



# Smartphone based music intervention in the treatment of episodic migraine headaches – A pilot trial

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## ARTICLE INFO

### Keywords:

Migraines  
Headaches  
Music intervention  
Pain  
Smartphone application

## ABSTRACT

**Objectives:** Migraine headaches are a prevalent and burdening disorder for the public worldwide. Both traditional preventive drugs and behavioral-based interventions have been used as treatment in the prevention of migraine attacks. However, benefits of alternative interventions in patients with primary headache disorders have not yet been fully explored.

The present investigation sought to examine the impact of a patient controlled music intervention (MUSIC CARE) on episodic migraine headache.

**Design:** A sample of 20 episodic migraine patients (17 females, mean age of 42 years) was included in the pilot trial. Patients completed a pre-treatment assessment on headache severity, associated psychopathological distress (anxiety and depression) and functional impairment, and provided reports on their medication intake. During the 3-months intervention period, patients required 1–2 music sessions (based on the “U” sequence) per day with a minimum of 15 per month.

**Results:** Following the intervention, patients reported a significant reduction in the frequency of migraine attacks ( $M_{Diff} = -2.8, p = .01$ ). Ten patients reported a 50% reduction in the frequency of migraine attacks. Additionally, there was a significant reduction in medication intake ( $M_{Diff} = -2.85, p = .02$ ), the duration of migraine attacks ( $M_{Diff} = -5.45, p = .002$ ), anxiety ( $M_{Diff} = -1.65 (2.88), p = .02$ ) and depression ( $M_{Diff} = -2.45 (3.5), p = .002$ ).

**Conclusion:** These data provide evidence that music intervention may significantly prevent migraine attacks. Moreover, this method is easily accessible and administered. Future well-controlled clinical trials are necessary to further explore the efficiency of the intervention.

## 1. Introduction

Migraine is a major concern and debilitating disorder worldwide,<sup>1</sup> and is strongly associated with comorbid anxiety and depression.<sup>2</sup> Thus, a number of treatment options are thought to help alleviate both the physical discomfort and psychological well-being from migraines. Traditional acute-drug medications are often utilized in alleviating physical pain associated with migraines.<sup>3</sup> For preventive purposes, maintenance therapy with medication is used to reduce the frequency of crises, whereas a number of relaxation techniques, biofeedback, and/or cognitive therapies can be used to help alleviate negative psychological (and in some cases physical pain) outcomes.<sup>4,5</sup> Interestingly, music

interventions have proved useful in decreasing pain in hospitals, outpatient specialist centers, and other clinical settings.<sup>6–8</sup> However, research has yet to explore the potential benefit of a music intervention for patients with migraine headaches.

### 1.1. The prevalence and impact of migraine headaches

Migraines are characterized as an idiopathic and debilitating disease that can significantly affect patients' quality of life by disrupting emotional relationships and daily activities. According to the International Classification of Headache Disorders,<sup>9</sup> common migraines are often referred to as migraines without aura, and are characterized by a

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<https://doi.org/10.1016/j.ctim.2021.102779>

Received 4 November 2020; Received in revised form 22 August 2021; Accepted 27 September 2021

Available online 30 September 2021

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unilateral location, pulsating quality, moderate to severe intensity, aggravation resulting from routine physical activity, and an association with nausea and/or photophobia and phonophobia. On the other hand, migraines with aura typically consist of speech, sensory, and/or visual symptoms. Various demographic factors can influence the prevalence of migraine attacks. For example, women experience migraine attacks more frequently in comparison to men.<sup>10</sup> Those who have lower education status, employment status, income level, and overall poverty status experience migraine attacks at a greater rate in comparison to their respective counterparts.<sup>10</sup> Additionally, there is a strong psychiatric comorbidity associated with migraine headaches, such that patients with migraine headaches have a higher prevalence of anxiety, depressive, and other serious psychiatric disorders.<sup>11,12</sup>

### 1.2. Treatments of migraine headaches

Migraine headaches are largely under diagnosed, with 60% of French patients being unaware of their migraine status. Given both the harmful, prevalent, and under-diagnose nature of the disorder, treatments aimed at decreasing the impact of migraines are warranted. In this regard, traditional pain medications are often used.<sup>3</sup> For example, *triptans* were introduced in the 1990's as acute drug agents aimed at decreasing symptoms of migraine attacks. While these medications are beneficial for symptoms following the migraine onset, it is important to note that no acute (or preventative) drug treatment has been shown to be effective (reducing episodes by at least 50%) in reducing the duration of a migraine.<sup>13</sup>

As mentioned, behavioral treatments have been shown to be effective in reducing the symptoms and severity of migraine headaches.<sup>4</sup> For example, clinicians may administer relaxation techniques, biofeedback training, and/or stress management (cognitive and behavioral) as therapies for migraine patients.<sup>5</sup> Interestingly, music has been used as a benefitting technique in hospital, clinical, and other settings. During a music intervention, an individual typically chooses their preferred genre of music that they would like to listen and relax to in response to physical pain or psychological distress. Converging evidence suggests that music interventions are indeed beneficial for physical pain in a number of domains,<sup>6-8,14</sup> in addition to psychological distress, ranging

from smaller-scale mood improvements to anxiety disorders.<sup>14,15</sup> However, research has yet to examine the impact of a music intervention on the symptomology in patients with migraine headaches. Few studies have examined the impact of music therapy – a therapeutic process that incorporates listening, composing, and/or making music – in patients with primary headache disorders.<sup>16</sup> In this regard, studies have shown that music therapeutic techniques can help alleviate the debilitating impact of migraines in children,<sup>17</sup> adolescences,<sup>18</sup> and adults.<sup>19</sup> Yet, it has been proposed that other factors, such as treatment expectancy, can account for the therapeutic effects of music therapy.<sup>16</sup> Thus, an understanding of how techniques in music therapy truly impact outcomes associated with migraine headaches is needed.<sup>16</sup> Active music intervention, a technique used in receptive music therapy, has not been adequately studied in patients with migraine. Therefore, work aimed at understanding how simply listening to music (i.e., a music intervention) may impact the negative functional and emotional outcomes of migraine headaches would be insightful.

### 1.3. Present study

Despite converging evidence that music interventions are beneficial in a number of pain domains, additional research is needed to understand the impact of a music intervention on the debilitating nature of migraine headaches. Interestingly, a recently developed smartphone application called *Music Care*, has been introduced as a music intervention tool, however music type is controlled by the individual. A patient-controlled music intervention administered by *Music Care* has shown to alleviate negative psychological (e.g., depression) and physiological (e.g., pain and discomfort) outcomes associated with general chronic pain.<sup>20</sup> However, no study has examined how music interventions administered via *Music Care* may be beneficial for individuals who experience migraines, thus potentially highlighting the effects of receptive music techniques in music therapy. Therefore, the present investigation sought to examine the potential benefits of a patient-controlled, 3-month music intervention in individuals diagnosed with migraine headaches using the *Music Care* application.

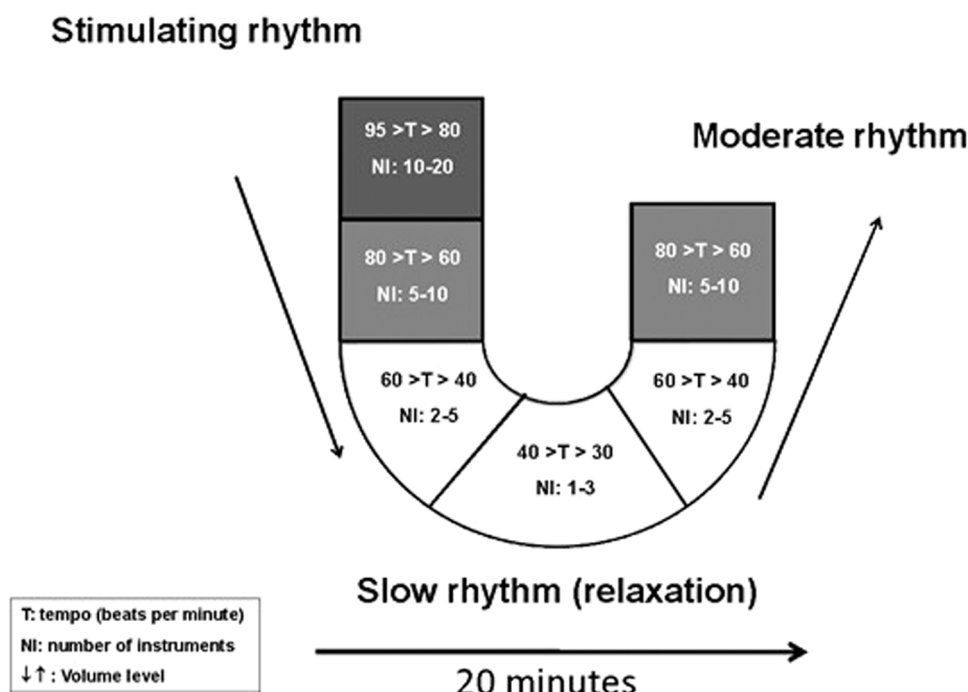


Fig. 1. "U" sequence.

## 2. Materials and methods

### 2.1. Participants

Thirty-two patients from the university hospital center Sud Reunion (Saint Pierre, Reunion Island, France) within the Chronic Pain Consultation Group were evaluated for inclusion in the study. Participants' migraine status was diagnosed by an expert clinician based on the International Headache Classification Disorders (IHCD) II guidelines.<sup>9</sup> Migraine patients who had "episodic" migraines (less than 15 days of migraine episodes per month)<sup>21</sup> with or without aura were included. Patients with chronic migraines (greater than 15 days of migraine episodes per month) were excluded as these individuals are often under complex care (e.g., nurse to ensure drug abuse does not ensue).<sup>21</sup> Diagnostic criteria for patients without aura included at least five attacks, where each attack must last 4–72 h, be unilaterally located, of pulsating quality, moderate to severe pain intensity, and interrupted physical routines. The patient was also eligible if during the attack, he/she experienced nausea and/or vomiting, in addition to photophobia and phonophobia. For those with aura, at least two attacks of fully reversible sensory, speech, and/or visual symptoms must occur for inclusion. Patients were allowed to receive recommended and standard migraine medication pharmacologic classes as background. Based on clinical evaluation it was determined that 12 of the 32 patients did not fit the above criteria, leaving a sample of 20 (females = 17, mean age = 42 years, age range 19–63 years) patients who were eligible to complete the 3-month music intervention. Following the collection of patient information and informed consent, baseline information on the severity of migraines, medication intake for migraines, and self-reports on the emotional and functional impact of migraines (*see below*) were collected. Pre-treatment data from the month prior to inclusion (frequency, severity of seizures, duration of seizures, crisis treatment medications) were collected prospectively on the migraine diary that was started 1 month prior to inclusion. The initial HAD and HIT-6 questionnaires were completed at inclusion. Patients were then given detailed instructions of

**Table 1**  
Pre- and post-treatment assessments for migraines.

	Pre-treatment	Post-treatment	n patients improved	p
Migraine Frequency	8.45 (3.03)	5.65 (3.73)	13	<b>0.01</b>
Acute Medication Taken	9.35 (4.65)	6.50 (5.93)	13	<b>0.02</b>
Duration of Migraines	10.95 (16.84)	5.50 (7.47)	10	<b>0.002</b>
Mild Migraine Episodes	1.85 (2.77)	1.75 (2.55)	6	0.70
Moderate Migraine Episodes	3.70 (3.08)	2.20 (2.82)	10	0.07
Severe Migraine Episodes	2.90 (3.81)	1.70 (1.72)	8	<b>0.05</b>
HADS-Anxiety	9.05 (3.75)	7.40 (3.79)	12	<b>0.02</b>
HADS-Depression	6.45 (3.88)	4.00 (3.46)	13	<b>0.002</b>
HIT Scores	62.75 (6.12)	59.10 (6.78)	16	<b>&lt;0.001</b>

*Note:* Table 1 gives mean and standard deviation (in brackets) of all variables before and after treatment. This table also indicates the number of patients (out of 18 analyzed patients) who showed improvement over the treatment period (n patients improved). Migraine frequency: how frequent the migraines (per month); Medication taken: quantified as the amount of pills taken for the month; Duration of Migraines: migraine duration in hours. Episode intensity is regarded as the number of episodes with varying intensity (mild, moderate, severe) for the month. The Hospital Anxiety and Depression scale (HADS) was used to index the emotional impact of migraines on anxiety (HADS-Anxiety) and depression (HADS-depression) separately using subscales with higher scores reflecting greater anxiety and depression. The Headache Impact Test (HIT-6) was used to index the functional impact of migraine headaches, with higher scores reflecting a greater negative impact. Significance values (p values) less than .05 are bolded.

the 3-month protocol requirements.

### 2.2. Protocol

During the 3-month patient-controlled home music intervention, participants were to complete 1–2 sessions of music intervention per day, with a minimum of 15 sessions per month. Patients were required to complete an agenda of their sessions for the 3-month period and monthly telephone interviews were used to check on compliance with the protocol over the 3-month period. The music intervention was administered via a smartphone- (and computer-) based application called *Music Care*. The *Music Care* app is a receptive music intervention, allowing the patient to freely adjust the length of and choose the preferred style between different sequences of instrumental music. All musical pieces were recorded in high-quality recording studios with professional musicians.

*Music Care* utilizes the "U" sequence (Fig. 1), designed to gradually relax the listener.<sup>20,22</sup> In the current study, music sequences during patients' sessions were based on the mount "U", and instrumental musical works were selected for a varying numbers styles (classical, jazz, world music, etc.) and adapted to the patient's style via patient request. The "U" sequence is implemented using a musical sequence of 20 min that was divided into 5 different musical pieces at 3–4 min each. Initially, the objective is to represent the patient's state of tension by stimulating musical rhythm (80–95 beats per minute (bpm)). From there, the remaining 4 sub-pieces are presented in a blended fashion in an attempt for the patient to gradually fall into a relaxed state via a gradual reduction in musical tempo (40–80 bpm), orchestral size, frequencies, and volume (descending arm of the "U"). The music session then reaches a phase of maximum relaxation (downward phase of the "U") before a phase that gradually returns to baseline dynamics (ascending arm of the "U").

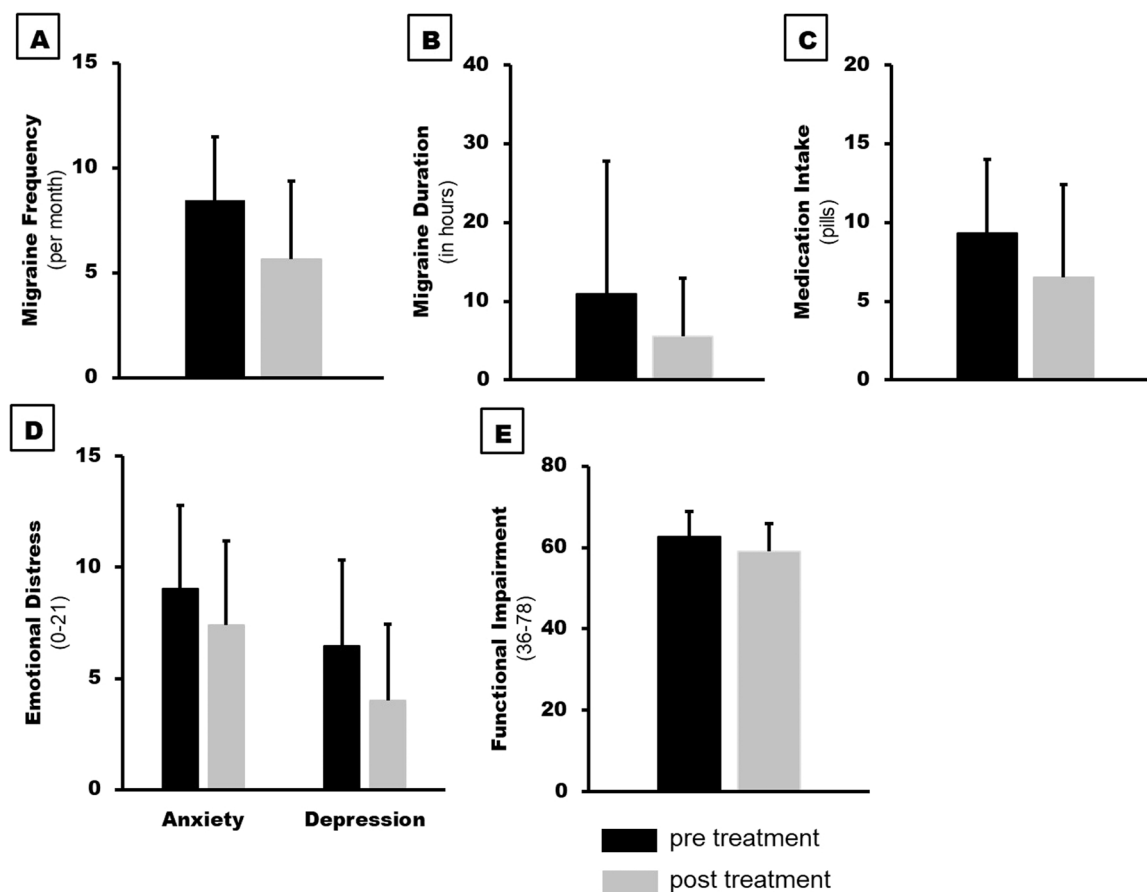
Headphones were required (provided at time of treatment), and patient were instructed to lay down (to promote muscle relaxation) with their eyes closed and lighting to a minimum. Participants answered questions related the frequency, duration, and other migraine related questions throughout the treatment. At the end of the 3-month of treatment, participants underwent the same assessment as at baseline.

### 2.3. Measures

Measures taken included (1) the frequency of migraine attacks (number of days per month), (2) average duration of migraine attacks (hours), and (3) average intensity of migraine attacks (choice of mild, moderate, or severe). The amount of acute medication taken for migraines (no preventive drug treatments) was quantified as the number of pills (single doses) taken per month. During this time, patients also rated levels of anxiety and depression associated with migraine headaches via the 14-item Hospital Anxiety and Depression Scale (HADS) scale. On the HADS, patients were to rate the severity to which they felt anxious or depressive symptoms (0 – not at all to 3 – most of the time), with higher scores reflecting greater anxiety and/or depression.<sup>11</sup> The impact migraines have on everyday level of functioning was indexed using the Headache Impact Test (HIT-6), where participants rated (1 – Never to 5 – Always), on six dimensions, the degree to which migraines impacted everyday level of function.<sup>23</sup> HADS and HIT-6 scales were completed twice by participants, both before and after the treatment (pre- and post-treatment), while migraine severity, frequency, duration, and medication taken was indexed pre-treatment and noted in their agenda monthly throughout the treatment. Migraine assessments final month were conceptualized as post-treatment migraine duration and severity.

### 2.4. Statistics

All statistical tests were conducted using SAS (ver. 9.2, SAS Institute Inc, Cary, NC, USA). Migraine frequency, duration, severity, and pills



**Fig. 2.** Effect of Music Based Intervention on Migraine Symptoms assessed as (A) Migraine Frequency; (B) Migraine Duration from; (C) Acute Medication Intake; (D) Emotional Distress as indexed using by the Hospital Anxiety and Depression scale (HADS) and (E) Functional Impairment as indexed using The Headache Impact Test (HIT-6). Mean and standard deviation are presented in the figure.

taken, in addition to HIT-6 and HADS scores of migraine attacks pre-and post-treatment were performed using Paired Sign tests (non-parametric form of Paired student *t*-tests, as distributions for all dependent variables were not normal). Statistics reported include the mean average of change (standard deviation in brackets) and associated two-tailed *p* values as significance levels (cut-off of 0.05 for statistical significance). Reducing number of days with migraine per month by 50% after 3-months is regarded as effective and thus, was selected as primary outcome of the current investigation (responder criterion: 50% reduction in migraine attacks from pre- to post- treatment). Of the 20 patients included in the trial, two patients had a failure to complete the protocol (minimum number of music sessions), one patient had a change in disease-modifying medicines, and two patients could not be contacted at the end of the intervention. Based on an Intention-to-Treat analysis these patients' data were included in the analysis. Missing post-line data was imputed based on baseline data. All statistical tests were evaluated at  $\alpha = 5\%$ . The research has been approved by the Comité de Protection des Personnes (CPP) from Bordeaux (approval number: 2013-A00148-37) and submitted on ClinicalTrials.gov (Registration no. NCT03763058).

### 3. Results

#### 3.1. Primary outcome: frequency of migraine attacks

Mean and standard deviation for all variables (pre and post treatment) are provided in Table 1 and Fig. 2.

Results showed that from pre- to post-music therapy, there were significant decreases in patients' frequency of migraines ( $M_{Diff} = -2.8$

(4.19),  $p = .012$ ). Data show a clinically meaningful reduction of migraine frequency - with at least 50% reduction - in 10 of the 20 analyzed patients.

#### 3.2. Secondary outcomes

Analyses also showed a reduction in acute medication taken ( $M_{Diff} = -2.85$  (5.35),  $p = .024$ ), and the duration of migraine attacks ( $M_{Diff} = -5.45$  (15.52),  $p = .002$ ). There were no significant reductions in mild episodes ( $M_{Diff} = -0.10$  (3.16),  $p = .791$ ); moderate episodes ( $M_{Diff} = -1.50$  (3.41),  $p = .068$ ); severe episodes ( $M_{Diff} = -1.20$  (2.71),  $p = .045$ ). Further, results on HADS subscales showed significant decreases from pre-treatment on the respective domains of psychopathological distress anxiety ( $M_{Diff} = -1.65$  (2.88),  $p = .015$ ) and depression ( $M_{Diff} = -2.45$  (3.5),  $p = .002$ ). Changes from pre- to post-treatment were also significant for the HIT-6 (functional impact of migraines) scores ( $M_{Diff} = -3.65$  (4.59),  $p < .001$ ).

### 4. Discussion

Migraine headaches remain a debilitating disorder to the public worldwide. Traditional medications are often used to decrease frequency of migraine of migraine attacks.<sup>3</sup> However, patient controlled music interventions have not yet been evaluated as a treatment for decreasing the frequency and impact of migraines. In the current study, we found several benefits of the music intervention using the *Music Care* app on outcomes of clinical relevance, including a significant reduction in: migraine attacks by at least 50% in 10 of our 20 patients, medication intake, duration of migraine attacks, and in both the emotional

(especially depressive) and functional impact scores. According to previous research, drug medications for migraines barely reach the effectiveness that the music intervention based on the “U” sequence displayed in the present study, that is, a reduction by 50% over a 3-month period.<sup>13</sup> Previously mentioned behavioral treatments’ effectiveness are comparable to the observed results in this study, overall suggesting that a music intervention using the “U” sequence can reduce the necessity of traditional acute medications.

#### 4.1. Implications

The present investigation is the first to show that patient-controlled music interventions via *Music Care* may prevent and/or alleviate migraine attacks. This work extends existing literature on music therapy and headaches;<sup>16</sup> receptive music techniques in music therapy may be especially important at alleviating the debilitating nature of migraines.

As it relates to the emotional impact (depression and anxiety) of migraine headache attacks, we previously noted that music interventions have been shown to decrease both depression and anxiety,<sup>14, 24–26</sup> in addition to overall mood<sup>15</sup> in various domains. Our data support these notions, extending them specifically to the domain of anxiety and depressive symptoms resulting from reoccurring and debilitating migraine attacks. Overall the particular impact of the “U” technique is not isolated to key factors directly related to migraine attacks such as pain and duration of attacks, but also on key negative psychological factors that can often result from the experience of migraine attacks.

Additionally, many individuals who experience migraine headaches do not seek treatment, largely due to a lack of financial resources.<sup>10</sup> Therefore, many individuals who tolerate migraines throughout their lifetime can experience detrimental psychological and physiological outcomes, no matter the severity.<sup>27</sup> The present study demonstrates that *Music Care* is an easy and cost-effective method of delivering the “U” music intervention as treatment for migraine headaches. *Music Care* and other programs effective at delivering a music intervention has the potential to be extremely beneficial in the global reduction of migraines in both those who seek and those who are unable to seek medical help.

#### 4.2. Limitations and future directions

Thus, one limitation of the current investigation is that we did not employ a control group. However, we indeed follow guidelines of IHS on the evaluation criteria and time of migraine attacks, in addition to the calculation of the therapeutic response rate. Thus, we propose and are confident that the current study provides, at the very least, a proxy of the effectiveness of the music intervention “U”. Nevertheless, future investigations should include a control group for comparison purposes. Future well-controlled clinical trials are also necessary to further explore the efficiency of the intervention compared to other therapeutic options.

Furthermore, it is important to note that as the self-monitoring of headache symptoms often produces an effect on its own<sup>16</sup> and thus, the current results must be interpreted with caution. However, the recruited patients had been previously followed in chronic pain consultation before and thus, had the practice and habit of keeping a diary of migraine headaches in hopes that such effects would be minimized in the current investigation.

#### 5. Conclusions

The present study provides empirical evidence that a patient-controlled music intervention, specifically using the “U” sequence in music therapy administered via *Music Care*, can decrease the overall impact and consequences of migraine headaches over a 3-month treatment period. By decreasing the frequency of migraine episodes by 50% (in 50% of the sample), the “U” sequence seems to be an effective treatment for migraine headaches, thereby highlighting the importance of receptive music techniques in music therapy in decreasing the

debilitating nature of migraines. Furthermore, this treatment can be easily accessible and distributable via the computer- and smartphone-based application, *Music Care*. Overall, we stress the possibility of using the “U” sequence as a potential large-scale treatment for those who experience migraine and possibly other primary headache disorders.

#### Acknowledgements

This work was made possible by the nurses of the university hospital center Sud Reunion and we strongly thank them.

#### Conflicts of interest

The authors have no conflict of interest to declare.

#### Sources or financial support

Not applicable.

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