

Case Report

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Case Report

Investigating the Feasibility of Virtual Reality Meditation for Managing Migraine in Females: A Multiple Baseline Replicated Case Study

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Abstract: **Background:** Virtual reality offers a potential way to facilitate amplified forms of meditation and distraction, potentially inducing greater states of stress and pain reduction. It is an intriguing possibility that VR-based meditation could disrupt migraine neurophysiology. **Objective:** We aimed to explore the feasibility, usability, and potential benefits of home-based virtual reality-delivered meditation as a non-pharmacological adjunct in migraine management. **Methods:** A multiple baseline replicated Single-Case Experimental Design using an A-B-A (A1-Baseline, B-Intervention, A2-Follow-up) procedure was employed. Two participants underwent serial observations before, during, and after an intervention involving brief daily meditations at key points relevant to migraine onset and peak. Systematic visual analysis of the data was supported by secondary Tau-U statistical analysis. **Results:** Visual analysis suggested no apparent change in pain intensity and migraine frequency across the study. The Tau-U index supported this finding, confirming that pain reports were non-phase-dependent (all $p > 0.4$). Adherence to the daily meditation was high (>89%), but adherence to meditations at onset and peak pain was low (0-43%). Both participants reported high System Usability Scale scores (>80/100). **Implications:** While it is premature to exclude a role for virtual reality meditation in migraine management in specific individuals, this case series provides no support for a potential benefit although utility in some individuals cannot be ruled out by the current design. Moreover, we highlight potential issues related to implementing VR-based interventions in groups experiencing migraine pain, particularly regarding protocol adherence at migraine onset and peak pain. **Plain language summary:** We aimed to explore the feasibility, usability, and potential benefits of home-based virtual reality-delivered meditation as a non-pharmacological adjunct in migraine management. A multiple-baseline replicated single-case experimental design was used, involving two females with medically diagnosed migraines. No support for a potential benefit of virtual reality-based meditation was found, although its utility in some individuals cannot be ruled out by the current design.

Keywords: migraine; virtual reality; pain; non-pharmacological treatment; meditation

1. Introduction

Migraine is a complex neurological disorder[1,2], and the second leading cause of disability worldwide[3]. Despite the profound prevalence, associated disability and wide-reaching psychosocial implications, they remain underdiagnosed and undertreated [4].

Migraine attacks are thought to be from a complex interplay of neurovascular events [5]. However, the pathophysiology of migraine remains largely theoretical and current treatments suboptimal— highlighting the necessity for innovative research and exploration of alternative management options. Currently, pharmacological approaches remain the mainstay of treatment[6], however for many, this is an incomplete solution, and in some cases, overuse of some classes of medications may even contribute to chronicity [7].

Research acknowledges a relationship between increased stress levels and the contribution to the overall burden of migraine [8]. While there is no conclusive evidence of a causal relationship, stress is the most commonly reported migraine attack trigger [8,9] and an established factor increasing the intensity of pain during a migraine attack [10]. The mechanisms underpinning the stress-migraine connection are thought to be contributed to by a cycle of stress-related physiological dysregulation that interacts with the mechanisms of migraine [7].

The migraine attack itself can be considered a stressful event, leading to a repeating cycle of physiological and psychological stress [7]. The effects may be observed in several ways. Hormonal signalling may be altered, for example, by influencing cortisol levels and triggering a sensitised pro-inflammatory state[11]. Additionally, heightened anxious thoughts and pain catastrophising can also play a role in altering sensory processing associated with pain, leading to increased, widespread sensitivity[11]. To disrupt the stress-migraine-stress cycle, there is a growing interest in stress-reducing techniques, such as meditation, as a potential treatment [8].

Mindfulness meditation involves intentionally focusing attention on the present moment without attempting to alter it but rather accepting it without attachment or judgment [12]. Other meditation techniques include concentrating on body sensations, repeating a mantra, or focusing on the breath [13]. While the exact mechanisms of meditation are not fully understood[12], research shows engagement with regular meditative techniques can improve a person's ability to manage pain associated with migraine [14] and reduce stress through enhanced coping skills, acceptance and emotional regulation [13,14].

Despite the established benefits of meditation-based methods[8], people often find engaging in regular practice difficult[15]. Pain itself can make meditation difficult, along with other distractors from the surrounding environment [15]. Delivering traditional meditation practices with virtual reality (VR) may help mitigate these internal and external distractors, helping to facilitate the achievement of relaxed meditative states [15]. VR uses a head-mounted display (HMD) to replace the real world with a digitally generated environment. Some limited evidence suggests that combining VR and meditation may be more effective at enhancing mindfulness than traditional methods alone [15].

This complimentary effect is not surprising in the context of pain management, where 'distraction-based analgesia' is a well-established effect of VR. It is thought that the immersive effects of VR occupy a significant proportion of attentional resources, leaving fewer resources available for pain processing[16].Thus, VR may improve the effectiveness of meditation for people in pain by reducing the attentional load of pain and allowing greater focus on the meditation itself.

Given the known and potential interactions between VR, the nervous system, and pain, it is an intriguing possibility that VR meditation may somehow interrupt the cycle of internal dysregulation theorised to underpin migraine. This could be achieved through VR stress-relieving techniques and distraction therapy. However, these links have not been explored in migraine populations, which is a clear gap in the existing literature.

The usability and feasibility of VR technology within this specific population raises potentially unexplored safety concerns. Understanding these factors could help refine and optimise future VR-based interventions. Some considerations include the potential impact of the headset's weight on the cervical spine, the potential for light and sound stimuli to trigger migraine attacks, and the pressure of the headset on the cheeks affecting the distribution of the trigeminal nerve.

We aimed to explore the feasibility and practicality of integrating home-based VR-delivered meditation as a non-pharmacological adjunct for migraine management. The study assessed protocol adherence, VR platform usability and intervention acceptability, and any preliminary efficacy in reducing migraine frequency and intensity.

We hypothesised that home-based VR meditation would be feasible and perceived as practicable and that the frequency and intensity of migraine attacks would be suppressed by VR meditation.

2. Material and Methods

The study received ethical approval from The University of [Anonymized] Human Research Ethics Committee ([Anonymized]) and was pre-registered with the [Anonymized] Clinical Trials Registry ([Anonymized]).

2.1. Participants

Recruitment occurred through The University of XXXXX through posters displayed on campus, social media advertisements, and word-of-mouth referrals.

Participants were required to have a medical diagnosis of migraine. Additionally, all participants were pre-menopausal females aged between 18 and 45 with a regular menstrual cycle of 25 to 35 days. Fluency in English, access to a computer or smartphone, adequate upper limb strength, and neck mobility to install and navigate the software using the head-mounted display (HMD) were prerequisites.

People with hearing or vision difficulties, such as glasses or hearing aids that prevented proper fitting of the HMD and were sufficient to impair the VR experience were excluded from the study. Other exclusion criteria included epilepsy or claustrophobia, poorly managed and severe psychiatric comorbidities, any significant changes in treatment over the preceding three months, and self-reported susceptibility to motion/cybersickness.

2.2. Experimental Design

We used a multiple baseline replicated Single Case Experimental Design (SCED) following an A-B-A approach (A-baseline, B- treatment, A-follow up). Participants completed daily diary recordings before, during and post-intervention phase. Given the exploratory nature of this study, we emphasised a meticulously designed protocol to collect a substantial amount of data to improve statistical power, in turn providing better indications of the stability of outcome variables and a more reliable estimate of symptoms within and across phases.

2.3. Recruitment

All study data was collected and managed using REDCap electronic data capture tools hosted at The University of XXXXX. Interested participants were emailed an eligibility questionnaire via REDCap.

Eligible participants were subsequently invited to an initial thirty-minute session at City East Campus at The University of XXXXX for a study and technology brief, headset fitting and cybersickness screen. Participants provided written consent and received a participant information leaflet.

2.4. Phase Length: Controlling for Hormonal Cycles

The study involved three phases; the initiation of phases was closely mapped to the individual's menstrual cycle as much as practicable. Since migraine fluctuates with hormonal cycles [17], it was important to account for this potential confound in study design. This approach allowed for a more confident comparison of symptoms across each phase. The VR was introduced at a hormonally stable phase of the cycle (mid-luteal) [17], to minimise hormonal variations as an extraneous factor and reduce potential erroneous conclusions of intervention effect.

We ensured that we collected data from approximately one complete menstrual cycle per study phase for each participant. In some instances, we extended the data collection period during the baseline and follow-up phases to accommodate individual differences in cycle length and the timing of the study start. The intervention was initiated on approximately day eighteen of the second menstrual cycle and the intervention study phase lasted for approximately twenty-eight days.

2.5. Data Collection and Outcome Measures

The primary outcomes were self-reported pain intensity, migraine frequency, VR technology usability and protocol adherence.

A daily symptom diary established each participant's 'usual' migraine symptoms during the baseline phase. Next, during the intervention phase, participants were instructed to perform a daily five-minute VR meditation. Additionally, they were requested to use VR in two other scenarios throughout the intervention period: 1-As a potential prophylactic technique by employing VR at the first signs of personal migraine pre-cursors/indicators, and 2-During each migraine episode when they considered their pain to be at its worst.

Data was collected via a diary sent electronically via REDCap at 18:00 hours daily. The diary necessitated a daily recording even without a migraine episode. Daily questions included: Are you in the VR phase of the clinical trial? Has your period started, continued, or ended today? Did a migraine start, continue, or end today? Participants confirming migraine onset were prompted for additional details such as average and peak pain scores measured using the visual analogue scale (VAS) from zero for no pain to ten indicating worst pain. During the intervention phase, there were further questions about pain scores before, during, and after daily VR meditation sessions. Additionally, participants were asked whether they initiated meditation at symptom onset and during peak pain periods. The thorough nature of the daily diary enabled us to garner information on adherence to protocol, also allowing us to see the frequency and duration of VR use relative to the number of migraine episodes.

The participants were sent the System Usability Scale (SUS) and the Global Perceived Effect (GPE) to complete after the intervention phase when their experience using the technology was still recent in their memory.

Participants were required to complete secondary outcome measures at study commencement and completion, including the Depression, Anxiety, and Stress Scale 21 (DASS-21) and Migraine Specific Quality of Life Questionnaire 2.1 (MSQoL 2.1). See Table 1. All outcome measures were scored and interpreted according to standardised approaches.

Table 1. Outcome Measures Timeline. DASS 21: Depression Anxiety Stress Scale 21; MSQoL 2.1: Migraine Specific Quality of Life Questionnaire 2.1; GPE: Global Perceived Effect; SUS System Usability Scale.

STUDY PHASE	OUTCOME MEASURES
Phase A1- Baseline	Daily Diary (pain intensity, migraine frequency, protocol adherence). Initial completion of Secondary Outcome Measures: DASS 21, MSQoL 2.1.
Phase B-Intervention	Daily Diary (pain intensity, migraine frequency, protocol adherence). At the completion of this phase- GPE and SUS.
Phase A2- Follow-Up	Daily Diary (pain intensity, migraine frequency, protocol adherence). Repeat DASS 21, MSQoL 2.1.

Migraine Specific Quality of Life Questionnaire (MSQ 2.1); RF-R, Role Function- Restrictive; RF-P, Role Function- Preventive; EF, Emotional Function. Depression Anxiety Stress Scale-21 (DASS-21); D, Depression; A, Anxiety; S, Stress.

2.6. Sample Size

Traditional sample size calculations are not typical for SCED studies that position themselves as explorations of new ideas rather than as more conclusive efficacy studies [18]. While sophisticated sample size calculations are possible in some cases, our primary analysis focused on a formalised visual analysis for which no power calculation can be made [19].

2.7. Data Analysis

Daily diary data for self-reported pain intensity (VAS) and migraine frequency for each participant was plotted across time and phase using a scatter plot. Lines representing the mean migraine peak VAS scores, the overall phase mean (including all zero-scored days), and linear regression trend lines for each phase were added.

Visual analysis of the graphical representations of daily diary data was conducted in line with best practice recommendations[20] and included examination of level (mean), variability (spread) and trend (linear regression) to assess the impact of the independent variable (VR meditation) on dependent variables (migraine frequency and intensity). Range lines were not applied to the graphical representations of data due to the episodic nature of data points associated with migraine frequency. Emphasis was given to identifying relationships between the variables rather than the magnitude and consistency of outcomes [21].

It is recommended that visual analysis is supported by statistical analysis [22]. We utilised Tau-U, a non-parametric statistical approach derived from Mann Whitley U (non-overlap test) and Kendall rank correlation [23]. Tau-U is a versatile statistical measure that can accommodate trends in data, perform effectively with a small number of data points, and not rely on the assumption of a normal distribution.[22]. Data points from three menstrual cycles (estimated mid-luteal to mid-luteal phase) were included for comparative statistical analysis. The threshold for baseline correction was $U > 0.40$. The level of significance was set at 0.05, and Tau-U was interpreted according to the Tau-U statistic, where indices closer to one indicate non-overlap (phase-dependent pain ratings) and scores closer to zero indicate overlap (non-phase-dependent pain ratings). That is, scores close to zero and/or with a non-significant p-value would be consistent with the null hypothesis that VR makes no difference to migraine.

2.8. Technology

The Meta Quest 3 HMD was utilised. Both participants used the Guided Meditation VR application, which gave access to a broad selection of guided meditations customisable to their preferences. Participants were advised to select low visual stimulation environments to minimise the likelihood of visual/vestibular conflict and only use the VR HMD while seated or recumbent.

3. Results

3.1. Participant Characteristics

Of the six individuals who initially expressed interest in participating, two did not meet the established criteria, and two declined to proceed. Two participants were deemed eligible to take part in the study.

Participant One was a 29-year-old female who experienced her first migraine at the age of 10. Pre-screening information revealed that her migraine attacks typically last for 24 hours, beginning with a warning aura and unilateral visual disturbances in her left eye, which she described as "blurry circles". The headache pain described as "throbbing, intense, and unbearable" with other associated symptoms, including sensitivity to light and sound, nausea, and vomiting. She noted migraine triggers, including increased stress and changes in body temperature, especially in hot weather. She was not taking any medications.

Participant Two was a 35-year-old female who experienced her first migraine attack at the age of 25. Pre-screening questions revealed a typical attack lasted around six hours with no known triggers. Warning symptoms include neck pain/tension followed by a headache. The head pain was described as being unilateral, primarily in the right temple area and occasionally on the right side of

the back of the head. A constant ache worsened to a throbbing sensation, and was further provoked by head movements including bending forward. The main migraine symptoms were headache and sensitivity to light. The participant was taking prescribed migraine medications (elitriptan).

3.2. Primary Outcome Measures

Mean, trends, and variability in migraine intensities within and between each phase can be observed in Figures 1 and 2.

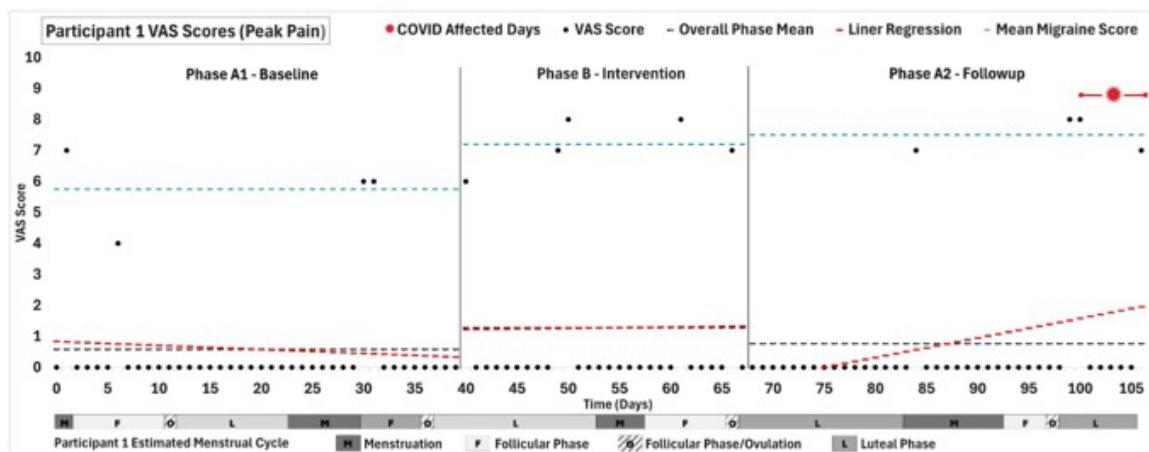


Figure 1. Participant One, Daily Diary Data across three study phases showing level (overall phase mean) and mean migraine peak VAS scores and trend (linear regression). Phase A1, Baseline; Phase B, Intervention; Phase A2, Follow-up.

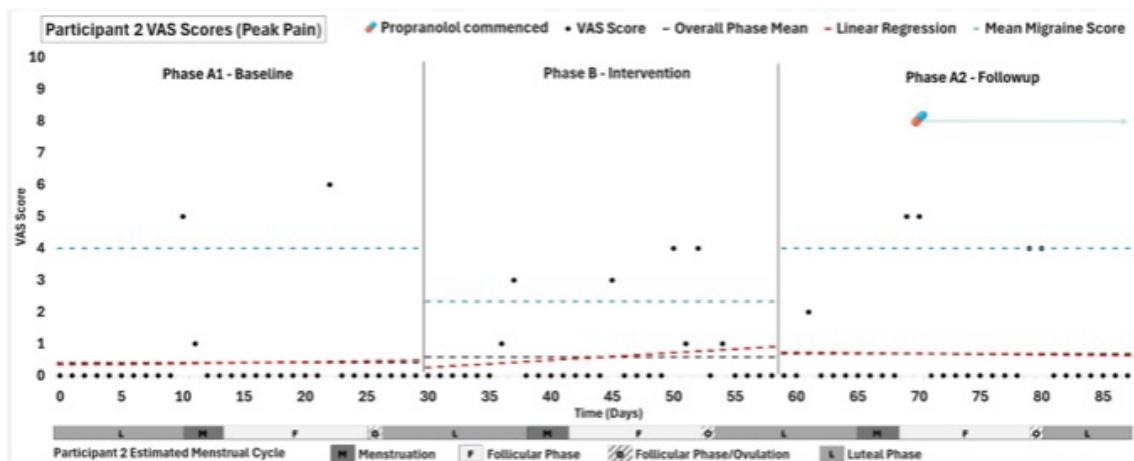


Figure 2. Participant Two, Daily Diary Data across three study phases showing level (overall phase mean), mean migraine peak VAS scores and trend (linear regression). Phase A1, Baseline; Phase B, Intervention; Phase A2, Follow-up.

Participant One (see Figure 1) experienced four migraine-affected days, with a mean peak pain intensity of 5.75 out of 10. There was a slightly negative regression line trend; however, this did not indicate baseline instability. The regression line showed a marginally positive trend during the intervention phase, with five migraine-affected days noted. This is not considered meaningful, with no further accumulation of symptoms throughout Phase B, indicating continued stability of symptoms. The steeper positive trend in the A2 follow-up phase can be attributed to the 18-day consecutive period without migraine following cessation of treatment. Revisiting baseline data, we note extended periods of migraine-free days, indicating a return to baseline frequency trends. Mean VAS pain intensity (average and peak) increased across phases (see Table 2). A2 follow-up phase

elevated pain scores may also align with a COVID-19 diagnosis within this period, which the participant attributed to higher-than-usual pain levels.

Table 2. Mean VAS scores for each phase (A1, B, A2) for Participant One and Participant Two, showing overall phase mean and migraine episodes only (not including zero scored days) peak and average scores.

		Participant 1			Participant 2			
		Phase A1	Phase B	Phase A2	Phase A1	Phase B	Phase A2	
VAS Score	(Average Pain)	Baseline	Interventi	Follow-Up	Baseline	Interventi	Follow-	
Overall								
VAS Score	(Average Pain)	Phase Mean	0.33 (1.54)	1 (2.28)	0.67 (2.00)	0.31(1.06)	0.31 (0.71)	0.38 (1.05)
		(SD)						
'AS Score	'Peak Pain)	Migraine						
		Only Mean	4.75 (1.89)	5.6 (1.67)	6.67 (0.58)	3 (2.00)	1.17 (0.84)	2.2 (1.64)
(SD)								
Overall								
'AS Score	'Peak Pain)	Phase Mean	0.59 (1.78)	1.29 (2.83)	0.77 (2.31)	0.41 (2.64)	0.59 (1.24)	0.69 (1.61)
		(SD)						
'AS Score	'Peak Pain)	Migraine						
		Only Mean	5.75 (1.26)	7.2 (0.84)	7.5 (0.58)	4 (1.43)	2.33 (1.40)	(1.22)
(SD)								

Participant Two (see Figure 2) experienced three migraine-affected days in the baseline phase, with a mean peak pain intensity of four out of 10. As evident in the flat regression line, there was no apparent baseline instability. There was an accelerating trend during the intervention phase, with an increase in migraine-affected days to seven compared to the baseline. Mean VAS pain intensity scores (both average and peak) showed improvement during the intervention phase, with lower pain intensity levels than the A1 baseline but returned to baseline levels during the A2 follow-up phase (refer to Table 2). A new migraine medication was initiated during the follow-up phase. Still, we are confident that this did not influence our results, considering the time needed for the medication to reach therapeutic levels.

3.3. Daily Outcomes- Tau U Statistical Analysis

Tau-U values for baseline trend analysis for Participants One and Two were $U = 0.05$, $p = 0.69$ and $U = -0.0074$, $p = 0.96$ respectively. This indicates that there was no baseline trend, and therefore no baseline correction was required for either participant (threshold for correction >0.40) [24].

The Tau-U analysis did not provide evidence of non-overlap ($p > 0.05$) between the baseline and intervention phase data for both participants. This is consistent with the visual analysis, which suggests that migraine was not phase dependent.

For Participant 1, phase non-overlap tests relating baseline and intervention, intervention and follow-up, and baseline and follow-up were $U = 0.12$ ($p=0.45$), $U = -0.11$ ($p=0.35$), and $U = -0.03$ ($p=0.83$), respectively. Similar results were seen for Participant 2, where baseline and intervention $U=0.13$ ($p=0.41$), intervention and follow-up $U= -0.04$ ($p=0.79$), and baseline to follow-up $U= 0.07$ ($p=0.69$).

Pooled data weighted average $U= 0.012$ ($p = 0.81$).

3.4. Adherence to Protocol, System Usability (SUS) and Global Perceived Effect (GPE)

Participant 1 showed high adherence to daily meditation at 92.8% (completing 26/28 sessions). However, they demonstrated low adherence at both migraine onset (0% adherence 0/5 sessions) and at peak pain (20% adherence 1/ 5 sessions). Participant 2 demonstrated 89.7% adherence to daily meditation (completing 26/29 sessions), with 42.9% adherence (3/7 sessions) at migraine onset and 14.2% adherence (1/7 sessions) at peak pain. Both participants had high usability scores (Participant 1=81.67/100, Participant 2=85/100).

GPE results showed Participant 1 reported “fairly good improvement”, while Participant 2 reported “no change”.

3.5. Pre- and Post-Intervention Secondary Outcome Measures.

Descriptive data is depicted in Table 3. Both Participants exhibited no meaningful clinical change pre-post-intervention as per the thresholds outlined by Speck, Yu [25] for MSQoL 2.1 assessments.

The DASS scores for anxiety and stress remained stable (both within the ‘mild’ range) pre- and post-intervention for Participant One. However, the depression score increased, resulting in a shift from the ‘normal’ to ‘mild’ category (Lovibond & Lovibond 1995). While Participant Two experienced changes within subscale scores, they all remained within the ‘normal’ category. See Table 3.

Table 3. Pre- and Post-Intervention Secondary Outcome Measures for Participant One and Participant Two.

Participant 1						Participant 2						
MSQ 2.1			DASS-21			MSQ 2.1			DASS-21			
	RF-R	RF-P	EF	D	A	S		RF-P	EF	D	A	S
Pre-	65.72	37.14	31.42	6	8	16	77.14	40	22.86	2	6	4
Post-	48.57	25.72	34.29	10	8	16	62.86	42.86	22.86	4	4	10
Difference	17.15	11.42	-2.86				14.28	-2.86	0			

4. Discussion

This study aimed to explore the feasibility, usability, and potential benefits of home-based VR-delivered meditation as a non-pharmacological adjunct in migraine management. Overall, usability was high, and daily meditation was feasible, with high adherence rates. However, participants did not reliably use VR during migraine attacks and there were no meaningful indicators of potential benefit. While meditation alone has been shown to be helpful for the treatment of migraine[8,26], the current case reports provide detailed insight into the challenges of applying VR-based meditation in this population. Although the study design precludes drawing a conclusion, it provides preliminary evidence suggesting that VR meditation may have limited utility in this population.

4.1. Feasibility and Usability

4.1.1. Feasibility

Overall, the daily intervention component appeared feasible, with high adherence rates for the daily meditation. The use of VR during migraine onset and peak pain, however, was low. Participant

One faced logistical constraints in carrying and accessing the HMD around work and study. This resulted in a 0% adherence rate for use at the initial onset of symptoms and very low utilisation at peak pain for Participant One. Participant Two showed slightly better, yet still low, adherence at both onset and the same adherence at peak pain.

Challenges in adhering to treatment during peak pain in migraine episodes may also stem from difficulties with participants accurately identifying when peak pain occurs. The wording used in the diary VAS scoring may play a role in this issue. According to a study by Tin et al., the wording of anchors can impact patients' ability to accurately assess peak pain in patient-reported outcomes. For example, the anchor text "worst pain imaginable" suggests the use of imagination, which may not be ideal as it requires participants to use cognitive skills to evaluate symptom severity. The study suggests that anchors such as "extremely severe pain" have better psychometric properties and may provide a more reliable assessment of pain intensity [27]. Therefore, it is reasonable to consider that modifying the language used in patient-reported outcomes could potentially enhance study fidelity.

4.1.2. Usability

Overall, participants reported high usability of the VR platform according to the system usability scale [28], with both reporting scores over 80/100 (indicating above-average user experience [28]). However, it is worth noting that both participants had significant computer game experience and showed proficiency with the VR equipment with little external support. Less proficient users would likely report less favourable acceptance, and these reports of usability should not be generalised. Future work should address the limitation by recruiting VR/gaming naïve participants from diverse populations.

4.2. Potential for Benefit

4.2.1. Migraine Frequency and Intensity

Visual and statistical analysis of the data from both participants provided no evidence that regular VR meditation could decrease migraine frequency. Participant One experienced an increase of one migraine-affected day during the intervention phase but returned to baseline levels during the follow-up period. She also reported slightly higher VAS scores during the intervention and follow-up periods compared to baseline. However, during the follow-up period, the participant associated higher-than-usual pain levels with a diagnosis of COVID-19.

During the intervention phase, Participant Two's frequency of migraine-affected days increased from three to seven, with one migraine lasting three days (while the baseline maximum duration was two days). There were five migraine-affected days during the follow-up period, two more than the baseline period. Although we cannot confidently attribute this increase in migraine to the use of VR, it is possible that this was an adverse effect. The weight and pressure of the head-mounted display on the head, face and neck, along with abnormal visual stimulation, could have contributed to negative effects. Participant Two appeared to have less intense migraines following the baseline phase. However, given the apparent increase in frequency, this could not be reasonably viewed as an indicator of potential improvement.

4.2.2. Global Perceived Effect

Despite the apparent null, or even adverse, response to VR meditation shown in primary outcomes, Participants One and Two reported "fairly good improvement" and "no change", respectively, on a rating of Global Perceived Effect. While neither rating can be taken as an indication of effectiveness, they do assist in interpreting the primary outcomes. That is, they both suggest that any apparent increase in migraine frequency or intensity was not perceived as meaningful.

4.2.3. Contribution to the Literature

There is scant literature investigating VR for migraine. One prior study, in 50 people with migraine, investigated the use of a VR-based biofeedback intervention [29] and observed significant

reductions in analgesic use and depression scores in the experimental group compared to the control group[29]. While these interventions are not comparable, since VR in the previous study may be viewed as simply the intervention delivery strategy and not the intervention itself [30]. Nonetheless, this previous work suggests that VR can be applied safely in this population without increasing overall migraine exacerbation. However, a key difference between this past work and the current study is the VR dose. Here, we employed daily VR meditations, whereas the Cuneo et al. protocol applied VR three times per week. A potential relationship between the frequency of VR use and migraine exacerbation should therefore be considered in future work.

4.2.5. Limitations

Case series, particularly those with small numbers of participants, provide only preliminary evidence for the efficacy of novel interventions. As such, while we did not detect any signals of potential benefit, we are limited in our ability to draw any firm conclusions [31] and it may be premature to close this avenue of research altogether. Indeed, it is possible that subgroups of people living with migraine may benefit more than others and that different types of VR meditation and dosages may be more effective than others [14].

Moreover, as technology progresses, issues such as physical discomfort (i.e. from the weight of the VR headset) and visuo-motor incongruence will improve, reducing their potential negative influence. While there were positive indications around usability and feasibility, we cannot generalise these results to a broader population. That is, while technology usability and daily VR meditation adherence appeared excellent, the participants already had high technology proficiency. However, patients, like research participants, may self-select interventions/research based on interest and even an intervention that only suits technology-proficient individuals may be worth pursuing, provided that participant proficiency with technology is measured and included in research reporting.

A further limitation of this study is that VR meditation was delivered as an isolated intervention, devoid of the education and clinical support often delivered concurrently with meditation-based interventions. For example, mindfulness meditation is not just a relaxation strategy but a space for rehearsing tools such as mindful presence, cognitive diffusion, and attentional control that assists in supporting more sustained stress-reducing effects. Future studies exploring VR meditation may seek to integrate these strategies to create a comprehensive intervention. This could facilitate the use of these skills outside the virtual environment, improving their utility.

Conclusion and Future Implications

This dual SCED is a novel exploration of VR-based interventions for migraine. While VR usability was high and participants partially adhered to the protocol, the intervention did not significantly reduce migraine pain intensity or frequency. Nonetheless, this study provides important insights, such as the potential for high-frequency VR use to increase migraine frequency, informing future investigations. Future research may aim to gradually introduce regular VR meditation, trial different forms of meditation and combine them with other strategies, explore dose-response relationships, and recruit larger samples.

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Data availability: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Conflicts: The authors declare no conflicts of interest.

Ethical approval and consent: Ethics was approved on the 11th of November, 2023, by the University of South Australia Ethics Committee (Application ID: 205629). All participants were over 18 years of age and gave written informed consent.

Competing Interests and Funding: The authors confirm that they have no conflicts of interest.

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