Justification and design of a randomized clinical trial to compare virtual reality vs current routine clinical practice to reduce anxiety during revascularization of chronic total coronary occlusions. The ReViCTO trial.

SUPPLEMENTARY DATA

Table 1 of the supplementary data. World Health Organization minimum standard list of items for clinical trials

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT05458999
Date of registration in primary registry	July 14, 2022
Source(s) of monetary or material support	Fundación para la Investigación del Hospital Clínico de Valencia (INCLIVA)
Primary sponsor	Fundación para la Investigación del Hospital Clínico de Valencia (INCLIVA)
Contact for public queries	*Fernández Cisnal, Agustín* fecia82@gmail.com
Contact for scientific queries	*Fernández Cisnal, Agustín* fecia82@gmail.com
Public title	Decreasing patient anxiety during revascularization of chronic total coronary occlusions using virtual reality glasses. (ReViCTO)
Scientific title	*A randomized trial to compare Virtual Reality versus current clinical practice for anxiety reduction during revascularization of coronary Chronic Total Occlusions. The ReViCTO trial.*
Countries of recruitment	Spain
Health condition(s) or problem(s) studied	Anxiety, chronic total coronary occlusion
Intervention(s)	Intervention: Virtual reality headset during percutaneous coronary intervention No intervention: Routine clinical practice
Main inclusion and exclusion criteria	Inclusion criteria: 1. Age >18 years. 2. Elective percutaneous coronary intervention on a chronic total coronary occlusion. 3. Physical and mental ability to wear VT goggles. Exclusion criteria. 1. Unable to or unwilling to give informed consent. 2. Visual impairment. 3. Dementia. 4. Language barrier (unable to communicate fluently in Spanish).

	5. Any other situations that would prevent the use of VR glasses.
Study type	Interventional allocation: randomized Intervention model: parallel assignment Masking: No masking
Date of first enrolment	December 2021
Target sample size	58
Recruitment status	Recruiting
Primary endpoint(s)	Maximum level of anxiety perceived by the patient measured by a visual analogue scale (VASa) (1-10) and determined at the end of the procedure.
Main secondary endpoints	Level of patient-perceived pain, need for intraoperative anxiolytic drug therapy, dose of drug administered, and satisfaction wearing the virtual reality goggles.

Table 2 of the supplementary data. Variables collected

Demographics and clinical history	Age Sex Cardiovascular risk factors (hypertension, hypercholesterolemia, diabetes mellitus, active smoker, former smoker) Past cardiovascular history (myocardial infarction, ischemic heart disease, previous PCI, previous CABG, heart failure, stroke) Routine drug therapy (antiplatelet agents, beta-blockers, nitrates, calcium antagonists, ranolazine, statins, diuretics, antidiabetics, antidepressants, benzodiazepines, hypnotics)
Preoperative	Indication for revascularization (persistent angina despite optimal medical therapy, silent ischemia) Seattle Angina Questionnaire Ischemia screening test (magnetic resonance imaging, stress echocardiogram) New York Heart Association functional class Lab test results (creatinine, hemoglobin, N-terminal pro-B-type natriuretic peptide) Left ventricular ejection fraction Number of previous CTO revascularization attempts Familiar with new technologies
Perioperative	Accesses (1 or 2 femoral, radial or radial-femoral accesses) Antegrade, retrograde or hybrid approach Total procedural duration Total fluoroscopy time Radiation dose (dose-area product, air kerma). Anxiety (measured as VASA before room entry and peak levels during the procedure) Dose of morphine chloride, midazolam or other anxiolytic drugs administered Maximum level of chest pain during the procedure (VASP) Nausea Dizziness Overall satisfaction with the procedure Overall satisfaction with the use of VR goggles

CABG, coronary artery bypass graft; PCI: percutaneous coronary intervention; VASA, visual analogue scale of anxiety; VASP, visual analogue scale of pain; VR, virtual reality.

Table 3 of the supplementary data. Questionaries

Questionnaire BEFORE the procedure:

1- Are you afraid of the procedure?

0 No anxiety Highest anxiety possible 10

1	2	3	4	5	6	7	8	9	10

2- Do you use a cell phone, PC?

- No
- Cell phone
- PC

3- Have you had any previous experiences using VR glasses?

- Yes
- No

4- Do you think you could relax watching a video during the procedure?

- Yes
- No
- Don't know/No answer

Questionnaire AFTER the procedure

1- Did you experience anxiety during the procedure?

0 No anxiety Highest anxiety possible 10

1	2	3	4	5	6	7	8	9	10

2- Did you have pain during the procedure?

0 No pain Worst pain possible 10

1	2	3	4	5	6	7	8	9	10

3- Would you like to watch a video again during another procedure to relax?

- Yes
- No
- Don't know/No answer