EFFECTS OF LIFESTYLE MODIFICATION ON VESTIBULAR MIGRAINE

*Richard A. Roberts, †Kenneth E. Watford, *Erin M. Picou, *Kelsey Hatton, †Timothy H. Trone, and †Emily Y. Brignola

Affiliations:
*Department of Hearing and Speech Sciences; †Department of Otolaryngology-Head and Neck Surgery, Vanderbilt University Medical Center, Nashville, TN

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Corresponding Author:

Richard A. Roberts, 1215 21st Avenue South, Suite 9318, Nashville, TN 37232-8025, Phone: 615-322-7384, Fax: 615-343-4692, Email: richard.a.roberts@vanderbilt.edu

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Introduction

Vestibular migraine (VM) is the most frequently encountered cause of episodic vertigo, having prevalence rates from 7 – 16% in clinics serving patients with dizziness and imbalance. Importantly, not only is VM common but nearly 70% of patients diagnosed with VM rated their symptoms as having a moderate to severe impact on health-related quality of life (HRQOL). The criteria for definite VM were formalized by the International Headache Society and the International Barany Society more recently, although alternative terms such as migraine-associated dizziness, migraine-related dizziness, and migraineurs with dizziness were used prior to consensus to diagnose patients with presumed VM. Within the current investigation, we will use VM as defined by the consensus groups.

The suggested interventions for VM have overlap with intervention for other types of migraine and include lifestyle modification and medications, either in isolation or in combination. Although many reports of VM management focused on treatment with medications, there is also evidence symptoms can be improved with interventions that involve lifestyle modifications including dietary restrictions, exercise, and sleeping recommendations. Collectively, the extant literature demonstrates improvement in symptoms using lifestyle modifications alone in 11 – 16% of patients with VM. However, these studies are limited in number and are predominantly retrospective.

It is unsurprising that lifestyle modification would improve symptoms of VM. There is sufficient evidence in the literature that lifestyle modification is beneficial for non-VM forms of migraine that we will refer to collectively as migraine. Migraine symptoms have been shown to improve in 63-93% of patients through dietary interventions and in 48.9% of patients through cognitive behavioral therapy to treat insomnia. Conversely, missing meals or fasting has been reported to trigger migraines in as many as 57% of migraineurs. Finally, low-level physical activity and exercise has been shown to reduce migraine symptoms. However, avoidance of dietary triggers, restful sleep, mealtime regularity, and exercise have not yet been systematically investigated as a comprehensive approach to management of symptoms of VM.

More work is needed to prospectively determine the outcomes of lifestyle modification on VM. As noted, VM accounts for a large percentage of individuals affected by symptoms of dizziness and imbalance. It is also important to understand the effects of lifestyle modification on VM to assist with evaluation of other interventions, including pharmacological ones. The purpose of the current investigation was to prospectively evaluate the effects of common lifestyle modifications on symptoms of dizziness and headache in patients diagnosed with definite VM.

Materials and Methods

Design and Participants

Participants were recruited from patients seen for consultation for dizziness and/or imbalance in the John S. Odess Otolaryngology and Head and Neck Surgery Clinic. Consultations were provided by two nurse practitioners and one otolaryngologist. All clinicians were experienced in diagnosis and management of dizziness and imbalance including VM. All adult patients diagnosed with definite VM using the consensus criteria were eligible for inclusion. Patients who were determined to need pharmacological management at initial consultation were excluded.

Forty-one patients were consented and enrolled as participants. Thirteen (31.7%) of the participants did not complete this investigation for the following reasons: seven requested pharmacological intervention during the experimental period and were withdrawn, one was diagnosed with Rocky Mountain Spotted Fever and withdrawn, and five were lost to follow-up. Twenty-eight participants (68.3%) completed the investigation. Analysis was performed for the 28 participants with completed data sets. Mean age was 46.4 years (standard deviation = 16) and participants were 78.6% female.

Study Materials

Participants completed the Dizziness Handicap Inventory (DHI), Headache Disability Inventory (HDI), and lifestyle scale (Table 1) prior to and again after lifestyle modification intervention. The DHI and HDI are 25-item self-report tools that examine impact of dizziness symptoms and headache symptoms on HRQOL. Lower total scores indicate less impact of the symptoms on HRQOL. The lifestyle scale was developed for this study to gain an understanding of self-perceived restful sleep, mealtime regularity, exercise, and avoidance of dietary triggers. Participants indicated their level of agreement with each statement using a 5-point Likert scale. Higher scores indicated better self-perceived compliance with the lifestyle component.

Procedures

Data were collected either paper/pencil or using an online Redcap survey, depending on participant preference and in-person COVID-related limitations. Participants completed the DHI, HDI, and lifestyle scale during a clinic appointment before and after the intervention. On average, participants completed post-intervention surveys after 105 days (standard deviation = 78.1).

Intervention

The intervention addressed four areas related to lifestyle modification that have been shown to be effective in at least some patients with VM or with migraine. These areas were restful sleep, mealtime regularity, exercise, and elimination of dietary triggers. The diagnosing clinicians provided a four-page handout (see supplemental digital content) with information about each area after their diagnosis and after the patient completed the informed consent process.

For restful sleep, we provided helpful tips adapted from the National Institute on Aging. To bring focus to mealtime regularity, the handout provided informational statements that skipping or missing meals can lead to symptoms and the participant should prepare ahead to ensure they are eating on a schedule. We also encouraged participants to continue or resume a preferred exercise program or start some type of formal exercise. A sample walking program from the National Heart, Lung, and Blood Institute[25] was adapted and provided along with the caveat to only begin such a program if medically cleared. Finally, we combined information from published research[16] and other publicly available resources to develop a comprehensive elimination list of potential dietary triggers. Participants were asked to follow this four-part intervention until follow-up, with an initial goal of at least 60 days.

Statistical Methods

Scores on the lifestyle scale were analyzed using linear mixed-effects models with two within-participant factors, Intervention (pre-intervention, post-intervention) and Lifestyle Factor (restful sleep, exercise, mealtime regularity, avoiding dietary triggers).

Scores on the two handicap inventories, DHI and HDI, were also analyzed using linear mixed-effects models with two within-participant factors, Intervention (pre-intervention, post-intervention) and Inventory (DHI, HDI). For all models, participant was included as a random factor. Models were constructed using the *lmer* function of the *lme* package in R and were analyzed using the *anova* function in base R. Significant main effects and interactions were evaluated using the *emmeans* function of the *emmeans* package. Pairwise comparisons were adjusted to account for false-discovery rates.

Inter-individual variability in pre- to post-intervention scores were analyzed by calculating change scores (subtracting post-intervention from pre-intervention scores [DHI and HDI] or subtracting pre-intervention from post-intervention scores [lifestyle scale]). Two linear mixed models were constructed, one for each inventory, with the change scores as the dependent variable. Independent variables were participant sex, age, and lifestyle change score for each lifestyle question. Models were constructed and analyzed with the *lmer* and *anova* functions, respectively.

Finally, to determine individual participant post-intervention change, we compared pre- and post-total scores for the DHI and HDI. On the DHI, a change of 18 points is considered significant. For the HDI, a change of 29 points is considered significant.

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Richard A. Roberts, Ph.D. Revision Date: 08/19/2019
Study Title: Effects of Lifestyle Modification on Vestibular Migraine
Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to adults who have been diagnosed with vestibular migraine.

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. What is the purpose of this study? You are being asked to take part in this research study because you have been diagnosed with vestibular migraine.
Vestibular migraine is one of the most common causes of dizziness and imbalance. The exact reason(s) people have vestibular migraine are unknown but researchers and medical professionals agree that vestibular migraine is different from other types of migraine. Treatment for vestibular migraine can be with medications and/or lifestyle modifications. This is done for vestibular migraine because these types of treatments are effective with most migraine. There are studies that show lifestyle modifications alone are helpful for many patients with migraine and this is often recommended for patients with vestibular migraine. However, no one has studied the effects of lifestyle modification alone on vestibular migraine. We are conducting this research study to find out if lifestyle modifications help decrease dizziness and headache in patients with vestibular migraine. If you decide to participate in this study, you will answer some questions about dizziness and headaches. Then, you will be provided with a written plan to follow for 60-days. When you return for your regularly scheduled follow-up appointment, you will again answer questions about dizziness and headache. It is possible that participation may cause you to change the things you eat and drink and could cause some inconveniences like changing your habits regarding sleeping and exercising. There is no expected risk for participation and you may experience decreased dizziness and headache. This is standard of care for treatment of migraine and vestibular migraine. Alternative treatment includes medication but that is not the purpose of the current investigation.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

2. Procedures to be followed and approximate duration of the study: If you agree to participate in this study, you will answer some questions about dizziness and headache. You will also answer questions about eating certain foods, sleep, exercise, and times of the day when you eat. We expect it will not take longer than 15 minutes to complete these questions. These are all factors that can be modified to help many patients with migraine. We think modifying these will also help patients with vestibular migraine.

We will provide you with a written plan to follow during the 60-days of this program. The plan will also be discussed with you so any questions can be answered.

We will ask you to:

- avoid certain foods and drinks that tend to cause migraine in some people
- follow good sleep hygiene tips so that you experience restful sleep
- start walking for exercise if you have no other exercise plan in place
- eat your meals at the same time every day.

It is important that you follow this plan for 60 days (two months).

Please continue to take all the medications prescribed by all of your doctors for all of your health issues. You should continue to take all medications you usually use for any migraine activity, dizziness, or nausea.

When you return for your regularly scheduled 2-month follow-up appointment, we will ask you the same questions that we asked before you started this treatment plan. This will help us determine if your vestibular migraine feels better, worse, or the same.

We will also collect some information about you and your medical history from your medical record. This may include balance function test results, age, gender, hearing test results, etc. We will not store any of this information in a way that would allow others to know your identify. We will maintain your privacy at all times.

3. Expected costs: Your travel, time, and typical medical costs are the same if you choose to participate or choose not to participate. There are no costs for this treatment plan.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study: Many people with

migraine benefit from avoiding eating and drinking things that trigger their migraine activity. Many people with migraine are helped by getting restful sleep, by exercising, and by eating at the same time during the day. We are attempting to determine if these same activities also help people with vestibular migraine. It is possible that you may be inconvenienced by some of these modifications. For example, you may need to plan ahead to make sure you can eat at the same time during a busy day. You may have disruption to your typical schedule by adding walking exercise. You may have changes in your activity schedule so that you can go to sleep at the same time and wake at the same time every day. You may be annoyed by not being able to eat or drink your favorite thing during the plan.

If you usually consume caffeine and stop suddenly, you may experience headache associated with caffeine withdrawal.

There is a chance of confidentiality breach. However, we are going to take every precaution to ensure your privacy is protected. Your information and data will only be available to key study personnel and will be kept in a locked, secure location.

5. Unforeseeable risks: If you usually consume caffeine and stop suddenly, you may experience headache associated with caffeine withdrawal. This has been reported to cause a migraine in some people. If you have health conditions that would keep you from exercising or starting to walk for exercise then you should consult with your primary physician prior to starting any type of exercise program.

6. Compensation in case of study-related injury: If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the treatment done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study: a) The benefits to science and humankind that might result from this study. A better understanding of vestibular migraine and its treatment. **b) The benefits you might get from being in this study.** Your vestibular migraine may be improved by the treatment.

8. Alternative treatments available: Some patients with vestibular migraine are treated with medications. That is not the purpose of the current investigation. You also have the alternative to not participate in this study.

9. Compensation for participation: Participants who complete the initial questions will receive a $25 gift card. Patients who complete the second set of questions in 60-days will receive a second $25 gift card.

10. Circumstances under which the Principal Investigator may withdraw you from study participation: If information through our study or other published studies indicates symptoms worsen with this treatment, you will be withdrawn from participation. You will be informed of the reason if you are withdrawn from this study.

11. What happens if you choose to withdraw from study participation: We will discard all data collected at this visit if you choose to withdraw from participation. This will not affect your previous or future appointments in our clinics, and you may withdraw for any reason at any time without penalty.

12. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact Richard A. Roberts, Ph.D. at 615-322-7384. His mailing address is Vanderbilt Bill Wilkerson Center: Medical Center East South Tower, 1215 21st Ave South, suite 9318, Nashville, TN 37232. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry: A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

14. Confidentiality: All reasonable efforts will be made to maintain the confidentiality of your personal information as well as your study data. Data will be de-identified and kept in a secure location. Access will be limited to the Study PI and key study personnel only. This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. Study Results: Results from this investigation will not be individually shared with participants. However, results are expected to be presented at scientific meetings and published in scientific journals which does allow for access.

16. Authorization to Use/Disclose Protected Health Information. What information is being collected, used, or shared? To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and

all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol, or STD treatment, genetic test results, or mental health treatment).

Who will see, use, or share this information? The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this authorization? You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared? Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related research studies.

What if you change your mind? You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your Authorization.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You may request a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY
I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____	_____
Date	Signature of patient/volunteer

Consent obtained by:

_____	_____	
Date	Signature	Printed Name and Title