## RESEARCH ARTICLE



# Effect of using virtual reality on fatigue and mental workload as key determinants of perceived stress in neonatal intensive care staff: A randomized controlled trial feasibility study and protocol

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## **Abstract**

**Background:** Health care professionals (HCPs) in neonatal intensive care units (NICUs) are prone to significant stress, leading to deleterious mental health effects. Recently, some studies have explored virtual reality (VR) immersion experience to mitigate these risks. However, these studies vary in clinical settings, design and mental health parameters.

**Aim:** To report on the safety and feasibility of VR immersion experience in busy tertiary NICU HCPs.

**Study Design:** Ten eligible NICU HCPs without photosensitive epilepsy or cardiopulmonary disease participated. Participants underwent VR immersion (intervention arm; maximum of 15 min/session and 1 session/shift) during breaktimes in three consecutive shifts. They underwent a washout period, after which they completed 3 sessions as routine breaks (control arm) without VR experience. They completed prepost break stress and survey questionnaires in both arms.

Results: Analyses comprised data from 28 VR immersion and 27 control arm sessions (nine participants completed three sessions in both arms and one participant completed one session in intervention arm only). All VR immersion sessions were 'really liked' (60.7%) or 'liked' (39.3%). As far as the usage of VR devices were concerned, majority were deemed to be 'really easy' (25%) or 'easy' (57.14%). Quality of VR environments were reported to be 'Excellent' (28.6%) or 'good' (60.71%) in majority

Clinical trial registration: This trial has been registered in the Australian and New Zealand Clinical Trials Registry (www.anzctr.org.au; ACTRN12622001012763).

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of sessions. Experience of chosen VR environments were 'really liked' (46.42%) or 'liked' (50%). Most importantly, the impact of VR experience on enhancing the break was deemed to be 'Yes, a lot' (46.42%) or 'Yes, a bit' (39.28%) in most sessions. Participants reported 'very minor' side effects in three VR sessions, none requiring any therapeutic interventions. Rest of the sessions reported 'no' side effects.

**Conclusions:** VR immersion experience is safe and feasible in busy HCPs in a tertiary NICU. Future recommendations would be to compare VR immersion experience with other well-being measures of staff.

**Relevance to Clinical Practice:** Virtual reality immersion experience could be utilized for stress reduction in NICU HCPs.

#### **KEYWORDS**

feasibility, health care professionals, stress reduction, study protocol, virtual reality

## 1 | INTRODUCTION

Health care professionals (HCP) in neonatal intensive care units (NICUs) experience physical and psychological stress. The constantly challenging environment, clinical acuity, noise levels and the complicated equipment exacerbate this. This results in a negative impact (low morale, fatigue and exhaustion) in the short term and increased absenteeism.<sup>1</sup> The cumulative exposure to such high stress levels is detrimental to the overall well-being of HCPs, affecting their employability.<sup>2</sup> Workforce attrition significantly affects patient care quality.<sup>3</sup> The COVID-19 pandemic has worsened this situation, with HCPs reporting higher stress.<sup>4,5</sup> Stressed HCPs are prone to developing anxiety, depression and insomnia.<sup>6,7</sup> It is crucial to prevent HCP stress, burnout and fatigue.

# 1.1 | Background

Recently, virtual reality (VR) techniques have been used to create an immersive environment of being in a virtual world, thereby changing sensory and affective experience. VR techniques have been used to reduce stress, procedural pain and preoperative anxiety in patients. PR has been used to treat anxiety disorders, depression and post-traumatic stress disorder (PTSD). VR-immersion relaxation supports emotion-based and meaning-focussed coping strategies through immediate reduction in stress levels. VR immersion sessions are easy to administer and require less effort in terms of attention and concentration leading to a larger increase in positive affect.

A recent systematic review (SR) suggested a lack of staff well-being measures and recommended adapting digital health strategies to help HCPs, with the goal of facilitating person-centric care. The use of VR techniques to manage HCP burnout has been explored recently. However, the majority of these studies were carried out in non-ICU settings or as observational studies.

#### What is known about the topic

 Virtual reality relaxation methods can be useful in reducing stress in busy health care professionals. This needs to be interpreted cautiously as there is a lack of high-quality randomized controlled trials.

#### What this paper adds

 Virtual Reality relaxation methods are safe and feasible for stress reduction in busy health care professionals in a tertiary neonatal intensive care unit.

## 1.2 | Aims and objectives

Given the potential benefits of VR immersion relaxation and the lack of randomized controlled trials (RCTs) in an ICU setting, we are conducting a clinical trial to assess the use of VR to reduce perceived stress in NICU HCPs. The present manuscript reports the results of Phase 1 (feasibility and safety) after recruiting 10 participants in a busy NICU and the protocol for Phase 2, that is crossover RCT.

## 2 | METHODS

## 2.1 | Design and setting

This trial has two phases: Phase 1—feasibility; Phase 2—crossover RCT. Phase 1 was conducted in a busy tertiary-level NICU in King Edward Memorial Hospital, Subiaco, Western Australia. This 100-bedded NICU admits approximately 1000 infants born <34 weeks and 120 infants born <28 weeks annually. Phase 1 aimed at assessing the feasibility and safety of conducting the study in a busy tertiary NICU.

# 2.2 | Ethics approval

Phase 1 was carried out in accordance with the principles of the Declaration of Helsinki. Phase 1 commenced after approval from the institutional Human Research Ethics Committee (HREC) Child and Adolescent Health Service (CAHS) (RGS0000005561, dated 20/10/2022). This trial has been registered in the (www.anzctr.org.au; RGS0000005561).

# 2.3 | Participants

Research protocol was presented at departmental meetings in King Edward Memorial Hospital, Subiaco, Western Australia. All HCPs were invited to participate.

# 2.3.1 | Eligibility criteria

HCPs in the tertiary NICU, irrespective of their employment duration or shift type, were eligible.

#### 2.3.2 | Exclusion criteria

HCPs with photosensitive epilepsy or significant cardiopulmonary disease were excluded.

## 2.3.3 | Phase 1

First 10 HCPs who expressed interest to participate were assessed for eligibility. Confirming the absence of exclusion criteria, they were

given a participant information sheet and consent form. Written informed consent was obtained from all eligible participants. Phase 1 was conducted over 5 months (October 2023–February 2024).

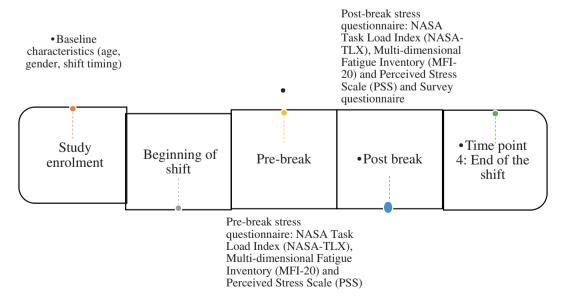
## 2.3.4 | Study details

Participants experienced the VR immersion experience in the intervention arm first, followed by a washout period (>2 weeks) and then the control arm (Figure 1). It was ensured that they completed three consecutive sessions for both study arms in the same diurnal shift pattern with prior reminders via SMS.

#### 2.3.5 | Intervention arm

Participants received a demonstration of instructions (use of VR equipment, disinfection, survey and stress questionnaire) from research team members prior to the first session in the intervention arm. Participants were requested to complete the stress questionnaire prior to their staff break. Then, participants were directed to a room opposite the intensive care nursery in XXXX during their break. Participants in the intervention arm wore the VR headset (Occulus Meta Quest 2) and chose a freely downloaded VR immersion experience. Pictorial instructions were posted in the intervention room. The participants were requested to complete the stress and survey questionnaires post-break (Figure 1). They underwent three consecutive sessions during the same diurnal shift pattern (day, evening or night shift) in the intervention arm doing the questionnaires pre- and post-break.

Participants could choose any free visual experiences on the Healium (https://www.tryhealium.com) app on the Oculus Meta Quest 2 headset. Free VR experiences included ancient sunrise, atlantis, awake the light, Butterfly Island, Hawaii beach, lost city of gold, nature



masterpiece, sparkling harbour, Sunflower Garden and Tulip Valley. Participants could choose either the same or different VR immersion experience in subsequent sessions.

# 2.3.6 | Safety

Symptoms of motion sickness after exposure to VR immersion were reported previously.<sup>21</sup> Visual discomfort from VR is attributed to misaligned accommodation and vergence depth cues. There is a theoretical possibility of addiction to the VR environment.<sup>22</sup> To mitigate these risks, VR immersion was offered only once per shift to the same participant and for a pre-specified maximum duration of 15 min only. The VR immersion was to be discontinued if a participant experienced any motion sickness symptoms. VR immersion experience did not involve any gaming sessions to reduce the chances of motion sickness. Medical treatment was to be offered for symptomatic relief in case of side effects. Side effects were monitored, and participants were encouraged to report them through a survey.

## 2.3.7 | Data collection tools

Demographic details (medical or nursing), age group, gender and timing of the shift (morning, evening or night) were recorded.

- Survey questionnaire: Participants completed a survey questionnaire at the end of each session. This questionnaire comprised 10 questions (Likert scale) graded from 1 to 6 (Table 1). Participants entered 'Not applicable' for VR questions in the control arm.
- Stress questionnaire: Participants completed the NASA Task Load Index (NASA-TLX),<sup>23,24</sup> Perceived Stress Scale (PSS)<sup>25</sup> and Multidimensional Fatigue Inventory (MFI-20)<sup>26</sup> at the beginning and at

the end of their shifts in both the intervention and control arms (Figure 1; Data S1). Participants reported the time taken to complete the stress questionnaires.

Requisite data (demographic characteristics, survey and stress questionnaire) were entered by participants on a REDCAP password-protected database on Samsung tablets kept next to VR devices. RED-CAP data collection were multiple-choice options except for two descriptive questions (free text options). Tablets contained instructions for the use of VR devices in the intervention arm. Survey questionnaire responses were evaluated for reporting Phase 1 results. Stress questionnaire responses shall be evaluated after the completion of Phase 2 (crossover RCT).

# 2.3.8 | Washout period

Participants then underwent a washout period (>2 weeks) with no interventions/data collection.

## 2.3.9 | Control arm

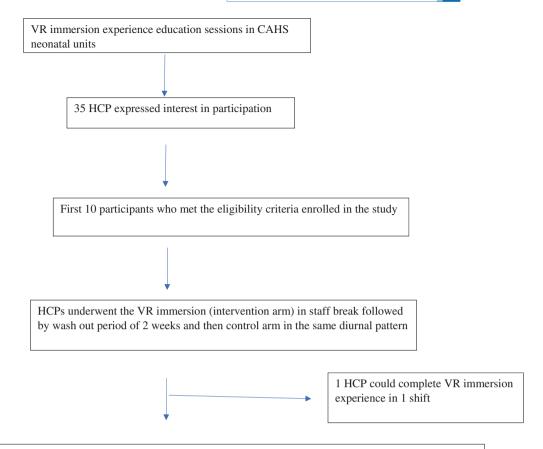
Subsequently, they entered the control arm and completed the prepost break survey and stress questionnaires like the intervention arm. They completed three consecutive control arm sessions in the same shift pattern similar to the intervention arm.

## 3 | RESULTS

Thirty-five HCPs expressed interest in participating after education sessions. The first 10 interested HCPs consented to participate in

**TABLE 1** Survey questionnaire.

1	How did you like the VR system	$\begin{array}{l} 1 = \text{Really liked it, } 2 = \text{Liked it, } 3 = \text{Neither liked nor disliked it,} \\ 4 = \text{Disliked it, } 5 = \text{Really disliked it, } 6 = \text{Not applicable} \end{array}$	
2	Did you find the device headset easy to use?	$\label{eq:continuous} \begin{split} 1 &= \text{Really easy, } 2 = \text{Easy, } 3 = \text{Neutral, } 4 = \text{Difficult, } 5 = \text{Very difficult,} \\ 6 &= \text{Not applicable} \end{split}$	
3	How would you rate the quality of VR immersion environment?	1= Excellent, $2=$ Good, $3=$ Neither Good nor Bad, $4=$ Bad, $5=$ Very Bad, $6=$ Not applicable	
4	What do you think about the length of time spent on VR immersion experience (15 min)?	1= Much too short, $2=$ a bit short, $3=$ the right time, $4=$ bit too long, $5=$ much too long, $6=$ not applicable	
5	Which VR immersion experience did you use?	Free text	
6	Please rate your experience of your chosen VR immersion experience	1= Really liked it, $2=$ Liked it, $3=$ Neither liked or disliked it, $4=$ Disliked it, $5=$ Really disliked it, $6=$ Not applicable	
7	Did you feel that the VR immersion experience enhance your break?	1= Yes, a lot, $2=$ Yes, a bit, $3=$ Neutral, $4=$ Waste of my break, $5=$ Big waste of my break, $6=$ Not applicable	
8	Did you experience any unpleasant side effects during VR immersion, for example discomfort, headache, nausea?	1 = No, 2 = Yes, 3 = Not applicable	
9	Describe the side effects if any	Free text	
10	How much time did you take to complete the stress questionnaires?	1 = less than 10 min, $2 = 11$ to 20 min, $3 = more$ than 20 min, $4 = not$ applicable	



9 HCPs could complete 3 sessions of VR immersion experience in consecutive shifts followed by washout period and then 3 sessions in the control arm in consecutive shifts in the same diurnal pattern

FIGURE 2 Study flow diagram.

**TABLE 2** Demographic characteristics of participants in Phase 1.

Participant number	Age group	Sex	Shift pattern
1	<25	F	Night
2	51-55	F	Day
3	26-30	F	Evening
4	>61	F	Day
5	56-60	F	Day
6	26-30	F	Night
7	26-30	F	Evening
8	26-30	F	Day
9	36-40	М	Evening
10	31-35	F	Day

Phase 1 after reading the participant information sheet (100% acceptance). The study flow diagram is depicted in Figure 2. Demographic characteristics are listed in Table 2.

Majority of participants were females (9/10; 90%). Four participants were in the age group of 26–30 years (range: <25 to >60 years). Five participants worked in the day shift, three in the evening shift

and two in the night shift Nine participants completed all three consecutive sessions in both arms. One participant could not complete three consecutive sessions in the VR arm because of a high clinical workload in subsequent sessions. That participant had completed the first VR immersion session in an evening shift. The completed session was included in the final analysis. Thus, 28 sessions (9 participants  $\times$  3 sessions, 1 participant  $\times$  1 session) in the VR-immersion arm and 27 sessions (9 participants  $\times$  3 sessions) in the control arm were completed. Participant responses in the survey questionnaire were evaluated for feasibility. Hence, the total number of responses for evaluation of the intervention and control arms were 28 and 27, respectively.

Participants in VR immersion sessions rated the first question, that is 'How did you like the VR system?' from one of the 6 responses (Table 3). Participants in 17 sessions (60.7%) rated the system as 'Really liked it' and 11 sessions (39.3%) were rated 'Liked it'. No participant rated the VR system as 'Neither liked or disliked it', 'Disliked it' or 'Really disliked it'. Participants in the control arm rated this 'Not applicable'.

Participants in 28 VR sessions rated the second question, that is 'Did you find the device headset easy to use?' from one of the six responses (Table 3). Participants in seven sessions (25%) rated the VR

**TABLE 3** Responses to each of the points in the survey questionnaire.

		Number of responses
A	How did you like the VR system	
1	Really liked it	17
2	Liked it	11
3	Neither liked nor disliked it	0
4	Disliked it	0
5	Really disliked it	0
5	Not applicable	27
	Total	55
В	Did you find the device headset easy to use?	
1	Really easy	7
2	Easy	16
3	Neutral	5
4	Difficult	0
5	Very difficult	0
6	Not applicable	27
	Total	55
С	How would you rate the quality of VR immersion environment?	
1	Excellent	8
2	Good	17
3	Neither good nor bad	3
4	Bad	0
5	Very bad	0
6	Not applicable	27
	Total	55
D	What do you think about the length of time spent on VR immersion experience (15 min)?	
1	Much too short	0
2	A bit short	9
3	The right time	19
4	A bit too long	0
5	Much too long	0
6	Not applicable	27
	Total	55
E	Which VR immersion experience did you use?	
1	Ancient sunrise	1
2	Atlantis	2
3	Awake the light	3
4	Butterfly Island	4
5	Hawaii beach	4
5	Lost city of gold	3
7	Raj's nature masterpiece	2
3	Sparkling harbour	2
9	Sunflower	1
10	Sunset	1
l1	Tulip Valley	3
=	Please rate your experience of your chosen VR immersion experience	
L	Really liked it	13

TABLE 3 (Continued)

		Number of responses
2	Liked it	14
3	Neither liked it nor disliked it	1
4	Disliked it	0
5	Really disliked it	0
6	Not applicable	27
	Total	55
G	Did you feel that the VR immersion experience enhance your break?	
1	Yes, a lot	13
2	Yes, a bit	11
3	Neutral	4
4	Waste of my break	0
5	Big waste of my break	0
6	Not applicable	27
	Total	55
Н	Did you experience any unpleasant side effects during the VR immersion, for example discomfort, headache and nausea?	
1	No	25
2	Yes	3
3	Not applicable	27
	Total	55
1	Describe the side effects if any	
J	How much time did you take to complete the stress questionnaires?	
1	1 = less than 10 min, 2 = 11-20 min, 3 = more than 20 min, 4 = not applicable	38
2	11-20 min	17
3	More than 20 min	0
4	Not applicable	0
	Total	55

device as 'Really easy' to use, in 16 sessions (57.14%) rated it as 'Easy' to use, and in 5 sessions (17.85%) it was rated 'Neutral' to use. No participant rated the VR device as 'Difficult' or 'Very difficult'. Participants in the control arm rated this 'Not applicable'.

Participants in 28 VR sessions rated the third question, that is 'How would you rate the quality of VR immersion environment?' from one of the six responses (Table 3). Participants in eight sessions (28.6%) rated the quality as 'Excellent' and 17 sessions (60.71%) received the rating of 'Good'. Participants in 3 sessions (10.71%) rated the quality as 'Neither good or bad'. None rated the quality of the VR environment as 'Bad' or 'Very bad'. Participants in the control arm rated this 'Not applicable'.

Participants in 28 VR sessions rated the fourth question, that is 'What do you think about the length of time spent on VR immersion experience (15 min)?' from one of the six responses (Table 3). Participants in 19 sessions (67.85%) rated the length of time on VR immersion experience as 'The right time' and the remaining nine sessions (32.41%) received the rating of 'A bit short'. None rated the length of time on VR immersion as 'Much too short' or 'A bit too long' or

'Much too long'. Participants in the control arm rated this 'Not applicable'.

For the fifth question, participants were asked to name the VR immersion experience they underwent. Eleven different VR experiences were used in total. Participants in two VR intervention sessions did not specify the experience they underwent. VR immersion experiences reported included 'Butterfly Island' and 'Hawaiian beach' in 4 instances. The rest of the experiences and the number of sessions when used are listed in Table 3.

Participants in 28 VR sessions rated the sixth question, that is 'Please rate your experience of your chosen VR immersion experience' from one of the 6 responses (Table 3). Participants in 13 sessions (46.42%) rated their experience as 'Really liked it'; 14 sessions (50.0%) received the rating of 'Liked it' and one session (3.57%) received the rating of 'Neither Liked it or disliked it'. None rated their chosen VR experience as 'Disliked it' or 'Really disliked it'.

In the subsequent question, participants in 28 VR sessions rated whether, that is 'Did you feel that the VR immersion experience enhance your break?' from one of the six responses (Table 3).

Participants in 13 sessions (46.42%) rated that the VR immersion experience enhanced their break as 'Yes a lot' 11 sessions (39.28%) received the rating of 'Yes, a bit' and four sessions (14.28%) received the rating of 'Neutral'. No participants rated in the categories of 'Waste of my break' or 'Big waste of my break'. This question was reported 'Not applicable' in the control arm.

The next question was about any unpleasant side effects during VR immersion sessions. Participants in 25 sessions (89.28%) reported 'No' unpleasant side effects. Participants in 3 sessions (11.72%) reported 'Yes' for minor side effects. The side effects reported were 'Pain in the left eye', 'minor head discomfort' and 'headset was uncomfortable'. None required any therapeutic interventions and lasted for only a few minutes. None required the VR immersion session to be discontinued.

The final question required the participants to mention the duration required to complete the stress questionnaires (i.e. 'How much time did you take to complete the 3 stress questionnaires?') from one of the four responses (Table 3). As the participants completed the stress questionnaire in all the VR-intervention and control arm sessions, there were a total of 55 responses. Study participants reported that they could complete the mental health scales/stress questionnaires in '<10 min' in 38 sessions and in '11–20 min' in the remaining 17 sessions. Participants required <20 min to complete the scales in all the sessions.

The results are depicted in pictorial form (bar graphs and pie charts) (available as Data S1).

#### 4 | DISCUSSION

Phase 1 results demonstrate that VR immersion relaxation sessions during staff breaks in a busy tertiary NICU were feasible and safe. Several NICU HCPs expressed interest in participating. A total of 9 out of 10 participants were able to complete all three consecutive VR-immersion and control arm sessions as per the planned protocol. Thus, a total of 28 VR immersion sessions were conducted over Phase 1 (5 months).

VR immersion experience was either 'really liked' or 'liked' by all participants (100% likeability). VR devices were 'Really easy' or 'easy' to use in more than 80% of sessions. The quality of VR environments was found to be 'excellent' or 'good' in more than 85% of sessions. The 'amount of time spent' was 'the right time' in more than two-third of the total sessions; it was deemed 'a bit short' in the remaining sessions. A majority of VR immersion experiences (97%) received the rating of 'Really liked it' or 'Liked it'. Further, in >85% of instances, the VR immersion sessions were rated as having enhanced their break by 'a lot' or 'by a bit'. No VR immersion session breaks were deemed to be a 'waste of time'. There were no major side effects. Three study participants reported minor side effects, that is 'minor headache' and 'discomfort'. These side effects lasted only a few minutes and did not require discontinuation of VR sessions or any therapeutic aids. Participants needed <20 min to complete the stress questionnaire in all sessions.

Recently, a few studies evaluated the utility of VR interventions to address stress in HCPs. 18,19,27-29 Nijland et al. (2021) did a pre-post

intervention observational study with 86 participants reporting less perceived stress and better resilience scores post-VR experience. 18 The study conducted by Weitzman et al. (2021) was a prospective randomized crossover trial (n = 18 otolaryngology residents) to assess the efficacy of VRbased therapy for reduction in burnout using the Maslach Burnout Inventory. The study reports a decrease in emotional exhaustion post-VR experience.<sup>19</sup> A single-centre crossover RCT also tested the feasibility and efficacy of VR-based interventions.<sup>27</sup> The authors reported decrease in fatigue scores and better feeling of work disconnection with VR interventions. Beverly et al. (2022) (102 frontline HCP) reported stress reduction using the Tranquil Cine-VR sessions.<sup>29</sup> Choo et al. (2023) included 50 participants (patients with cancer and staff). The study reported stress reduction (qualitative verbal feedback) after using a VR-based app. 30 Croghan et al. (2022) was a pilot, single-blinded RCT (N = 24 HCP).<sup>31</sup> The study reported improvement in anxiety and resilience scores post-VR-based interventions. Pascual et al. (2023) conducted a RCT (n = 32) and reported anxiety reduction by VR-based mindfulness interventions.<sup>32</sup> Adhyaru and Kemp (2022) was a pre-post intervention pilot study (n = 39 clinicians) in a trauma ward. The study reported increased relaxation and happiness after VR experience.<sup>33</sup> Results of these studies suggest that the VR interventions are feasible and useful to help HCPs for fatigue, burnout and stress. However, there are many limitations of these studies apart from the small sample size (not adequately powered to test the effectiveness of the VR interventions). The majority of these studies were conducted as prospective observational studies without a control arm. 18,20,28-30,33-36 There were only some RCTs that looked at the efficacy of VR interventions for staff relaxation, although the majority of them were performed in non-ICU settings involving allied HCP, technicians or medical students. 16,19,31,32,37 Desai et al. (2024) recently conducted a SR to assess the efficacy of VR immersion experience to relieve stress, burnout, fatigue and anxiety in HCP. The unpublished SR concluded that 'VR interventions are useful to address fatigue, burnout, stress, and anxiety in healthcare professionals. However, majority of the included studies (14/17) had a global rating in the "weak" category on the qualitative analysis using the standardized Effective Public Health Practice Project (EPHPP) tool. 38 Hence, the beneficial effects of VR interventions for HCPs should be interpreted with caution because of methodology limitations and lack of adequately powered RCTs.

In summary, the pilot phase results suggest that it is feasible to conduct a randomized crossover trial to evaluate the effect of using VR immersion experience on fatigue and mental workload in busy HCP's working in NICU.

# 5 | PHASE 2 STUDY PROTOCOL

The institutional ethics committee has approved the research team to commence Phase 2 of the trial after reviewing Phase 1 results King Edward Memorial Hospital, Subiaco, Western Australia. Phase 2 will be a RCT using a crossover design with a 2- week washout period. This RCT has been registered in the Australian and New Zealand Clinical Trials Registry (www.anzctr.org.au; ACTRN12622001012763).

## 5.1 | Aim

The primary aim was to evaluate the impact of VR-immersion-based relaxation on fatigue and mental workload (key determinants of perceived stress levels) in HCPs during their busy NICU work shifts.

## 5.2 | Sample size

157 HCPs are rostered daily across the NICUs. Approximately 100 HCPs are expected to participate in the study. A sample size of 50 in each sequence group (AB/BA) gives 80% power to detect a standardized effect size of 0.4 using a  $2 \times 2$  crossover design t-test with a 0.05 two-sided significance level (Figure 3). Based on an expected mean NASA score of 49 and standard deviation of 18, this would equate to an absolute difference of 7.2 or an approximate 15% decrease in score from 49 to 42. Mean NASA score of 49 and standard deviation of 18 was derived from the study by Hertzum. This calculation incorporates sample size inflation for an expected dropout rate of 10%. Sample size calculation was performed with the Power and Sample Size (PASS) software (PASS 2019 Kaysville, Utah, USA). Demographic data collection would be similar to Phase 1 materials and methods (Figures 1 and 3).

#### 5.3 | Randomization

Group assignment would be done using a computer-generated randomization sequence in a 1:1 ratio, and allocation concealment will be achieved using opaque, sealed envelopes by a study facilitator. Data will be stored in a password-protected electronic database (REDCAP).

# 5.4 | Blinding

As evident, participants and the study facilitator shall not be blinded to the intervention. The primary investigators and the biostatistician shall be blinded to participant allocation.

# 5.5 | Washout period

The enrolled participants will undergo a washout period (>2 weeks).

As part of the crossover design, the participants in the intervention arm (A) shall then be switched to the control arm (B) and those in the control arm shall then switch to the intervention arm. The included participants shall undergo 2 sessions in each arm when the data shall be collected. The design of Phase 2 is depicted in Figure 3.

Given the difficulty in having participants on the same roster / shift for three consecutive sessions, it was decided to make it more flexible:

- 1. Two sessions each in the intervention and control arms.
- 2. To have flexibility in the shift pattern for the participants. This would mean the shifts in each arm need not be consecutive.

#### 5.6 | Outcomes

Primary outcome will be the difference in NASA-TLX scores between the two groups. Mental fatigue, workload and emotional stress are directly related to stress in HCPs, particularly in NICU HCPs, putting them at highrisk of burnout. 1.23,24,40,41

Secondary outcomes will be PSS and MFI-20 scores. A survey post-participation will be done to assess the ease of use. Enrolled participants shall also complete the NASA Task Load—A priori rating document (only once) at the time of enrolment.

#### 5.7 | Statistical analysis

Comparisons of mean NASA scores between periods of VR intervention and control will be assessed using a generalized linear model approach with individual subjects modelled as random effects to account for the within-subject correlation arising from crossover design. No formal assessment of carryover will be made as the study design includes a two-week washout period between periods, and no carryover effect is expected. Comparisons of secondary outcomes including MFI, PSS-10 or change in scores will be made using the same generalized linear

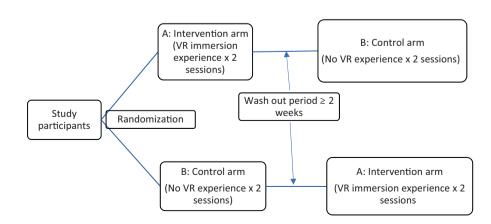


FIGURE 3 Crossover randomized controlled trial (RCT) design: Sequence AB: Intervention arm first followed by a control arm. Sequence BA: Control arm first followed by intervention arm.

models' approach. The Stata version 16 statistical software will be used for final analysis. Results of this RCT will be reported using the CONSORT guidelines for cross-over trials after Phase 2.42

To the best of the authors knowledge, this shall be the first trial exploring the efficacy of VR immersion experience over multiple sessions in a randomized methodology in a busy NICU set-up frXXXX. The other strength of this RCT is the robust crossover study design with the participants being their own controls. Another strength is that the trial has been adequately powered to accurately reflect the differences in the standardized mental health scales (NASA-TLX).

#### 5.8 | Limitations

One of the limitations of the present trial could be the lack of comparison of the VR immersion experience with other well-being measures. Another limitation of the Phase 1 trial is the relatively small sample size. The inclusion of only the first 10 respondents in this pilot study could be considered a limitation. The main phase of the trial shall be inclusive of respondents who expressed interest subsequently. Hence, caution is needed in interpreting the results regarding the efficacy of the intervention. The ongoing Phase 2 of the trial is expected to throw further light on this.

# 5.9 | Implications and practice recommendations

Virtual Reality Relaxation methods appear to be safe and feasible in NICU HCPs and could be considered for stress reduction.

# 6 | CONCLUSION

VR immersion experience is safe and feasible in busy HCPs in a tertiary NICU.

#### **AUTHOR CONTRIBUTIONS**

Saumil Desai: Conceptualization, methodology, investigation, writing original draft and visualization. Gayatri Athalye-Jape: Conceptualization, methodology, validation, investigation, and writing – Review and editing. Sarah Bottcher: Investigation, resources and data curation. Catherine Campbell: Resources and validation. Debbie Chiffings: Resources, data curation, supervision and project administration. Lindsay Kinnaird: Software, investigation and data curation. Ali Fardinpour: Software and resources. Elizabeth Nathan: Methodology, validation and formal analysis. Max Bulsara: Validation and formal analysis. Shripada Rao: Writing – review and editing, supervision and project administration. All authors approve the final manuscript as submitted and agree to be accountable for all aspects of the work.

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#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

#### CONSENT

Written informed consent was obtained from all eligible participants (NICU health care professionals). The authors declare that they have not used any AI tools to collect or analyse data, produce images/graphs or for writing the manuscript.

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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