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## Article

# Psychometric and Physiological Assessment of the Effects of Virtual Reality in Cardiovascular Rehabilitation: A Randomized Controlled trial

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**Abstract: Background:** Virtual reality (VR) is a promising tool for cardiac rehabilitation, but conflicting results have been reported in the literature. **Methods:** A Randomized Controlled Trial was conducted on 60 subjects undergoing a cardiac rehabilitation program. The experimental group replaced 20 daily minutes of the therapy with virtual car driving simulation sessions. Both groups received the same amount of therapy time. Hospital Anxiety and Depression Scale (HADS), the Short Form 12 questionnaire for quality of life, and other clinical scales were administered to assess the efficacy of integrating VR into the rehabilitative intervention. **Results:** HADS-score ( $p < 0.001$ ) and quality of life ( $p < 0.02$ ) significantly improved only in the VR group, whereas other parameters such as pain, perceived exertion and oxygen saturation improved in both groups. **Conclusions:** VR resulted effective in improving patients' conditions, likely due to its high level of engagement. When assessing the effects of a VR system, it is important to consider the specific software with the exergame and the tasks administered: in this study, we selected a car driving simulation, which yielded positive effects.

**Keywords:** virtual environment; digital rehabilitation; heart; cardiology; gamification

## 1. Introduction

Virtual reality (VR) is a high-end user-computer interface involving real-time stimulation and interaction of an embedded subject through visual and auditory sensorial channels, based on a synthetic environment in which the subject feels to be present [1]. Over the past few decades, virtual reality (VR) has been extensively used in psychological and neuroscientific research, as well as clinical applications [2], yielding promising results for diverse clinical conditions [3,4]. Furthermore, VR has also been employed in the cardiovascular field across various settings, including cardiac rehabilitation, interventional cardiology, and cardiac surgery, to assess both physiological and psychological outcomes [5,6]. A recent meta-analysis conducted on almost one thousand patients showed that VR-based cardiac rehabilitation significantly reduced symptoms such as anxiety and depression in patients with cardiovascular diseases compared to standard rehabilitation; however, the effects on cardiorespiratory functions were not significantly different between the two approaches [6]. Another meta-analysis confirmed that VR may reduce negative emotions in cardiac rehabilitation, and also added that VR can be effective in improving patients' exercise capacity [7].

VR does not seem to be less effective than conventional cardiac rehabilitation when tested in a longitudinal randomized controlled trial [8].

However, the advantages of using VR could be related to the fact that it is a customizable intervention that may enhance the rehabilitation experience by providing cognitive, emotional, and physical benefits to patients, improving their motivation and engagement, reducing anxiety, but at the same time may provide discomfort [9]. The evidence of this assumption has already been demonstrated for neurological therapy [10,11], but not yet for cardiac rehabilitation.

In general, the effect of VR in cardiac rehabilitation seems more related to mental health improvements, and hence to psychological aspects, despite its superiority not being proven on other factors such as adherence, satisfaction, and quality of life [12].

The aim of this study was to test the efficacy of integrating the use of a VR system based on driving simulation in cardiac rehabilitation through a randomized controlled trial. Cardiovascular disease has been linked to decreases in driving performance, and rehabilitation may also aim at the recovery of driving ability [13]. The use of driving simulators has already been tested in neurological [14] and orthopedic [15] patients. We tested this approach in a virtual reality system for cardiac patients. The objective was not only to facilitate the recovery of driving ability, but also to improve psychological and physiological outcomes of cardiac rehabilitation.

## 2. Materials and Methods

### 2.1. Study design and Participants

The study is a randomized controlled trial (RCT) conducted at an Italian clinic that provides intensive inpatient cardiac rehabilitation. Patients were enrolled according to the following inclusion/exclusion criteria and randomized into two possible groups.

The inclusion criteria were: diagnosis of cardiovascular disease and need for intensive inpatient cardiac rehabilitation after cardiac surgery, age over 18 years, absence of comorbidities, ability to understand and follow instructions provided by physiotherapists. The exclusion criteria were: presence of cognitive impairments (Mini Mental State Evaluation score < 24), presence of altered consciousness, psychotic symptoms, bipolar disorder, or other severe psychiatric conditions, conditions contraindicating physical training (e.g., bone fractures), conditions contraindicating the use of VR (e.g., blindness or deafness), refusal to participate in any phase of the research project, or failure to provide informed consent.

### 2.2. Rehabilitative interventions

The control group (CG) of this study performed a conventional cardiac rehabilitation protocol that consisted of 1.5-hour group calisthenics sessions with a 10-minute break, held six times per week. This was accompanied by aerobic reconditioning exercises on a stationary bike or treadmill, depending on medical prescription and the patient's health status.

Patients were randomly allocated to the experimental virtual reality group (VRG) and underwent the standard cardiac rehabilitation program, but some sessions were substituted by the virtual reality rehabilitation protocol. The VR intervention consisted of a simulated driving experience delivered over nine sessions, three times per week, each lasting 20 minutes, over a three-week period. Participants observed the virtual scenario through Meta Quest 2 head-mounted display (HMD), offering an approximate 90-100° field of view (FOV) and a resolution of 3840 x 1920 pixels per eye. The virtual reality (VR) therapy employed a full immersion approach, delivering intense multisensory visual-auditory stimulation. Patients were exposed to diverse driving scenarios, specifically: urban streets (featuring intersections, traffic lights, and pedestrians to simulate complex urban environments), ring roads (designed for practicing smooth and confident high-speed driving in dense traffic), and tunnels (sections aimed at gradually desensitizing users to claustrophobic responses during driving). The virtual environment was designed by combining 3D objects and 360° VR videos using Unity 60000.0.33f1 game software environment (<https://unity.com/>). The 3D

environment consisted of a realistic 3D model of a car's interior, simulating the driver's perspective (1:1 scale). The virtual cockpit incorporated an interactive steering wheel, controlled by participants from their perspective using Meta Controllers. This interaction, however, did not alter the vehicle's movement path. To optimize immersion, the Meta Controllers were rendered as hands, integrated with a 3D avatar model. Real-time arm movements of the avatar were achieved using inverse kinematics (IK), precisely mirroring the participants' physical actions. The 3D cabin was fully enveloped by 360° VR video showcasing the driving scenarios detailed previously. The VR 360° videos were taken with a GoPro Max® 360° camera (GoPro Inc., San Mateo, CA, USA), with a spherical resolution of 5376 × 2688 at 30 fps and 3D spatial audio with an external Zoom H1 microphone. The spherical 360° videos were processed with Adobe Premier Pro® 2021 (Version 15) (Adobe, San Jose, CA, USA). The various scenarios the patient encountered corresponded to a progressively increasing level of difficulty as the rehabilitative sessions proceeded. Examples of challenging elements included narrow roads, urban traffic, tunnel driving, and high-speed roads. Each session lasted approximately 20 minutes, which was the time required to complete the driving route. However, the session might end earlier if the patient was unable to continue.

### 2.3. Assessment

All patients were assessed at baseline after enrollment (Pre) and again three weeks later at the end of the rehabilitation protocol (Post).

The outcome measures assessed not only functional status, endurance capacity, and mental state, but also quality of life and patient engagement in daily activities. In particular, we measured: Hospital Anxiety and Depression Scale (HADS): A 14-item scale used to assess anxiety (7 items) and depression (7 items) levels related to illness [16,17]; Quality of life (SF-12): A 12-item health survey generating physical and mental health summary scores [18]; Pain Visual Analogue Scale (VAS): A psychometric scale for pain intensity ranging from 0 (no pain) to 10 (worst possible pain) [19]; Borg Scale: A self-assessment tool for perceived exertion, ranging from 0 ("no exertion") to 10 ("maximum exertion") [20]; Upper limb Range of Motion (ROM): Assessment of changes in upper limb range of motion: shoulder flexion/extension, elbow flexion/extension; Manual Muscle Test (MMT): Evaluation of upper limb strength (MMT score from 0 to 5 for shoulder abduction, elbow flexion, and grip strength; total score ranges from 0 = no strength to 15 = normal strength) [21,22].

Additionally, during each session, the following clinical parameters were monitored and recorded: heart rate (HR), arterial oxygen saturation (SpO<sub>2</sub>), and the maximum and minimum blood pressure (BP max, min).

### 2.4. Statistical Analysis

Data are reported in terms of mean ± standard deviation for clarity, but given the ordinal scales used, non-parametric tests were used within subjects (Wilcoxon test) and between subjects (Mann-Whitney u-test). Sample size was computed on the basis of previous data related to the use of VR in cardiac rehabilitation [23], setting an alpha level at 5%, power of the test (1-beta) at 80% and with an effect size of 0.9, obtaining a minimum number of participants of 58. The alpha level of statistical significance for all the analyses was set at 0.05.

## 3. Results

Sixty patients were enrolled in this study. Their mean age was 70±9 years old, with 77% men and 23% women. All of them needed cardiac rehabilitation. Ninety-seven percent of them had a surgical intervention: 40% for the replacement of mitral and/or aortic valve, 33% after bypass surgery, 24% after other kinds of cardiac surgeries. The mean time between surgery and beginning of rehabilitation was 16±11 days. Only 3% of patients had a heart failure without any surgical intervention. These patients were randomly allocated in the two groups, each consisting of 30 patients.



Table 1 shows the clinical variables assessed pre- and post-rehabilitation, revealing significant improvements in terms of pain and Borg-score in both groups, and HADS-total score, physical and mental health only in Virtual Reality Group. Borg-score resulted significantly lower in VRG than in CG ( $p<0.01$ ). The analysis of upper limb ROM and MMT-score did not show any significant differences between groups before rehabilitation, except for left elbow flexion (CG:  $143\pm15^\circ$ , VRG:  $137\pm8^\circ$ ,  $p=0.006$ ). After rehabilitation, significant differences in ROM were observed for left (CG:  $123\pm9^\circ$ , EG:  $129\pm14^\circ$ ,  $p=0.020$ ) and right (CG:  $121\pm13^\circ$ , VRG:  $129\pm15^\circ$ ,  $p=0.042$ ) shoulder flexion, without differences at left elbow flexion (CG:  $147\pm12^\circ$ , EG:  $146\pm8^\circ$ ,  $p=0.187$ ). In terms of MMT-scores, after rehabilitation significant differences were observed for right shoulder flexion (CG:  $4.8\pm0.5$ ; VRG:  $5.0\pm0$ ,  $p=0.042$ ) and right elbow flexion (CG:  $4.9\pm0.4$ , VRG:  $5.0\pm0$ ,  $p=0.042$ ).

Physiological parameters were also assessed before the 1<sup>st</sup> session of therapy, immediately after it, and before the last session. Data are reported in Table 2. Both groups showed an increase in SpO<sub>2</sub> after rehabilitation. The maximum blood pressure resulted slightly but significantly increased in patients in the control group.

**Table 1.** Mean  $\pm$  standard deviation of the clinical variables assessed in Virtual Reality (VR) group and control group, pre- and post- rehabilitation. The p-values refer to the within group comparison performed with Wilcoxon test.

| Clinical variables | VR Group       |                |         | Control Group   |                 |         |
|--------------------|----------------|----------------|---------|-----------------|-----------------|---------|
|                    | Pre            | Post           | p-value | Pre             | Post            | p-value |
| HADS               | 37.0 $\pm$ 2.6 | 34.2 $\pm$ 1.9 | <0.001  | 36.6 $\pm$ 2.6  | 34. $\pm$ 2.2   | 0.187   |
| HADS-A             | 20.9 $\pm$ 2.3 | 20.9 $\pm$ 2.3 | 0.919   | 20.1 $\pm$ 2.5  | 21.4 $\pm$ 1.8  | 0.209   |
| HADS-D             | 16.0 $\pm$ 1.8 | 16.7 $\pm$ 1.7 | 0.097   | 16.5 $\pm$ 2.2  | 16.0 $\pm$ 2.1  | 0.092   |
| SF-12-PH           | 38.0 $\pm$ 7.4 | 41.9 $\pm$ 7.5 | 0.012   | 33.0 $\pm$ 5.7  | 39.2 $\pm$ 6.1  | 0.153   |
| SF-12-MH           | 46.0 $\pm$ 9.3 | 51.8 $\pm$ 8.7 | 0.002   | 43.0 $\pm$ 12.0 | 51.6 $\pm$ 11.9 | 0.511   |
| Pain VAS           | 3.9 $\pm$ 2.7  | 1.1 $\pm$ 1.9  | <0.001  | 3.7 $\pm$ 2.4   | 1.7 $\pm$ 2.0   | 0.014   |
| BORG               | 3.8 $\pm$ 2.4  | 1.1 $\pm$ 1.8  | <0.001  | 5.6 $\pm$ 2.1   | 3.2 $\pm$ 2.0   | 0.002   |

**Table 2.** Mean  $\pm$  standard deviation of the physiological variables assessed before the first session of therapy (Pre 1<sup>st</sup> S), immediately after it (Post 1<sup>st</sup> S) and before the last session (Pre Last S). The p-values refer to the Wilcoxon test with respect to the Pre 1<sup>st</sup> S evaluation.

| Physiological parameters | VR Group              |                             |                             | Control Group         |                             |                             |
|--------------------------|-----------------------|-----------------------------|-----------------------------|-----------------------|-----------------------------|-----------------------------|
|                          | Pre 1 <sup>st</sup> S | Post 1 <sup>st</sup> S      | Pre Last S                  | Pre 1 <sup>st</sup> S | Post 1 <sup>st</sup> S      | Pre Last S                  |
| BP max                   | 110 $\pm$ 13          | 110 $\pm$ 9<br>$p=0.908$    | 110 $\pm$ 8<br>$p=0.828$    | 106 $\pm$ 12          | 103 $\pm$ 14<br>$p=0.108$   | 112 $\pm$ 14<br>$p=0.021$   |
| BP min                   | 72 $\pm$ 8            | 70 $\pm$ 6<br>$p=0.111$     | 71 $\pm$ 9<br>$p=0.916$     | 65 $\pm$ 6            | 64 $\pm$ 6<br>$p=0.060$     | 67 $\pm$ 7<br>$p=0.326$     |
| HR                       | 78 $\pm$ 10           | 80 $\pm$ 10<br>$p=0.075$    | 75 $\pm$ 11<br>$p=0.171$    | 73 $\pm$ 12           | 75 $\pm$ 13<br>$p=0.097$    | 76 $\pm$ 11<br>$p=0.321$    |
| SPO2                     | 97.7 $\pm$ 1.4        | 97.7 $\pm$ 1.1<br>$p=0.873$ | 98.4 $\pm$ 0.8<br>$p=0.026$ | 97.2 $\pm$ 1.1        | 97.3 $\pm$ 1.3<br>$p=0.624$ | 97.6 $\pm$ 1.3<br>$p=0.029$ |

4. Discussion

This study aimed to assess the efficacy of integrating virtual reality treatment into a cardiac rehabilitation program, in which patients simulated driving in a different stressful simulated context. Thirty patients received conventional cardiac rehabilitation and the other thirty patients underwent the VR-based treatment combined with conventional therapy. At baseline, the VR group had a slightly lower Borg score for perceived exertion, higher physical health, but also slightly higher blood pressure and heart rate, and reduced mobility in the left elbow.

After rehabilitation, we found that in both groups pain and exertion were reduced, and oxygen saturation increased. For VR group (and not for CG), physical and mental health improved, upper limb mobility improved, and HADS total score was reduced. Conversely, for Control group (and not for VR group) the maximum blood pressure after rehabilitation slightly but significantly increased.

The effects on HADS total score (and to a lesser extent on HADS-anxiety) have already been reported in many previous studies on the use of VR in cardiac rehabilitation [23-26].

However, some other studies reported contrasting results. One study showed a positive effect of VR in cardiac rehabilitation on selective attention, conflict resolution ability, and executive functions, but not on quality of life, depression, anxiety and stress [27]. This latter study included smaller patient groups compared to our study and the previously cited ones, which could have limited the statistical power of the performed analyses. Another study tested exergaming, performed with a commercial videogame console, in cardiac rehabilitation, without finding clinically or statistically significant improvements compared to those obtained with conventional rehabilitation [28]. However, the use of video-game based trainings is very different from the use of virtual reality systems, which are immersive and facilitate the sense of presence and the sense of action in the digital environment [2].

The impact of VR on quality of life is also controversial. We found positive improvements in terms of physical and mental health only in the VR group, and not in the control group. Our findings were in accordance with a previous study reporting the positive effects of a VR-based video game program in ergometry, resistance to fatigue, and health-related quality of life, with excellent adherence and patient-perceived satisfaction in individuals with ischemic heart disease [29]. However, another study reported no statistically significant impact of VR on health-related quality of life in patients undergoing cardiac rehabilitation [30]. At the same time, this study confirmed the positive impact of VR on HADS score.

In our study, also kinematic (ranges of motion) and kinetic (muscle strength) aspects of upper limb were assessed, finding significant positive effects in the group of patients who experienced the VR system, especially at shoulder level. This result is in accordance with the positive effect of VR rehabilitation on upper limb strength already observed in neurological patients [31].

There are two main pitfalls in using VR in rehabilitation: the definition of VR systems, and the poor importance given to content [2]. The former problem is related to the fact that in some studies commercial consoles and computer-based systems were used, but authors referred to them as VR systems, even if they are not immersive [27,32]. The latter problem is that most of the studies discussed the effects of VR regardless of the type of stimuli or games used. In our study, we used a car driving simulator featuring realistic 360° VR videos that depicted real-life city driving. This setup provided a highly controlled and safe environment for practice within the hospital, offering a realistic simulation of an important daily activity patients aim to recover and may sometimes fear resuming. Our application also allowed for progressive increases in task difficulty during rehabilitation by adjusting speed, the number of cars, and street width.

Our study has some limitations that should be taken into account when generalizing its results to the population of cardiac patients needing rehabilitation. First of all, the wide variability in the subjects limited the significance of between-group differences, and statistically significant results were mainly found for within-group analyses. Then, despite enrolling 60 patients, the sample is quite small when that variability is taken into account. Finally, we tested only one driving simulator, and hence, to replicate our results, similar software would be required.

## 5. Conclusions

Cardiac rehabilitation aims to help individuals recover from heart events or procedures by improving their cardiovascular health and overall well-being. It encompasses a multi-faceted approach including exercise training, lifestyle modification, education, and psychological support for returning to a complete independence and functioning during the activities of daily living. The use of VR in cardiac rehabilitation has shown some positive findings in the scientific literature, but also

some controversial results [5,6,33]. These controversies could be due to the developed tasks. We tested a VR system with a car driving simulator that combined realistic 360° video and computer graphics. This approach led to significant improvements in physical and mental health, psychological well-being, and upper limb ranges of motion, which were not observed in patients undergoing a conventional therapy program. Other parameters, such as oxygen saturation, showed improvements in both groups. In conclusion, VR seems to be a promising technology that could be easily and positively integrated into cardiac rehabilitation, but it is fundamental to take into account the type of digital task proposed to the patients according to a personalization of therapy within the framework of evidence-based rehabilitation. We selected a car driving simulated task because allowed a progressive increment of difficulty, involving a mix of psychological and physiological factors, and a good level of engagement of patients also because driving is a fundamental activity that the subjects would recover for recovery their autonomy.

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**Informed Consent Statement:** Signed written informed consent was obtained from all subjects involved in the study.

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