The effect of virtual reality on postoperative pain and anxiety in cardiac surgery. (VRECOVERY trial)

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The objective of this study is to investigate the effect of VR on post-operative pain and anxiety management in cardiac surgery patients undergoing a coronary artery bypass grafting (CABG) procedure.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51697

Source
ToetsingOnline

Brief title
VR for pain and anxiety management after cardiac surgery

Condition

- Other condition

Synonym
pain and anxiety after cardiac surgery, Post-operative pain and anxiety

Health condition

Post-operatieve pijn en angst

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Cardiac Surgery, Pain, Virtual Reality

Outcome measures

Primary outcome

The main study parameters are;

- the Numeric Rating Scale (NRS) to assess the effect of pain on mobility

- the Quality of Recovery-15 questionnaire

- the State-Trait Anxiety Inventory-6 questionnaire

- assessment of analgesic use.

Secondary outcome

-Functional Ambulation Categories Score

Study description

Background summary

Post-operative pain and anxiety are common problems in cardiac surgery. These two components can lead to many adverse outcomes in patients, resulting in a longer recovery time and a lower overall well-being. Common treatment of these problems is by use of analgesics such as opioids, NSAIDS and paracetamol. However, analgesics come with side effects which affect the quality of life. Therefore there is a need for alternative pain and anxiety management.

Virtual Reality (VR) modalities are currently emerging as non-pharmacological tools for post-operative pain and anxiety management. Earlier studies in other surgical fields showed the potential positive effects of VR modalities on postoperative pain and anxiety. However, such a study is never performed in the field of cardiac surgery. Therefore we decided to perform a randomized control trial (RCT) in which we assess the feasibility of VR in postoperative pain and

anxiety management in the field of cardiac surgery.

Study objective

The objective of this study is to investigate the effect of VR on post-operative pain and anxiety management in cardiac surgery patients undergoing a coronary artery bypass grafting (CABG) procedure.

Study design

This study is a single-center randomized control trial.

Intervention

The intervention group (n=50) will use the VR distraction therapy device at day 1, 2 and 3 after surgery on the general ward. The control group (n=50) will be treated with conventional post-operative pain and anxiety management.

At follow-up, participants will be called to gather one-time QoR-15 and STAI-6 questionnaire data 6 weeks after the surgery.

Study burden and risks

This is a study with use of a digital VR distraction therapy device. This device is known to have potential adverse effects of nausea and dizziness. However, the used software is optimized to minimize these adverse effects. And the potential benefits of reducing pain and anxiety in the post-surgical phase outweigh these potential adverse effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

A patient undergoing an uncomplicated surgical coronary artery bypass graft procedure

Exclusion criteria

- Major comorbidities besides coronary artery disease
- Complicated surgical procedure
- Hearing and/or visual impairments
- Facial wounds and skin defects at site of application
- Psychiatric impairments
- Complaints of vomiting and nausea
- History of epilepsy
- Claustrophobia
- Patients placed in clinical isolation
- Readmission to the intensive care unit

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-12-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality distraction therapy device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79616.018.21