

# Virtual reality to reduce periprocedural anxiety during invasive coronary angiography: rationale and design of the VR InCard trial

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**To cite:** Breunissen EHW, Groenvelde TD, Garms L, *et al*. Virtual reality to reduce periprocedural anxiety during invasive coronary angiography: rationale and design of the VR InCard trial. *Open Heart* 2024;**11**:e002628. doi:10.1136/openhrt-2024-002628

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Received 31 January 2024  
Accepted 24 March 2024



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## ABSTRACT

**Introduction** Patients undergoing invasive coronary angiography (ICA) experience anxiety due to various reasons. Procedural anxiety can lead to physiological and psychological complications, compromising patient comfort and overall procedural outcomes. Benzodiazepines are commonly used to reduce periprocedural anxiety, although the effect is modest. Virtual reality (VR) is a promising non-pharmacological intervention to reduce anxiety in patients undergoing ICA.

**Methods and analysis** A single-centre open-label randomised controlled trial is conducted assessing the effectiveness of add-on VR therapy on anxiety in 100 patients undergoing ICA and experiencing anxiety in a periprocedural setting. The primary outcome is the Numeric Rating Scale (NRS) anxiety score measured just before obtaining arterial access. Secondary outcomes include postarterial puncture and postprocedural anxiety, patient-reported outcome measures (PROMs) of anxiety and physiological measurements associated with anxiety. The NRS anxiety level and physiological measurements are assessed five times during the procedure. The PROM State-Trait Anxiety Inventory and Perceived Stress Scale are completed preprocedure, and the PROM STAI and the Igroup Presence Questionnaire are performed postprocedure.

**Ethics and dissemination** The protocol of this study has been approved by the Research Ethics Committee of the Radboud University Medical Centre, the Netherlands (CMO Arnhem-Nijmegen, 2023–16586). Informed consent is obtained from all patients. The trial is conducted according to the principles of the Helsinki Declaration and in accordance with Dutch guidelines, regulations, and acts (Medical Research involving Human Subjects Act, WMO).

**Registration details** Trial registration number: NCT06215456.

## INTRODUCTION

Invasive coronary angiography (ICA) with potential percutaneous intervention or coronary function testing is a commonly performed procedure under local anaesthesia in the assessment of ischaemic heart disease. It is an essential procedure for the

### WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Patients undergoing invasive coronary angiography (ICA) experience significant periprocedural anxiety.
- ⇒ Virtual reality (VR) is a non-pharmacological intervention that can be used to reduce anxiety with very limited and minor side effects.

### WHAT THIS STUDY ADDS

- ⇒ This study will provide evidence for VR alleviation of anxiety in interventional cardiology.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ This study will provide evidence for the effectiveness of VR in alleviating anxiety in patients undergoing ICA.
- ⇒ VR might become an alternative to anxiolytics which is especially important in procedures where benzodiazepines are contraindicated or negatively affect diagnostic outcome.
- ⇒ The use of VR to alleviate patient anxiety during invasive coronary angiographies could lead to increased patient and caregiver satisfaction.

diagnosis and treatment of coronary artery disease but can cause high anxiety levels in patients.<sup>1</sup> Up to one in three patients undergoing ICA experiences anxiety, with peak levels occurring prior to the procedure.<sup>1,2</sup> Patients' concerns are mainly related to the potential diagnostic outcomes, fear of the unknown, worries about possible procedural complications and the unfamiliar hospital environment.<sup>1</sup> Psychological triggers may include negative experiences shared by other patients who underwent a similar procedure or not being properly introduced to the treatment team in advance.<sup>3</sup> Anxiety can lead to physiological and psychological complications, compromising patient comfort and overall procedural outcomes.<sup>4</sup> Therefore, identifying effective strategies to

reduce anxiety in patients undergoing an ICA is important.

Medication such as benzodiazepines is commonly administered to reduce anxiety. Although research shows that while preprocedural administration of benzodiazepines yields significant results in anxiety reduction, the absolute effect is only modest.<sup>5</sup> Moreover, these drugs can potentially lead to undesirable side effects such as respiratory depression and adverse drug interactions.<sup>6</sup> Additionally, benzodiazepines can influence the diagnostic outcome in patients who undergo coronary vasomotor function testing.

In a search for non-pharmacological alternatives to medication with broad application and few side effects, multiple approaches have been proposed including educational videos, music therapy and virtual reality (VR).<sup>7</sup> Educational videos demonstrated to contribute to better understanding and adherence to the procedure in comparison with other forms of information.<sup>8</sup> Music therapy is an effective alternative in reducing anxiety, pain and sedative use.<sup>9</sup> Both non-pharmacological interventions are effective in reducing anxiety in patients undergoing diagnostic procedures. However, educational videos are an intervention often given prior to admission, and during the use of music therapy, patients remain aware of their surroundings as a potential cause of anxiety.<sup>8,9</sup>

VR is a computer technology providing an immersive experience in a three-dimensional simulated world allowing the users to interact with a virtual environment. VR can effectively distract patients from the medical situation and surrounding by creating a sense of presence in a virtual world.<sup>10</sup> VR can also contribute to increased patient satisfaction and overall quality of life.<sup>11</sup> Three universal current VR methods include VR patient education, VR distraction (VRD) and VR hypnosis (VRH). VR patient education is commonly a 360° video of the procedure enhancing patients' knowledge of the procedure and managing (negative) expectations.<sup>12</sup> However, similar to preprocedural educational videos, only virtual experience of the procedure prior may not be sufficient in reducing anxiety, pain and stress. VRD and VRH are primarily developed to reduce anxiety, pain and stress. VRD involves engaging patients in a virtual environment that diverts their attention away from events happening in reality.<sup>13,14</sup> Patients are visually captivated by virtual environments or interactive games, creating a pleasant experience and redirecting the focus away from the experienced anxiety. VRD ensures that patients are distracted from their surroundings that allows them to be immersed in a relaxing environment, which can result in reduced awareness of experienced anxiety and pain symptoms.<sup>15</sup>

VRH uses immersive and interactive experiences to focus patients' attention on positive things, enhancing the patient's ability to manage anxiety, stress and pain through guided imagery and narration.<sup>16</sup> VRH might be preferable to VRD during procedures where patients need to remain in a still position, as patients do not have

to engage in activities or movements. VRH has shown to reduce acute pain intensity and anxiety in hospital-admitted trauma patients.<sup>16</sup>

There are only limited data available on the use of VR therapy for the reduction of anxiety in the setting of cardiac catheterisation.<sup>12-14</sup> A small trial has shown the feasibility of VR therapy to reduce anxiety in patients undergoing ICA.<sup>13</sup> The majority of these patients were referred for chronic coronary artery disease, while in clinical practice, around half of the ICA are performed as unplanned acute procedures. Patients with acute coronary syndrome undergoing acute ICA report higher anxiety levels.<sup>1</sup> Moreover, the effect of VR in addition to benzodiazepine use is unknown. We designed the 'VR to reduce periprocedural anxiety during ICA' (VR InCard) trial to test the hypothesis that VR therapy in addition to standard care reduces anxiety compared with standard care in patients undergoing elective or urgent ICA.

## METHODS

### Study design

This is a single-centre open-label randomised controlled trial assessing the effect of VR therapy on periprocedural anxiety in patients undergoing ICA under local anaesthesia. The study is designed and sponsored by the departments of cardiology and surgery of the Radboud University Medical Centre in Nijmegen, the Netherlands. The trial is performed at the cardiology department of the Radboudumc. All data are collected by research team members and captured in Castor Electronic Data Capture (EDC). Data are securely stored in the database of the department of surgery of the study centre accessible to the investigators, in accordance with the General Data Protection Regulation (in Dutch: Algemene Verordening Gegevensbescherming).

### Study population and setting

Patients are eligible if they are listed for ICA due to chronic coronary syndrome, before cardiovascular surgery or for coronary vasomotor function testing (CFT), or if they undergo urgent ICA for non-ST-elevation acute coronary syndrome (NSTEMI-ACS). Patients are not eligible if there is an indication for emergency ICA including primary percutaneous coronary intervention or ICA for unstable NSTEMI-ACS because the use of preprocedural VR may not lead to postponing the emergent procedure. Inclusion criteria are as follows: (1) the patient is 16 years or older and will undergo ICA, (2) the patient speaks and understands the Dutch language, (3) the patient is willing and able to comply with the study protocol and (4) the patient has an NRS anxiety score of 4 or higher on arrival at the day-care unit. Exclusion criteria are as follows: (1) history of dementia, (2) severe hearing/visual impairment not corrected and (3) depression or general anxiety disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.<sup>17</sup> The study takes place at the cardiology day-care unit and

the cardiac catheterisation rooms. The day-care unit is an open unit with multiple beds (14 beds in total) where patients are admitted before undergoing ICA, electrophysiological procedures or device implantations. Due to the open unit, patients may be influenced by each other, as shared experiences, results and other information are audible. The personnel of the cardiac catheterisation room includes a minimum of two nurses and one intervention cardiologist to perform the procedure.

### Informed consent and randomisation

Within usual care, patients are routinely assessed by a specialised nurse at the day-care unit after hospital admission and before ICA. This assessment includes physiological measures and the assessment of anxiety levels using the Numeric Rating Scale (NRS) anxiety score. Research team members screen patients for eligibility following the inclusion and exclusion criteria. Patients are screened at least 3 days per week depending on scheduling of ICAs. Each day, only patients treated in the same cardiac catheterisation room are screened to ensure adherence to study protocol and to ensure the availability of VR headsets and research personnel. A research team member provides oral and written information about the study to eligible patients. After ample opportunity to comprehend the study information, the patient is asked for informed consent by the research team member. Any reasons for not participating are documented if provided by the patient. After obtaining informed consent, patients are randomised in a 1:1 ratio to the VR intervention or control group (standard care) using computer-generated block randomisation in Castor EDC. Stratification is applied for an indication for ICA, categories being elective ICA, CFT and NSTEMI-ACS.

### Control group

The control group is treated according to the local protocol. This means that based on nurses' assessment, patient preference, comorbidity and medication use, patients with moderate to severe anxiety (NRS anxiety score  $\geq 4$ ) have an indication for preprocedural oxazepam (10 mg, oral) at the day-care unit and diazepam (5 mg, intravenous) before arterial puncture at the catheterisation laboratory. In patients planned for CFT, benzodiazepines are withheld per protocol.

### Intervention

Patients in the VR intervention group receive two sessions of VRH in addition to standard care. Before starting the first session in this study, patients become acquainted with the VR headset using VRD. Patients can determine the duration of the VRD session themselves, also depending on the schedule at the catheterisation room. The first session of VRH is administered at the day-care unit 20 min prior to the procedure and has a duration of approximately 20 min. To adequately time this session, the nurse at the catheterisation room informs the research team member of the expected time



**Figure 1** PICO G2 4K headset.

the patients are transported to the catheterisation room. After the first VRH session and before the patients are moved from the day-care unit to the catheterisation laboratory, the VR headset is removed. This is done to prevent patients from becoming disoriented in place and to allow preprocedural introduction of the treatment team. After introducing the treatment team, the second session of VRH is administered. This session starts 5 min prior to arterial puncture and terminates when the diagnostic or guiding coronary catheter is in position. The duration of this second VRH session depends on how smoothly arterial access is obtained. After this second session, the VR headset is removed, and the rest of the procedure continues according to standard practice without the use of VR.

VR therapy is applied using a head-mounted display, the PICO G2 4K headset (Barcelona, Spain) (figure 1). For VRD, the application 'SyncVR Relax & Distract' (SyncVR Medical, Utrecht, the Netherlands) is used. This application contains a wide range of relaxation games, 360° relaxation videos and relaxation exercises, each with a duration of 5–20 min. Patients can choose videos, gamers or exercises according to their own preferences. For VRH sessions, the application HypnoVR (Strasbourg, France) is used, in which the content is described as 'medical hypnosis'. HypnoVR actively directs the focus of patients away from their surrounding and guides patients virtually through a natural environment. Although not everyone is receptive to hypnosis, the exercises in controlled breathing stimulate the patients to slow their breathing rate and apply cardiac coherence, which is a breathing technique aimed at lowering the heart rate, particularly in stressful situations. Patients can also apply these learnt breathing techniques after the VR sessions during the rest of the procedure. Each VRH session can be personalised through selecting different environments with different musical compositions integrating the recognised principles of music therapy (including an ocean, beach or forest as shown in figure 2). Patients can choose for Dutch narration with either a male/female voice or no narration. The narration is similar for all environments. Sessions can be set to last 10 min, 20 min or indefinite duration. The first VRH session is set to last 20 min, and the second VRH session is set to indefinite duration. Headphones are used during the sessions at the day-care unit to prevent patients from being distracted by surrounding sounds and being influenced by other



**Figure 2** Examples of available environments in HypnoVR.

patients in the unit. At the catheterisation room, patients do not wear headphones to allow communication between the treatment team and patient.

### Outcome measures

The primary outcome is the NRS anxiety score measured just before obtaining arterial access. Secondary outcomes include physiological parameters of stress, patient-reported outcome measures (PROMs), caregiver-reported outcome measures and VR-related outcome measures. Baseline data including demographics (year of birth and sex) and medical history, indication for ICA and preprocedural use of benzodiazepines. All measures are collected by a research team member.

Physiological parameters of anxiety include blood pressure, respiration rate, heart rate and heart rate variability (HRV). The HRV measures are obtained using the Polar H10 chest strap device (Polar Electro Oy, Kempele, Finland) with a standard sampling rate of 1000 Hz. Snapshot measurements of 1 min are taken at planned moments as described below. The application EliteHRV (Elite HRV Inc, Asheville, NC, USA) is used to read out the HRV data with automatic artefact correction. Both the Polar H10 chest strap device and EliteHRV are well-validated instruments for research purposes.<sup>18–20</sup> The following HRV parameters are extracted: the root mean square of successive differences, SD of normal-to-normal RR intervals and the low-frequency spectral power to high-frequency spectral power ratio.

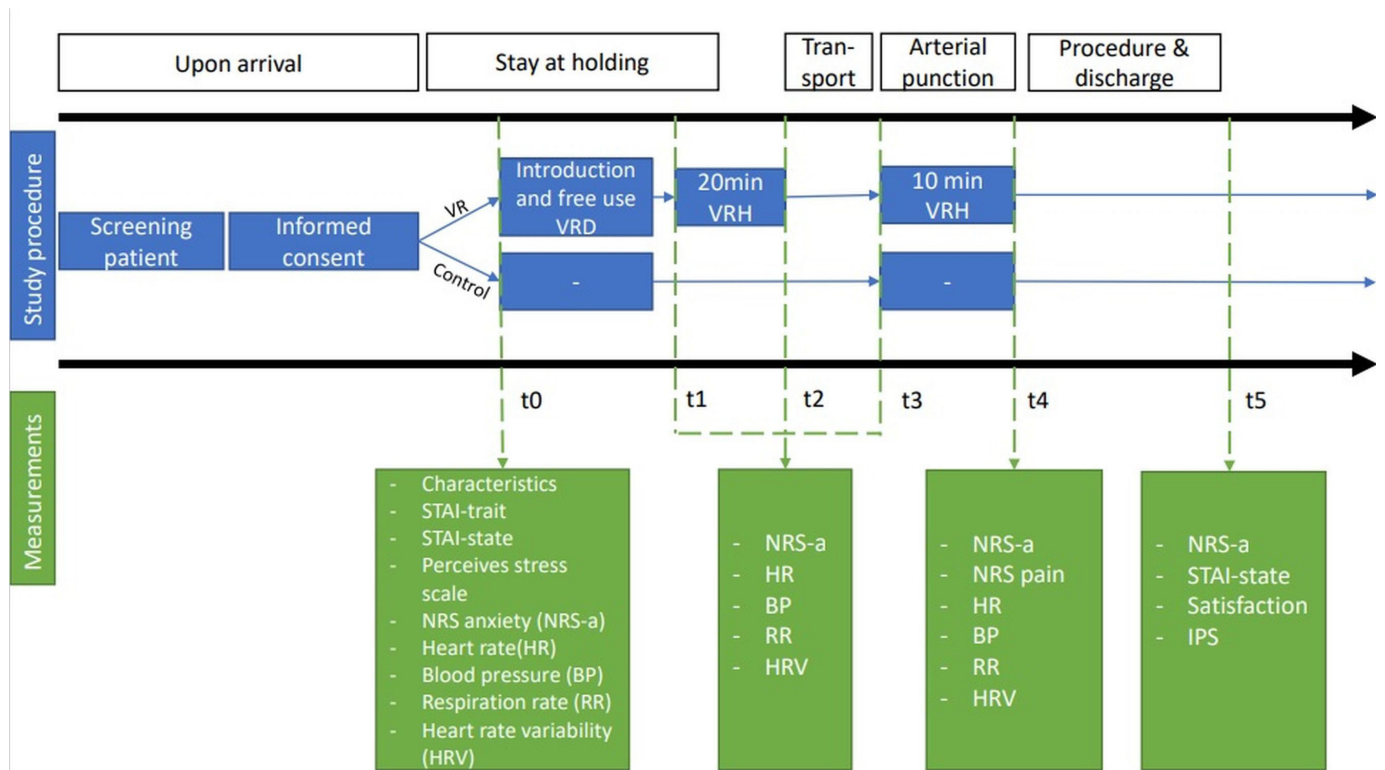
PROMs include the NRS anxiety score and NRS pain score, the State-Trait Anxiety Inventory (STAI) questionnaire, the Perceived Stress Scale (PSS) and patient satisfaction. The NRS score for anxiety ranges from 0 to 10 with 0 representing no anxiety and 10 the worst anxiety imaginable. The NRS score for pain ranges from 0 to 10 representing no pain and 10 the worst pain imaginable. STAI consists of two separate measures: (1) the state of anxiety, that is, how anxious patients feel at the time of completion and (2) the trait of anxiety, that is, how anxious patients feel in general.<sup>21 22</sup> PSS is used to measure how patients generally perceive and handle stress. PSS gives an indication about how often patients felt stressed in the past month, ranging between 0 (never) and 4 (very often).<sup>23</sup> Patient satisfaction with the course of the entire admission is measured using an NRS scale ranging from 0 (not satisfied) to 10 (very satisfied). Caregiver-reported outcome measures comprise caregiver satisfaction with

the procedure using an NRS scale ranging from 0 (not satisfied) to 10 (very satisfied). Furthermore, the general complexity of the procedure is reported, categorised as ‘less complex than expected’, ‘as expected’ or ‘more complex than expected’. In the case of radial artery access, the presence of radial spasm according to the treating cardiologist is registered together with any other complications or difficulties.

VR-related outcome measures include the Igroup Presence Questionnaire (IPQ) and the duration of VR use. The duration of VR use (in minutes) is measured by recording the start time and end time per session. IPQ is used to measure the sense of presence experienced in a virtual environment.<sup>24</sup> The questionnaire provides information about the patient’s experience with the VR environment using three subscales, ‘spatial presence’ (the feeling of being physically present in the virtual environment), ‘involvement’ (the perceived involvement and attention paid to the virtual environment) and ‘perceived realism’ (experience of realism in the virtual environment).

### Study procedures and data collection

After randomisation, patients are asked to complete the STAI state and trait questionnaires and the PSS. For both groups, six measurements of NRS and physiological parameters are performed at scheduled times (figure 3). First, a baseline measurement (T0) is performed immediately after the arrival of the patient at the day-care unit. Patients in the intervention group subsequently receive an introduction to VR and are allowed to use VRD. A second measurement is taken 20 min before transport to the cardiac catheterisation room (T1). Directly following this measurement, the intervention group receives the first session of VRH. Third measurements are taken 20 min later (T2). This is right before transport to the cardiac catheterisation room and for the intervention group right after the first VRH session. After entering the catheterisation room and before the start of the procedure, measurements are collected again for the primary outcome of the study (T3). For the intervention group, this is the moment the second VRH session starts. Fifth measurements are taken after arterial puncture and when the coronary catheter is in position (defined as arrival at the aortic root) including NRS pain after arterial puncture (T4). For the intervention group, the VR headset is removed at this point. For both VRH sessions,



**Figure 3** Timeline study procedures. VRD, virtual reality distraction; VRH, virtual reality hypnosis; STAI, State-Trait Anxiety Inventory; NRS, Numeric Rating Scale.

the total use of VR therapy in minutes is registered. The rest of the procedure is performed according to standard clinical practice. After the procedure, when the patient has returned to the day-care-unit, the NRS anxiety and satisfaction are obtained, and the participant is asked to complete the second STAI state questionnaire and the IPQ (T5).

After the procedure, the intervention cardiologist is asked to answer the NRS satisfaction about the procedure, complexity of the procedure, radial spasm during arterial puncture, conversion to the femoral artery and other complications or difficulties during procedure.

### Sample size

There are no previous studies using NRS anxiety scales at various moments in patients undergoing ICA to perform a power calculation. Based on a previous randomised controlled trial in conscious non-cardiac surgery, we expect a 20% difference in the NRS anxiety score with the use of VR.<sup>25</sup> Based on a mean NRS of 5 in the control group and 4 in the intervention group, with SD of 1.5, we have 90% power to detect a significant difference with a sample size of 48 per group. Based on our previous experience with regard to dropout with the use of VR in non-cardiac surgery studies, 100 patients will be included. Patients not starting the first VRH session due to logistical reasons will be replaced.

### Statistical analysis

Intention to treat and per protocol analyses will be performed for the primary endpoint. Patients who are

replaced because of not starting the first VRH sessions will not be included in the analyses. Patients are eligible for per-protocol analysis if they completed both VR therapy sessions. The difference in NRS anxiety before arterial puncture is compared between groups using an independent sample t-test and Wilcoxon signed rank test, depending on the distribution. Other outcomes are compared using the independent sample t-test,  $\chi^2$  test, Wilcoxon rank sum test or Wilcoxon signed rank test, depending on the type of data and distribution. Tests are performed two tailed. Results are considered statistically significant when  $p < 0.05$ .

Prespecified subgroup analyses include analyses according to sex, indication for ICA (elective, NSTEMI-ACS, and CFT) and preprocedural use of benzodiazepines.

### DISCUSSION

VR InCard is the first study to investigate the effectiveness of VR added to the standard of care including the selective use of benzodiazepines on the experienced anxiety in patients undergoing elective or urgent ICA.

This study provides a more comprehensive understanding of the effect of VR in reducing periprocedural anxiety in patients undergoing ICA. Previous investigations highlighted the need for a non-pharmacological intervention to reduce anxiety in patients undergoing ICA.<sup>6</sup> Preoperative education has shown effectiveness in reducing non-cardiac surgery-related anxiety, and VR as patient education is an effective educational tool to enhance patients' knowledge.<sup>26</sup> In addition, VRH

is possibly an important additional or alternative non-pharmacological intervention to reduce anxiety in the preprocedural setting in patients undergoing ICA. There is evidence supporting the use of VRD to reduce anxiety, pain and discomfort in hand surgery and dental and gynaecological procedures, performed under local anaesthesia.<sup>27–29</sup> The VR InCard trial can provide valuable information on the feasibility of VR therapy in the catheterisation room. If VR is feasible and results in decreased anxiety, this is a valuable non-pharmacological tool for patients. Furthermore, it might be an attractive alternative for patients with contraindications to benzodiazepines, for patients who refuse benzodiazepines or for those in whom the protocol prohibits the use of benzodiazepines, like vasomotor function testing. Without the required study measurements, VR therapy can be administered on demand to all patients, also when anxiety is developed during preparation or in the course of the procedure.

In a broader view, the results of this study are added to the growing evidence of VR therapy for anxiety and pain across various medical settings. Since anxiety and pain are closely related to each other and patient satisfaction, new interventions addressing anxiety can significantly improve treatment outcomes and enhance the overall patient experience. Furthermore, as healthcare continues to evolve towards patient-centred care models, integrating innovative approaches like VR therapy can play a meaningful role in optimising patient comfort, reducing procedural distress and fostering positive healthcare experiences.

This study's strengths include a large patient group, including different indications for ICA (elective ICA, CFT and NSTEMI-ACS), an extensive VR protocol where patients wear the VR headset during two specific sessions at relevant times before the procedure and during the radial artery puncture. By assessing both multiple psychological and physiological measurements, this study aims to determine the effectivity of add-on VR therapy on top of standard care on more subjective parameters of periprocedural anxiety, as well as quantitative parameters associated with periprocedural anxiety. Standard care includes the selective use of benzodiazepines. In addition to patient outcomes, we additionally include the cardiologists' perspective because previous research in palliative care demonstrated that caregiver-reported outcome measures are crucial indicators of patients' needs.<sup>30</sup> The evaluation with caregivers identifies areas where improvements may be made. Therefore, a postprocedure evaluation with the cardiologist is incorporated to assess satisfaction and procedural outcomes and is expected to add in the identification of areas for potential improvements.

Challenges include potential technical and practical problems with the used applications, the VR headset and the polar band. This can lead to suboptimal use of VRH, potentially diminishing the effectiveness of VR therapy. By design, we account for these potential challenges.

First, VRH provides patients with a virtual environment in which patients engage in activities such as breathing exercises without necessitating an active physical position. This allows the patient to remain still during the arterial puncture. Second, while patients are immersed in the virtual world, potential influence by other patients in immediate vicinity is mitigated through the use of headphones provided in the day-care unit. Lastly, in the catheterisation room, communication with the patient, including introduction of the treatment team to the patient, is possible as no headphones are worn. Another challenge lies in the clinical setting in which VR therapy is used. The catheterisation room logistics are subject to a dynamic programme influenced by emergency procedures. While this does not impede the use of VR therapy in itself, it might hinder the accurate collection of measurements for research purposes. This is the reason all measurements are conducted by a designated research member, who can closely monitor planning and timing in response to any scheduling shifts caused by intervening emergency cases.

If this study proves VR is feasible and results in reduced anxiety, VR will become a potential non-pharmacological therapy that can be used in diagnostic cardiological angiography. Results may hold promise for other diagnostic or therapeutic cardiology procedures including electrophysiology procedures and percutaneous valve procedures, where anxiety may impact the patient outcome and effectiveness of the procedure. If proven effective, an implementation study will be designed to obtain key factors for the integration of VR into daily workflow.

## CONCLUSION

The VR InCard trial is the first randomised study that is specifically designed to evaluate the use of VR therapy in addition to standard care to reduce preprocedural anxiety before ICA.

## TRIAL STATUS

This article presents a current protocol, which was last updated on 28 June 2023. Recruitment began on 16 September 2023, with an anticipated recruitment completion date of 30 April 2024.

Data analysis is expected to be completed by May 2024 and results will be published in the following months.

**Contributors** EHWB, TDG, LG, JLB, PD and HvG conceived the study and were responsible for the study design and methodology. TDG will manage the data and will perform quantitative data and statistical analyses. TDG, LG and EHWB collected the data. All authors contributed to writing, reviewing and editing the manuscript. PD and HvG supervised the study design including the writing of this manuscript.

**Funding** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** The ethical approval has been obtained from the Research Ethics Committee of the Radboud University Medical Centre, the Netherlands (CMO Arnhem-Nijmegen, 2023–16586). This trial is registered in ClinicalTrials.

gov (NCT06215456) and conducted according to the principles of the Helsinki Declaration and in accordance with Dutch guidelines, regulations and acts (Medical Research Involving Human Subjects Act, WMO).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** No data are available.

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