The efficacy of Virtual Reality in Burn Care
Psychological variables associated with the effect of VR during wound care

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42779

Source
ToetsingOnline

Brief title
The efficacy of Virtual Reality in Burn Care

Condition

- Other condition

Synonym
Pain, Satisfaction

Health condition

Brandwonden

Research involving

Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: de Vriendenloterij

Intervention

Keyword: Pain management, Psychological factors, Virtual Reality, Wound care

Outcome measures

Primary outcome

VR is effective in reducing pain, when there are both statistically and clinically significant differences between the VAS-scores of overall pain during care as usual with VR and care as usual. The clinically significant difference include that the VAS-score of overall pain during care as usual with VR is *0.9 cm lower than the VAS-score of overall pain during care as usual

Secondary outcome

- The satisfaction with the use of VR is meaningful when the VAS-score of satisfaction with care as usual with VR is not statistically and clinically significantly lower than the VAS-score of satisfaction with care as usual. The clinically significant difference include that the VAS-score of satisfaction with care as usual with VR is not *0.9 cm lower than the VAS-score of satisfaction with care as usual.

- The identification of independent variables associated with the expected statistically and clinically significant differences in pain and satisfaction, between care as usual with VR and care as usual.

- The number of milligrams sedation and/or analgesics used during care as usual

with VR compared to care as usual.

- The number of minutes of care as usual with VR compared to care as usual.

- The number of patients reporting nausea as a consequence of the use of VR.

- The description of the user friendliness of the VR-equipment with patients

and medical professionals.

Study description

Background summary

VR turned out to be promising as adjunct non-pharmacological intervention during wound dressing changes. Because the evidence for VR as pain relief is limited, more high-quality studies are needed to investigate the effect of VR on procedural pain. This study focuses on both the effectiveness and efficacy of VR, and succeeds previous study in Martini Hospital Burn Centre (METC 2004-42).

Study objective

Primary, this study investigates the effect of VR on procedural pain. Secondary, this study investigates the effect of VR on satisfaction with the procedure, identifies patient-related, burn wound-related and psychology-related variables associated with the effectiveness of VR. Furthermore, this study focuses on sedation and/or analgesic requirements, procedure time and nausea as a side-effect. Lastly, this study investigates the user friendliness of the VR-equipment with both patients and medical professionals.

Study design

Randomized controlled trial; the admission order determines the allocation to the treatment or control group. After ten inclusions to one group, the following ten patients are allocated to the other group. In total, 128 patients are needed.

Study burden and risks

Using VR during wound dressing changes has several benefits. Patients benefit a reduction in pain experience, but also reduction in amount of sedation and therefore reduction in risk on side effects. A few studies describe nausea as

possible side effect of the use of VR. Patients recover directly by putting off the VR glasses.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Age 8 years and older
- Expected admission time for at least 4 days
- Informed consent
- Mentally competent
- Dutch speaking and reading

- Permission of doctor
- Permission of psychiatrist
- Ability to use VR

Exclusion criteria

- Physical impairments (facial burns)
- Need for intensive care / severe comorbidity

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2016
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	03-05-2016

Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29656
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL54030.099.15
OMON	NL-OMON29656