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VALIDATION OF ANTI-KINETOSE READING GLASSES IN VEHICLES: RANDOMIZED CLINICAL TRIAL

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Letícia de Queiroz Cunha[a,b]*, Laércio José de Oliveira Filho[a], Anne Isabelle Nogueira de Araújo[b], Amália Cinthia Menezes do Rego[a,b], Irami Araújo Filho[a,b,c], Kleyton Santos de Medeiros[b], Francisco Irochima Pinheiro[a,b,c]

Potiguar University – UNP, Natal – RN, Brasil[a]
Instituto de Ensino, Pesquisa e Inovação | Liga Contra o Câncer, Natal – RN, Brasil[b]
Federal University of Rio Grande do Norte – UFRN, Natal – RN, Brasil[c]
E-mail: lequeiroz17@gmail.com

ABSTRACT

Motion sickness, better known as motion sickness, is a common and complex syndrome that occurs in response to real or perceived movement. The objective of the study is to test the effectiveness of motion sickness goggles in individuals who have proven to have this condition and are not taking medications to prevent any symptoms of the disease. This is a Single-Blind Randomized Clinical Trial involving the participation of 10 volunteers, in two trips in a motor vehicle, one of them wearing functional motion sickness goggles , purchased online, and the other wearing adulterated goggles, also purchased online. Nausea, headache and dizziness were the most significant complaints among the participants, in addition, the number of mild to moderate symptoms was higher when using adulterated goggles. The functional goggles were able to prevent the occurrence of the reported symptoms: pressure in the eye, malaise and drowsiness; as well as reducing the frequency of headache and dizziness.

Keywords: Reading, Motion Sickness, Dizziness.

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INTRODUCTION

Motion sickness, better known as motion sickness, is a common and complex syndrome that occurs in response to real or perceived movement, in which environmental circumstances that result in ambiguity or conflict with sensory stimulation patterns can adversely affect the vestibular system (BRONSTEIN *et al*., 2020; TAKOV *et al*., 2022).

This condition was first described by the Greek physician Hippocrates, who wrote: "sailing at sea proves that motion disturbs the body", but it was not until 1881 that the term was first used by Irwin to describe a disease resulting from repeated oscillatory movement of the body (LEUNG *et al*., 2019).

It can be observed that the symptoms of motion sickness develop during sea, air or land travel and mainly when moving in automated vehicles, a condition in which the passenger involved in tasks not related to driving may feel nausea, vomiting, disorientation, sweating, fatigue and headache (LEUNG *et al*., 2019; KESHAVARZ *et al*., 2022; LI *et al*., 2022).

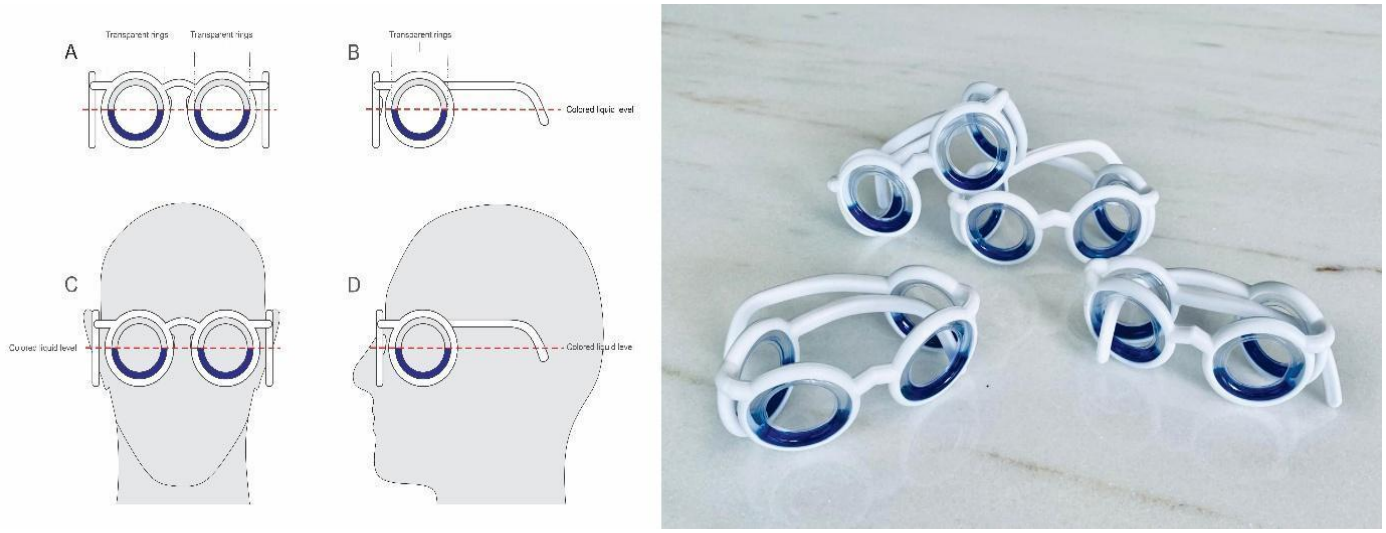
Furthermore, medications for treating motion sickness are only partially effective and may have unwanted side effects. They are most effective when used prophylactically or at the early onset of symptoms, since motion sickness, in particular, is easier to prevent than to cure (TAKOV *et al*., 2022; LEUNG *et al*., 2019).

In addition to medications such as anticholinergics, antihistamines and sympathomimetics, behavioral and environmental measures can be adopted to prevent the onset of symptoms. It is recommended to reduce head and body movement, avoid reading or watching screens during travel and even that susceptible individuals should avoid large meals, intake of caffeine, alcohol, foods with high histamine content or a large volume of liquids, before traveling (LEUNG *et al*., 2019).

The use of antihistamines has been identified as a viable therapy to combat the symptoms of motion sickness, however, when compared with other drug or non-drug therapies, such as the use of antiemetics, scopolamine or acupuncture, there has been no evidence of their greater effectiveness (KARRIM *et al*., 2022).

In this context, analyzing the clinical importance of motion sickness, its effects and limited treatment, anti-motion sickness glasses were developed , which promote the alleviation of clinical effects, mainly of motion sickness, through their mechanism. Anti-motion sickness glasses work by recreating the horizon line through a colored fluid that moves in the rings arranged around the eyes, and their main objective is to eliminate sensory stimulation that affects the vestibular system and causes motion sickness (Figure 1).

Figure 1. Motion sickness goggles . (Left) A and C – Front view showing the transparent rings with colored liquid level. B and D – Side view. (Right) Anti-motion sickness glasses purchased online (Source: Illustration: Prof. Dr. Francisco Irochima).



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Thus, the present study, which consists of a randomized clinical trial, aimed to test the effectiveness of one of the types of anti-motion sickness glasses in 10 volunteers who were proven to have this condition and were not using medication to prevent any symptoms of the disease.

METHODS AND ANALYSES

This article followed the Standard Protocol Items for Randomization Trials and Consolidated Standards of Reporting Trials (CONSORT). It was a single-blind, placebo-controlled study in the presence of two people who promoted the intervention.

A prospective study with a control group (crossover) was carried out, using inclusion criteria for conducting the research, in the city of Natal/RN, from July 2022 to February 2023. This study is registered in the Brazilian Clinical Trials Registry Platform (REBEC) under RBR-3n7pzqt (08/17/2023), was approved by the Research Ethics Committee of the League Against Cancer under CAAE 52.586.521.8.0000.5537 and was approved by the CEP of the Plataforma Brasil under number 60133022.3.0000.5296 (07/27/2022). This protocol complies with the items of the Standard Protocol for Randomized Trials (SPIRIT).

The research recruited a group of 10 individuals previously selected by a specific questionnaire, meeting the following requirements: being a medical student; having signs or symptoms of motion sickness while reading in vehicles; not using anti-motion sickness medication and being at least 18 years old. Failure to me*et al*l the inclusion criteria meant unsuitability to participate as a study subject, which was the exclusion criterion.

In the first stage, a virtual form was published, seeking to identify 10 individuals among medical students who were eligible to make up the research sample, selecting those who were known to meet the inclusion criteria.

In a second stage, volunteers participated as passengers seated in the back seat of passenger cars, and were asked to read a standard text while traveling along a standardized route, in order to check for the presence of symptoms secondary to motion sickness. All participants traveled the same route using motion sickness glasses. If the participant used corrective lenses (conventional glasses), they were instructed to put on motion sickness glasses, purchased online, over them. Each participant underwent this stage twice, configuring the crossover, but in one of the times using functional glasses and in the other using adulterated glasses.

The glasses were tampered with so that participants could not tell which glasses they were using on each route. The tampering of the functional glasses was carried out by removing the liquid present in their transparent rings with a syringe and a fixed level was painted with the same color.

The glasses were placed on each participant's face without them realizing what type of glasses they were wearing.

In order to properly perform the tests, it was important to make braking movements and changes in vehicle direction at strategic points to better assess the symptoms of motion sickness. In order to avoid bias, all participants were subjected to similar routes, with the same vehicle, reading exactly the same standard text, under the same daylight conditions and with similar speeds of movement during the tests. Throughout the route, a researcher remained next to the participant to assess the occurrence or not of motion sickness symptoms, their type and intensity. In case of intensity that prevented continuation, the test had to be stopped and the participant adequately attended to.

It is important to highlight that, during and after each trip, a research instrument in the form of a questionnaire was applied, which quantified the presence and intensity of symptoms for each volunteer. Thus, it was possible to associate the symptoms of motion sickness with the type of glasses used, functional or adulterated, and to assess the effectiveness of the object of the study in eliminating or, alternatively, attenuating these symptoms (Figure 2).

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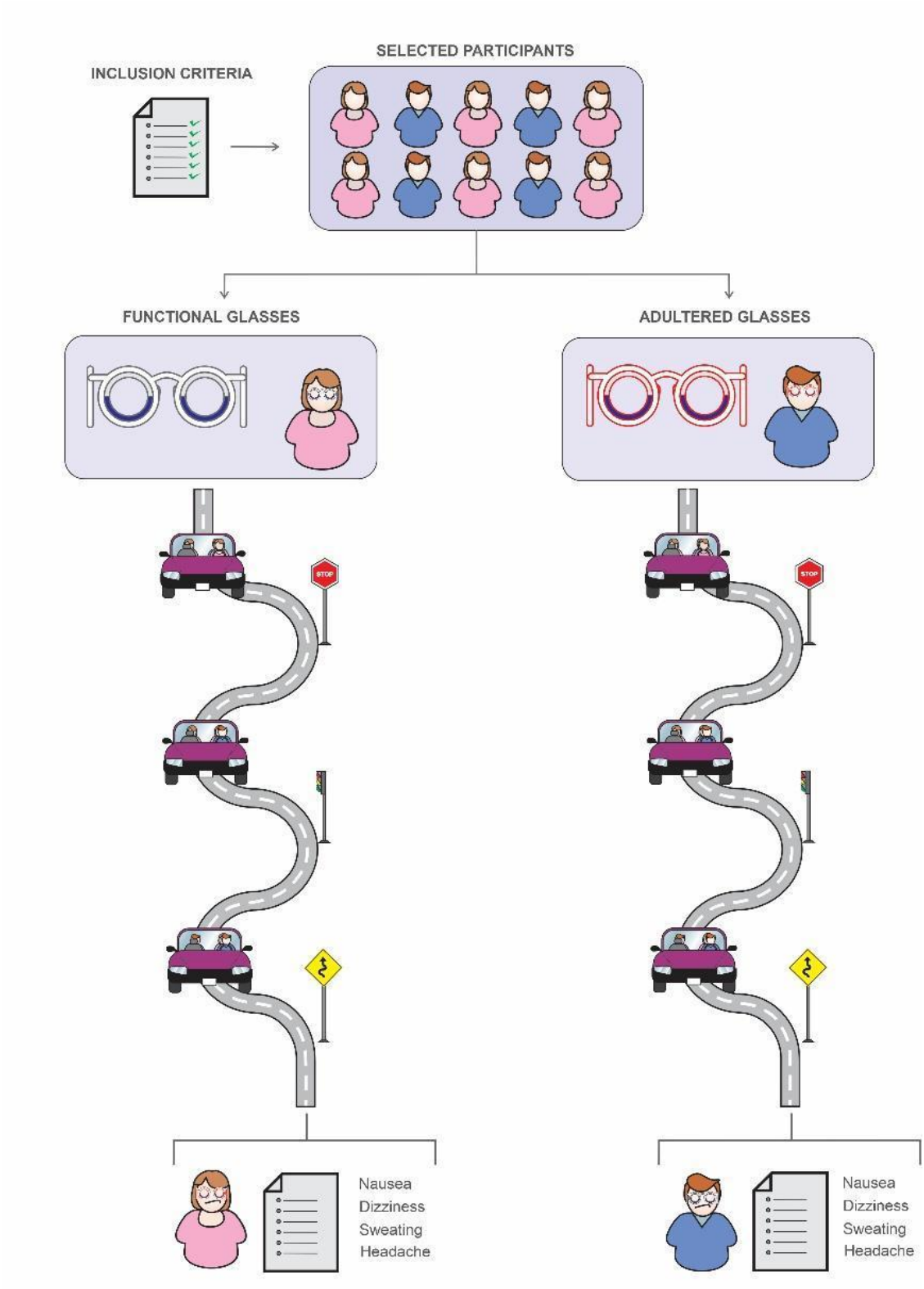
Figure 2. Testing stage with functional and adulterated glasses (crossover). (Source: Illustration: Prof. Dr. Francisco Irochima).



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The data were described using descriptive statistics, in which quantitative variables were represented by frequency and percentage. The number of symptoms that the participants in the experiment presented when using each type of glasses was compared. The paired Wilcoxon test was used to test the difference between the groups, at a significance level of $\alpha = 5\%$. This test was chosen after the hypothesis of data normality was rejected using the Shapiro-Wilk test. All analyses were performed using the R language (R CORE TEAM, 2020).

RESULTS

Description of variables

Table 1 contains information regarding the experiment, i.e., gender, route, type of glasses used by participants, use of prescription glasses, presence of any symptoms during the test and symptoms in the post-test, on the first and second day of the research (D1) and (D2).

The test was attended by 10 participants, of which 60.0% were female. On the first day of the test, 8 participants performed the test with the route from street A to street B, returning to the starting point at A, totaling 15 minutes. The others performed the route from street C to street D, returning to the starting point at C, also totaling 15 minutes. In (D2) of tests, all 10 participants performed the ABA route.

In D1, 2 participants used the adulterated glasses and the others used functional glasses. In D2, the inversion was performed, 8 of the participants used adulterated glasses and 2 participants used functional glasses, thus closing the crossover. Only 2 (20%) of the 10 participants were users of corrective lenses to correct ametropias.

On the first day (D1) of testing, dizziness and nausea were the most common symptoms among the experiment participants (62.5% and 50.0%, respectively). On the second day, headache and nausea symptoms were present in 40.0% of the participants.

Considering D1 and D2 and the main symptoms of motion sickness, among those who used functional glasses, 05 (50%) reported dizziness, 05 (50%) complained of nausea, 02 (20%) headache and sweating, while in users of adulterated glasses the complaints were: dizziness 02 (20%), nausea 04 (40%), headache 05 (50%) and sweating 03 (30%).

Table 1. Characterization information of study variables by test days.

Feature	Glasses Type - D1		Glasses Type - D2	
	Adulterated	**Functional**	**Adulterated**	**Functional**
Sex				
Feminine	1 (50.0%)	5 (62.5%)	5 (62.5%)	1 (50.0%)
Masculine	1 (50.0%)	3 (37.5%)	3 (37.5%)	1 (50.0%)
Path				
Midway - Romualdo G. - A. Pena - Hermes	2 (100.0%)	6 (75.0%)	6 (75.0%)	2 (100.0%)
Natal Shopping - Jaguarari - Drogasil - Return Jaguarari	0 (0.0%)	2 (25.0%)	0 (0.0%)	0 (0.0%)
Midway - Romualdo G. - A. Pena - Return A. Pena	0 (0.0%)	0 (0.0%)	2 (25.0%)	0 (0.0%)
Prescription glasses				
Yes	0 (0.0%)	2 (25.0%)	2 (25.0%)	0 (0.0%)
No	2 (100.0%)	6 (75.0%)	6 (75.0%)	2 (100.0%)
Pre-test				
Asymptomatic	2 (100.0%)	8 (100.0%)	8 (100.0%)	2 (100.0%)
Post test				
Dizziness	0 (0.0%)	5 (62.5%)	2 (25.0%)	0 (0.0%)
Nausea	2 (100.0%)	3 (37.5%)	2 (25.0%)	2 (100.0%)
headache	1 (50.0%)	2 (25.0%)	4 (50.0%)	0 (0.0%)
Sweating	2 (100.0%)	0 (0.0%)	1 (12.5%)	2 (50.0%)
Pressure in the eye	0 (0.0%)	0 (0.0%)	2 (25.0%)	0 (0.0)
Discomfort	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)
Sleep	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)
Diplopia	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)

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Symptom analysis

The comparison between the number of symptoms reported by participants in each group (using adulterated or functional glasses) is presented in Tables 2 and 3. The use of both types of glasses demonstrated a prevalence of 3 symptoms in common: headache, nausea and sweating.

The graphs suggest that there is not much difference between the groups. At the significance level α = 5%, it was not possible to detect a statistically significant difference between the number of different symptoms for the two groups (p-value: 0.2568). A similar interpretation can be made based on the number of mild (p-value: 0.7055) and moderate (p-value: 0.3173) symptoms.

Table 2. Characterization information of study variables by type of glasses.

Feature	Type of Glasses		p-value
	Adulterated	Functional	
Sex			-
Feminine	6 (60.0%)	6 (60.0%)	
Masculine	4 (40.0%)	4 (40.0%)	
Path			-
Midway - Romualdo G. - A. Pena - Hermes	8 (80.0%)	8 (80.0%)	
Midway - Romualdo G. - A. Pena - Return A. Pena	2 (20.0%)	0 (0.0%)	
Natal Shopping - Jaguarari - Drogasil - Return Jaguarari	0 (0.0%)	2 (20.0%)	
Prescription glasses			-
Yes	2 (20.0%)	2 (20.0%)	
No	8 (80.0%)	8 (80.0%)	
Pre-test			-
Asymptomatic	10 (100.0%)	10 (100.0%)	
Post test			
Headache	5 (50.0%)	2 (20.0%)	0.3498
Nausea	4 (40.0%)	5 (50.0%)	1.0000
Sweating	3 (30.0%)	2 (20.0%)	1.0000
Dizziness	2 (20.0%)	5 (50.0%)	0.3498
Pressure in the eye	2 (20.0%)	0 (0.0%)	0.4737
Discomfort	1 (10.0%)	0 (0.0%)	1.0000
Sleep	1 (10.0%)	0 (0.0%)	1.0000
Diplopia	0 (0.0%)	1 (10.0%)	1.0000

Table 3. Number of symptoms by type of glasses.

Symptoms	Type of glasses		*p-value*
	Adulterated	Functional	
Qty . Different symptoms	18	15	0.2568
Qty . Mild symptoms	13	12	0.7055
Qty . Moderate symptoms	8	4	0.3173

DISCUSSION

This study quantitatively assessed how the use of functional and tampered glasses impacted the onset of motion sickness symptoms. In addition, it was possible to estimate the prevalence of certain symptoms during a standardized car journey through the act of reading.

In the present study, volunteers attended two test days, in order to test, on each day, different glasses. The mechanism of motion sickness was theorized to be the result of a sensory incompatibility, that is, modulated by visuo -vestibular conflicts. However, a study conducted in 2019, with virtual motion sickness simulators, used blindfolds for the participants exposed to the simulator

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and, despite this, was successful in inducing motion sickness in three quarters of the participants (WILLEM *et al*., 1998; JELTE *et al*., 2008; OUREN *et al*., 2019).

The present study included participants of both sexes, male and female, who were randomly distributed between the two days of testing and reported feeling different symptoms, associated with both the experience of reading in vehicles with functional glasses and with the adulterated ones.

Gender is probably an independent factor capable of influencing reactions to movement. And it is expected that the severity of motion sickness symptoms will be greater in females (HOLMES *et al*., 2006). The highlighted prevalence of nausea and headache symptoms may be associated with the larger contingent of female participants in the research.

This is because migraine is a more frequent, prevalent and disabling symptom in women (ALLENA *et al*., 2019), a group that makes up 60% of the study participants. Despite this, the number of reported nausea symptoms remained unchanged between days 1 (D1) and 2 (D2) of the experiment (n = 2), when there was a variation in the number of females using the adulterated glasses.

However, a more recent update highlighted an atypical scenario, in which the average total MSSQ score was higher among men than among women, when subjected to the motion sickness simulator (OUREN *et al*., 2019). . Added to this result is the fact that, in its primary outcome, another study did not find prevalence of the headache symptom in one sex to the detriment of the other (ALLENA *et al*., 2019). Therefore, it is not possible to relate the overlap of the symptoms: headache and nausea, observed more frequently when using glasses, only with the fact that the female audience exceeds the male audience, in the present study.

Regarding the most frequent symptoms in the study, tampered glasses, when used for reading in vehicles, showed the prevalence of the headache symptom. This symptom ends up being caused more by visual movements than by real ones (BIJVELD *et al*., 2008). In this sense, the reading experience, in itself, is configured as a potential factor that generates headache.

Migraine, a headache preceded by nausea, is, above all, a prevalent symptom in society. A study carried out in the eastern region of Saudi Arabia analyzed the most common type of headache among the 877 individuals interviewed, highlighting, in the end, that 32.1% of the symptoms were related to migraine, that is, headache accompanied by nausea, vomiting or photophobia (ALBARQI *et al*., 2022).

Gastrointestinal symptoms (nausea and vomiting) are the most common in the real world. Exogenous stimuli, including emetogenic cancer chemotherapy, bacterial toxins in the gut, viral and fungal infections, food poisoning, epigastric radiation, various medications, and movement, provoke vomiting, which is often, but not always, accompanied by nausea (ROBERT *et al*., 2010; WICKHAM *et al*., 2020).

On the other hand, not only these experiences, but also very intense and frequent optokinetic stimuli, such as reading in a vehicle, carried out in the experiment, are nauseagenic. This is because the movement of the head, both sideways and forwards and backwards, causes subclinical vestibular abnormalities by activating the velocity storage mechanism (PARK *et al*., 2019; KIM *et al*., 2012).

When the simulator experience is also evaluated, the following symptoms are reported: sweating, heat, tiredness, malaise, dizziness and headaches (TESSA *et al*., 2023; XU *et al*., 2022). These findings are in line with the present study, with regard to nausea, reported by 50% of patients.

Dizziness, one of the most recurrent symptoms when using functional glasses, reported by 50% of participants, deserves to be analyzed carefully, since 15 to 20% of the adult population is affected by dizziness and vertigo (NEUHAUSER *et al*., 2016). In this context, it is also known that vestibular hypofunction is a potentially disabling condition, whose symptoms are dizziness, imbalance, oscilloscopy deserve to be investigated accurately when making the differential diagnosis with the symptoms caused by motion sickness (STRUPP *et al*., 2023; LI *et al*., 2022; NURNBERGER *et al*., 2021).

Furthermore, regarding the complaint of dizziness, the meta-analysis completed in 2022 proved that there is a relationship between COVID-19 infection and the symptoms of dizziness and tinnitus (JAFARI *et al*., 2022). Given the high prevalence of these symptoms and the various possible associated etiologies, another study suggests carrying out different tests, so that the symptoms are not attributed to the wrong disorder (VAN DE BERG *et al*., 2021). However, the present study proved to be weak in not classifying the participants according to their previous disorders.

The application of vestibular rehabilitation in a virtual reality environment, according to recent research, can lead to improvements in symptoms of dizziness,

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disability and imbalance (KANYILMAZ *et al*., 2022). Similarly, functional glasses, through optokinetic properties , were able to reduce the perception of symptoms such as headache, sweating, eye pressure, discomfort and sleep.

Although felt by only 10% of participants, the symptoms of malaise and sleepiness did not occur when using the functional glasses. In disagreement with the research findings, a study conducted in 2015, which evaluated the experience of users using functional virtual reality glasses in virtual movement simulators, highlighted, among the main complaints of the research participants, drowsiness and general discomfort (DAVIS *et al*., 2015).

The coherent perception of the moving environment is something that, today, with the attribute of virtual reality brought about by video games or simulators, generates a second type of Motion Sickness (MS), known as Visually Induced Motion Sickness. MS, simulator sickness, and cybersickness share similar symptoms: dizziness, headache, blurred vision, salivation, paleness, cold sweat, nausea, and vomiting, although the conditions are caused by exposure to slightly different situations (RAHIMZADEH *et al*., 2023; AGRAWAL *et al*., 2018; PAI MANGALORE *et al*., 2019) **.**

In the meantime, the results of the single-blind study carried out with participants experiencing movement in real reality were compatible with the literature, including in the case of virtual experiences. The integration of vestibular and emetic gastrointestinal signals is the main hypothesis to justify the MS condition (DA SILVA *et al*., 2022). For this reason, even though they were using functional anti-motion sickness glasses, 50% of the research participants, when exposed to the movement situation while reading, reported symptoms of nausea and dizziness.

Regarding the evaluation of the quality of anti-motion sickness glasses in reducing motion sickness symptoms, it was observed that, proportionally, the number of symptoms considered moderate was half of that reported by the same participants when using the adulterated glasses. And, in order to overcome this reality, several artifacts have emerged whose applicability aims to reduce motion sickness symptoms, such as training programs with virtual reality glasses, Virtual Reality headsets, the use of ginger and practices of Alternative and Complementary Medicine, such as the acupuncture and hypnosis techniques (ROBERT *et al*., 2010; MORA *et al*., 2022; MOLISZ *et al*., 2020; PAN *et al*., 2021) .

Among the limitations of the study, it is possible to mention the low sample size, justified by the low participation of the chosen public, the short period of time used for the tests, as well as the incompatibility of schedules between the potential volunteers and those who would promote the intervention. Furthermore, it was impossible to precisely standardize the route taken by each of the volunteers, given the external conditions related to the flow of other cars and people.

On the other hand, the relevance of this research project lies in the search for proposing a solution to motion sickness, a disease that has a significant prevalence in the general population and causes dysfunctional damage to the lives of affected individuals.

CONCLUSION

This study evaluated the effectiveness of one type of anti-motion sickness glasses available for sale online in young people suffering from this condition while reading in vehicles, under controlled conditions. The functional glasses were able to prevent the occurrence of symptoms: pressure in the eye, discomfort and drowsiness; however, with regard to nausea and dizziness, there was no prevention or control of the symptoms. Statistically, there was no significant difference when comparing the use of the two glasses tested.

The low statistical difference between the two groups can be expected due to the small number of participants in the study. Therefore, we hope to promote new discussions and encourage further research, as well as the expansion of this study, with a greater number of volunteers and through the use of the original anti-motion sickness glasses.

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