Online Psychological Treatment for Pediatric Recurrent Pain: A Randomized Evaluation

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Objective To evaluate the efficacy of a distance treatment delivered through Internet and telephone for pediatric recurrent pain. **Methods** Forty-seven participants (9–16 years of age) were randomly assigned to either an Internet-based treatment or a standard medical care waitlist. Treatment employed a Web-based manual for children and parents with weekly therapist contact by telephone or e-mail. At 1- and 3-month follow-ups, participants were assessed on the outcome variables of pain and quality of life. A 50% reduction in diary pain scores was considered clinically significant. **Results** Significant between-group differences were found: 71 and 72% of the treatment group achieved clinically significant improvement at the 1- and 3-month follow-ups, respectively, whereas only 19 and 14% of the control group achieved the criterion. No significant differences were found on the quality of life variable. **Conclusions** Distance methods have considerable potential for making effective treatments more accessible with lower associated costs.

Key words abdominal pain; distance treatment; headache; Internet; online; pediatric; recurrent pain.

Although the potential of conducting clinical trials and services online is appealing, online health care applications are relatively unexplored (McAlindon, Formica, Kabbara, LaValley, & Lehmer, 2003). Distance applications, such as those delivered over the Internet or by telephone, offer significant promise for rural and other underserved populations as they expand both provider and client access to health care (Devineni & Blanchard, 2005; Jerome & Zaylor, 2000). Underserved populations that may particularly benefit from distance treatments include those with chronic or recurrent conditions that require multiple treatment sessions and patient work between sessions. In particular, youth may be receptive to receiving online health care services, as the Internet has emerged as one of this age group's top health information resources (Gray, Klein, Noyce, Sesselberg, & Cantrill, 2005). If carefully designed and implemented, distance treatment models could ultimately transcend barriers such as geography, economic status, and access (Stamm, 1998).

Children with recurrent pain are one such health care population that is underserved (Zahner, Pawelkiewicz, DeFrancesco, & Adnopoz, 1992). In a recent study, Perquin et al. (2000) found that 25% of children in a large community sample reported experiencing ongoing or recurrent pain over a 3-month period. Typically, the most commonly reported physical pediatric symptoms are headaches, abdominal pain, back pain, limb pain, and fatigue (Anttila, Metsahonkala, Mikkelsson, Helenius, & Sillanpaa, 2001). Of these difficulties, recurrent pediatric headache (RPH) and recurrent or functional abdominal pain (RAP) have undergone the most intensive study.

Prevalence rates of RPH are estimated to be approximately 10–15% for school-aged children (Abu-Arefeh & Russell, 1994; Passchier & Orlebeke, 1985) and up to

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Journal of Pediatric Psychology 31(7) pp. 724–736, 2006
doi:10.1093/jpepsy/jsj065
Advance Access publication August 10, 2005

28% in older adolescents (Split & Neumann, 1999), with tension headaches occurring more commonly than migraines. Prevalence rates of RAP are estimated to be between 10 and 20% for school-aged children (Apley, 1975; Farrell, 1984; Rappaport, 1989), with the pain most common in children between 8 and 10 years of age (Engstrom & Lindquist, 1998).

Recurrent pain problems often interfere with activities of daily living, including school, social functioning, physical activity, and family responsibilities and relationships (Kashikar-Zuck, Goldschneider, Powers, Vaught, & Hershey, 2001), with potential negative outcomes in both the short- and long-term. For most children with recurrent pain, current models of health care delivery are insufficient. Although some individuals have spontaneous remissions with usual care after only a few recurrent pain episodes, a large proportion do not show significant improvement without treatment (Larsson, Dalefold, Hakansson, & Melin, 1987; Sanders et al., 1989).

Cognitive-behavioral approaches that include relaxation strategies appear to be the most effective psychological treatment for recurrent pain problems (Eccleston, Morley, Williams, Yorke, & Mastroyannopoulou, 2002; Holden, Deichmann, & Levy, 1999; Janicke & Finney, 1999). The efficacy of such treatments has been established through many studies with children and adolescents (Kroener-Herwig & Denecke, 2002; Larsson et al., 1987; McGrath et al., 1992; Sanders et al., 1989; Sanders, Shepherd, Cleghorn, & Woolford, 1994).

Sanders et al. (1989) used a randomized control group design to examine the effectiveness of a cognitive-behavioral approach in treating nonspecific RAP. At 3-month follow-up, participants in both groups had experienced a reduction in pain, but children in the treatment group showed more rapid improvement, were more likely to be pain-free (88% vs. 38%), and were observed by teachers to have improved at school (Sanders et al., 1989).

In a randomized controlled group comparison of therapist-led relaxation therapy versus self-help relaxation in a school-based sample Larsson et al. (1987) demonstrated that both treatment modalities were equally effective. As well, Larsson et al. found that self-administered treatment was 3.5 times more cost-effective than the traditional approach and that participants evaluated both treatments very positively. Furthermore, Larsson (1992) suggested that the cost-effectiveness of self-help training makes it a good candidate to be offered on a large scale.

In a randomized controlled trial, McGrath et al. (1992) assigned participants from a clinical sample to one of three conditions: clinic treatment, self-administered treatment, or placebo attention control. Significant treatment effects were found for both the clinic and self-administered approaches as compared to the control group; however, in examining success rates (i.e., 50% reduction in a headache index) the self-administered treatment was found to have the highest proportion of participants with clinically significant results and was most efficient.

This Study

The main purpose of this study was to evaluate the clinical efficacy of an Internet-based treatment program for pediatric recurrent pain as compared to a standard medical care waitlist control group. The primary outcome of interest was a pain index based on 2-week pain diary scores recorded at 1-month and 3-month follow-ups. Following standard clinical trial methodology (further discussed below), a clinically significant improvement or "success" was defined a priori as a 50% or greater reduction compared with baseline in the sum of pain intensity scores over a 2-week period. Secondary outcomes included quality of life, child and parent satisfaction with the treatment, and efficiency of the treatment.

Method

Participants

Following institutional ethics approval, participants and their parent(s) were recruited over a 12-month period through several sources including media, posters in physicians' offices, and advertisements in school newsletters. Youth were included if they (a) were between the ages of 9 and 17, (b) met the diagnostic criteria of at least three episodes of head or abdominal pain within a 3-month period, severe enough to affect activities as per youth and parent report, (c) had seen their family physician regarding the pain in the previous 12 months as per parent report, (d) had not been previously diagnosed with any serious physical disease underlying the pain as per parent report, and (e) had access to a personal computer and the Internet in their homes.

Figure 1 adapted from the CONSORT statement (Moher, Shulz, & Altman, 2001) illustrates the enrollment process and the progression of participants through the randomized clinical trial (RCT). The 47 participants were stratified by age (9–12 and 13–16 years) and pain severity (high vs. low) and randomly assigned by blocks to either the treatment condition (n = 25) or the standard medical care waitlist condition (n = 22).

Table I summarizes the characteristics of the sample both overall and by group, including baseline pain

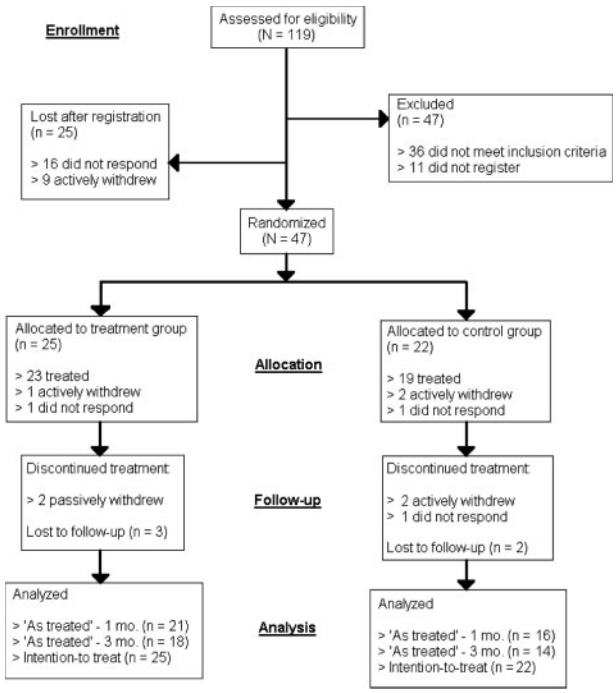

Figure 1. Flow chart of the progression of participants through phases of the randomized clinical trial (RCT).

scores. Six of the youth reported RAP only, 8 reported RPH only, and 33 (70%) reported both RAP and RPH. Table II summarizes participants by diagnosis. Participants identified having many additional difficulties including allergies (30%), asthma (21%), sleep problems (64%), and other health problems (25%). The family socioeconomic status (SES) index (Blishen, Carroll, & Moore, 1987) ranged from 28.3 to 70.3 (M = 44.0), indicating the inclusion of a wide range of occupations, educational levels, and incomes in the present sample. Although most of the participants (61%) lived in cities, several lived 6 to 8 hours away from a major center.

Measures

Demographic and Background Information

Semi-structured telephone intake interviews were conducted with both children and parents to complement the quantitative data obtained from diaries and questionnaires. The aim of these interviews was to obtain pain and health histories and verify eligibility for the study.

Pain

A daily pain diary was used to assess pain intensity before and after treatment through a time sampling method. Participants had the option to complete either paper or online diaries. Pain was recorded by the participant four times per day over a 2-week period, thus at 56 time intervals, using a 0 (no pain) to 10 (worst pain) Numeric Rating Scale (NRS) which yielded four pain indices: (a) pain index (ie., sum of all pain reports; range 0–560), (b) pain frequency (range 0–56), (c) mean intensity of reported pain (range 0–10), and (d) pain-free days (range 0–14).

The daily diary is a frequently used technique to measure pain frequency and intensity, with recording

Table I. Characteristics of the Sample, Overall and by Group at Baseline

Variable	Randomized sample (N = 47)	Treatment group (n = 25)	Waitlist control (n = 22)
Mean age in years (*SD*)	11.7 (2.1)	12.1 (2.0)	11.3 (2.2)
9–12 years (*n*)	28	13	15
13–16 years (*n*)	19	12	7
Gender: female/male	30/17	16/9	14/8
Median duration of pain problem in years (minimum/maximum)	3.0 (0.25/11)	3.0 (0.75/11)	3.0 (0.25/7)
Median frequency of medical contact per year (minimum/maximum)	2.0 (0.5/26)	2.0 (0.5/26)	3.0 (0.5/12)

Table II. Recurrent Pain Diagnosis by Frequency in this Sample: Number of Participants (Percentage)

Diagnosis	Randomized sample [N = 47 (%)]	Treatment group [n = 25 (%)]	Waitlist control [n = 22 (%)]
RAP only	6 (12.8)	3 (12.0)	3 (13.6)
Tension headache only	4 (8.5)	3 (12.0)	1 (4.5)
Migraine headache only	0	0	0
Mixed headache	4 (8.5)	3 (12.0)	1 (4.5)
RAP and tension headache	20 (42.6)	11 (44.0)	9 (40.9)
RAP and migraine headache	2 (4.3)	2 (8.0)	0
RAP and mixed headache	11 (23.4)	3 (12.0)	8 (36.4)

RAP, recurrent or functional abdominal pain.

periods typically ranging from 2 to 4 weeks (Jurish et al., 1983; Kroener-Herwig & Denecke, 2002; Larsson et al., 1987; Scharff, Marcus, & Masek, 2002). Several pediatric headache studies (Richardson, McGrath, Cunningham, & Humphreys, 1983; van den Brink, Bandell-Hoekstra, & Abu-Saad, 2001) have supported the reliability and validity of the pain diary. According to van den Brink et al. (2001), the use of a daily diary for pediatric pain minimizes the recall bias often found with retrospective questionnaires.

Quality of Life

The Pediatric Quality of Life Inventory™ Version 4.0 (PedsQL™ 4.0; Varni, 1998) assessed participants' health-related quality of life before and after treatment. The 23-item Generic Core Scales assess physical, emotional, social, and school functioning over a 1-month period. Developmentally appropriate versions (i.e., ages 8–12 and 13–18) were used. The parent proxy-report of the PedsQL™ 4.0 was used to assess parents' perceptions of their children's health-related quality of life. For both self- and parent-report, three overall scores are calculated: Total Scale Score, Physical Health Summary Score, and Psychosocial Health Summary Score.

In the initial field trials of the PedsQL™ 4.0 Generic Core Scales, 1677 participants were recruited from pediatric health settings, including well-child clinics (Varni, Seid, & Kurtin, 2001). With respect to reliability, the internal consistency coefficients for the three overall scores on the child-report version ranged from 0.80 to 0.89 (Varni et al., 2001; Varni, Burwinkle, Katz, Meeske, & Dickinson, 2002). Construct validity was established through the known-groups method and through correlations between PedsQL™ 4.0 scores and indicators of illness burden.

Treatment Expectation

Upon entry to the study, participants indicated on a Visual Analogue Scale (VAS) how much they expected treatment to help them. The VAS has been used to elicit judgments of expectations (Spafford, von Baeyer, & Hicks, 2002) and opinions regarding health (Tosteson, Kneeland, Nease, & Sumner, 2002). Endpoints on this VAS were labeled "Don't think it will help at all" and "Think it will help a lot." The VAS was scored 0–100 mm.

Participant Feedback

A 100-mm VAS was also used to assess participants' evaluations of treatment and perceived benefit of treatment. After completing treatment, participants were asked to indicate on a VAS how much they were satisfied with the distance treatment modality. Endpoints on this VAS were labeled "Not satisfied" and "Very satisfied." They also used a VAS to indicate how much they thought that treatment had helped with pain management. Endpoints on this VAS were labeled "Don't think it helped at all" and "Think it helped a lot."

Participants and parents also completed checklists to help identify positive features of the program. Feedback was elicited on the program in three areas: appeal, design, and helpfulness.

Treatment Program

The content of the treatment program was adapted from a draft of the Pain Module (McGrath, 2000) for the Family Help project at Dalhousie University. A summary of the treatment program and sample pages from the treatment website can be retrieved from: www.usask.ca/childpain/research/hicks/. The main therapeutic elements of the cognitive-behavioral treatment were relaxation techniques (i.e., deep breathing, relaxation, visualization/imagery) and cognitive strategies (e.g., self-talk). As well, background information was presented on RPH and RAP to promote understanding and to help children recognize that some of their peers deal with similar problems. Positive lifestyle choices such as diet, exercise, and social activity were also emphasized. Each chapter is summarized in Table III. At the end of each chapter, participants answered three to five questions about the information on an online form. There were also two chapters specifically for parents, which discussed ways of encouraging healthy behavior.

During the development phase, the website and materials were revised to incorporate the feedback of nurses, psychologists, parents, psychology graduate and undergraduate students, children, and a physician. Access to the treatment website was given to participants only after randomization.

Very few participants reported difficulty accessing the website. Two families experienced computer problems due to viruses unrelated to study participation. As well, to minimize the likelihood that participation would be affected by server problems, two identical versions of the website were maintained on separate servers.

Each participant in the treatment group also received a personalized relaxation tape, which included many relaxation and imagery techniques. A thought journal was also included in the package, to be used in conjunction with cognitive restructuring strategies.

Table III. Chapter Outlines for the Online Treatment Program

Chapter	Summary
Welcome[a]	Introduction to the program and therapist
	Responsibilities of therapist, child, and parent
1	Confidentiality and its limits
	Tracking pain with a diary
	Identifying pain triggers
	Overview of pain reduction methods
2	Identifying pain management strategies already used
	Information on headaches and stomach aches (i.e., RAP)
	Setting goals for the program
	Deep breathing (included breathing exercise)
3	Physical pain management methods (e.g., heat, cold, massage)
4	Effects of tension
	Benefits of relaxation
	Introduction to full body relaxation and imagery
5	Positive versus negative thinking
	Challenging negative thoughts
	Problematic ways of thinking (e.g., catastrophizing)
	Strategies for changing thinking (e.g., thought stopping)
6	Benefits of social and physical activity
	The story of the tortoise and the hare–pacing yourself
	Mini relaxation
7	Planning to manage pain episodes
	Managing pain at school
	Recognizing progress
	Maintaining the program
	Checkups

RAP, recurrent or functional abdominal pain.
[a]Each chapter corresponds to a week in the program, with the exception of the Welcome chapter which is completed in the same week as chapter 1.

Procedure

Pretreatment

Each potential participant and a parent were screened by telephone. During the screening, the parent was oriented to the study including the length and scope of involvement and the possibility of being placed on a waiting list. The researcher assessed suitability for inclusion and each parent of a child who met the inclusion criteria was given the opportunity to register in the study. After parents indicated that they were interested in participating, registration packages were mailed out. Parental consent and youth assent to participate in the study were obtained. To ensure compliance with diary completion, participants were contacted at least twice during the baseline phase. Following the return of the premeasures, participants were randomly assigned to either the treatment group or the standard medical care waitlist group. Individuals assigned to the waiting list were reminded to see their physician as needed while awaiting the follow-up and treatment.

Treatment

Individuals in the treatment group accessed the online manual, which consisted of a welcome message and seven chapters. They were instructed to work through one chapter per week and to complete the online questions at the end of each chapter. Participants were assigned skills to practice during the week (e.g., deep breathing) and these skills were then subsequently discussed in an e-mail or a telephone call. Parents were also asked to review the welcome message and the two parent chapters.

Over the 7-week treatment, the researcher regularly e-mailed and telephoned participants to check on progress and to review materials. During treatment, participants were contacted, according to a set schedule, by e-mail in weeks 1, 2, 3, 5, and 7 and by telephone in weeks 2, 4, and 6. Parents were contacted by telephone in weeks 2 and 6 and could opt to receive copies of the e-mail messages sent to their children. Additionally, participants and parents were encouraged to contact the researcher by either telephone or e-mail at any time, as needed. All contact between the participants and researcher/therapist was timed during treatment (M = 189 min) and telephone calls constituted the majority of therapist contact time.

Posttreatment

At 1 and 3 months after the completion of treatment, participants and their parents from both the treatment and waitlist groups completed postmeasures. To ensure compliance with diary completion, participants were contacted at least once during the posttreatment phases. After the 3-month follow-up was completed, participants in the waitlist group were offered treatment.

Analyses

Criterion for Success

The use of dichotomous primary outcomes in RCTs has been recently advocated on the grounds that the underlying raw data distributions are generally skewed, making analyses based on mean pain scores misleading (Moore, McQuay, & Gavaghan, 1996; Moore, Moore, McQuay, & Gavaghan, 1997). Specifically, many investigators now use, as a dichotomous criterion for success, a reduction in pain of at least 50% from baseline to posttreatment measures (Barden, Edwards, Mason, McQuay, & Moore, 2004; Janicke & Finney, 1999; McGrath et al., 1992). That criterion was also adopted as the common standard of treatment success in a systematic review and meta-analysis of RCTs related to chronic pain in children and adolescents (Eccleston et al., 2002). Such a measure "allows unequivocal allocation of treatment

success or failure for any chosen level of success" (Barden et al., 2004; p. 355). Comparison of the proportion of successful patients in the treated versus control groups is, therefore, the primary object of statistical analysis. This approach also permits calculation of the number needed to treat (NNT) which is increasingly accepted as an index of treatment effectiveness in relation to placebo or other controls.

Skewness and Kurtosis

The distributions of all variables were examined. Significant skewness and kurtosis were identified using the methods of Tabachnik and Fidell (1996), with alpha set at .05. Significant skewness and kurtosis were found in the pain index scores and the percent change in pain index scores based on the pain diary. The significant values for skewness and kurtosis on the pain index supported the a priori decision to use nonparametric statistical analyses for this primary outcome variable. None of the secondary outcome variables showed significant deviation from normality ($p > .05$ for all skewness and kurtosis statistics), thereby not precluding the use of parametric analyses for all secondary variables.

Equivalence of Groups

The pain index (the sum of diary pain scores over 14 days) was compared for treatment and control groups at baseline using a nonparametric test; the difference was nonsignificant, Mann–Whitney $U = 228$, $p > .31$.

Pretreatment comparisons (t tests) also revealed no significant differences between the treatment and control groups on any demographic, descriptive, or outcome variables. Tables I and IV present the values on these variables for the randomized sample and for each

Table IV. Descriptive Statistics for Pain Outcome Measures by Group and Time of Measurement

	M	*SD*	*Mdn*	Minimum	Maximum
Treatment group					
Baseline ($N = 25$)					
Pain frequency	22.0	16.3	15.0	6	56.0
Mean pain intensity	4.8	1.3	4.9	2.5	7.4
Pain index	—	—	69.0	23	280.0
Pain-free days	4.4	3.6	4.0	0	12.0
One-month follow-up ($N = 21$)					
Pain frequency	11.6	19.1	3.0	0	56.0
Mean pain intensity	3.4	2.4	3.0	0	7.7
Pain index	—	—	11.0	0	429.0
Pain-free days	9.5	4.8	11.0	0	14.0
Three-month follow-up ($N = 18$)					
Pain frequency	13.1	20.4	4.0	0	56.0
Mean pain intensity	2.9	2.1	3.0	0	6.5
Pain index	—	—	9.0	0	362.0
Pain-free days	9.0	5.3	11.5	0	14.0
Control group					
Baseline ($N = 22$)					
Pain frequency	18.1	13.5	14.0	2.0	52.0
Mean pain intensity	4.3	1.6	4.6	1.7	6.9
Pain index	—	—	75.0	8.0	344.8
Pain-free days	5.7	3.8	5.5	0.0	12.0
One-month follow-up ($N = 16$)					
Pain frequency	14.5	11.6	13.5	0.0	49.0
Mean pain intensity	4.7	2.2	4.8	0.0	8.1
Pain index	—	—	64.0	0.0	197.0
Pain-free days	7.1	4.2	7.0	0.0	14.0
Three-month follow-up ($N = 14$)					
Pain frequency	12.1	10.4	10.0	3.0	44.0
Mean pain intensity	4.9	1.3	4.8	2.7	8.0
Pain index	—	—	45.0	8.0	206.0
Pain-free days	7.3	3.4	7.5	0.0	12.0

Pain index, sum of pain scores over 14 days analyzed nonparametrically. Scale range of pain frequency is 0–56, mean pain intensity is 0–10, pain index is 0–560, and pain-free days is 0–14.

of the treatment and waitlist groups, demonstrating the pretreatment similarity.

Randomized participants who completed the pain outcome measures (N = 32) were compared to those randomized participants who withdrew or did not respond (N = 15). No significant baseline differences were found between completers and noncompleters on the pain index, Mann–Whitney U = 183, p > .19, nor on any of the secondary outcome measures, all t < 1.4, p > .24.

Results

Primary Outcome

Detailed descriptive statistics for the pain outcome measures are provided in Table IV. All retained participants returned complete pain diaries at baseline and 3-month follow-up; however, at 1-month follow-up, one participant who wished to withdraw submitted a partially completed diary and was excluded. Only participants who provided complete pain diaries were included in the analyses.

Treatment efficacy was assessed by examining the proportion of participants achieving a 50% or greater reduction on the summed total pain score from baseline to follow-up within each condition (Larsson et al., 1987). As depicted in Fig. 2, significantly more participants in the treatment group (15 of 21; 71%) than in the control group (3 of 16; 19%) achieved this criterion at 1-month follow-up, $\chi^2(1, N = 37) = 10.09$, p = .001. Similarly, at 3-month follow-up, significantly more participants in the treatment group (13 of 18; 72%) than in the control group (2 of 14; 14%) achieved this criterion, $\chi^2(1, N = 32) = 10.62$, p = .001.

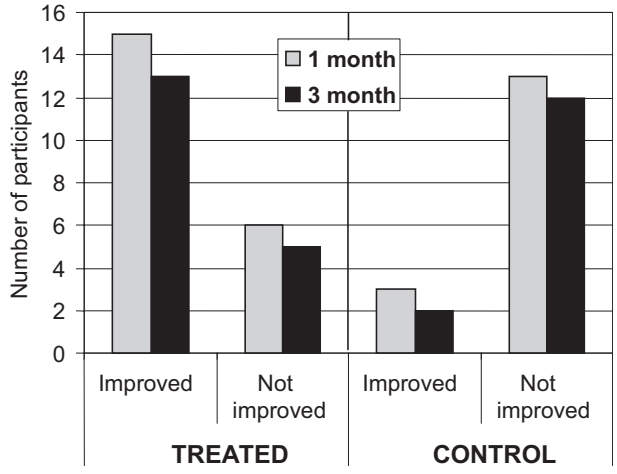

Figure 2. Number of participants who met and did not meet the criterion for improvement, by treatment condition and time of follow-up. The criterion for success was set at 50% or greater reduction in summed total pain score from baseline to follow-up.

Mixed repeated-measures analyses of variance (time by group) were carried out to determine effects on pain frequency, pain intensity, and number of pain-free days. Comparisons with pretreatment means were done separately for 1-month and 3-month follow-ups because of the reduction in number of participants across the successive time points. Effect sizes are shown for these analyses using partial eta-square or η_p^2. For mean pain frequency, there was a significant time by group interaction at 1-month follow-up, $F(1, 35) = 4.52$, p = .041, η_p^2 = .11, but not at 3-month follow-up, $F(1, 30) = 1.26$, *ns*. For mean pain intensity, there was a significant time by group interaction at 1-month follow-up, $F(1, 35) = 7.22$, p = .011, η_p^2 = .17, and also at 3-month follow-up, $F(1, 30) = 14.3$, p < .001, η_p^2 = .32. Thus the treatment group improved more than the control group on pain frequency at 1-month follow-up and on pain intensity at both follow-ups. The number of pain-free days increased significantly more in the treatment group than the control group at 1-month follow-up, $F(1, 35) = 6.34$, p = .017, η_p^2 = .15, and also at 3-month follow-up, $F(1, 30) = 7.03$, p = .013, η_p^2 = .19.

Given that the assumption of the analysis of variance (ANOVA) test of equal cell sizes was not met (Table IV), the data were also subjected to nonparametric analyses. For pain frequency, nonparametric tests results mirrored those reported above: a significant between-group difference was found at 1-month (Mann–Whitney U = 99, p = 0.035) but not at 3-month follow-up. For pain intensity, no difference was found at 1-month follow-up, but the difference at 3-month follow-up reported above was found (Mann–Whitney U = 55, p = 0.006). For pain free days, the nonparametric test did not detect the between group differences that are reported above.

Quality of Life

The internal consistency coefficients for the three overall PedsQL™ scores across times of measurement ranged from 0.93 to 0.95 on the child report version and from 0.91 to 0.94 on the parent report version. All retained participants completed the PedsQL™ at baseline and 1-month follow-up; at 3-month follow-up quality of life data was not available from one child and two parents in the treatment group and from one child and three parents in the control group.

At baseline, the mean total score on the child version of the PedsQL™ was 76.7 (SD = 13.9), and the mean total score on the parent version of the PedsQL™ was 74.0 (SD = 13.6). On the child report PedsQL™, the

Table V. Total Quality of Life Scale Scores by Group and Time of Measurement

	M	*SD*	Minimum	Maximum
Treatment group				
Baseline				
Quality of life total score–child	75.6	14.7	40.2	95.7
Quality of life total score–parent	72.9	13.5	43.5	94.6
One-month follow-up				
Quality of life total score–child	76.3	15.3	50.0	97.8
Quality of life total score–parent	77.9	13.2	51.1	95.7
Three-month follow-up				
Quality of life total score–child	76.2	15.2	50.0	96.7
Quality of life total score–parent	78.6	13.7	43.5	96.7
Control group				
Baseline				
Quality of life total score–child	79.1	11.7	56.5	93.5
Quality of life total score–parent	76.1	13.5	43.5	96.7
One-month follow-up				
Quality of life total score–child	77.7	14.0	48.9	97.8
Quality of life total score–parent	80.2	9.8	63.0	95.7
Three-month follow-up				
Quality of life total score–child	79.5	13.0	54.4	96.7
Quality of life total score–parent	80.8	14.2	55.4	96.7

The Pediatric Quality of Life Inventory™(PedsQL™) is reverse scored and linearly transformed to a 0–100 scale score, with higher scores corresponding to higher quality of life.

mean physical health score was 80.7 (*SD* = 14.9) and the mean psychosocial score was 74.5 (*SD* = 15.1). On the parent-proxy report PedsQL™, the mean physical health score was 78.1 (*SD* = 15.6) and the mean psychosocial score was 71.8 (*SD* = 14.9). Overall, the PedsQL™ scores reflected a moderately high quality of life.

Table V summarizes the total quality of life scores by group. Neither analyses of variance nor nonparametic tests revealed any significant differences between the treatment and control groups on any of the PedsQL™ measures at baseline, 1-month follow-up, or 3-month follow-up. This finding also held when overall average PedsQL™ values were inserted for the few unavailable data points at 3-month follow-up that were described previously. There were also no differences between the treatment and control groups with respect to either percent or absolute change (pre- to 1-month follow-up and pre- to 3-month follow-up) in quality of life scores, as reported by either parents or children. As well, there were no significant correlations between percent changes (pre- to 3-month follow-up) in pain scores and percent changes in child or parent quality of life total scores.

Intention-to-Treat Analysis

An intention-to-treat analysis, in which all participants were included in the analysis regardless of subsequent withdrawal from the study, was conducted to ensure that the clinical effectiveness of the treatment was not overestimated as an artifact of attrition. The last observation carried forward (LOCF) method (see Hollis & Campbell, 1999) was used, in which missing responses on the primary outcome measures were replaced with the last available values on those variables for that participant. When the primary outcome data were reanalyzed using the intention-to-treat methodology, the previously significant effects remained. Furthermore, the nonsignificant findings on the quality of life measures also remained the same.

Clinical Significance

The NNT (Cook & Sackett, 1995) which is the number of individuals needed to enrol in a treatment to have one successfully achieve the desired criterion (with 95% probability) was calculated to be 2 at both 1- and 3-month follow-ups. Thus, only two individuals needed to receive the treatment before one would have a positive result (i.e., meeting the criterion of at least 50% reduction in pain).

Expectation Effects

There were no significant differences between the treatment and control groups in initial expectation. Parent-rated expectations for treatment ($M = 69.7$; $SD = 14.7$) were significantly higher ($t(46) = -3.76$, $p < .0001$) than those reported by the children ($M = 58.3$; $SD = 21.4$).

However, no significant relationships were found between either parent or child expectations for change and subsequent outcome.

Efficiency

For participants who completed the treatment program, the mean therapist time spent was approximately 189 min (Range 121–363 min). An index of the efficiency of the treatment was calculated by dividing the mean percent improvement in the treatment group at the 3-month follow-up by the mean number of minutes of therapist-client contact, resulting in a value of 0.31% per minute. By comparison, other pain studies with a minimal-contact approach with clinic comparisons revealed values of 0.056–0.38% per minute (Jurish et al., 1983; Kroener-Herwig & Denecke, 2002; Larsson et al., 1987; McGrath et al., 1992).

Participant Feedback

Treatment Effectiveness

A strong positive correlation existed between child and parent reports of treatment effectiveness (r = .91, p < .0001). Moderate to strong negative correlations, ranging from –.56 to –.78, were found between effectiveness ratings of children and parents and most outcome measures of percent reductions in pain, indicating that as pain decreased, participant and parent evaluations of treatment effectiveness increased.

Treatment Satisfaction

A strong positive correlation existed between child and parent reports of treatment satisfaction (r = .76, p < .0001), but no significant relationships were found between these reports and scores on outcome measures.

Treatment Checklists

Participants and parents frequently identified "doing treatment from home," "better able to manage pain," and "flexibility" as appealing aspects of the treatment program. The least commonly endorsed aspect by participants, in terms of appeal, was "having parents participate with treatment" and by parents was "not having to see the therapist in person." The "treatment website" was identified by all participants and parents as one of the well-designed aspects of the program, whereas the "end of chapter questions" was least often endorsed by participants and the "thought journal" was least often endorsed by parents. With respect to helpfulness, "telephone call with the therapist" was endorsed most frequently by both participants and parents, whereas the "thought journal" and "questions to answer on the website" were least often endorsed.

Discussion

The primary index of improvement in this study was the proportion of participants achieving a clinically significant (i.e., 50% or greater) reduction on the pain index (summed diary pain scores over 2 weeks) from baseline to follow-up within each condition. Youth participating in the treatment program demonstrated significant post-treatment reductions in pain, as measured by percent change scores from baseline to follow-ups. In the treatment group, 71% of participants achieved clinically significant pain reduction which increased to 72% at 3-month follow-up. By contrast, in the control group, only 19% showed clinically significant reduction of pain at 1-month follow-up (14% at 3 months).

In examining the efficacy of the online treatment program, the central comparisons were between the treatment and standard medical care (i.e., waitlist control) conditions at various points over the course of the study. Considering the baseline equivalence of the groups before treatment, statistically and clinically significant differences in pain scores between these groups at follow-ups provided specific evidence for the efficacy of the Internet-based treatment protocol. The present results were consistent with the findings of previous studies (Kroener-Herwig & Denecke, 2002; McGrath et al., 1992) which have supported the use of minimal-contact programs with children and adolescents to foster self-management of recurrent pain.

Quality of life was expected to improve with concomitant decreases in pain; however, the present results did not support this hypothesis. Quality of life ratings were not significantly different across groups at any time of measurement and there were no significant correlations between these ratings and changes in pain scores. It is unclear whether quality of life did not, in fact, improve, or whether improvement occurred but was not detected. Given that previous treatment studies (Youssef et al., 2004) have found the PedsQL™ to be sensitive to treatment effects in clinical populations, it is unlikely that a lack of responsiveness in the measure can account for the present findings. Other factors including the inclusion of a community rather than referred sample or the moderately high quality of life scores at baseline (i.e., a ceiling effect) may account for the lack of change in quality of life scores.

Quality of life and functional impairment are important outcome dimensions that have been neglected in pediatric pain intervention trials. Comprehensive treatment must ameliorate both pain experience and functional impairment; however, interventions that demonstrate efficacy in treating one, but not both, of these dimensions may still be useful. Moreover, when such interventions

have additional strengths, such as cost-effectiveness, accessibility, and patient satisfaction, they can potentially contribute significantly to comprehensive treatment programs.

Comorbidity

Surpassing rates typically cited in the literature, 70% of the sample met criteria for both RAP and RPH. Multiple measures (i.e., interviews, pain diaries) were used to confirm that youth met the research criteria for each type of pain reported, but wording on recruitment advertisements (i.e., "Are headaches or stomach aches a problem for your child?") may have contributed to this finding. No differences were found between participants reporting one type of pain problem and those reporting both, in terms of attrition or primary outcome measures.

Admittedly, this high rate of comorbidity could affect the generalizability of the present findings to other pediatric pain populations; however, comorbidity rates of recurrent pains vary greatly across studies. Comorbidity rates for RAP with RPH have been estimated to range from 5 to 51% (Anttila et al., 2001; Aromaa, Sillanpaa, Rautuva, & Helenius, 2000; Perquin et al., 2000). A lack of consistency in definitions of recurrent pain and differences in population samples have led to such disparate comorbidity estimates.

Practical Implications

Cost-Effectiveness

Recurrent pain produces many types of costs, including those that are direct, indirect, and intangible (Michel, 2000). Not surprisingly, a primary goal in health care is to develop cost-effective treatments that reduce the incidence of costly illnesses. Recurrent pain problems are time-consuming, and thus costly, for medical practitioners. With an average treatment time per participant of approximately 3 h, the present distance treatment program is estimated to be 5.5 times more cost-effective, with respect to consumption of therapist time, than office-based individual therapy, such as that described by Jurish et al. (1983). Online treatments are also cost-effective with respect to treatment materials, compared to paper version alternatives. Not only are the immediate costs of production and distribution less, but so, too, the costs incurred at later times when treatment materials must be modified or updated are significantly less. Given that this evaluation of cost-effectiveness only accounts for the therapist's time and treatment materials, future studies should measure cost-effectiveness from the perspective of the participants (e.g., taking into account their travel time and time away from work).

Clinical Significance and Efficiency

The NNT is the number of individuals needed to include in the treatment to have one succeed to a criterion. Values close to 1 are considered to be very rare and values of 2 or 3 denote that a treatment is very effective. The present results yielded NNT = 2, indicating that this treatment program shows promise for both efficacy and efficiency. Comparable results have been found with other psychological interventions for recurrent pain. In a meta-analysis of RPH and RAP trials, Eccleston et al. (2002) found that the odds ratio for a 50% reduction in pain was 9.62, with a NNT of 2.32.

Limitations

Sample Size and Attrition

The sample size in this study, like many, was reduced because of attrition, which has obvious implications for statistical power and analyses. Attrition rates in traditional office therapy tend to range from 30 to 60% (Garfield, 1994). With the anonymity inherent in distance treatment, there is a risk that attrition rates will be comparable to, if not higher, than those observed in traditional settings. In the present case, the attrition rate was similar to that observed with in-office therapy. Additionally, when compared to other pediatric pain intervention studies with a self-administered condition (Larsson et al., 1987; McGrath et al., 1992), in which attrition ranged from 15 to 25%, the level of attrition after randomization in the present sample was comparable.

In this study, the first and largest block of attrition was the 35% of those who expressed initial interest but did not complete baseline measures ("nonresponders"). The second block of attrition occurred between baseline and 1-month follow-up, and the third block of attrition occurred at follow-up. Even with attrition, the present sample was larger than 25 of the 31 studies included in a meta-analysis of RPH treatments conducted by Holden et al. (1999) and seven of the nine RAP intervention studies reviewed by Janicke and Finney (1999).

Differential attrition was also a limitation in this study. Within the treatment group, there were gender and age effects with younger children and males being more likely to withdraw; however, the issue was addressed, in part, using an intention-to-treat analysis, with significant treatment effects maintained.

Pain Severity

If the overall pain of the present participants is considered to be mild to moderate (with a mean baseline pain intensity of 4.6/10), then the present results may not

generalize to more severely affected pain populations. Children with more severe pain, such as those with chronic daily headache, might require more intensive treatment. The efficacy of a distance treatment program for youth with moderate to severe pain is an important area for future research.

Additionally, given the cyclical nature of recurrent pain, care must be taken to identify temporally-based confounding variables, such as season of the year, which may contribute to changes in the dependent variables. In this study, the continuous intake allowed participants to be enrolled at different times of the year, thus limiting the influence of season on the outcome measures. Nonetheless, future studies should follow participants over a longer period to determine whether treatment gains are maintained and to systematically address the effects of the cyclical nature of recurrent pain.

Future Directions

Although there is an emerging sense of the possibilities afforded by distance treatments, there is also a need to determine optimal ways to implement such programs. For example, an initial face-to-face office visit to establish rapport may significantly enhance retention and efficacy. Ultimately, combining the best aspects of the traditional and alternative approaches may be the way to maximize effective service delivery resources. Distance treatments merit continued clinical trials, given the efficacy and cost-effectiveness of this alternative modality.

Acknowledgments

This paper is based on the first author's PhD dissertation in clinical psychology at the University of Saskatchewan under the supervision of the second author. The research was presented in part as a poster at the 2002 Annual Meeting of the International Association for the Study of Pain, San Diego, CA, USA, August 2002. The first author acknowledges the support received through the Peter Samuelson STARBRIGHT Foundation 2002 Dissertation Award in pediatric psychology and the Canadian Pain Society Small Grant for Local and Regional Initiatives. McGrath is supported by a Canada Research Chair. The authors are also grateful for the assistance of Elizabete Rocha, Lara Spagrud, and Stephen Shaw.

Received March 5, 2004; revisions received June 22, 2004; accepted July 26, 2004

References

Abu-Arefeh, I., & Russell, G. (1994). Prevalence of headache and migraine in schoolchildren. *British Medical Journal*, *309*, 765–769.

Anttila, P., Metsahonkala, L., Mikkelsson, M., Helenius, H., & Sillanpaa, M. (2001). Comorbidity of other pains in schoolchildren with migraine or nonmigrainous headache. *Journal of Pediatrics*, *138*, 176–180.

Apley, J. (1975). *The child with abdominal pains* (2nd ed.). Oxford: Blackwell Scientific Publications.

Aromaa, M., Sillanpaa, M., Rautuva, P., & Helenius, H. (2000). Pain experience of children with headache and their families: A controlled study. *Pediatrics*, *106*, 270–275.

Barden, J., Edwards, J. E., Mason, L., McQuay, H. J., & Moore, R. A. (2004). Outcomes in acute pain trials: Systematic review of what was reported? *Pain*, *109*, 351–356.

Blishen, B. R., Carroll, W. K., & Moore, C. (1987). The 1981 socioeconomic index for occupations in Canada. *Canadian Review of Sociology and Anthropology*, *24*, 465–488.

van den Brink, M., Bandell-Hoekstra, E. N. G., & Abu-Saad, H. H. (2001). The occurrence of recall bias in pediatric headache: A comparison of questionnaire and diary data. *Headache*, *41*, 11–20.

Cook, R. J., & Sackett, D. L. (1995). The number needed to treat: A clinically useful measure of treatment effect. *British Medical Journal*, *310*, 452–454.

Devineni, T., & Blanchard, E. B. (2005). A randomized controlled trial of an internet-based treatment for chronic headache. *Behavior Research and Therapy*, *43*, 277–292.

Eccleston, C., Morley, S., Williams, A., Yorke, L., & Mastroyannopoulou, K. (2002). Systematic review of randomised controlled trials of psychological therapy for chronic pain in children and adolescents, with a sub-set meta-analysis of pain relief. *Pain*, *99*, 157–165.

Engstrom, I., & Lindquist, B. L. (1998). Gastrointestinal disorders. In R. Ammerman & J. Campo (Eds.), *Handbook of pediatric psychology and psychiatry* (pp. 206–223). Boston, MA: Allyn & Bacon.

Farrell, M. K. (1984). Abdominal pain. *Pediatrics, 74*(5, Pt. 2), 955–957.

Garfield, S. L. (1994). Research on client variables in psychotherapy. In S. L. Garfield & A. E. Bergin (Eds.), *Handbook of psychotherapy and behavior change* (4th ed., pp. 190–228). New York: Wiley & Sons.

Gray, N. J., Klein, J. D., Noyce, P. R., Sesselberg, T. S., & Cantrill, J. A. (2005). Health information-seeking behaviour in adolescence: The place of the internet. *Social Science and Medicine*, *60*, 1467–1478.

Holden, E. W., Deichmann, M. M., & Levy, J. D. (1999). Empirically supported treatments in pediatric psychology: Recurrent pediatric headache. *Journal of Pediatric Psychology*, *24*, 91–109.

Hollis, S., & Campbell, F. (1999). What is meant by intention to treat analysis? Survey of published randomised controlled trials? *British Medical Journal*, *319*, 670–674.

Janicke, D. M., & Finney, J. W. (1999). Empirically supported treatments in pediatric psychology: Recurrent abdominal pain. *Journal of Pediatric Psychology*, *24*, 115–127.

Jerome, L. W., & Zaylor, C. (2000). Cyberspace: Creating a therapeutic environment for telehealth applications. *Professional Psychology: Research and Practice*, *31*, 478–483.

Jurish, S. E., Blanchard, E. B., Andrasik, F., Teders, S. J., Neff, D. F., & Arena, J. G. (1983). Home- versus clinic-based treatment of vascular headache. *Journal of Consulting and Clinical Psychology*, *51*, 743–751.

Kashikar-Zuck, S., Goldschneider, K. R., Powers, S. W., Vaught, M. H., & Hershey, A. D. (2001). Depression and functional disability in chronic pediatric pain. *Clinical Journal of Pain*, *17*, 341–349.

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? *Journal of Psychosomatic Research*, *53*, 1107–1114.

Larsson, B. (1992). Behavioral treatment of somatic disorders in children and adolescents. *European Child and Adolescent Psychiatry*, *1*, 68–81.

Larsson, B., Dalefold, 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.

McAlindon, T., Formica, M., Kabbara, K., LaValley, M., & Lehmer, M. (2003). Conducting clinical trials over the internet: Feasibility study. *British Medical Journal*, *327*, 484–487.

McGrath, P. J. (2000). *Family help: Pain module (draft)*. Unpublished manuscript, Dalhousie University, Halifax, Nova Scotia, Canada.

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

Michel, P. (2000). Socioeconomic costs of headache. In J. Olesen, P. Tfelt-Hansen, & K. M. A. Welch (Eds.), *The headaches* (2nd ed., pp. 33–40). Philadelphia, PA: Lippincott, Williams & Wilkins.

Moher, D., Shulz, K. F., & Altman, D. G. (2001). The CONSORT statement: Revised recommendations for improving the quality of parallel-group randomised trials. *Lancet*, *357*, 1191–1194.

Moore, A., McQuay, H., & Gavaghan, D. (1996). Deriving dichotomous outcome measures from continuous data in randomised controlled trials of analgesics. *Pain*, *66*, 229–237.

Moore, A., Moore, O., McQuay, H., & Gavaghan, D. (1997). Deriving dichotomous outcome measures from continuous data in randomised controlled trials of analgesics: Use of pain intensity and visual analogue scales. *Pain*, *69*, 311–315.

Passchier, J., & Orlebeke, J. F. (1985). Headaches and stress in school children: An epidemiological study. *Cephalalgia*, *5*, 167–176.

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

Rappaport, L. (1989). Recurrent abdominal pain: Theories and pragmatics. *Pediatrician*, *16*, 78–84.

Richardson, G. M., McGrath, P. J., Cunningham, S. J., & Humphreys, P. (1983). Validity of the headache diary for children. *Headache*, *23*, 184–188.

Sanders, M. R., Rebgetz, M., Morrison, M., Bor, W., Gordon, A., Dadds, M., et al. (1989). Cognitive-behavioral treatment of recurrent nonspecific abdominal pain in children: An analysis of generalization, maintenance, and side effects. *Journal of Consulting and Clinical Psychology*, *57*, 294–300.

Sanders, M. R., Shepherd, R. W., Cleghorn, G., & Woolford, H. (1994). The treatment of recurrent abdominal pain in children: A controlled comparison of cognitive-behavioral family intervention and standard pediatric care. *Journal of Consulting and Clinical Psychology*, *62*, 306–314.

Scharff, L., Marcus, D. A., & Masek, B. J. (2002). A controlled study of minimal-contact thermal biofeedback treatment in children with migraine. *Journal of Pediatric Psychology*, *27*, 109–119.

Spafford, P., von Baeyer, C. L., & Hicks, C. L. (2002). Expected and reported pain in children undergoing

ear piercing: A randomized trial of preparation by parents. *Behavior Research and Therapy*, *40*, 37–50.

Split, W., & Neumann, W. (1999). Epidemiology of migraine among students from randomly selected secondary schools in Lodz. *Headache*, *39*, 494–501.

Stamm, B. H. (1998). Clinical applications of telehealth in mental health care. *Professional Psychology: Research and Practice*, *29*, 536–542.

Tabachnik, B. G., & Fidell, L. S. (1996). *Using multivariate statistics* (3rd ed.). New York: HarperCollins.

Tosteson, A. N. A., Kneeland, T. S., Nease, R. F., & Sumner, W. (2002). Automated current health time-trade-off assessments in women's health. *Value in Health*, *5*, 98–105.

Varni, J. W. (1998). Pediatric Quality of Life Inventory™ (Version 4.0). Lyon, France: Mapi Research Institute.

Varni, J. W., Burwinkle, T. M., Katz, E. R., Meeske, K., & Dickinson, P. (2002). The PedsQL™ in pediatric cancer: Reliability and validity of the Pediatric Quality of Life Inventory™ Generic Core Scales, Multidimensional Fatigue Scale, and Cancer Module. *Cancer*, *94*, 2090–2106.

Varni, J. W., Seid, M., & Kurtin, P. S. (2001). Pedsql™ 4.0: Reliability and validity of the Pediatric Quality of Life Inventory™ version 4.0 generic core scales in healthy and patient populations. *Medical Care*, *39*, 800–812.

Youssef, N. N., Rosh, J. R., Loughran, M., Shuckalo, S. G., Cotter, A. N., Verga, B. G., et al. (2004). Treatment of functional abdominal pain in childhood with cognitive behavioral strategies. *Journal of Pediatric Gastroenterology and Nutrition*, *39*, 192–196.

Zahner, G. E., Pawelkiewicz, W., DeFrancesco, J. J., & Adnopoz, J. (1992). Children's mental health service needs and utilization patterns in an urban community: An epidemiological assessment. *Journal of the American Academy of Child and Adolescent Psychiatry*, *31*, 951–960.