

Does massage with or without essential oils enhance relaxation in hospitalized children with burn injuries in South Africa?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27056

Source

NTR

Health condition

pediatric burn patients, massage with carrier oil, aromatherapy massage, essential oils

Sponsors and support

Primary sponsor: Red Cross War Memorial Children's Hospital
Cape Town, South Africa

Source(s) of monetary or material Support: Nederlandse Brandwondenstichting

Zeestraat 29 -1941 AJ Beverwijk

Postbus 1015 - 1940 EA Beverwijk
0251 - 275575

Intervention

Outcome measures

Primary outcome

The primary outcome is the mean difference between before and after massage behavioral scores from videotaped material assessed by a researcher who is blind for treatment allocation.

Assessment instruments:

1. Muscle Tension Inventory: The Muscle Tension Inventory (MTI) has been validated by Tan et al. (2010) in burn patients aged 8 to 71 years of age.(Tan, Yowler et al. 2010) The MTI evaluates muscle tension of each of 8 body areas (forehead, eyes, facial expression, mouth/jaw, head/neck, chest, arms, legs) on a scale from 1 (relaxed) to 5 (tense) giving a total score between 8 to 40;
2. Behavioral Relaxation Scale: The Behavioral Relaxation Scale (BRS) has been validated in adults and children (Schilling and Poppen 1983; Raymer and Poppen 1985; Norton, Holm et al. 1997). It consists of a description of 10 postures or behaviors characteristic of a fully relaxed person: 1) breathing – scored as relaxed if less than the baseline rate; 2) quiet – no vocalizations; 3) body – no movement of the trunk; 4) head in midline; 5) eyes – closed with smooth eyelids; 6) jaw – lips parted in center; 7) throat – no movement; 8) shoulders – sloped and even, no movement; 9) hands – curled in ‘claw like’ position; 10) feet – pointed away from each other forming an approximate 90° angle. The total score ranges from 0 (totally relaxed) to 50 (totally not relaxed) with lower scores indicating greater relaxation;
3. COMFORT behavior scale: The COMFORT behavior scale (van Dijk, de Boer et al. 2000; Ista, van Dijk et al. 2005) has been validated in children between 0-to-3 years of age. It consists of six items: 1. Alertness; 2. Calmness; 3. Respiratory response (for ventilated children) or Crying (for spontaneously breathing children); 4. Body movements; 5. Facial tension; and 6. Muscle tone. Each item has five response alternatives rated 1 to 5 representing the different intensities of the behavior in question. Summating the six ratings leads to a total score, theoretically ranging from 6 to 30.

Secondary outcome

The secondary outcome will be change in oxygen saturation and heart rate between before and after massage/control condition. A handheld pediatric Pulse Oximeter (Clinical Guard®, OxtiveTech 300AH) will be used to record heart rate and oxygen saturation.

Study description

Background summary

N/A

Study objective

We hypothesize that massage with aromatherapy or massage with carrier oil enhances relaxation whereas no intervention does not. We hypothesize that massage with essential oils is more effective than massage without essential oils.

Study design

Assessments will be performed during 2 minutes before massage/control condition and 2 minutes after massage. Each child will be assessed across 5 massage/control sessions across 2 weeks.

Intervention

Two massage interventions will be compared to control condition. One includes massage with grapeseed oil only. The other, the aromatherapy massage condition will be performed with essential oils in grape seed oil. Essential oils: a blend of Lavender (*Lavendula angustifolia*), German Chamomile (*Matricaria recutita*) and Neroli (*Citrus arantium*) essential oil.

Contacts

Public

Roessingsbleekweg 33b
M. Tabak
Enschede 7522 AH
The Netherlands
+31 (0)53 4875777

Scientific

Roessingsbleekweg 33b
M. Tabak
Enschede 7522 AH
The Netherlands
+31 (0)53 4875777

Eligibility criteria

Inclusion criteria

1. Burns greater 19%, burns of face, hands, feet, genitalia, perineum and major joints,

3 - Does massage with or without essential oils enhance relaxation in hospitalized c ... 5-05-2025

electrical and chemical burns, inhalation injury, circumferential burns;

2. Patients are admitted to the burns unit of the Red Cross War Memorial Children's Hospital in Cape Town.

Exclusion criteria

1. Patients whose parents do not give informed consent for the study and patients > 11 years who are not willing to participate;
2. Patients who are considered not to respond well to massage due to the type of trauma (intentional injury);
3. Burn area too large and not enough unburned or healed skin available;
4. Children being prepared for theatre or just having returned from theatre;
5. Children already sleeping;
6. Older children saying they did not want treatment;
7. Younger children – especially toddlers – who show extreme fear when strangers approach them;
8. Children who have not yet been stabilized.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped

Start date (anticipated):	03-04-2013
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion	
Date:	30-03-2013
Application type:	First submission

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
NTR-new	NL3771
NTR-old	NTR3929
Other	: WO/13.103
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A