The efficacy of Virtual Reality in Burn Care

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29656

Source
Nationaal Trial Register

Health condition

Virtual Reality
Wound care / wondverzorging
Pain management / pijnmanagement
Psychological factors / psychologische factoren

Sponsors and support

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

Intervention

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.

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 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 patients reporting side-effects (like nausea) as a consequence of the use of VR. If patients using VR report significant more side effects than patients not using VR (care as usual), we have to investigate the reason of these (game choice / equipment, other).

- The description of the user friendliness of the VR-equipment with patients and medical professionals.

Study description

Study objective

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.

Study design

- VAS-score pain

- VAS-score satisfaction

- Question to presence of side-effects

- Question to user-friendliness of VR-equipment

- Questionnaires (ZBV, BSPAS, BDI/CDI, CERQ)

Intervention

Interactive Virtual Reality computerbased distraction through 3D Head Mounted Display

Contacts

Public
Postbus 30033
K.F. Lamberts
Groningen 9700 RM
The Netherlands
+31 (0) 50 524 5990
Scientific
Postbus 30033
K.F. Lamberts
Groningen 9700 RM
The Netherlands
+31 (0) 50 524 5990

Eligibility criteria

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 nurse,

- if in doubt, consultation doctor, clinical psychologist, psychiatrist and/or principal investigator

- Ability to use VR

Exclusion criteria

- Physical impairments (facial burns)

- Need for intensive care / severe comorbidity

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2016
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-05-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42779
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5705
NTR-old	NTR5858
CCMO	NL54030.099.15
OMON	NL-OMON42779

Study results