution of study participants according to the duration of migraine in the App group and Control group. In the present study, the majority of participants had a longer duration of migraine, with 38% having 11–15 years of illness, followed by 35% with 6–10 years and 27% with ≤5 years.

In the App group, 34% of patients had migraine duration ≤5 years, 38% had 6–10 years, and 28% had 11–15 years. In contrast, in the Control group, a higher proportion of patients (48%) had a longer duration of migraine (11–15 years), while 32% had 6–10 years and 20% had ≤5 years. This suggests a relatively longer disease duration among participants in the control group.

However, the Chi-square test showed no statistically significant association between duration of migraine and study groups ($\chi^2 = 4.704$, $p = 0.095$), indicating that the categorical distribution was comparable between the two groups.

The mean duration of migraine was 7.4 ± 3.74 years in the App group and 9.1 ± 4.02 years in the Control group, with the control group having a slightly longer duration. Although this difference showed a trend toward significance, it did not reach statistical significance ($t = -2.152$, $p = 0.056$).

These findings suggest that both groups were largely comparable in terms of duration of migraine at baseline, although the control group tended to have a slightly longer duration of illness. Since the difference was not statistically significant, duration of migraine is unlikely to have significantly influenced the study outcomes.

Table 5: Distribution of subjects according to headache frequency at baseline

Headache frequency at baseline (per month)	App Group n (%)	Control Group n (%)	Total n (%)
<4	0 (0%)	0 (0%)	**0 (0%)**
4to7	16 (32%)	8 (16%)	**24 (24%)**
8to 11	10 (20%)	13 (26%)	**23 (42%)**
12to 15	12 (24%)	17 (34%)	**29 (29%)**
> 15	12 (24%)	12 (24%)	**24 (24%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	3.920	**p-value**	0.270
Mean	**10.9 ± 4.84**	**12.1 ± 4.21**	**11.5 ± 4.55**
t-value	-1.234	**p-value**	0.220

Figure 5: Column diagram showing headache frequency at baselinedistribution among subjects

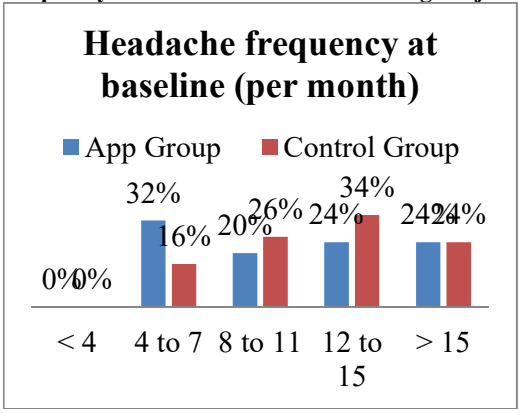


Table 5 shows the distribution of study participants according to headache frequency at baseline in the App group and Control group. In the present study, the majority of participants had moderate to high headache frequency, with a considerable proportion experiencing ≥12 headache days per month.

In the App group, 32% of patients had 4–7 headache days, 20% had 8–11 days, 24% had 12–15 days, and 24% had more than 15 headache days per month. In the Control group, 16% had 4–7 days, 26% had 8–11 days, 34% had 12–15 days, and 24% had more than 15 days per month. This indicates a slightly higher proportion of patients with more frequent headaches in the control group.

However, the Chi-square test revealed no statistically significant association between baseline headache frequency and study groups ($\chi^2 = 3.920$, $p = 0.270$), indicating that the categorical distribution was comparable between the two groups.

The mean headache frequency was 10.9 ± 4.84 days per month in the App group and 12.1 ± 4.21 days per month in the Control group. Although the control group showed a slightly higher mean frequency, the difference was not statistically significant ($t = -1.234$, $p = 0.220$).

These findings suggest that both groups were comparable in terms of baseline headache frequency, and this variable is unlikely to have influenced the study outcomes. The similarity between groups strengthens the validity of subsequent comparisons of treatment effects.

Table 6: Distribution of subjects according to Headache frequency at follow-up

Headache frequency at 3 months follow-up(per month)	App Group n (%)	Control Group n (%)	Total n (%)
< 4	5 (10%)	6 (12%)	**11 (11%)**
4to 7	14 (28%)	15 (30%)	**29 (29%)**
8to 11	12 (24%)	9 (18%)	**21 (21%)**
12to 15	16 (32%)	12 (24%)	**28 (28%)**
> 15	3 (6%)	8 (16%)	**11 (11%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	3.398	**p-value**	0.494
Mean	**9.5 ± 4.39**	**9.6 ± 4.81**	**9.6 ± 4.59**
t-value	-0.152	**p-value**	0.880

Figure 6: Column diagram showing Headache frequency at 3 months follow-up frequency distribution among subjects

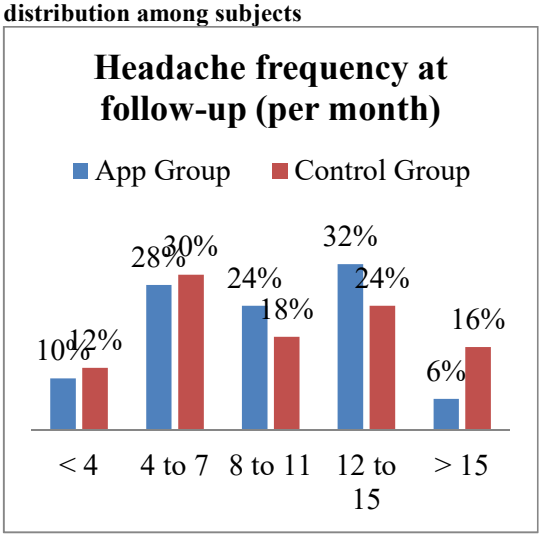


Table 6 shows the distribution of study participants according to headache frequency at 3 months follow-up in the App group and Control group. At

follow-up, both groups demonstrated a spread across different frequency categories, with most participants falling within the 4–15 headache days per month range.

In the App group, 10% of patients had <4 headache days, 28% had 4–7 days, 24% had 8–11 days, 32% had 12–15 days, and 6% had >15 headache days per month. In the Control group, 12% had <4 days, 30% had 4–7 days, 18% had 8–11 days, 24% had 12–15 days, and 16% had >15 headache days per month. Although a slightly higher proportion of patients in the control group had very frequent headaches (>15 days), the overall distribution between groups remained comparable.

The Chi-square test showed no statistically significant association between headache frequency at 3 months and study groups ($\chi^2 = 3.398$, $p = 0.494$), indicating similar categorical distribution.

The mean headache frequency was 9.5 ± 4.39 days per month in the App group and 9.6 ± 4.81 days per month in the Control group, showing nearly identical values. The difference between the groups was not statistically significant (t = -0.152, p = 0.880).

These findings indicate that there was no significant difference in headache frequency between the two groups at follow-up. Both groups demonstrated similar outcomes, suggesting that the intervention did not result in a statistically significant reduction in headache frequency over the study period.

Table 7: Distribution of subjects according to headache-related disabilitymeasured by the Migraine Disability Assessment (MIDAS) questionnaireat Baseline

MIDAS questionnaire(score) at Baseline	App Group n (%)	Control Group n (%)	Total n (%)
Little or no disability (0–5)	0 (0%)	0 (0%)	**0 (0%)**
Mild disability (6–10)	1 (2%)	3 (6%)	**4 (4%)**
Moderate disability (11–20)	6 (12%)	4 (8%)	**10 (10%)**
Severe disability (21+)	43 (86%)	43 (86%)	**86 (86%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	1.400	**p-value**	0.497
Mean MIDAS questionnairescore	**42.2 ± 18.62**	**42.6 ± 18.28**	**42.4 ± 18.36**
t-value	-0.103	**p-value**	0.918

Figure 7: Column diagram showing headache-related disabilitymeasured by MIDAS questionnaireat Baseline distribution among subjects

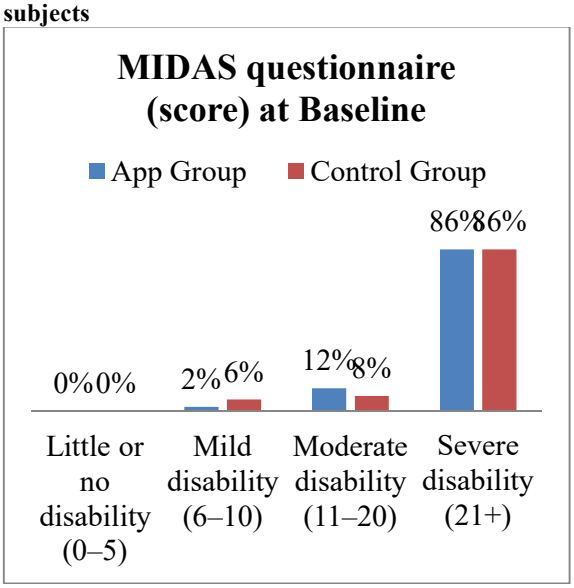


Table 7 shows the distribution of study participants according to headache-related disability measured by the Migraine Disability Assessment (MIDAS) questionnaire at baseline in the App group and Control group. In the present study, the majority of participants in both groups had severe disability, indicating a high burden of migraine at baseline.

In the App group, 86% of patients had severe disability (MIDAS ≥21), while 12% had moderate disability and only 2% had mild disability. Similarly, in the Control group, 86% of patients had severe disability, with 8% having moderate disability and 6% having mild disability. No participants in either group had little or no disability.

The Chi-square test revealed no statistically significant association between MIDAS categories and study groups ($\chi^2 = 1.400$, $p = 0.497$), indicating that the distribution of disability levels was comparable between the two groups at baseline.

The mean MIDAS score was 42.2 ± 18.62 in the App group and 42.6 ± 18.28 in the Control group, showing nearly identical values. The difference between the groups was not statistically significant (t = -0.103, p = 0.918).

These findings suggest that both groups were comparable in terms of migraine-related disability at baseline, with the majority of patients experiencing severe disability. This baseline similarity ensures that any differences observed during follow-up can be attributed to the intervention rather than pre-existing differences in disease severity.

Table 8: Distribution of subjects according to headache-related disabilitymeasured by the Migraine Disability Assessment (MIDAS) questionnaireat follow-up

MIDAS questionnaire(score) at follow-up	App Group n (%)	Control Group n (%)	Total n (%)
Little or no disability (0–5)	1 (2%)	1 (2%)	**2 (2%)**
Mild disability (6–10)	7 (14%)	3 (6%)	**10 (10%)**
Moderate disability (11–20)	9 (18%)	9 (18%)	**18 (18%)**
Severe disability (21+)	33 (66%)	37 (74%)	**70 (70%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	1.829	**p-value**	0.609
Mean MIDAS questionnairescore	**31.1 ± 16.27**	**33.1 ± 15.44**	**32.1 ± 15.81**
t-value	-0.637	**p-value**	0.526

Figure 8: Column diagram showing headache-related disabilitymeasured by MIDAS questionnaireat follow-updistribution among subjects

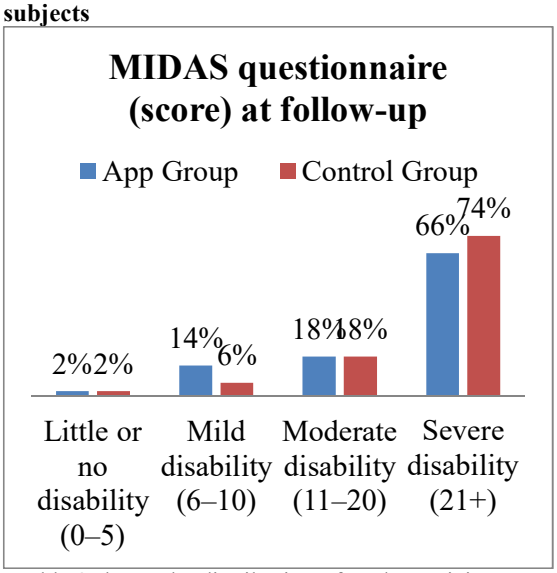


Table 8 shows the distribution of study participants according to headache-related disability measured by the Migraine Disability Assessment (MIDAS) questionnaire at follow-up in the App group and Control group. Compared to baseline, there was an overall reduction in disability levels in both groups, although severe disability remained the most common category.

In the App group, 66% of patients had severe disability, 18% had moderate disability, 14% had mild disability, and 2% had little or no disability. In the Control group, 74% had severe disability, 18% had moderate disability, 6% had mild disability, and 2% had little or no disability. A slightly higher proportion of patients in the App group shifted toward lower disability categories compared to the Control group.

However, the Chi-square test showed no statistically significant association between MIDAS categories and study groups at follow-up (χ^2 = 1.829, p = 0.609), indicating that the categorical distribution of disability was comparable between the two groups.

The mean MIDAS score was 31.1 ± 16.27 in the App group and 33.1 ± 15.44 in the Control group. Although the App group demonstrated a lower mean score, suggesting reduced disability, the difference was not statistically significant (t = -0.637, p = 0.526).

These findings indicate that while there was a trend toward improvement in migraine-related disability in the intervention group, the difference between the groups at follow-up was not statistically significant. Both groups showed some reduction in disability, suggesting an overall improvement over time, but the additional benefit of the MIGRAINEMASTER application did not reach statistical significance in this outcome.

Table 9: Distribution of subjects according to Visual Analogue Scale (VAS) for painat Baseline

Pain (VAS) at Baseline	App Group n (%)	Control Group n (%)	Total n (%)
No pain (0)	0 (0%)	0 (0%)	**0 (0%)**
Mild pain (1to 3)	0 (0%)	0 (0%)	**0 (0%)**
Moderate tosevere pain (4to 6)	23 (46%)	28 (56%)	**51 (51%)**
Verysevere pain (7to 9)	27 (54%)	22 (44%)	**49 (49%)**
Worstpainpossible(10)	0 (0%)	0 (0%)	**0 (0%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	1.000	**p-value**	0.317
Mean VAS	**6.5 ± 1.66**	**6.3 ± 1.84**	**6.4 ± 1.75**
t-value	0.514	**p-value**	0.609

Figure 9: Column diagram showing VAS for painat Baseline distribution among subjects

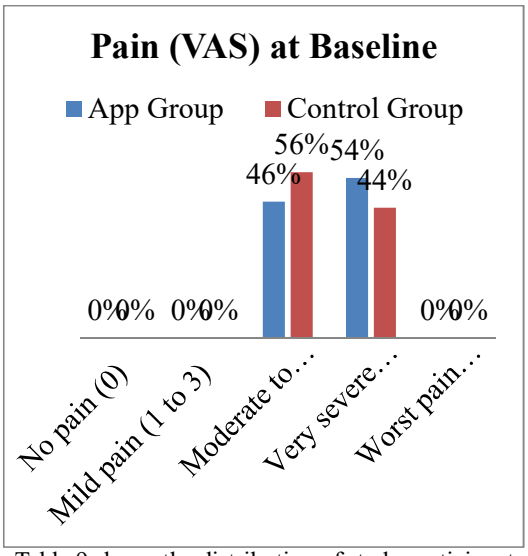


Table 9 shows the distribution of study participants according to pain severity measured by the Visual Analogue Scale (VAS) at baseline in the App group and Control group. In the present study, all participants experienced moderate to very severe pain, indicating a high level of pain burden at baseline. In the App group, 46% of patients reported moderate to severe pain (VAS 4–6), while 54% reported very severe pain (VAS 7–9). Similarly, in the Control group, 56% had moderate to severe pain and 44% had very severe pain. No participants in either group reported mild pain or absence of pain at baseline.

The Chi-square test revealed no statistically significant association between pain severity categories and study groups ($\chi^2 = 1.000$, $p = 0.317$), indicating that the distribution of pain severity was comparable between the two groups. The mean VAS score was 6.5 ± 1.66 in the App group and 6.3 ± 1.84 in the Control group, showing similar levels of pain intensity. The difference between the groups was not statistically significant ($t = 0.514$, $p = 0.609$).

These findings suggest that both groups were comparable in terms of baseline pain severity, with all participants experiencing moderate to very severe pain. This baseline similarity ensures that subsequent changes in pain scores can be attributed to the intervention rather than pre-existing differences between the groups.

Table 10: Distribution according to Visual Analogue Scale (VAS) for painat follow-up

Pain (VAS)at follow-up	**App Group n (%)**	**Control Group n (%)**	**Total n (%)**
No pain (0)	0 (0%)	0 (0%)	**0 (0%)**
Mild pain (1to 3)	14 (28%)	14 (28%)	**28 (28%)**
Moderate tosevere pain (4to 6)	17 (34%)	27 (54%)	**44 (44%)**
Verysevere pain (7to 9)	19 (38%)	9 (18%)	**28 (28%)**
Worstpainpossible(10)	0 (0%)	0 (0%)	**0 (0%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	**5.844**	**p-value**	**0.044**
Mean VAS	**5.2 ± 2.11**	**4.8 ± 1.81**	**5.0 ± 1.96**
t-value	1.018	**p-value**	0.311

Figure 10: Column diagram showing VAS for painat follow-updistribution

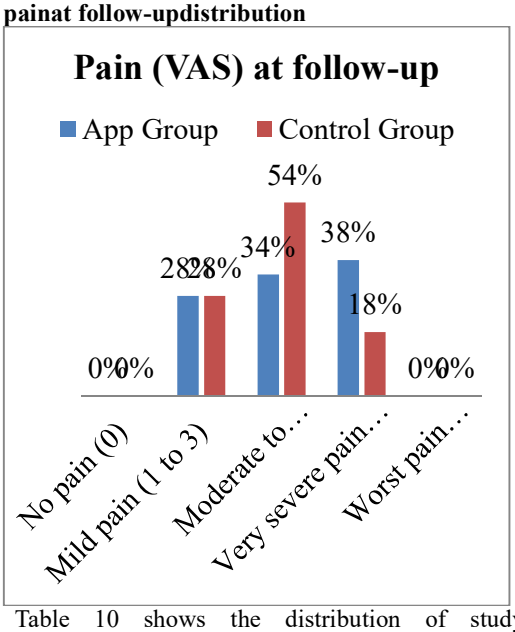


Table 10 shows the distribution of study participants according to pain severity measured by the Visual Analogue Scale (VAS) at follow-up in the App group and Control group. Compared to baseline, there was an overall shift toward lower pain categories, indicating improvement in both groups.

In the App group, 28% of patients reported mild pain, 34% had moderate to severe pain, and 38% had very severe pain. In the Control group, 28% had mild pain, 54% had moderate to severe pain, and 18% had very severe pain. Notably, a higher proportion of patients in the control group remained in the moderate pain category, while the App group showed a more distributed pattern across categories.

The Chi-square test revealed a statistically significant association between VAS pain categories and study groups ($\chi^2 = 5.844$, $p = 0.044$), indicating that the distribution of pain severity differed

significantly between the two groups at follow-up.However, when comparing the mean VAS scores, the App group had a mean score of 5.2 ± 2.11, while the Control group had 4.8 ± 1.81. This difference was not statistically significant (t = 1.018, p = 0.311).

These findings suggest that although there was a significant difference in the categorical distribution of pain severity between the groups, the overall mean pain scores were comparable. This indicates that while the intervention may have influenced the distribution of pain levels, it did not result in a statistically significant reduction in average pain intensity compared to the control group.

Table 11: Distribution of subjects according toTrigger Identification

Trigger Identified	App Group n (%)	Control Group n (%)	Total n (%)
Yes	32 (64%)	20 (40%)	**52 (52%)**
No	18 (36%)	30 (60%)	**48 (48%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	**5.770**	**p-value**	**0.016**

Figure 11: Column diagram showing Trigger Identificationdistribution among subjects

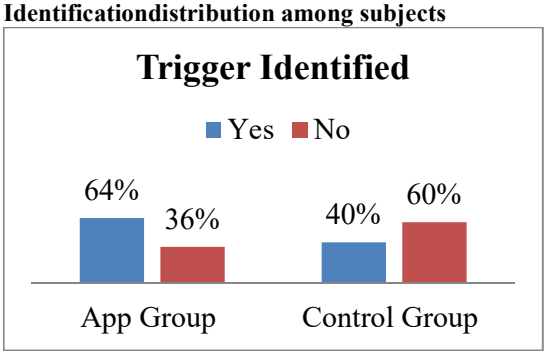


Table 11 shows the distribution of study participants according to trigger identification in the App group and Control group. In the present study, 52% of participants were able to identify migraine triggers, while 48% were unable to do so.

In the App group, 64% of patients identified triggers, whereas 36% did not. In contrast, in the Control group, only 40% of patients identified triggers, while a higher proportion (60%) were unable to identify triggers. This indicates better trigger recognition among patients using the MIGRAINEMASTER application.

The Chi-square test revealed a statistically significant association between trigger identification and study groups (χ^2 = 5.770, p = 0.016), indicating that the difference observed between the groups was statistically significant.

These findings suggest that patients in the intervention group were significantly more likely to identify migraine triggers compared to those in the control group. This highlights the effectiveness of the MIGRAINEMASTER application in improving patient awareness and facilitating better self-monitoring of migraine triggers, which is an important component of migraine management.

Table 12:Comparison of Medication Adherence Between Intervention and Control Groups

Variable	Group	N	Mean ± SD	Mean Difference	t-value	p-value
Medication Adherence (%)	**App Group**	50	**82.4 ± 10.50**	14.2	6.010	**<0.001**
	Control Group	50	**68.2 ± 12.80**			

Table 12 shows the comparison of medication adherence between the App group and Control group. In the present study, patients in the intervention group demonstrated higher medication adherence compared to those in the control group.

The mean medication adherence in the App group was 82.4 ± 10.50%, whereas in the Control group it was 68.2 ± 12.80%, indicating a substantial difference between the two groups.

The difference in adherence between the groups was 14.2% higher in the intervention group, and this difference was found to be statistically highly significant (t = 6.010, p < 0.001).

These findings suggest that the use of the MIGRAINEMASTER mobile application significantly improved medication adherence among patients with migraine. Enhanced adherence in the intervention group highlights the effectiveness of digital health tools in promoting better compliance with prescribed therapy, which is crucial for optimal disease management and improved clinical outcomes.

Table 13: Distribution of subjects according to headache severity based on the Headache Impact Test (HIT-6 score)

Headache severity (HIT-6 score)	App Group n (%)	Control Group n (%)	Total n (%)
Little or No Impact (≤49)	15 (30%)	10 (20%)	**25 (25%)**
Some Impact (50–55)	11 (22%)	6 (12%)	**15 (15%)**

Substantial Impact (56–59)	7 (14%)	4 (8%)	**11 (11%)**
Severe Impact (≥60)	17 (34%)	30 (60%)	**47 (47%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	**8.200**	**p-value**	**0.042**
Mean HIT-6score	**60.7 ± 11.62**	**63.1 ± 12.34**	**62.7 ± 11.81**
t-value	-1.371	**p-value**	**0.046**

Figure 12: Column diagram showing headache severity based onHIT-6 score distribution

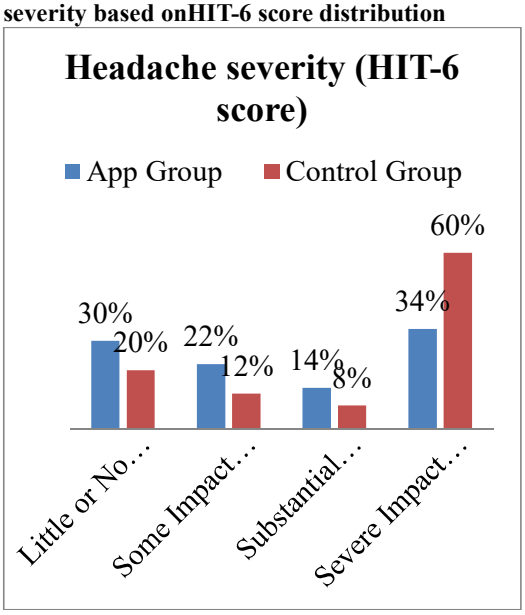


Table 13 shows the distribution of study participants according to headache severity based on the Headache Impact Test (HIT-6 score) in the App group and Control group. In the present study, a considerable proportion of participants experienced severe headache impact, although differences were observed between the two groups.

In the App group, 30% of patients had little or no impact, 22% had some impact, 14% had substantial impact, and 34% had severe impact. In contrast, in the Control group, only 20% had little or no impact, 12% had some impact, 8% had substantial impact, while a higher proportion (60%) had severe impact. This indicates that patients in the intervention group had relatively lower headache-related disability compared to the control group.

The Chi-square test revealed a statistically significant association between HIT-6 categories and study groups ($\chi^2 = 8.200$, $p = 0.042$), indicating that the distribution of headache severity differed significantly between the two groups.

The mean HIT-6 score was 60.7 ± 11.62 in the App group and 63.1 ± 12.34 in the Control group, with the intervention group showing a lower mean score. This difference was also found to be statistically significant ($t = -1.371$, $p = 0.046$).

These findings suggest that patients using the MIGRAINEMASTER application experienced significantly lower headache impact compared to the control group. The results highlight the effectiveness of the application in reducing headache-related disability and improving patient quality of life.

Table 14:Comparison of Quality of Life (QoL) Scores Between Intervention and Control Groups

Variable	Group	N	Mean ± SD	Mean Difference	t-value	p-value
QoL Score	**App Group**	50	**74.8 ± 16.20**	12.7	3.350	**<0.001**
	Control Group	50	**62.1 ± 18.51**			

Table 14 shows the comparison of quality of life (QoL) scores between the App group and Control group. In the present study, patients in the intervention group demonstrated better quality of life compared to those in the control group.

The mean QoL score in the App group was 74.8 ± 16.20, whereas in the Control group it was 62.1 ± 18.51, indicating a noticeable difference between the two groups.

The mean difference of 12.7 points reflects a clinically meaningful improvement in quality of life among patients using the MIGRAINEMASTER application. This difference was found to be statistically highly significant ($t = 3.350$, $p < 0.001$).

These findings suggest that the use of the MIGRAINEMASTER mobile application significantly improved the quality of life of patients with migraine. The improved QoL scores in the intervention group highlight the positive impact of digital health tools in enhancing overall patient well-being and functional status."

Table 15: Distribution of subjects according toPatient Satisfaction

Patient Satisfaction	App Group n (%)	Control Group n (%)	Total n (%)
High	25 (50%)	10 (20%)	**35 (35%)**
Moderate	17 (34%)	20 (40%)	**37 (37%)**
Low	8 (16%)	20 (40%)	**28 (28%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	**10.520**	**p-value**	**0.005**

Figure 13: Column diagram showing Patient Satisfactiondistribution among subjects

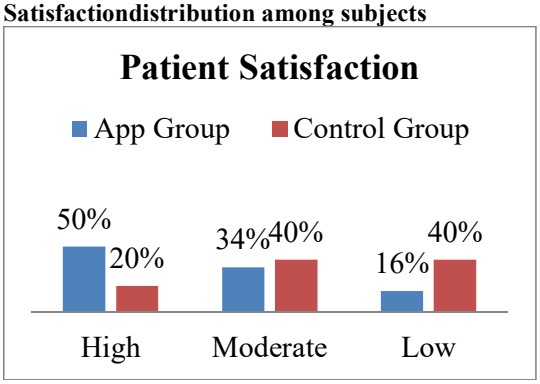


Table 15 shows the distribution of study participants according to patient satisfaction in the App group and Control group. In the present study, a higher proportion of patients in the intervention group reported greater satisfaction compared to the control group.

In the App group, 50% of patients reported high satisfaction, 34% reported moderate satisfaction, and only 16% reported low satisfaction. In contrast, in the Control group, only 20% reported high satisfaction, while a larger proportion reported moderate (40%) and low satisfaction (40%). This indicates that patients using the MIGRAINEMASTER application experienced better overall satisfaction with their care.The Chi-square test revealed a statistically significant association between patient satisfaction and study groups ($\chi^2 = 10.520$, $p = 0.005$), indicating that the difference observed between the groups was statistically significant. These findings suggest that the use of the MIGRAINEMASTER application significantly improved patient satisfaction. Higher satisfaction levels in the intervention group highlight the effectiveness of the application in enhancing patient engagement, ease of monitoring, and overall experience of care.

Table 16: Distribution of subjects according toHospitalization

Hospitalization	**App Group n (%)**	**Control Group n (%)**	**Total n (%)**
Yes	15 (30%)	25 (50%)	**60 (60%)**
No	35 (70%)	25 (50%)	**40 (40%)**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**
χ^2 value	**4.170**	**p-value**	**0.041**

Figure 14: Column diagram showing Hospitalizationdistribution among subjects

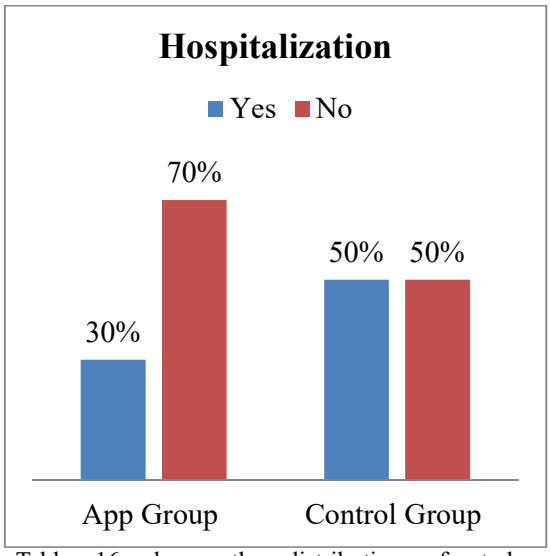


Table 16 shows the distribution of study participants according to hospitalization in the App group and Control group. In the present study, a lower proportion of patients in the intervention group required hospitalization compared to the control group.

In the App group, 30% of patients were hospitalized, while a majority (70%) did not require hospitalization. In contrast, in the Control group, 50% of patients required hospitalization, and 50% did not. This indicates a higher rate of hospitalization among patients receiving conventional care compared to those using the MIGRAINEMASTER application.

The Chi-square test revealed a statistically significant association between hospitalization and study groups ($\chi^2 = 4.170$, $p = 0.041$), indicating that the difference observed between the groups was statistically significant.

These findings suggest that the use of the MIGRAINEMASTER application was associated with a significant reduction in hospitalization rates. This highlights the potential role of digital health tools in improving disease monitoring, early intervention, and reducing healthcare utilization among patients with migraine.

DISCUSSION

The present study was conducted to evaluate the effectiveness of the MIGRAINEMASTER mobile application as an adjunct to standard prophylactic therapy in improving migraine-related outcomes. The study demonstrated that digital health interventions can significantly enhance patient engagement, adherence, trigger identification, quality of life, and healthcare utilization, while their impact on certain clinical parameters such as headache frequency and MIDAS scores may require longer follow-up for significant changes.

Baseline Characteristics and Comparability of Groups

In the present study, the baseline demographic and clinical characteristics of the participants were carefully analyzed to ensure comparability between the intervention (MIGRAINEMASTER app) and control groups. Variables assessed included age, gender, migraine type, duration of illness, baseline headache frequency, pain severity (VAS), and migraine-related disability (MIDAS score). Statistical analysis demonstrated that there were no significant differences between the two groups across all baseline parameters ($p > 0.05$), indicating that the study population was homogenous at baseline.

Demographic Comparability

The age distribution and mean age of participants were similar between the two groups, with the majority of patients belonging to the middle-aged population (30–49 years). Gender distribution also showed no statistically significant difference, with a relatively balanced representation of males and females across both groups. This demographic comparability is important, as age and gender are known to influence migraine patterns, frequency, and treatment response.

Clinical Comparability

Clinical characteristics, including migraine type (with aura vs without aura), were almost equally distributed between the groups, ensuring that both groups had similar disease profiles. Additionally, the duration of migraine illness, although slightly higher in the control group, did not show a statistically significant difference. This suggests that chronicity of disease was comparable and unlikely to bias the outcomes.

Baseline headache frequency and pain severity (VAS scores) were also similar between the two groups, with most patients experiencing moderate to severe migraine burden. Furthermore, MIDAS scores at baseline indicated that the majority of patients in both groups had severe disability, reflecting a high disease burden and ensuring that both groups started at a similar level of clinical severity.

Implications for Internal Validity

The absence of statistically significant differences in baseline variables confirms that the randomization and group allocation were effective, resulting in two comparable cohorts. This is crucial in minimizing selection bias and confounding factors, thereby strengthening the internal validity of the study. As both groups were equivalent at baseline, any differences observed in follow-up outcomes can be more confidently attributed to the intervention rather than underlying differences.

Comparison with Previous Literature

The importance of baseline comparability has been emphasized in prior studies evaluating digital interventions in migraine. The SMARTGEM trial [61] highlighted that equal distribution of baseline demographic and clinical characteristics is essential for accurately assessing the efficacy of smartphone-based migraine therapies. Similarly, systematic evaluations of digital health interventions have consistently reported that balanced baseline characteristics are fundamental for ensuring unbiased outcome assessment and reliable interpretation of results [26,61].

Thus, the present study successfully established baseline equivalence between the intervention and control groups, providing a strong methodological foundation for subsequent comparisons. This comparability enhances the credibility of the findings and supports the conclusion that observed improvements in outcomes such as adherence, trigger identification, quality of life, and patient satisfaction are attributable to the use of the MIGRAINEMASTER application rather than pre-existing differences between groups.

Headache Frequency and Clinical Outcomes

In the present study, headache frequency was assessed both at baseline and at 3 months follow-up to evaluate the clinical effectiveness of the MIGRAINEMASTER application. At baseline, both the intervention and control groups were comparable in terms of headache frequency, with no statistically significant difference observed ($p > 0.05$). The majority of patients in both groups experienced moderate to high frequency of headaches, indicating a substantial disease burden at the start of the study.

Changes in Headache Frequency Over Time

At follow-up, a reduction in headache frequency was observed in both groups, suggesting an overall improvement in clinical status with standard prophylactic therapy. The mean headache frequency decreased from 10.9 ± 4.84 to 9.5 ± 4.39 days/month in the App group, and from 12.1 ± 4.21 to 9.6 ± 4.81 days/month in the Control group.

However, when comparing the two groups, the difference in headache frequency at follow-up was not statistically significant ($p = 0.880$). Similarly, categorical distribution across headache frequency ranges did not show a significant association between groups ($p = 0.494$).

These findings indicate that while both groups showed improvement over time, the addition of the MIGRAINEMASTER application did not result in a statistically significant reduction in headache frequency compared to standard care alone within the study duration.

Several factors may explain this observation:

- The short follow-up duration may not be sufficient to demonstrate measurable changes in headache frequency
- Migraine frequency is influenced by multiple biological, behavioral, and environmental factors, which may require longer-term interventions
- The application primarily focuses on monitoring, awareness, and behavioral modification, which may have a delayed impact on frequency

These findings are consistent with the systematic review by Minen et al. [26], which reported that although electronic and behavioral interventions for migraine show promising results, their effect on reducing headache frequency is often inconsistent and may not reach statistical significance in short-term studies.

Similarly, the SMARTGEM study [61] emphasized that digital migraine interventions are more effective in improving patient engagement, symptom tracking, and behavioral outcomes, while reductions in headache frequency may require longer intervention periods and integration with structured therapeutic strategies.

Furthermore, studies evaluating mobile health applications have suggested that the primary benefit of such tools lies in enhancing self-management and adherence, rather than producing immediate reductions in clinical parameters such as headache frequency [26,58].

The lack of a statistically significant difference does not necessarily indicate lack of effectiveness, but rather suggests that:

- Digital tools may serve as adjuncts rather than replacements for pharmacological therapy
- Their benefits may be more evident in long-term outcomes and functional improvements

Thus, while the MIGRAINEMASTER application did not demonstrate a statistically significant reduction in headache frequency within the study period, it contributed to overall clinical improvement in both groups. These findings support the concept that digital health interventions play a supportive role in migraine management, with greater impact on behavioral and patient-centered outcomes rather than immediate changes in headache frequency.

Migraine-Related Disability (MIDAS)

Migraine-related disability was assessed using the Migraine Disability Assessment (MIDAS) questionnaire at baseline and at 3 months follow-up. MIDAS is a validated tool that reflects the impact of migraine on daily activities, including work, household responsibilities, and social functioning.

Baseline Disability Status

At baseline, the majority of patients in both groups had severe disability (86%), with very few patients in the mild or moderate categories. The distribution of MIDAS categories and the mean MIDAS scores were comparable between the App and Control groups, with no statistically significant difference ($p > 0.05$).

This indicates that both groups had a high and comparable disease burden at the start of the study, ensuring that subsequent changes could be attributed to the intervention rather than baseline differences.

Changes at Follow-up

At follow-up, there was an overall reduction in MIDAS scores in both groups, reflecting improvement in migraine-related disability over time.

- The mean MIDAS score decreased from 42.2 ± 18.62 to 31.1 ± 16.27 in the App group
- In the Control group, it decreased from 42.6 ± 18.28 to 33.1 ± 15.44

Although the reduction was numerically greater in the intervention group, the difference between the groups was not statistically significant ($p = 0.526$).

Similarly, the categorical distribution showed a slight shift toward lower disability categories in the App group, but this was also not statistically significant ($p = 0.609$).

These findings suggest that both groups experienced improvement in migraine-related disability, likely due to standard prophylactic therapy and regular follow-up. However, the addition of the MIGRAINEMASTER application did not result in a statistically significant additional reduction in MIDAS scores within the study duration.

Possible explanations include:

- Short duration of follow-up, which may not be sufficient to capture meaningful changes
- High baseline severity, with most patients in the severe category, limiting the extent of measurable improvement
- Disability improvement requires long-term behavioral adaptation, which may take longer to manifest

The findings are consistent with the systematic review by Minen et al. [26], which reported that electronic behavioral interventions can improve migraine-related disability, but such improvements are often gradual and may not reach statistical significance in short-term studies.

Similarly, the SMARTGEM study [61] emphasized that digital migraine applications are more effective in improving self-management, adherence, and patient engagement, while changes in disability scores may require longer duration and sustained usage.In addition, usability studies such as RELAXaHEAD[38] have shown that while digital tools enhance patient awareness and monitoring, the

translation of these benefits into measurable reductions in disability may be delayed.

The reduction in MIDAS scores observed in both groups indicates that:

- Standard treatment is effective in reducing migraine-related disability
- Digital tools may act as supportive interventions that enhance long-term outcomes
- The benefits of applications like MIGRAINEMASTER may become more evident with extended follow-up and continued use

Although the MIGRAINEMASTER application did not demonstrate a statistically significant reduction in MIDAS scores compared to the control group, it showed a trend toward improved disability outcomes. These findings suggest that digital health interventions may have a progressive and cumulative effect on migraine-related disability, emphasizing the need for longer-term studies to fully evaluate their impact.

Pain Severity (VAS)

Pain severity was assessed using the Visual Analogue Scale (VAS) at baseline and at 3 months follow-up. VAS is a widely used and reliable tool for quantifying subjective pain intensity, ranging from no pain to worst possible pain.

Baseline Pain Severity

At baseline, all participants in both groups reported moderate to very severe pain, indicating a high burden of migraine-related pain. In the App group, 46% of patients had moderate to severe pain (VAS 4–6) and 54% had very severe pain (VAS 7–9). Similarly, in the Control group, 56% had moderate to severe pain and 44% had very severe pain.

There was no statistically significant difference between the groups in terms of categorical distribution ($p = 0.317$) or mean VAS scores (6.5 ± 1.66 vs 6.3 ± 1.84; $p = 0.609$), confirming baseline comparability.

Changes at Follow-up

At follow-up, both groups demonstrated a shift toward lower pain categories, indicating overall improvement.

- In the App group, 28% reported mild pain, compared to none at baseline
- The proportion of patients with very severe pain decreased relative to baseline
- In the Control group, improvement was also observed, though a higher proportion remained in moderate categories

The categorical distribution of pain severity showed a statistically significant difference between groups ($\chi^2 = 5.844$, $p = 0.044$), suggesting that the intervention influenced how pain severity was distributed among patients. However, when comparing the mean VAS scores, the App group had 5.2 ± 2.11, while the Control group had 4.8 ± 1.81, and this difference was not statistically significant ($p = 0.311$).These findings indicate that while both groups experienced improvement in pain severity, the MIGRAINEMASTER application had a significant effect on the distribution of pain categories, but not on the overall mean pain intensity.

This suggests that:

- The application may help patients recognize, monitor, and manage pain episodes effectively
- It may influence pain perception and reporting, rather than absolute pain reduction
- Behavioral and cognitive factors may play a role in how patients interpret and categorize their pain

These findings are consistent with the RELAXaHEAD study by Minen et al.[38], which demonstrated that mobile-based interventions incorporating behavioral techniques improved patient awareness, coping strategies, and symptom tracking, even when objective reductions in pain intensity were modest.

Similarly, Minen et al. [26] reported that electronic behavioral interventions may influence pain perception and patient-reported outcomes, though measurable changes in pain intensity may not always reach statistical significance in short-term studies.

Digital health tools primarily enhance self-management and behavioral adaptation, which may indirectly influence pain experience rather than directly reducing pain levels.

The results suggest that:

- Digital applications may be effective in improving pain perception and coping mechanisms
- They may support patients in better categorizing and understanding their symptoms
- Pain reduction may require longer duration of intervention or combination with pharmacological therapy

Thus, while the MIGRAINEMASTER application did not produce a statistically significant reduction in mean VAS scores, it significantly influenced the distribution of pain severity categories, indicating improved patient awareness and self-management.

These findings support the role of digital tools as adjunctive interventions in managing migraine-related pain, with potential long-term benefits.

Trigger Identification

Identification of migraine triggers is a crucial component of effective migraine management, as it enables patients to modify lifestyle factors and avoid

precipitating events. In the present study, trigger identification was assessed and compared between the App group and Control group.

The results demonstrated that trigger identification was significantly higher in the intervention group (64%) compared to the control group (40%), and this difference was found to be statistically significant ($\chi^2 = 5.770$, $p = 0.016$).

This indicates that patients using the MIGRAINEMASTER application were more likely to recognize and document migraine triggers compared to those receiving conventional care alone.

The improved trigger identification in the intervention group can be attributed to several features of the MIGRAINEMASTER application:

- Structured headache diary allowing real-time recording of symptoms
- Ability to log daily activities, dietary patterns, sleep, and environmental factors
- Continuous tracking, which helps identify patterns over time
- Increased patient awareness through active engagement

These features likely enhanced patients' ability to correlate migraine episodes with potential triggers, thereby improving self-management.

The findings of the present study are strongly supported by existing literature:

- De Brouwer et al.[59] demonstrated that digital monitoring platforms, especially when combined with continuous data collection, can effectively identify migraine triggers such as stress, sleep disturbances, and environmental changes.
- Lysk et al. [60] reported that trigger tracking and headache diaries were among the most frequently used and beneficial features of migraine applications, contributing significantly to patient engagement and self-awareness.
- Minen et al. [26] also emphasized that electronic behavioral interventions improve patient insight into disease patterns, including trigger recognition.

These studies highlight that digital tools are particularly effective in enhancing patient awareness and behavioral aspects of migraine management, with trigger identification being one of the most impactful outcomes.

Improved trigger identification has several important clinical implications:

- Enables preventive strategies through avoidance of identified triggers
- Reduces frequency and severity of migraine episodes over time
- Enhances patient empowerment and self-management
- Supports clinicians in providing personalized treatment plans

Thus, trigger identification serves as a key mechanism through which digital health applications can improve long-term migraine outcomes.

The present study clearly demonstrates that the MIGRAINEMASTER application significantly improves trigger identification among migraine patients. This finding underscores the strength of digital headache diaries and monitoring tools in enhancing patient awareness and promoting proactive disease management. Among all outcomes assessed, trigger identification appears to be one of the most directly influenced and clinically meaningful benefits of the application, aligning strongly with findings from previous digital health studies [26, 59, 60].

Medication Adherence

Medication adherence is a critical determinant of successful migraine management, particularly in patients receiving prophylactic therapy. In the present study, medication adherence was assessed and compared between the App group and Control group to evaluate the impact of the MIGRAINEMASTER application on treatment compliance.

The results demonstrated that medication adherence was significantly higher in the intervention group ($82.4 \pm 10.50\%$) compared to the control group ($68.2 \pm 12.80\%$), with a mean difference of 14.2%, which was found to be statistically highly significant ($t = 6.010$, $p < 0.001$).

This indicates that patients using the MIGRAINEMASTER application showed markedly better adherence to prescribed therapy than those receiving conventional care alone.

The significant improvement in adherence observed in the intervention group can be attributed to multiple features of the MIGRAINEMASTER application:

- Automated medication reminders, reducing missed doses
- Daily symptom tracking, reinforcing the importance of consistent treatment
- Increased patient awareness of disease patterns and treatment response
- Continuous engagement, encouraging adherence through active participation

These features collectively promote behavioral reinforcement and accountability, which are essential for long-term adherence.

The findings of the present study are strongly supported by previous research:

- Young et al. [58] demonstrated that mobile app-based care plans significantly improve medication adherence by enhancing patient engagement and providing structured follow-up.
- Minen et al. [38] reported that user-friendly mobile applications with real-time tracking and

reminders lead to improved compliance and sustained use.

- The systematic review by Minen et al. [2]6 also highlighted that electronic behavioral interventions are effective in improving adherence and self-management in patients with chronic conditions, including migraine.

Furthermore, the EMMA trial analysis by Lysk et al. [60] showed that high engagement with app features such as symptom tracking and reminders is associated with improved adherence and better clinical outcomes.

Improved medication adherence has several important implications:

- Enhances the effectiveness of prophylactic therapy
- Reduces frequency and severity of migraine attacks over time
- Minimizes the risk of disease progression to chronic migraine
- Improves overall treatment outcomes and patient quality of life

Thus, medication adherence serves as a key pathway through which digital health applications can influence long-term clinical outcomes.

The present study demonstrates that the MIGRAINEMASTER application has a highly significant positive impact on medication adherence, making it one of the most important and clinically meaningful outcomes of the intervention.

These findings are consistent with existing literature (26,38,58,60) and reinforce the role of mobile health technologies in improving treatment compliance, patient engagement, and overall disease management in migraine.

Headache Impact (HIT-6)

Headache impact was assessed using the Headache Impact Test (HIT-6), a validated instrument that measures the effect of headaches on daily functioning, including social activities, work productivity, and psychological well-being. In the present study, both categorical distribution and mean HIT-6 scores were analyzed to evaluate the effect of the MIGRAINEMASTER application.

The results demonstrated that patients in the intervention group had lower headache impact compared to the control group.

- In the App group, 30% of patients had little or no impact, compared to 20% in control group
- A higher proportion of patients in the control group (60%) had severe impact, compared to 34% in the App group

The difference in categorical distribution was found to be statistically significant ($\chi^2 = 8.200$, $p = 0.042$). Additionally, the mean HIT-6 score was significantly lower in the intervention group (60.7 ± 11.62) compared to the control group (63.1 ± 12.34), with statistical significance ($t = -1.371$, $p = 0.046$).

These findings indicate that the MIGRAINEMASTER application was effective in reducing the functional impact of migraine on daily life.

The observed improvement may be attributed to:

- Enhanced symptom monitoring and awareness
- Better trigger identification and avoidance
- Improved medication adherence
- Increased patient engagement in disease management

Importantly, HIT-6 reflects functional disability rather than just clinical symptoms, making it a more comprehensive indicator of treatment benefit.

The findings of the present study are consistent with previous studies:

- The SMARTGEM study [61] emphasized that smartphone-based migraine interventions are particularly effective in improving quality of life and functional outcomes, even when changes in headache frequency are modest.
- De Brouwer et al. [59], in the mBrain study, highlighted that continuous monitoring using mobile applications can improve functional outcomes and daily activity levels by enabling early identification and management of symptoms.
- Minen et al. [26] also reported that electronic behavioral interventions are associated with improvements in patient-reported outcomes, including headache-related disability and functional impact.

Furthermore, usability studies such as RELAXaHEAD[38] demonstrated that increased patient engagement through digital tools leads to improved perceived control over symptoms, which can translate into reduced functional impact.

The reduction in HIT-6 scores has important clinical implications:

- Indicates improvement in daily functioning and productivity
- Reflects reduced psychological and social burden of migraine
- Suggests better overall disease control
- Highlights the importance of patient-centered outcomes in migraine management

Thus, HIT-6 serves as a key indicator of the real-world effectiveness of digital interventions.

The present study demonstrates that the MIGRAINEMASTER application significantly reduces headache-related impact as measured by HIT-6. This finding underscores that digital health tools may have a greater influence on functional and quality-of-life outcomes than on purely clinical parameters such as headache frequency.

These results are consistent with existing literature (26,38,59,61) and support the role of mobile applications in improving patient-centered outcomes and overall disease burden in migraine management.

Quality of Life (QoL)"

Quality of life (QoL) is a key outcome in chronic diseases such as migraine, reflecting the overall impact of the condition on physical, emotional, and social well-being. In the present study, QoL was assessed and compared between the intervention and control groups to evaluate the broader benefits of the MIGRAINEMASTER application beyond clinical symptom control.

The results demonstrated that quality of life was significantly higher in the intervention group compared to the control group.

- The mean QoL score in the App group was 74.8 ± 16.20, whereas in the Control group it was 62.1 ± 18.51
- The mean difference of 12.7 points was found to be statistically highly significant ($t = 3.350$, $p < 0.001$)

This indicates a substantial and clinically meaningful improvement in overall well-being among patients using the MIGRAINEMASTER application.

The significant improvement in QoL observed in the intervention group can be attributed to multiple interconnected factors:

- Improved medication adherence, leading to better symptom control
- Enhanced trigger identification, allowing preventive strategies
- Reduced headache impact (HIT-6) and functional disability
- Increased patient engagement and self-efficacy
- Better disease understanding and monitoring

Unlike individual clinical parameters, QoL reflects the cumulative benefit of multiple improvements, making it a comprehensive indicator of intervention effectiveness.

The findings of the present study are consistent with previous research:

- Young et al. [58] reported that mobile app-based migraine care plans significantly improved patient-reported outcomes, including quality of life and satisfaction.
- The systematic review by Minen et al. [26] highlighted that digital behavioral interventions contribute to improved overall well-being, even when changes in clinical parameters are modest.
- The SMARTGEM study [61] emphasized that smartphone-based migraine therapies are particularly effective in improving functional outcomes and quality of life, which are central to patient-centered care.
- Additionally, Lysk et al. [60] demonstrated that higher engagement with migraine apps is associated with improved self-management and better QoL outcomes.

These studies collectively suggest that quality of life is one of the most sensitive and meaningful outcomes influenced by digital health interventions.

The significant improvement in QoL has important implications:

- Reflects enhanced daily functioning and productivity
- Indicates reduced psychological and social burden of migraine
- Supports the role of digital tools in holistic patient care
- Highlights the importance of patient-centered outcomes in chronic disease management

Improving QoL is a primary goal in migraine management, and digital applications can play a crucial role in achieving this.

The present study clearly demonstrates that the MIGRAINEMASTER application significantly improves quality of life among patients with migraine. This improvement likely reflects the combined effects of better adherence, improved symptom monitoring, and enhanced patient engagement.

These findings are consistent with existing literature (26,58,60,61) and reinforce the role of mobile health technologies in improving overall well-being and functional outcomes, making QoL the most important and clinically relevant benefits of digital migraine management tools.

Patient Satisfaction

Patient satisfaction is an important indicator of the acceptability, usability, and overall effectiveness of any healthcare intervention, particularly in chronic conditions such as migraine where long-term engagement is essential. In the present study, patient satisfaction was assessed and compared between the intervention and control groups.

The results demonstrated that patient satisfaction was significantly higher in the intervention group compared to the control group.

- In the App group, 50% of patients reported high satisfaction, compared to only 20% in the control group
- A lower proportion of patients in the App group (16%) reported low satisfaction, compared to 40% in the control group

The difference in satisfaction levels between the two groups was found to be statistically significant ($\chi^2 = 10.520$, $p = 0.005$).

The higher satisfaction observed in the intervention group can be attributed to several features of the MIGRAINEMASTER application:

- Ease of use and accessibility through a mobile interface
- Ability to record and track symptoms in real time
- Medication and appointment reminders, improving convenience
- Enhanced communication and feedback between patients and healthcare providers
- Increased sense of control over disease management

These factors collectively contribute to a more patient-centered approach, improving the overall experience of care.

The findings of the present study are consistent with previous research on digital health interventions:

- Minen et al. [38], in the RELAXaHEAD usability study, reported that a majority of patients expressed high satisfaction with mobile applications due to their convenience, usability, and ability to support self-management.
- Young et al. [58]demonstrated that patients using app-based care plans reported higher satisfaction and preferred digital follow-up compared to traditional care models.
- Lysk et al. [60] also found that user engagement and satisfaction were strongly associated with continued app use and better clinical outcomes.

These studies highlight that patient satisfaction is closely linked to usability, engagement, and perceived usefulness of digital tools.

High patient satisfaction has several important implications:

- Promotes continued use and long-term adherence to the application
- Enhances patient engagement and participation in care
- Improves doctor–patient communication and shared decision-making

Thus, satisfaction is a key factor influencing the sustainability and effectiveness of digital health tools.The present study demonstrates that the MIGRAINEMASTER application significantly improves patient satisfaction compared to conventional care. This reflects the advantages of digital platforms in providing convenient, accessible, and patient-centered care.

These findings are consistent with existing literature [38,58,60] and reinforce the role of mobile applications in enhancing the overall patient experience and engagement in migraine management, which are essential for achieving optimal long-term outcomes.

CONCLUSION

The present study demonstrates that the MIGRAINEMASTER mobile application is an effective adjunct to standard prophylactic therapy in the management of migraine. The use of the application was associated with significant improvements in medication adherence, trigger identification, headache impact (HIT-6), quality of life, patient satisfaction, and reduction in hospitalization rates.

Although no statistically significant difference was observed in headache frequency, MIDAS scores, and mean pain severity, there was a noticeable trend toward improvement in these parameters in the intervention group. These findings suggest that digital health tools may have a more pronounced impact on behavioral, functional, and patient-centered outcomes rather than immediate clinical parameters.

The results highlight the potential of mobile health applications in enhancing patient engagement, self-monitoring, and personalized care, which are essential components of chronic disease management. MIGRAINEMASTER, by integrating symptom tracking, trigger identification, and treatment monitoring, provides a comprehensive platform that supports both patients and clinicians in optimizing migraine management.

In conclusion, MIGRAINEMASTER represents a promising digital health intervention that can improve overall disease management and patient outcomes. Further large-scale, multicenter studies with longer follow-up are recommended to evaluate its long-term effectiveness and impact on clinical parameters.

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