

A Pilot Study of Amitriptyline Combined with Coping Skills Training for Youth with Chronic Daily Headache

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Background

Evidence-based interventions currently do not exist for youth with chronic daily headache (CDH) and this condition is known to result in significant functional disability for children, adolescents, and their families.

Objective

This pilot study examined the impact of combined behavioral (i.e., coping skills training) and pharmacological (i.e., amitriptyline) treatment in reducing headache frequency and functional disability in youth with CDH.

Methods

Participant Characteristic

N = 7	M	±	SD
Age	14.3		1.5
Gender	Frequency	Percent	
male	4	57%	
female	3	43%	
SES ¹			
I	0	0%	
II	0	0%	
III	1	14%	
IV	4	57%	
V	2	29%	
Family member with chronic pain	3	43%	

Inclusion Criteria

- Participants ages 12 to 17 years of age with CDH were recruited through the Headache Center at Cincinnati Children's.
- CDH was defined as 15 or more headache days per month; diagnosis made after neurological exam².

Exclusion Criteria

- Medication overuse
- PedMIDAS > 140
- Current use of a prevention migraine medication

Intervention

Cognitive-Behavioral Coping Skills Training

Session #1 (Parent and child)	Introductions and rapport building. Provide an overview of the program and rationale for behavioral pain management. Demonstrate biofeedback procedure. Discuss parent guidelines for being a good "coach" for their child.
Session #2 (Child only)	Review diaries. Begin biofeedback-assisted training in progressive muscle relaxation and mini-relaxation procedures. Application of these techniques for improving sleep and decreasing pain. Establish a home practice schedule.
Session #3 (Parent and child)	Review diaries. Train subject in pleasant imagery and use of pleasant activities as distraction techniques. Biofeedback review. Work with subject to schedule pleasant activities and set up practice schedule for pleasant imagery practice.
Session #4 (Child only)	Review diaries. Discuss subject's typical activity level. Instruct subject in how to pace activities. Discuss problem-solving technique to reduce and manage pain flare-ups.
Session #5 (Parent and child)	Review diaries and progress so far. Review coping skills learned in previous sessions. Assess parent's adherence to parent guidelines. Problem-solve any difficulties.
Session #6 (Child only)	Review diaries. Discuss the impact of thoughts and feelings on pain perception. Use vignettes to help them recognize negative thoughts. Teach subject use of calming statements.
Session #7 (Child only)	Review diaries. Review all strategies learned so far, practice biofeedback-assisted relaxation. Continued training in problem-solving skills and use of cognitive strategies. Plan for maintenance.
Session #8 (Parent and child)	Review diaries. Brief review of techniques learned to date. Assess parent's perception of the subject's progress and review their role as "coach." Plan for maintenance of skills.

Pharmacological Intervention

Participants were given amitriptyline, a tricyclic antidepressant previously studied for prophylaxis of headache in youth (Hershey, Powers et al., 2000)³.

A goal dosage of 1.0 mg/kg/day was prescribed.

Side effects were minimized by dosing

- *.25 mg/kg for 2 weeks
- *.50 mg/kg for the next 2 weeks
- *.75 mg/kg for the following 2 weeks
- * and then 1.0 mg/kg thereafter.

Outcome Measures

Headache Diary

DID YOU TAKE YOUR STUDY MEDICATION? ____ Yes ____ No
 DID YOU HAVE A HEADACHE TODAY? ____ YES ____ NO
 AT WHAT TIME? ____ AM ____ PM
 WHAT PAIN MEDICATIONS DID YOU TAKE? _____
 HOW LONG DID IT LAST? ____ HOURS ____ MINUTES

PLEASE RATE HOW MUCH IT HURT ON THE LINE BELOW:
 No _____ Worst Possible Pain

HOW BAD DID YOUR HEADACHE GET? ____ MILD ____ MODERATE ____ SEVERE

PLEASE DESCRIBE YOUR HEADACHE

throbbing/pounding/stabbing pressing/squeezing/constant sharp other

LOCATION ____ one-side ____ both sides

AND

top back front temples behind eyes all over

ANY OTHER SYMPTOMS?

Nausea Sensitive to light Aura Vomiting
 Sensitive to sound Worse with activity/avoided activity

Pediatric Migraine Disability Assessment (PedMIDAS)⁶

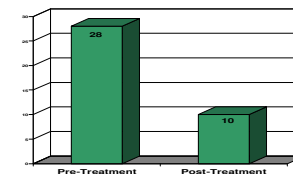
The following questions try to assess how much the headaches are affecting day-to-day activity. Your answers should be based on the last three months. There are no "right" or "wrong" answers so please put down your best guess.

- How many full school days of school were missed in the last 3 months due to headaches?
- How many partial days of school were missed in the last 3 months due to headaches (do not include full days counted in the first question)? _____
- How many days in the last 3 months did you function at less than half your ability in school because of a headache (do not include days counted in the first two questions)? _____
- How many days were you not able to do things at home (i.e., chores, homework, etc.) due to a headache? _____
- How many days did you not participate in other activities due to headache (i.e., play, go out, sports, etc.)? _____
- How many days did you participate in these activities, but functioned at less than half your ability (do not include days counted in the 5th question)? _____

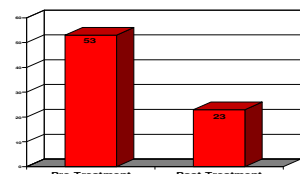
Results

Findings regarding headache frequency and disability were evaluated in two ways. First, number of headaches per month and PedMIDAS total scores were examined at pre-treatment and post-treatment using paired t-tests. Second, clinical significance was defined in each outcome ($\geq 50\%$ reduction in headache frequency and disability grade of "mild" to "none"⁴) and the proportion of subjects meeting these endpoints at post-treatment were examined using chi-square analysis.

Headache Frequency



PedMIDAS Total Scores



Clinical Significance of the Results

% with $\geq 50\%$ Reduction in Headache Frequency	71%
% with a Post-Treatment PedMIDAS Grade of "Mild" to "None"	57%

Conclusions

- Youth with chronic daily headaches reported improvement in headache frequency and disability following combined pharmacological and behavioral intervention.
- Although preliminary, these findings support the development and conduct of controlled clinical trials examining the efficacy of combined interventions compared to single modality treatment (pharmacologic or behavioral).

Implications

- Evidence-based treatments for children and adolescents with CDH are needed, and such interventions need to impact both headache symptoms and quality of life.
- A randomized clinical trial of combined therapy versus pharmaceutical therapy alone is currently being planned based upon the results of the pilot study.

¹ Families' socioeconomic status was evaluated using the Hollingshead Four-Factor Index (Hollingshead, 1975), with I = lowest level and V = highest level

² Hershey AD, Powers SW, Benti AL, LeCates S, deGrauw TJ. Characterization of chronic daily headaches in children in a multidisciplinary headache center. *Neurology*. 2001; 56(8):1032-1037.

³ Hershey AD, Powers SW, Benti AL, deGrauw TJ. Effectiveness of amitriptyline as a prophylactic treatment for pediatric migraines. *Headache*. 2000; 40:539-549.

⁴ Hershey AD, Powers SW, Vockell A-LB, LeCates SL, Segers A, & Kabbouche MA. Development of a patient-based grading scale for PedMIDAS. *Cephalalgia*. 2004; 24:844-849.