Immersive VR after cardiac surgery with thoracotomy, a feasibility study

Published: 07-08-2024
Last updated: 21-12-2024

To investigate whether the use of VR is feasible in patients after coronary artery bypass graft surgery (cardiac surgery with thoracotomy)

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

Summary

ID

NL-OMON56935

Source
ToetsingOnline

Brief title
SyncVR-CABG-01

Condition

- Other condition

Synonym
postoperative pain, stress and anxiety

Health condition

er is gekozen voor patienten na een CABG waarbij thoracotomie wordt verricht. voor de homogeniteit is gekozen voor post-CABG patienten. Het primaire doel van het onderzoek richt zich niet op het ziektebeeld maar op de uitvoerbaarheid

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: het innovatiefonds van de afdeling cardiologie

Intervention

Keyword: CABG, cardiothoracic surgery, immersive virtual reality, thoracotomy

Outcome measures

Primary outcome

The primary outcome is to investigate whether the use of immersive VR is practically feasible, using the System Usability Scale, in cardiac postoperative patients who have undergone a coronary artery bypass graft procedure and whether application of this technique results in a reduction in pain experience.

Secondary outcome

Use of pain medication and score on various scales including scoring anxiety level and quality of life

Study description

Background summary

Virtual reality (VR) methods have previously been investigated in postoperative patients and represent a novel non-pharmacological approach to alleviating postoperative pain. Previous research has shown that pain ratings decreased after VR sessions, that patients spent less time on their pain and that the majority of them perceived the simulated experience as positive. While some evidence shows a decrease in subjective pain measures when using VR, others show that no significant differences were found in pain or anxiety. However, these studies show that the simulations were effective in terms of distraction. In addition to the potential pain reduction, VR has also proven useful in reducing preoperative anxiety. However, the use of VR in cardiac surgery has

not been extensively investigated in randomized controlled trials, with most studies being case studies. Furthermore, previous VR intervention studies provided limited information on the challenges of implementing VR intervention in patients undergoing cardiac surgery, nor did they demonstrate its acceptance by nursing staff, which is imperative for its successful implementation. Therefore, we designed a pilot feasibility study to determine the acceptability and effects of a VR intervention in patients admitted postoperatively to the cardiothoracic surgery department.

Study objective

To investigate whether the use of VR is feasible in patients after coronary artery bypass graft surgery (cardiac surgery with thoracotomy)

Study design

This is a prospective pilot study to investigate feasibility

Intervention

maximal 3 postoperative days 1-3x per day immersive VR sessions for ca 15 minutes

Study burden and risks

Patients will be informed about the examination, the functioning and use of the immersive VR prior to the thoracic surgical procedure. After the operation, they will be offered the VR glasses 1-3 times a day for a maximum of 3 days. This takes in total approximately 30 minutes each time.

Contacts

Public
Selecteer

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Selecteer

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

post-CABG patients
uncomplicated postoperative recovery
signed informed consent

Exclusion criteria

non-CABG thoracic surgery
visual or auditive disablled patients
patients not capable of performing study intervention

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-08-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	SyncVR Relax & Distract
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-08-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86371.100.24