



A multi-center prevalence study and randomized controlled parallel-group pragmatic trial to compare the effectiveness of standardized skin care regimens on skin health in nursing home residents: A study protocol



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ABSTRACT

Background: Aged long-term residents suffer from a wide range of skin problems. Dry skin associated with severe pruritus, scratching and inflammation is the most prevalent, but exact figures are lacking. Maintaining skin and tissue health as well as enhancing the quality of life are major goals in institutional long-term care. Using mild and moisturizing skin care products is considered to improve the skin barrier and to reduce adverse events. However, the available evidence supporting particular skin care approaches is limited.

Objective: This study aims at answering two general questions: (1) What is the prevalence of skin conditions and skin diseases in aged nursing home residents and how are they associated with general person and health related characteristics? (2) Does a structured skin care regimen improve the skin health of aged nursing home residents?

Design and methods: Using a random sample of all nursing homes of the state of Berlin, residents of seven institutions will undergo nursing, medical, and dermatological assessments. Biophysical skin parameters like transepidermal water loss or skin surface pH will be measured. Residents with dry skin will be included in a three arm randomized pragmatic trial investigating the effectiveness of two standardized skin care regimens compared to usual care. The primary outcome will be the Overall Dry Skin score. The follow-up period will be two months.

Settings: Institutional long-term care facilities in Berlin, Germany.

Participants: Long-term care residents being 65+ years who gave their informed consent.

Sample size and statistical methods: Due to the explorative nature of this study a formal sample size analysis is not possible. The expected sample size in the first part of the study is considered sufficiently large ($n=280$) to obtain precise point estimates. It is planned to allocate $n=50$ eligible nursing home residents in a 1:1:1 ratio per group in the intervention part. The detectable mean difference using these group sizes would be 0.32 between groups. Depending on the level of measurement variables will be described using absolute and relative frequencies, means, medians, and associated spread estimates. Possible bi- and multivariable associations will be analyzed. The primary outcome of dry skin will be

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described by mean differences and one-way ANOVA analysis with post-hoc pairwise two-sample *t*-tests.

Results: The study started in September 2014. The results are expected in July 2015.

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

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Contributions of the paper

What is already known about the topic?

- Skin of aged care dependent nursing home residents is dry, fragile and at risk to develop a wide range of adverse skin conditions.
- The frequency of skin problems and dermatological diseases in aged nursing home residents is unknown.
- Targeted skin care interventions are considered to maintain and/or to improve skin integrity in aged skin.

What this paper adds

- A multicenter randomized controlled pragmatic trial will be conducted to estimate the frequencies of skin problems in aged nursing home residents and to investigate the effectiveness of standardized skin care regimens.
- Nursing assessments, dermatological diagnoses and biophysical parameters are obtained in parallel in the institutional long-term care setting for the first time.
- A multi-perspective and interdisciplinary approach is necessary for valid theory building and practice improvement.

1. Introduction

Aged long-term care residents are affected by health problems like immobility, malnutrition, incontinence, or falls (Lahmann et al., 2014a). Additionally, advanced age, chronic diseases, and functional limitations increase the susceptibility to develop a wide range of adverse skin conditions and diseases. Dry skin (including pruritus), infections (e.g. tinea pedis, candidiasis), or neoplastic changes (e.g. actinic keratoses, malignant melanoma) belong to the most prevalent skin conditions in this group (Jafferany et al., 2012; Polat et al., 2009). In the nursing and healthcare community there has been a strong and long-enduring interest in pressure ulcers for decades. Recently, also the phenomena of skin tears, intertrigo, and incontinence-associated dermatitis (IAD) gained attention (Carville et al., 2014; Gray et al., 2011). Although epidemiological figures for selected phenomena like IAD or pressure ulcers in this population have already been published (e.g. Gray et al., 2012; Kottner et al., 2014; Lahmann et al., 2014a), a comprehensive characterization and quantification of skin and dermatological as well as general health conditions in aged long term-care residents is not available so far. Different scopes of practice and research perspectives on health and disease of research groups (e.g., gerontologists, dermatologists, nurses) might be the major reason for that. However, because of the

complex interplay between multiple risk factors, diseases, functional and cognitive impairments, and (poly-) medication (Endo et al., 2013; Inouye et al., 2007) it is important to consider all factors and aspects for valid theory and effective practice development.

Skin care is a core activity of nursing practice (Kottner et al., 2013b; Walsh et al., 2003). Besides cleansing and caring for the skin in a technical sense, skin care is also regarded as a particular way for non-verbal communication and interaction with care receivers conveying attributes of warmth and care (e.g. Butts and Janes, 1995; Twigg, 2000). Skin care activities are part of the concept of 'embodied practice' being considered relevant to the discipline of nursing (Draper, 2014). However, because of the increased vulnerability of aged skin and the high prevalence of adverse age related skin conditions, nurses do have considerable responsibility and opportunities to enhance and to maintain skin health and integrity. Although clinical studies investigating washing and skin care approaches are increasingly published (e.g. Carville et al., 2014; Schoonhoven et al., 2014) the overall available evidence supporting appropriate skin care strategies in aged care depend people is weak (Cowdell and Steventon, 2013; Kottner et al., 2013a). Thus, high quality clinical trials are required to enhance skin care knowledge and to inform skin care practice.

This investigation will answer two main questions: (1) What is the prevalence of skin conditions and skin diseases in aged nursing home residents and how are they associated with general person and health related characteristics? (2) Does a structured skin care regimen improve the skin health of aged nursing home residents?

2. Methods

2.1. Study design and setting

In order to answer the first research question, an observational prevalence study will be conducted. Based on an inventory of all nursing homes in the state of Berlin ($n = 291$), seven institutions will be randomly selected and all residents will be examined ('prevalence study'). Within this first part, assessed residents who have dry skin will be included in a subsequent three arm pragmatic randomized controlled trial ('intervention study'). Block randomization will be performed with a 1:1:1 allocation.

2.2. Eligibility criteria

Nursing homes with at least 30 residents are eligible. Inclusion criteria for the prevalence study are (1) permanent

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