



# Feasibility and effect of mindfulness approach by web for chronic migraine and high-frequency episodic migraine without aura at in adolescents during and after COVID emergency: preliminary findings

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## Abstract

**Background** Migraine disorders are common among adolescents: however, the efficacy of medical prophylaxis is limited in this population. This study reports preliminary findings on the feasibility and effect of a mindfulness-based intervention delivered via web for adolescents with chronic migraine (CM) and high-frequency episodic migraine (HFEM) without aura.

**Methods** Patients with CM or HFEM received six sessions of a mindfulness-based treatment and were followed-up for 6 months as part of a larger study. Repeated measure analyses were carried out to test the effect of this behavioral intervention.

**Results** A total of 12 patients were included in this analysis. A significant improvement was observed up to 6 months for headache frequency, symptoms of depression, and catastrophizing, and up to 3 months for patients' disability. No change was detected for patients' anxiety level.

**Conclusions** The results of our study provides initial support to the hypothesis that patients' education and mindfulness-based programs can be very useful in populations of adolescents with CM or HFEM.

**Keywords** Chronic migraine · High-frequency episodic migraine · Mindfulness · Catastrophizing · Depression

## Introduction

Migraine disorders are common among adolescents: prevalence is 18.6% among adolescents, predominantly girls, and 1.5% have chronic migraine (CM), characterized by 15 or more days per month [1]. There are different pharmacological treatments for migraine in adolescents, but none of them has specific indication for these patients and doubts on the efficacy of pharmacological prophylaxis exists. The results of Locher's meta-analysis show a minor efficacy for propranolol and topiramate vs placebo, but only in the short term:

none of the prophylactic drugs showed superior efficacy in the long course, and the safety and acceptability profiles were comparable to placebo [2]. Therefore, nonpharmacologic targets for migraine prophylaxis in young populations have to be identified.

The feasibility and the effectiveness of behavioral approaches has already been showed in clinical experiences during the last decades: these approaches are not associated to side effects and revealed efficacy in long-term studies contrasted to control groups with a 36–72% reduction of headache frequency [3]. Most of the evidence is referred to cognitive behavioral therapy and, among the emerging treatments, mindfulness practice seems to be one of the most promising [4]. Mindfulness makes patients conscious about their problem and able to learn techniques alternative to medications for managing pain, avoiding any possible side effect of medications: therefore, it is deemed to be a suitable and adequate alternative to treat adolescent patients with migraine.

The lockdown period represented a phase of general improvement for migraine pattern among adolescents, and

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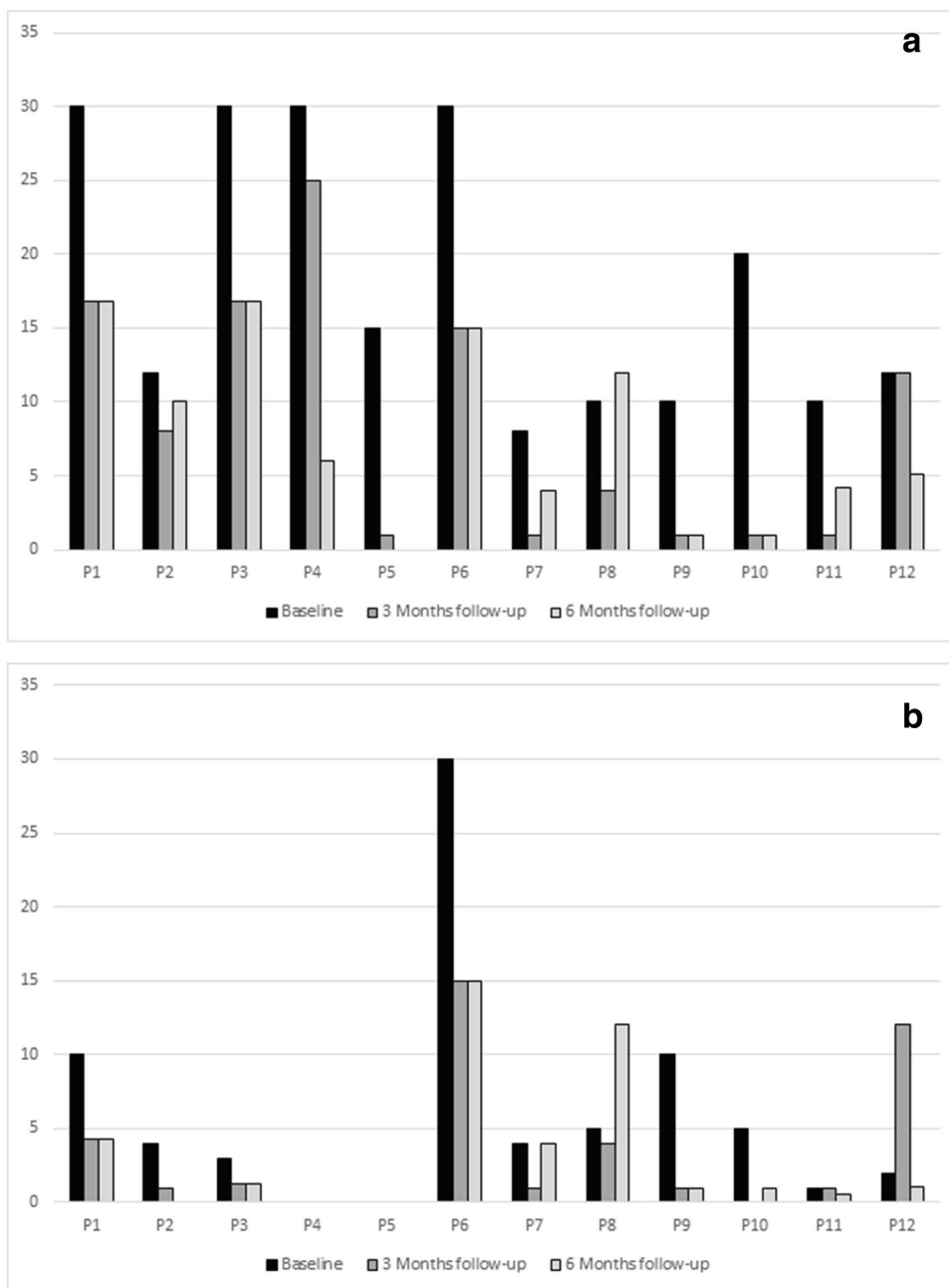
hypotheses on reduced school-related stress have been made, but at the same time, isolation might have increased stress levels and pain [5, 6]; therefore, strategies to reduce the frequency of headache and headache-related pain had to be identified.

The general aim of this pilot study was to assess the feasibility and the effect over 12 months of a mindfulness-based web-based protocol designed to be appropriate during emergency situations, like that due to the lockdown. Here, we present the preliminary results with follow-up to 6 months.

### Methods

This was a mono-center, single-arm, open-label interventional non-pharmacological pilot study carried out at the headache center of the Neurological Institute C. Besta of Milan, Italy. Adolescents aged 12–18 with CM or high-frequency episodic migraine (HFEM), i.e., patients with baseline headache frequency  $\geq 8$  days/month, without aura were enrolled during school period on occasion of outpatient neurological examination. Exclusion criteria were as follows: major psychiatric disorders (e.g., personality or psychotic

**Fig. 1** Patient-level information on headache frequency and medication intake. Notes: **A** patient-level information on headache frequency. **B** Patient-level information on medication intake



**Table 1** Longitudinal course of headache frequency, medication intake, disability, anxiety, depression, and catastrophizing in adolescents receiving web-based mindfulness program

	Friedman's test			Chi-square ( <i>p</i> -value)	Wilcoxon post hoc analysis		
	Baseline	3 M	6 m		Baseline-3 M Z ( <i>p</i> -value)	Baseline-6 M Z ( <i>p</i> -value)	3 M-6 M Z ( <i>p</i> -value)
Headache frequency	18.1 (2.7)	8.6 (2.4)	7.7 (1.8)	15.9 ( <i>p</i> < .001)	−2.94 ( <i>p</i> = .003)	−2.94 ( <i>p</i> = .003)	−0.17 ( <i>p</i> = .866)
Medication intake	6.2 (2.4)	3.4 (1.4)	3.3 (1.4)	8.6 ( <i>p</i> = .013)	−1.72 ( <i>p</i> = .086)	−1.84 ( <i>p</i> = .066)	−0.21 ( <i>p</i> = .833)
PedMIDAS	85.3 (17.6)	37.1 (9.6)	57.8 (13.2)	8.9 ( <i>p</i> = .012)	−2.63 ( <i>p</i> = .009)	−1.65 ( <i>p</i> = .099)	−1.26 ( <i>p</i> = .208)
STAI-State	34.3 (1.6)	36.7 (2.0)	33.8 (1.9)	1.5 ( <i>p</i> = .478)	–	–	–
STAI-Trait	42.6 (2.6)	33.6 (4.8)	32.8 (5.0)	2.9 ( <i>p</i> = .231)	–	–	–
CDI	13.8 (2.2)	8.6 (1.3)	7.7 (1.7)	7.8 ( <i>p</i> = .020)	−2.16 ( <i>p</i> = .031)	−2.59 ( <i>p</i> = .010)	−0.91 ( <i>p</i> = .362)
PCS	29.0 (2.5)	19.3 (2.6)	16.5 (2.6)	6.5 ( <i>p</i> = .038)	−2.28 ( <i>p</i> = .023)	−2.83 ( <i>p</i> = .005)	−1.47 ( <i>p</i> = .141)

Data are reported as means and SE. *PedMIDAS*, Pediatric Migraine Disability Assessment; *STAI*, State-Trait Anxiety Inventory; *CDI*, Kovacs's Children's Depression Inventory

disorders); psychotherapy in the previous 18 months; previous experience with mindfulness-like approaches. Both patients and caregivers signed an informed consent form prior to enrolment, and the study was approved by the institute's ethical committee (protocol no. 75.01/2020).

The program included education on the correct use of drugs and on lifestyle issues, and attendance to six sessions of a mindfulness-based behavioral approach, delivered by video calls and smart phone. These modalities have demonstrated good effectiveness for the treatment of pain conditions in preceding reports [3]. Patients accepting to participate were given lifestyle indications, and instructions for compilation of the research protocol and on how to connect to the online mindfulness sessions.

The research protocol included the following: headache frequency, our primary endpoint, and medication intake, both measured with structured headache diaries; disability, measured with the Pediatric Migraine Disability Assessment (*PedMIDAS*); anxiety, measured with the State-Trait Anxiety Inventory (*STAI*) for children; depression, measures with the Kovacs's Children's Depression Inventory (*CDI*); catastrophizing, measured with the Pain Catastrophizing Scale (*PCS*).

Six weekly 60-min sessions were scheduled on order to discuss strategies to manage pain and stressful situations that can induce pain episodes and to reinforce the mindfulness practice [7]. Lifestyle indications included regular physical activity, avoiding skipping meals, adequate hydration, control over cigarettes' smoke, and maintaining a regular sleep/wake pattern with at least 7–8 h of sleep per night.

Descriptive statistics, i.e., frequencies, means and standard errors of the mean (SE) were used to describe variables. For the two main variable of clinical interest, namely headache frequency and medication intake, we also reported patient-level information. We addressed changes in primary and secondary endpoints using non-parametric Friedman test and Wilcoxon test as a post hoc analysis when Friedman test was significant at *p* < 0.05 level. Data were analyzed using SPSS 27.0.

## Results

A total of 12 patients (9 females, mean age 15.8, SE 1.1; mean age at onset 12.3, SE 1.7) completed the follow-up up to 6 months after enrolment. Baseline and follow-up means and SE for each variable of interest are reported in Table 1. Figure 1 shows patient-level information for headache frequency and medication intake.

Table 1 also showed the results of follow-up analyses. Significant reductions over 6 months were observed for all variables, excluding state and trait anxiety (*STAI-S* and *STAI-T*). Post hoc evaluation showed that headache frequency, symptoms of depression, and catastrophizing improved between baseline and 3 months and that the improvement was maintained up to 6 months. Disability, as measured by *PedMIDAS*, improved between baseline and 3 months, but such improvement was not maintained up to 6 months.

## Discussion

The result of our open-label trial provides initial support to the hypothesis that patients' education and mindfulness based programs can be very useful in populations of adolescents with CM or HFEM and represent a valid alternative to pharmacological prophylaxis [3].

The online delivery modality also enables to preliminarily support being feasible with this kind of patients. In fact, although this analysis was conducted on a portion of the sample and on an interim time point, it has to be noted that none of the patients was lost to follow-up. As other studies have previously suggested, behavioral and mindfulness-based approaches can be of great support in reducing headache frequency, medication intake, disability, symptoms of depression, and catastrophizing in young patients [3, 4] and represent a valid alternative to pharmacological prophylaxis which showed little or no superiority against placebo [2]. Finally, this novel web-based approach, applied during an emergency moment due to the COVID-19 pandemic, is suitable for young patients with migraine [8]: the good clinical improvement and the good adherence constitute in fact encouraging preliminary results. No change was observed for anxiety scores: it has however to be noted that the scores reported were far below thresholds for relevant anxiety in all patients.

Limitations to this study include small sample size, short-term of follow-up, and absence of a control condition. Despite these limitations, our pilot study showed feasibility and effect in the use of non-pharmacological therapies in adolescents with CM or HFEM, delivered via a web-based application, as part of the treatment for this specific population.

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## Declarations

**Ethical standards** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

**Conflict of interest** The authors declare no competing interests.

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