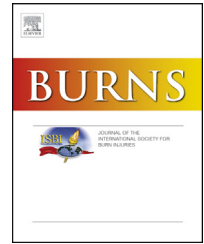


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Massage has no observable effect on distress in children with burns: A randomized, observer-blinded trial

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ABSTRACT

Importance: In a previous observational study we found that massage therapy reduced anxiety and stress in pediatric burn patients. We aimed to test this effect in a randomized controlled trial.

Objective: To determine whether (1) aromatherapy massage can provide relaxation to hospitalized children with burns; (2) massage with aromatherapy oil is more effective than without; and (3) massage sessions are more effective when repeated.

Design, setting, and participants: Randomized controlled clinical trial with 3 arms conducted in a burns unit from April 2013 to December 2014 in Cape Town, South Africa.

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Interventions Massage with carrier oil, massage with aromatherapy oil, and standard nursing care only.

controlled clinical trial. Future studies should evaluate the effectiveness of massage with a different study design.

Key points

Question: Can massage therapy with or without essential oils enhance relaxation of pediatric burn patients?

Findings: It proved problematic to assess relaxation, especially in the under 3-year-olds. We found no evidence for beneficial effects of either type of massage on distress levels, probably because baseline distress levels were already low. Repeat massage sessions had no amplifying effect.

Meaning: We could not replicate the positive effects of observational studies within the context of a randomized

1. Introduction

Burns are a source of pain, anxiety and posttraumatic stress which cannot fully be prevented with drugs [1]. Healthcare workers have therefore suggested massage as a useful complement. Massage was among the 10 most used complementary health approaches in children and adults in the US in 2012 [2]. In the burns unit of the Red Cross War Memorial Children's Hospital in Cape Town aromatherapy massage is offered since 2004. Aromatherapy is the therapeutic use of plant-derived aromatic essential oils to promote physiological

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and psychological well-being [3,4]. It does not harm patients; has anti-inflammatory properties [5]; improves sleep; reduces muscle tension and stress [6]; and relieves pain [7-9]. The oils are absorbed into the body through digestion, inhalation, or via massage or topical application [3,10]. The chemicals in the essential oils can trigger the limbic system and thereby produce changes in emotions and behaviour [11]. A recent controlled trial in adult burn patients showed that aromatherapy massage indeed reduced pain and anxiety [12].

To our knowledge only three studies have evaluated the effectiveness of massage therapy in pediatric burn patients. Hernandez-Reif et al. found that receiving a 15-min massage before change of dressing in 12 children reduced distress during dressing change compared to 12 other children who did not receive massage [13]. A second study involved a twice-weekly, 15-min massage with baby oil over 5 weeks for 32 burn patients between 12 and 18 years and concluded that self-reported itch, pain and anxiety were lower in this group than in the control group not receiving massage [14]. The third study is an observational study from our group in a convenience sample of 71 pediatric burn patients with age range 3 months to 11 years [15]. This study found that aromatherapy massage statistically significantly decreased heart rate and respiratory rate. Firm conclusions could not be drawn due to study design and therefore we set up a randomized controlled, parallel group trial with three study arms that could provide more evidence. This could eventually stimulate the use of this inexpensive and noninvasive treatment. The objectives of the study were threefold: to determine (1) the effectiveness of aromatherapy in terms of relaxation in hospitalized children with burns; (2) if massage with aromatherapy oil has more effect than without; and (3) if massage sessions tend to be more effective when repeated.

2. Methods

2.1. Study design

A single-center 3-arm parallel randomized clinical trial with blinded assessment of the primary outcome.

2.2. Patients

Children between 0 and 13 years of age admitted to the burns unit of the Red Cross War Memorial Children's Hospital, Cape Town, South Africa were eligible if the burn incident had occurred less than one week ago. Children were excluded at the discretion of the attending staff or if parents or children refused participation or parents were not available for consent. Other exclusion criteria were: too little unburned skin.

2.3. Massage interventions

The aromatherapy consisted of a 1% blend of Chamomile (*Matricaria recutita*), Lavender (*Lavandula angustifolia*), and Neroli (*Citrus arantium*) essential oils in grapeseed oil. Chamomile is an analgesic and anti-inflammatory agent because it is rich in chamazulene, which works well on inflamed, sensitive skin. Chamomile also boosts the immune

system. Lavender exerts analgesic, antiseptic, sedative, cytophylactic properties. Neroli is chosen for its alleviating effects on shock, trauma, anxiety and depression [11]. A 1% concentration was opted for because essential oils in undiluted form can cause skin irritations, photosensitivity or allergic reactions. The essential oils were produced by Aromatic Apothecary (Cape Town, South Africa; www.aromatic.co.za). The dilution was stored in a brown glass bottle until use. First, the aromatherapist warms the oil in her hands and then massages it on skin that has not been burnt or on areas that have already healed. The massage usually starts at the feet as it is the least intrusive area of the body and allows the patient to get used to being massaged.

Massage was provided by four aromatherapists trained in the 'M' technique^{*} [16] in which each stroke and sequence is performed in a set pattern, at a set pressure and set speed, and repeated three times. The child was either sitting in a chair or lying in bed. A session lasted between 10 (young children) and 20min (older children). The massage groups received a maximum of five sessions within the first 2 weeks of admission.

2.4. Control intervention

Children randomized to the control group underwent the same procedures for data collection as the two other groups. After baseline assessment they were left undisturbed, this means that other health care professionals were asked to postpone interventions for 20min.

2.5. Procedure

A transcutaneous oxygen saturation device was attached to the finger or toe if not already in place, and the pulse and SATS rate were recorded. A video-camera was trained at the child's whole body and face, switched on after which the operator left the bedside to avoid distraction. For children in the massage groups the aromatherapist would then begin the massage; children in the control group would be left undisturbed. Parents were allowed to attend to their child. The whole massage session and the 20-min 'undisturbed' period was filmed. The aromatherapist would then leave the bedside, but filming continued for a further 2 min, after which the pulse rate and SATs were measured once again.

2.6. Outcomes

The Muscle Tension Inventory (MTI) assesses level of relaxation and has been validated for burn patients aged 8-71 years of age [17]. Muscle tension of the forehead, eyes, facial expression, mouth/jaw, head/neck, chest, arms, legs is each scored from 1 (relaxed) to 5 (tense) giving a total score between 8 to 40. The MTI should be scored with the subject in bed or in a recliner.

The Behavioral Relaxation Scale (BRS) has been validated for adults and children [18,19]. It consists 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

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