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Introduction of a Smartphone Based Behavioral Intervention for Migraine in the Emergency Department

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Abstract

Objective: To determine whether a smartphone application (app) with an electronic headache diary and a progressive muscle relaxation (PMR) intervention is feasible and acceptable to people presenting to the Emergency Department (ED) with migraine.

Methods: This single arm prospective study assessed feasibility by actual use of the app and acceptability by satisfaction with the app. We report preliminary data on change in migraine disability and headache days.

Results: The 51 participants completed PMR sessions on a mean of 13±19 (0,82) days for the 90-day study period, lasting a median of 11 minutes (IQR 6.5, 17) each. Median number of days of diary use was 34 (IQR 10, 77). Diaries were completed at least twice a week in half of study weeks (337/663). Participants were likely (≥4/5 on a 5-point Likert scale) to recommend both the app (85%) and PMR (91%). MIDAS scores significantly decreased by a mean of 38 points/

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participant (p<.0001). More frequent PMR use was associated with a higher odds of headache free days (p=0.0148).

Conclusion: Smartphone-based PMR introduced to patients who present to the ED for migraine is feasible and acceptable. More frequent users have more headache free days. Future work should focus on intervention engagement.

Keywords

Progressive muscle relaxation; Headache; Engagement; Recruitment; Healthcare utilization

1. INTRODUCTION

According to the Global Burden of Disease study, migraine is the world's second most disabling medical condition.[1] It affects an estimated 40 million Americans,[2] produces over $20 billion in annual direct and indirect costs,[3,4] and is responsible for the majority of the five million headache visits per year to U.S. emergency departments (EDs).[5,6] In the ED, treatment focuses on acute therapies.[7,8] Many patients leave the ED with residual pain, post-discharge treatment plans are often inadequate, and recurrent ED visits are not rare.[9]

Given the high rate of return to the ED[10] and the high human and financial costs of ED visits for migraine,[11] interventions that might reduce the need for recurrent ED visits merit exploration. The average wait time to see a neurologist in the US is six weeks; this is considered excessive and is projected to increase.[12] Furthermore, referral to primary care for migraine management may not result in accurate diagnosis or optimal treatment, with a 4-year delay between migraine diagnosis and the start of preventive treatment.[13] In the US, close to 40% of people with migraine need preventive therapies, but only 13% of those who qualify actually receive one.[14] Improving migraine management following an ED discharge should be a high priority.

The prevalence of psychiatric comorbidities associated with migraine, including anxiety, depression, bipolar disorder and post-traumatic stress disorder, is high and often overlooked.[15–17] Patients with migraine and a psychiatric comorbidity have higher healthcare utilization rates than patients with migraine without psychiatric comorbidities.[18] Further, if untreated, comorbid psychiatric conditions can negatively impact treatment outcomes, lead to migraine progression, increase migraine-related disability, and reduce quality of life for migraine patients.[19–21]

Research indicates that mind-body intervention (MBIs) such as progressive muscle relaxation (PMR) and biofeedback are effective treatments for migraine prevention with few adverse effects[22] and enduring benefits.[23] They may be less costly than pharmacologic interventions[24] and are particularly suitable for patients with psychiatric comorbidities as they do not disrupt pharmacological treatments.[19] The acute care setting may serve as a teachable moment when patients are willing to try new preventive treatment strategies. Smartphone-based electronically delivered MBIs developed for chronic pain conditions might be ideal interventions for testing in acute medical settings because they (1) are

portable; (2) do not require an appointment with a behavioral health provider; (3) are relatively cheap; and (4) can be conducted post-discharge according to one's own schedule.

In the current prospective single-arm trial, we assessed the feasibility and acceptability of providing migraine patients in the ED with an electronically-delivered MBI, specifically, PMR. PMR is a standardized, evidence-based MBI used for migraine since the 1980s.[25,26] PMR was selected because: 1) it is brief, 2) patients can be taught to perform PMR independently of a healthcare provider, 3) it has a long history of use in migraine and is a foundational component of multi-modal behavioral migraine treatments.[27–30] PMR has successfully been delivered electronically in a smartphone application (app)[31–34] To facilitate PMR, we developed a migraine-specific smart-phone based application (app), RELAXaHEAD modelled after the app with PMR used in prior epilepsy studies.[31,32] Use of the RELAXaHEAD app, which include an electronic headache diary and PMR, has been reported in previous headache studies.[33–36]

This study was designed to assess the feasibility and acceptability of the RELAXaHEAD app in patients who present to the ED for the management of migraine. Feasibility was assessed by determining the frequency of use for the smartphone-based diary and PMR. Acceptability was defined as satisfaction scores on a Likert scale with mean scores >3 being acceptable after app use in the ED.

In exploratory analyses, we also assess (1) whether recruitment in the ED versus recruitment post discharge from the ED affects the feasibility outcomes, (2) predictors of high and low PMR use, (3) preliminary effects of whether PMR use improves migraine disability and headache days and (4) longitudinal trajectories of PMR and diary users.

2. METHODS

2.1 Study Design

This was a single-arm prospective study assessing the feasibility and acceptability of the RELAXaHEAD intervention and predictors of engagement for patients who present to the ED with migraine. The study was approved by our center's Institutional Review Board.Written informed consent was obtained. Eligible patients were asked to download the app. The intervention lasted 3 months, and measurements were obtained at baseline, 3 and 6 months.

2.2 Recruitment/Eligibility Criteria

From June 2017-January 2019, patients were recruited from an urban academic medical center's ED. Research volunteers screened ED charts for age and chief complaint before approaching each patient's provider. Providers confirmed eligibility and granted permission for research volunteers to approach patients and discuss the study. Eligible patients were ≥18 and ≤65 years old, spoke English, owned a smartphone, had migraine as defined by the International Classification Headache Disorders criteria (determined using a comprehensive questionnaire used in prior migraine ED studies[37,38]), reported more than minimal migraine disability on the Migraine Disability Assessment Scale (MIDAS score ≥5), had 4+ headache days/month, and were willing to engage in a smartphone-based behavioral therapy.[39,40]

Patients were ineligible if they were awaiting diagnostic testing to exclude secondary headache or had used behavioral therapy (CBT, biofeedback or PMR) for migraine in the past year.

We also invited patients who had been discharged from the ED who met study criteria to attend in-person enrollments following discharge from the ED.

2.3 Intervention

We used PMR, a standardized, evidence-based behavioral treatment[25,26] and modelled our RELAXaHEAD app after the app used in the SMILE study, an epilepsy study examining the impact of PMR on stress and epilepsy.[31,32] The app includes the same PMR as the SMILE study in addition to a daily symptom-based reporting diary. The PMR was divided into two sessions (one ~5 minutes, one ~15 minutes). The RELAXaHEAD app, developed in partnership between NYU and IRODY, an IT company that created the app platform, records the amount of time spent playing the PMR intervention audio. It also has in-app reminders to complete the PMR program and input data in the diary. The research team monitored data using an online portal. The app has been studied in patients with migraine in the neurology setting[33] as well as in patients with post-traumatic headache.[34]

Participants were asked to complete the headache diary and perform app-assisted PMR for 20 minutes per day for the three-month study period. Participants were offered a total of $25 at enrollment and $1/day for each day data were entered into the app for up to 90 days.

2.4 Measurements

Baseline variables included age, gender, race, self-reported number of headache days in the past month, self-reported average headache intensity on a numeric rating scale, MIDAS score based on the 5-question score[41] (developed to assess headache-related disability with the goal of improving migraine care, has internal consistency and test-retest reliability[42–44]), self-reported usage of behavioral therapy for migraine one year prior to enrollment (yes/no), PROMIS depression and PROMIS anxiety,[45,46] self-reported use of any migraine preventive medicines (yes/no), and prior use of ED/number of prior ED visits.

Primary outcome measures were feasibility and acceptability measures. Feasibility measures were: 1) # of days the app-based daily diary was used during the 90-day study period, 2) # of days of PMR use/90-day period, and 3) dose (minutes) of PMR use/day among users. These data were abstracted from a back-end report maintained by IRODY. Acceptability measures were based on satisfaction using 5-point Likert scale questions on RELAXaHEAD usability, content, and functionality after trying out the app at the initial enrollment session.

Secondary outcomes were characterization of participants as high and low users (for this analysis, a priori, high users were defined as having used PMR an average of at least 2 times/week the first month after enrollment based on the observed pattern of use[33]) using their longitudinal data, and efficacy as measured by the change from baseline to six month MIDAS score and the ratio of the number of headache free days reported and number of days the diary was used. We conducted an exploratory analysis to assess whether recruitment method was associated with use.

Data were collected by the research study team at baseline (in-person enrollment), from the app, and during 48–72 hour, 1,2, 3, and 6-month follow-up telephone calls.

2.5 Statistical Plan

2.5.1 Sample Size Calculation—As indicated by Kraemer and colleagues,[47] our pilot sample size was based on the pragmatics of recruitment and requisites for examining feasibility.

2.5.2 Quantitative Analyses—Descriptive statistics were used to characterize baseline participant characteristics and app use. We report number of days the diary was used (median, IQR). We also report number of days PMR audio was used (median, IQR), and minutes per session (median, IQR). We separately analyzed the number of days of diary use and PMR use. A longitudinal mixed effect binomial regression model was used to characterize the number of days per week the diary was used accounting for method of recruitment (in the ED vs. post-discharge) and number of prior ED visits. Each individual was treated as a random effect. Method of recruitment was a binary variable indicating whether the patient was recruited in-person in the ED or post-discharge from the ED. A similar approach was used to model PMR use over time. We also examined baseline predictors of PMR use including baseline age, headache days, MIDAS, PROMIS anxiety and PROMIS depression. When analyzing app usage, time since enrollment in weeks was included as a continuous predictor.

Additionally, to obtain preliminary estimates of app efficacy on headache-related outcomes, we reported the association between app use and change in MIDAS score between baseline and 6 months. The Kruskal-Wallis test was used to test for significant group differences based on recruitment method, number of prior ED visits, and frequency of app use.

We computed the ratio of number of headache-free days reported and number of days diary was used. A random intercept mixed effect binomial regression was used to assess change in the relationship between headache free days/month over the 3-month period and recruitment method and use of PMR (high or low users). Time since enrollment (in months) was included as a continuous predictor.

Statstical tests were two sided at significance level of 0.05, unadjusted for multiple testing given the exploratory nature of this analysis.

3. RESULTS

3.1 Baseline Data

Of the 51 participants, 47/51 (92%) were female with a mean age of 37±13. Participants reported a median of 10 [5–20] headache days/month (N=42) with a mean headache pain intensity of 7±2 (0–10). Median MIDAS score was 47 [25–93]. More than half (57%) or participants had previously taken a triptan, 37% had used a migraine preventive medication, but fewer people reported current use of triptans (33%) or current use of a migraine preventive medication (22%). Only 8% had previously used behavioral therapy for migraine.

About half (51%) reported seeing a physician in an office setting for their headaches. One third (34%) reported 5+ prior ED visits for headache.(Table 1)

3.2 Feasibility/Acceptability Outcomes

PMR and diary use statistics are shown in Table 2. Participants completed the PMR sessions a mean of 13±19 SD (0, 82) days during the study period of 90 days. The median duration of each session was 11 minutes (IQR 1, 29). The median number of days of diary use was 34 (IQR 10, 77) days. The satisfaction likert scales are in Table 1, and the mean ratings for each question exceeded 3. The lowest mean score was 3.8±0.81 for “The relaxation taught me skills that will help me handle future problems” and the highest mean scores were 4.2±0.79 for “I would be happy to use the app again” and 4.2±0.68 “I would be happy to do the relaxation again.”

3.3 PMR Usage and Baseline Predictors of Use

There was attrition in PMR usage, with 24/27 (89%) reporting PMR usage at one month, 18/25 (72%) reporting usage at 2 months, 14/27 (52% reporting usage at 3 months and 14/28 (50%) reporting usage at 6 months. The Figure shows weekly PMR use over time. Using the backend analytics capturing the PMR use, a participant’s odds of using PMR decreased 28% each week on average from the previous week. However, none of the baseline covariates were significantly associated with weekly use.

The odds of using PMR decreased by 30% each week in participants with one prior ED visit, 28.2% in those with 2–4 prior visits ($p=0.5794$) but was significantly different from those with 5+ visits that saw a 19.4% ($p=0.0002$) weekly reduction in PMR use. These results suggest that app users with more prior visits to the ED are more likely to continue using PMR and headache diaries than those with fewer visits.

3.4 Diary App Usage and Baseline Predictors of Use

There was a significant decrease in number of days the diary was used weekly when adjusting for the baseline covariates (age, headache days, MIDAS, PROMIS anxiety and PROMIS depression, and prior ED visit). A participant’s odds of use decreased an average of 49% each week relative to the previous one. The Figure shows weekly diary app use over time.

Persistent use of the diary was higher in those with a greater number of previous ED visits. Compared to the first week of enrollment, the odds of using the app decreased by 59.7% ($p<0.0001$) each week in participants with no or one prior visit, 51.4% ($p=0.0394$) each week in participants with 2–4 prior visits and by 37.5% ($p<0.0001$) each week in participants with 5+ prior visits.

3.5 App Usage and Recruitment Method

Of the 51 participants, 12 were recruited in the ED (labelled in the figure as “ED”) and 39 were recruited post-discharge from the ED (labelled in the figure as “DC”). The Figure suggests that patients recruited in the ED were more likely to continue use of both the PMR and diary than those recruited after discharge.

3.5 Efficacy

3.5.1 Migraine Disability (MIDAS)—In the 28 participants with both baseline and 6-month follow-ups, MIDAS significantly decreased by a meanof 38 points (p<.0001) per participant. While patients recruited in the ED showed a 24.3 point drop and patients recruited post-discharge saw a 41.6 point drop in MIDAS over 6 months, there was no difference in the changes over time based on the recruitment method (p=0.4494). Patients with 1 prior ED visit saw a 51.9 point reduction, those with 2–4 prior ED visits saw a 17.4 point reduction, and those with 5+ prior ED visits showed a 41.5 point reduction in MIDAS, but these differences were not significantly different (p=0.3186). There were also no significant differences in changes in MIDAS between the frequent PMR users, defined as using the app at least twice a week the first month, mean reduction of 30 points from infrequent users mean reduction of 54.5 points (p=0.4167). Frequent diary users, defined as using the diary at least 15/30 days in the first month, had a 6 month reduction in MIDAS of 33.5 points, which was not significantly different from the infrequent users that saw a 54.2 point reduction (p=0.4007).

3.5.2 Headache Free Days and PMR Use—Within the app, there were recorded 1120 headache-positive days, 992 headach-free days, resulting in 1.13 headache positive/ headache free days. There were 27 higher users, defined as using PMR an average of twice a week the first month after enrollment, and 23 low users. While there was no significant change in the number of HA free days/month over the course of the study (p=0.1011), the higher users had 3.8 times higher odds of HA free days (p=0.0148) than lower users.

4. DISCUSSION

In this single-arm prospective trial, we found that a smartphone-based PMR intervention was broadly acceptable and feasible in migraine patients recruited from the ED. However, we also observed variations in engagement and specifically attrition with PMR audio usage over the course of the study. Migraine disability scores decreased substantially throughout the course of the study, independent of engagement (e.g., high or low use of the app).

In a population in which nearly half (47%) self-reported anxiety and two-fifths (39%) self-reported depression, participants used the diary a median of 33.5±28 (0, 90) days and at least once a week 56% of the time. Among those who used the diary at least once a week, it was used a mean of 5.7±2 (1,7) days/week over the 90-day study period, consistent with prior research showing that smartphone apps with electronic headache diaries are acceptable and preferred to paper diaries by both patients and clinicians/researchers,[48] with fewer secondary data errors,[49] less administrative burden,[50,51] high participant acceptance,[51] and potential cost savings.[52] Additionally, electronic diaries allow time-stamping, the use of electronic reminders as well as detection and and timely follow-up of non-compliant participants via real-time data monitoring.

On average, participants completed a PMR session 11±12 (1, 47) days within the 90-day study period for 10±6 (0, 22) minutes per day. Participants with at least once/week diary use used the PMR an average of 2.3±2.4 (0,7) days/week. The PMR sessions included in the current study are considerably shorter than PMR sessions originally developed by Jacobson,

but PMR was adapted to be used for briefer periods of time and no specific dose is known to bemost efficacious for migraine behavioral treatment.[31,32,53] The average length of PMR session completed exceeded the length of the short file, suggesting an acceptability of the proposed duration of PMR for patient adherence. Taken into context with prior studies,[33] our results also suggest that for those who engage with the app i.e. download it and use the diary at least weekly, we may be able to get them to use the PMR at least two days/week. As is consistent with prior studies,[33] there was substantial attrition with PMR usage, particularly by week 6.

4.1 Migraine Disability

There was a significant decrease in MIDAS scores between baseline and end of the study, and this change in MIDAS was not based on PMR usage. Possible factors are: 1) Treatment received in the ED may reduce migraine disability. 2) Presentation at the ED likely represents a particularly severe period of migraine activity, and the relative less severe disability during three months following an ED visit may represent, at least in part, regression to the mean. 3) Self-monitoring is a well-established behavior change technique;[54,55] with migraine, self-monitoring might enhance awareness of lifestyle factors contributing to attacks and early awareness of attacks to better optimize acute therapy, which could reduce migraine-related disability. Prior research has shown that RELAXaHEAD users engaged in their own self-monitoring to determine triggers, better understand sleep patterns and their headaches in general.[56] 4) Enrollment in a study may improve outcomes through interaction with study staff and common therapeutic factors like rapport. Reductions in MIDAS have been seen in the placebo arm of migraine trials.[57] Future research should evaluate which of these possible explanations is most likely.

4.2 Considerations for Conducting Migraine Research in the ED with a Focus on Smartphone Based Behavioral Research

We observed a variety of considerations pertinent to administration of a smartphone-based behavioral intervention study in the ED. First, as patients present to the ED at all hours, coverage with research personnel can be challenging. Our study recruited during weekends as well as non-traditional hours (e.g., 3pm-12am) based on availability, creating a potential for sampling bias. Patients with migraine in the ED may be symptomatic when approached or may be engaged with visitors who brought them to the ED. Our study team was trained to pause the enrollment process as needed so that ED personnel can address symptoms (e.g., pain and nausea) and to offer eye masks for photophobia. Enrollment was often interrupted to address the clinical needs of the patient or the logistical needs of ED personnel, and took from 30–120 minutes. Many patients were eager to leave the ED, sometimes making it difficult to complete enrollment. While we think we addressed these challenges thoughtfully in the current study, we continue to incorporate feedback from patients, medical staff, and research team members into trainings for future studies. Because these are low-touch studies with virtual follow-ups, particular attention should be given to the quality of enrollment as this may affect retention rates. We found post-discharge enrollment the more successful strategy.

ED-based studies of this kind may also face technical challenges. Points of acute care may have poor or unstable internet connections; we augmented connectivity with portable wifi hotspots. Patient phones may not be charged; we provided portable phone chargers for Android and Apple devices. Because of the noisy environment, we provided headphones to facilitate audibility without disturbing other patients or staff.

4.3 Study Strengths

This was a pragmatic study of a nonpharmacologic behavioral intervention for patients in the ED at a teachable moment. PMR is an evidence-based MBI. We were able to determine differences in recruitment strategies between recruiting patients while they are in the ED versus once they are discharged from the ED. Our participant sample was racially and ethnically heterogenous, which is reflective of our urban hospital environment. Our participants were frequent ED users, with 34% having had 5+ ED visits. Yet few (12%) had previously done behavioral therapy so this study was an opportunity to try a new treatment modality. Participants practiced PMR in a time-limited manner before attrition set in, and high users had nearly four times odds of having headache-free days.

4.4 Study Limitations

This study was limited to a single-center ED within a large tertiary care academic medical center. We only included participants who were eligible for preventive migraine treatment (4+ headache days/month). In fact, the majority of our participants met criteria for high frequency episodic migraine/chronic migraine. We recruited in selected hours, often evenings and weekends when research personnel were available. For all of these reasons, the data are not generalizable to all patients who present to our ED or other EDs with migraine. Only a small number of participants (12) were actually recruited while in the ED; we recruited the majority of the sample subsequent to the visit using the ED visit to identify potentially eligible patients. We only included PMR sessions recorded with the backend analytics of the app. If participants practicd PMR without the app, we did not capature those treatments. This may contribute to lack of association between the number of PRM sessions and change in MIDAS scores. This was a low touch smartphone-based study with limited study staff contact. As such, the adherence may not have been optimized. Because this was a feasibility and acceptability study, we did not have a contemporaneous control group. As a consequence, we cannot determine if changes in MIDAS scores reflect our intervention, the influence of monitoring, regression to the mean, other treatments or other factors. Finally, because of the exploratory nature of the study and the modest sample size, we did not adjust for multiple comparisons.

4.5 Future Work

Future studies might consider the following recruitment approaches: 1) recruit ED headache “champion” clinicians who recommend the study for a discreet period of time to patients who present with migraine, with screening and informed consent occurring electronically among participants who download the app; 2) study the feasibility of virtual enrollments; or 3) plan for a substantial investment in research team staffing to allow participants to be recruited in the ED outside of routine clinical care (less pragmatic). Future studies

require strategies for improving adherence, capturing PMR practice not using the app, assess concomitant treatments and include a control group that uses the diary app without PMR.

Future work might also examine who are high users/ low users, and what can be done to better engage low users.

5. CONCLUSION

Patients who present to the ED with migraine can engage in smartphone-based PMR and electronic diary use. Those who frequent the ED were higher users, and those who are higher users had more headache free days during the course of PMR. Further, rates of decline in use were higher in those recruited post-discharge from the ED as compared to those recruited while in the ED. Future work needs to examine ways in which adherence to a smartphone-delivered PMR intervention for migraine following an ED visit can be improved.

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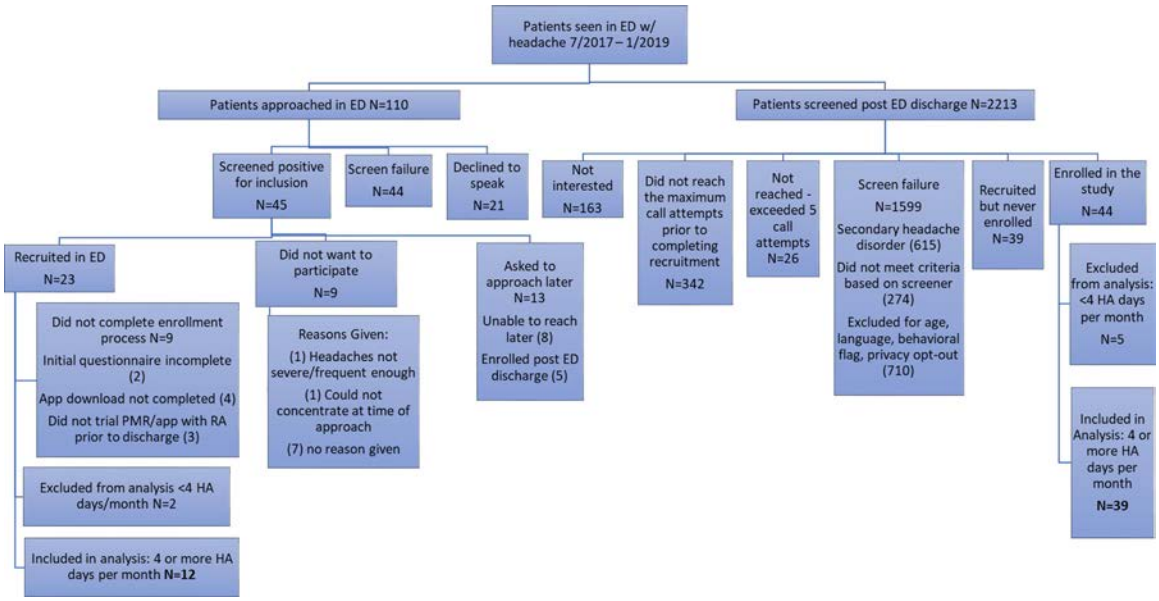

Figure 1:
Flow diagram

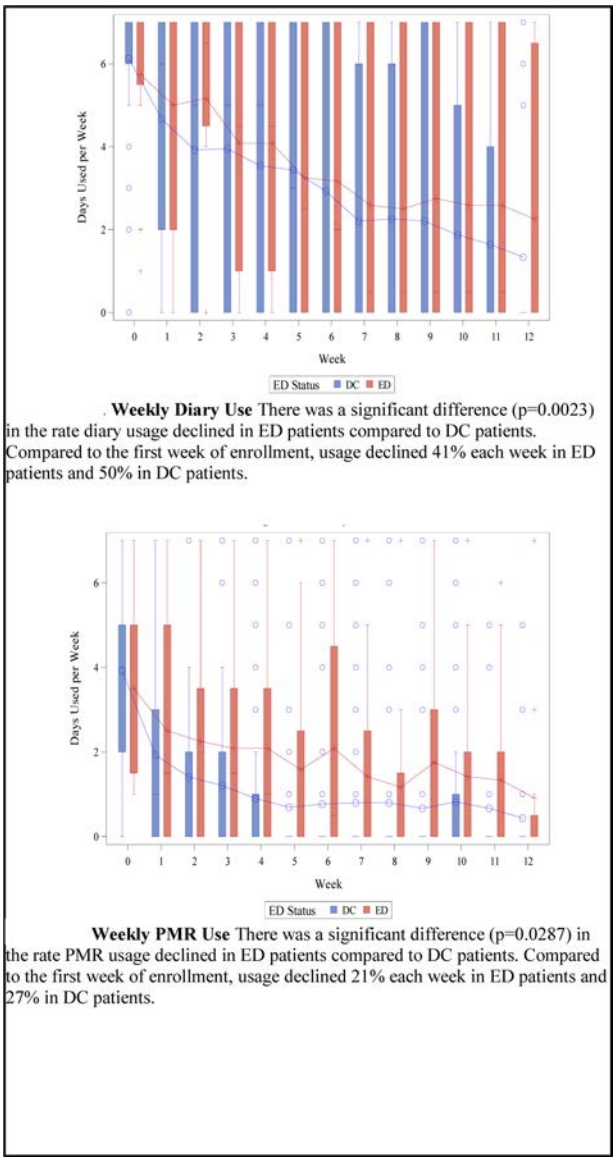

Figure 2:
Use of the RELAXaHEAD Diary and Progressive Muscle Relaxation (PMR) over time

Table 1:

Baseline Demographics, Headache Characteristics, Prior Healthcare and Intervention Methods and App Satisfaction Responses

Participant Information	***Summary (N=51)***
Female, n (%)	*47 (92%)*
Current Age, Mean ± SD	*37±13 (19–64),*
Race/Ethnicity, n(%)	
White/Caucasian	*23 (46%)*
African American	*13 (26%)*
Asian or Pacific Islander	*3 (6%)*
Other	*11 (22%)*
Hispanic or Latino	*12 (24%)*
Not Hispanic or Latino	*38 (76%)*
Self Reported Past psychiatric conditions, n(%)	
Anxiety	*24 (47%)*
Depression	*20 (39%)*
Medication Usage, n(%)	
Prior oral migraine preventive medication	*19 (37%)*
Prior triptan use	*29 (57%)*
Current oral migraine preventive	*11 (22%)*
Current triptan use	*17 (33%)*
Migraine Disability (MIDAS) Sum of the first 5 questions	
Mean *± SD (min-max) Median [Q1,Q3]*	*72±72 (4–400), 47 [25–93]*
Little or no disability (0–5)	*2 (4%)*
Mild disability (6–10)	*0*
Moderate disability (11–20)	*9 (18%)*
Severe disability (21+)	*40 (78%)*
Psychiatric Screens, Median [IQR]	
PROMIS Depression t-score (Sum)	*48 [41–57]*
PROMIS Anxiety t-score (Sum)	*49 [42–58] n=51*
Headache Healthcare Utilization, n(%)	
Sees a physician in an office setting who treats headaches	*26 (51%)*
Emergency Department visit for headaches	
1 time	*20 (39%)*
2–4 Times	*14 (27%)*
5–10 times	*11 (22%)*
11–20 times	*4 (8%)*

Participant Information

	Summary (N=51)
>20 times	*2 (4%)*
Previously done any behavioral therapy for migraine	*4 (8%)*
Satisfaction Responses, Mean + SD	**Mean Likert Rating**
I would be happy to do the relaxation again	4.2 ± 0.68
I would be happy to use the app again	4.2 ± 0.79
The app kept my interest and attention	3.9 ± 0.79
The app was easy to use	4 ± 0.88
The daily diary was relevant to me to help me track my headaches	4 ± 0.88
The information was easy to understand	4.1 ± 0.8
The relaxation helped to improve my stress and low mood	3.9 ± 0.78
The relaxation kept my interest and attention	4.1 ± 0.67
The relaxation taught me skills that will help me handle future problems	3.8 ± 0.81

Table 2:

Feasibility Data: Usage Data

Usage Statistics	Mean ± SD (median)	IQR [Range]
Total time PMR played/day per person (in mins)	12±7 (11)	10 [1, 29]
Number of days PMR Done: Short file	13±18 (7)	13 [0,82]
Number of days PMR Done: Long file	13±20 (4.5)	13.5 [0, 76]
Overall (Long and/or short combined)	13±19 (5)	13 [0, 82]
Total Headache Free Days	20±46 (9)	33 [0, 207]
Total Diary Days Used	58±63 (34)	73 [0, 254]