

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27056

Bron

Nationaal Trial Register

Aandoening

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

Ondersteuning

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

Overige ondersteuning: Nederlandse Brandwondenstichting

Zeestraat 29 -1941 AJ Beverwijk

Postbus 1015 - 1940 EA Beverwijk
0251 - 275575

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	03-04-2013

Aantal proefpersonen: 300
Type: Werkelijke startdatum

Ethische beoordeling

Positief advies
Datum: 30-03-2013
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3771
NTR-old	NTR3929
Ander register	: WO/13.103
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A