

# Integrating Virtual Reality with Savoring to Promote Well-being of Patients With Chronic Respiratory Diseases: a Pilot Randomized Controlled Trial

Elisa Pancini, Alessia Fumagalli, Sveva Maggiolini, Clementina Misuraca, Davide Negri, Luca Bernardelli, Daniela Villani

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### Table of Contents

Original Manuscript	5
Supplementary Files	27
Multimedia Appendixes	
Multimedia Appendix 1	
CONSORT (or other) checklists	
CONSORT (or other) checklist ()	20

## Integrating Virtual Reality with Savoring to Promote Well-being of Patients With Chronic Respiratory Diseases: a Pilot Randomized Controlled Trial

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#### Abstract

**Background:** Chronic respiratory diseases (CRDs) are widespread pathologies that cause non-reversible airflow limitations as well as a variety of extrapulmonary adverse effects. For these reasons, these pathologies are related to frequent hospitalizations and, consequently, high levels of anxiety, depression, and stress. In this respect, relaxation in Virtual Reality (VR) integrated with savoring, which is the ability to generate and amplify positive emotions, can be used to increase well-being and relaxation in CRDs patients.

**Objective:** This pilot randomized controlled trial aimed to investigate the effectiveness of a two-week VR-based relaxation intervention integrated with savoring in CRDs patients in increasing emotional and psychological well-being, positive emotions, relaxation, oxygen saturation levels (SpO2) and decreasing negative emotions.

**Methods:** This study involved 45 hospitalized CRDs patients from the Pulmonary Rehabilitation Unit of IRCCS INRCA Casatenovo. Alongside traditional pulmonary rehabilitation, the experimental group (N = 23) took part in the four-session VR-based intervention, while the active control group (N = 22) listened to relaxing music. In each session, the experimental group experienced a relaxing virtual scenario followed by a savoring exercise. Both groups filled out the self-reported questionnaires before the intervention (T0), after (T1), and in the one-month follow-up (T2), and before and after each session. The experimental group's VR acceptance and sense of presence were also measured.

**Results:** Regarding the primary outcomes, taking T0 and T1 into account, repeated measures ANCOVAs revealed a significant increase for the experimental group in emotional and psychological well-being, positive emotions, relaxation, and a significant decrease in negative emotions compared to the control group. The psychological changes were maintained at T2. Concerning secondary outcomes, patients reported high VR acceptance and sense of presence.

Conclusions: These results suggest that relaxation VR integrated with savoring can promote well-being and reduce clinical symptoms not only in the post-intervention, but also in the long term. Indeed, savoring can amplify the positive effects of relaxing VR and help patients to focus and amplify their positive experiences, thus counteracting the negative psychological consequences of CRDs. Clinical Trial: anzetr.org, ACTRN12624000435583; https://www.anzetr.org.au/ACTRN12624000435583.aspx (retrospectively registered). This study was approved by the Ethics Committee of the IRCCS INRCA Casatenovo but for administrative issues the trial registration was no completed prospectively. The registration was therefore completed retrospectively before data analysis and paper writing.

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### **Original Manuscript**

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**Keywords**: chronic respiratory diseases, psychological well-being, virtual reality, savoring, positive emotions, relaxation.

### Introduction Background

Chronic respiratory diseases (CRDs) are conditions that negatively impact the lungs and airways [1]. They include, for example, chronic obstructive pulmonary disease (COPD), interstitial lung diseases (ILD), bronchiectasis, idiopathic pulmonary fibrosis, and chronic asthma [2-3]. CRDs were the third greatest cause of mortality in 2019, accounting for 4.0 million deaths and a global prevalence of 454.6 million cases [4]. These disorders result in frequent and chronic respiratory inflammations and infections [5] and can be caused by continual exposure to environmental stimuli such as smoke from cigarettes, air pollution, or job-related risks [2]. People with CRDs experience cough, dyspnoea, breathlessness, limiting functional capacity, decline in lung function, reduced exercise tolerance, and frequent hospitalizations [2, 6-7]. As a result, several CRDs patients can suffer restrictions in their daily activities due to the need to do daily home therapies such as oxygen therapy [8]. To improve

the physiological conditions and physical activity of people with chronic respiratory diseases, pulmonary rehabilitation can be delivered through exercise training accompanied by education and behaviour change [2,9]. Pulmonary rehabilitation can be delivered in an inpatient setting [10] by providing daily exercise training during cyclical hospitalizations.

Because of all these factors, CRDs patients' quality of life is adversely affected, and patients frequently report high levels of anxiety and stress, as well as high levels of depression and low levels of emotional and psychological well-being [11-12]. Anxiety and stress, in particular, can have a severe impact on patients' quality of life and functional capacity [13-14], thus increasing dyspnoea and impairing compliance with home therapies [11]. In this context, promoting relaxation can be an effective way to decrease anxiety and stress levels in CRDs patients. In fact, several studies have shown that listening to relaxing music is effective in relieving anxiety, stress, and dyspnoea, improving lung capacity, and promoting greater exercise tolerance [15-18].

#### Promoting relaxation with virtual reality

Another promising tool to promote relaxation in CRDs patients is immersive virtual reality (VR). This technology enables the creation of interactive worlds generated by computers that replace realworld sensory experiences with digitally created ones, generating the sensation of being in digital settings [19]. VR involves several key processes, including the sense of presence, which is the feeling of being there in the digital experience [20-22]. Virtual reality has been successfully employed in promoting relaxation and reducing stress, anxiety [20, 23-24], and depression [25-27]. It has also shown relevant potential in improving and regulating emotional well-being and mood and promoting positive emotions [28-31] also in patient populations [32-33]. Thanks to VR, the user can immerse himself in various digital environments, such as restorative natural scenarios, and this can be particularly suitable for hospitalized patients who cannot move to natural outside environments [30]. Specifically, virtual restorative scenarios usually show pleasant and peaceful natural environments such as islands, the sea, parks, and gardens, and they can be integrated with naturerelated auditory elements with relaxation properties and have been shown to be effective in different contexts [29]. To date, however, with CRDs patients, immersive VR has been mainly used to facilitate pulmonary rehabilitation, as immersive scenarios enable "attention shifting" and distract patients from negative feelings (e.g., fatigue, dyspnoea, and monotony) and motivate them during exercise training [34-36]. To our knowledge, only a recent RCT evaluated the effectiveness of a 2week intervention based on 10 sessions of immersive VR-therapy on the intensity of depressive, anxiety, and stress symptoms in hospitalized COPD patients [7]. A virtual garden based on the Ericksonian psychotherapy approach, representing symbolically the patient's health and its improvement during the hospitalization through changes in the colouring of the scenario, was used. By comparing this VR intervention with the control group experiencing 10 sessions of Schultz autogenic training, the within-subjects analysis showed significant changes in depression, anxiety, and stress levels in the experimental group.

#### **Amplification of positive emotions**

To enhance the positive effect of VR, an additional tool related to the amplification of positive emotions can be employed [24]. Indeed, positive emotions can play an important role in counteracting the negative effects of anxiety and stress in CRDs patients. In this respect, according to the broaden and build theory of positive emotions, positive emotions broaden habitual ways of thinking and acting [37]. Furthermore, according to the undoing hypothesis, positive emotions can neutralize the harmful effects of negative emotions, as a consequence, they allow the increase of intellectual resources and build a pool of resources from which to draw in future difficult situations [37-39]. A positive psychology technique strictly related to this approach is savoring, which refers to the ability to recognize, appreciate, and amplify positive experiences and emotions in one's life [40]. Interestingly, people can savor a positive past event and relive in the present the same positive emotions experienced in the past and experience new ones (positive reminiscence) [40], but they can

also savor the present moment or a future positive experience (positive anticipation). Literature has shown the consistent impact of savoring interventions on increasing positive emotions and well-being, as well as decreasing negative emotions and reducing depression [40-44]. Up to now, savoring has not yet been applied to CRDs patients, and its possible integration with VR could promote patients' awareness of the positive states experienced during the virtual experience and enable them to create a connection with their personal experiences.

#### The present study

Starting from these premises and taking advantage of the potential of virtual reality and savoring, we conducted a pilot RCT aimed at investigating the effectiveness of an innovative two-week VR-based relaxation integrated with savoring intervention in CRDs patients. This RCT was conducted in collaboration with the Italian VR company Become-Hub that provided the software and the VR equipment and the Pulmonary Rehabilitation Unit of xxx. Specifically, taking the primary outcomes into consideration from the baseline (T0) to the post-intervention (T1), we hypothesized that (1) emotional and psychological well-being would increase more in the experimental group compared to the active control group who listened to relaxing music. In addition, we hypothesized that (2) patients of the experimental group would achieve higher levels of positive affect and lower levels of negative affect, and (3) higher levels of relaxation compared to the active control group. We also hypothesized that (4) the experimental group would maintain the psychological changes at the one-month follow-up (T2) compared to the active control group.

As secondary outcomes, taking pre- and post-sessions into consideration, we also hypothesized that (5) self-report relaxation and peripheral oxygen saturation ( $SpO_2$ ) would increase more in the experimental group compared to the active control group. Through self-report, we also evaluated VR acceptance, the sense of presence experienced in VR, and the perceived usefulness of the intervention. Finally, we qualitatively explored patients' experiences with VR and the savoring exercises. G\*Power 3.1.9.7 software [45] was used to calculate the sample size. Calculation was based on repeated-measures ANOVA: the within–between interaction type I error rate was set at 5% ( = 0.05), the effect size of the main outcomes was 0.25, and the type II error rate gave 90% power for the two groups and two repeated sets of measurements [7]. Correlation among the repeated measures was 0.5 gave 90% power for the two groups and two repeated sets of measurements; correlation among the repeated measures was 0.5 and non-sphericity correction  $\varepsilon$  was 1.0 and it was found that 46 participants would be needed. The anticipated attrition was estimated around 15% [46] and, for this reason, 54 participants were involved.

#### Methods

#### **Design and participants**

This RCT used a between-subjects design. It included three assessment moments, i.e., baseline (T0), post-intervention (T1), and one-month follow-up (T2), and was carried out from January 2023 to September 2023. 54 patients from the xxx Pulmonary Rehabilitation Unit who met the inclusion and exclusion criteria were recruited by the doctors together with the researchers. Age over 18 years and a diagnosis of chronic respiratory disease according to ERS/ATS criteria were the inclusion criteria. The exclusion criteria included pre-existing medical disorders that prevent the use of the Oculus Quest 2 headset, such as (1) the existence of binocular vision anomalies, (2) a history of seizures or epileptic conditions, (3) the presence of cardiac pacemakers, defibrillators, or implanted devices, and (4) the use of hearing aids. A diagnosis of dementia or cognitive impairment documented in the medical records, as well as a Mini Mental State Examination score of < 26, were other exclusion criteria. These patients were hospitalized for about 3 weeks to undergo pulmonary rehabilitation and were not allowed to leave the ward (directives issued by the hospital as a result of the COVID-19 pandemic). Two patients refused to participate due to personal reasons, thus, 52 patients were

randomly assigned by the researchers to the experimental and control groups using block randomization. A label of A or B (A=intervention, B=control) was assigned to each group (block size = 4). Free online software (Research Randomizer 4.0) was used to generate the randomization list. Data were screened for outliers and no outliers were found. Three patients of the experimental group and 2 patients of the active control group were excluded from the analysis because they did not complete the T1 questionnaires due to an early hospitalization discharge. Moreover, 2 patients of the active control group were excluded from the analysis because of severe physical issues during the weeks of hospitalization that greatly impacted their psychological health thus requiring a psychotherapeutic consultation. Consequently, the final sample size resulted in 23 patients in the experimental condition ( $M_{age} = 71.70$ , SD = 7.14) and 22 patients in the control condition ( $M_{age} = 68.18$ , SD = 8.66) (Figure 1). The xxx Ethics Committee approved this study (protocol number:  $3739\_2023$ ) and the study was retrospectively registered in anzetr.org (ACTRN12624000435583).

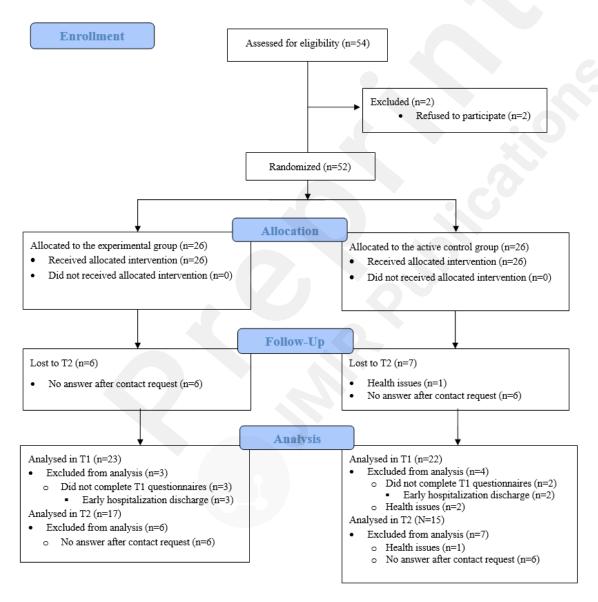


Fig. 1. CONSORT flow diagram.

At baseline, demographic information such as age, gender, educational level, employment status, marital status, and type of chronic respiratory disease were collected. The characteristics of the final sample (after the screening for outliers and missing data) are shown in Table 1.

**Table 1.** Participants' characteristics of the final sample.

		Experimental group	Control group
		(N = 23)	(N=22)
Age, Mean (SD)		71.70 (7.14)	69.18 (8.66)
Gender, N (%)	Male	11 (48%)	11 (50%)
	Female	12 (52%)	11 (50%)
Education level, N (%)	Elementary school	4 (17%)	6 (27%)
	Middle school	11 (48%)	9 (41%)
	Senior high school	8 (35%)	4 (18%)
	Bachelor's degree	-	2 (9%)
	Master's degree	-	1 (5%)
Marital status, N (%)	Single	2 (9%)	1 (5%)
	Cohabitant	1 (4%)	1 (5%)
	Married	13 (56%)	15 (67%)
	Divorced	2 (9%)	1 (5%)
	Widowed	5 (22%)	4 (18%)
Employment status, N (%)	Worker	1 (4%)	1 (5%)
	Unemployed	-	1 (5%)
	Retired	20 (87%)	19 (85%)
	Other	2 (9%)	1 (5%)
Smoke	Non-smoker	4 (17%)	9 (41%)
	Active smoker	3 (13%)	4 (18%)
	Ex smoker	15 (66%)	9 (41%)
	Other	1 (4%)	-
Respiratory disease, N (%)	COPD mild (FEV1≥80%)	2 (9%)	-
	COPD moderate (79%>FEV1≥50%)	4 (17%)	5 (23%)
	COPD severe (49%>FEV1≥ 30%)	7 (30%)	7 (31%)
	COPD very severe (FEV1 <u>&lt;</u> 29%)	2 (9%)	-
	Idiopathic pulmonary fibrosis	3 (13%)	-
	Chronic asthma	2 (9%)	1 (5%)
	Bronchiectasis	1 (4%)	3 (14%)
	Interstitial lung disease	-	2 (9%)
	Other	2 (9%)	4 (18%)

#### **Measures**

To assess cognitive impairment prior to the intervention, the Italian version of the Mini Mental State Examination (MMSE), consisting of 11 items, was used to evaluate patients' cognitive functions [47-49]. The maximum score achievable was 30 and the cut-off was set at 26 and no patients were excluded [50-52].

To assess psychological changes before (T0) and after the intervention (T1) and the maintenance of these changes in the one-month follow-up (T2), both groups completed several questionnaires.

#### **Primary outcomes**

Emotional well-being (defined as enjoyment and absence of unpleasant feelings) and psychological well-being (defined as taking steps toward one's goals and having a life purpose) [53] were measured using the emotional well-being subscale (EWB,  $\omega$  = .76,  $\alpha$  = .65) (3 items) and the psychological well-being subscale (PWB,  $\omega$  = .81,  $\alpha$  = .80) (6 items) of the Italian Mental Health Continuum Short Form (MHC-SF) [54-55]. A 6-point Likert scale can be used to answer (0 = *never* and 5 = *every day*). Positive and negative affect were measured using the Italian version of the Scale of Positive and Negative Experiences (SPANE) [56-57]. This self-report scale consists of 12 items and is divided into two subscales: positive affect (SPANE-P,  $\omega$  = .83,  $\alpha$  = .83) and negative affect (SPANE-N,  $\omega$  = .85,  $\alpha$  = .84). The response scale for all items was a 5-point Likert scale (1 = *very rarely or never* and 5 = *very often or always*).

Furthermore, changes in relaxation within each session were assessed both subjectively through a 10-

point Visual Analogue Scale (relaxation VAS) [58] (in T0, T1, T2, and before and after each session), and objectively through the NONIN Palm Saturimeter that measures peripheral oxygen saturation (SpO<sub>2</sub>, the proportion of oxygen-saturated haemoglobin to total haemoglobin in the blood; it was assessed before and after each session).

#### **Secondary outcomes**

To assess the VR acceptance and the sense of presence experienced in VR by the experimental groups, two questionnaires were proposed after each session. The Slater Usoh Steed Presence Questionnaire (SUS) [59] was used to examine the patients' sense of presence in the virtual environment ( $\omega$  = .84,  $\alpha$  = .82). This questionnaire consists of 6 items that can be answered via a 7-point Likert scale (1 = *not at all* and 7 = *very much*).

VR acceptance was also assessed through an ad hoc questionnaire based on the Unified Theory of Acceptance and Use of Technology (UTAUT) model [60] and measuring behavioural intention ( $\omega$  = .88,  $\alpha$  = .88), performance expectancy ( $\omega$  = .94,  $\alpha$  = .93), effort expectancy ( $\omega$  = .95,  $\alpha$  = .94), and anxiety ( $\omega$  = .94,  $\alpha$  = .86). The response scale for all the 10 items was a 7-point Likert scale (1 = *strongly disagree* and 7 = *strongly agree*).

At the end of each session, patients in the experimental group were asked to freely share their impressions about the virtual experience and to describe the positive events they thought about during the savoring exercise. They were also asked to rate the intensity of 5 emotions felt during the session (love, awe, enjoyment, gratitude, and hope) on a 10-point VAS ranging from 1 (*not at all*) to 10 (*very much*).

A final item was used to assess the perceived usefulness of the intervention on a 5-step Likert scale  $(1 = not \ useful \ at \ all \ and \ 5 = completely \ useful)$  ("Referring to the entire intervention, how much do you think it was useful for you?"). Finally, patients were invited to share their opinions and suggestions about the intervention.

#### **Procedure**

After giving informed consent, patients of both groups completed the pre-intervention questionnaires (T0 - MMSE, MHC-SF, SPANE, relaxation VAS). Then, together with the traditional pulmonary rehabilitation, the experimental group (N = 23) participated in the VR-based relaxation and savoring intervention, while the active control group (N = 22) listened to relaxing music on the headphones, as already done in previous studies with this population [7]. The music was selected from previous studies that have already used it [61-62] also with chronic respiratory diseases patients [15] and the songs used can be found in Appendix A, section 1.

The intervention lasted two weeks and included four 25-minute sessions in the afternoon after the pulmonary rehabilitation physical exercises (Figure 2). The baseline assessment was done in a separate session earlier to avoid overloading the patients. In each session, the experimental group experienced an immersive 10-minute relaxing virtual scenario (provided by the Italian VR company Become-Hub) using the Oculus Quest 2 headset integrated with a narrative voice. It was a prerecorded virtual scenario and patients could explore the virtual environment seated and without using the hand controllers (Figure 3). These scenarios were already used in other relaxation protocols [26, 31, 63-65]. In addition, these scenarios have recently become medical CE (*Conformité Européenne*, a medical device that meets all applicable health, and safety regulations in the European Union).

Moreover, patients completed a savoring exercise proposed through pre-recorded audio after each virtual scenario to consolidate and amplify the positive emotions generated by the VR experience. The sessions were administered by the researchers and occurred one-on-one with each participant. Furthermore, 4 patients in the experimental group and 3 patients in the control group did not complete the fourth session due to early hospitalization discharge. At the end of the intervention (T1)

and at one-month follow-up (T2), both groups completed the questionnaires again (MHC-SF, SPANE, relaxation VAS). At the one-month follow-up, depending on patients' preferences, they were contacted by phone to fill out the questionnaires, while those who wanted could fill them out online on Qualtrics.

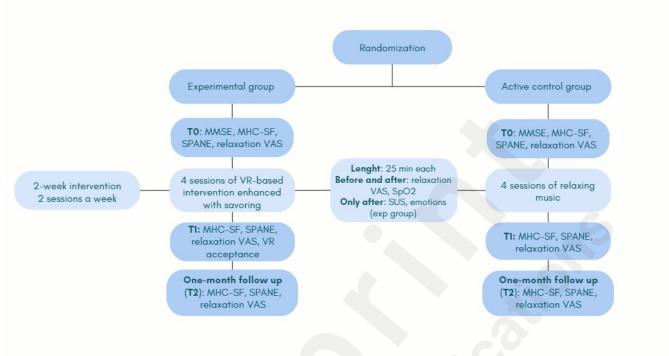


Fig. 2. Study procedure.



**Fig. 3.** A participant during the VR experience.

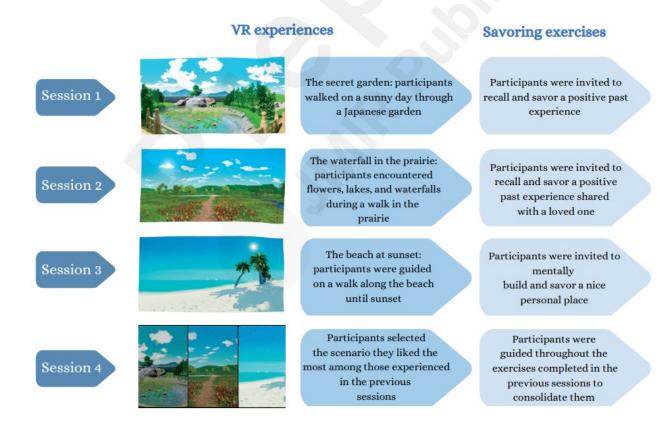
#### VR and savoring protocol

The protocol included four VR-based relaxation integrated with savoring sessions. Specifically, in the first session, patients watched "the secret garden," where they were guided through a quiet and peaceful environment. Throughout the virtual scenario, a relaxing narrative voice guided the participant on a walk inside a Japanese garden on a sunny day. Moving forward, it was also possible to cross a calm pond thanks to a small wooden bridge and pass through cherry blossom trees [26, 63-65]. After that, patients were guided through a savoring exercise (an example of the savoring exercises script can be found in Appendix A, section 2). In particular, they were invited to remember the positive emotions and sensations felt during the VR experience. Afterwards, they were asked to recall and savor a positive memory where they felt similar emotions (Figure 4).

In the second session, the patients watched "the waterfall in the prairie" [31]. The relaxing narrative voice made them notice the colourful flowers, the quiet lakes, and the waterfalls during a walk in the prairie. In this environment, the patients could also listen to the sounds of water, the chirping of birds, and the quiet voices in the distance from a small, distant village. Later, they were invited to recall the positive emotions felt during the virtual experience and were asked to savor a positive past event shared with a loved one.

In the third session, the patients watched "the beach at sunset," where the narrative voice guided them on a walk along the beach until sunset. In this scenario, they could see the colours of the sand and the sea, the relaxing, soothing hues of the sunset, and the beauty of the starry sky. They could also pay attention to the sound of the waves on the shore and notice the light wind moving the palms. Afterwards, the patients were invited to recall the positive emotions felt during the VR experience and to mentally create and savor a personal nice place connected to these emotions [66-67].

In the fourth session, the patients selected the scenario they liked the most among those experienced in the previous sessions. After that, they were guided through the exercises completed in the previous sessions to consolidate them.



**Fig. 4.** Sessions of the VR-based integrated with savoring intervention.

#### **Data analysis**

Data analysis was conducted using IBM SPSS Statistics 29.0.1.0. and the data were screened for outliers and missing data. Group differences regarding emotional and psychological well-being, positive emotions, negative emotions, and relaxation were examined at baseline using the Student ttest for independent samples. The intervention primary outcomes for the experimental group (N = 23) and for the active control group (N = 22) were investigated by considering MHC-SF EWB, MHC-SF PWB, SPANE-P, SPANE-N, and relaxation VAS scores at pre- (T0) and post-intervention (T1). A repeated measures ANCOVA was used with group condition (experimental group and active control group) as the between-subjects factor and time (T0 and T1) as the within-subjects factor to investigate the time x group interactions as they would indicate a significant change due to the intervention. To assess the maintenance of the changes at the one-month follow-up, another repeated measures ANCOVA was performed on a subsample at the one-month follow-up (T2) of the experimental group (N = 17) and active control group (N = 15) who also completed the T2 questionnaires. Group condition (experimental group and active control group) was used as the between-subjects factor, and time (T1 and T2) was used as the within-subjects factor. For both ANCOVAs, the centred variables (MHC-SF EWB, MHC-SF PWB, SPANE-P, SPANE-N, and relaxation VAS scores at baseline) were created and used as a covariate to adjust the baseline differences between groups. The covariates were centred by subtracting the mean covariates score from each covariate score. Repeated contrasts were used to test the differences between groups. Furthermore, group differences regarding relaxation and SpO<sub>2</sub> in each of the four sessions were investigated by creating the delta scores (by subtracting the pre-session scores to the post-session scores) and then using the Student t-test for independent samples.

Thematic analysis was used to assess qualitative data [68]. To address the research question, a thematic analysis detects, analyses, and provides patterns of meaning (themes) across the dataset. This method allowed for the concise analysis of a huge amount of textual material using a deductive approach in which unexpected themes could emerge "bottom-up" from the data. Relevant data points were found methodically before being classified into prospective themes that were refined, defined, and labelled by two judges. Finally, the themes were subjected to a narrative analysis and they are reported in Appendix A.

#### Results

To investigate differences between groups regarding the psychological dimensions at baseline, the Student t-test for independent samples was used. Significant differences in emotional (MHC-SF EWB) (t(43) = -4.01, P<.001) and psychological well-being (MHC-SF PWB) (t(43) = -2.62, P=.012), and in positive emotions (t(43) = -4.51, t=-4.51, t=-4.51, t=-4.51, t=-4.51, were found. No significant differences between groups in negative emotions (SPANE-N) and relaxation (relaxation VAS) were found.

#### Effectiveness of the VR-based relaxation integrated with savoring intervention

A repeated measures ANCOVA with group condition as a between-subjects factor (experimental group N = 23, active control group N = 22) and time (T0 and T1) as a within-subjects factor was performed for all variables with centred MHC-SF EWB, MHC-SF PWB, SPANE-P, SPANE-N, and relaxation VAS baseline scores as covariates and each of them was used for each analysis. The time x group interactions were examined as they would indicate a significant change due to the intervention. Descriptive data are shown as mean (M) and standard deviation (SD) (Table 2). The repeated measures ANCOVA indicated a significant greater increase in the experimental group in emotional (MHC-SF EWB, P<.001; repeated contrast: P<.001) and psychological well-being (MHC-SF PWB P<.001; repeated contrast: P<.001), positive emotions (SPANE-P, P<.001; repeated contrast: P<.001), and relaxation (relaxation VAS, P<.001; repeated contrast: P<.001) compared to the control group. Furthermore, the repeated measures ANCOVA revealed a significant decrease in the experimental group in negative emotions (SPANE-N, P<.001; repeated contrast: P<.001) compared

to the control group. See Figure 5 for emotional and psychological well-being, positive and negative emotions, and relaxation scores in T0 and T1 for both groups.

**Table 2.** Comparison between groups in T0-T1: repeated measures ANCOVA interactions effects.

	Experimental group M (SD)			Active control group M (SD)		Time x group, interaction effect		
	Т0	<b>T1</b>	Т0	<b>T1</b>	F	P	Partial $\eta^2$	
MHC-SF EWB	3.05 (1.38)	3.92 (0.85)	5.84 (3.02)	4.18 (1.01)	165.85	<.001a	.888	
MHC-SF PWB	3.31 (1.15)	4.02 (0.70)	4.09 (0.80)	4.31 (0.71)	26.61	<.001 <sup>a</sup>	.559	
SPANE-P	17.87 (4.84)	23.30 (4.38)	23.86 (4.00)	24.64 (4.88)	14.38	<.001 <sup>a</sup>	.407	
SPANE-N	11.91 (6.05)	9.48 (5.12)	11.09 (5.01)	10.00 (3.61)	17.60	<.001 <sup>a</sup>	.456	
Relaxation VAS	7.13 (2.91)	8.65 (2.12)	7.73 (2.52)	8.95 (1.52)	31.22	<.001 <sup>a</sup>	.598	

<sup>a</sup>Significant (p < 0.05).

Note. M: mean; SD: standard deviation.

MHC-SF EWB: Mental Health Continuum Short Form - Emotional Well-Being; MHC-SF PWB: Mental Health Continuum Short Form - Psychological Well-Being; SPANE-P: Scale of Positive and Negative Experiences - Positive affect; SPANE-N: Scale of Positive and Negative Experiences - Negative affect; Relaxation VAS: Relaxation Visual Analogue Scale.

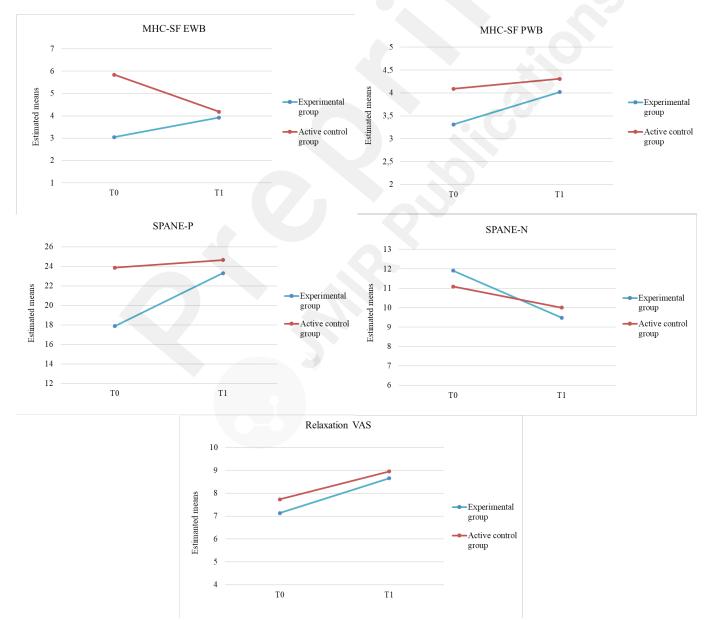


Fig. 5. Emotional and psychological well-being, positive and negative emotions, and relaxation scores in T0 and T1 in

both groups.

#### Maintenance of the psychological changes at the one-month follow-up

To assess the maintenance of psychological changes achieved post-intervention (T1) after one month (T2), a repeated measures ANCOVA with group condition as a between-subjects factor (experimental group N = 17, active control group N = 15) and time (T1 and T2) as a within-subjects factor was performed for all variables with centred MHC-SF EWB, MHC-SF PWB, SPANE-P, SPANE-N, and relaxation VAS baseline scores as covariates and each of them was used for each analysis. No significant differences between groups were found in emotional (repeated contrast: P = .299) and psychological well-being (repeated contrast: P = .173), in positive (repeated contrast: P = .071) and negative emotions (repeated contrast: P = .329), and in relaxation (repeated contrast: P = .473) (Table 3).

**Table 3.** Comparison between groups in T1-T2: repeated measures ANCOVA interactions effects.

	Experimental group M (SD)		Active control group M (SD)		Time x group, interaction effect		
	T1	<b>T2</b>	T1	<b>T2</b>	F	P	Partial η²
MHC-SF EWB	4.00 (0.92)	3.52 (1.25)	3.97 (1.16)	3.53 (1.11)	1.25	.299	.080
MHC-SF PWB	4.02 (0.70)	3.90 (0.66)	4.08 (0.71)	4.05 (0.67)	1.86	.173	.114
SPANE-P	23.65 (4.62)	22.65 (5.24)	24.40 (5.36)	24.07 (4.14)	2.90	.071	.167
SPANE-N	9.53 (5.42)	11.00 (4.69)	10.13 (3.73)	11.13 (4.50)	1.15	.329	.074
Relaxation VAS	9.00 (1.36)	7.53 (2.15)	8.80 (1.74)	7.80 (2.33)	0.76	.473	.052

<sup>&</sup>lt;sup>a</sup>Significant (p < 0.05).

Note. M: mean; SD: standard deviation.

MHC-SF EWB: Mental Health Continuum Short Form - Emotional Well-Being; MHC-SF PWB: Mental Health Continuum Short Form - Psychological Well-Being; SPANE-P: Scale of Positive and Negative Experiences - Positive affect; SPANE-N: Scale of Positive and Negative Experiences - Negative affect; Relaxation VAS: Relaxation Visual Analogue Scale.

#### **Relaxation changes within sessions**

To investigate differences between groups in each session, delta scores for self-reported relaxation and  $SpO_2$  were created by subtracting the pre-session scores from the post-session scores. The Student t-test for independent samples was performed on delta scores. Both relaxation and  $SpO_2$  increased in all sessions in both groups and no significant differences were found between groups (Table 4).

**Table 4.** Relaxation and oxygen saturation levels ( $SpO_2$ ) before and after each session.

		Experimental group M (SD)	Active control group M (SD)	-	nt sample t- sts	<ul> <li>aSignific</li> <li>nt (p</li> <li>0.05).</li> </ul>
		,	,	t	P	_ 0.03). _ Note. M
Relaxation 1	Pre-session 1	6.78 (2.58)	7.64 (2.28)			mean; SI
	Post-session 1	8.83 (1.11)	9.32 (1.04)			standard
	Delta score	2.04 (2.10)	1.68 (1.84)	0.61	.542	deviation.
Relaxation 2	Pre-session 2	6.74 (2.16)	6.86 (2.78)			
	Post-session 2	8.84 (1.50)	9.14 (1.78)			VR
	Delta score	1.74 (2.03)	2.27 (2.29)	-0.83	.412	
Relaxation 3	Pre-session 3	7.43 (2.17)	7.32 (2.66)			
	Post-session 3	8.57 (1.41)	9.14 (1.39)			
	Delta score	1.13 (1.77)	1.82 (1.97)	-1.24	.223	
Relaxation 4	Pre-session 4	8.21 (1.78)	8.00 (2.03)			
	Post-session 4	9.21 (1.03)	9.47 (1.12)			
	Delta score	1.00 (1.33)	1.47 (1.50)	-1.03	.311	
SpO <sub>2</sub> 1	Pre-session 1	92.04 (3.57)	92.50 (3.49)			
1 -	Post-session 1	94.26 (2.12)	95.55 (1.71)			
	Delta score	2.22 (2.71)	3.05 (2.89)	-0.99	.327	
SpO <sub>2</sub> 2	Pre-session 2	92.26 (3.63)	93.09 (2.2)			
•	Post-session 2	94.87 (2.28)	95.73 (2.16)			
	Delta score	2.61 (3.14)	2.64 (2.26)	-0.03	.973	
SpO <sub>2</sub> 3	Pre-session 3	91.39 (3.09)	93.68 (2.57)			
<b>.</b> -	Post-session 3	93.91 (3.13)	95.41 (2.20)			
	Delta score	2.52 (2.31)	1.73 (2.90)	1.02	.314	
SpO <sub>2</sub> 4	Pre-session 4	93.42 (1.80)	94.21 (2.23)			
	Post-session 4	95.21 (1.47)	95.74 (1.94)			
	Delta score	1.79 (1.93)	1.53 (1.74)	0.44	.662	

#### acceptance and sense of presence

Regarding VR acceptance, patients reported high levels of behavioural intention (range: 1-7 for each subscale; M = 5.55, SD = 1.91). They also showed high levels of performance expectancy (M = 5.21, SD = 1.91) and effort expectancy (M = 5.64, SD = 1.54) for this intervention. In addition, patients reported very low levels of VR anxiety when experiencing the intervention (M = 1.16, SD = 0.64). Furthermore, patients experienced a high sense of presence (range: 1-7; session 1: M = 5.25, SD = 1.45; session 2: M = 5.20, SD = 1.77) especially during the last 2 sessions (session 3: M = 5.73, SD = 1.32; session 4: M = 5.77, SD = 1.69).

#### Qualitative analysis of the virtual reality experiences and the savoring exercises

After each session, we asked patients to freely describe how they had felt during the VR experience, and we categorized their impressions into some thematic areas. These thematic areas and the in-depth analysis of the contents of the narrated experiences is in Appendix A, section 3.

Regarding savoring exercises, they have stimulated the memory of several positive experiences related to childhood, adolescence, births of children and grandchildren, marriages, travel, day-trips, illnesses, and retirement. Some memories were related to specific elements of virtual scenarios they had seen before, whereas others were not. A qualitative evaluation of the emotions and positive bodily sensations experienced by the patients during the savoring exercises can be found in Appendix A, section 4.

#### Perceived usefulness of the intervention

Regarding perceived usefulness, 8 patients in the experimental group evaluated the intervention as

completely useful, 4 patients rated it as very useful, 8 as quite useful and 2 as little useful. Two patients of the active control group evaluated listening to relaxing music as completely useful, 13 patients rated it as very useful, 5 as quite useful, and one as not useful at all. A qualitative analysis of patients' explicit opinions and suggestions about the intervention was also conducted. It is possible to identify 6 main categories from the patients' comments, 4 of which are common to both groups (Table 5).

Table 5. Qualitative analysis of perceived usefulness of the intervention.

	Experimental group (number of patients)	Active control group (number of patients)
Organization and procedures of the intervention	Sessions and timing were adequate (23) Times between sessions were helpful in reflecting on and appreciating the positive memories that came to mind during the sessions (1) Desire to have more sessions and to view longer VR scenarios (3)	Sessions and timing were appropriate (21)
Expectations about the intervention	Initial hesitation to begin the intervention, but later reconsidered (2)	-
Intervention strengths	Opportunity to relive very good past moments (2) Opportunity to learn something new (1) Break the monotony of hospitalization (2) Breathing better as a result of the intervention (4)	Listening to music was very relaxing (9) Appreciation for the sessions even though they preferred other music genres (3) Disconnect from daily hospitalization routine (1) Breathing better after listening to music (1)
Intervention weaknesses	Preference for more realistic scenarios (2)	
Future expectations	Desire to follow the intervention again in future hospitalizations (6)  Desire to financially support the intervention (1)	Request to receive additional relaxing music to listen to even after the conclusion of the intervention (2) Suggestions of other relaxing music to use for future sessions (1)

#### Discussion Emotional and psychological well-being

People with CRDs often face significant challenges due to their conditions, which go beyond the physical aspect and extend to emotional and psychological impacts. Therefore, it is crucial to develop innovative approaches to promote CRDs patients' well-being. Taking into account all these elements, this RCT investigated the effectiveness of an innovative VR-based relaxation integrated with savoring intervention in promoting emotional and psychological well-being, positive emotions, relaxation, and reducing negative emotions in CRDs patients. The maintenance of the psychological changes at the one-month follow-up was also investigated.

The findings are very encouraging and partially supported our hypothesis. Regarding the primary outcomes, such as the effectiveness of the intervention on increasing emotional and psychological well-being (H1), patients reported significant improvements, and these results are in line with other studies in which VR scenarios were employed to promote emotional and psychological well-being [31] and also in patients with chronic diseases [69]. Indeed, the 3 virtual experiences took patients on a first-person exploration of natural surroundings, guided by a soothing narrative voice that helped them focus on their positive bodily and emotional sensations [31]. In this regard, savoring may have helped patients amplify the positive states experienced during the virtual experience. This means that

the intervention may have helped patients connect with their own thoughts and emotions experienced during the virtual experiences. Furthermore, through the savoring exercises, patients may have had the opportunity to reflect on their own positive memories, savor them, and amplify them deeply.

#### **Positive and negative affect**

Regarding the intervention's effect on positive and negative affect, the second hypothesis (H2) was supported. Indeed, the intervention was effective in increasing positive emotions. As highlighted by previous studies, natural environments and nature-related auditory elements included in the VR experiences are effective in promoting positive emotions [29]. They are also successful in creating effects comparable to restorative natural surroundings [30, 70] and are particularly suitable for hospitalized patients who cannot move outside the hospital. Furthermore, the savoring exercises can be especially effective for older patients who have several positive memories in which they can immerse themselves [71]. These findings are also in line with savoring interventions addressed to older people in which participants were able to savor positive past events and experience in the present the positive emotions experienced then [40, 42, 71]. The intervention was also effective in decreasing negative emotions. Previous studies have shown both VR [72] and savoring to be effective in reducing negative emotions [73-74]. This may be due to the positive emotions experienced both in VR and during savoring exercises, which neutralize the harmful effects of negative emotions related to the pathology and the hospitalization, as stated by the undoing hypothesis [37].

#### Relaxation

Concerning the effectiveness of the intervention in increasing relaxation (H3), patients reported significant improvements. This result is in line with other studies demonstrating the VR relaxation effect, especially when including natural and peaceful settings and natural auditory elements [20, 29]. Indeed, relaxing virtual scenarios were already employed with patients with CRDs showing positive effects on depression, anxiety, and stress [35]. This means that Become-Hub's virtual scenarios were effective in promoting relaxation in hospitalized patients with chronic respiratory conditions.

#### Maintenance of the psychological changes at the one-month follow-up

Concerning the maintenance of the psychological changes at the one-month follow-up, the fourth hypothesis (H4) was supported, suggesting the positive long-term effects of the intervention on emotional and psychological well-being, positive and negative emotions, and relaxation. This means that the intervention provided patients with tools to cope with daily life once hospitalization was over and savoring may have played a role. Thanks to the savoring exercises learned during the intervention, patients were sustained in the formation, maintenance, and amplification of positive feelings, which in turn positively influenced their well-being over time. In particular, savoring practice can motivate patients to be engaged in a broader range of thoughts and behaviours, and it allows for the development of long-term resources [39, 76-77]. Because of the psychological burden that CRDs entail, as highlighted in the literature in several reviews [77-79], having such a tool available to deal with daily life can be a valuable resource.

#### **Relaxation within sessions**

Regarding the secondary outcomes, such as the intervention's effect on self-reported relaxation and  $SpO_2$  pre- and post-sessions (H5), the absence of differences between groups can be understood in light of the positive effects of music on relaxation [17] already positively tested with COPD patients

[80-81]. It seems that the effects of VR-based integrated with savoring relaxation intervention and relaxing music are similar in the short term (post-session). In contrast, the VR-based intervention was more effective than listening to music after the 2-week intervention and this could be due to its engaging properties, which allow patients to reflect and amplify their positive experiences, while listening to music has immediate positive effects but is less effective considering a 2-week time period.

#### VR acceptance and sense of presence

Regarding VR acceptance, patients reported a favourable intention to experience the VR-based relaxation integrated with savoring intervention during their future hospitalizations. They also showed a high performance expectancy for this intervention, evaluated it as easy and understandable, and reported very low VR anxiety. These findings are in line with previous studies that employed VR or savoring with people of similar age [71, 82-83]. Patients experienced a high sense of presence in all 4 sessions and these results are in line with previous research [59, 84]. Indeed, qualitative analysis revealed that they experienced mainly positive bodily sensations related to VR and the sense of being there in the virtual environments. Moreover, the VR scenarios helped several patients breathe deeper and promote principally positive affective states, including tranquillity, peace, and safety. Many patients felt relaxed and were able to connect specific elements of the scenarios to positive past memories, suggesting that virtual experiences can help people in this process through autobiographical recall. Indeed, when the sense of presence and personal importance of VR experiences are considered, they may be experienced in a way that is personally relevant [85], leading to the creation of a connection with the personal experiences.

Qualitative analysis of the savoring exercises also revealed that patients mainly savored positive memories shared with loved ones from the past (e.g., their parents or grandparents) and present (e.g., their sons, daughters, and grandchildren). During the savoring exercises, patients experienced several positive emotions and positive bodily sensations related to these emotions. In addition, most patients in both the experimental and active control groups perceived the respective sessions as useful. Specifically, patients in the experimental group appreciated the organization and procedure, and some of them reported breathing better as a result of the intervention, while others asked to do the intervention again in future hospitalizations. Regarding the active control group, patients found the organization and procedures of the sessions appropriate and found listening to music very relaxing.

#### Strengths and limitations

Taking into account the findings of this study, it is possible to recognize some strengths of this study. One is that, to the best of our knowledge, this RCT was the first to integrate VR and savoring and to investigate the effectiveness of a VR-based relaxation integrated with savoring intervention in CRDs patients in increasing well-being in terms of emotional and psychological well-being, positive emotions, relaxation, and decreasing negative emotions. In addition, the maintenance of the psychological changes was investigated, highlighting the importance of creating well-being promotion interventions that can help patients even after hospitalization and assess their long-term effects. As underlined by Riches et al. [30], there is a lack of data in the literature regarding the VR effects on relaxation in the long term, and assessing follow-up is encouraged. The presence of an active control group that listened to relaxing music was another strength of this study because it is a widely used technique that has proven to be effective in enhancing mental and physical well-being in CRDs patients [17, 81]. Moreover, the presence of an active control group contributed to improving the intervention's effectiveness. The fourth strength was the employed methodology which included several approaches, such as quantitative self-report measurements, objective data such as peripheral oxygen saturation, and qualitative data such as patients' memories and opinions, in order to have as complete an overview as possible of the intervention's effects. The session organization and timing were also strengths of this study, probably due to the engaging activities and the two-week duration that was considered appropriate by the patients. Furthermore, some limitations can be identified. First, the sample is heterogeneous, as it includes patients with different chronic respiratory diseases.

Investigating the intervention effects on specific CRDs could provide a deeper understanding. Second, these results can be considered only partially generalizable as they involve a sample of CRDs patients from Northern Italy. Third, the sample size decreased considerably at the one-month follow-up, reducing the statistical power. Moreover, given the integrated nature of the protocol that combined VR and savoring, it is not possible with this study to analyse the contribution of the individual components of the protocol (VR-based relaxation and savoring). Future studies are encouraged to investigate the role of both separately. In addition, the occurrence of negative side effects (e.g., cybersickness) of VR was not systematically measured after each session even if the patients' qualitative responses mainly highlighted positive bodily sensations after watching the scenario.

#### **Conclusions**

VR-based relaxation integrated with savoring intervention in CRDs patients is effective in enhancing emotional and psychological well-being, positive emotions and relaxation, and reducing negative emotions and its effectiveness is even higher than widely used techniques such as listening to relaxing music [15, 17]. The findings obtained and the appreciation for the intervention showed the potential of VR integrated with savoring, in which savoring can amplify and prolong the positive emotions experienced during VR beyond the virtual scenario, allowing patients to shift their focus and dwell on the positive parts of their lives. Moreover, given the CRDs patients' psychological burden, this intervention underlines the importance of promoting well-being during the hospitalization weeks and leaving patients with tools they can use in their daily lives and in future difficult situations to recognize and appreciate their positive moments. Furthermore, the psychological changes were maintained one month after the intervention, highlighting the great potential of this intervention in maintaining well-being in the long term. Future studies are encouraged to assess the maintenance of these results with a larger sample size to broaden the understanding of long-term effects and to explore the intervention's effects on specific chronic respiratory diseases.

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#### **Ethics approval and consent to participate**

This study has been conducted in compliance with the Declaration of Helsinki and approved by the xxx Ethics Committee (protocol number: 3739\_2023). All participants signed an informed consent form before beginning the research about the research protocol, data protection and privacy according to the General Data Protection Regulation (GDPR; EU 2016/679). The study's objectives, confidentiality, and anonymity were described, and volunteers were given full authority to complete the study. All methods were performed in accordance with the relevant guidelines and regulations in the declaration.

#### **Conflicts of interests**

The authors declare no conflicts of interests.

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### **Supplementary Files**

### **Multimedia Appendixes**

Integrating Virtual Reality with Savoring for CRDs patiens. URL: http://asset.jmir.pub/assets/62275b08b3e757d2e7ad45912ee014c3.doc

### **CONSORT** (or other) checklists

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