Häufige Kopfschmerzen im Kindes- und Jugendalter.

Ein Überblick zur Wirksamkeit psychologischer Behandlungsansätze und die Evaluation eines internet-basierten Selbsthilfetrainings.

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Anmerkung

Bei der Arbeit handelt es sich um eine publikationsbasierte Dissertation. Sie setzt sich aus drei englischen Manuskripten zusammen, welche als Zeitschriftenbeiträge in *Cephalalgia* (1.Manuskript) und *Behavioural and Cognitive Psychotherapy* (2.Manuskript) veröffentlicht wurden; das dritte Manuskript ist zur Veröffentlichung in der Fachzeitschrift *Pain* eingereicht.

Um die einzelnen Beiträge inhaltlich zusammenzuführen sowie das Gesamtkonzept der Dissertation besser zu verdeutlichen, wird ein Rahmentext um die vorliegenden Beiträge erstellt, welcher die einzelnen Publikationen verbindet. Der Rahmen besteht aus dem einleitenden ersten Kapitel, kurzen Einführungen der Kapitel 2 und 3, die die Manuskripte beinhalten sowie der abschließenden Diskussion in Kapitel 4.

Abstract

In addition to pharmacological therapies, psychological treatments are also used in the reduction of recurrent headache in children and adolescents, in order to achieve an alleviation of the complaints on the one hand and on the other, a long-term basis for the possible reduction of chronic manifestation. The aim of the present thesis is to investigate the efficacy of these psychological interventions as well as to evaluate the first German Internet-based self-help training programme for reducing recurrent headache. In the first chapter an introduction is provided regarding epidemiological findings on headache in childhood and adolescence, and in addition the aims of the present work are formulated. The second chapter delivers an overview of previous meta-analyses for the treatment of headache in children and adolescents and highlights their weaknesses. The necessity of the new meta-analysis (first paper) is explained and this is then subsequently presented. The third chapter provides an introduction to a new, cost effective possibility of psychological self-help via the Internet. The two original papers that follow describe the evaluation of the Internet-based self-help training programme for children and adolescents with recurrent headache. The dissertation finishes with a general discussion in chapter 4, in which the findings of the papers are critically discussed and recommendations for future investigations are given.

Zusammenfassung

Bei der Behandlung häufig auftretender Kopfschmerzen im Kindes- und Jugendalter finden zunehmend psychologische Therapieverfahren Anwendung, um so zum einen eine Linderung der Beschwerden und zum anderen langfristig eine Minderung des möglichen Chronifizierungsrisikos zu erreichen. Das Ziel der hier vorgelegten Arbeiten ist die Wirksamkeitsüberprüfung dieser psychologischen Interventionen sowie die Evaluierung eines ersten deutschsprachigen internet-basierten Selbsthilfetrainings zu Reduzierung häufiger Kopfschmerzen. Im ersten Kapitel wird eine kurze Einführung in epidemiologische Befunde bei Kopfschmerzen im Kindes- und Jugendalter gegeben sowie das Ziel der vorliegenden Arbeiten formuliert. Das zweite Kapitel gibt einen Überblick über bisherige Meta-Analysen zur Behandlung von Kopfschmerzen im Kindes- und Jugendalter und unterstreicht durch die Erläuterung inhaltlicher und methodischer Schwächen dieser Arbeiten die Notwendigkeit der hier vorgelegten, neuen Meta-Analyse (1.Manuskript), welche anschließend vorgestellt wird. Das dritte Kapitel gibt eine inhaltliche Einführung in eine neue, kosteneffektive Möglichkeit psychologischer Selbsthilfe via Internet. Es folgen die zwei Manuskripte (Manuskript 2 und 3) zur Evaluierung des internet-basierten Selbsthilfetrainings zur Reduzierung häufiger Kopfschmerzen bei Kindern und Jugendlichen. Die Arbeit schließt mit einer allgemeinen Diskussion in Kapitel 4 ab, in welcher die Befunde der vorgelegten Manuskripte kritisch besprochen und Empfehlungen für zukünftige Untersuchungen gegeben werden.

Inhaltsverzeichnis

1 Einleitung

1.1 Kopfschmerzen im Kindes- und Jugendalter

Migräne und Kopfschmerz von Spannungstyp sind häufige Beschwerden bei Kindern und Jugendlichen. Zwei aktuelle epidemiologische Untersuchungen an deutschen Stichproben konnten zeigen, dass sehr viele Kinder und Jugendliche davon betroffen sind. So berichteten 37.6% (3 Monats Prävalenz) der Befragten, dass sie unter häufigen Kopfschmerzen leiden (Fendrich et al. 2007). In einer weiteren epidemiologischen Untersuchung (Kröner-Herwig, Heinrich & Morris, 2007) wurden die Eltern von 8800 Kindern und Jugendlichen im Alter von 7 bis 14 Jahren zur Kopfschmerzsymptomatik ihrer Kinder befragt. 6.5% der Befragten berichteten von wöchentlich auftretenden Kopfschmerzen. Insgesamt stieg die Kopfschmerzhäufigkeit signifikant mit dem Alter an. Bei 7.5% der Kinder und Jugendlichen zeigte sich eine Migräne, bei weiteren 18.5% Kopfschmerz vom Spannungstyp (Heinrich, Morris, Gaßmann & Kröner-Herwig, 2007). Die Diagnose erfolgte in Anlehnung an die IHS-Kritierien (2004). Eine weitere Befragung dieser Elternstichprobe machte deutlich, dass auch ein Jahr später weiterhin 6.5% der Kinder und Jugendlichen von wöchentlichen Kopfschmerzen berichteten (Gaßmann, Morris, Heinrich & Kröner-Herwig, in press).

Die Befunde zeigen, dass primäre Kopfschmerzen wie Migräne und Kopfschmerz vom Spannungstyp, auch in Deutschland häufige Beschwerden der Kinder und Jugendlichen sind. In Untersuchungen an schwedischen Schulkindern wurde sogar festgestellt, dass junge Betroffene mit häufigen Kopfschmerzen eine schlechtere Prognose und somit ein erhöhtes Risiko haben, auch im Erwachsenenalter unter den Beschwerden zu leiden (Laurell, Larsson, Mattsson & Eeg-Olofsson, 2006; Brattberg, 2003).

Neben der medikamentösen Behandlung häufiger Kopfschmerzen finden auch psychologische Therapien wie Entspannungsverfahren, kognitiv-verhaltenstherapeutische Strategien sowie Biofeedbackverfahren Anwendung. Diese (präventiven) Behandlungsansätze bieten den Betroffenen die Chance, aktiv Verhaltensstrategien im

Umgang mit den Kopfschmerzen zu erlernen, um so ihre Kopfschmerzen langfristig zu reduzieren.

1.2 Ziel der vorgelegten Arbeiten

Die Wirksamkeit psychologischer Therapieverfahren ist in verschiedensten Studien bereits untersucht worden (z.B. Kröner-Herwig & Denecke, 2002; Siniatchkin, Hierundar, Kropp, Kuhnert, Gerber & Stephani, 2000; Kröner-Herwig, Mohn, & Pothmann, 1998; Griffiths & Martin, 1996; Guarnieri & Blanchard, 1990). Eine Generalisierung der Ergebnisse sowie Aussagen über die praktische Relevanz der Befunde sind jedoch aufgrund einzelner Studien nicht möglich. Nur die Anwendung meta-analytischer Verfahren ermöglicht generalisierbare Wirksamkeitsaussagen über die untersuchten Therapien. Ziel des in Kapitel 2 vorgelegten Manuskriptes ist eine solche Überprüfung der Effektivität psychologischer Therapien bei Kindern und Jugendlichen mit häufigen Kopfschmerzen. Bisherige Meta-Analysen (Ecclestone, Morley, Williams, Yorke & Mastroyannoploulou, 2002; Hermann, Kim & Blanchard, 1995) konnten zwar zeigen, dass der Einsatz psychologischer Verfahren sinnvoll und effektiv ist, ihre Aussagen sind jedoch aufgrund inhaltlicher und methodischer Einschränkungen begrenzt. Die hier vorgelegte Meta-Analyse knüpft an die beiden Untersuchungen an und trifft aktuelle Aussagen über die Wirksamkeit der Interventionen.

Die Inanspruchnahme wirksamer psychologischer Therapien durch den Betroffenen ist leider oft mit erheblichen Wartezeiten und hohem Zeitaufwand verbunden bspw. aufgrund langer Fahrtzeiten zu ausgebildeten Schmerztherapeuten. Um den Betroffenen sowohl eine attraktive als auch zeiteffektive Alternative der psychologischen Intervention zu ermöglichen, wird im Rahmen der im Kapitel 3 vorgelegten Arbeiten (Manuskript 2 und 3) ein internet-basiertes Selbsthilfetraining zur Reduzierung häufiger Kopfschmerzen bei Kindern und Jugendlichen als eine neue und vor allem kosteneffektive Intervention evaluiert.

2 Eine Meta-Analyse zur Überprüfung der Effektivität psychologischer Therapien bei häufigen Kopfschmerzen im Kindes- und Jugendalter (Manuskript 1)

Trautmann, E., Lackschewitz, H. & Kröner-Herwig, B. (2006). Psychological treatment of recurrent headache in children and adolescents – a meta-analysis. *Cephalalgia, 26,* 1411-1426.

2.1 Einführung in die Fragestellung

Bisherige meta-analytische Befunde zur psychologischen Behandlung von Kopfschmerzen bei Kindern und Jugendlichen (Hermann et al., 1995; Ecclestone et al., 2002) konnten zusammengefasst zeigen, dass Biofeedback, Entspannungsverfahren sowie kognitiv-verhaltenstherapeutische Therapien in ihrer Anwendung effektiv sind und die Kopfschmerzhäufigkeit deutlich reduzieren. Beide Meta-Anaylsen weisen jedoch inhaltliche und methodische Probleme auf, auf welche im Folgenden näher eingegangen wird.

Die Meta-Analyse von Hermann und Kollegen (1995) untersuchte sowohl die Wirksamkeit pharmakologischer als auch verhaltenstherapeutischer Therapien. Die Autoren konnten für 24 pharmakologische Untersuchungen und 17 Primärstudien, welche verhaltenstherapeutische Therapieverfahren untersuchten, im Prä-Post-Vergleich zeigen, dass sowohl verschiedene pharmakologische Therapien als auch Entspannungsverfahren (Progressive Muskelrelaxation), Multikomponentenprogramme und Biofeedback gegenüber einer Kontrollbedingung (Placebo, Warteliste) effektiv sind. Thermales Biofeedback und Progressive Muskelentspannung in Kombination mit Biofeedback erwiesen sich als die effektivsten Therapieverfahren. Einschränkend ist jedoch festzustellen, dass die Meta-Analyse von Hermann und Kollegen (1995) nicht den aktuellen Forschungsstand widerspiegelt. So flossen lediglich Primärstudien aus dem Zeitraum 1970 bis 1993 ein. Nur neun der Primärstudien waren kontrollierte

Untersuchungen. In den letzten zwölf Jahren gab es jedoch eine zunehmende Anzahl neuer, kontrolliert, randomisierter Studien (siehe Trautmann, Lackschewitz & Kröner-Herwig, 2006; Kapitel 2.2), welche dem CONSORT-Statement (Moher, Schulz & Altmann, 2005) und somit einem hohen Qualitätsanspruch an Studien entsprechen. Die Durchführung von Studien mit randomisiertem Kontrollgruppen-Design (RCT) führt zu einer verbesserten Wirksamkeitseinschätzung. Auch hinsichtlich der eingesetzten meta-analytischen Verfahren ist die Arbeit von Hermann und Kollegen (1995) kritisch zu bewerten. Eine methodische Einschränkung der Meta-Analyse ist die Integration der Studieneffektstärken zu einem Gesamteffekt. Die Autoren verwendeten zur Integration der einzelnen Studieneffektstärken das Fixed Effects-Modell, welches keine Generalisierung der ermittelten Ergebnisse zulässt. In die Schätzung der mittleren Effekte flossen sowohl Einzeleffektstärken berechnet aus Mittelwerten und Standardabweichungen, t- oder p-Werten als auch aus Responderraten (50% verbesserte Symptomatik) ein. Das Responderkriterium wird jedoch im Rahmen von klinischen Meta-Analysen als ein eigenständiges Effektstärkenmaß und eigene Symptomkategorie verwendet, um eine klinisch relevante Verbesserung der Symptomatik zu erfassen. Wohingegen Veränderungen in der Symptomatik (z.B. der Kopfschmerzhäufigkeit, -intensität oder –dauer) repräsentiert durch Mittelwerte und Standardabweichungen bereits kleinere Verbesserungen erfassen, welche jedoch nicht in jedem Fall klinisch bedeutsam sind. Eine Vermischung dieser statistischen Informationen verzerrt die Aussagen hinsichtlich der Effektstärke und führt somit zu Schwierigkeiten in der Interpretation der Effekte. Weiterhin erfolgten in dieser Meta-Analyse keine differenziellen Aussagen über einzelne Schmerzparameter (z.B. die Kopfschmerzhäufigkeit oder -intensität). Eine weitere Einschränkung der Meta-Analyse ist der Ausschluss von Untersuchungen mit Patienten mit Kopfschmerz vom Spannungstyp. Die Analyse bezog sich lediglich auf pädiatrische Migräne. Im Weiteren fehlen Analysen zur Langzeitwirkung der Therapien.

Die meta-analytische Untersuchung von Ecclestone und Kollegen (2002) überprüfte die Wirksamkeit psychologischer Therapien von chronischem Schmerz im Kindes- und Jugendalter. Die meta-analytischen Befunde zeigten ebenfalls, dass psychologische

Therapien (Entspannungsverfahren und kognitiv-verhaltenstherapeutische Therapien) effektiv sind. In die Analysen flossen jedoch lediglich 13 Primärstudien mit unterschiedlichen Schmerzsyndromen ein (12 Untersuchungen zu Reduzierung von Kopfschmerzen und eine weitere zu Verringerung häufiger Bauchschmerzen). Allerdings waren die eingeschlossenen Studien von methodisch hoher Qualität (randomisiert, kontrollierte Untersuchungen). Die Autoren nutzten für die Integration der einzelnen Studieneffektstärken zu einer Gesamteffektstärke das Random Effects-Modell, welches im Gegensatz zu dem häufig genutzten Fixed Effects-Modell eine Generalisierung der meta-analytischen Befunde über die einfließenden Primärstudien hinaus erlaubt (Mitte, 2005). Als Effektstärkemaß wurde jedoch lediglich das Responder-Kriterium genutzt. Damit gehen wichtige Informationen der Primärstudien verloren und differenzierte Aussagen zu einzelnen Symptomkategorien (Kopfschmerzhäufigkeit, -intensität, -dauer) sind nicht möglich. Weiterhin wurden lediglich veröffentlichte Studien (bis 1999) mit einbezogen, somit fehlen Untersuchungen, welche nicht in Fachzeitschriften veröffentlicht wurden (z.B. aufgrund nicht signifikanter Ergebnisse). Dies kann zu einer Überschätzung der mittleren Effekte führen, da häufig nicht-signifikante Studien nicht veröffentlicht werden (file drawer-Problem; Beelmann & Bliesner, 1994; Sharpe, 1997). Auch methodische Verfahren wie die Berechnung der Fail-Safe-N oder der Trim-und-Fill-Analyse (Begg, 1994) wurden nicht eingesetzt, so dass nicht eingeschätzt werden kann, inwieweit die Ergebnisse durch den Publikationsbias beeinflusst sind. Im Weiteren ist die Aussage der Meta-Analyse durch fehlende Analysen zur Langzeiteffektivität der Therapien beschränkt.

Keine der beiden Meta-Analysen untersuchte weitere nicht - schmerzassoziierte Parameter wie die Lebensqualität, Angst, Depression oder allgemeine psychopathologische Symptome. Allerdings war die Erfassung und Analyse solcher Variablen ein Ziel der Arbeit von Ecclestone und Kollegen (2002). Aufgrund der geringen Studienanzahl, welche nicht - schmerzassoziierte Parameter erfassten, erfolgte jedoch keine meta-analytische Berechnung.

Die hier vorliegende aktuelle Meta-Analyse (Manuskript 1) zeigt den aktuellen Stand der psychologischen Therapieforschung auf und trifft Aussagen über die Wirksamkeit der Interventionen bei Kindern und Jugendlichen mit häufigen Kopfschmerzen (Migräne und Kopfschmerzen vom Spannungstyp). Als zu untersuchende Variablen wurden neben den Schmerzparameteren wie Kopfschmerzhäufigkeit, Intensität und Dauer, die Responderrate sowie die Medikation erfasst. Es wurden Aussagen über die Effektivität direkt nach Beendigung der Therapien sowie über die langfristige Wirksamkeit (Follow-up) der Verfahren angezielt. Um die Aussagekraft der meta-analytischen Untersuchung zu erhöhen wurden nur Studien mit randomisiertem Kontrollgruppendesign einbezogen. Die Generalisierbarkeit der Befunde erfolgte durch Einsatz des Random Effects-Modells (Shadish & Haddock, 1994). Um dem Publikationsbias zu begegnen fand die Trim-und-Fill-Analyse Anwendung.

Insgesamt wurden die Ergebnisse von 23 Primärstudien in die vorliegende Meta-Analyse integriert. Im direkten Vergleich der Behandlungsgruppen mit den Kontrollgruppen (Warteliste) zum Zeitpunkt Post (n=10) zeigte sich ein kleiner, jedoch signifikant bedeutsamer Effekt für die Kategorie Kopfschmerz. Eine weitere Analyse der einzelnen Kopfschmerzparameter zeigte, dass sich lediglich die Kopfschmerzintensität in einem signifikant bedeutsamen Ausmaß (kleiner Effekt) verbesserte. Die Responderanalyse, welche die meisten Primärstudien einschloss (n=16), wies jedoch einen großen, signifikant bedeutsamen Effekt auf. Die Variable Medikation zeigte keine bedeutsamen Unterschiede zwischen den Behandlungs- und Kontrollbedingungen (kleiner Effekt).
Im Vergleich der Prä-Post-Veränderungen (n=12) der einzelnen Bedingungen erwiesen sich die Behandlungsgruppen als effektiv: Es zeigten sich mittlere Effekte für die Symptomkategorien Kopfschmerz allgemein und Kopfschmerzhäufigkeit und –intensität, lediglich die Dauer des Kopfschmerzes veränderte sich nur in kleinerem Ausmaß (kleiner Effekt). Auch die Variable Medikation wies eine mittlere, jedoch nicht signifikant bedeutsame Effektstärke auf. Keine der Kontrollgruppen zeigte einen signifikant bedeutsamen Effekt in den Kategorien Kopfschmerz oder Medikation. Auch die Langzeiteffektivität der psychologischen Therapien (Prä – Follow-up Analysen) konnte an

acht Primärstudien überprüft werden. Es zeigte sich ein großer bedeutsamer Effekt für die Kategorie Kopfschmerz. Eine Gesamteffektstärke für die Kategorie Medikation konnte aufgrund der kleinen n nicht bestimmt werden (n=2). Auch in der Post - Follow-up Analyse zeigte sich, dass die Effekte langfristig stabil blieben und sich teilweise sogar noch steigerten (Kategorie Kopfschmerz).

Es wurden keine Random Effects-Modelle für den Vergleich mit einer aktiven Kontrollbedingung berechnet, da lediglich vier Primärstudien diesen Vergleich durchführten und jeweils verschiedene Symptomkategorien verwendeten. Ebenso wurden keine Meta-Analysen für nicht-schmerzassozierte Variablen berechnet, da lediglich neun Primärstudien jeweils verschiedene Variablen (z.B. Lebensqualität, Depression, Coping) erhoben. Die Trim-und-Fill-Analyse, welche den Publikationsbias korrigiert, zeigte dass die Ergebnisse der vorliegenden Meta-analyse den aktuellen Stand der Forschung widerspiegeln. Lediglich im Prä-Post-Vergleich reduzierte sich der Effekt der Kategorie Kopfschmerz von einem mittleren auf einen kleinen.

Zusammenfassend lässt sich zum einen feststellen, dass die untersuchten psychologischen Therapien zu einer deutlichen Reduzierung der Kopfschmerzen führen und zum anderen, dass weiterhin ein Bedarf an Studien mit hohem Qualitätsstandard besteht, um die vorliegenden Befunde zu stützen. Da lediglich 23 Primärstudien in die Analysen einflossen.

2.3 Manuskript 1

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REVIEW

Psychological treatment of recurrent headache in children and adolescents – a meta-analysis

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Cephalalgia

Trautmann E, Lackschewitz H & Kröner-Herwig B. Psychological treatment of recurrent headache in children and adolescents – a meta-analysis. Cephalalgia 2006; 26:1411–1426. London. ISSN 0333-1024

Psychologically based interventions such as relaxation training, biofeedback and cognitive-behavioural therapy are increasingly discussed as options for the treatment of migraine and tension-type headache in children and adolescents. In order to determine the state of evidence regarding the efficacy of these treatments, a meta-analysis of randomized controlled studies was conducted. In a comprehensive literature search including data from 1966 to 2004, 23 studies were found meeting the inclusion criteria. Due to the application of the random effects model, generalization of the results is possible. Specific statistical procedures were used to account for a possible publication bias. Significantly more patients improved to a clinically relevant extent (headache reduction ≥50%) in treatment conditions compared with waiting list conditions (high effect sizes). Long-term stability was also confirmed. The analysed treatments lead to improvement (up to 1 year) in headache status in children and adolescents with primary headache. However, more well-designed studies are needed to support and consolidate the conclusions of this meta-analysis and to compare the effects of psychological treatment with those of prophylactic medical interventions (in migraine), to examine potential differences between treatments, to identify moderators of efficacy and to determine effects of treatment on other health-related variables such as quality of life. □*Adolescents, biofeedback, children, headache, meta-analysis, migraine, relaxation and cognitive-behavioural treatment*

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Introduction

Headache in childhood and adolescence is an almost ubiquitous phenomenon. According to a recent epidemiological study in Germany of more than 5400 children and adolescents, 65% of children at the age of 14 years have experienced headache and 10.5% regularly suffer from headache at least once per week (1). Several other studies have yielded similar results (2–5). Sillanpää and Anttila (6) reported a significant increase in the prevalence of paediatric headache in Finland over two decades. The negative consequences of headache in childhood and adolescence are often underestimated. Long-term consequences can include impairment of social interaction and deterioration of functioning in school, including increased absence from school, a greater amount of school problems, more time needed to finish homework and more self-reported exhaustion after school (7–10). Anxiety and depression can also sometimes be heightened, which could be interpreted as a consequence of suffering from recurrent pain (11). Thus, headache can substantially reduce a child's quality of life (12).

These findings underline the need for effective treatments of paediatric and juvenile headaches. The two main approaches to treating headache are pharmacological and psychological therapy. In light of the drawbacks of frequent medication (13) and the lack of knowledge regarding its effects on children (14), psychological treatments have gained increasing attention. Relaxation techniques (including progressive muscle relaxation, autogenic training and self hypnosis), biofeedback (EMG feedback, hand temperature feedback, vasomotor feedback, neuro-feedback) and cognitive-behavioural interventions are the most frequently examined interventions. Two recent meta-analyses (15, 16) (see also (17)) on the treatment of migraine and tension-type headache have corroborated the efficacy of these psychological interventions for adults.

Although a number of published reviews have documented the effectiveness of psychological treatment for paediatric and juvenile headache (e.g. (18–20)), only two meta-analyses have been conducted so far (21, 22). The analysis of Hermann et al. (21) does not include more recent studies and can be criticized for lacking transparency regarding methodology. Moreover, some of the sophisticated methods allowing for the correction of biases in the estimation of effect sizes were not available at that time, which may have led to unrealistically high effect sizes in that review. The authors limited their analysis to paediatric migraine by excluding treatment studies of tension-type headache.

The more recent study by Eccleston et al. (22) used advanced methods for meta-analysis but included treatment studies on different types of paediatric pain (e.g. recurrent abdominal pain). Furthermore, only a responder analysis was carried out and the outcome regarding the extent of symptom reduction in specific headache variables (e.g. intensity, frequency, duration) was left unexplored.

The purpose of the current study is to describe the up-to-date state of evidence in the treatment of paediatric headaches using only randomized controlled trials (RCTs) and including studies conducted and published up to 2004. Furthermore, methodologically advanced strategies for meta-analysis were employed. Thus, estimation of effect sizes took into account all possible sources of information (from means and SDs to significance levels). Also, the statistically advanced random effects model was used, which allows generalization of results. The trim-and-fill method used in the analysis offers a mode for adjustment of effect sizes for publication bias.

Methods

Inclusion criteria

To be included, studies had to fulfil the following criteria regarding design, objective, and presentation of the study, participants, type of intervention and type of outcome measure.

1. The study had to be a RCT (allowing for randomization after matching procedures regarding specific subject characteristics, e.g. symptom severity). Trials had to incorporate psychological treatments aimed at preventing the occurrence of migraine or tension-type headache episodes and/or at reducing their intensity and duration. The control condition was to include waiting list or therapy placebo (active control group). Therapy placebo was defined as realizing unspecific 'treatment' factors common to all psychological therapies. Studies with a comparative design were excluded.
2. All subjects (including those in the control groups) had to suffer from at least two headache attacks per month before starting treatment.
3. Studies had to be available in English or German.
4. Study participants had to be children or adolescents in their majority, i.e. the average age of the sample had to be <18 years.
5. Studies had to examine one or more of the following types of treatment: relaxation training, biofeedback, (cognitive-) behavioural therapy, or combinations of these interventions.
6. The number of subjects in each treatment and/or control group had to be $n \geq 4$ [based on bias estimation, see (23)].
7. Sufficient data had to be available to calculate effect sizes regarding headache frequency, duration, intensity and/or medication. Effect size calculation was based on means and SDs, *t*- or *F*-values, change scores, or other statistical scores (frequencies or significance levels).

Medication (number of days analgesics or anti-migraine medication were taken) was also explored. Analysis was restricted to headache variables and medication since no other outcome measures were assessed in a sufficient number of studies to qualify for meta-analysis.

Coding schemes comprising methodological and clinical aspects of the original studies (Table 1) were conducted by the first and second author. The coding form had an overall interrater reliability of $\kappa = 0.73$, with a minimum of 0.70 regarding

Table 1 Studies included in the meta-analysis

Study	Inclusion criteria	Sample description: sample size (*N*); % female; mean age; age range	Groups, treatment duration (in sessions)	Drop-outs
Allen and Shriver (34)	≥3 headache attacks per month	*N* = 87; 72% female; M: not given; 11–18 years	CBT (self-administered), 6 sessions; CBT (clinic-based), 6 sessions; AC, 6 sessions	1%
Barry and von Baeyer (53)	≥2 headache attacks per month	*N* = 29; 66% female; M = 9 years; 7–12 years	CBT, 2 sessions; WLC	0%
Bussone et al. (66)	≥1 headache attack per week	*N* = 30; 50% female; M = 12 years; 11–15 years	EMG-BFB, PMR, 0 sessions; AC, 10 sessions	14%
Engel and Rapoff (58)	≥3 headache attacks per month	*N* = 20; 65% female; M = 13 years; 7–17 years	Autogenic relaxation, 5 sessions; PMR, 5 sessions; treatment package (AT + PMR), 5 sessions; WLC	0%
Fentress et al. (61)	≥3 headache attacks during the last month	*N* = 18; 61% female; M = 10 years; 8–12 years	Relaxation response, 9 sessions; relaxation response + EMG-BFB, 9 sessions; WLC	0%
Fichtel and Larsson (50)	≥2 migraine attacks per week over ≥6 months	*N* = 36; 69% female; M = 15 years; 13–18 years	Relaxation treatment, 8–10 sessions; WLC	Not given
Griffiths and Martin (54)	≥1 headache attack per week over the last 6 months	*N* = 42; gender: not given; M: not given; 10–12 years	CBT (clinic-based), 8 sessions; CBT (home-based), 8 sessions; WLC	18%
Guarnieri and Blanchard (63)	AHC criteria	*N* = 16; 65% female; M = 11 years; 8–16 years	Skin temperature; BFB (clinic-based), 10 sessions; BFB (home-based), 4 sessions	6%
Kröner-Herwig and Denecke (46)	≥2 headache attacks per month	*N* = 75; 47% female; M = 12 years; 10–14 years	CBT group (manualized), 8 sessions; CBT (home-based, manualized), 8 sessions; WLC	7%
Kröner-Herwig et al. (52)	≥2 headache attacks during the last month	*N* = 50; 60% female; M = 11 years; 8–14 years	PMR, 6 sessions; PMR + parent involvement, 6 sessions; EMG-BFB, 12 sessions; EMG-BFB + parent involvement, 12 sessions; WLC	0%
Labbé (55)	≥2 migraine attacks per month	*N* = 30; 43% female; M = 12 years; 8–18 years	Biofeedback (BFB) + AT, 10 sessions; AT, 10 sessions; WLC	65%
Labbé and Williamson (56)	≥2 migraine attacks per month	*N* = 28; 50% female; M = 11 years; 7–16 years	Autogenic feedback training, 10 sessions; WLC	0%
Larsson et al. (59)	≥1 headache attack per week over ≥1 year	*N* = 46; 87% female; M: not given; 16–18 years	Therapist-assisted relaxation (PMR, cued relaxation), 9 sessions; self-help relaxation; WLC	11%

Table 1 (Continued)

Study	Inclusion criteria	Sample description: sample size (*N*); % female; mean age; age range	Groups, treatment duration (in sessions)	Drop-outs
Larsson and Melin (44)	≥1 headache attack per week	*N* = 32; 94% female; M: not given; 16–18 years	PMR + cued relaxation, 9 sessions; information contact, 9 sessions; WLC	9%
Larsson et al. (45)	≥1 headache attack per week over ≥1 year	*N* = 48; 90% female; M: not given; 16–18 years	PMR + cued relaxation, 5 sessions; WLC	0%
Larsson et al. (60)	≥1 headache attack per week over ≥1 year	*N* = 36; 94% female; M: not given; 16–18 years	PMR + cued relaxation; problem-discussion group; WLC (sessions not specified)	6%
McGrath et al. (64)	≥1 migraine attack per week	*N* = 99; 70% female; M = 13 years; 9–17 years	Relaxation training, 6 sessions; self-help relaxation training, 6 sessions; psychological placebo: 'Own best efforts', 1 session	37%
McGrath et al. (67)	≥3 headache attacks per month	*N* = 87; 72% female; M: not given; 11–18 years	CBT (self-administered), 8 sessions; CBT (clinic-based), 8 sessions; AC, 1 session	1%
Osterhaus et al. (1997) (69)	≥2 headache attacks per month	*N* = 39; 74% female; M = 15 years; 12–22 years	CBT, 8 sessions; WLC	0%
Richter et al. (65)	≥1 migraine attack per week	*N* = 42; gender: not given; M = 13 years; 9–18 years	Relaxation training, 6 sessions; cognitive coping, 6 sessions; placebo treatment, 6 sessions	16%
Sartory et al. (62)	≥5 migraine attacks; ≥2 attacks during the last month	*N* = 43; gender: not given; M = 11 years; 8–16 years	Cephalic vasomotor feedback + stress management training, 6 sessions; PMR + stress management training, 6 sessions; Metoprolol	0%
Scharff et al. (57)	≥1 migraine attack per week ≥5 migraine attacks per month	*N* = 36; 67% female; M = 13 years; 7–17 years	Handwarming BFB, 4 sessions; handcooling BFB, 4 sessions; WLC	0%
Siniatchkin et al. (51)	≥5 migraine attacks	*N* = 30 (20 children with migraine, 10 healthy controls); 23% female; M = 11 years; 7–12 years	EEG-BFB (children with migraine), 10 sessions; WLC; EEG-BFB (healthy children), 10 sessions	0%

PMR, Progressive muscle relaxation; BFB, biofeedback; CBT, cognitive-behavioural therapy; AC, active control group; WLC, waiting list control group.

variables which were used for effect size calculation and description of the studies.

Search strategy

Studies were located through a systematic search of the following databases: Medline, PsycInfo, Psyndex, and the Cochrane Library. Searches were carried out from the first available year to July 2004 using combinations of the keywords 'headache', 'migraine', 'tension headache', '(psycho)therapy', 'treatment', 'biofeedback', 'relaxation', 'cognitive', 'behavioural', 'paediatric', 'juvenile', 'children' and 'adolescent'. Additionally, a literature search was done in secondary sources (reviews and previous meta-analyses) and on the internet. Effort was made to locate unpublished work by contacting researchers in order to reduce the file-drawer problem. Of more than 30 authors contacted, only two answered.

On the basis of the evaluated abstracts 43 outcome studies on the treatment of paediatric headache employing a control group were identified as potential candidates for the meta-analysis. Twenty studies were excluded for the following reasons: six studies did not include sufficient information for the calculation of effect sizes; four included only one treatment group and no control group; five used control or treatment conditions which did not fulfil the inclusion criteria of at least two headache attacks per month (criterion 2); in two studies assignment of subjects to conditions was not randomized; one study reported on treatments with fewer than four subjects; one included patients with different pain syndromes; and one study recapitulated data of a study already included in our analysis. The 23 original studies (Table 1) which finally entered the meta-analysis comprise a sample of 935 children and adolescents in total (see Table 2 for study characteristics).

Statistical analysis

Computation of effect sizes was accomplished using Hedges' g (24, 25). The only difference of g from Cohen's d is the use of the sample standard deviation (26). If possible, the calculation of Hedges' g was based on means and SDs. However, some studies ($n = 6$) indicated results only by description of probability levels. For these studies effect sizes were inferred from the reported significance levels (non-significant results were set to

Table 2 Characteristics of studies included in the meta-analysis

Study characteristics	Frequency	Percentage
General		
Publication year		
1980–1995	12	52
>1995	11	48
Country		
Australia	1	4
Canada	4	18
Germany	4	18
The Netherlands	1	4
Sweden	5	21
USA	8	35
Methodological issues		
Sample size		
<30	6	26
30–50	14	61
>50	3	13
Type of assignment		
Randomized	18	78
Matched	5	22
Type of control group		
Waiting list control group	16	70
Active control group	5	21
None	2	9
Mean drop-out rate		
<5%	8	40
5–10%	5	25
10–20%	5	25
>20%	2	10
Treatment characteristics		
Treatment format		
Individual training	15	65
Group training	4	17
Individual and group training	4	17
Headache type		
Migraine	9	39
Tension-type headache	1	4
Combined*	13	57
Type of intervention**		
Relaxation training	16	27
Cognitive-behavioural intervention	10	17
Biofeedback	7	11
Combination	6	10
Waiting list control group	16	27
Active control group	5	8

*Study subjects with migraine, tension-type headache and/or both and mixed headache (no diagnoses of migraine or tension-type headache, but recurrent headache).

**Some studies investigated more than one intervention. In those cases, each of the interventions have been included separately.

$g = 0$). Odds ratios were computed for dichotomous data and subsequently transformed into Hedges' g (27).

A correction formula to account for small sample bias was also applied (24). Effect sizes were calculated for the following outcome categories: headache symptom variables (frequency, intensity and duration of headache or a comprehensive headache index), medication, and clinical significant change (reduction of headache symptoms ≥50% based on the headache index or any of the above-mentioned variables). If more than one measure was used in one outcome category, a mean g was calculated by averaging the corresponding effect sizes.

Before computing the average effect sizes, the scores of each single study were weighted by the reciprocal of the variance components, and a random effects analysis was carried out.

The random effects model (REM) is preferable to the fixed effect model (FEM) because interpretations of results are not limited to the actually analysed studies, but can be generalized to the universe of potential studies on treatment efficacy in the analysed domain of research: psychologically based interventions like relaxation, biofeedback and (cognitive-) behavioural treatments in comparable children and adolescents with recurrent headache. In contrast to the often used FEM, a variance component is included (the random effects variance) to account for the variance resulting from drawing studies from the population of all possible studies in the given domain of research. For a more comprehensive description regarding the advantages of the REM see Mitte (28).

The analyses examined two different aspects of outcome: between-group effects (comparing treatment and control groups) and within-group effects (comparing different assessment periods within treatment and control groups). No analyses could be conducted for between-group effects at follow-up and within-group effects for wait list control at pre-follow-up and post-follow-up comparisons, since they were treated after the waiting period and no follow-up measures were available.

As a consequence of the standardization of effect size polarity, a positive score indicates a better outcome in the treatment condition and an improvement in pre-post-, pre-follow-up and post-follow-up comparisons.

The trim-and-fill method (29) was applied to account for a possible publication bias. This analysis checked the robustness of the results by taking into account that insignificant effects are less likely to be published (30). In systematic reviews and meta-analyses such studies are thus less likely to be identified. The trim-and-fill method offers an estimation of missing studies and their effect sizes and consequently an estimation of 'true' treatment effects.

The computations were accomplished with the statistical software Study Input 2.08 (31).

Results

Descriptive characteristics of the studies

Most studies were conducted in North America ($n = 12$), the remainder in Europe ($n = 10$) and Australia ($n = 1$) (Table 2). Eighteen studies (78%) used randomization for the assignment of subjects to the treatment conditions without a matching procedure. The most frequently examined treatment was relaxation training ($n = 16$) with four studies adding behavioural components to it (pain or stress management techniques, Tables 1 and 2). Ten trials analyse (cognitive-) behavioural therapy and seven biofeedback. Fifteen studies evaluated individual training formats, four examined group trainings and four both types. Sixteen studies had implemented a waiting list control group (continuously monitoring their headaches by means of a diary).

The selection criteria for treatment inclusion in the original studies varied (e.g. ≥2 migraine attacks per month; ≥1 attack per week). In 10 studies only children with migraine, in one study only subjects with tension-type headache were treated, 12 studies included subjects with tension-type headache, migraine or both diagnoses. Twenty-one trials comprised a follow-up, which varied in length from 4 to 12 months. The average age of the participants was 12 years (data available from 19 studies), 64% were female. On average 11% of the sample dropped out (data available from 20 studies), which can be considered to be within the normal range or even below (28). Headache symptoms and medication ($n = 6$) were always assessed by diaries. Two trials did not allow medication to be taken by the participants, three gave no information about it. In nine trials medication was allowed, but not assessed. In three studies allowing medication, no data were reported to calculate effect sizes.

When conducting meta-analyses many decisions on procedures have to be made. It is therefore recommended to examine whether alternative decisions would have been likely to influence the results. This was done by two sensitivity analyses. Five of the 23 primary studies reported on

non-clinical, school-based interventions and were included in the original analysis. The first sensitivity analysis excluded these studies and effect sizes were compared with that of the comprehensive analysis. Also the consequence of the use of REM was examined by concurrently calculating the fixed effect model. The assumed advantage of REM is attained at the cost of a lower statistical power in case of a small study sample (23). The *Q*-test for homogeneity of effect sizes was conducted with $P \leq 0.10$ as a level of significance to compensate for the low power of the test (32). When the *Q*-test is non-significant, REM and FEM yield comparable results for mean effect size and random-effects variance is not significantly different from zero.

Between-group effects (post-treatment measures)

Only 10 of the 23 selected original studies allowed for a between-group comparison (treatment vs. control) regarding headache symptoms in the post-therapy period (Table 3, Fig. 1). Children and adolescents from 16 treatment/control groups were included ($n = 407$). The mean effect size regarding all headache variables is small ($g = 0.35$). Table 4 gives detailed information on the specific headache variables: frequency, duration and intensity. These analyses show that only intensity of headache is significantly affected by treatment (Table 4). Excluding the non-clinical, school-based interventions, comparable effects are found [$n = 8$; REM: $g = 0.36$, 95% confidence interval (CI) 0.03, 0.69, $\tau^2 = 0$; FEM: $g = 0.36$, 95% CI 0.10, 0.63]. Medication intake (Table 3) is not significantly modified by treatment (CI including zero). The analysis of clinically significant change is based on the largest sample (16 studies, 22 groups, 587 subjects) and displays a large effect size ($g = 0.87$) with a small positive, but non-significant, random effects variance (Fig. 2). Comparable results can be demonstrated when excluding the five non-clinical school-based interventions ($n = 11$, REM: $g = 0.80$, 95% CI 0.50, 1.08, $\tau^2 = 0$; FEM: $g = 0.80$, 95% CI 0.54, 1.05).

Additionally, binomial effect size displays (BESD) for clinically significant change and headache variables were calculated, after converting Hedges' *g* to *r* (68). The BESD represents the difference in outcome rates between treatment and

Table 3 Effect sizes for outcome categories: headache variables, medication, and clinically significant change

Comparison Outcome category	REM *g* (95% CI)	FEM *g* (95% CI)	τ^2	*Q*	*N*
Between-group analysis, treatment vs. waiting condition					
Headache variables	0.35 (0.08, 0.61)	0.35 (0.12, 0.58)	0	8.80	10
Medication	0.32 (–0.17, 0.81)	0.32 (–0.03, 0.66)	0	2.38	5
Clinically significant change	0.87 (0.57, 1.16)	0.83 (0.62, 1.06)	0.07	19.34	16
Within-group analyses					
Treatment, pre-post					
Headache variables	0.55 (0.33, 0.77)	0.55 (0.35, 0.75)	0	8.05	12
Medication	0.59 (–0.04, 1.22)	0.59 (0.21, 0.98)	0	1.75	4
Waiting condition, pre-post					
Headache variables	0.10 (–0.26, 0.37)	0.10 (–0.21, 0.32)	0	1.89	8
Medication	0 (–0.66, 0.65)	0 (–0.41, 0.40)	0	0.81	4
Treatment, pre-follow-up					
Headache variables	1.00 (0.64, 1.33)	0.97 (0.73, 1.23)	0.04	10.80	8
Medication	–	–	–	–	2
Treatment, post-follow-up; period: 1–6 months					
Headache variables	0.36 (0.10, 0.70)	0.36 (0.10, 0.62)	0	0.43	6
Medication	–	–	–	–	1
Clinically significant change	0.27 (–0.08, 0.62)	0.28 (0.05, 0.51)	0.11	15.49	11
Treatment, post-follow-up; period: >6 months					
Headache variables	0.26 (–0.33, 0.85)	0.26 (–0.11, 0.62)	0	1.60	4
Medication	–	–	–	–	1
Clinically significant change	–	–	–	–	1

FEM, Fixed effects model; *g*, effect size/Hedges' *g*; 95% CI, 95% confidence interval; REM, random effects model; τ^2, random effects variance; *Q*, χ^2 (all Q-tests were non-significant); *N*, number of effect sizes.

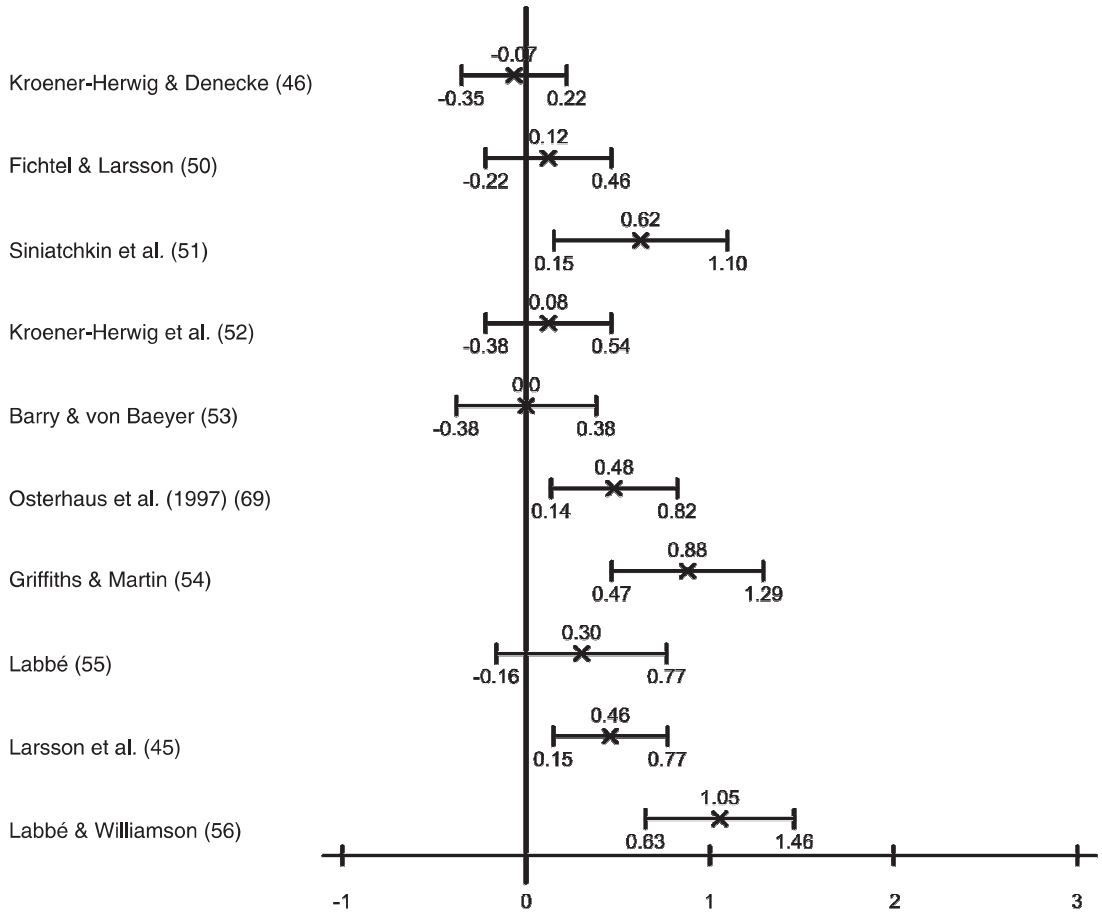

Figure 1 Study effect sizes (between groups) and confidence intervals in the outcome category 'headache variables' (post-treatment, $n = 10$).

Table 4 Effect sizes for headache variables frequency, duration and intensity

Comparison Outcome category	REM *g* (95% CI)	FEM *g* (95% CI)	τ^2	*Q*	*N*
Between-group analysis, treatment vs. waiting condition					
Frequency	0.22 (–0.13, 0.58)	0.22 (–0.03, 0.47)	0.02	8.15	7
Duration	0.28 (–0.11, 0.67)	0.26 (0.01, 0.51)	0.08	11.68	8
Intensity	0.43 (0.11, 0.74)	0.42 (0.18, 0.66)	0	4.55	9
Within-group analyses					
Treatment, pre-post					
Frequency	0.54 (0.29, 0.79)	0.54 (0.33, 0.75)	0	3.21	9
Duration	0.29 (0.04, 0.54)	0.29 (0.07, 0.50)	0	5.58	9
Intensity	0.54 (0.27, 0.80)	0.54 (0.31, 0.76)	0	6.79	8
Waiting condition, pre-post					
Frequency	0.21 (–0.17, 0.59)	0.21 (–0.09, 0.50)	0	4.75	6
Duration	–0.02 (–0.36, 0.32)	–0.02 (–0.29, 0.26)	0	3.85	7
Intensity	–0.08 (–0.42, 0.26)	–0.08 (–0.36, 0.20)	0	2.29	7

FEM, Fixed effects-model; *g*, effect size/Hedges' *g*; 95% CI, 95% confidence interval; REM, random effects model; τ^2, random effects variance; *Q*, χ^2 (all Q-tests were non-significant); *N*, number of effect sizes.

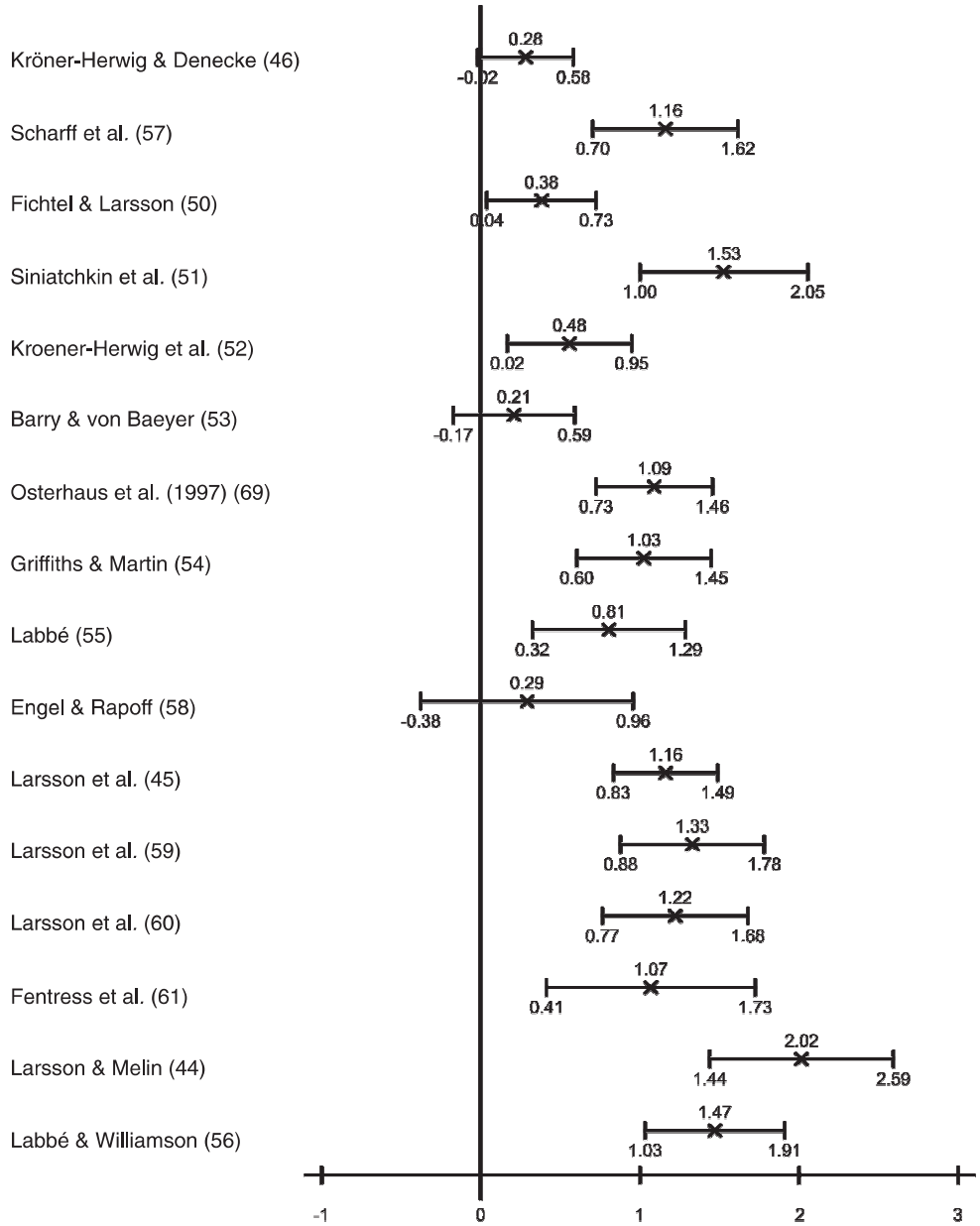

Figure 2 Study effect sizes (between groups) and confidence intervals in the outcome category 'clinically significant change' (post-treatment, $n = 16$).

control group (33). Success rates of 70% for the treatment condition and 30% for the control group at post treatment were found for clinically significant change. For headache variables a success rate of 60% for psychological treatment was found, whereas the control condition showed a rate of only 40%.

Only four trials included an active control group design, with only two of them using comparable outcome variables, so that no meta-analysis could be conducted. The comparison of intervention and active control groups at post therapy displays the following effect sizes: headache variables (two studies): $g_1 = -0.06$; $\sigma^2 = 0.11/g_2 = 0.10$, $\sigma^2 = 0.15$; clinical significance (two studies): $g_1 = 1.33$, $\sigma^2 = 0.20/g_2 = 0.66$, $\sigma^2 = 0.20$. Thus no differences between treatment and active control were found regarding headache symptom variables, medium to

large effect sizes were found, however, regarding the number of responders (clinically significant change).

Within-group effects

Regarding the difference between outcome variables assessed before and directly after therapy (pre-post), 12 studies with 23 groups including 322 children and adolescents entered the analyses (Fig. 3). Both REM and FEM show moderate mean effects regarding headache variables ($g = 0.55$) in the treatment conditions. Excluding the non-clinical, school-based interventions, similar effects are found ($n = 11$, REM: $g = 0.55$, 95% CI 0.31, 0.80, $\tau^2 = 0$; FEM: $g = 0.55$, 95% CI 0.34, 0.77).

Frequency and intensity of headache (Table 4) display moderate mean effects and duration a small effect. No improvement is seen in the waiting list control groups ($n = 8$, $g = 0.10$, see Table 3). Regarding medication, only four studies with six groups could be analysed, demonstrating a moderate average effect for FEM in the treatment condition. However, in REM the effect size is not significant (Table 3). The waiting list condition does not achieve a significant pre-post change in medication ($n = 4$, $g = 0$; see Table 3). No information was available for medication in the active control conditions. Two of these studies, however, presented information on headache variables with moderate to large effect sizes ($g_1 = 0.80$; $\sigma^2 = 0.09$/$g_2 = 0.49$, $\sigma^2 = 0.18$).

Long-term efficacy was determined by analysing pre-follow-up differences. Eight studies included follow-up data on headache variables for the treatment groups (three studies with a 12-month follow-up, three studies with a 6-month follow-up, one study each with 4-month and 8-month follow-up). A small positive random effects variance did not reach significance (Table 3). Large mean effect sizes were calculated for the pre-follow-up changes in REM ($g = 1.0$) and FEM ($g = 0.97$). Only two studies provided information necessary for pre-follow-up

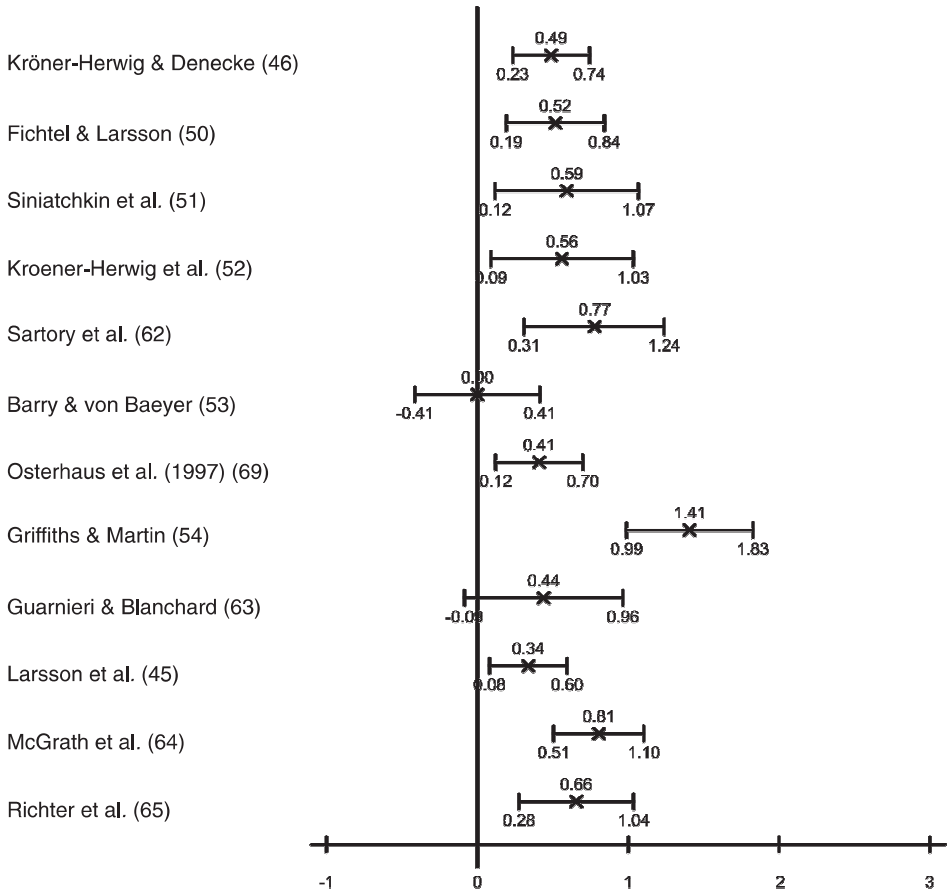

Figure 3 Pre-post study (within groups) effect sizes and confidence intervals for headache variables ($n = 12$).

comparison for medication ($g_1 = 0.36$; $\sigma^2 = 0.21$/ $g_2 = 0.47$, $\sigma^2 = 0.19$); no REM or FEM could be computed.

Improvement after post-therapy assessment

Examination of a possible gain in symptom reduction after the post-therapy assessment period was attempted by computation of post-follow-up effect sizes for the treatment conditions. Two analyses were conducted. Follow-up periods, 1–6 months and 6–12 months, were analysed separately regarding headache variables and clinically significant change. If a study included more than one follow-up period an average effect size was calculated (Table 3). Only two studies provide data on medication in the follow-up period, so no REM or FEM could be calculated.

From 20 studies presenting long-term results, only 16 provide information for these analyses. The positive mean effect sizes indicate small improvements from post-therapy to the 1–6-month follow-up assessments regarding headache variables ($g = 0.36$, $n = 6$) and clinically significant change ($g = 0.27$, $n = 11$), but the latter fails to reach significance. For 6–12-month follow-up assessments, improvement in headache symptoms also descriptively, but not significantly increases, indicated by a small effect size and a CI including zero ($g = 0.26$, $n = 4$). For clinically significant change no REM and FEM could be calculated at the 6–12-month follow-up, since only one original study (34) provided information ($g = 0.2$, $\sigma^2 = 0.16$).

Differential analyses (types of intervention, type of headache)

To examine possible differential effects regarding types of intervention, separate between-group analyses were calculated. REM and FEM regarding headache variables could be calculated only for relaxation treatments and revealed a small, but non-significant mean effect ($n = 4$, REM: $g = 0.20$, 95% CI 0.42, 0.77, $\tau^2 = 0$; FEM: $g = 0.20$, 95% CI –0.20, 0.54). Relaxation and biofeedback treatments both display large effect sizes when clinically significant change is used as outcome criterion (relaxation treatments, $n = 7$; REM: $g = 0.80$, 95% CI 0.23, 1.35, $\tau^2 = 0.14$, NS; FEM: $g = 0.80$, 95% CI 0.45, 1.11; biofeedback, $n = 4$; REM: $g = 0.90$, 95% CI 0.10, 1.68, $\tau^2 = 0$; FEM: $g = 0.90$, 95% CI 0.40, 1.38). A within-group comparison of headache variables was possible only regarding relaxation treatments. A small and non-significant mean effect size were found ($n = 5$; REM: $g = 0.28$, 95% CI –0.15, 0.72, $\tau^2 = 0$; FEM: $g = 0.28$, 95% CI –0.02, 0.59).

Only four studies allow direct comparison of different treatment approaches. Three studies compared relaxation combined with biofeedback vs. relaxation training alone (headache variables: $g_1 = 0$, $\sigma^2 = 0.21$; $g_2 = 0.5$, $\sigma^2 = 0.10$; $g_3 = 0.25$, $\sigma^2 = 0.20$; clinically significant change: $g_1 = 0.20$, $\sigma^2 = 0.20$; $g_2 = 0.34$, $\sigma^2 = 0.11$; $g_3 = 0$, $\sigma^2 = 0.35$). Only one study compared biofeedback with cognitive-behavioural treatment vs. relaxation with cognitive-behavioural treatment (headache variables: $g = 0.6$, $\sigma^2 = 0.14$; clinically significant change: $g = 0.25$, $\sigma^2 = 0.19$). No REMs or FEMs could be calculated.

In a further analysis, REM and FEM were separately computed for patients suffering from migraine (between-group comparison). A large effect size is displayed in the outcome variable clinically significant change ($n = 5$, REM: $g = 1.22$, 95% CI 0.61, 1.84, $\tau^2 = 0$; FEM: $g = 1.22$, 95% CI 0.78, 1.65). No REM and FEM were computed for headache variables and medication, and only two studies provided this information. Headache variables: $g_1 = 0.62$, $\sigma^2 = 0.22$; $g_2 = 0.12$, $\sigma^2 = 0.11$; medication: $g_1 = 0.15$, $\sigma^2 = 0.20$; $g_2 = 0.21$, $\sigma^2 = 0.11$.

The within-group analysis for migraine patients also results in a significant but moderate effect size regarding headache variables ($n = 4$; REM: $g = 0.68$, 95% CI 0.10, 1.30, $\tau^2 = 0$; FEM: $g = 0.68$, 95% CI 0.30, 1.06). No REM or FEM could be computed for medication, since only one study presented relevant data ($g = 0.21$, $\sigma^2 = 0.20$). Only one study was dedicated to the treatment of tension headache, thus no REM or FEM could be determined.

Publication bias

To check for publication bias, the robustness of the results was evaluated (30). After trim-and-fill analyses (between-group comparison) had been conducted, estimated effect sizes were only marginally smaller than those calculated on the basis of the original data (headache variables, REM: $g = 0.23$, 95% CI –0.03, 0.50, $\tau^2 = 0$; FEM: $g = 0.23$, 95% CI 0, 0.45, $\chi^2 = 7.89$; clinical significance, REM: $g = 0.76$, 95% CI 0.50, 1.02, $\tau^2 = 0.04$; FEM: $g = 0.76$, 95% CI 0.55, 0.96, $\chi^2 = 19.95$).

When the trim-and-fill analysis was applied to the within-group effect scores (pre-post), the corrected means were reduced from moderate to small effect sizes (headache variables, REM: $g = 0.40$, 95% CI 0.17, 0.61, $\tau^2 = 0.04$; FEM: $g = 0.40$, 95% CI 0.20, 0.60, $\chi^2 = 5.61$).

Discussion

The analysis presented here provides an up-to-date estimate of the evidence regarding psychologically based interventions for children and adolescents with recurrent headache based on a total of 23 studies. The results have specific validity for the treatment of headaches, both tension-type and migraine, since studies including the treatment of other pain syndromes were excluded. For the outcome criterion 'clinically significant change', large effects sizes are observed regarding between-group comparisons at post-treatment. Thus, it can be concluded that taking the percentage of responders into account, psychological treatment demonstrates greater efficacy when compared with a control. The parametric outcome variables used (headache intensity, duration, frequency, headache activity index), however, yield markedly smaller effect sizes in the between-group analysis.

The within-group effect sizes reflecting the change in headache in the patients over different assessment periods point to a significant, but only moderate, treatment effect. They are, however, distinctly larger in the treatment than in the control groups. The differences between effect sizes regarding headache symptom variables and the criterion clinically significant change are in need of interpretation. Treatment obviously increases the number of responders considerably (headache reduction ≥50%), whereas the waiting list self-monitoring procedure in the control groups stimulates small but no marked improvements in the participants. Thus a subject in the control condition may reduce their headache frequency by 20%, but will not reach the criterion of clinically significant change. It can be argued that the considerable amount of self-monitoring induced by diary keeping may have led to changes in symptom-provoking behaviour (35) resulting in some decrease of headache.

Within-groups effect sizes document a trend towards increasing improvement at follow-up. It is thus safe to say that improvement experienced after therapy is not lost, but at least maintained up to 12 months after the end of treatment. Since the outcome criteria clinically significant change and headache variables could not be determined in a between-group analysis at follow-up, a further corroboration of this finding is not possible. It can be assumed that the practising of coping strategies aimed at the prevention of headache attacks acquired during therapy and applied in daily life leads to a stable decrease of headache.

Separate analyses of intensity, frequency and duration of headache reveal differences regarding sensitivity to change. Between-group analyses demonstrate a significant effect of treatment only for the intensity of headache. Within-group analyses indicate significant improvement also for frequency and duration of headache. The assumption of a significant decrease in medication parallel to symptom decrease could not be statistically supported. However, only six studies contributed to this finding, making it less robust. Furthermore, the studies used different, and sometimes not clearly defined, definitions of medication. Further studies examining the influence of psychological treatment on medication intake are therefore needed.

Because of the relatively small number of RCTs found, the range of differential analyses was limited. Separate analyses for children with migraine ($n = 9$) could be performed and supported the general conclusions regarding treatment efficacy. Tension-type headache, however, could not be analysed separately. Separate analyses for younger and older participants were also not feasible. Neither could comparative analyses of different treatment approaches be conducted.

Since REM rather then FEM (sensitivity analysis shows small differences to the REM) was chosen for the analysis and interpretation of data, the conclusions derived from the analyses can be assumed to be very robust with a strong potential for generalization. However, it has to be acknowledged that our results may be not generalizable to the treatment of children and adolescents from countries not represented by a trial in our study sample, such as South America, Asia or Africa.

The existence of moderators of efficacy, e.g. conducting treatment in a clinical or non-clinical setting, is not supported by the data (non-significant Q-tests), thus giving another reason for generalizing the findings.

The trim-and-fill analysis correcting for bias due to unpublished studies supports the assumption that the results reflect the 'true' state of evidence, although corrected pre-post effect sizes regarding headache symptoms are somewhat lower than the original mean effect sizes.

Despite the relatively large number of initially identified original studies, only a small number of trials remained in the analysis. This reflects a scarcity of methodologically adequate data evaluation. Personally contacting the authors did not lead to a significant enrichment of available data.

Only a few of the original studies examined the efficacy of psychological treatment in comparison to

an active control group which controls for non-specific effects of giving attention to the child's problem and allowing for positive social interaction. Therefore evidence for the efficacy of psychological treatment of paediatric headache so far is based only on the 'soft' criterion of being more effective than waiting for future treatment and monitoring one's headache in a diary.

Our meta-analytic approach did not include outcome measures such as subjective disability, anxiety, quality of life, depression, coping, self-efficacy or physiological measures, which are known to be associated with recurrent headache (36–43). Only nine studies assessed one or the other of these variables, so that a meta-analytic approach was not possible. It seems worthwhile to examine whether psychological treatment can positively affect these concomitant variables. A few studies gave the first evidence of the beneficial influence of headache treatment on stress coping, somatic complaints and self confidence (44–46). The findings of our study imply that future research should widen its focus to include further outcome parameters and correlates of headache improvement due to psychological treatment. In outcome studies of adult treatment of pain a broad range of variables, such as those mentioned above, are commonly assessed (47), which is also recommended for treatment of paediatric headache.

Some methodological weaknesses of the studies should be mentioned. There is a large variance in the age of the treated participants within the samples, even within one study (see Table 2). Patients have different or even unspecified diagnoses; the severity of headache also varies as well as allowing medication during treatment. However, if these differences are assumed to affect treatment outcome differentially, they should have led to a significant heterogeneity in the results of the analyses, which was not confirmed.

A major characteristic of the original studies (and thereby a possible limitation of the conclusions derived from this meta-analysis) is that only completer analyses were conducted, which may have lead to an overestimation of efficacy. Comparing our results with those of Hermann et al. (21), however, the difference in the general level of effects sizes is striking, with the average effect score being much lower in the current study. Although the origin of this discrepancy cannot be explained completely, some differences in methodology may have contributed: Hermann et al. (21) did not limit their analyses to RCTs, which means that they included methodologically weaker studies. However, the most important reason may be the use of rather liberal strategies for meta-analysis, whereas the present analysis utilized very conservative methods (e.g. small sample size correction, REM).

Our results, however, compare very well with the findings of Eccleston et al. (22). The authors used a responder criterion comparable to the one applied in our analysis. Their findings point to a high efficacy (number needed to treat = 2.3, clinically significant change), as does our mean effect size of $g = 0.87$ in clinically significant change at post-therapy assessment. The additionally calculated binomial effect size display depicts with a 70% success rate in the treatment groups (compared with 30% in the control groups) the satisfying level of efficacy and its clinical relevance.

Our general conclusion derived from the meta-analysis is that efficacy of psychological treatment in paediatric headache patients is corroborated on evidence level 1a (several consistent RCTs support efficacy (48)). Treatment success can at least be maintained up to 1 year but shows a trend even towards a further increase.

Various research questions still remain to be examined by studies with methodologically adequate designs. Can differences in improvement be expected between children with different diagnoses? Is there an interaction between diagnosis and treatment type? The mechanisms of change should also be explored by assessing further process and outcome parameters such as behavioural and cognitive coping, changes in dysfunctional cognition, self-efficacy and health-related attitudes and behaviour. Possible physiological mediators should also be explored. Furthermore, disability and emotional distress, main outcome variables in adult pain treatment, need to be included in future research. Disability should be assessed by adequate instruments for the behavioural (e.g. PedMIDAS, see (9)) and emotional levels (anxiety, depression). Quality of life could be the most comprehensive and meaningful index of improvement.

Also, comparative efficacy of pharmacological treatments should be explored, especially for migraine, where treatment recommendations for the use of preventive drug treatment exist. The combined effectiveness of psychological and medical interventions deserves examination.

Thus, future researchers can be reassured by the high probability of treatment success in applying psychological interventions, but they will have to contribute to the elucidation of mechanisms, differential effects and moderators of efficacy. They are

advised to establish active control groups or use a comparative treatment design and to incorporate intent-to-treat analyses. A detailed overview of guidelines for the design of such clinically based investigations is given by Penzien et al. (49), who describe important areas of critical needs and priorities for headache research which are in concordance with the conclusions drawn here. Further data are needed to establish psychological intervention as a valid treatment option in clinical settings.

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3 Evaluation eines internet-basierten Selbsthilfetrainings (Manuskript 2 und 3)

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3.1 Einführung in die Fragestellung

Zunehmend kommen auch Selbsthilfemanuale bei der Behandlung häufiger Kopfschmerzen zum Einsatz. So untersuchten in der Meta-Analyse der vorliegenden Dissertation (Manuskript 1; Trautmann et al., 2006) 30% der Primärstudien parallel zu den sog. „clinic-based“ Interventionen auch Selbsthilfemanuale der Therapien (Kröner-Herwig & Denecke, 2002; Allen & Shriver, 1998; Griffith & Martin, 1996; McGrath et al., 1992; Guarnieri & Blanchard, 1990; McGrath et al., 1988; Larsson, Daleflod, Hakansson & Melin, 1987). Der Einsatz von Selbsthilfemanualen zielt auf eine systematische und eigenständige Durchführung von Verhaltensänderungen ab, basierend auf einem bereits evaluierten Therapieprogramm (Angenendt, 2000). Variierend kann hierbei das Ausmaß des therapeutischen Kontaktes sein, so sind Selbsthilfemanuale ohne Therapeutenkontakt über minimalen Therapeutenkontakt bis hin zu regelmäßigen, persönlichen Treffen mit dem Therapeuten zu finden. Ein wesentlicher Vorteil einer solchen Therapiealternative ist die leichte Zugänglichkeit, also das niedrigschwellige Hilfsangebot für den Betroffenen. Weiterhin können auf ökonomische Weise psychologische Therapieinhalte an eine große Zahl Betroffener weitergegeben werden (Angenendt, 2000).

Eine Meta-Analyse von Haddock und Kollegen (1997) untersuchte die Wirksamkeit von Selbsthilfemanualen im Vergleich zu herkömmlichen ambulanten Therapieangeboten für Kinder und Erwachsene mit häufigen Kopfschmerzen. Die Autoren konnten zeigen, dass beide Interventionsformen bzgl. ihrer Effektivität vergleichbar sind, während sich die Selbsthilfemanuale sogar als kosteneffizienter herausstellten.

Der Einsatz neuer Technologien wie z.B. des Internets, stellt eine Möglichkeit dar, Selbsthilfemanuale noch attraktiver zu gestalten. So existiert eine Vielzahl von Kommunikationsmöglichkeiten (z.B. E-Mail, Chat, Forum, Videokonferenzen) um bspw. einen minimalen Therapeutenkontakt begleitend anzubieten. Gerade für Kinder und Jugendliche kann somit die Attraktivität einer Therapie enorm gesteigert werden. Diese neue, komfortable und äußerst ökonomische Chance der Selbsthilfe wurde bereits in verschiedenen Bereichen der Klinischen Psychologie erfolgreich untersucht (Ott, 2003). Dennoch wird die Nutzung des Internets im klinischen Bereich auch sehr kontrovers diskutiert (Childress, 1998; Hsiung, 2002). So erfordert der Umgang mit diesem Medium eine entsprechende Kompetenz der Betroffenen. Auch ethische Verantwortlichkeiten des Professionellen gegenüber dem Patienten wie bspw. der Schutz der Patientendaten oder das „Annehmen“ einer positiven therapeutischen Allianz seitens des Patienten in Online-Gruppen werden diskutiert (Humphreys, Winzelberg & Klaw, 2000). Des Weiteren wird befürchtet, dass in internet-basierten Selbsthilfeprogrammen keine therapeutische Beziehung entstehen kann. Dies ließ sich jedoch in bisherigen Studien nicht bestätigen (Newman, 2004). Außerdem erfordern Krisensituationen der Betroffenen ein sofortiges Eingreifen des Professionellen, das jedoch in Abhängigkeit vom Grad des Therapeutenkontaktes und der Anonymität im Rahmen des Selbsthilfeprogramms oftmals problematisch ist. Trotz der kontroversen Diskussionen ist die Nutzung internet-basierter Interventionen zunehmend auch im deutschen Sprachraum zu finden (Ott, 2003).

Ein weiteres Anliegen der hier vorliegenden Dissertation ist die Implementierung eines solchen internet-basierten Selbsthilfetrainings für Kinder und Jugendliche mit häufigen Kopfschmerzen basierend auf dem bereits evaluierten kognitiv-verhaltenstherapeutischen

Therapieprogramm für 8-14 Jährige von Denecke und Kröner-Herwig (2000). Das Therapieprogramm, welches bereits in einem Selbsthilfeformat untersucht wurde, führte zu einer deutlichen Reduzierung der Kopfschmerzen (Kröner-Herwig & Denecke, 2002). Auch eine Evaluierung in der Praxis mit 23 niedergelassenen Psychotherapeuten unterstützt die Befunde (Kröner-Herwig & Denecke, 2007).

Das internet-basierte Selbsthilfetraining wurde für Kinder und Jugendliche bis zum 18. Lebensjahr adaptiert. Über eine Website erhielten die Betroffenen Zugang zu dem Training und wurden über den Ablauf der Studie informiert. Das ursprünglich acht Sitzungen umfassende Training wurde auf sechs internet-basierte Module reduziert. Die Teilnehmer bekamen wöchentlich ein Passwort zugesandt (per Chat oder E-Mail), welches Ihnen den Zugang zum nächsten Trainingsmodul ermöglichte. Basierend auf Befunden aus der E-Learning Forschung (Clark & Mayer, 2003) „begleiteten“ zwei Jugendliche und eine Expertin die Teilnehmer durch das Training. Die inhaltliche Gestaltung der einzelnen Trainingsmodule erfolgte mit Hilfe von Photos und Audio-Dateien. Ein Trainingsmodul bestand aus vier Einheiten. Der Aufbau der Trainingssitzungen war wie folgt strukturiert: In einem ersten Teil berichteten die zwei Jugendlichen jeweils ihr aktuelles Problem (Umgang mit Kopfschmerzen und Stress, Probleme etc.) und suchten im zweiten Teil im Gespräch mit einer Expertin, gemeinsam nach Strategien im Umgang mit den Schmerzen. In einer weiteren Einheit wurden mit Hilfe von Arbeitsmaterialien (PDF-Dateien) die wichtigsten Informationen der jeweiligen Trainingssitzung zusammengefasst und Instruktionen für die selbstständige Bearbeitung von Aufgaben gegeben. Abgeschlossen wurde jedes Trainingsmodul durch ein Wissensquiz, welches mit Hilfe einer automatisch versendeten E-Mail an den Trainer ging. Dieser besprach die Quizergebnisse sowie die Hausaufgaben dann mit dem Teilnehmer per Chat bzw. E-Mail.

In einer randomisiert, kontrollierten Pilotstudie (Manuskript 2) wurde das Training in einem ersten Schritt an einer kleinen Stichprobe (n=18) evaluiert. Der minimale Therapeutenkontakt erfolgte mit Hilfe eines Chatprogramms (Schäfer, 2005). Um den

Anforderungen an zukünftige Studien zur Behandlung von Kopfschmerzen zu entsprechen (Trautmann et al., 2006), wurde eine aktive Kontrollbehandlung (Edukation) als Vergleichsbedingung verwendet. Ziel der Pilotstudie war zum einem die Untersuchung der Effektivität des Trainings bzgl. der Reduzierung der Kopfschmerzen und der Schmerzkatastrophisierung und zum anderen die Erfassung der Zufriedenheit mit dem Training sowie die subjektiv wahrgenommene Verbesserung der Kopfschmerzen. Ebenso wurde die Patienten-Trainer-Beziehung erfasst. Die Therapiebedingung wies nach dem Training signifikante Reduktionen in der Kopfschmerzhäufigkeit und der Schmerzkatastrophisierung auf, während die Teilnehmer der Kontrollbedingung keine signifikanten Verbesserungen zeigten. Auch sechs Monate nach dem Training waren die erzielten Trainingserfolge stabil. Die Untersuchung der Patienten-Trainer-Beziehung zeigte, dass auch im Rahmen der internet-basierten Intervention der Aufbau einer guten Beziehung möglich ist. Alle Teilnehmer berichteten eine hohe Zufriedenheit mit dem Trainingsangebot sowie eine subjektive Verbesserung ihrer Beschwerden. Hinsichtlich der Kosteneffizienz erwies sich das Training als vergleichbar mit dem ursprünglichen Training. So wurde aufgrund der langen Chatzeiten (verursacht durch die Teilnehmer der Studie) der Zeitaufwand der Trainer nicht deutlich reduziert. Durchschnittlich verbrachten die Trainer 55 Minuten mit den Teilnehmern der Trainingsbedingung im Chat und weitere 41.3 Minuten mit den Probanden der Kontrollbedingung.

Basierend auf den Befunden der Pilotstudie erfolgte in der Hauptuntersuchung der minimale Therapeuten- bzw. Trainerkontakt über die Versendung von verschlüsselten E-Mails (Schäfer, 2005), um somit eine höhere Kosteneffizienz zu erzielen. In dieser Studie (Manuskript 3) wurde die Trainingsbedingung neben der Edukationsbedingung auch mit Angewandter Entspannung verglichen.

Ziele der randomisierten, kontrollierten Untersuchung waren wiederum die Wirksamkeitsüberprüfung der Trainingsbedingung im Vergleich zur Angewandten Entspannung und zu der aktiven Kontrollgruppe bzgl. der Kopfschmerzvariablen und der Schmerzkatastrophisierung sowie die Erfassung weiterer gesundheitsrelevanter Variablen wie Depression, psychopathologische Auffälligkeiten und die Lebensqualität. Im Weiteren

wurden die Patient-Trainer-Beziehung, die Bewertung des Trainings und die subjektiv wahrgenommene Verbesserung der Kopfschmerzen erhoben. Insgesamt konnten von ursprünglich 87 Interessenten 65 Kinder und Jugendliche mit häufigen Kopfschmerzen einer der drei Bedingungen zugeteilt werden. 60 Probanden beendeten das Training und 41 nahmen auch an den Follow-up Untersuchungen teil. Die Ergebnisse zeigten, dass die Teilnehmer aller Studienbedingungen ihre Kopfschmerzhäufigkeit und –dauer, jedoch nicht die Intensität der Kopfschmerzen, langfristig signifikant reduzieren konnten wie auch die Schmerzkatastrophisierung. Es gab keine Unterschiede in der Effektivität zwischen den Gruppen. Während sich jedoch 63% der Teilnehmer der kognitiv-verhaltenstherapeutischen Trainingsbedingung in einem klinisch bedeutsamen Maße nach dem Training verbesserten (Responderkriterium: 50% Verbesserung der Kopfschmerzhäufigkeit), erreichten lediglich 32% die Teilnehmer der Angewandten Entspannung und 19% der Kontrollbedingung eine klinisch bedeutsame Verbesserung ihrer Kopfschmerzsymptomatik. Hierbei zeigten sich signifikante Gruppenunterschiede zugunsten der Trainingsbedingung. Sechs Monate nach dem Training wies die kognitiv-verhaltenstherapeutische Bedingung weiterhin eine Responderrate von 63% auf, während sich die Responderraten der Angewandten Entspannungs-Bedingung (56%) sowie der aktiven Kontrollbedingung (55%) steigerten. Sowohl die Variable Depression als auch die gesundheitsbezogene Lebensqualität der Teilnehmer veränderten sich nicht signifikant durch das Training. Im Prä- Follow-up Vergleich wiesen die Teilnehmer aller Gruppen signifikante Reduktionen in der Variable psychopathologische Auffälligkeiten auf. Ebenso wie in der Pilotstudie zeigte sich eine gute Patienten-Trainer-Beziehung. Wiederum waren die Teilnehmer mit dem Training zufrieden und berichteten eine subjektive Verbesserung der Kopfschmerzen. Hinsichtlich der Zeiteffizienz verbrachten die Trainer durchschnittlich 22 Minuten mit jedem Teilnehmer pro Trainingsmodul und Woche.

Zusammenfassend lässt sich feststellen, dass die teilnehmenden Kinder und Jugendlichen mit dem internet-basierten Training zufrieden waren. Allerdings konnten die Teilnehmer aller Gruppen ihre Kopfschmerzen deutlich reduzieren. Lediglich die Responderrate zum Zeitpunkt Post zeigte signifikante Verbesserungen für die

Trainingsbedingung im Vergleich zur Kontrollbedingung. Hinsichtlich der Kopfschmerzvariablen (Häufigkeit, Intensität, Dauer) und der gesundheitsbezogenen Variablen gab es somit keine differenziellen Wirksamkeitsunterschiede zwischen den Studienbedingungen.

3.2 Manuskript 2

Trautmann, E. & Kröner-Herwig, B. (2008). Internet-based self-help training for children and adolescents with recurrent headache: A pilot study. *Behavioural and Cognitive Psychotherapy, 36 (2),* 241-245.

In der Online-Ausgabe der Zeitschrift *Behavioural and Cognitive Psychotherapy* wurde zusätzlich eine weitere, ausführlichere Version (Supplementary Materials) des Manuskriptes veröffentlicht (siehe Anhang).

Anmerkungen der Autoren:

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Internet-Based Self-Help Training for Children and Adolescents with Recurrent Headache: A Pilot Study

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Abstract. We report the results of a randomized controlled trial that compared the efficacy of an internet-based self-help treatment for paediatric headache including chat communication (cognitive-behavioural treatment, CBT) with an internet-based psychoeducation intervention (EDU). In the CBT group, significant pre- to post-treatment decreases were found for headache frequency and pain catastrophizing, but not for headache intensity or duration. In the EDU group none of the variables (frequency, intensity, duration, pain catastrophizing) showed improvement. No significant between group differences were found for headache variables and pain catastrophizing at post-treatment. The patients reported high satisfaction with the internet-based training and a good patient-trainer-alliance. Results were maintained at 6-month follow-up. Due to the small sample size, no general conclusions can be drawn regarding the efficacy of the internet-based training regarding the outcome variables, but the training was well accepted by patients. Further research is necessary to evaluate the therapeutic potential of such interventions.

Keywords: Child/adolescent, recurrent headache, internet-based, cognitive-behavioural therapy, self-help.

Introduction

Headaches can be a serious health problem for children and adolescents, with adverse effects on well-being (Sillanpää and Aro, 2000); therefore it is essential to have effective treatments. Preventive treatment options can be derived from the psychological domain, but many children and adolescents with recurrent headaches do not have ready access to these treatments, as they are not ubiquitously offered. One way of expanding the accessibility of preventive treatments is the implementation of self-help programs, in particular via internet-based interventions (IBI). IBI are able to transcend barriers and thus make treatment more easily available (particularly to those living in remote areas without treatment options). So far, only one study (Hicks, Baeyer and McGrath, 2004) has examined an IBI including mail and telephone contact for paediatric recurrent headache and abdominal pain in a randomized controlled trial. The authors reported significant reductions of the pain score (assessed through a pain diary) for the IBI at post-treatment and follow-up.

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The present study evaluated an IBI including chat communication for recurrent headache. The main aims of this pilot study are:

1. Evaluation of the efficacy of an internet-based training in reducing headache and pain catastrophizing. It was hypothesized that cognitive-behavioural self-help (CBT) would lead to greater improvement than education (EDU) and that the results would remain stable at 6-month follow-up.
2. Evaluation of satisfaction with the internet-based format and subjective headache improvement.
3. Evaluation of the patient-trainer-alliance and whether IBI impedes a positive alliance is examined.

Method

Participants

Eighteen patients with migraine and/or tension-type headache (at least two headache attacks per month) aged 10 to 18 (mean = 13.4, $SD = 2.6$) were recruited for the study. They were randomly assigned to the two conditions. Pre-treatment comparisons revealed no significant differences between groups regarding age, diagnosis, headache variables (frequency, intensity, duration), and pain catastrophizing. After completing the post-assessment, participants of EDU were given the opportunity to complete CBT.

Procedure

The treatments were evaluated in a comparative design.

CBT included 6 self-help sessions (focusing on education on headaches, stress management, relaxation, cognitive restructuring, self-assurance strategies, problem solving) based on a face-to-face training manual (Kröner-Herwig and Denecke, 2002). The sessions could be downloaded on a weekly basis from the training website. In addition, the patients had 6 weekly chat sessions with the trainer, in which the assigned exercises were reviewed.

EDU consisted of the first training session of CBT on headache information plus chat communication (and thus served as an active control group). EDU patients had the same number of chat contacts as those in the CBT, but the chat focused on the diary records of the previous week rather than on cognitive-behavioural elements. Two additional chat sessions (booster sessions) were performed in both groups 4 and 8 weeks after the end of training. In CBT the main topics of the training, including coping strategies, were reiterated, in EDU the diary records were discussed.

Trainers. Three graduate students of clinical psychology served as trainers supporting the children (via the chat). The students received intensive training prior to conducting the treatment as well as weekly supervision (from a PhD student/psychotherapist in training).

Internet specifics. The patients had access to the training web-site (self-help sessions) and the chat from their own home computers by means of standard browsers. They received the passwords for the sessions on a weekly basis (during the chat) and were encouraged to download and read the text material and to print out and complete the exercise handouts. The feasibility of the training material was assessed before; in particular, we examined the

comprehensibility of the training website and the ease of use of the chat with 5 children and adolescents with recurrent headache (10–16 years, 4 female and 1 male). In addition, the trainers had structured chat guidelines for both conditions.

Measures

The central outcome variables were frequency, duration, and intensity of headache assessed by means of an internet-based 4-week diary. Clinical significance was defined as a reduction of 50% or more in headache frequency compared to the baseline. Pain catastrophizing was assessed (by mail) using the German version of the Pain Catastrophizing Scale for Children (PCS-C, Crombez et al., 2003). The diary and PCS-C were administered at pre-treatment, post-treatment, and 6-month follow-up, but the patients also completed the diary during the training. After treatment, patients and parents were asked to complete a postal questionnaire about their satisfaction and their perceived change in headache. In an internet-based questionnaire (based on Krampen and Wald, 2001) the patient-trainer-alliance was assessed in the second, fourth, and last session (patient's view only). Two subscales, the "patient-therapist-alliance/assistance" scale and the "helping to cope with problems" scale, were adapted for use with children and adolescents and the conditions of an internet-based training.

Statistical analyses. These were used to examine the changes in outcome variables between group comparisons. Treatment outcomes for each condition were also computed. When prerequisites of *t*-tests were not achieved, nonparametric testing was used (Mann-Whitney U-Test or Wilcoxon paired rank sum test). For all tests, the level of significance was set at $p > .05$, two-tailed.

Results

Of the18 patients, 2 (one in each condition) dropped out at post-treatment by failing to return the questionnaires and headache diaries. On average, the chat sessions were longer in CBT than EDU (mean duration: CBT: Mdn = 55.0 min, range 45.8–75.0 min; EDU: Mdn = 41.3, range 28.2–58.0 min). The difference was not significant ($U = 18.0$, $p > .05$).

No significant differences were found between the two treatment groups at post-treatment in any of the outcome variables (frequency: $t = 0.239$, $p > .05$; intensity: $t = -0.995$, $p > .05$; duration: $U = 27.0$, $p > .05$; pain catastrophizing: $t = -2.051$, $p > .05$).

The frequency of headache decreased significantly from pre- to post-treatment ($t = 2.480$, $p < .05$) in CBT, but not in EDU ($t = 1.016$, $p > .05$) (see Table 1). Duration and intensity of headache did not change significantly in either group (CBT: intensity: $t = -0.708$, $p > .05$; duration: $z = -0.681$, $p > .05$; EDU: intensity: $t = 0.881$, $p > .05$; duration: $z = 1.483$, $p > .05$). Five patients in the CBT group reached the criterion of clinical significance at post-treatment; only 1 patient in the EDU group fulfilled this criterion. Pain catastrophizing was significantly reduced in CBT at post-treatment ($t = 2.427$, $p < .05$), but not in EDU ($t = 0.010$, $p > .05$). Treatment effects maintained at 6-month follow-up (only CBT, $n = 10$). No significant deteriorations or improvements took place between post-treatment and follow-up (frequency: $t = -0.938$, $p > .05$; intensity: $t = 0.594$, $p > .05$; duration: $z = -0.533$, $p > .05$; pain catastrophizing: $t = 0.742$, $p > .05$). Only 3 patients showed clinically significant improvement, 5 (who reached clinical significance at post-treatment) reported a marked improvement in a telephone interview after follow-up, but failed to return the diaries.

Table 1. Headache variables and pain catastrophizing (means and *SD*)

Measure	CBT	EDU
Headache (diary for 4 weeks)		
frequency		
pre	15.2 (10.9)	13.8 (10.1)
post	8.1 (8.0)	12.3 (8.6)
follow-up	8.0 (7.8)	–
duration		
pre[1]	3.8 (2–24)	6.0 (5–24)
post[1]	3.5 (2–24)	5.1 (2–23)
follow-up[1]	3.3 (1–23)	–
intensity		
pre	4.7 (0.8)	5.8 (1.5)
post	4.7 (1.3)	5.0 (1.3)
follow-up	4.2 (1.9)	–
PCS-C		
pre	33.0 (6.5)	36.4 (9.7)
post	30.0 (5.9)	37.3 (7.9)
follow-up	28.3 (5.8)	–

[1]Medians and Range of duration are given, because of violation of prerequisites of *t*-test.

All patients and parents reported satisfaction with the training (self and parent rating; 0 = not satisfied, 3 = very satisfied; CBT: self-rating: Mdn = 3.0, range 2–3; parents' rating: Mdn = 2.0, range 1–3, EDU: self-rating: Mdn = 2.0, range 1–3, parents' rating: Mdn = 2, range 1–3). Six patients and 8 parents in the CBT group reported subjective improvement of headache directly after the training; whereas 4 members of EDU experienced subjective improvement, supported by 3 parents. There are no significant differences between the two groups regarding satisfaction ($U = 16.0$, $p > .05$) or subjective improvement of headache ($U = 29.0$, $p > .05$).

The results of the "patient-therapist-alliance/assistance" scale showed no significant differences between the groups (the scale ranges from 0–3, higher scores signify higher patient-trainer alliance/helping to cope with problems, CBT: Mdn = 2.8, range 2–3; EDU: Mdn = 2.7, range: 2–3; $U = 21.0$, $p > .05$). The scores on the "helping to cope with problems" scale revealed significant differences (CBT: Mdn = 2.0, range 1–3; EDU: Mdn = 1.0, range 0–2; $U = 6.0$, $p < .05$).

Discussion

The outcome measures demonstrate significant reductions of headache frequency from pre- to post-treatment in CBT, but not in EDU. Descriptively, conditions show some reduction in duration and intensity of headache, but the reductions fail to reach significance; thus the assumed superiority of CBT could not be shown by inter-group-comparisons. The improvement in CBT remained stable at the follow-up. While 5 patients of CBT reached clinical significance at post-treatment, only 1 in the EDU group fulfils this criterion (> 50% reduction), but it would be premature to draw any conclusions about general efficacy of CBT

for reducing headache. The significant changes in pain catastrophizing in CBT emphasize the importance of cognitive restructuring of thoughts about pain and coping with headache. The training format and the chat contacts with the trainer were well accepted by all patients. They reported high satisfaction with the internet-based self-help training. Furthermore, both groups evaluated patient-trainer-alliance/assistance as positive and CBT reported significantly more help regarding coping through the trainer. The lower perceived help through the trainer in EDU did not influence the relationship between patient and trainer. The findings imply that the internet-based training does not impede a positive alliance.

Limitations

Only a small number of paediatric headache sufferers were treated; thus the power of the present study is low. Therefore conclusions about the general efficacy of CBT cannot be drawn as yet. A further limitation relates to the cost effectiveness of the training: inspection of the time spent in chat communication (involving the presence of the trainer) revealed CBT-IBI to be of similar efficiency as face-to-face CBT. This was in contrast to our expectation of a superior efficiency of the internet format. Nevertheless, the chat communication was generally well accepted by the patients and seems to have allowed for the development of a positive patient-trainer alliance. The internet format therefore appears to be a viable alternative, particularly when face-to-face intervention options are lacking.

Clinical implications and future directions

The present results support future examination of efficacy of IBI in children and adolescents with recurrent headaches.

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3.3 Manuskript 3

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A randomized controlled trial of Internet-based self-help training for recurrent headache in childhood and adolescence.

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Abstract:

Two different self-help training programmes (multimodal cognitive behavioral training programme (CBT) / applied relaxation (AR)) presented via the internet were compared with an educational intervention (EDU) in an RCT. Sixty-five children and adolescents (mean age: 12.7 years) with recurrent headache (at least 2 attacks per month) were each assigned to one of the three treatment conditions. Main outcome variables related to changes in headache frequency, intensity, duration as well as the responder rate (50% reduction of headache frequency). Secondary outcome variables were pain catastrophizing and general well-being (depression, psychopathological symptoms, and health-related quality of life). All groups showed significant reduction in headache frequency, duration and pain catastrophizing, but not in headache intensity, depression, psychopathological symptoms or health-related quality of life at post assessment. Highest responder rates at post were from CBT (63%), significantly different compared to AR (32%) and EDU (19%), whereas at follow-up no significant differences were found (CBT: 63%, AR:56%, EDU:55%). Long-term effects (pre - to follow-up) demonstrate significant changes in headache frequency, pain catastrophizing and psychopathological symptoms over all groups. CBT showed the highest within-effect size in headache frequency, duration and pain catastrophizing. The results support the use of Internet programmes for paediatric
recurrent headache, especially given their accessibility and suitability for children and adolescents. Further studies are needed to improve their quality and efficacy.

Key words: Child/adolescent, recurrent headache, internet-based, self-help

1. Introduction

Psychological intervention can be regarded as an important treatment option for recurrent headache in childhood and adolescence. Two recent meta-analyses [8,25] provided evidence for the efficacy of relaxation training, biofeedback and cognitive-behavioral treatment. However, due to the lack of skilled professionals and the resulting long waiting-lists few headache sufferers receive psychological therapy, meaning that only a small proportion of children has access to it. But Internet-based intervention (IBI) could fill the gap between demand and availability in the health care system. Most recently, a few studies on IBI for recurrent headache in adults and children have been published [1,7,13,24]. The findings showed that IBI is a promising new and cost effective treatment tool.

In a pilot study we examined an IBI for children and adolescents, including online chat communication for minimal therapist contact [26]. Significant decreases in frequency of headache and pain catastrophizing were found in the treatment group. The participants described the alliance with their trainers as being positive and satisfying. The pilot study demonstrated that the IBI combined with chats resulted in a similar efficacy as face-to-face treatment [26]. The chat, however, was cost-intensive as the therapist had to be present for a considerable period of time each week. Hicks, Baeyer & McGrath [13] used e-mail contact instead in their IBI of children with recurrent pain and were able to demonstrate this to be more cost effective.

Only a small number of paediatric headache patients were treated (n=18) in the pilot study; consequently, we planned for a larger sample to be treated. Furthermore chat contact was substituted by e-mail contact, requiring less time from the trainer to be spent

on the participants. Three active treatment conditions were incorporated into the design. Firstly, the cognitive-behavioural treatment (CBT), which had proved to be very effective in prior studies [15,16]. Applied relaxation (AR) was chosen as a more "simple" treatment strategy, which has demonstrated its efficacy in face to face treatments [9,17,19]. Finally, as a control condition, educational intervention (EDU) was introduced.

The primary aim of this study was to examine the efficacy of an IBI regarding improvement of headache (frequency, intensity and duration) as measured by a pain diary. As secondary outcome variables the effects on pain catastrophizing and general well-being (depression, psychopathological symptoms and health-related quality of life) were assessed. It was predicted that:

- CBT and AR would lead to greater reduction in headache symptoms and higher responder rates than EDU. Improvement should remain stable at 6-month follow-up assessment. CBT was expected to be more effective than AR.
- Pain catastrophizing in participants was expected to decrease in CBT, but not in AR and EDU, because of cognitive restructuring interventions only being part of CBT [26].
- It was expected that the CBT would be more improved in secondary outcome variables than AR and EDU.

Furthermore, we wanted to assess the quality of patient-trainer-alliance (patient's view) and their subjective evaluation of the training conditions. Furthermore trainers' time spent in e-mail contact with participants was explored.

2. Method

The study was conducted with the consent of the ethics committee of the DGPs (German

Society for Psychology eV).

2.1. Participants

Participants were recruited from January 2006 to March 2007 through newspaper advertisements, the webpage of the training programme, information on the website of the German Migraine and Headache Society (DMKG) and several websites focusing on children's and adolescents' issues (e.g., www.wissensschule.de, www.teachersnews.net; www.sign-project.de). To be eligible for the study (inclusion criteria) the children had to be between the ages of 10 and 18 years and had to suffer from primary headache (migraine, tension type headache (TTH) or combined headache) at least twice per month. They had to be able to read and write in German and have access to a personal computer and the Internet. Participants were excluded if they had recently started taking prophylactic medication for the headache or were in psychotherapeutic treatment.

The enrollment process (according to the CONSORT statement) and the participants' survival in the study are illustrated in the flow chart (figure1). A total of 87 children and adolescents expressed interest in the Internet-based training programme, of whom 78 fulfilled the inclusion criteria. Ten participants dropped out after registration. Two did not start the training after randomization and their baseline data were excluded from all analyses. All participants were randomly assigned to one of the three conditions. One participant was excluded from all analyses because of a secondary headache diagnosis received after training (EDU). Five participants dropped out at different stages of the trial, providing no post-assessment. Only 41 participants completed the 6-month follow-up assessment (figure 1).

Thirty-six participants were female and 30 were male (table 1). Mean age was 12.7 years

(SD=2.2). The participants had suffered from headache for a mean duration of 2.8 years (SD=3.0). All of the children and adolescents reported that they routinely used computer-mediated communication (e-mail and chat; table 1).

Figure 1

Table 1

2.2. Assessment

Demographic and Background Information

The participants and their parents responded to a questionnaire presented online regarding headache frequency, duration and intensity in the last 6 months, as well as their level of impairment and physical symptoms during the headache attack.

Headache diary

The primary outcome measures were frequency, duration and intensity of headache as measured by a four-week diary at pre-and post-treatment and at the 6-month follow-up. A clinically significant improvement (responder rate) was defined as a reduction of greater than 50% in headache frequency compared to baseline. The headache diary also enquired about medication.

Pain Catastrophizing Scale for Children (PCS-C)

The PCS-C was developed as a self-report instrument. Pain catastrophizing was assessed by the German version of PCS-C (Nagel, unpublished) developed by Crombez et al. [5].

The PCS-C assesses the dimensions of rumination, magnification and helplessness and demonstrates good reliability (0.88). These dimensions are subsumed under the high-order construct of pain catastrophizing, which was used in our study.

Children's Depression Inventory (CDI)

The German version of the CDI includes 27 items measuring cognitive, affective and behavioural symptoms of depression in childhood [23]. The children were asked to select the statement that characterised them best during the previous two weeks. The German version has good test-retest reliability (0.76).

Health-related Quality of Life (KINDL-R)

Health-related quality of life was assessed with the German KINDL-questionnaire [21] for children and adolescents. The instrument included six dimensions of health-related quality of life (physical health, general health, family functioning, self-esteem, social functioning). The authors report good reliability (0.80) [22]. In our analysis the total score of health-related quality of life was used.

Strength and Difficulties questionnaire (SDQ)

The Strength and Difficulties questionnaire [2,10] is a brief behavioural screening questionnaire with five subscales (emotional symptoms, conduct problems, hyperactivity/inattention peer relationship problems, and prosocial behaviour) for assessing relevant psychopathological symptoms in children and adolescents. In this study the self-report was used. Good reliability (0.78) was reported for the German version of the SDQ [2]. In the statistical analyses the total score from all scales was used.

All instruments were sent (by post) at pre- and post-treatment and 6 months after the completion of the training (follow-up assessment).

Patient-Trainer-Alliance

The patient-trainer-alliance was assessed by an Internet-based questionnaire (based on [14]; for more information see [28]) with two subscales: “patient-therapist-alliance/assistance” scale and “helping to cope with problems” scale (the scales range from 0-3, higher scores signify better alliance). The patients filled in the questionnaire on the Internet in the second, fourth, and last module (patient’s view only).

Evaluation of the training programme by the participants

After the end of the training period the participants and their parents were asked to complete a postal questionnaire about treatment satisfaction, the perceived change in headache, about coping with their headache, and whether they would recommend the Internet-based self-help training (0-3, higher scores signify a more positive evaluation).

2.3. Design

2.3.1. Randomization and Pre-Treatment Assessment

Patients were randomized into two treatment conditions (n=24, n=22) and an active control condition (n=19). We randomly selected participants by using the “select cases” random selection option in SPSS (the statistical software program SPSS 15.0).The participants were informed about group assignment and instructed to complete the pre-treatment assessment.

2.3.2. Treatment Conditions

All participants received information about mechanisms, symptoms and types of headache and the role of stress as a trigger of attacks in the first training module. All groups received 6 weeks of the training programme with weekly e-mail contact.

CBT was adapted from the face-to-face group training format from Denecke and Kröner-Herwig [6] and included 6 self-help modules. The first module presented education on headaches, whereas the second unit focused on stress management (perception of own stress symptoms, cope with stress). In the following modules the participants acquired progressive relaxation techniques, cognitive restructuring (identification of dysfunctional cognitions regarding headache and stress, and identifying functional cognitions), self-assurance strategies (to be assertive and be sensitive to one's own needs), as well as problem solving. Participants of the CBT were offered a CD with relaxation instructions and they could download the relaxation instructions from the training website.

AR is based on the training developed by Öst [20]. The participants were taught in several phases: progressive relaxation, cue-controlled relaxation and differential relaxation. Participants were offered a CD with specific instructions for different stages of AR training to be used at home.

Participants of the *EDU* condition had the same number of e-mail contacts as those in the CBT and AR, but the e-mails focused on the diary records of the previous week (e.g. Did you have any headache last week?; What did you do?), rather than on cognitive-behavioural elements or applied relaxation instructions.

2.3.3. E-mail contacts

E-mails were sent to the participants from a standardized mail manual on a weekly basis during the training. In CBT and AR, each e-mail from the participants responded to the assigned exercises and reported about their headache in the previous week. Participants in the EDU exclusively reviewed their experiences of headache (self-monitoring in diaries) in e-mails. In addition, participants received a list of questions related to the weekly training module to demonstrate their understanding of the learning targets. Two additional e-mail contacts (booster) were performed at week 4 and 8 after the end of training programme. The participants were reminded of the coping strategies learnt during the training and advised to continue practicing them in their daily lives.

2.3.4. Trainers

Seven graduate students of clinical psychology served as trainers supporting the children and adolescents via e-mail. The students received intensive training prior to conducting the treatment as well as weekly supervision (by the first author: a psychotherapist in training and doctoral candidate). Each trainer was involved in supervising participants from each treatment condition.

2.3.5. Internet Specifics

General information about the training programme and informed consent for the study were accessible on the training website. The training was offered at no cost. Participants had access to the websites and e-mail contact from their home computer by means of a standard browser (e.g. Internet Explorer, Netscape). They received the "modules" on a weekly basis and were encouraged to download and read the text material, and to print out the information and exercises for practice. Passwords were given by e-mail so that they

could access the following week's training. The rating scale for patient-trainer alliance was also password protected and sent by e-mail. If a participant was unable to connect to the Internet, they had the option to contact a trainer by phone. Responses were provided within 48 hours. In the treatment phase, trainers encouraged the participants to follow the scheduled programme by reading the information. If the participant did not answer, they received a friendly reminder from the trainer.

2.4. Procedure

Each individual interested in the training programme was instructed on the website to complete the downloadable questionnaire about demographic and background information, as well as information about the headache and to send back the questionnaire. If this signaled the suitability of the child or adolescent for the study the complete battery of questionnaires and the diary was then sent to them. After pre-assessment measures were received from the potential participants and the inclusion and exclusion criteria checked, randomization was conducted and the participants were informed by telephone by their trainers that they could start with the training. Post-treatment and 6-month follow-up assessments included the headache diary, PCS-C, KINDL-R, SDQ and the evaluation of the training programme questionnaire. The patient-trainer-alliance was assessed during the 6 training weeks. After completing the follow-up assessment, participants of the EDU were given the opportunity to enter the CBT programme. All contact with the participants was via e-mail and telephone.

2.6. Statistical Procedures and Analyses

One-way ANOVAs or χ^2 tests were conducted on all pre-treatment measures and demographic variables to explore differences between groups. Differences between

dropouts and completers from whom baseline data existed were analyzed as well using χ^2 tests and ANOVAs regarding demographic variables and pretreatment data (table 1).

ANOVA (2x3) with repeated measures were performed for all headache parameters, PCS-C, CDI, SDQ, and KINDL-R to test the hypotheses. Only a small number of participants completed all measurements at all three assessment points, which considerably reduced the number of participants in analyses. Therefore, separate ANOVAs with repeated measures were performed for pre- and post- assessment and, post- and follow-up assessment. Significant main effects on groups were investigated further by using pairwise comparisons for group effects (post hoc test Scheffé). Significant interactions were assessed with separate repeated measures ANOVAs for each condition. Additionally, within-group effect sizes (Hedges g) were calculated. Cohen [3] defined effect sizes of 0.2 as small, effect sizes of 0.5 as medium, and effect sizes of 0.8 or greater as large. This guideline can also be used for the interpretation of Hedges *g*. Therefore the results of our study are comparable to current meta-analytic findings. Furthermore, ANOVAs with repeated measures were conducted for pre- follow-up to confirm the long term changes. Differences in the rate of responders between the conditions were analyzed by χ^2 test (Kruskal-Wallis test). Mann-Whitney U tests were used for pairwise group comparisons. Participant's evaluation of the training programme and patient-trainer-alliances were tested with ANOVAs. Data analysis was carried out with SPSS 15.0. Alpha level was set at 5%.

3. Results

3.1. Attrition

Of the 87 children and adolescents, who were interested in participating, only 65 participants commenced the training programme. Five discontinued during training. The

dropout rate for CBT was 16.6% (4/24), 5.3% (1/19) in EDU, and no dropouts in the AR condition. However, χ^2 test revealed no significant differences in dropouts between the three conditions (χ^2= 4.71, df=2, p=0.10) Reasons for dropout were no motivation (n=3), migraine attacks when reading the training materials (n=1) and computer problems (n=1).

3.2. Treatment Outcome at post-treatment

There were no significant pre-treatment differences for any of the pre-treatment measures and demographic variables between the three conditions (all p>0.05, table1). Furthermore, no significant differences were found between dropouts and completers (all p>0.05).

In the following the findings on trainer's time spent in supporting the participants, the results of headache symptoms, secondary outcome variables, patient-trainer alliance and participant's evaluation of the training programme presented. Furthermore, long-term results (post - follow-up and pre - follow-up comparisons) were reported.

Additionally, there were no significant differences between the groups for average time spent in e-mail (and telephone) contact by the trainer per week (F(2,32)=0.57, p=0.57; CBT: M=19.3 min, SD=8.22; AR: M=22.5 min, SD=13.68; EDU: M=24.36 min, SD=10.32) and the average number of e-mail contacts by the trainer per week (F(2,32)=1.63, p=0.21; CBT: M=1.8, SD=0.55; AR: M=2.1, SD=0.42; EDU: M=2.2, SD=0.57). The average trainer time spent in e-mails or phone calls per participant (over all groups) across all 6 training modules was 132 min (SD=66.1). No group differences were found regarding the number of responded weekly e-mails from the trainer (week 1: χ^2=0.40, df=2, p=0.82; week 2: χ^2=2.07, df=2, p=0.36; week 3: χ^2=0.35, df=2, p=0.84; week 4: χ^2=1.29, df=2, p=0.53; week 5: χ^2=1.07, df=2, p=0.59; week 6 χ^2=0.93, df=2, p=0.63).

Headache Diary and Clinical Significant Improvement (responder)

Means and standard deviations for headache variables presented in Table 2. Repeated measures ANOVA (table 3) presented no significant interactions (time x group) or main effects for the group factor. However, a significant time effect was found for the variables headache frequency and duration indicating that all three groups showed a reduction of these variables.

Sixty-three percent of participants in the CBT group (10/16 who completed pre- and post-diaries) reached the responder criterion at post-treatment; only 32% of participants in the AR group (6/19 who completed pre- and post diaries) fulfilled this criterion and 19% (2/16) in the EDU condition. The Kruskal-Wallis test showed a significant difference between the three groups (χ^2=6.83, df=2, p=0.03). Pairwise comparisons between the groups indicate a significant difference between CBT and EDU (U=72.00, p=0.03), but none for the other comparisons (AR and EDU: U=132.50, p=0.52; CBT and AR: U=105.00, p=0.12).
No significant changes or group differences were found in medication at post-treatment (χ^2=0.45, df=2, p=0.80).

Pain Catastrophizing

ANOVA on PCS-C data revealed no significant interactions (time x treatment group) or main effect of groups (see table 3), but a significant effect of time indicating that all three groups showed a reduction in pain catastrophizing.

Depression, Health-related Quality of Life, Strength and Difficulties

The ANOVA with repeated measures showed no interactions (time x group) or main effect group factor, nor a time effect for CDI, KINDL and SDQ.

Table 2

Table 3

Patient-Trainer-Alliance

The “patient-therapist alliance/assistance” scale displayed no significant differences between the three training groups (F(2,46)=0.98, p=0.38; CBT: M=2.6, SD=0.51; AR: M=2.6, SD=0.48; EDU: M=2.4, SD=0.79), whereas the scores on the “helping to cope with problems” scale are significantly different between the groups (F(2,45)=13.20, p=0.00; CBT: M=2.1, SD=0.42; AR: M=2.2, SD=0.43; EDU: M=1.2, SD=0.53). Pairwise comparisons between the groups showed significant differences between CBT and EDU (p=0.00) and AR compared to EDU (p=0.00). There were, however, no significant differences between the two treatment groups (CBT vs. AR; p=0.90).

Evaluation of the training programme by the participants

Findings from the postal questionnaire showed significant group differences in treatment satisfaction reported by the children (F(2,48)=3.49, p=0.03; CBT: M=2.3, SD=0.60; AR: M=2.7, SD=0.57; EDU: M=2.0, SD=0.90). Post hoc tests between groups revealed

significant differences between the AR and EDU groups (p=0.04) indicating that AR reported more satisfaction. No significant results were found for CBT vs. EDU (p=0.53) and CBT vs. AR (p=0.32). Results of ANOVA showed no significant differences between the groups in subjective improvement of headache directly after the training (F(2,48)=0.86, p=0.92, CBT: M=2.8, SD=0.88; AR: M=2.9, SD=0.85; EDU: M=3.7, SD=0.70). Twelve participants of CBT (12/14) and 12 of AR (12/20) reported subjective improvement of headache directly after the training, whereas 9 (9/14) members of EDU experienced subjective improvement.

Significant differences between the groups were found regarding reported coping with their headache (F(2,47)=10.87, p=0.00; CBT: M=1.9, SD=0.80; AR: M=2.3, SD=0.82; EDU: M=1.3, SD=1.08). Post hoc analyses showed significant differences between CBT and EDU (p=0.00) and significant differences between AR and EDU (p=0.02). No significant results were found for the comparison between CBT and AR (p=0.47). There were no significant differences between the three conditions for recommending the Internet-based self-help training: (F(2,48)=0.21, p=0.81; CBT: M=2.4, SD=0.61; AR: M=2.4, SD=0.88; EDU: M=2.2, SD=0.97).

3.3. Long Term Results (6-month follow-up)

ANOVAs between the three conditions at post- and follow-up-assessment showed that the improvements in headache were maintained (table 3). Sixty-three percent of participants in the CBT (7/11) reached the responder criterion at follow-up - treatment; 56% of participants in the AR group (9/16) fulfilled this criterion, and 55% (5/9) in the EDU condition. The Kruskal-Wallis test did not display significant differences between the three groups (χ^2=0.179, df=2, p=0.91).

Medication did not change from post to follow-up (school absence: F(2,28)=0.33, η^2=0.01,

p=0.57; medication: χ^2=4.55, df=2, p=0.10) nor were there differences between the conditions.

A non-significant main effect on groups for the PCS-C was qualified by the significant interaction (time x group). Separate repeated measures ANOVAs for groups showed only significant effect for the AR condition (AR: F(1,17)=34.21, η^2=0.67, p=0.00; CBT: F(1,11)=0.43, η^2=0.04, p=0.53; EDU: F(1,9)=0.08, η^2=0.01, p=0.79). There was no change in CDI, KINDL-R and SDQ from post- to follow-up assessment.

Additionally, pre - follow-up ANOVA with repeated measures confirm the findings for headache frequency. There was only a significant time effect. Analysis (ANOVA with repeated measures) of headache intensity was comparable to the previous analyses as well. However, headache duration showed different results: there were no main effects on group and time, nor an interaction.

Following the effect sizes were computed. Within effect sizes for pre - follow-up assessment indicated moderate improvements for headache frequency in treatment groups (CBT: g=0.75, AR: g=0.67), and only a small effect in EDU (g=0.43). Duration and intensity demonstrate only small changes in effect sizes (duration: CBT: g=0.36, AR: g=0.06, EDU: g=0.12; intensity: CBT: g=0.06, AR: g=-0.22, EDU: g=-0.17). ANOVAs on the PCS-C and the CDI were similar to the previous results. Effect sizes for the PCS-C demonstrate a large effect for treatment groups (PCS-C: CBT: g=1.20, AR: g=0.97), but not for EDU (g=0.39). However, there was a moderate effect for the CDI in EDU, but only small effect sizes for the treatment conditions (EDU: g=0.56, CBT: g=0.36, AR: g=0.33). However, ANOVA for SDQ data revealed a significant time effect, but no main effect on group or interaction. The significant time effect was reflected in the effect sizes (CBT: g=0.68, AR: g=0.38, EDU: g=0.53). Furthermore there was no interaction nor a time or

group effect in ANOVA for KINDL-R. However, the results were not reflected in effect sizes: CBT: g=0.63, AR: g=0.40, EDU: g=0.

4. Discussion

The present investigation demonstrates the evaluation of the first German Internet-based training programme for children and adolescents with recurrent headache. The internet-based offer seemed to be well accepted by the participants, as reflected in a low dropout rate (8%), which is comparable to the original face-to-face group training [15] and the IBI from Hicks and colleagues [13]. Most of the participants reported high satisfaction with the training programme and said that they would recommend it. However, all children and adolescents perceived a positive change in their headache without group differences. Furthermore, only the two treatment groups described better coping with their headache whereas the control condition reported good coping to a significantly lesser extent. It is important to enhance positive coping. Therefore participants of the treatment groups find to a greater extent alternatives to negative strategies during headache. All participants (over all groups) rated the patient-trainer- alliance as positive, which conforms to the results of the pilot study [26]. The findings emphasize that communication over the Internet instead of face-to-face contact does not impede the relationship between the children or adolescents and their trainer. But there are significant differences between the perceived help through the trainer regarding coping. By contrast only the treatment groups reported more help from their trainers, whereas the control condition describes lower perceived help.

4.1. Efficacy of Internet-based self-help training programmes

The analyses of change in headache frequency and duration showed a significant

decrease for all groups at post-treatment, which were reflected in large to medium effect size (CBT and EDU) in headache frequency and medium effect size in headache duration (CBT only). However, differences in the effect sizes between the groups were not reflected in significant group effects, which could be caused by the small sample size per group. Given the pre – follow-up effect sizes, CBT will be superior to AR and especially to EDU. Contrary to our expectations no condition led to any change in the perception of the intensity of headache. Furthermore, the improvement in the control group confirms the results of the pilot study [26] and reflects long term changes in EDU, as well. When comparing the results of the present study, especially those for CBT with the current meta-analytic findings, it become apparent that effect sizes for CBT are higher than the average effect sizes found of this meta-analysis (overall effect sizes for headache frequency: 0.54, duration: 0.29) [25].

Both treatment conditions showed higher responder rates in children and adolescents after post-treatment in contrast to EDU. Additionally, the responder rate of CBT was superior to AR. Furthermore, the responder rates that we found in CBT and EDU are comparable with the findings of Hicks and colleagues [13] and quite similar to the responder rate of the original face-to-face training [15]. As predicted, the comparisons of CBT and EDU did in fact demonstrate a significant difference. This illustrates that EDU leads to minor, but not clinically relevant improvement. However, AR and EDU showed higher responder rates at follow-up assessment whereas the results of CBT remained stable. However, the results at follow-up might be affected by high attrition rates in CBT and EDU. Therefore, conclusions about general efficacy could be distorted and premature.

Furthermore, the present results indicated a general improvement of pain catstrophizing at

post-treatment for all groups. The repeated measures ANOVA suggests a marginally significant interaction which fails the defined level of significance. However, the result could be indicative of a trend of reduced pain catastrophizing in CBT following treatment, which is underlined by the large pre-post and pre- follow-up effect sizes in contrast to the small effect sizes in EDU. The significant improvement for AR at 6-month follow-up is somewhat unexpected. Possibly, AR achieved a reduction of their pain-associated thoughts without the cognitive restructuring techniques of cognitive-behavioural therapy.

None of the conditions reached marked improvements in depression at post- and follow-up assessment. Notably, the results in psychopathological symptoms (SDQ) showed most improvement at 6-month follow-up (reflecting in small to medium effect size in the groups and the significant time effect at pre –follow-up analysis). However, there were no improvements for health-related quality of life over all groups. The results are comparable to Hicks and colleagues'[13].

The Internet-based self-help training programme is time effective with an average treatment time from approximately 2.2 hours. An individual face-to-face training programme [6] has a treatment time of at least 12 hours (8 modules a 90 min). With respect to demands on therapist time (and treatment materials) the IBI which we have examined seems to be more cost effective than traditional individual training programmes. Additionally, the average time per participant is comparable with the treatment time of other Internet-based headache programmes (e.g. 3 hours; see [13]).

In summary, all groups benefit from the Internet-based offer and training via Internet is a viable alternative for treating recurrent headache in childhood and adolescence. But

treatment conditions, particularly CBT, reached greater clinical improvements at post-treatment and reported a higher rate of subjective improvement of headache and better coping with their headache.

It should be noted that the control condition that we used did include several headache-related aspects (education, self-monitoring procedures (diary records), and weekly contact with a professional for discussion of diary records). Thus the weekly correspondence with their trainers about headache also seems to achieve marked improvements.

4.2. Limitation

In the current study we only used completer analyses. An intention-to-treat analysis was not carried out because of a low dropout rate in comparison with the high rate of non-compliant participants, who did not complete all questionnaires and diaries at assessment points but received all training modules. However, encouraging the participants to complete post- and follow-up assessment was not improved despite friendly reminders from the trainer by telephone. Half the participants in CBT and EDU did not return the follow-up assessment; whereas the participants in AR showed good compliance. This differential attrition is surprising, because all trainers coached participants from all groups and used standardized e-mail manuals. This differential dropout compromises the conclusion that can be drawn from this study and limits the generalizability of its results.

A further limitation is the self-selection bias of the participants. Headache sufferers who feel uncomfortable when using a computer do not respond to offers of treatment via the Internet. We therefore cannot know whether know the results could be generalized to an unselected sample of children and adolescents. The relatively small sample size in each treatment group is a further weakness of the present study, which was below the recommended criteria (25-30 per group; [3]). Therefore, lack of power does seem to be a

major issue in the current study as power in the post hoc analysis was 0.41. However, one argument, though perhaps less valid, is that our sample was larger than most studies included in recent meta-analyses, and therefore our sample size was comparable to, or larger than those in other paediatric headache intervention studies [8,25].

4.3. Future Directions

It is necessary to perform further clinical Internet-based treatments and the practical implementation of Internet-based self-help. Moreover, the improvements found in the education group call for further explanation, perhaps by renewed testing of minimal intervention by means of the Internet. Further investigation is required to examine the efficacy of this approach in a larger sample.

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Table 1: Characteristic of the sample size and pre-measures

	CBT (n=24)	AR (n=22)	EDU (n=20)	Drop out (n=5)	Significance Test p
Gender					
male	12	8	10	2	0.53
female	12	14	10	3	
Diagnosis[1]					
Migraine	16	13	10	4	
Tension type headache	7	3	8	1	
both diagnoses	1	6	2	0	0.63
Age (mean, SD), years	13.1 (2.3)	12.8 (2.1)	11.9 (1.6)	13.4 (3.0)	0.23
Duration of headache in years (mean, SD)	3.6 (3.6)	2.9 (3.1)	2.0 (1.9)	1.6 (3.0)	0.34
using computer, years	3.5 (2.0)	3.0 (2.0)	2.8 (2.1)	3.0 (2.1)	0.69
using the Internet, years	2.4 (2.0)	2.1 (1.4)	1.8 (1.2)	1.3 (0.7)	0.42
using e-mails/chat, years	1.6 (1.0)	1.5 (1.0)	1.3 (1.1)	0.8 (0.8)	0.52
Headache diary					
Frequency	11.5 (8.2)	10.3 (7.8)	10.7 (7.4)	6.8 (3.1)	0.79
Intensity	5.0 (1.8)	5.1 (1.7)	5.2 (1.7)	5.6 (2.2)	0.98
Duration	6.8 (4.0)	8.1 (6.7)	7.8 (5.8)	7.0 (4.5)	0.74
PCS-C	32.5 (8.5)	34.9 (7.8)	32.2 (10.4)	30.6 (9.5)	0.52
CDI	10.2 (6.6)	8.5 (4.8)	9.2 (4.8)	8.0 (4.3)	0.71
KINDL-R					
SDQ	11.8 (3.5)	8.9 (4.5)	10.7 (3.9)	7.8 (5.4)	0.18

PCS-C – Pain Catastrophizing Scale; CDI – Children's Depression Inventory, SDQ – Strength and difficulties Questionnaire, KINDL-R – health-related Quality of life questionnaire
No statistically significant differences ($p<.05$) were found between the groups.
[1]The variable 'diagnosis' includes patients who have the diagnosis migraine/TTH or suspicion of having this diagnosis.

Figure 1: schematic presentation of the number of participants recruited, the attrition, drop outs, and the number of participants completing the treatment and participating in the follow-up assessment

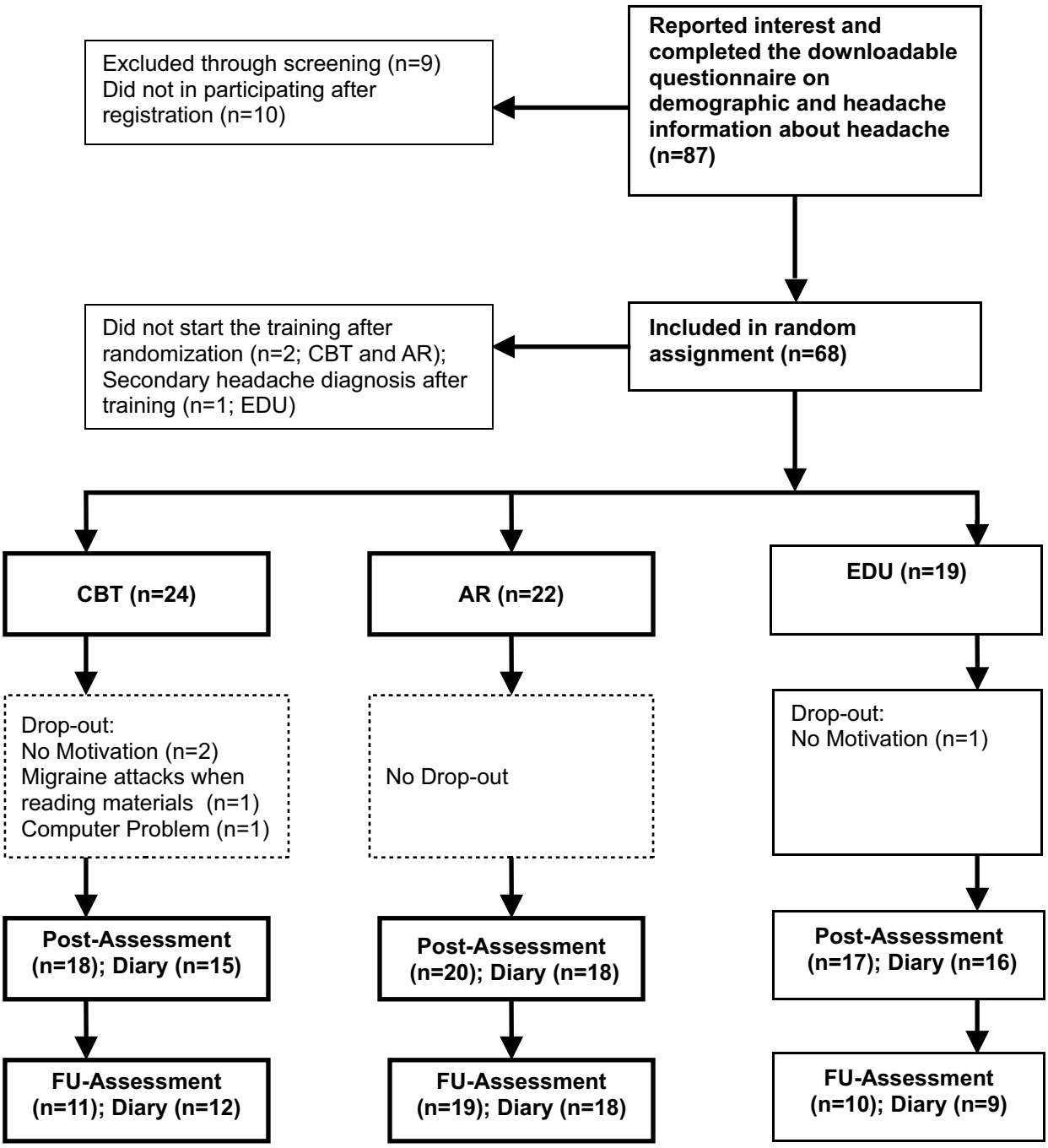

Table 2: Outcome measures, mean (SD), n and effect sizes (Hedges g)

Measure	Pre-assessment	Post-assessment	ES (within; pre-post)	Follow-up-assessment	ES (within; post-follow up)
Headache diary					
Frequency					
CBT	11.5 (8.2) n=19	4.9 (4.3) n=16	0.96	6.0 (4.8) n=12	-0.24
AR	10.3 (7.8) n=20	7.4 (7.6) n=20	0.37	5.3 (6.6) n=18	0.29
EDU	10.7 (7.4) n=19	6.7 (6.5) n=17	0.56	7.3 (8.4) n=9	-0.08
Intensity					
CBT	5.0 (1.8) n=19	5.0 (2.4) n=13	0	4.9 (1.4) n=12	0.05
AR	5.1 (1.7) n=18	5.6 (1.9) n=19	-0.27	5.5 (1.9) n=16	0.05
EDU	5.2 (1.7) n=18	5.4 (2.0) n=13	-0.11	5.5 (1.6) n=7	-0.05
Duration					
CBT	6.8 (4.0) n=18	4.8 (2.9) n=13	0.54	5.5 (2.5) n=12	-0.25
AR	8.1 (6.7) n=18	6.2 (3.9) n=19	0.34	7.7 (5.3) n=16	-0.32
EDU	7.8 (5.8) n=18	6.1 (5.1) n=15	0.30	7.1 (5.3) n=8	-0.19
PCS-C					
CBT	32.5 (8.5) n=20	27.1 (7.1) n=18	0.67	23.6 (4.3) n=12	0.55
AR	34.9 (7.8) n=22	34.7 (8.8) n=20	0.02	26.3 (9.7) n=19	0.89
EDU	32.2 (10.4) n=19	31.7 (8.3) n=18	0.05	28.1 (9.9) n=10	0.39
CDI					
CBT	10.2 (6.6) n=20	11.0 (9.2) n=17	-0.10	7.7 (7.1) n=10	0.38
AR	8.5 (4.8) n=22	8.1 (9.0) n=20	0.06	6.8 (5.2) n=16	0.17
EDU	9.2 (4.8) n=18	7.7 (5.2) n=18	0.29	6.6 (3.7) n=9	0.22
SDQ					
CBT	11.8 (3.5) n=20	11.2 (4.3) n=16	0.15	9.3 (3.7) n=11	0.45
AR	8.9 (4.5) n=22	9.5 (4.2) n=19	-0.13	7.1 (4.8) n=19	0.54
EDU	10.7 (3.9) n=19	10.0 (4.9) n=18	0.16	8.4 (4.8) n=9	0.32
KINDL-R					
CBT	3.6 (0.5) n=20	3.6 (0.4) n=17	0	3.9 (0.4) n=12	0.52
AR	3.8 (0.6) n=22	3.8 (0.6) n=20	0	4.0 (0.5) n=19	0.40
EDU	3.8 (0.3) n=18	3.9 (0.3) n=17	0.24	3.8 (0.3) n=10	-0.32

CBT- cognitive-behavioral treatment group, AR – applied relaxation group, EDU – education group, PCS-C – Pain Catastrophizing Scale; CDI – Children's Depression Inventory, SDQ – Strength and difficulties Questionnaire, KINDL-R – health-related Quality of life questionnaire

Table 3: Analyses of Variance (repeated measures design): F-ratios, p-values, partial η^2

Measure	df	F	η^2	p
		Between subjects		
Headache diary				
Frequency				
pre - post	2, 47	0.45	0.02	0.64
post - follow-up	2, 34	0.20	0.01	0.82
pre - follow-up	2. 33	0.61	0.04	0.55
Intensity				
pre - post	2, 39	0.07	0.01	0.93
post - follow-up	2, 29	1.01	0.07	0.38
pre - follow-up	2. 29	0.77	0.05	0.47
Duration				
pre - post	2, 39	0.42	0.02	0.66
post - follow-up	2, 29	0.56	0.04	0.58
pre - follow-up	2, 29	0.77	0.05	0.47
PCS-C				
pre - post	2, 52	1.93	0.07	0.15
post - follow-up	2, 37	2.66	0.13	0.08
pre - follow-up	2, 38	0.62	0.03	0.55
CDI				
pre - post	2, 50	0.68	0.03	0.51
post - follow-up	2, 31	0.25	0.02	0.78
pre - follow-up	2, 32	0.16	0.01	8.85
SDQ				
pre - post	2, 49	1.60	0.06	0.21
post - follow-up	2, 33	0.40	0.02	0.67
pre - follow-up	2, 36	1.65	0.08	0.21
KINDL-R				
pre - post	2, 51	1.57	0.05	0.22
post - follow-up	2, 36	0.04	0.00	0.96
pre - follow-up	2, 38	0.23	0.01	0.79
		Within subjects		
Headache diary				
Frequency				
pre - post	1, 47	17.99	0.28	0.00
post - follow-up	1, 34	0.56	0.02	0.46
pre - follow-up	1, 33	24.74	0.43	0.00
time x group				
pre - post	2, 47	0.74	0.03	0.48
post - follow-up	2, 34	0.52	0.03	0.60
pre - follow-up	2, 33	0.44	0.03	0.65
Intensity				
pre - post	1, 39	1.34	0.03	0.25
post - follow-up	1, 29	0.29	0.01	0.59
pre - follow-up	1, 29	2.38	0.08	0.14
time x group				
pre - post	2, 39	0.08	0.01	0.93
post - follow-up	2, 29	0.54	0.04	0.59

pre - follow-up	2. 29	1.09	0.07	0.35
Duration				
pre - post	1, 39	5.22	0.12	0.02
post - follow-up	1, 29	2.88	0.09	0.10
pre - follow-up	1, 29	0.68	0.02	0.42
time x group				
pre - post	2, 39	0.54	0.03	0.59
post - follow-up	2, 29	0.75	0.05	0.48
pre - follow-up	2, 29	0.22	0.02	0.81
PCS-C				
pre - post	1, 52	4.45	0.08	0.04
post - follow-up	1, 37	10.13	0.22	0.00
pre - follow-up	1, 38	27.83	0.42	0.00
time x group				
pre - post	2, 52	2.45	0.08	0.09
post - follow-up	2, 37	6.07	0.25	0.00
pre - follow-up	2, 38	0.77	0.04	0.47
CDI				
pre - post	1, 50	0.30	0.01	0.56
post - follow-up	1, 31	0.69	0.02	0.41
pre - follow-up	1, 32	3.53	0.09	0.07
time x group				
pre - post	2, 50	0.67	0.03	0.51
post - follow-up	2, 31	1.21	0.07	0.31
pre - follow-up	2. 32	0.69	0.04	0.51
SDQ				
pre - post	1, 49	0.42	0.01	0.52
post - follow-up	1, 33	1.97	0.06	0.17
pre - follow-up	1, 36	9.66	0.21	0.00
time x group				
pre - post	2, 49	1.15	0.05	0.32
post - follow-up	2, 33	1.72	0.09	0.20
pre - follow-up	2, 36	0.48	0.03	0.62
KINDL-R				
pre - post	1, 51	0.13	0.00	0.72
post - follow-up	1, 36	1.02	0.03	0.32
pre - follow-up	1, 38	1.24	0.03	0.27
time x group				
pre - post	2, 51	0.15	0.01	0.86
post - follow-up	2, 36	2.45	0.12	0.10
pre - follow-up	2, 38	0.55	0.03	0.58

CBT- cognitive-behavioral treatment group, AR – applied relaxation group, EDU – education group, PCS-C – Pain Catastrophizing Scale; CDI – Children's Depression Inventory, SDQ – Strength and difficulties Questionnaire, KINDL-R – health-related Quality of life questionnaire

4 Diskussion

Insgesamt zeigen die Publikationen der vorliegenden Arbeit, dass es effektive psychologische Interventionen zur Behandlung häufiger Kopfschmerzen im Kindes- und Jugendalter gibt. Während das erste Manuskript einen aktuellen Überblick über die Wirksamkeit bisheriger psychologischer Therapien gibt, zeigen die zwei folgenden Manuskripte eine kostengünstige, zeiteffektive und attraktive Alternative gegenüber dem klassischen ambulanten und stationären Setting einer Schmerztherapie auf.

Die Ergebnisse der durchgeführten Meta-Analyse (Manuskript 1) bestätigen und erweitern die Befunde der bisherigen meta-analytischen Literatur (Ecclestone et al., 2002; Hermann et al., 1995). Psychologische Therapienverfahren erweisen sich somit bei der Behandlung häufiger Kopfschmerzen im Kindes- und Jugendalter als ebenso effektiv wie bei der Behandlung von Erwachsenen (Andrasik, 2007; Nestoriuc & Martin, 2007; Penzien, Rains & Andrasik, 2002; Haddock, Rowan, Andrasik, Wilson, Talcott & Stein, 1997).
Die vorliegende Meta-Analyse zeigt, dass das Erlernen (kognitiv-) verhaltenstherapeutischer Strategien ebenso wie die Nutzung von Biofeedbackverfahren das Auftreten von Kopfschmerzattacken sowie deren Intensität und Dauer deutlich und langfristig reduzieren können. Aussagen über differenzielle Wirksamkeitsunterschiede der verschiedenen Therapieverfahren sind jedoch nur sehr eingeschränkt möglich, da nur wenige Primärstudien direkte Vergleiche zwischen den unterschiedlichen Therapien ermöglichten. Die ermittelten Effektstärken fallen sehr heterogen aus, so dass aktuell keines der Therapieverfahren zu bevorzugen ist. Inwieweit psychologische Therapien auch Einfluss auf die Einnahme von Medikamenten zur Schmerzreduktion nehmen, kann ebenfalls nur begrenzt beantwortet werden. Vor allem da nur eine geringe Studienanzahl in die Meta-Analyse der Medikamenteneinnahme einfloss. So zeigen die vorliegenden Befunde lediglich einen möglichen Trend, dass die Medikamenteneinnahme der Patienten nicht bedeutsam reduziert werden kann. Aussagen zur Effektivität der Therapien im Vergleich zur „harten“ Kontrollbedingung (aktive Kontrollgruppe) sind aufgrund der geringen Primärstudienanzahl nicht möglich. Ein Vergleich mit dieser realistischeren

Bedingung sollte in zukünftigen Studien unbedingt angezielt werden, ebenso die Berücksichtigung nicht - schmerzassoziierter Parameter als Veränderungsvariablen.
Abschließend muss hinsichtlich der dennoch geringen Anzahl an eingeschlossenen Primärstudien darauf verwiesen werden, dass weitere Studien mit hohem methodischem Standard wünschenswert sind, um die vorliegenden Befunde zu bestätigen.

Die folgenden zwei Manuskripte zeigen, dass die Nutzung des Internets als ein modernes Medium der Information auch in der Therapie von Kopfschmerzen erfolgversprechend ist. Die Befunde stehen in Einklang mit einer Studie von Hicks und Kollegen (2006), welche mit Hilfe eines internet-basierten Trainings ebenfalls deutliche Reduzierungen der Schmerzsymptomatik (Kopf- und Bauchschmerzen) bei Kindern- und Jugendlichen erzielten. Während die Pilotuntersuchung (Manuskript 2) bereits deutliche Reduktionen der Kopfschmerzhäufigkeit und Katastrophisierung für die Trainingsbedingung aufzeigt, erweisen sich in der Hauptuntersuchung (Manuskript 3) alle angebotenen Studienbedingungen hinsichtlich der Reduzierung der Kopfschmerzvariablen (mit Ausnahme der Intensität) und der Schmerzkatastrophisierung als effektiv. Es finden sich keine signifikanten Gruppenunterschiede für alle Variablen. Lediglich die Anzahl klinisch Verbesserter direkt nach dem Training ist signifikant höher in der kognitiv-verhaltenstherapeutischen Bedingung. Auch wenn keine weiteren statistisch bedeutsamen Wirksamkeitsvorteile für das kognitiv-verhaltenstherapeutische Training zu finden sind, so zeigen sich positive Trends in der subjektiv wahrgenommenen Besserung der Kopfschmerzen und der Bewältigung der Kopfschmerzen.
Die geringen Dropoutraten zum Zeitpunkt Post der vorliegenden Untersuchungen (Manuskript 2: 11%; Manuskript 3: 8%) sind deutlich geringer als die bisheriger internet-basierter Studien aus dem Erwachsenenbereich (Andersson, Lundström und Ström, 2003: 29%; Ström, Pettersson & Andersson, 2000: 56%; Devineni & Blanchard, 2005: 38.1%). Einschränkend muss jedoch auf die geringe Compliance der Probanden beim Ausfüllen der Fragebögen und Tagebücher verwiesen werden. Dadurch wird die Aussage der vorliegenden Befunde deutlich eingeschränkt. Möglicherweise ist die Ursache dafür in der Internetimplementierung des Trainingsangebotes zu sehen. Keiner der Teilnehmer

hatte persönlichen (face-to-face) Kontakt mit den Trainern. Es wurde ausschließlich per E-Mail oder Telefon kommuniziert, so dass die Verbindlichkeit gegenüber den Trainern gering war im Vergleich zu den klassischen face-to-face Therapieangeboten.

Eine weitere Einschränkung liegt auch in der Stichprobengröße und somit der geringen Power der beiden Studien. Zukünftige Studien sollten eine größere Stichprobe anzielen.

Die vorliegenden Befunde lassen verschiedene Fragen offen. So ist zu vermuten, dass bereits ein internet-basiertes edukatives Angebot ausreichend sein kann zur Behandlung häufiger Kopfschmerzen. Dennoch bleibt offen, inwieweit dieses Angebot auch bestimmten Patientengruppen, z.B. in Abhängigkeit vom Schweregrad der Beeinträchtigung durch die Kopfschmerzen, helfen kann. Im Weiteren kann keine Aussage zur generellen Eignung des Patientenklientels für internet-basierte Selbsthilfeangebote getroffen werden, da die vorliegende Stichprobe aufgrund der Art der Rekrutierung einer Selbstselektion unterlag. Gibt es also Kinder und Jugendliche mit häufigen Kopfschmerzen, bei denen dieses Trainingsangebot bereits aufgrund der Internetimplementierung ungeeignet ist? Oder gibt es sogar junge Betroffene, welche von einem internet-basierten Training deutlich mehr profitieren würden als von einer klassischen ambulanten Therapie? Zukünftige Forschergruppen sollten diesen Fragen nachgehen, um so den Betroffenen ein spezifisches Therapieangebot bieten zu können.

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6 Anhang

In der Online-Ausgabe der Zeitschrift *Behavioural and Cognitive Psychotherapy* wurde zu dem Manuskript 2 zusätzlich eine ausführlichere Version (Supplementary Materials) veröffentlicht, welche im Folgenden zu finden ist.

Trautmann, E. & Kröner-Herwig, B. (2008). Internet-based self-help training for children and adolescents with recurrent headache: A pilot study. *Behavioural and Cognitive Psychotherapy, 36 (2)*, supplementary materials. Online verfügbar: http://journals.cambridge.org/action/displayJournal?jid=BCP.

Internet-based self-help training for children and adolescents with recurrent headache - a pilot study

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Abstract

We report the results of a randomized controlled trial that compared the efficacy of an internet-based self-help treatment for paediatric headache including chat communication (cognitive-behavioural treatment, CBT) with an internet-based psychoeducation intervention (EDU).

In the CBT group, significant pre- to post-treatment decreases were found for headache frequency and pain catastrophizing, but not for headache intensity, duration or depression score. In the EDU group none of the variables (frequency, intensity, duration, pain catastrophizing, depression score) showed improvement. No significant between group differences were found for headache variables, pain catastrophizing and depression score at post-treatment. The patients reported high satisfaction with the internet-based training and a good patient-trainer-alliance. Results were maintained at 6-month follow-up. Due to the small sample size, no general conclusions can be drawn regarding the efficacy of the internet-based training regarding the outcome variables, but the training was well accepted by patients. Further research is necessary to evaluate the therapeutic potential of such interventions.

Key Words

Child/adolescent, recurrent headache, internet-based, cognitive-behavioural therapy, self-help

Introduction

Epidemiological studies report the occurrence of recurrent headache in children and adolescents in various countries (Kröner-Herwig, Heinrich & Morris, 2007; Zwart, Dyb, Holmen, Stovner & Sand, 2004). Headaches can be a serious health problem for children and adolescents with adverse effects on well-being (Sillanpää & Aro, 2000; Palermo, 2000); therefore, it is essential to have effective treatments.

Most commonly used medical interventions for headache are pharmacological in character, but the rates of medication intake (analgesics and anti-migraine drugs) vary substantially. Wang, Fuh, Juang, and Lu (2005) report that 62% of adolescents with chronic daily headache used pain medication in the last year. Over 83% of high school students with headache reported taking over-the-counter analgesics, but only 11.8% used prescription analgesics (Egilius & Schellekens, 1991).

Preventive treatment options can be derived from the psychological domain. Meta-analyses of psychological treatments for headache in children and adolescents support the efficacy of psychological treatments for paediatric headache (Trautmann, Lackschewitz & Kröner-Herwig, 2006; Ecclestone, Morley, Williams, Yorke & Mastroyannoploulou, 2002; Herrmann, Kim & Blanchard, 1995). Controlled trials demonstrated the efficacy in face-to-face treatment settings; relaxation techniques, cognitive-behavioural therapy, and biofeedback being the most frequently used interventions. But many children and adolescents with recurrent headaches do not have ready access to these treatments, as they are not ubiquitously offered. One way of expanding the accessibility of preventive treatments is the implementation of self-help programs, in particular via internet-based interventions (IBI). IBI are able to transcend barriers and thus make treatment more easily available (particularly to

those living in remote areas without treatment options). IBI provide a new and comfortable method for self-help treatments. In IBI, different settings of computer-mediated communications exist, such as using electronic mail, forums, real time text correspondence (e.g. chat), voice exchange, face-to-face video communication (video conferencing), and open virtual discussion groups (Barak, 1999). These online environments require different sets of skills and knowledge (Suler, 2004), but today such computer-mediated communications have become routine and are normal activities in business, education, and pleasure (Barak, 1999). Furthermore, internet-based interventions vary with regard to the mixture of computer-mediated communication and face-to-face communication. They can range from interventions that are wholly computer-mediated to interventions which combine computer-mediated elements with direct personal interaction. However, the use of the Internet in clinical settings is still controversial. For example, internet-based interventions require the availability of an Internet access and the competence of the patient and therapist to use the Internet. Furthermore, the protection of patient data in the Internet context has to be considered. Ethical aspects are also critically discussed (Childress, 1998; Hsiung, 2002). A further main reservation is that these technologies could interfere with the therapeutic relationship; however, this is not borne out by the research in this area (Newman, 2004). In a critical overview Emmelkamp (2005) discusses technological innovations such as the Internet in clinical psychotherapy and stresses its attractiveness as a medium for a self-help intervention. According to the author IBI are feasible and further research is needed.

Various research groups examined effective IBI for clinical disorders such as panic disorder (Carlbring, Ekselius & Andersson, 2003), eating disorders (Winzelberg, Eppstein & Eldredge, 2000), posttraumatic stress disorder (Lange, Ven & Schrieken,

2001), and depression (Christensen, Griffiths & Mackinnon, 2006). There are also studies of IBI for various pain syndromes in adults (Buhrmann, Fältenhag & Ström, 2004; Lorig et al., 2002; Andersson, Lundström & Ström, 2003; Ström, Pettersen & Andersson, 2000; Devineni & Blanchard, 2005). So far, only one study (Hicks, Baeyer & McGrath, 2004) has examined an IBI including mail and telephone contact for paediatric recurrent headache and abdominal pain in a randomized controlled trial. The authors reported significant reductions of the pain score (assessed through a pain diary) for the IBI at post-treatment and follow-up.

The present study evaluated an IBI including chat communication for recurrent headache. The main aims of this pilot study are:

1. Evaluation of the efficacy of an internet-based training in reducing headache, pain catastrophizing, and the depression score. It was hypothesised that cognitive-behavioural self-help (CBT) would lead to greater improvement than education (EDU) and that the results would remain stable at 6-month follow-up.
2. Evaluation of satisfaction with the internet-based format and subjective headache improvement.
3. Evaluation of the patient-trainer-alliance and examination whether IBI impedes a positive alliance.

Method

Inclusion Criteria and Participants

To be included in the study patients had to fulfil the following criteria. Only patients with migraine and/or tension-type headache (at least two headache attacks per month) aged 10 to 18 (mean=13.4, SD=2.6) were recruited for the study.

Internet access and the ability to read and write in German were further requirements. Children and adolescents who met these conditions agreed not to take up any further psychotherapeutic treatment or to take any new prophylactic medication for the headache. Children were excluded if they reached the cut off score (>17) in the Children's Depression Inventory (Stiensmeier-Pelster, Schürmann & Duda, 2000) or showed any sign of suicidal ideas.

Patients were recruited in December 2005 through articles appearing in regional newspapers as well as through the webpage of the training program, through information on the webpage of the German Migraine and Headache Society (DMKG), and additionally through some webpages focussing on the interests of children and adolescents (e.g. webpages of youth associated journals, portals to youth interest).

Twenty-nine participants with recurrent primary headache were interested in taking part in the treatment study. Twenty-six seriously intended to participate. Three of them were excluded because they reached the cut off score of the Children's Depression Inventory (Stiensmeier-Pelster, Schürmann & Duda, 2000). Four were interested in participating but at a later point in time. One was excluded because of a recent start of prophylactic medication intake. The remaining 18 participants were randomly assigned to the two conditions. Pre-treatment comparisons revealed no significant differences between groups regarding age, diagnosis, headache variables (frequency, intensity, duration), pain catastrophizing, and depression score. After completing the post-assessment, participants of EDU were given the opportunity to complete CBT.

The participants had used the computer for at least 4 years and the Internet for more than 2 years. All of the children and adolescents reported that they routinely use computer-mediated communication such as e-mail and chat (see table1). But experience with computers and the Internet was not an inclusion criterion.

Table 1: Sample characteristics

	CBT (n=11)	EDU (n=7)
Gender		
male	2	1
female	9	6
Diagnosis[1]		
Migraine	5	5
Tension type headache	5	2
Both diagnoses	1	0
Age (mean, SD), years	12.8 (2.3)	14.3 (3.1)
Duration of headache in years (mean, SD)	2.75 (3.5)	4.14 (1.0)
using computer, years	4.4 (2.1)	4.6 (2.4)
using the internet, years	2.2 (1.0)	2.6 (1.5)
using e-mails/chat, years	1.5 (1.1)	2.3 (1.5)

No statistically significant differences were found between the groups (by using the t-Test).
[1]The variable 'diagnosis' includes patients who have the diagnosis migraine/TTH or suspicion of having this diagnosis.
[2] Only 9 patients and one parent of the CBT and only 5 patients and 4 parents of the EDU group completed the questionnaire.

Procedure

The treatments were evaluated in a comparative design.

CBT included 6 self-help sessions (focussing on education on headaches, stress management, relaxation, cognitive restructuring, self-assurance strategies, problem solving) based on a face-to-face training manual (Kröner-Herwig & Denecke, 2002). CBT was reduced from 8 to 6 sessions, and the protocol was adapted to adolescents

up to 18 years. Based on the research in the area of self-help (Richardson & Richards 2006) and e-learning (Clark & Mayer 2003) we have given considerable thought to the design of the materials presented. We used photos of the peer group to illustrate the explanations (a “personality” in self-help materials, case studies) and the embedding of the weekly themes in short stories, thus using verbal and visual material rather than verbal material alone. The sessions could be downloaded on a weekly basis from the training website. In addition, the patients had 6 weekly chat sessions with the trainer in which the assigned exercises were reviewed.

EDU consisted of the first training session of CBT on headache information plus chat communication (and thus served as an active control group). EDU patients had the same number of chat contacts as those in the CBT, but the chat focussed on the diary records of the previous week, rather than on cognitive-behavioural elements. Two additional chat sessions (booster sessions) were performed in both groups 4 and 8 weeks after the end of training. In CBT the main topics of the training, including coping strategies, were reiterated, in EDU the diary records were discussed.

Trainers: Three graduate students of clinical psychology served as trainers supporting the children (via the chat). The students received intensive training prior to conducting the treatment as well as weekly supervision (from a Ph.D. student/psychotherapist in training).

Internet specifics: The patients had access to the training web-site (self-help sessions) and the chat from their own home computers by means of standard browsers. If a patient was unable to connect to the Internet, they could contact a trainer by telephone. The general information about informed consent and the

application form were accessible to all users on the training website. The training was offered free of charge. They received the passwords for the sessions on a weekly basis (during the chat) and were encouraged to download and read the text material and to print out and complete the exercise handouts. The feasibility of the training material was assessed before; in particular we examined the comprehensibility of the training website and the ease of use of the chat with 5 children and adolescents with recurrent headache (10-16 years, 4 female and 1 male). In addition the trainers had structured chat guidelines for both conditions.

Measures

The central outcome variables were frequency, duration, and intensity of headache assessed by means of an internet-based four-week diary. Clinical significance was defined as a reduction of 50% or more in headache frequency compared to the baseline.

Pain catastrophizing was assessed (by mail) using the German version of the Pain Catastrophizing Scale for Children (PCS-C, Crombez et al., 2003; Morris, Nagel, Heinrich & Kröner-Herwig, 2006).

Furthermore, the severity of depressive symptoms was assessed (by mail) using the Children's Depression Inventory (CDI, Stiensmeier-Pelster et al., 2000). The diary, PCS-C, and depression score were administered at pre-treatment, post-treatment, and 6-month follow-up, but the patients also completed the diary during the training.

After treatment, patients and parents were asked to complete a postal questionnaire asking about their satisfaction and their perceived change in headache.

In an internet-based questionnaire (based on Krampen & Wald, 2001) the patient-trainer-alliance was assessed in the second, fourth, and last session (patient's view only). Two subscales, the "patient-therapist-alliance/assistance" scale and the "helping to cope with problems" scale, were adapted for use with children and adolescents and the conditions of an internet-based training (e.g. My trainers explanations helped and support me; or, this week I learnt something that can help me to cope with my headache.).

In the sixth session participants had to answer 5 items about internet-based training in particular (adapted from Knaevelsrud, Jager & Maercker, 2004).

Statistical Analyses: To examine the changes in outcome, variables between group comparisons were used. Treatment outcomes for each condition were also computed. When prerequisites of t-tests were not achieved, nonparametric testing was used (Mann-Whitney U-Test or Wilcoxon paired rank sum test). For all tests, the level of significance was set at $p>.05$, two-tailed.

Results

Of the 18 patients, 2 (one in each condition) dropped out at post-treatment and 8 at follow up by failing to return the questionnaires and headache diaries.

On average, the chat sessions were longer in CBT than EDU (mean duration: CBT: Mdn=55.0 min, range 45.8-75.0 min; EDU: Mdn= 41.3, range 28.2-58.0 min). The difference was not significant ($U=18.0$, $p>.05$). The main reason for long chat duration was the slow typing of some children.

No significant differences were found between the two treatment groups at post-treatment in any of the outcome variables (frequency: $t=0.239$, $p>.05$; intensity: $t=-0.995$, $p>.05$; duration: $U=27.0$, $p>.05$; pain catastrophizing: $t=-2.051$, $p>.05$, depression score: $t=0.139$, $p>.05$). The frequency of headache decreased significantly from pre- to post-treatment ($t=2.480$, $p<.05$) in CBT, but not in EDU ($t=1.016$, $p>.05$) (see table 2). Duration and intensity of headache did not change significantly in either group (CBT: intensity: $t=-0.708$, $p>.05$; duration: $z=-0.681$, $p>.05$; EDU: intensity: $t=0.881$, $p>.05$; duration: $z=1.483$, $p>.05$). Five patients in the CBT group reached the criterion of clinical significance at post-treatment; only 1 patient in the EDU group fulfilled this criterion. Pain catastrophizing was significantly reduced in CBT at post-treatment ($t=2.427$, $p<.05$), but not in EDU ($t=0.010$, $p>.05$). Both groups showed no significant change from pre- to post-treatment in the depression score (CBT: $t=1.548$, $p>.05$; EDU: $t=1.146$, $p>.05$). Treatment effects maintained at 6-month follow-up (only CBT, $n=10$). No significant deteriorations or improvements took place between post-treatment and follow-up (frequency: $t=-0.938$, $p>.05$; intensity: $t=0.594$, $p>.05$; duration: $z=-0.533$, $p>.05$; pain catastrophizing: $t=0.742$, $p>.05$; depression score: $t=1.098$, $p>.05$). Only 3 patients showed clinically significant improvement; 5 (who reached clinical significance at post-treatment) reported a marked improvement in a telephone interview after follow-up, but failed to return the diaries.

Table 2: Headache variables, pain catastrophizing and depression score (Means and SD)

Measure	CBT	EDU
Headache (diary for 4 weeks)		
frequency		
pre	15.2 (10.9)	13.8 (10.1)
post	8.1 (8.0)	12.3 (8.6)
follow-up	8.0 (7.8)	-
duration		
pre[1]	3.8 (2-24)	6.0 (5-24)
post[1]	3.5 (2-24)	5.1 (2-23)
follow-up[1]	3.3 (1-23)	-
intensity		
pre	4.7 (0.8)	5.8 (1.5)
post	4.7 (1.3)	5.0 (1.3)
follow-up	4.2 (1.9)	-
PCS-C		
pre	33.0 (6.5)	36.4 (9.7)
post	30.0 (5.9)	37.3 (7.9)
follow-up	28.3 (5.8)	-
CDI		
pre	9.7 (5.1)	9.4 (3.5)
post	7.7 (4.8)	7.3 (5.6)
follow-up	6.3 (3.2)	-

[1]Medians and Range of duration are given, because of violation of prerequisites of t-test.

All patients and parents reported satisfaction with the training (self and parent rating: 0=not satisfied, 3=very satisfied; CBT: self-rating: Mdn=3.0, range 2-3; parents' rating: Mdn=2.0, range1-3, EDU: self-rating: Mdn=2.0, range1-3, parents' rating: Mdn=2, range1-3). Six patients and 8 parents in the CBT group reported subjective improvement of headache directly after the training, whereas 4 members of EDU experienced subjective improvement, supported by 3 parents. There are no significant differences between the two groups regarding satisfaction ($U=16.0$, $p>.05$) or subjective improvement of headache ($U=29.0$, $p>.05$).

The results of the “patient-therapist-alliance/assistance” scale showed no significant differences between the groups (the scale ranges from 0-3, higher scores signify higher patient-trainer alliance/helping to cope with problems, CBT: Mdn=2.8, range 2-3; EDU: Mdn=2.7, range: 2-3; U=21.0, p>.05). The scores on the “helping to cope with problems” scale revealed significant differences (CBT: Mdn=2.0, range 1-3; EDU: Mdn=1.0, range 0-2; U=6.0, p<.05).

In the last session we asked the patients about their opinion regarding the internet-based training. The responses were analyzed on a quantitative level. Five patients of each group would have preferred to meet the trainer personally, whereas 4 of CBT and 2 of EDU would not. Ten patients of the CBT and 5 of the EDU felt “comfortable” with the training presentation via the Internet; none of the participants felt “uncomfortable”. Eight patients of CBT and 6 of EDU had no problems with writing during the chats, whereas one in each group felt “uneasy”.
Eight patients in CBT and 4 in EDU described it as personal, and only 1 in the CBT and 2 in EDU described it as impersonal. Nine of the CBT and all of the EDU described their feeling towards the trainer as comfortable, and only 1 in CBT rated it as “uncomfortable”.

Discussion

The outcome measures demonstrate significant reductions of headache frequency from pre-to post-treatment in CBT, but not in EDU. Descriptively, conditions show some reduction in duration and intensity of headache, but the reductions fail to reach significance; thus, the assumed superiority of CBT could not be shown by inter-group-comparisons. The improvement in CBT remained stable at the follow-up. While 5 patients of CBT reached clinical significance at post-treatment, only 1 in the EDU

group fulfils this criterion (>50% reduction), but it would be premature to draw any conclusions about general efficacy of CBT for reducing headache.

The significant changes in pain catastrophizing in CBT emphasise the importance of cognitive restructuring of thoughts about pain and coping with headache.

However, both conditions show non-significant trends for reducing depression score; it seems the internet-based self-help training positively affects this variable, but further research is needed for confirming this hypothesis.

The training format and the chat contacts with the trainer were well accepted by all patients. They reported high satisfaction with the internet-based self-help training. Furthermore, both groups evaluated patient-trainer-alliance/assistance as positive and CBT reported significantly more help regarding coping through the trainer. The lower perceived help through the trainer in EDU did not influence the relationship between patient and trainer. The findings imply that the internet-based training does not impede a positive alliance. Most of the participants felt comfortable with the training presentation, felt at ease with the computer-mediated communication, and rated the contact with the trainer as personal. Although many participants would have liked to see the trainer personally, this did not seem to reduce the satisfaction with the internet-based self-help training and the contact with the trainer.

Limitations

Only a small number of paediatric headache sufferers were treated. Most statistical comparisons regarding outcome measures failed to show a significant level of change. However, only very large effects would reach significance due to the low

statistical power resulting from the small sample size. Therefore, conclusions about the general efficacy of CBT cannot be drawn as yet.

Although we had no drop-out during the intervention itself, patients were less conscientious in returning their diaries at post-assessments and follow-up. Though most of these patients reported headache improvements on the phone, due to the subjective nature of these data they did not enter into our analyses. The missing data negatively affects the evaluation of results (esp. headache variables) because of the small size of the initial sample.

EDU in combination with self-monitoring in a diary protocol also leads to some headache reduction. The findings are consistent with the research literature (Arrindell 2001; Trautmann et al. 2006) that self-monitoring conditions often show small, but not marked, improvement. Therefore, in future studies the EDU group should not complete training after post-treatment, so that long term effects can be analyzed and compared to the treatment group.

A further limitation relates to the cost effectiveness of the training: inspection of the time spent in chat communication (involving the presence of the trainer) revealed CBT-IBI to be of similar efficiency as face-to-face CBT. This was in contrast to our expectation of a superior efficiency of the Internet format. Nevertheless, the chat communication was generally well-accepted by the patients and seems to have allowed for the development of a positive patient-trainer alliance. The Internet format, therefore, appears to be a viable alternative, particularly when face-to-face intervention options are lacking.

Clinical Implications and Future Directions

The present results support future examination of efficacy of IBI in children and adolescents with recurrent headaches. Another planned study in our research project will focus on the feasibility and the acceptance by, and satisfaction of, the children and adolescents and their parents. In addition, we will investigate which computer-mediated communication, e-mail or chat, is best with regard to both the relationship between trainer and patient and the time and cost effectiveness. Furthermore, the effectiveness of internet-based self-help training should be ascertained using a larger sample. Additionally, future research should seek to illuminate by means of moderator analyses whether different patient groups profit to a differing extent from internet-based treatments.

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