



# 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 programs (multimodal cognitive-behavioral training (CBT) and 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. The main outcome variables related to changes in headache frequency, intensity and duration as well as the responder rate (50% reduction of headache frequency) and NNTs. 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. NNTs were 2.0 for the comparison CBT and EDU; 5.2 for the comparison of AR and EDU at post-treatment. The 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%) reflecting in the NNTs.

The effects remain stable in headache frequency, pain catastrophizing and psychopathological symptoms across all groups at follow-up assessment. CBT showed the highest within-effect size in headache frequency, duration and pain catastrophizing. The results support the use of Internet programs for pediatric recurrent headache, especially given their accessibility and suitability for children and adolescents. Further studies are needed to improve their quality and efficacy.

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## Introduction

Psychological intervention can be regarded as an important treatment option for recurrent headache in childhood and adolescence. Two recent meta-analyses (Eccleston, Morley, Williams, Yorke, & Mastroyannoploulou, 2002; Trautmann, Lackschewitz, & Kröner-Herwig, 2006) have 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 intervention could fill the gap between demand and availability in the health care system. More recent published research includes a few studies on Internet

intervention for recurrent headache in adults and children (Andersson, Lundström, & Ström, 2003; Devineni & Blanchard, 2005; Hicks, Baeyer, & McGrath, 2004; Ström, Pettersson, & Andersson, 2000). Their findings show that Internet intervention is a promising new and cost-effective treatment tool.

The aim of the present investigation was to evaluate the first (German) Internet intervention for children and adolescents with recurrent headache. In a pilot study we examined an Internet intervention, including an online chat in which participants with minimal therapist contact could discuss their progress with the exercises of the self-help modules of the intervention (Trautmann & Kröner-Herwig, 2008). Significant decreases in frequency of headache and pain catastrophizing were found in the treatment group. The participants described the alliance with their therapists as positive and satisfying. The pilot study demonstrated that Internet intervention combined with chats resulted in an efficacy similar to face-to-face treatment (Trautmann & Kröner-Herwig, 2008). Therefore, several investigators have demonstrated the importance of support in Internet interventions. Accordingly, Spek et al. (2007) found larger effect sizes in Internet intervention with therapist

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support. The chat, however, was cost-intensive as the therapist had to be present for a considerable period of time each week. Hicks et al. (2004) used e-mail contact instead in their Internet intervention of children with recurrent pain and were able to demonstrate this to be more cost-effective.

Only a small number of pediatric 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, which reduced the amount of time the therapist spent on the participants. Three active treatment conditions were incorporated into the design. Firstly, the cognitive-behavioral training (CBT), which had proved to be very effective in prior studies (Kröner-Herwig & Denecke, 2002; Kröner-Herwig & Denecke, 2007). Secondly, applied relaxation (AR) was chosen as a "simpler" treatment strategy, whose efficacy has been demonstrated in face-to-face treatments (Engel & Rapoff, 1990; Larsson, Daleflod, Hakansson, & Melin, 1987; McGrath et al., 1988). Finally, as an active control condition, educational intervention (EDU) was introduced.

The primary aim of this study was to examine the efficacy of an Internet intervention regarding improvement of headache (frequency, intensity and duration) as measured by a pain diary. Another outcome variable is pain catastrophizing because it has emerged as a critical aspect in adjustment to pain (Crombez et al., 2003). Further outcome variables include the effects on general well-being such as depression; psychopathological symptoms and health-related quality of life were also 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 cognitive restructuring interventions are only included in CBT (Trautmann & Kröner-Herwig, 2008).
- It was expected that the CBT would result in more improvement in secondary outcome variables than AR and EDU.

Furthermore, we wanted to assess the quality of the patient-therapist alliance (from the point of view of the patient) and the patients' subjective evaluation of the training conditions. Additionally, the therapists' time spent in e-mail contact with participants was explored.

## Method

### Participants

Participants were recruited from January 2006 to March 2007 through newspaper advertisements, the webpage of the training program, 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](http://www.wissensschule.de), [www.teachersnews.net](http://www.teachersnews.net), [www.sign-project.de](http://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 since younger children often need help from their parents. Furthermore, they had to suffer from primary headache (migraine, tension type headache (TTH) or combined headache) at least twice a month (diagnosed by their personal physician and reported by their parents). They had to be able to read and write in German and to 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 (Fig. 1). A total of 87 children and adolescents expressed interest in the Internet-based training program, 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 (Fig. 1).

Thirty-six participants were female and thirty were male (Table 1). The 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).

### Assessment

#### Demographic and background information

The participants and their parents responded to an online questionnaire regarding headache frequency, duration and intensity in the last 6 months, the actual primary headache diagnosis of their physician (parent report), and their level of impairment and physical symptoms during the headache attack.

#### Headache diary

The primary outcome measures were frequency, duration and intensity of headache at pre- and post-treatment and at the 6-month follow-up as measured using a four-week diary. Participants had to report everyday whether they had headache attacks (yes/no), the intensity (rated by a Visual Analogue Scale: 0 – no pain; 10 – strong pain) and duration of the attack (in hours) and return the diary after the 4 weeks (by mail). A clinically significant improvement (responder rate) was defined as a reduction of more than 50% in headache frequency compared to the 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. (2003). It consists of 13 items on which participants are asked to report using a 5-point rating scale. The PCS-C has shown good internal consistency ( $\alpha = 0.88$ ) with satisfactory predictive validity (Crombez et al., 2003; Morris, Nagel, Heinrich, & Kröner-Herwig, 2006).

Several investigators found a correlation between recurrent headache and the several health-related variables (Bandell-Hoekstra, Abu-Saad, Passchier, & Knipschild, 2000; Egger, Angold, & Costello, 1998; Guidetti et al., 1998; Powers, Patton, Hommel, & Hershey, 2003; Silanpää & Aro, 2000), perhaps suggesting that psychological treatment positively affects such variables. So far, the following variables have been assessed.

#### Children's Depression Inventory (CDI)

The German version of the CDI includes 27 items measuring cognitive, affective and behavioral symptoms of depression in childhood (Stiensmeier-Pelster, Schürmann, & Duda, 2000) on a 3-point rating scale. The children were asked to select the statement that characterized them best during the previous two weeks. The German version is a valid and reliable measure ( $\alpha = 0.84$ ; test-retest interval 0.76) (Stiensmeier-Pelster et al., 2000).

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