



## Research Paper

# The effectiveness of standardized skin care regimens on skin dryness in nursing home residents: A randomized controlled parallel-group pragmatic trial



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## ABSTRACT

**Background:** Aged residents of institutional long-term care facilities are at high risk for developing skin and tissue diseases. Besides various common skin problems, dry skin (xerosis cutis) is one of the most frequent skin conditions in this setting.

**Objectives:** To investigate the effectiveness of two structured skin care regimens in comparison to routine skin care on xerosis cutis in nursing home residents.

**Design:** A multi-center, pragmatic, randomized, controlled, investigator blinded study with three parallel groups.

**Settings:** The study was conducted in a random sample of ten out of 291 institutional long-term care facilities of the federal state of Berlin, Germany.

**Participants:** Long-term care residents being 65+ years affected by dry skin were included.

**Methods:** The residents were allocated into one of three study groups. Two interventional groups used standardized skin care regimens, consisting of a body wash and twice daily applications of leave-on products for eight weeks. The third control group performed skin care as usual. All participating residents were examined at baseline and after 4 and 8 weeks. Xerosis cutis was measured with the Overall Dry Skin score. Instrumental skin barrier measurements were performed at baseline and after 8 weeks. Diaries were used to document washing and skin care frequencies.

**Results:** In total, 133 residents were included and allocated to one of the three groups. Mean age was 83.8 (SD 8.3) years, 65.4% were female and most residents had care levels I (42.9%) or II (42.9%) according to the German Social Code Book XI. Mean Barthel score was 46.8 (SD 24.2) and mean Braden score was 17.6 (SD 3.7). Leg skin areas were drier compared to arms and trunk areas. At the end of the study the Overall Dry Skin scores in the intervention groups were lower compared to the control group. There were statistically significant improvements of skin dryness in both intervention groups compared to the control group over time.

**Conclusions:** The results of this pragmatic trial indicate that structured skin care regimens are effective in reducing skin dryness in aged nursing home residents within eight weeks.

**Trial registration:** The study is registered at <https://clinicaltrials.gov/ct2/show/NCT02216526>.

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## What is already known about the topic?

- Dry skin in elderly nursing home residents is highly prevalent.

- Targeted skin care interventions are considered to restore, maintain and/or to enhance skin integrity of aged skin.
- Lipophilic emulsions are widely used in preventing and treating dry skin.

## What this paper adds

- Targeted and structured skin care regimens decrease the prevalence and improve the clinical signs of dry skin in aged nursing home residents.

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- Functional skin parameters like stratum corneum hydration and transepidermal water loss seemed to be less influenced by structured skin care regimens in aged nursing home residents.
- Twice daily applications of skin care leave-on products might not be feasible in daily practice.

## 1. Introduction

Residents of institutional long-term care facilities are at high risk for developing skin and soft tissue disorders. Besides highly prevalent conditions like pressure ulcers (National Pressure Ulcer Advisory Panel et al., 2014), incontinence associated dermatitis (Kottner and Beeckman, 2015) or fungal infections (Deo et al., 2015; Polat et al., 2009), dry skin (xerosis cutis) is one of the most frequent skin conditions in the elderly (Lichterfeld et al., 2015a; Paul et al., 2011). The prevalence of dry skin in institutional long-term care settings ranges from 45.3% (Kilic et al., 2008; Lichterfeld et al., 2016) to 59% (Frantz et al., 1986; Reszke et al., 2015). Dry skin is often accompanied by pruritus which is also highly prevalent in multimorbid and older patients (Polat et al., 2009). Pruritus induced scratching leads to excoriations and enhances inflammatory reactions leading to secondary infection/superinfection.

Biophysical skin measurements are widely used in dermatological research and are increasingly recognised in other research contexts today, e.g. nursing (Gillis et al., 2015). Using non-invasive instruments, parameters like stratum corneum hydration, transepidermal water loss, or skin surface pH can be measured and used for characterising skin integrity before and during treatments. These measurements could complement clinical evaluations and advance our understanding about treatment effects.

Today, the role of adequate and standardized skin care in nursing practice is being given more and more attention. On one hand, there is the assumption that daily routine skin cleansing and care activities might do more harm than good (e.g. (Coddell, 2011)). On the other hand, it is believed that adequate and targeted skin care can improve the structural and functional properties of aging skin and increase skin health and wellbeing (Kottner et al., 2015a, 2015b). Empirical evidence supporting certain skin care strategies and regimens in nursing practice is emerging (Coddell and Steventon, 2015; Kottner et al., 2013a, 2013c; Schoonhoven et al., 2015) but the overall evidence supporting specific strategies is extremely weak. Based on available research and expert opinion skin health may be improved by using low-irritating cleansing products and humectant-containing lipophilic emulsions (Kottner et al., 2013a, 2013c; Surber et al., 2015). Occlusives may be useful for skin protection (Lichterfeld et al., 2015a, 2015b; Surber et al., 2015). However, little is known about the performance of different types of skin care products and strategies, because head-to-head comparisons are generally lacking. This situation is extremely problematic since professional caregivers, especially those in institutional long-term care, have a considerable responsibility in selecting products, providing skin care and educating care receivers and their relatives. Above all, the available evidence to treat dry skin in aged nursing home residents is very low (Kottner et al., 2013a, 2013c). Therefore, the aim of this study was to investigate the effectiveness of two different structured skin care regimens in comparison to routine skin care on dry skin in aged nursing home residents.

## 2. Methods

### 2.1. Trial design

A randomized, controlled, pragmatic, investigator blinded, exploratory study with three parallel groups (allocation ratio

1:1:1) was conducted in ten nursing homes in the city of Berlin, Germany. The study was approved by the ethics committee of the Charité-Universitätsmedizin Berlin (EA1/190/14). The study protocol was published previously in this journal (Kottner et al., 2015a) and the study was registered at clinicaltrials.gov.

### 2.2. Important changes to methods after trial commencement

During the conduct of the study, it appeared that the expected participation rate per institution was lower than 50%. One reason was the failure to obtain written informed consent by the legal representatives in case of cognitive impairments and a number of residents declined to participate because they did not want to change their skin care behavior. In order to achieve the planned total number of participants, ten instead of initially planned seven nursing homes were recruited. In one institution only n=28 residents were living in total, thus meeting one of the exclusion criteria. But as this institution was highly motivated to participate in the study, it was included as well.

### 2.3. Eligibility criteria for participants

The inclusion criteria for the participants were (1) being resident of the respective nursing home, (2) being 65+ years old, (3) written informed consent given by themselves or on their behalf by legal representatives and (4) an Overall Dry Skin score of 2 to 4. Major exclusion criteria were residents at the end of life and dermatological or other clinical conditions and treatments which might have interfered with the study protocol (e.g. applications of corticosteroids, antihistamines).

### 2.4. Settings and locations

The study was conducted in a random sample of ten out of 291 institutional long-term care facilities of the federal state of Berlin, Germany. Each institutional long-term care facility participating in this study was identified by a simple random selection process. Using computer generated random numbers potentially eligible nursing homes from a comprehensive list of all nursing homes in the state of Berlin were contacted subsequently and invited to participate by regular mail and email. Institutions with less than 30 beds were considered too small (Kottner et al., 2015a). In case of non-response until a defined deadline the next randomly selected nursing home was invited. Baseline characteristics of non-responders were listed in order to estimate a possible selection bias.

### 2.5. Interventions

All examinations, assessments, and biophysical measurements were performed onsite in the nursing homes. During a maximum of three days all participating residents of one nursing home underwent a comprehensive demographic, nursing, medical and dermatological full body examination by a board certified dermatologist. Nursing home residents were assisted to undress.

If a medical or dermatological condition was detected, which in the opinion of the dermatologist required further diagnostic and/or interventional activities, a written recommendation for the responsible physician and/or nurses was prepared. Residents and/or legal representatives were informed as well. If an acute threatening health problem was detected, appropriate medical action was taken immediately (e.g. referral to a hospital).

The non-invasive biophysical skin measurements included stratum corneum hydration, transepidermal water loss, skin surface pH and skin temperature. All measurements were conducted at baseline and after eight weeks. An eight weeks

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