Mobile Behavioral Therapy for Headache: A Pilot Study

Rebecca Shingleton, Ph.D.[1,2,3], Robert Bratzler, Ph.D.[1], William C. Lillydahl, M.D.[1], Adam Kirell, M.Eng.[1]
[1]BioTrak Therapeutics
[2]Harvard University
[3]Shingleton Psychology

Introduction

- Recurring tension headaches, migraines, and orofacial pain affect 2.4+ billion people globally, representing the second most prevalent medical condition in the world[1]
- In-office cognitive behavioral therapy (CBT) (*e.g.*, relaxation, biofeedback, and mindfulness exercises) have shown to be effective treatments for these conditions[2]
- These therapies lack side effects relative to medication, are cost effective, and may address comorbidities such as anxiety and depression[3]
- Despite the above stated benefits, these treatments are underutilized due to stigma associated with seeking therapy, lack of reimbursement, accessibility, and limited provider availability[4]
- Mobile health applications (apps) are one way to improve access to care[5] in real time, in a natural environment, and at an affordable price. They are available to over 75% of the US[6] and encourage sufferers to take more responsibility for their own healthcare.
- Apps have shown to be an effective way to reach other populations who benefit from CBT (*e.g.,* anxiety, depression)[7]
- In this study we piloted a mobile app that integrated mindfulness and relaxation exercises, with and without a biofeedback device, for headache sufferers

Purpose

- To assess the feasibility and acceptability of delivering a clinically validated behavioral therapy for migraine/headaches through a mobile app "Halo"

Methods

Participants:

Inclusion criteria: 1) Adults (ages 18-70); 2) self-reported >4 headache, migraine or orofacial incidents during two week baseline period; 3) Score >7 Monthly MIDAS one month prior to study enrollment; 3) had an iPhone.
Exclusion criteria: 1) cognitive impairment; 2) self-reported psychiatric illness; 3) new headache medication regime or had Botox within last 3 months

Study Design:

Study A (n=10): Halo app + in home, real-time biofeedback using a proprietary sEMG headband

Study B (n=9): Halo app only

Across both studies, participants completed a two week baseline period during which they completed a daily self-report headache diary on the Halo app

Following the baseline period, they began a four-week intervention phase during which they were instructed to complete ten minutes of relaxation training exercises (*e.g.,* diaphragmatic breathing, progressive muscle relaxation, mindfulness) via the app daily and complete the headache diary

Participants in Study A were instructed to use the headband to monitor their frontalis muscle tension on their phone while conducting the relaxation exercises for a minimum of 10 minutes/day

Post-intervention assessments were collected at end of the trial

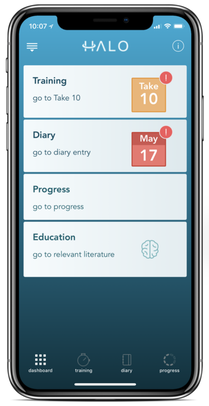

Figure 1a. Halo application **Figure 1b**. Halo sEMG biofeedback headband

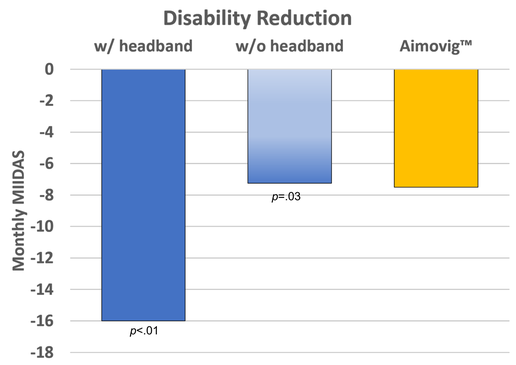

Figure 2. Pre-Post Monthly MIDAS score across Study A (w/ headband), Study B (w/o headband), and recent medication trial data[8]

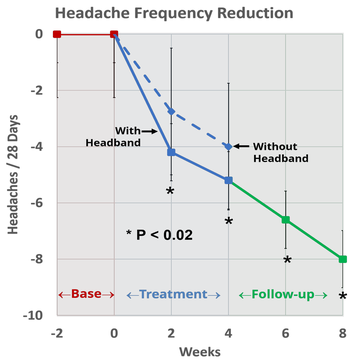

Figure 3. Headache frequency change over course of trial in Study A & B

Participant	Sample Feedback Quotations – Study A
P3, Age 28, F	"I was able to deal with headaches in a better way when I got them. I have more control over headaches and stress compared to this time last year. I was able to feel calmer in 5 minutes."
P5, Age 37, F	"Looking at the graphs was really helpful. Was very easy to use. Noticed that after using Halo my headaches weren't as intense."
P6, Age 28, M	"Being able to see the information visually helped me be more mindful of stress."
P 7, Age 27, M	"Using breathing exercises has helped with my headaches. I have a tool to use now."
Participant	**Sample Feedback Quotations – Study B**
P2, Age 29, F	"This can help a lot of people. It will definitely help people manage the pain. I would totally keep using the app. I noticed myself sitting up in my chair and taking deep breaths."
P6, Age 31, F	"I definitely noticed after I started the training that my headaches weren't lasting as long as they used to. I want to keep using it. It's a really good app."
P7, Age 57, F	"This app made me realize that I get headaches in the morning, and I like that I can take notes on the app. It was super helpful to me. I was able to know that if I was feeling one at night, I should take care of myself because I would get a worse one in the morning."
P8, Age 39, M	"I didn't have a headache for weeks! I don't want to take medication because I have asthma, and some of the headache meds interact with asthma meds. This obviously can't hurt me, I wanted to see what this is all about."

Table 1. Participant feedback

Results

Study	Age (years) M (SD)	Gender	Baseline Monthly MIDAS M (SD)	Post Intervention MIDAS M (SD)	Baseline HFA M(SD)	Post Intervention HFA M (SD)
Study A	31.2 (13.8)	8 Female 2 Male	27.6 (14.0)	11.5 (13.3)**	12.0 (5.0)	4.0 (4.9)**
Study B	32.1 (10.3)	7 Female 2 Male	25.6 (10.4)	17.4(12.7)*	14.4 (7.4)	11.1 (9.9)

Note. Monthly MIDAS score above 7 indicates severe disability. **p<0.01; *p<0.05

Effectiveness:

Study A: Participants reported significant decrease in monthly MIDAS score (p<0.01) and headache frequency average (HFA; p<0.01) between baseline and post-intervention. Treatment gains were maintained through follow-up; 54% of participants' monthly MIDAS disability scores reduced to below 7 post intervention (See Figures 2 & 3)

Study B: Participants reported significant decrease in MIDAS score (p=0.03) and a directional decrease in HFA (p=0.09) between baseline and post intervention (See Figures 2 & 3)

Compliance: (*i.e.,* completion of daily monitoring & exercises) **Study A**: 51%; **Study B:** 67%

Acceptability: Halo app was easy to use and helped participants manage and reduce frequency of headaches (See Table 1)

Constructive feedback: Headband was difficult to operate at times (*e.g.,* needed to charge); difficult to find time to use the headband and app at same time; Halo app may benefit from more content and interactive material; phone screen was difficult to look at when having a headache

Conclusion

- Mobile app "Halo" with and without a biofeedback device for headache sufferers was both feasible and acceptable
- Behavioral modification via Halo resulted in significant reduction in disability scores in a sample with severe disability ratings
- Halo outcome data are similar to (Study B) or more favorable (Study A) (*i.e.,* greater reduction in disability scores) than recent medication trial outcomes[8] and participants maintained gains at follow-up, indicating successful use of skills after the intervention phase
- Halo app may be an effective way to increase access to care for headache sufferers and provide an alternative treatment option for individuals who would benefit from non-medication-based therapy
- Further product development is needed to improve the interface (*e.g.,* increased interactivity) and compliance
- Larger scale studies are needed to 1) identify for whom this intervention is most effective; 2) compare to traditional medication inventions

References

1. Lipton RB, Stewart WF, Diamond S, et al. Prevalence and burden of migraine in the United States: data from the American Migraine Study II. Headache. 2001;41:646-657.
2. Cott A, Parkinson W, Fabich M, et al. Long-term efficacy of combined relaxation: biofeedback treatments for chronic headache. Pain. 1992;51:49–56
3. Sobel DS. Mind matters, money matters: the cost-effectiveness of mind/body medicine. JAMA 2000, 284:1705
4. McGrady AV, Andrasik F, Davies T, et al. Psychophysiologic therapy for chronic headache in primary care. Primary Care Companion to The Journal of Clinical Psychiatry. 1999:96-102.
5. Wallace LS, Dhingra LK: A systematic review of smartphone applications for chronic pain available for download in the United States. J Opioid Manag 2014, 10:63–68
6. Pew Research Center. Mobile Fact Sheet. http://www.pewinternet.org/fact-sheet/mobile/ Accessed October 5 2018
7. Rathboth AL, Clarry L, Prescott J. Assessing the efficacy of mobile health apps using the basic principles of cognitive behavioral therapy: Systematic review. JMIR 2017,19, e399
8. Buse DC, Lipton RB, Hallstrom Y, et al. Migraine-related disability, impact, and health-related quality of life among patients with episodic migraine receiving preventative treatment with erenumab. Cephalalgia 2018, 1622-1631