The effect of Virtual Reality on pulmonary recovery and mobility in patients with blunt chest trauma.

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Primary Objective:To investigate the effect of respiratory and physical exercises in VR on pulmonary recovery compared to the standard of care of patients suffering from blunt chest trauma.Secondary Objective(s):- To investigate if VRx can improve...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries NEC
Study type	Interventional

Summary

ID

NL-OMON50573

Source
ToetsingOnline

Brief title
VR Trauma

Condition

- Injuries NEC
- Thoracic disorders (excl lung and pleura)

Synonym
blunt chest injury, Blunt chest trauma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: EFRO subsidie

Intervention

Keyword: Blunt chest trauma, Pulmonary recovery, Trauma, Virtual Reality

Outcome measures

Primary outcome

mean daily inspiration volume in mL, measured with an incentive spirometer (Voldyne).

Secondary outcome

Patient mobility:Time spent lying, sitting and moving measured with a wearable activity monitor (ActivPal/Activ8).

Clinical outcomes: Length of hospital stay in days, pulmonary complications during admission, transfer to ICU, readmission within 30 days

Pain: VAS score during breathing exercise, analgesic use (paracetamol, NSAIDs, opioids), use of add-on/escape medication

Activities of daily livin: Powerlessness in Daily Living questionnaire (PDL)

Patient reported outcomes: Quality of Recovery-15 questionnaire, treatment satisfaction questionnaire

Safety outcomes: Reasons for withdrawal, adverse events during VR therapy incl. virtual reality sickness questionnaire (VRSQ)

Barriers to implementation: Treatment adherence, measured by the number of times pulmonary and physical exercise are performed, technical problems, feedback on apps.

Study description

Background summary

Blunt chest trauma comprises over 10% of all trauma patients presenting to emergency departments worldwide and is the most frequent injury (44.5%) in polytrauma patients.The most frequent thoracic injuries are rib fractures, pneumothorax and pulmonary contusion, with rib fractures being present in 40-80% of patients. Chest trauma is associated with high risk (>10%) of pulmonary complications such as pneumonia, ARDS and patients often require ventilatory support. Mortality after blunt chest trauma is 4-20%, with pneumonia being its most important risk factor.
Management is mainly focussed on prevention of pulmonary complications. The most important pillars herein are adequate pain relief, respiratory function exercises and rapid mobilisation. Because these different aspects all affect each other, they are targeted in care bundles. These care bundles improve clinical outcomes and decrease ICU and hospital length of stay. Inadequate pain control can result in restricted ventilatory function and in reduced mobility, both adding to a higher risk of complications. Currently, multimodal analgesics (i.e. different combinations of epidural analgesics, opioids, NSAIDs etc.) are recommended for pain control. Epidural and systemic opioids are the most frequently used modalities.However, especially opioids can have deleterious side-effects such as sedation and respiratory depression, which directly negatively affects pulmonary recovery. Additionally, side-effects such as nausea and dizziness can make patients refrain from physical activity. As a result, effective pain control without disrupting pulmonary recovery remains a challenge in daily practice.
A second problem in the recovery after blunt chest trauma is the fact that hospitalized patients with blunt chest trauma spend between 53-57% of the time lying in bed, despite interventions to improve physical activity. Inactivity can lead to general deconditioning and ultimately to complications, whereas higher levels of physical exercise are associated with better functional outcomes and reduced length of hospital stay. Furthermore, daily practice learns that adherence to prescribed pulmonary and physical exercise is low. Therefore, ongoing research is needed into new innovative methods that affect all these pillars by reducing pain effectively and motivating patients to exercise.
VR is a technique with the possibility to promote both physical and mental wellbeing of patients with blunt chest trauma. The ability of VR to immerse someone into another world brings opportunities that, amongst others, can reduce acute pain and procedural pain, helps patients to relax and motivate patients to do more physical exercises. VR has proven effective for reducing procedural pain by distracting patients from the painful experience through an immersive and playful environment. Exergaming, gaming that requires physical exercise, has shown to improve patient adherence and physical fitness. Furthermore, VR therapy (VRx) in an inhospital setting has shown to reduce pain and anxiety and possibly length of stay. Another advantage of VRx is the few side-effects, which are usually mild and transient.

To our knowledge VRx has not been administered to patients with chest trauma. We hypothesize it might improve respiratory recovery by breaking the vicious circle of pain, pain avoidance and passivity of patients with blunt chest trauma. Respiratory and physical exercises can be made fun through VRx, while distracting patients from pain and stress. The primary objective of this study is to investigate if VR respiratory and physical exercises can improve the pulmonary recovery in inpatients suffering from blunt chest trauma. Secondary objectives are to investigate if VRx can improve patient mobility, clinical outcomes, pain reduction, patient reported outcomes and to investigate the safety of VRx and barriers to implementations, and last to generate hypotheses which individual characteristics might be used to determine which patients can benefit most from VR.

Study objective

Primary Objective:
To investigate the effect of respiratory and physical exercises in VR on pulmonary recovery compared to the standard of care of patients suffering from blunt chest trauma.

Secondary Objective(s):
- To investigate if VRx can improve mobility of patients recovering from blunt chest trauma, compared to a control condition.
- To investigate if using VRx during different stages of inpatient rehabilitation from blunt chest trauma can improve clinical outcomes, compared to a control condition.
- To investigate if VRx can improve pain reduction in patients after blunt chest trauma, compared to a control condition
- To investigate if VRx can improve patient reported outcomes of patients with blunt chest trauma, compared to a control condition.
- To investigate the safety of VR treatment
- To generate hypotheses which individual characteristics might be used to determine which patients can benefit most from VR.
- To investigate barriers to implementation

Study design

Randomized controlled parallel design.

Intervention

All patients from both groups will receive care according to existing guidelines (Guideline: *thoraxwandletsels*). Similarly, pain management will be according to the standardized Radboudumc guideline for acute pain in adults (Guideline: *Acute pijn bij volwassenen*). Only the treatment regarding the breathing exercises will differ between control and intervention group.

Participants will be randomly assigned to the control group or intervention group.
The control group will receive usual care. Patients will be instructed to perform respiratory exercises 8 times daily for 10 minutes and to extend these exercises 2 times daily with (sitting) physical exercises for an additional 10 minutes. Respiratory exercises include using incentive spirometry and exercises for deep breathing, huffing and coughing. Patients receive a leaflet with the exercises described and the exercises will be performed once daily under supervision of a physiotherapist. The other sessions will be unsupervised.
The intervention group will be instructed to perform the respiratory exercises using the VR-intervention 8 times daily for 10 minutes and to extend these exercises 2 times daily with (sitting) physical exercises for an additional 10 minutes. The respiratory exercises in VR are comparable to the exercises in usual care but performed in a virtual environment and without incentive spirometry. The physical exercises consist of several games through which patients are challenged to reach out to objects while engaging their core. Patients are allowed to continue these exercises or play some relaxation games for up to 30 minutes per session in total. The exercises will be performed once daily under supervision of a physiotherapist. The other sessions will be unsupervised.
For all VR exercises a head mounted display (HMD), the PICO G2 4K (Barcelona, Spain) will be used. Together with SyncVR Medical (Utrecht, Netherlands) a VR dashboard has been created from which patients can chose the different exercises

Study burden and risks

Participants in the intervention group may benefit in the form of accelerated pulmonary recovery, increased mobility and decreased post-traumatic pain. The results from the study will provide new insights into feasibility and effectivity of VR therapeutics in recovery after blunt chest trauma. The risks for participants are negligible. We expect no or only minimal adverse effects from the VR intervention. The burden of the participants associated with this study is related to measurements of endpoints and, in the intervention group, the time spent on the VR intervention. The questionnaires will take approximately 5 minutes to fill out at the beginning and 10 minutes at the end of the study. Filling out the diary will take approximately 5 minutes daily.
The intervention group will spend approximately 100 minutes on VR therapy daily. However, part of this will be spent on respiratory exercises which would normally also take approximately 40-80 minutes daily. The participants are allowed to use VR longer, with an advised daily maximum of 240 minutes spread over 8 sessions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Admitted to the trauma ward with sustained blunt chest trauma
- Age>=16
- Patient is willing and able to comply with the study protocol

Exclusion criteria

- Neurotrauma with GCS <=13
- History of dementia, seizures, epilepsy
- Severe hearing/visual impairment not corrected
- Headwounds or damaged skin with which comfortable and hygienic use is not possible.
- Stay at intensive care unit (ICU) during current hospital admission.

- Erect position in bed not possible/allowed.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2022
Enrollment:	126
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80011.091.21