Headstrong: A Pilot Study of a CD-ROM Intervention for Recurrent Pediatric Headache

Mark Connelly,[1] PHD, Michael A. Rapoff,[1] PHD, Nicole Thompson,[2] MA, and Wendy Connelly,[2] BA

[1]University of Kansas Medical Center, Division of Behavioral Pediatrics and [2]University of Kansas

Objectives   To empirically evaluate a minimal therapist contact CD-ROM pain management program for recurrent pediatric headache developed as part of this study.   **Methods**   Participants were 37 children aged 7–12 attending a pediatric neurology clinic for evaluation of recurrent headache. Children who were randomly assigned to the treatment group worked through the CD-ROM program on home computers for 4 weeks following baseline assessment, whereas those assigned to the wait-list group continued following the prescriptions of their neurologist. Data on daily headache activity and headache-related disability were collected at baseline and up to 3 months after treatment.   **Results**   Children who received the adjunctive CD-ROM program had significant improvements in headache activity above and beyond those in the control group. Results provide initial support for the utility of adding an adjunctive CD-ROM psychological intervention to standard medical care for recurrent pediatric headache and potentially other chronic pain conditions in children.

Key words   CD-ROM; child; chronic daily headache; headache disorders; migraine; tension headache; treatment.

Recurrent pediatric headache is one of the most common chronic pain syndromes in children and is second only to seizure as the most common reason for referral to a pediatric neurologist (Jay & Tomasi, 1981; Perquin et al., 2000). Headache syndromes in children are associated with marked impairments in quality of life, including impairment in physical, academic, and social functioning (McGrath, 2001). Further, recurrent headache syndromes in children are often precursors to debilitating headache syndromes into adulthood (Bille, 1981; Hockaday, 1978; Holden, Levy, Deichmann, & Gladstein, 1998). The extensive impact of headache on functioning has been the impetus for a recently announced global campaign to reduce the burden of headache worldwide (Steiner, 2004). Thus, research on interventions for pediatric headache is a timely issue.

Previous research has demonstrated that pharmacological treatments of pediatric headache are capable of significantly reducing headache activity (Levin, 2001; Lewis, Diamond, Scott, & Jones, 2004; Wasiewski, 2001), albeit some studies fail to support this (Forsythe, Gillies, & Sills, 1984; Hermann, Kim, & Blanchard, 1995). Typically, recurrent headache syndromes in children are treated abortively using mild pain relievers or triptan medications, prophylactically using cardiovascular drugs or psychotropic medications, or some combination of these (Levin, 2001). Several problems have been associated with pharmacological interventions for pediatric headache, including concerning side effect profiles, the prevalence of contraindications, poor adherence, high cost, and questionable efficacy in some cases (McGrath, Stewart, & Koster, 2001). This has prompted an interest in psychological interventions. Studies have suggested that psychological interventions, including relaxation and cognitive pain management strategies, are as effective as pharmacological interventions for

recurrent pediatric headache and are capable of bolstering gains made on medication alone (Hermann et al., 1995; Holroyd et al., 1995; Olness, MacDonald, & Uden, 1987; Sartory, Müller, Metsch, & Pothmann, 1998). However, several issues have limited the viability of psychological approaches in practice. For example, clinic-based psychological interventions are often costly to the family and healthcare system, may not be accessible to many families, require missed school or work to attend sessions, and are time-intensive (McGrath, 1999; Rowan & Andrasik, 1996). Thus, an important advancement in pediatric headache research is to develop efficacious psychological interventions capable of addressing these limitations.

The objective of this study was to test a minimal therapist contact treatment for recurrent pediatric headache by using the CD-ROM as a medium for delivering empirically-supported psychological interventions. We hypothesized that children receiving the adjunctive CD-ROM program would demonstrate superior reductions in headache activity relative to those in a wait-list control condition receiving standard medical care only. We further hypothesized that the reductions in headache activity associated with using the CD-ROM program would effect relatively greater positive changes in headache-related disability than those observed in the wait-list control condition.

Method
Participants

Figure 1 shows the number of participants screened and those comprising the final sample. Participants were 37 children (19 male and 18 female) between the ages of 7 and 12 years ($M = 10.00$, $SD = 1.66$) who attended the outpatient neurology clinic at a large children's hospital in the Midwestern part of the United States from August of 2002 through February of 2003. Children were largely Caucasian (86%) and middle-class consistent with the general trend in the literature (Martin, Dorfman, McMillan, & McMillan, 1994; Schwartz, Stewart, Simon, & Lipton, 1998; Stewart, Lipton, & Liberman, 1996). The remainder of the self-identified ethnic breakdown was as follows: 8% Hispanic, 3% African-American, and 3% Asian. The majority of participants had migraine without aura (76%), followed by chronic migraine (24%). Most patients (65%) were prescribed prophylactic medications including beta-blockers (e.g., Inderal®), tricyclic antidepressants (e.g., Elavil®), or anticonvulsants (e.g., Topamax®), followed by non-steroidal anti-inflammatory drugs (e.g., Midol®) or triptans (e.g., Imitrex®).
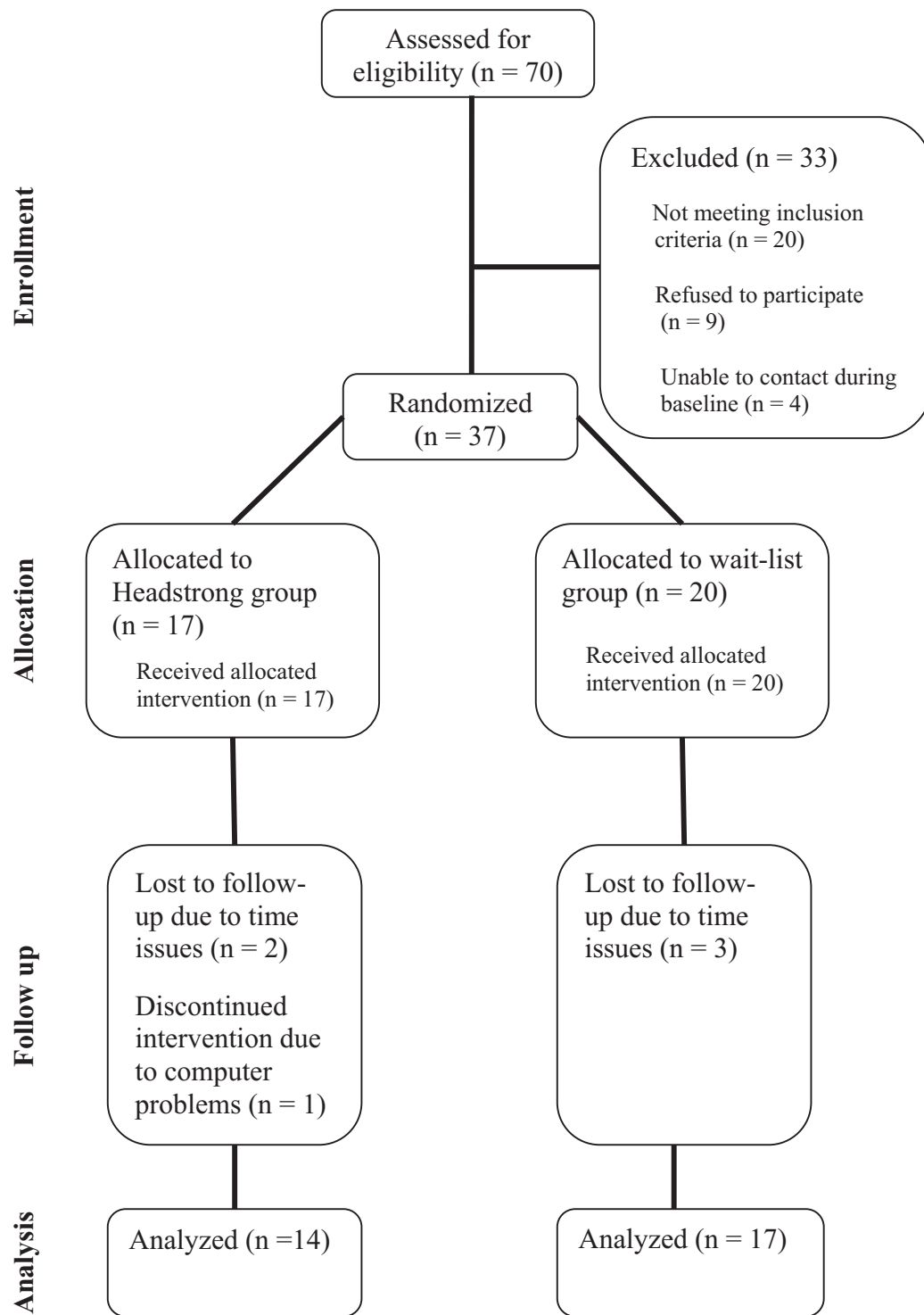
Patients were recruited who had clinical diagnosis by a neurologist of a nonmalignant recurrent headache syndrome (migraine with or without aura and tension-type, including chronic migraine and chronic tension-type headache) based on revised International Headache Association classification standards for pediatric headache (Headache Classification Subcommittee of the International Headache Society, 2003; Winner, Wasiewski, Gladstein, & Linder, 1997). Headaches had to occur at an average frequency of at least four times monthly per caregiver or child report and be separated by symptom-free periods. Children were deemed otherwise healthy by means of a medical history, physical examination, and vital-sign measurement.

Exclusion criteria were history of seizure, significant developmental delay per parent report, or psychological impairments determined through interview by psychology research staff to have impeded ability to complete study requirements (e.g., clinical depression). Children having concurrent chronic or acute illness or taking other medication that might confound headache ratings were excluded. Children who were non English-speaking were also excluded from participation. Children provided signed assent, and their legal guardians signed a consent form approved by the institutional review boards of the participating institutions. Of the 70 children approached for recruitment, 20 did not meet criteria for entry into the study (15 did not meet headache frequency inclusion criteria, 3 had a history of seizure, and 2 were non-English speaking), 9 refused to participate due to time constraints, and 4 could not be contacted during the baseline assessment period.

Measures

Headache Activity
The headache diary is the standard dependent variable in headache treatment outcome studies (Blanchard & Andrasik, 1985). In this study, child participants were asked to independently record the occurrence, duration, and intensity of headache activity at the end of each day. Children also recorded medication use in response to the headache. Caregivers were asked to record the occurrence, duration, and intensity of their child's headache activity independently from their child using daily headache diaries. Cross-informant (child-caregiver) concordance (assessed using one-way random effects intraclass correlation coefficients) at baseline for the current sample were all statistically significant (<.01) and were found to range from .75 to .80 for frequency per week, .60–.75 for duration per episode, and .41–.50 for intensity per episode. Information from the diaries

Enrollment

Assessed for
eligibility (n = 70)

Excluded (n = 33)

Not meeting inclusion
criteria (n = 20)

Refused to participate
(n = 9)

Unable to contact during
baseline (n = 4)

Randomized
(n = 37)

Allocation

Allocated to
Headstrong group
(n = 17)

Received allocated
intervention (n = 17)

Allocated to wait-list
group (n = 20)

Received allocated
intervention (n = 20)

Follow up

Lost to follow-
up due to time
issues (n = 2)

Discontinued
intervention due
to computer
problems (n = 1)

Lost to follow-
up due to time
issues (n = 3)

Analysis

Analyzed (n =14)

Analyzed (n = 17)

Note: Intent-to-treat (ITT) analysis was used, and therefore the effective number of cases

analyzed for the ITT sample was $n = 17$ for the treatment group and $n = 20$ for the control group.

Figure 1. Number of participants screened, randomized, and analyzed in the Headstrong study. Intent-to-treat (ITT) analysis was used, and therefore the effective number of cases analyzed for the ITT sample was $n = 17$ for the treatment group and $n = 20$ for the control group.

on headache frequency per week, duration and intensity per episode, and headache index composite (duration × intensity summed across occurrences) was used for statistical analyses.

Headache-Related Disability

The Pediatric Migraine Disability Assessment (PedsMIDAS) (Hershey et al., 2001) is a developmentally sensitive six-item questionnaire quantifying the level of headache-related disability in the past month at school, at home, and at sport and social activities. Reliability has been found to be 0.78 for internal consistency and 0.80 for 2-week test–retest reliability (Hershey et al., 2001). Support for the convergent validity of the measure was obtained by finding significant positive correlations with frequency, duration, and severity of headaches. The PedsMIDAS was also found to be sensitive to medical treatment response. A parent proxy measure for the PedsMIDAS was included to assess convergence between child and parent reports of headache-related disability. In this study, estimates of internal reliability (Cronbach's alpha) at baseline were found to be .66 (child) and .73 (caregiver), and caregiver–child concordance assessed by an intraclass correlation coefficient was found to be .71.

Procedure

Children were recruited for the study by research staff during their initial appointment at an outpatient neurology clinic. Following a brief screening interview to ensure inclusion criteria were met, the study was discussed with the child and caregiver and consent/assent was obtained from those families interested in participating. Packets containing baseline diaries and questionnaires were then given and explained to participating families, and they were told they would be called each week to see if they had any questions regarding completing the diaries. Families also were told that they would be paid $10 for completing each assessment packet (for $50 per family over the course of the study).

Participating children and their caregivers completed daily headache diaries for 14 days during the baseline phase. Families returned the diary information weekly via prepaid envelopes. Following the baseline period, participants were stratified by age (7–9 and 10–12) to ensure relatively equal representation of ages across groups and were randomly assigned to one of two groups (treatment or wait-list control) by a research assistant using a Uniform Random Numbers (URN) table. No restriction was placed on the randomization such that unequal group sample sizes were possible.

Study neurologists remained blind to randomization condition throughout the study. Chances of unblinding were limited because follow-up appointments with the study neurologist were scheduled for 3 months following the initial assessment. Further, all interim phone contacts related to medical issues were managed by nurses who were not directly affiliated with the research study.

Following the baseline period, participants in the wait-list control group continued to submit records weekly while following the recommendations of their neurologist. Such recommendations consisted of medication prescriptions (see Table 2 for breakdown of medications prescribed) and dietary and sleep schedule advice. Participants in the wait-list control condition were contacted weekly to encourage consistent record-keeping and to ensure there was no systematic bias in the level of therapist attention received by both groups. The wait-list period continued for 2 months, at which point children were offered the opportunity to receive the Headstrong program and followed the procedures outlined for the treatment group.

Participants in the treatment group continued to follow the recommendations of their neurologist and were sent the Headstrong CD-ROMs immediately following the baseline period. Table I gives an overview of the components covered in the Headstrong program. Participants completed one module per week for 4 weeks (education, relaxation, thought-changing, and pain behavior modification) and were contacted by phone weekly to address questions. Each treatment module covered in the Headstrong program was adapted from interventions found to be efficacious in the pediatric headache literature (Hillier & McGrath, 2001).

Each lesson on the Headstrong program took an average of approximately 10 min to complete (not including home practice); each module could thus be completed within approximately 1 hr. The educational module of the Headstrong program consisted of several fully narrated lessons for which the child would click through in a predetermined order over the course of 1 week. The relaxation module consisted of a rationale and subsequent graphic demonstrations and experiential learning of various relaxation techniques (deep breathing, imagery, and progressive muscle relaxation). For imagery, the child could choose among three different images for experiential learning based on his/her preference. The thought-changing module consisted of a rationale and interactive means of demonstrating how to change thoughts about common stressful experiences (e.g., academic and social stress as well as headaches) to more helpful thoughts. Finally, pain behavior modification

Table I. Overview of the Content Covered on the Headstrong CD-ROM Program

Lesson number	Module number 1: education	Module number 2: relaxation	Module number 3: coping	Module number 4: behavior
1	How to use the Headstrong program	Rationale for relaxation	Rationale for coping	Positive and negative pain behaviors
2	Types of headache	How to use guided imagery	Thought-changing	Pain behavior management
3	Prevalence of headache	How to use deep breathing	Problem-solving	Review of all lessons
4	Typical features of headache	How to use progressive muscle relaxation		
5	How headache is diagnosed and treated			
6	The headache pain puzzle			
Home-work	Submit record sheets (password and quiz sheet) Complete headache triggers assignment	Submit record sheets Submit logs of relaxation practice	Submit record sheets Submit thought-changing and problem-solving worksheets	Submit record sheets Submit pain behavior management plan worksheet

primarily required the child to involve the caregiver(s) in devising and implementing an active pain-coping plan based on the skills learned. Graphics, language, and music were selected to be developmentally appropriate, and all components were fully narrated. Further, children were required to complete quizzes and password sheets at the end of each module and submit these via prepaid mail as a means of assessing adherence and use of the content covered in the program.

After completion of the Headstrong program, participants submitted daily diaries weekly via prepaid mail for 3 months after treatment. The PedsMIDAS questionnaires were completed and returned at the end of each month. Weekly phone calls continued to ensure consistent record keeping and to corroborate frequency data reported in the diaries.

Data Analyses

Data were analyzed using the Statistical Package for the Social Sciences (SPSS, 2004). Missing data on the primary headache variables (frequency, duration, and intensity) were limited in the current sample and appeared to be randomly dispersed (i.e., no systematic differences in missing data between the wait-list and treatment groups, younger or older children, and low or severe baseline headache-related disability). Of the total 2,324 daily diary entries, missing data were limited to 2.9% of all entries. Owing to the relatively small number of missing data and that initial correlation analyses between dummy-coded outcome variables (missing vs. not-missing) and patient characteristics suggested data were missing-at-random (MAR), within-case mean imputation was used to complete the missing data

(Tabachnick & Fidell, 1996). All analyses are based on the intent-to-treat sample using the last-observation-carried-forward method (averaged by week) for imputation of values for participants dropping out of conditions.

To check if randomization was successful, initial univariate analyses of variance (ANOVAs) on averaged baseline headache indices, symptom duration, and participant age were conducted to ensure baseline group equivalency. Chi-square analyses were also used to evaluate potential relationships between group membership and sex, headache type, and treatment type (whether or not the child was taking prophylactic medication vs. only abortive medication).

General Linear Model (GLM) procedures were used for the primary analyses. The composite index of headache activity ("Headache Index") was evaluated as a primary outcome measure by using an analysis of covariance (ANCOVA) as the omnibus pre–post (baseline and 1-month follow-up) statistical test. Group was specified as a fixed between-subject factor, and baseline Headache Index values were entered as a covariate into these models. For this and all subsequent ANCOVA analyses, the statistical assumption of equality of variances within conditional distributions was evaluated using Levene's Test. The assumption of homogeneity-of-slopes was evaluated by specifying a statistical test for the interaction between the covariate and factor. Statistical assumptions for the analyses were found to be supported.

ANCOVAs using the GLM procedure also were used to evaluate posttreatment differences in the specific individual headache variables (headache frequency, duration, and intensity) as a function of group assignment.

Baseline values on these variables served as covariates in these models. Alpha values were adjusted for these tests using a Bonferonni correction (.05/3 = .017). Similar models were used to assess changes in headache-related disability.

With respect to follow-up data, one-way ANOVAs for repeated measures were conducted on Headache Index and headache-related disability scores within the treatment group. The Wilks' Lambda multivariate test statistic was used for these analyses to account for violations of the sphericity assumption in repeated-measures tests.

For the purpose of evaluating "clinically significant improvement," percent improvement in Headache Index was computed for both groups. Individuals attaining 50% improvement in Headache Index values were considered clinically significantly improved as is typical for the headache literature (Blanchard & Schwarz, 1988). The chi-square statistic was used to evaluate the association between clinically significant improvement and group.

Results
Baseline Data

Table II summarizes patient demographic and headache type information for the intent-to-treat (ITT) sample. Univariate ANOVAs or chi-square analyses revealed no significant baseline group differences with regard to age, $F(1, 35) = .01$, ns, symptom duration, $F(1, 35) = .795$, ns, sex, $\chi^2(1, N = 37) = .23$, ns, headache type, $\chi^2(2, N = 37) = 1.84$, ns, or medical treatment, $\chi^2(4, N = 37) = 1.82$, ns. Thus, randomization appeared to be successful.

Pre–Posttreatment Results
Headache Index

Table III displays the descriptive statistics on the primary and secondary outcome variables from baseline to 3-month follow-up. The baseline-adjusted ANCOVA used to evaluate group differences on child-reported Headache Index values at posttreatment was significant, $F(1,34) = 4.22$, $p = .04$, partial $\eta^2 = .11$. The mean posttreatment Headache Index values adjusted for initial differences were ordered as expected, with the treatment group having a smaller adjusted posttreatment mean ($M = 73.61$) relative to the wait-list control group ($M = 116.76$). The identical analysis on caregiver-reported Headache Index values demonstrated a statistical trend in the same direction as the analyses conducted on the child-reported Headache Index values, $F(1,34) = 3.09$, $p = .09$, partial $\eta^2 = .08$.

Individual Headache Variables

Headache Frequency   The baseline-adjusted ANCOVA used to evaluate group differences on child-reported headache frequency values at posttreatment was significant at the adjusted alpha level, $F(1,34) = 7.13$, $p = .01$, partial $\eta^2 = .17$. The strength of relationship between the group factor and dependent variable was strong, with the group factor accounting for 17% of the variance of posttreatment headache frequency whereas holding constant average pretreatment headache frequency. The pattern of adjusted means demonstrated that the treatment group on average had lower posttreatment headache frequency ($M = 2.44$) relative to the wait-list control group ($M = 3.52$). The analysis performed on the caregiver reports of headache frequency was consistent with the findings from child reports, $F(1,34) = 8.90$, $p < .01$, partial $\eta^2 = .21$.

Table II. Demographics and Headache Characteristics for the Treatment and Wait-List Groups

Variable	Treatment group ($n = 17$)	Wait-list group ($n = 20$)
Age, mean (*SD*)	9.88 (1.73)	9.95 (1.64)
Gender [n (%)]		
Male	8 (47.1)	11 (55.0)
Female	9 (52.9)	9 (45.0)
Headache type [n (%)]		
Migraine without aura	11 (64.7)	16 (80.0)
Migraine with aura	1 (5.9)	0 (0.0)
Chronic migraine	5 (29.4)	4 (20.0)
Prescription type [n (%)]		
Beta-blocker (e.g., Inderal)	5 (29.4)	9 (45.0)
NSAID (e.g., Midol®, Aleve®)	6 (35.3)	5 (25.0)
Tricyclic (e.g., Elavil®)	4 (23.5)	4 (29.0)
Triptan (e.g., Imitrex®)	0 (0.0)	1 (5.0)
Anticonvulsant (e.g., Topamax®)	2 (13.8)	1 (5.0)
Symptom duration in months, *M* (*SD*)	31.59 (32.10)	23.90 (19.78)

Headache Duration. Baseline-adjusted ANCOVAs evaluating group differences on posttreatment headache duration were significant at the corrected α level for both child report, $F(1,34) = 23.86$, $p < .01$, partial $\eta^2 = .41$, and caregiver report, $F(1,34) = 10.76$, $p < .01$, partial $\eta^2 = .24$. The strength of the relationship between group and adjusted posttreatment headache duration values was very strong as assessed by partial η^2. The direction of the relationships showed that children in the treatment group on average had shorter posttreatment headaches relative to the wait-list control group per child and caregiver report.

Headache severity Similarly, the baseline-adjusted ANCOVA evaluating group differences on posttreatment headache severity was significant at the corrected alpha level for the child report, $F(1,34) = 11.97$, $p < .01$, partial $\eta^2 = .26$. The identical analysis on caregiver report approached statistical significance with a good effect size, but was not significant at the corrected alpha level, $F(1,34) = 5.24$, $p = .03$, partial $\eta^2 = .24$. Both analyses suggested that children receiving the CD-ROM intervention in addition to standard medical care on average demonstrated superior adjusted posttreatment headache severity values relative to those in the wait-list control condition receiving standard medical care alone.

Headache-Related Disability

After controlling for initial baseline differences in headache-related disability values, groups were not significantly different at immediate posttreatment, $F(1, 34) = .46$, *ns*, partial $\eta^2 = .01$. These results were comparable for the analysis performed on the caregiver proxy measure, $F(1, 34) = .56$, *ns*, partial $\eta^2 = .01$. Within-subjects analyses revealed a trend in which participants in both groups had a reduction in headache-related disability between baseline and posttreatment, Wilks' $\lambda = .914$, $F(1, 35) = 3.28$, $p = .08$, partial $\eta^2 = .09$, with no difference as a function of group assignment.

Two- and Three-Month Posttreatment Follow-Up Results

Headache Index

Data on Headache Index values across all follow-up phases were unavailable for three participants; two of these families cited time constraints associated with daily record keeping as the reason for not completing all follow-up phases, and one of these families moved out of state during the follow-up phase. We continued to use ITT for follow-up analyses by imputing last-observation-carried-forward for these individuals. The repeated measures ANOVA evaluating changes in Headache Index values based on child report across posttreatment phase demonstrated no significant changes between the 1-month ($M = 77.74$, $SD = 88.51$), 2-month ($M = 74.11$, $SD = 87.23$), and 3-month follow-up periods ($M = 85.00$, $SD = 98.43$), Wilks' $\Lambda = .95$, $F(2, 15) = .43$, *ns*, partial $\eta^2 = .05$. Findings held for the Headache Index values based on caregiver report, Wilks' $\Lambda = .85$, $F(1, 16) = 2.78$, *ns*.

Headache-Related Disability

Child-reported headache-related disability values within the treatment group on average continued to decrease from 1-month follow-up ($M = 12.20$, $SD = 9.92$) through 3-month follow-up ($M = 8.29$, $SD = 8.29$). Overall reductions in headache-related disability based on child report immediately following treatment did not significantly change throughout follow-up, Wilks' $\Lambda = .77$, $F(2, 15) = 2.18$, *ns*, partial $\eta^2 = .22$, suggesting general maintenance of posttreatment disability levels throughout the 3-month follow-up period. Posttreatment reductions in headache-related disability levels based on caregiver report were also maintained throughout the follow-up period, Wilks' $\Lambda = .91$, $F(2, 15) = .68$, *ns*, partial $\eta^2 = .08$.

Clinical Significance

The two-way contingency table analysis evaluating the association between clinically significant improvement

Table III. Unadjusted Descriptive Statistics from Baseline through Follow-Up for the Intent-to-Treat (ITT) Sample

Variable	Baseline		1-month posttreatment		2-month follow-up		3-month follow-up	
	T(x)	WL	T(x)	WL	T(x)	WL	T(x)	WL
Frequency/week [*M* (*SD*)]	3.82 (1.71)	4.30 (2.05)	2.33 (1.84)	3.68 (1.77)	2.50 (2.25)	N/A	2.89 (2.66)	N/A
Duration/episode [*M* (*SD*)]	2.87 (.71)	2.41 (.91)	2.46 (1.05)	2.40 (.88)	2.30 (1.06)	N/A	2.20 (1.22)	N/A
Intensity/episode [*M* (*SD*)]	3.30 (.96)	2.79 (1.10)	2.69 (1.24)	2.88 (1.01)	2.52 (.99)	N/A	2.61 (1.32)	N/A
Headache Index [*M* (*SD*)]	134.79 (92.20)	136.86 (120.30)	72.97 (84.99)	117.31 (91.23)	74.11 (87.23)	N/A	85.00 (98.42)	N/A
PedsMIDAS total [*M* (*SD*)]	14.17 (8.15)	15.10 (16.09)	12.20 (9.92)	10.74 (11.61)	9.88 (8.10)	N/A	8.29 (6.00)	N/A

Values in the table are based on child-reported data. T(x) refers to the treatment group; WL refers to the wait-list control group. Duration/episode was measured in hours (range for sample = 0–4 hr). Intensity/episode was measured using a visual analog scale ranging from 0 to 6. Headache Index was computed by multiplying duration by intensity, summing across all headache episodes, and averaging across week (range for sample = 6.30–486.00). PedsMIDAS total comprises headache-related disability days related to school, home, and other activities (range for sample = 0–50).

(i.e., 50% or greater pre-post change on the Headache Index) and group assignment was significant when examining child-reported Headache Index values, Pearson χ^2 (1, N = 37) = 4.37, p = .03, Cramér's V = .34, and caregiver-reported Headache Index values, Pearson χ^2 (1, N = 37) = 6.04, p = .01, Cramér's V = .40. The percentage of participants who were clinically significantly improved at immediate posttreatment for the treatment and wait-list control group were 53% (for both child and parent report) and 20% (15% by caregiver report), respectively. The percent clinically improved in the treatment group increased to 59% by the third month of follow-up based on child report, and decreased somewhat by the third month of follow-up to 47% based on caregiver report.

Predictors of Treatment Success

Sample size in this study precluded a thorough analysis of variables predicting clinically significant changes. However, an exploratory logistic regression that regressed symptom duration, age, sex, and headache type (dummy-coded) on clinical improvement (below vs. above 50% pre–post change in the headache index) did not find any significant predictors for the collapsed sample or within conditions, all b-values <.05, all p's > .10. Further, percent changes in pre–post headache index values did not correlate with any baseline headache indices nor baseline headache-related disability. Data on dose–response relationships were unavailable because of all children in the completer study sample finishing the treatment and returning adherence measures (quiz, password, and workbook sheets) and those lost to follow-up being unavailable to furnish posttreatment data.

Discussion

Results of this study supported the hypothesis that the use of an adjunctive CD-ROM self-management treatment program effects greater reductions in headache activity than standard medical care alone. Greater posttreatment reductions in headache frequency, duration, and intensity, adjusted for baseline values, were attained by the treatment group relative to the wait-list control group. Pre–post reductions in overall headache activity were maintained through the 3-month follow-up period for the treatment group. Moreover, significantly more members of the treatment group than the control group attained the benchmark for clinical significance (i.e., a reduction of 50% or greater on the Headache Index). After adjusting for baseline values, no between-group differences in headache-related disability were observed

at 1-month posttreatment; disability scores on average decreased for both groups from baseline to posttreatment and were maintained through the follow-up period for the treatment group. Results held regardless of informant source; analyses were computed on both child- and caregiver-reported data and were found to be comparable.

This study is the first known to test the CD-ROM as a medium for psychological intervention delivery for pediatric headache, but the results dovetail with findings from related literature on the effect of psychological interventions on headache activity. Previous studies that have attempted to reduce the number of clinic visits by giving families workbooks and audiotaped relaxation exercises between sessions ("minimal contact interventions") have found improvements in the composite Headache Index ranging from 23–64%, and the percentage of those in treatment conditions who were clinically improved by 1-month posttreatment ranges from 38–67% (Allen & McKeen, 1991; Burke & Andrasik, 1989; Griffiths & Martin, 1996; Guarnieri & Blanchard, 1990; Kroener-Herwig & Denecke, 2002; Larsson, Daleflod, Hakansson, & Melin, 1987; McGrath et al., 1992). Although few studies have evaluated psychological interventions as adjuncts to medical care in pediatric headache, the one study directly evaluating this combined approach found a significant increase in treatment efficacy associated with adding a psychological intervention to prophylactic medication management (Holroyd et al., 1995). Thus, the findings of this study fit well with previous work in the area.

There are several departures between this study and previous research on psychological interventions for recurrent pediatric headache. Previous studies on minimal contact psychological treatments were designed to demonstrate that these treatments are as (or close to as) effective as traditional clinic-based psychological interventions rather than to demonstrate efficacy as adjuncts to medical care. Moreover, these studies were rarely consistent with respect to what constituted minimal contact, with protocols ranging from single clinic sessions (McGrath et al., 1992) to several clinic sessions (Allen & McKeen, 1991; Burke & Andrasik, 1989). This study is thus unique from previous research in that it initially demonstrates that a self-management psychological CD-ROM intervention requiring only a few therapist phone call contacts may provide efficacy above and beyond standard medical care alone and thus represent an important adjunctive treatment.

This study was also one of the only studies on a minimal contact psychological intervention to date to attempt to deliver a psychological intervention to children

as young as 7 years old. Generally, psychological interventions for pediatric headache have targeted children at least 10 years of age, yet the typical age of onset is often much earlier (McGrath, 2001). The CD-ROM format for minimal contact psychological intervention delivery in pediatric headache may be ideal to attract younger children and to tailor these types of interventions in a way that allows younger children to profit from them. Equipping children with efficacious psychological tools for headache self-management early on may help prevent the development of a lifelong syndrome (Labbé, 1998).

The failure to observe significant posttreatment group differences on the headache-related disability measure may be a function of several factors. The PedsMIDAS is a new measure still undergoing empirical validation in pediatric headache samples and was derived from its adult counterpart. Some of the items are difficult to understand and to respond accurately for children (e.g., "How many days in the last month 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?"). However, the PedsMIDAS is the only headache-specific measure of disability currently available for children. Another possibility is that group differences may have emerged had the follow-up period been extended for both groups, given that the measure asks the child to reflect back over the past month, and as such potential gains in headache-related disability resulting from the adjunctive treatment program may have not yet been realized. This is supported by our data showing that headache-related disability scores on average continued to decline somewhat at the 2-month and 3-month follow-up periods for the treatment group.

The results of this study must be interpreted within the limitations of the methodology. The sample size on which the analyses in this study were based is limited given that this was a pilot study. Further, the evaluation of the Headstrong program was in the context of a controlled efficacy study, and thus external generalizability is unclear. Relatedly, the sample for this study was drawn from a pediatric neurology clinic and therefore may not be representative of all recurrent childhood-headache cases. Children in this study also were not "blind" to the fact that they were receiving an adjunctive intervention. Finally, we are unable to determine which modules of the CD-ROM intervention were necessary for beneficial outcomes.

Although these issues warrant prudence in interpreting the results, this study found initial support for the utility of using a CD-ROM as a minimal contact adjunctive psychological treatment modality for children with recurrent headache syndromes. Using the Headstrong CD-ROM was found to produce benefits beyond what was obtained by receiving standard medical care alone. Combining standard medical care with an adjunctive minimal contact psychological intervention like the Headstrong program in the treatment of recurrent pediatric headache appears to be an effective and comprehensive headache-management system in which children get the "best of both worlds." Moreover, such an approach may improve accessibility, reduce costs, and limit burdens to both families and the healthcare system.

Acknowledgments

References

Allen, K. D., & McKeen, L. R. (1991). Home-based multi-component treatment of pediatric migraine. *Headache, 31,* 467–472.

Bille, B. O. (1981). Migraine in children and its prognosis. *Cephalalgia, 1,* 71–75.

Blanchard, E. B. & Andrasik, F. (Eds.). (1985). *Management of chronic headaches: A psychological approach.* New York: Pergamon Press.

Blanchard, E. B., & Schwarz, S. P. (1988). Clinically significant changes in behavioral medicine. *Behavioral Assessment, 10,* 171–188.

Burke, E. J., & Andrasik, F. (1989). Home vs. clinical-based biofeedback treatment for pediatric migraine: Results of treatment through 1-year follow-up. *Headache, 29,* 434–440.

Forsythe, W. I., Gillies, D., & Sills, M. A. (1984). Propranolol in the treatment of childhood migraine. *Developmental Medicine and Child Neurology, 26,* 737–741.

Griffiths, J. D., & Martin, P. R. (1996). Clinical- versus home-based treatment formats for children with chronic headache. *British Journal of Health Psychology, 1,* 151–166.

Guarnieri, P., & Blanchard, E. B. (1990). Evaluation of a home-based thermal biofeedback treatment of pediatric migraine headache. *Biofeedback and Self-Regulation*, *15*(2), 179–184.

Headache Classification Subcommittee of the International Headache Society. (2003). *The international classification of headache disorders, 2nd edition.* Cephalalgia, 24 (Suppl. 1), 1–150.

Hermann, C., Kim, M., & Blanchard, E. B. (1995). Behavioral and prophylactic pharmacological intervention studies of pediatric migraine: An exploratory meta-analysis. *Pain*, *60*, 239–256.

Hershey, A. D., Powers, S. W., Vockell, A. L., LeCates, S., Kabbouche, M. A., & Maynard, M. K. (2001). Pedsmidas: Development of a questionnaire to assess disability of migraines in children. *Neurology*, *57*(11), 2034–2039.

Hillier, L. M., & McGrath, P. A. (2001). A cognitive-behavioral program for treating recurrent headache. In P. A. McGrath & L. M. Hillier (Eds.), *The child with headache: Diagnosis and treatment* (Vol. 19, pp. 183–219). Seattle: IASP Press.

Hockaday, J. M. (1978). Late outcome of childhood onset migraine and factors affecting outome, with particular reference to early and late EEG findings. In R. Green (Ed.), *Current concepts in migraine research* (pp. 41–48). New York: Raven.

Holden, E. W., Levy, J. D., Deichmann, M. M., & Gladstein, J. (1998). Recurrent pediatric headaches: Assessment and intervention. *Developmental and Behavioral Pediatrics*, *19*(2), 109–116.

Holroyd, K. A., France, J. L., Cordingley, G. E., Rokicki, L. A., Kvaal, S. A., Lipchik, G. L., et al. (1995). Enhancing the effectiveness of relaxation-thermal biofeedback training with propranolol hydrochloride. *Journal of Consulting and Clinical Psychology*, *63*, 327–330.

Jay, G., & Tomasi, G. (1981). Pediatric headache: A one year retrospective analysis. *Headache*, *21*, 5–9.

Kroener-Herwig, B., & Denecke, H. (2002). Cognitive-behavioral therapy of pediatric headache: Are there differences in efficacy between a therapist-administered group training and a self-help format? *Headache*, *42*(8), 810–818.

Labbé, E. E. (1998). Pediatric headaches. In T. H. Ollendick & M. Hersen (Eds.), *Handbook of Child Psychopathology* (3rd ed., pp. 381–394). New York: Plenum Press.

Larsson, B., Daleflod, B., Hakansson, L., & Melin, L. (1987). Therapist-assisted versus self-help relaxation treatment of chronic headaches in adolescents: A school-based intervention. *Journal of Child Psychology and Psychiatry*, *28*, 127–136.

Levin, S. D. (2001). Drug therapies for childhood headache. In P. A. McGrath & L. M. Hillier (Eds.), *The child with headache: Diagnosis and treatment* (Vol. 19, pp. 109–127). Seattle: IASP Press.

Lewis, D. W., Diamond, S., Scott, D., & Jones, V. (2004). Prophylactic treatment of pediatric migraine. *Headache*, *44*(3), 230–237.

Martin, B. C., Dorfman, J. H., McMillan, J. A., & McMillan, C. A. (1994). Prevalence of migraine headache and association with sex, age, race, and rural/urban residence: A population-based study of Georgia Medicaid recipients. *Clinical Therapeutics*, *16*(5), 855–872.

McGrath, P. A. (1999). Recurrent headaches: Making what works available to those who need it. *Journal of Pediatric Psychology*, *24*(2), 111–112.

McGrath, P. A. (2001). Headache in children: The nature of the problem. In P. A. McGrath & L. M. Hillier (Eds.), *The child with headache: Diagnosis and treatment* (Vol. 19, pp. 1–27). Seattle: IASP Press.

McGrath, P. J., Humphreys, P., Keene, D., Goodman, J. T., Lascelles, M. A., Cunningham, S. J., et al. (1992). The efficacy and efficiency of a self-administered treatment for adolescent migraine. *Pain*, *49*, 321–324.

McGrath, P. A., Stewart, D., & Koster, A. L. (2001). Nondrug therapies for childhood headache. In P. A. McGrath & L. M. Hillier (Eds.), *The child with headache: Diagnosis and treatment* (Vol. 19, pp. 129–158). Seattle: IASP Press.

Olness, K., MacDonald, J. T., & Uden, D. L. (1987). Comparison of self-hypnosis and propranolol in the treatment of juvenile classic migraine. *Pediatrics*, *79*(4), 593–597.

Perquin, C. W., Hazebroek-Kampschreur, A. A., Hamfield, J. A., Bohnen, A. M., van Suijlekom-Smit, L. W., Passchier, J., et al. (2000). Pain in children and adolescents: A common experience. *Pain*, *87*, 51–58.

Rowan, A. B., & Andrasik, F. (1996). Efficacy and cost-effectiveness of minimal therapist contact treatments of chronic headaches: A review. *Behavior Therapy*, *27*, 207–234.

Sartory, G., Müller, B., Metsch, J., & Pothmann, R. (1998). A comparison of psychological and pharmacological treatment of pediatric migraine. *Behavior Research and Therapy*, *36*, 1155–1170.

Schwartz, B. S., Stewart, W. F., Simon, D., & Lipton, R. B. (1998). Epidemiology of tension-type headache.

Journal of the American Medical Association, *279*(5), 381–383.

SPSS. (2004). *SPSS 12.0 Base user's guide*. Mahwah: Prentice Hall.

Steiner, T. (2004). Lifting the burden: The global campaign against headache. *Lancet Neurology*, *3*(4), 204–205.

Stewart, W. F., Lipton, R. B., & Liberman, J. (1996). Variation in migraine prevalence by race. *Neurology*, *47*(1), 52–59.

Tabachnick, B. G., & Fidell, L. S. (1996). *Using multivariate statistics*. New York: Harper Collins Publishers Inc.

Wasiewski, W. (2001). Preventive therapy in pediatric migraine. *Journal of Child Neurology*, *16*(2), 71–78.

Winner, P., Wasiewski, W., Gladstein, J., & Linder, S. (1997). Multicenter prospective evaluation of proposed pediatric migraine revisions to the IHS criteria. *Headache*, *37*, 545–548.