



Effects of a physical exercise program executed through immersive virtual reality on physical fitness and body composition in college adults: protocol for a randomized controlled trial

Efecto de un programa de ejercicio físico ejecutado a través de realidad virtual sobre la condición física y la composición corporal en adultos universitarios. Protocolo para un ensayo controlado aleatorio

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Abstract

Introduction and objective: The constant practice of physical activity contributes to obtaining adequate values of physical fitness and body composition, which brings benefits to people's health. Even though scientific evidence exposes the health effects of physical activity, the adult population has a low prevalence of exercise due to lack of time, lack of sports venues, factors that increase in university students due to academic demands. One tool that could be useful in removing barriers to not practicing physical activity may be immersive virtual reality, as evidence suggests that it can be a tool that promotes the practice of physical activity, so the objective of this randomized controlled trial protocol is to evaluate the impact of a physical exercise program performed through immersive virtual reality on physical fitness and body composition in a university population.

Methodology: An intervention group (n=18) and a control group (n=18) will be randomly selected. The intervention group will execute a physical exercise program through immersive virtual reality for 12 weeks. All participants will be evaluated at the beginning and end of the intervention to determine the effect of the program on physical fitness and body composition. **Conclusions:** This randomized controlled trial will provide information on the effect of physical exercise through virtual reality on the variables studied.

Keywords

Cardiorespiratory fitness; fat; strength; muscle; physical activity.

Resumen

Introducción y objetivo: La práctica constante de actividad física contribuye a la obtención de valores adecuados de condición física y composición corporal, lo que trae beneficios a la salud de las personas. A pesar de que la evidencia científica expone los efectos de la actividad física en la salud, la población adulta tiene una baja prevalencia de ejercicio debido a la falta de tiempo, falta de recintos deportivos, factores que aumentan en los estudiantes universitarios debido a las exigencias académicas. Una herramienta que podría ser útil para eliminar las barreras para no practicar actividad física puede ser la realidad virtual inmersiva, ya que la evidencia sugiere que puede ser una herramienta que promueva la práctica de actividad física, por lo que el objetivo de este protocolo de ensayo controlado aleatorizado es evaluar el impacto de un programa de ejercicio físico realizado a través de la realidad virtual inmersiva sobre la aptitud física y la composición corporal en una población universitaria.

Metodología: Se seleccionará aleatoriamente un grupo de intervención (n=18) y un grupo control (n=18). El grupo de intervención ejecutará un programa de ejercicio físico a través de realidad virtual inmersiva durante 12 semanas. Todos los participantes serán evaluados al principio y al final de la intervención para determinar el efecto del programa en la aptitud física y la composición corporal.

Conclusiones: Este ensayo controlado aleatorizado aportará información sobre el efecto del ejercicio físico a través de la realidad virtual sobre las variables estudiadas.

Palabras clave

Resistencia cardiorrespiratoria; grasa; fuerza; músculo; actividad física.

Introduction

Physical fitness (PF) is a measure that integrates most of the body's functions that are involved in the performance of any physical activity or physical exercise (Caspersen et al., 1985). Although its variation depends largely on genetic components, the physical exercise factor is one of the environmental conditioning factors that most influences its development (Martínez-Vizcaíno & Sánchez-López, 2008). There is evidence to suggest that adequate PF values are considered important for people's health as they are related to better cardiovascular, skeletal, and mental health (Ortega et al., 2008; Ruiz et al., 2000; Lavie et al., 2014). This is why PF is considered an important component of a healthy lifestyle (Martínez-Vizcaíno & Sánchez-López).

The study of body composition is fundamental to the quantification, determination of relationships and definition of quantitative changes in the components of the human body (Wang et al., 1992). Its importance lies in the elucidation of the impact of environmental factors, including growth, diet, diseases and physical fitness, on the body (González-Jiménez, 2013).

Previous studies showed that physical activity interventions improve people's body composition, such as reductions in fat (Thompson et al., 2012; Kutac et al., 2023) and increases in muscle mass (Plaza-Díaz et al., 2022). This is beneficial for health, as a greater accumulation of fat in regions such as the waist and abdomen increase the risk factor for the development of metabolic diseases and insulin resistance (Longo et al., 2019; Kahn et al., 2019). Conversely adequate muscle mass values are associated with improvements in the metabolism of liver, pancreatic, and immune tissue, among others (González-Gil & Elizondo-Montemayor, 2020).

Despite compelling evidence attesting to the salutary effects of physical activity, more than a quarter of adults worldwide remain physically inactive (Who, 2023). One of the factors that contribute to this phenomenon is the perception of physical exercise as a tedious and challenging activity (Qian et al., 2020). When coupled with extended work hours, this perception can deter individuals from engaging in physical activity. Additionally, a lack of motivation, inadequate family and social support, the absence of accessible sports facilities and a tendency to prioritize other activities can collectively shape negative attitudes towards physical activity, ultimately leading to its avoidance (Méndez-Giménez et al., 2013; Kane, 1972).

The aforementioned factors contribute to a decline in physical activity among university students, a particularly complex population. The transition from secondary to tertiary education, coupled with the demands of academic studies and the necessity to balance academic commitments with other obligations, can lead to the adoption of unhealthy habits (Ali et al., 2015; MacMillan, 2007).

A tool that could be useful to eliminate the barriers described for not practicing physical activity can be immersive virtual reality [IVR]. This technology, which employs a screen mounted on the head, enables users to receive images, sounds, and tactile sensations from a simulated environment (Pasco et al., 2013; Gao et al., 2019). This is achieved through an avatar that allows for movements to be shown in a way that is consistent with the subject's body.

In a first-person perspective, participants are prompted to adjust their real actions in response to the observed movements of the avatar, this is driven by the illusory sensation of having the avatar's body, which generates measurable motor and physiological responses in the real body (Burin et al., 2019). In this sense, the IVR permits the exploration of scenarios that, due to the requisite temporal or spatial constraints, would otherwise be inaccessible (Freina & Ott, 2015).

Several studies have analyzed the potential benefits of IVR in the field of public health, identifying greater effectiveness in the work of repetitive tasks, the provision of graphic and acoustic feedback, and improved adherence to physical therapies (Vieira et al., 2014).

This has been reflected in several studies that describe the effects of programs implemented through IVR in the rehabilitation of patients with cardiovascular accidents (Chen et al., 2022), Parkinson's disease (Brandín-De la Cruz et al., 2022), fibromyalgia (Carvalho et al., 2020; Collado-Mateo et al., 2017) and obstructive pulmonary diseases (Rutkowski et al., 2020), among others.

In terms of physical exercise, the evidence suggests that IVR can be an effective tool for promoting healthy behaviors and the practice of physical activity, thereby increasing adherence to exercise over



the long term (Burin et al., 2019). A recent scoping review has indicated that its use stimulates moderate and vigorous intensity levels, which could contribute to meeting physical activity recommendations (Giakoni-Ramírez et al., 2023a).

In turn, other studies have reached the conclusion that the practice of physical exercise through IVR results in moderate and vigorous intensity physical activity (Evans et al., 2021; Souza et al., 2022; Giakoni-Ramírez et al., 2023b), which are the levels of exertion that are associated with health benefits. Furthermore, previous evidence indicates that the performance of physical activity through IVR is perceived as highly enjoyable by participants (Debska et al., 2019), results in greater calorie burning, greater concentration and the sensation of being able to continue exercising for longer (Bonnechère et al., 2016).

Given the relatively low prevalence of physical exercise among adults, particularly among university students (Castro et al., 2020), the IVR represents a potential avenue for overcoming the barriers that hinder the practice of physical exercise in this population. Furthermore, if the utilization of this technology is perceived as enjoyable by the users and contributes to adherence to the recommended physical activity guidelines, it is reasonable to hypothesize that a physical exercise programme conducted via IVR could enhance PF, reduce body fat percentage and increase muscle mass. Nevertheless, the extant evidence does not encompass any findings pertaining to the impact of running exercise programmes via IVR on physical fitness, nor on the fat and muscle components of body composition.

The findings of this study will contribute valuable insights to this nascent field of research. It is hypothesized that the physical exercise programme carried out through immersive virtual reality will result in improvements in physical fitness and body composition when compared to the control group. The objective of this randomized controlled trial [RCT] is to evaluate the impact of a physical exercise programme conducted through immersive virtual reality on physical fitness and body composition in a university population.

Method

Design

The study will be a two-arm, open-label, parallel RCT to analyze a supervised physical exercise programs in university students for 12 weeks. The RCT will be reported in accordance with the CONSORT Statement (Butcher et al., 2022) and the SPIRIT guidelines for protocol studies (Chan et al., 2013) (Supplementary Tables 1 and 2, respectively). Participants will be randomly assigned with the objective of forming groups with similar characteristics to reduce confounding factors and increase the internal validity of the study.

Ethical considerations

All procedures will be carried out in accordance with the updated Declaration of Helsinki and has received the approval of the Scientific Ethics Committee of the Universidad Autónoma de Chile (N°26-24). All study subjects, prior to participating, will provide their written informed consent. In addition, the study has been registered in the ClinicalTrial.gov (NCT06580769).

Participants

The following inclusion criteria will be considered: 1) be enrolled as a university student; 2) be between the ages of 18 and 25; 3) present medical consent authorizing the performance of physical activity; and 4) Signing of informed consent. The exclusion criteria will be: 1) having a physical or mental impairment that precludes the ability to engage in physical activity; 2) having a vision impairment that precludes the ability to utilize the IVR; 3) belonging to a special interest group (e.g., professional athletes or pregnant women). All evaluations and interventions will be carried out using the equipment and infrastructure of the eSports laboratory associated with the Pedagogy in Physical Education career.

The student participants will be recruited from all faculties belonging to the Universidad Autónoma de Chile, Temuco campus, Chile. Information regarding the program will be disseminated via institutional email, social media, and informative posters.



Randomization

This study adopts a double-blind (evaluator and data analyst blind to each other) controlled trial design. Participants will be divided into two groups by means of an electronic draw (group 1, IVR; group 2, control group). This will be done randomly using the EPIDAT 4.2 software.

Sample size calculation

The number of participants will be calculated based on what Grayling & Watson (2020) proposed for the design of clinical trials. The sample will be calculated considering a mean effect size (Cohen's $d = 0.5$), an alpha of .05, and a power of 0.8, based on an RCT that aimed to assess changes in health variables of an exercise platform directed by means of IVR (Mologne et al., 2024). Thus, the total required will be 18 participants.

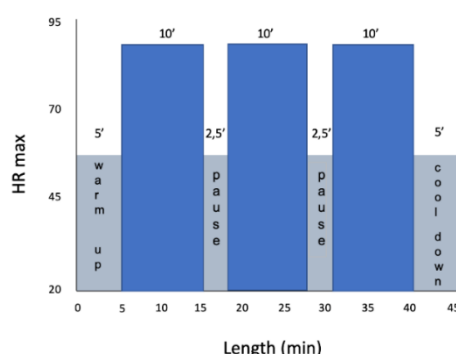
Intervention

Training interventions

The intervention group will engage in supervised training through IVR. A maximal cardiorespiratory stress test will be conducted at the outset of the study to ascertain the individual's maximum heart rate [HRmax], which will then be employed to determine the appropriate exercise intensity.

Each session will begin with a 5-minute warm-up at moderate intensity (60-70% of HRmax). Subsequently, the physical activity program will be executed through the FIT XR (FITAR LIMITED) application, which is a game that combines fist punches are combined with sideways movements. The program will comprise three levels, which will become increasingly complex in terms of the speed of the movements that must be executed. Participants will commence at the beginner level, subsequently progress to the intermediate level, and finally conclude with the advanced level. Each level will last for a period of ten minutes. The intensity of the physical activity at each level will be between 80 and 95% of HRmax. Previous evidence indicates that these levels executed through IVR produce moderate-vigorous physical activity intensities in participants [Giakoni-Ramírez et al., 2023]. The session will conclude with a 5-minute cool-down at 50-60% of HRmax, comprising joint mobility exercises and stretching. The entire session will be conducted via IVR using the Oculus Meta Quest 2 instrument. The total exercise time will be 45 minutes (Figure 1). A physical education professional will be present in each session to oversee the positioning of the implements, supervise the intensity of the exercise, and address any issues that may arise.

Figure 1. Total exercise intervention group.



Source: Own elaboration

Control group

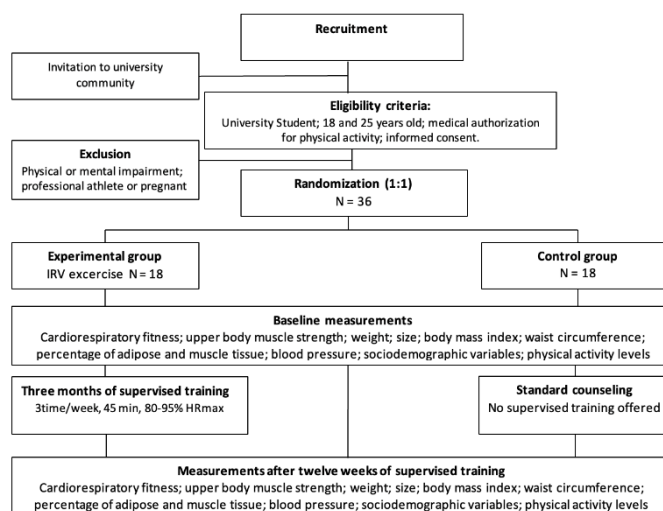
The control group will be provided with general information regarding the benefits that the practice of physical exercise brings on the cardiovascular system. The information will be given once a week, through informative brochures that will be distributed through social networks. The content will be

based on how different actions they could take (e.g., walking, playing, dancing, fitness) will contribute to their health. Throughout the course of the study, they will continue with their usual physical activity.

Duration of the intervention

The intervention will be conducted over a period of 12 weeks. The flow chart in Figure 2 shows the inclusion and exclusion criteria for participants, as well as the selection, randomization, and overall characteristics of the intervention. It also depicts the procedures for baseline and follow-up assessments.

Figure 2. Flow chart for participant inclusion and follow-up: screening, inclusion and exclusion, randomization, baseline testing, and testing after follow-up.



Source: Own elaboration

Criterion of adherence to the intervention

In order to be deemed compliant with the training program, participants are required to attend a minimum of 70% of the scheduled sessions within the designated timeframe.

Procedures

Once the sample to be included in the study has been established, the participants will be invited to sign an informed consent form, complete preliminary evaluations (including physical fitness, body composition, blood pressure and sociodemographic information), and schedule the schedules of the sessions.

Main outcome variables

To determine the intensity of the exercise, a maximum cardiorespiratory effort test will be performed on a Monark LC7TT ergometric bicycle. Maximum heart rate will be determined by means of PolarH10 and average exercise time. Five minutes of warm-up will be carried out without load; then, every two minutes the intensity will be increased by 25 W, maintaining a cadence of 60 rpm. The test will conclude when the cadence cannot be maintained. This test will be performed in the exercise physiology laboratory under the supervision of a cardiologist.

Physical fitness

Cardiorespiratory endurance will be measured through the 20-meter running test (Léger et al., 1988), where participants must run between two lines separated by 20 meters and reach the lines along with the sound delivered by a pre-recorded tape. The first minute of the race is run back and forth between the two lines at a speed of 8.5 km/h. The speed is increased by 0.5 km/h every minute. The test concludes when the participant is unable to reach the lines in conjunction with the sound stimulus. The maximum oxygen consumption will be estimated through the formula proposed by Léger (Léger et al.,

1988). This test has reliability values of $r=0.95$ (Léger et al., 1988). It is recommended that the subject does not perform intense exercise for the 48 hours prior to its execution, wear sportswear and appropriate footwear. In addition to constantly delivering messages of encouragement and motivation to the participants, to obtain the maximum performance from them (Ruiz et al., 2011).

Upper body muscle strength will be measured through manual grip strength with a TKK 5401 GripD Adjustable Grip Digital Dynamometer (Takey, Tokyo, Japan). The average of two measurements taken with the right hand and two with the left hand will be calculated.

Body composition

Weight will be evaluated through a digital scale (Tanita MC780U), with the participant barefoot and with as little clothing as possible. Size will be obtained with a height gauge (Seca 222), with the participant barefoot, in an upright position, at the end of a normal inspiration. Both measures will be taken in duplicate, using the mean for statistical analyses.

Body mass index shall be determined by dividing weight by height squared. The results will be classified as underweight ($BMI \leq 18.4 \text{ kg/m}^2$); normal ($BMI 18.5 - 24.9 \text{ kg/m}^2$); overweight ($BMI 25 - 29.9 \text{ kg/m}^2$) and obesity ($\geq 30 \text{ kg/m}^2$).

Waist circumference shall be determined at the midpoint between the last rib and the iliac crest, at the end of a normal expiration. The average of two measurements will be used.

The percentage of adipose and muscle tissue will be calculated using the mean of two assessments conducted in a state of rest and fasting, wearing the minimum amount of clothing, and after urinating and resting for 15 minutes, by means of tetrapolar electrical bioimpedance (Tanita MC 780U). The protocol described by the International Society for the Advancement of Kineanthropometry will be followed for the measurement of body perimeters, bone diameters and skin folds (Marfell-Jones et al., 2012).

Blood pressure

The data will be evaluated twice using an Omrom monitor (Omrom healthcare OK ltd., Milton Keynes, United Kingdom). The following recommendations need to be considered. Physical exercise should be avoided for 30 minutes prior to the measurement, total rest 5 minutes before the measurement, and not wearing thick clothing that compresses the arm to be evaluated. The subject will be seated, with the arm semi-flexed at the level of the heart. Two evaluations will be carried out, with a time interval of at least 1 minute. The average of the two assessments will be used for subsequent statistical analyses (O'Brien et al., 1990).

The assessment of body composition and blood pressure variables will be carried out at the beginning of the day, between the hours of 8:00 am and 10:00 am, within the exercise physiology laboratory by researchers duly trained to maintain standardization.

Following the administration of nourishment to the evaluated subjects, physical fitness evaluations will be carried out at the sports gym of the Universidad Autónoma de Chile, Temuco campus. The tests will be evaluated by graduates in Physical Education, who will be trained to maintain standardization. The training will last 4 hours, with a theoretical and practical nature regarding the evaluation procedure. It will be taught by the researcher responsible for the project.

Co-variables

The study will also include the collection of data on a number of sociodemographic variables. These will be obtained from participants at the outset of the program through the completion of a questionnaire. The information requested will include the participants' age, sex, geographical area of residence and socioeconomic level.

The assessment of physical activity will be conducted objectively using ActiGraph wGT3X-BT accelerometers (AG; ActiGraph, Pensacola, FL, USA), which has proven to be a valid way to classify physical activity levels (Freedson et al., 1998; Sasaki et al., 2011). The device must be worn on the right side of the hip for a period of seven consecutive days. The data will be collected at a frequency of 100 Hz. The data will be deemed valid if a minimum of five consecutive days of recording is provided, including one day of the weekend. The total minutes of sedentary behavior and the intensities of physical activity will be calculated according to the cut-off points proposed by Arias-Palencia et al. (2015).



Statistical analysis

The statistical analyses will be conducted using the SPSS software (version 29 for Windows, IBM Statistics, New York, USA). The normality of the data will be determined using the Shapiro-Wilk test, and a two-step approach will be employed to facilitate the transformation of non-normal variables (Templeton, 2011). Subsequently, intergroup analyses will then be conducted to ascertain the homogeneity of the groups in the initial phase. The descriptions will be presented in accordance with the principles of central tendency and dispersion (in the case of continuous variables) and as percentages (in the case of categorical variables). A two-way repeated measures analysis of variance (ANOVA) will be employed to ascertain the impact of the interventions. The model effects are the group (intervention group; control group), times (pretest; posttest), and their interaction over time (time x group). The Bonferroni post hoc test will be employed to identify statistically significant comparisons (p -value $< .05$). When statistically significant differences are identified, the effect size will be calculated using Cohen's d estimates (< 0.2 negligible; ≥ 0.2 to ≤ 0.49 small; ≥ 0.5 to ≤ 0.79 moderate; and ≥ 0.8 large) (Cohen, 1998). All analyses will be performed using the multiple imputation method (Sterne et al., 2009), with all subjects retained in their originally assigned intervention or control group, irrespective of the number of sessions of the physical activity program attended (McCoy, 2017). The analyses will be performed by intention to treat, keeping the subjects originally assigned in the intervention or control groups, regardless of the number of sessions attended, and considering CONSORT guidelines. In addition, sensitivity analyses will be carried out on valid cases (Gupta, 2011).

Discussion

The objective of this study protocol is to provide a comprehensive methodology for a RCT designed to assess the impact of a physical exercise program conducted through immersive virtual reality on the physical fitness of university students.

Considering that the adult population worldwide exhibits high rates of physical inactivity (Who, 2022) and that the university population in particular engages more time of sedentary behavior than the adult population in general, which is associated to adverse health outcomes (Castro et al., 2010), it is imperative to implement measures that can effectively reverse this trend. This is of particular importance considering the global objective of achieving a 15% reduction by 2030 (WHO, 2020).

One potential mechanism for reducing levels of physical inactivity is the implementation of physical exercise programs. These programs have been demonstrated to not only facilitate the modification of sedentary behavior but also to maintain this change over time (Howlett et al., 2019). This, in conjunction with IVR, could serve as a tool that contributes to reducing the rates of physical inactivity that the university population currently has.

The evidence about the effects of virtual reality-based exercise programs on physical fitness and body composition is still evolving. Systematic reviews conclude that these approaches may be efficacious in promoting physical activity and contributing to active aging. However, the findings thus far are inconclusive and require corroboration through additional randomized controlled trials (Tatnell et al., 2022; Yen & Chiu, 2021). Consequently, the results of this study will provide scientific evidence substantiating the benefits of engaging in physical activity through immersive virtual reality.

The results of this study can inform the development of strategies by universities to improve the health of university students, implement physical activity interventions with IVR, assess their impact, and subsequently utilize this information as an input for decision-making in the creation of programs aimed at the comprehensive well-being of students. In this case, the objective is to promote greater adherence to physical activity through the implementation of targeted interventions.

Finally, some of the limitations that must be considered in the application of IVR is that the devices are required to have a wireless internet connection, and a battery charge that is limited which requires to be connected to the electrical network from time to time (in the same way as mobile phones). situations that are technical challenges that need to be mentioned in order to have them taken into account.

Conclusions

This study protocol delineates a methodology for the development of a randomized controlled trial that will be employed to ascertain the effect of a physical exercise program conducted through immersive virtual reality on the physical fitness and body composition of university students. The findings of this trial will provide evidence that will be instrumental in enhancing the overall well-being of the university population.

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