



## Short-term effectiveness of an online behavioral training in migraine self-management: A randomized controlled trial



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### ARTICLE INFO

#### Article history:

Received 26 November 2013

Received in revised form

8 July 2014

Accepted 16 July 2014

Available online 27 July 2014

#### Keywords:

Migraine

Behavioral training

Online BT

Randomized controlled trial

Attack prevention

Self-management

Self-efficacy

### ABSTRACT

Behavioral training (BT) is recommended as a supplementary preventive treatment for migraine. Online interventions have been successful in promoting health behavior change, the evidence for online BT in migraine is limited, however. This randomized controlled trial aimed to determine the post-treatment effectiveness of online BT ( $n = 195$ ) compared to a waitlist control group (WLC;  $n = 173$ ) on migraine attack frequency (primary outcome), headache self-efficacy and locus of control (secondary outcomes). BT aims to counteract attacks in the prodromal stage through early detection of prodromal features and self-management via physical relaxation and cognitive behavioral regulation, and was offered with minimal e-mail support in eight online lessons. Results showed that 120 (62%) participants completed BT. A decrease of 20–25% in migraine attack frequency was found in both conditions without a between-group difference ( $ES = 0.02, p = .71$ ). BT participants improved more than WLC participants on migraine related self-efficacy ( $ES = 0.86, p < .001$ ), developed more internal ( $ES = 0.57, p < .001$ ), and less external control ( $ES = 0.78, p < .001$ ). To conclude, results at post-training did not corroborate that improvements in migraine attack frequency were due to online BT, the waitlist control group improved accordingly. However, positive effects of BT on self-efficacy and locus of control were established. We have to await the long term effects to see if improvements in psychological variables translate to a reduction in migraine headache.

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### Introduction

Migraine is a common neurological disorder with a year prevalence of approximately 18% in women and 6% in men in the general population (Breslau & Rasmussen, 2001; Lipton et al., 2007). Migraine attacks are characterized by severe headache accompanied by nausea or vomiting, and sensitivity to light and sound (Goadsby, Lipton, & Ferrari, 2002), and its occurrence may be triggered by weather conditions, perceived stress, and hormonal changes related to the menstrual cycle (Lipton et al., 2007). Migraine attacks can be highly debilitating and many patients report daily life problems such as disrupted family life, restricted social activities, and reduced work performance (Bigal & Lipton, 2009). The societal costs of migraine are high and largely

attributable to health care use, work absenteeism, and loss of work productivity (Stewart, Lipton, Dowson & Sawyer, 2001).

Optimal management of migraine is important considering the high burden for both patients and society. Pharmacological treatment for the abortion or prevention of migraine attacks is well-established (Silberstein, 2000; Sprenger & Goadsby, 2009) and neurological guidelines endorse behavioral training (BT) as an evidence-based supplementary preventive treatment (Silberstein, 2000). BT includes strategies for the identification of headache triggers and the acquisition of self-regulation skills. At the physiological level, self-regulation is provided by relaxation training that may be supported by biofeedback of involuntary physiological processes. Self-regulation at the psychological level is delivered through cognitive-behavioral intervention (Rains, Penzien, McCrory, & Gray, 2005). BT can reduce attack occurrence by 35–55% when delivered individually and face-to-face by health care professionals in the clinic (Andrasik, 2007; Rains et al., 2005). An increased focus on treatment accessibility, cost-effectiveness, and patient empowerment in people with chronic illness instigated the development of self-management programs that are

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applied in the home setting with minimal guidance (Haddock et al., 1997; Mérelle, Sorbi, Van Doornen, & Passchier, 2008). These programs generally include the same components as clinic-based BT and show comparable treatment effects (Haddock et al., 1997; Rowan & Andrasik, 1996).

The internet offers great opportunities for the delivery of self-management programs and promises wider availability and higher efficiency (Cuijpers, Van Straten, & Andersson, 2008). The evidence for online BT in migraine is limited, however. Six studies investigated its effect in primary headache (Andersson, Lundström, & Ström, 2003; Bromberg et al., 2012; Devineni & Blanchard, 2005; Nicholson, Nash, & Andrasik, 2005; Ström, Petterson, & Andersson, 2000; Trautmann & Kröner-Herwig, 2010), five were randomized controlled (Andersson et al., 2003; Bromberg et al., 2012; Devineni & Blanchard, 2005; Ström et al., 2000; Trautmann & Kröner-Herwig, 2010), one concerned adolescents (Trautmann & Kröner-Herwig, 2010). The results were promising, particularly concerning psychological benefits (Andersson et al., 2003; Bromberg et al., 2012; Devineni & Blanchard, 2005; Nicholson et al., 2005; Trautmann & Kröner-Herwig, 2010). Regarding headache frequency, two studies reported a significant decrease compared to a control group (Devineni & Blanchard, 2005; Ström et al., 2000), two showed no effect compared to an active control (Andersson et al., 2003; Trautmann & Kröner-Herwig, 2010), two did not have a control group or did not report on the issue (Bromberg et al., 2012; Nicholson et al., 2005). Since sample sizes were limited, more evidence is required from larger controlled trials.

The purpose of the present randomized controlled trial was to establish the post-treatment effectiveness of online BT delivered with minimal guidance for adults with episodic migraine compared to a waitlist control group (WLC). Our first aim was to examine whether the training could reduce attack frequency (primary outcome). The second goal was to determine if BT could strengthen self-efficacy and locus of control, two aspects that are considered imperative for behavior change to occur and represent patient empowerment (secondary outcomes) (Bandura, 2004; Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010). Additional training gains were examined for attack peak intensity, number of day parts with severe headache, number of days with headache, and for migraine-specific disability and quality of life.

## Methods

### Design

A randomized controlled trial was conducted to compare online behavioral training (BT) in migraine self-management with a waitlist-control group (WLC: wait period of 10 months since control extended to 6-months follow-up).

### Participants

The study was carried out at the Department of Clinical and Health Psychology at Utrecht University, the Netherlands. Participants were recruited between September 2010 and December 2011 through referral of Dutch headache specialists associated with the Society of Dutch Headache Centers ([www.hoofdpijncentra.nl](http://www.hoofdpijncentra.nl)) (26%) and the website of the Dutch Society of Headache Patients ([www.hoofdpijnpatienten.nl](http://www.hoofdpijnpatienten.nl)) (21%), or were self-referred (53%), mostly in response to a domestic campaign of flyers in GP offices, and small notifications (not initiated by the researchers) in a national newspaper and a lifestyle magazine. The participant flow through the study, consistent with the CONSORT statement (Schulz, Altman & Moher, 2010) is depicted in Fig. 1.

Inclusion criteria were (1) being aged 18–65 years, (2) meeting the ICHD-II criteria for migraine without (ICD-10NA code G43.0) or with aura (ICD-10NA code G43.1), (3) an attack frequency of 2–6 in the 30 days prior to randomization. Exclusion criteria were (1) headache occurring on more than 15 days in the 30 days before randomization, (2) headache due to medication overuse ( $\geq 10$  triptans – or analgesics on  $\geq 15$  days – in the 30 days before randomization), (3) a score of 178 or higher on the SCL-90R screening instrument for psychopathology, (4) a migraine duration of less than one year, (5) current or planned pregnancy.

### Procedure

The study was approved by the Medical Ethics Committee of the University Medical Centre Utrecht (no. 10–304). Interested patients were referred to the research website where more information about the study was available and where they could create their own account with a personalized login name and password. To determine eligibility for the study, patients were asked to complete two online screening questionnaires (SCL-90R, ID migraine) and to keep an online headache diagnostic diary for 30 consecutive days.

The headache diagnostic diary corresponded with the guidelines for clinical trials in prophylactic treatments (Penzien et al., 2005; Tfelt-Hansen et al., 2012) and assessed migraine according to the ICHD-II criteria (Headache Classification Committee of the International Headache Society, 2004). Participants were asked to mark the occurrence of headache per day on four time-points (morning, afternoon, evening, night). In case of headache, pain intensity was rated per time-point on a visual analogue scale (VAS ranging from 0.1 to 10.0). Completing the headache diary required a few minutes per day. In order to reinforce registration, the diary was extended with a graphical migraine monitor that could be accessed at any time. The monitor displayed the course of headache over time with migraine attacks according to ICHD-II indicated by a yellow background.

Patients who met the inclusion criteria received additional information by mail, and were asked to sign and return an informed consent form within two weeks after receipt. Next, participants were asked to complete the baseline measures. If eligibility criteria were met, they were then randomly assigned to either the BT group or the WLC group. Randomization was done at the individual level and we used an unrestricted randomization procedure with no constraints to generate an allocation sequence. The randomization scheme was derived by computer and participants each had an equal probability of being assigned to BT or WLC. Allocation was done by a research assistant who was unaware of the next study group assignment. Participants were informed about the outcome by email. Blinding was not possible because the study concerns a psychological intervention. Both groups were asked to keep the online headache diary throughout the study and kept access to their migraine monitor. The online headache diary and migraine monitor were used frequently and consistently by BT and WLC participants who completed the protocol (see Fig. 1) in the days from baseline to post-assessment (BT: 92% of 167 days, WLC: 68% of 162 days on average). Patients who were not eligible for taking part were offered advice and, if desired, were offered contact information of a nearby headache center. Psychosocial help was suggested in case of serious psychological problems as indicated by the SCL-90R. The intervention group completed follow-up measures after they had finished the training (3.6 months on average, SD = 1.4). The control group completed post-test assessments at 3 months after baseline (3.4 months on average, SD = 0.7).

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