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The effectiveness of using a bath oil to reduce signs of dry skin: A randomized controlled pragmatic study

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ABSTRACT

Background: Dry skin (xerosis cutis) is increasingly recognized as a relevant health problem in daily life and in health and nursing care. The use of bath additives such as oils is common to reduce dry skin, but empirical evidence supporting this practice is limited.
Objectives: The aim of this study was to investigate the effectiveness of using a bath oil additive in improving skin barrier function and ameliorating dry skin in comparison to non-oil containing skin cleansers for bathing or showering.
Design: Single centre randomized observer blind pragmatic parallel group trial.
Settings: Outpatient/community care.
Participants: Volunteers showing clinically mild to moderate dry skin recruited from the city of Berlin.
Methods: Healthy children and adults were randomly assigned to use either a commercially available bath oil or to continue using their regular non-oil containing skin cleansers every other day over a study period of 28 days. Skin barrier parameters and the severity of dry skin were assessed at baseline and at two follow-up visits at the study centre. Transepidermal water loss was the primary outcome.
Results: All sixty participants randomized completed the trial. Median age was 32.5 (IQR 8.3 to 69) years. At the end of study the mean transepidermal water loss in the intervention group was statistically significant lower compared to the control group (mean difference −1.9 (95% CI −3.1 to −0.8) g/m^2/h). Stratum corneum hydration was statistically significantly higher in the intervention group at the end of the study. Skin surface pH and roughness were comparable in both groups and remained unchanged, while both groups showed a trend to improvement in dry skin symptoms
Conclusions: This pragmatic trial provides empirical evidence that the regular use of the investigated bath oil is effective in improving the skin barrier function in children and adults with mild dry skin when used in routine skin care and supports its use as a basic element for the management of a broad spectrum of dry skin conditions.
Trial registration: ClinicalTrials.gov Identifier NCT02557698.

What is already known about the topic?

- Dry skin is a highly prevalent skin problem.
- Bath oil additives are used to treat dry skin symptoms, but there is no evidence of their effectiveness in daily skin care.

What this paper adds

- The regular use of the bath oil improves the skin barrier in terms of reduced transepidermal water loss.
- The investigated bath oil additive had no effect on skin surface pH and roughness.

1. Introduction

Dry skin (xerosis cutis) is increasingly recognized as a relevant health problem in daily life and in health and nursing care settings (Hardy, 1990; Kottner et al., 2015). Due to

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inflammatory skin diseases (e.g. atopic dermatitis), unfavourable environmental conditions (e.g. low humidity during winter, frequent use of harsh soaps), or due to ageing-related skin changes the stratum corneum, the uppermost layer of the epidermis, is unable to maintain a sufficient water concentration gradient between the living epidermal cells and the skin surface (Rawlings and Harding, 2004; White-Chu and Reddy, 2011). This results in a stratum corneum that is too dry, especially in the uppermost cell layers. Dry skin is usually associated with an impaired skin barrier function manifesting as increased transepidermal water loss (Kottner et al., 2013a; Rogiers, 2001). Symptoms of dry skin range from unpleasant feelings of itch and 'tightness' and a scaly and flaky appearance, to severe inflammation and cracks with high risk of secondary infection (White-Chu and Reddy, 2011). Severe itch with scratching is one of the most burdensome and distressing symptoms in dry skin (Berger et al., 2013).

Epidemiological studies suggest that dry skin is frequent across the life course. It is a key symptom of atopic dermatitis (Simpson et al., 2012) which starts early in life and is increasing worldwide. Depending on the diagnostic criteria applied and country reported prevalence figures range from 4% to 28% in early childhood (e.g. Draaisma et al., 2015; Doğruel et al., 2016; Guo et al., 2016) decreasing to 2 to 7% in adults (e.g. Saeki et al., 2009; Hwang et al., 2010). A recent population-based survey in the United States reported a one year prevalence of 10% in adults (Silverberg and Hanifin, 2013). Skin dryness is also associated with a number of internal diseases, for instance with diabetes mellitus (Demirseren et al., 2014) which is also increasing. Irrespectively from disease related symptoms, dry skin is especially prevalent in the elderly. Dry skin and itch were reported to be the most common skin concerns of senior community citizens in the USA (Caretti et al., 2015). In elderly populations prevalence estimates range from 48 to 85% in community and outpatient care settings and from 20 to 77% in institutional care (Smith and Leggat, 2005; Lichterfeld et al., 2016).

Common interventions for the management of dry skin are use of mild skin cleansers, reducing the frequency and the duration of exposure to water, and topical application of lipophilic and humectant containing skin care products (Guenther et al., 2012; Lichterfeld et al., 2015). The use of bath additives such as oils is also common. Scientific reports of using bath oils to ameliorate dry skin date back to the 1950s (Franks, 1958). The assumed mechanism of action of bath oils is by depositing a lipid film which remains on the skin surface after the bath. Consequently bath oils are sometimes regarded as moisturizing leave-on products applied to a large skin surface area (Hill and Edwards, 2002). Although bath oils are widely used at home and in care settings published scientific evidence supporting this practice is limited. Studies investigating effects of baths oils were either conducted on small selected investigational skin areas (Gloor et al., 1975; Stender et al., 1990) or by using artificial skin irritation models (Hill and Edwards, 2002; Puschmann, 1991). Thus in recent systematic reviews addressing evidence based skin care, studies investigating the effects of bath oils are lacking (Cowdell and Steventon, 2015; Kottner et al., 2013b; Lichterfeld et al., 2015). As skin cleansing and caring are fundamental activities in nursing practice, there is an urgent need to underpin skin care interventions by empirical evidence, especially regarding emollient and moisturizing practice (Penzer, 2010). Because bath oil additives are widely applied in various populations and settings, the aim of this clinical trial was to investigate the effectiveness of using a bath oil additive in comparison to non-oil containing skin cleansers for bathing or showering in the treatment of dry skin.

2. Methods

2.1. Design and setting

This was a mono-centre randomized observer blind pragmatic parallel group trial using a balanced block randomization in a 1:1 ratio. It was conducted at the Clinical Research Centre for Hair and Skin Science at the Charité-Universitätsmedizin Berlin, Germany between October 2014 and April 2015. Inclusion, baseline, and study visits including all measurement procedures were conducted at the research centre. The bathing procedures were performed by the study participants at home.

2.2. Eligibility criteria

Subjects were eligible for participation when meeting the following inclusion criteria: (1) male or female gender, (2) age between 6 months and 85 years; (3) signed informed consent; (4) in general good and stable health condition as confirmed by medical history and by a physical examination; (5) or medical conditions, clinically stable e.g. adequately treated hypertension, diabetes mellitus type II, hypercholesterolemia, osteoarthritis; (6) mild or moderate dry skin corresponding to a score of 1 to 2 according to the Overall Dry Skin Score (Serup, 1995) at arms and lower legs; (7) transepidermal water loss > 12 g/m^2/h on the left midvolar forearm. Exclusion criteria were among others: (1) subject currently participating in or being in the exclusion period of another study; (2) any dermatological condition or skin affection which may interfere with the study assessments, e.g. scars or other lesions at the investigational sites; (3) clinically significant, possibly unstable medical conditions; (4) use of oil-containing bath additives or other oil-contain cleansers; (5) current topical or systemic treatments affecting the skin (e.g. diuretics). A complete list of all in- and exclusion criteria can be found in the clinical trial register (NCT02557698).

In order to avoid any imbalance in the randomisation across the whole age range the treatment allocation was stratified according to four age groups: 6 months to 23 months, 2 to 11 years, 12 to 64 years, and 65 to 85 years.

2.3. Interventions

Interested persons contacted the Clinical Research Center for Hair and Skin Science and were invited to screening visits. During these screening visits potential study subjects were informed about the study and study procedures by an investigator and had the opportunity to ask questions. After giving informed consent and if meeting the inclusion criteria volunteers were randomly assigned to use either a commercially available bath oil (Balneum Hermal®) or to continue their usual skin cleansing practice.

Participants in the intervention group were instructed to bath every other day with the bath additive containing 85% refined soy bean oil. According to the manufacturer's instructions participants were instructed to use two measuring beakers (30 millilitres) for a full bath (approx. 150 L) and 1/3 of a measuring beaker (5 millilitres) for a child bath (approx. 25 L). In both cases the concentration was identical (1 mL of bathing additive per 5 L of bath water). The recommended duration of a bath was 20 min at a maximum temperature of 36 °C. After the bath the skin should be gently patted dry with a towel. Participants were also informed about an increased risk of falls when using the bath oil in the tubs.

Participants in the control group were instructed to follow their usual individual personal bathing or showering regime using their regular non-oil containing cleanser or bath additive. Control group participants were requested to show their cleanser/bath additive at the inclusion visit. Each product was checked by an investigator