INTRODUCTION

Temporomandibular disorder (TMD) is a musculoskeletal disorder that affects masticatory structures. TMD is the most common cause of oro-facial pain of non-dental origin.1 The age group in which TMD is more prevalent is 20–40 years. The commonly reported areas of pain in TMD are masseter muscle, periauricular area, and/or anterior temporalis muscle regions.2,3 TMD has adverse effects on the functioning of the jaw and the affected patients have difficulty in opening the mouth.4,5 Further, higher levels of stress and poor sleep quality have been reported in patients with TMD.6 Pharmacological therapy may relieve the pain temporarily, but is associated with side effects. Further, psychological aspects like stress, anxiety may increase the intensity of the pain. Hence,
the management of pain is an arduous task for clinicians and dentists. Vestibular system is basically a structure that maintains the Posture and equilibrium. It is labeled as sixth sense as it is involved in various functions from the level of reflexes to the level of cognition and coordination. In historical view, vestibular stimulation was applied through hanging beds to relieve pain and induce sleep by Greek physicians. Vestibular stimulation has been suggested as a cure for many clinical disorders, including sleep, mood disorders, chronic pain, Schizophrenia, neuronal development, and neurodegenerative disorders. Vestibular system possesses more than 18500 neuronal connections to and fro with cortical and sub cortical structures. Stimulating the vestibular system relieves pain through modulating the sensitivity of touch and pain which is similar to gate control mechanism, stimulating the thalamus, cerebellum, dorsal raphe nucleus, periventricular nucleus, and inhibiting the attention areas. Further, vestibular stimulation also relieves negative emotions such as stress, anxiety, and depression and promotes sleep. Earlier studies have reported a high success rate in the management of migraine and chronic post-stroke pain through vestibular stimulation. It was hypothesized that electrical vestibular stimulation may be an effective adjunctive therapy in the management of TMD. The aim of the present study was to assess the effectiveness of electrical vestibular nerve stimulation (VeNS) in the management of pain in patients with temporomandibular disorders.

Aims and objectives
The aim of the present study was to assess the effectiveness of electrical vestibular nerve stimulation (VeNS) in the management of pain in patients with temporomandibular disorders.

MATERIALS AND METHODS

Study design
The present study was a pilot study. After recording the baseline values, electrical VeNS was administered as adjunctive therapy along with routine treatment to the intervention group. Placebo stimulation was administered to the control group along with the routine therapy. Post-intervention values were recorded after 4 weeks of the intervention and compared.

Study setting
The present study was conducted at the Department of Physiology in collaboration with the Department of General Medicine at R. D. Gardi Medical College, Ujjain, Madhya Pradesh, India.

Study participants
A total of 24 male and female participants newly diagnosed with TMD were recruited after obtaining the written informed consent. The recruitment of the participants was based on the following inclusion and exclusion criteria.

Inclusion criteria
Male and female participants within the age group of 20–40 years, having pain in temporomandibular joint (TMJ) with a minimum score of 6–8 on a numerical pain rating scale and reduced mouth opening (3–5 mm) and willing to participate were included in the study.

Exclusion criteria
Patients with a history of trauma, dislocation of the TMJ, vestibular disorders, ear disorders, and any other clinical complications or disorders were excluded from the study. Pregnant women were also excluded from the study.

Pre-enrollment screening
The participants were assessed for TMD that includes a general examination of the head and neck, a detailed examination of the masticatory muscles, an evaluation of the TMJs, and evaluation of the mandibular range of motion, and a detailed intraoral examination. The examination was carried out by qualified physicians and dentists respectively.

After recruiting the participants, they were randomly assigned into two groups with 12 participants in each group. Treatment assignments were generated via a randomized block procedure, with block sizes were randomly chosen in the set {2, 4, 6, 8, 10}. Participants were assigned randomly 1:1 between treatment and control groups. There was no exclusion from the study on the basis of race, gender, socioeconomic status, language spoken, or ethnicity.

Group A: Control group (n=12): Placebo stimulation along with regular treatment
Group B: Intervention group (n=12): Electrical VeNS along with regular treatment

Electrical VeNS
VeNS was administered for 4 weeks. Each daily session was for an hour (1 h), with three sessions being carried out each week. Bilateral application of electrical VeNS using a battery-powered vestibular nerve stimulator (ML1000, Neurovalens, UK) was practiced. It consists of a headset, electrode pads, and skin swabs. The power button helps to turn on the device. The intensity of the stimulation can be controlled manually by the subject using either the buttons on the device or through the Bluetooth mobile app. The electrodes are placed over each mastoid process after cleaning the area with a swab, and then through a gentle electrical pulse, the vestibular nerves get stimulated.
Power analysis and sample size estimation
As there are no studies in the literature in this area, the pilot study sample size is fixed as 24 that is 12 participants per group as suggested by Julious (2005).13

Outcome measures
Assessment of pain
Pain was assessed using a numerical pain rating scale. The participants were asked to circle the numbers between zero and ten where the zero represents “no pain at all” and ten represents “the worst pain ever possible.”

Assessment of jaw function limitation (JFLS-8)
The JFLS-8 is a short form for measuring the global functional limitation of the jaw.16 It comprises eight conditions where the participant has to respond on a 10 point scale. Zero represents no limitation and ten represents a severe limitation.

Assessment of depression, anxiety, and stress
The DASS-21 questionnaire is comprised of three self-reported scales to measure negative emotional states of depression, anxiety, and stress. Each scale has seven items. Participants will be asked to respond to 21 items based on a 4-point scale from 0=did not apply to all to 3=applied very much, to grade the extent of the items applied to them over the past week. DASS’s final score will be obtained by summing all items in each scale and multiplying it by 2. High scores indicated increased severity of depression, anxiety, and stress respectively.17

Ethical considerations
The study protocol was approved by the Institutional human ethical committee of R. D. Gardi Medical College, Ujjain. (IEC Ref No:01/2020. Date of approval 18/03/2020)

Statistical analysis
Data were analyzed using SPSS 20.0. Student t-test was used to observe the difference between the pre and post-values. P<0.05 was considered statistically significant.

RESULTS
Results are presented in Tables 1 and 2. Age, height, weight and, BMI were not significantly different between the control and intervention groups (Table 1). There was a significant decrease in the pain score in the intervention group when compared with the control group (P<0.001). Jaw function score was significantly improved followed by the intervention in the intervention group (P<0.001). Depression scores were significantly decreased followed by the intervention in the intervention group (P<0.001). Stress scores were significantly decreased followed by the intervention in the intervention group (P<0.001).

DISCUSSION
The aim of the present study was to assess the effectiveness of electrical VeNS in the management of pain in patients with temporomandibular disorders. Results are presented in Tables 1 and 2. Height, weight and, BMI were not significantly different between the control and intervention groups (Table 1). There was a significant decrease in the pain score in the intervention group when compared with the control group (P<0.001). Jaw function score was significantly improved followed by the intervention in the intervention group (P<0.001). Depression scores were significantly decreased followed by the intervention in the intervention group (P<0.001). Stress scores were significantly decreased followed by the intervention in the intervention group (P<0.001). Anxiety scores were significantly decreased followed by the intervention in the intervention group (P<0.001).

Managing pain is always a herculean task in the medical field. Further, the negative emotional aspects involved like depression, anxiety, and stress increase the intensity of pain and also affect the outcome. Hence, the management methods should not only target pain relief but also should reduce the negative emotional aspects such as depression, anxiety, and stress.

The vestibular system develops early in fetal life and gets stimulated due to shifting of the amniotic fluid when the mother is walking. The same stimulation should be maintained throughout his life for homeostasis. In fact, the vestibular system is the important sensory system that can influence all vital functions. It was reported that vestibular stimulation increases the body’s sensitivity to tactile sensation and decreases the sensitivity to pain which is called sensory modulation. It was reported that vestibular stimulation has an inhibitory effect on the area of attention and altering the attention relieves pain. Prominent connections were established between the thalamus and the vestibular system. It is well known that thalamic stimulation is used to relieve pain. Vestibular stimulation is known to stimulate the vagal nerve fibers and relieve pain. Vestibular stimulation activates the dorsal raphe nucleus and causes the release of serotonin and norepinephrine and causes inhibition of the lamina of the spinal cord where the pain pathway passes through.

It was reported that vestibular stimulation activates the cerebellum and relieves pain through cerebellar pathways. Vestibular stimulation not only relieves pain but also relieves negative emotions such as depression, anxiety,
and stress and also promotes sleep. This multimodal effect of vestibular stimulation is highly beneficial in the management of pain.

Limitations of the study
This initial pilot study has provided valuable insights into the use of vestibular nerve stimulation for the use of pain management, however, further studies with larger sample sizes are recommended.

CONCLUSION
The study introduced new technology that is electrical VeNS for the management of pain. Electrical vestibular stimulation is effective in the management of pain and decreases the negative emotions that are depression, anxiety, and stress, and improves sleep quality in patients with temporomandibular disorders. The study recommends further detailed studies in this area to recommend electrical vestibular stimulation as adjunctive therapy for the management of pain.

ACKNOWLEDGMENT
Our sincere thanks to Dr. Jason McKeown, CEO of Neurovalens for providing the electrical vestibular nerve stimulators to our study. We also thank all the participants of the study for their support throughout the study. Special thanks to our Dean, R.D.Gardi Medical College for providing all required resources to accomplish the study.

REFERENCES

Table 1: Demographic characteristics of the participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Intervention Group</td>
<td>12</td>
<td>39.92</td>
<td>8.49</td>
<td>−0.355</td>
<td>0.726</td>
</tr>
<tr>
<td></td>
<td>Control Group</td>
<td>12</td>
<td>41.25</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>Intervention Group</td>
<td>12</td>
<td>69.06</td>
<td>10.44</td>
<td>0.047</td>
<td>0.963</td>
</tr>
<tr>
<td></td>
<td>Control Group</td>
<td>12</td>
<td>68.88</td>
<td>8.74</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>Intervention Group</td>
<td>12</td>
<td>163.42</td>
<td>7.62</td>
<td>−0.146</td>
<td>0.886</td>
</tr>
<tr>
<td></td>
<td>Control Group</td>
<td>12</td>
<td>163.92</td>
<td>9.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>Intervention Group</td>
<td>12</td>
<td>26.11</td>
<td>5.31</td>
<td>0.080</td>
<td>0.937</td>
</tr>
<tr>
<td></td>
<td>Control Group</td>
<td>12</td>
<td>25.94</td>
<td>4.92</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Pain score, Jaw functional score, depression, anxiety, and stress in participants before and after the intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>N</th>
<th>SD</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score before</td>
<td>9.42</td>
<td>12</td>
<td>0.79</td>
<td>13.266</td>
<td>0.000***</td>
</tr>
<tr>
<td>Pain score after</td>
<td>5.42</td>
<td>12</td>
<td>0.51</td>
<td></td>
<td>0.027</td>
</tr>
<tr>
<td>Depression score before</td>
<td>9.67</td>
<td>12</td>
<td>0.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression score after</td>
<td>9.08</td>
<td>12</td>
<td>0.51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaw function score before</td>
<td>66.92</td>
<td>12</td>
<td>3.80</td>
<td>15.204</td>
<td>0.000***</td>
</tr>
<tr>
<td>Jaw function score after</td>
<td>29.42</td>
<td>12</td>
<td>5.65</td>
<td></td>
<td>0.002</td>
</tr>
<tr>
<td>Depression score before</td>
<td>18.00</td>
<td>12</td>
<td>3.44</td>
<td>5.715</td>
<td>0.000***</td>
</tr>
<tr>
<td>Depression score after</td>
<td>9.67</td>
<td>12</td>
<td>3.45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety score before</td>
<td>12.42</td>
<td>12</td>
<td>1.98</td>
<td>6.691</td>
<td>0.000***</td>
</tr>
<tr>
<td>Anxiety score after</td>
<td>6.75</td>
<td>12</td>
<td>1.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress score before</td>
<td>13.42</td>
<td>12</td>
<td>3.03</td>
<td>1.328</td>
<td>0.211</td>
</tr>
<tr>
<td>Stress score after</td>
<td>12.50</td>
<td>12</td>
<td>3.21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress score before</td>
<td>14.33</td>
<td>12</td>
<td>2.40</td>
<td>2.90</td>
<td></td>
</tr>
<tr>
<td>Stress score after</td>
<td>24.17</td>
<td>12</td>
<td>2.81</td>
<td>12.988</td>
<td>0.000***</td>
</tr>
<tr>
<td>Stress score after</td>
<td>20.83</td>
<td>12</td>
<td>4.30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

***P<0.001 is significant
Kumar, et al.: Electrical vestibular nerve stimulation in the management of pain

https://doi.org/10.1016/j.cden.2006.10.002


Authors' Contributions:
SSKG-Concept and design of the study, data acquisition, interpreted the results, reviewed the literature and manuscript, and prepared first draft of manuscript.
NG- Statistical analysis and interpretation, NK, AC and SG - data acquisition, preparation and editing of manuscript; and RSC, DSC and MVK- Reviewed the literature and manuscript.

Work attributed to:
R. D. Gardi Medical College, Ujjain - 456 001, Madhya Pradesh, India

ORCID ID:
Dr. Sai Sailesh Kumar G - https://orcid.org/0000-0002-5838-3994

Source of Funding: The devices used in this study were provided by Neurovalens (Belfast, UK), Conflicts of Interest: None.