DISSERTATION

Epidemiologie und Prävention pflegerelevanter Hautschäden in der stationären Langzeitpflege

Epidemiology and prevention of care-related adverse skin conditions in residential long-term care

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Zusammenfassung

Mit fortschreitendem Lebensalter kommt es vermehrt zu funktionalen Einschränkungen sowie einer Zunahme chronischer Erkrankungen. Von diesen natürlichen Alterungsprozessen ist auch die Haut betroffen, welche infolgedessen anfälliger für das Auftreten von Hautschäden wird.
Ziel der vorliegenden Arbeit war es, präventive Effekte einer evidenzbasierten Pflegeroutine sowie adäquater Lagerung hinsichtlich der Vermeidung von Hautschäden im Alter und bei Pflegebedürftigkeit zu untersuchen.

Im Rahmen der vorliegenden Dissertation wurde zum einen eine explorative, kontrollierte, clusterrandomisierte, pragmatische Studie in der stationären Langzeitpflege in Berlin durchgeführt. Die Epidemiologie pflegerelevanter Hautschäden sowie Effekte der Implementierung eines evidenzbasierten Hautpflegealgorithmus, welcher Maßnahmen zu Prävention und Pflege der häufigsten pflegerelevanten Hautschäden vereint, wurden untersucht. Die Analyse von 314 Pflegeheimbewohnenden über 65 Jahre zeigte eine hohe Prävalenz pflegerelevanter Hautschäden, wie Xerosis cutis, Inkontinenz-assoziierte Dermatitis, Intertrigo, Skin Tears und Dekubitus. Skin Tears waren besonders mit kognitiven und physischen Einschränkungen, und Dekubitus war ebenfalls mit eingeschränkter Mobilität sowie erhöhter Pflegebedürftigkeit assoziiert. Nach der Einführung eines Hautpflegealgorithmus für sechs Monate war die kumulative Inzidenz der häufigsten pflegerelevanten Hautschäden, bis auf die Inkontinenz-assoziierte Dermatitis, in der Interventionsgruppe geringer als in der Kontrollgruppe. Neben der Verbesserung der Hautgesundheit konnte gezeigt werden, dass eine adäquate Hautpflege mit vorausgehendem Hautassessment in der Praxis umsetzbar ist.

Zum anderen wurde eine Sekundärdatenanalyse einer randomisierten, kontrollierten, exploratorischen Studie mit Crossover-Design durchgeführt und in vivo Veränderungen sowie Assoziationen hautphysiologischer Parameter im Sakral- und Fersenbereich nach Druckbelastung beschrieben. Die Messungen erfolgten vor und nach 120-minütiger Liegedauer auf einer Standardschaummatratze. Bei beiden Studienarealen wurde eine Zunahme von Hautfeuchtigkeit, Hautrötung und Hauttemperatur festgestellt. Eine Korrelationsanalyse zeigte, dass eine Zunahme von Hautrötung und Hauttemperatur nicht miteinander assoziiert ist. Es ist anzunehmen, dass der einwirkende Druck eine mechanische Deformation der Haut und der darunter

liegenden Schichten bedingt. In der Folge verstärkt sich das Erythem. Dieses findet jedoch unabhängig von einer Veränderung des Mikroklimas, das heißt einer Zunahme von Hautfeuchtigkeit und Hauttemperatur, statt.

Abstract

With increasing age, functional limitations and chronic diseases occur more frequently. During this progress, the skin undergoes a natural ageing process, which increases the risk of adverse skin conditions.

The aim of this dissertation was to investigate the effects of an evidence-based preventive skincare programme and adequate loading, to reduce adverse skin conditions in older nursing home residents.

One the one hand, an explorative, controlled, cluster-randomised, pragmatic trial was conducted in institutional long-term care in Berlin, Germany. The epidemiology of care related skin problems and the effects of implementing an evidence-based skincare programme were analysed. The analysis of 314 residents over 65 years in long-term care facilities showed a high prevalence of adverse skin conditions e.g., xerosis cutis, incontinence-associated dermatitis, intertrigo, skin tears and pressure ulcers. Skin tears were in particular associated with cognitive and physical impairment, and pressure ulcers were associated with reduced mobility and increased care dependency. By implementing a structured and evidence-based skincare programme for a period of six months, the cumulative incidence of the most common care-related skin conditions was, except incontinence-associated dermatitis, lower in the intervention group compared to the control group. Besides preventive effects regarding skin health in aged nursing home residents, it could have been shown that adequate skincare with prior skin assessment was possible to implement in care practice.

On the other hand, a secondary data analysis of a randomised, controlled, exploratory trial with crossover design investigated in vivo changes of skin properties after 120 minutes loading at sacral and heel skin, as well as possible associations. The measurement of skin physiological parameters after 120 minutes of loading on a basic foam mattress showed an increase of skin moisture, skin redness and skin temperature. Further analysis displayed that loading and pressure during mechanical deformation increased the erythematous response. Independently, an increase of skin temperature and humidity, as part of occlusion and a change of the microclimate, occurred.

1 Einleitung

1.1 Hintergrund

Der Anteil von Menschen über 65 Jahren ist in Deutschland von 1950 bis 2021 von 12 % auf 22 % angestiegen (Destatis, 2023a). Mit fortschreitendem Lebensalter und einem Anwachsen der Population über 65 Jahre kommt es zu einer Zunahme chronischer Erkrankungen. In der Folge resultiert dies in funktionellen Einschränkungen und einer Zunahme von Immobilität und Pflegebedürftigkeit. Aktuelle Berechnungen gehen davon aus, dass die Anzahl pflegebedürftiger Personen deutschlandweit von 5,0 Millionen Ende 2021 auf 6,8 Millionen im Jahr 2055 zunehmen wird (Destatis, 2023b) – ein Trend, welcher auch weltweit zu beobachten ist (World Health Organization, 2015).

Als Teil dieser Veränderungen kommt es ebenfalls zu einer Alterung der Haut. Man unterscheidet dabei zwischen extrinsischer und intrinsischer Hautalterung. Die extrinsische Hautalterung wird vorrangig durch Umwelteinflüsse, insbesondere das UV-Licht, bedingt. Parallel kommt es zur intrinsischen Hautalterung als Folge des natürlichen chronologischen Alterungsprozesses. Dieser wird von genetischen, metabolischen und hormonellen Faktoren beeinflusst und kann potentiell mit Hauttrockenheit, Wunden oder Infektionen der Haut assoziiert sein (Global Coalition on Aging, 2014). Infolge des Alterungsprozesses reduziert sich die Funktionalität der Haut, denn diese hat, als hochspezialisiertes Organ, neben der Abgrenzung des Körpers zur Umwelt noch eine mechanische und immunologische Schutzfunktion des Körpers. Gleichzeitig dient die Haut der Sinneswahrnehmung, Thermoregulation und der Abwehr von Mikroorganismen (Farage et al., 2008). Im Alter und bei Pflegebedürftigkeit kommt es zu einer Veränderung dieser Schutzmechanismen. Zusätzlich können neben eingeschränkter Mobilität chronische Krankheiten, wie beispielsweise Diabetes mellitus, kortisonhaltige Medikamente, und weitere Umweltfaktoren wie das UV-Licht die Anfälligkeit für Hautschäden begünstigen (Blume-Peytavi et al., 2016) und eine steigende Inzidenz dermatologischer Erkrankungen bedingen (Hahnel, Lichterfeld, et al., 2017). Zur Förderung der Hautintegrität und damit zur Prävention möglicher Hautschäden sind pflegerische Interventionen, insbesondere im Alter und bei Pflegebedürftigkeit, unabdingbar. Die Hautintegrität definiert sich als Zusammenspiel einer intakten Hautstruktur und deren Fähigkeit, diese Struktur aufrechtzuerhalten. Dadurch wird eine Kompensation potentieller interner und externer Gefährdungen ermöglicht (J. Kottner et

al., 2020). Zu den am häufigsten auftretenden Hautschäden in der stationären Langzeitpflege gehören Hauttrockenheit, Inkontinenz-assoziierte Dermatitis, Skin Tears, Dekubitus und Intertrigo (Blume-Peytavi et al., 2016; Hahnel, Lichterfeld, et al., 2017). Da die Prävention und Behandlung von Hautschäden pflegerische Kerntätigkeiten sind, wird in diesem Zusammenhang nachfolgend der Terminus pflegerelevante Hautschäden verwendet.

Die höchste Prävalenz dermatologischer Diagnosen in der geriatrischen Langzeitpflege weist Xerosis cutis (Hauttrockenheit) mit Anteilen zwischen 41,2 % und 99,1 % auf (Hahnel, Blume-Peytavi, Trojahn, Dobos, Jahnke, et al., 2017; Lechner et al., 2019). Hauttrockenheit, eine beeinträchtigte Hautbarriere und Juckreiz sind dabei eng miteinander verbunden und können im weiteren Verlauf zu Verletzungen und Entzündungen der Haut führen (Hahnel, Blume-Peytavi, Trojahn, & Kottner, 2017; Yosipovitch et al., 2019). Daraus resultierend können sich Schmerzen oder Schlafprobleme als potentielle Begleiterscheinung entwickeln. In der Folge kann sich die Lebensqualität reduzieren und körperliche oder soziale Aktivitäten der Betroffenen werden eingeschränkt (Gorecki et al., 2009; Hahnel et al., 2019). Zusätzlich sind extreme Formen trockener Haut, durch eine Veränderung der Hautbarriere, ein Risikofaktor für die Entstehung von Kontaktdermatitiden, wie Inkontinenz-assoziierter Dermatitis und Intertrigo.

Zu einer Inkontinenz-assoziierten Dermatitis kann es bei inkontinenten Personen durch die wiederholte Exposition der Haut mit Urin und/oder Stuhl kommen. Dadurch wird die Hautbarriere geschädigt und Entzündungsreaktionen, wie Mazeration (Aufweichung der Haut) und Erosion (oberflächlicher Hautverlust), oder Infektionen durch Bakterien und Pilze können entstehen. Die Inkontinenz-assoziierte Dermatitis kann großflächig im gesamten Hautbereich auftreten, welcher mit Urin und/oder Stuhl in Kontakt kommt. Von Urin- und/oder Stuhlinkontinenz betroffen sind ungefähr die Hälfte der Personen in der geriatrischen Langzeitpflege. Etwa ein Drittel davon entwickelt eine Inkontinenz-assoziierte Dermatitis (Gray, 2010; Van Damme et al., 2017).

Eine weitere Form der Kontaktdermatitis, die Intertrigo, kann sich in Hautfalten entwickeln. Durch wiederholtes Reiben von Haut auf Haut in Verbindung mit Feuchtigkeit entsteht diese bei bis zu 16,1 % der Pflegeheimbewohnenden (Gabriel et al., 2019). Intertrigo werden begünstigt durch vermehrtes Schwitzen, einen erhöhten Body-Mass-Index, Inkontinenz, steigendes Alter und einen erhöhten pflegerischen Unterstützungsbedarf (Everink et al., 2021; Gabriel et al., 2019).

Durch Einschränkungen der Mobilität können Dekubitus (Druckgeschwüre, engl.: Pressure ulcers / Pressure injuries) entstehen. Diese lokalen Schädigungen der Haut und/oder des umgebenden Gewebes werden durch Druck, oder Druck in Kombination mit Scherkräften, ausgelöst (EPUAP/NPUAP/PPPIA, 2019a). Die Prävalenz für Dekubitus in der stationären Langzeitpflege liegt zwischen 3,4 % und 32,4 % (Anthony et al., 2019). Insbesondere immobile Personen mit schlechter Durchblutung und vorausgegangenen Dekubitus weisen diesbezüglich ein erhöhtes Risiko auf (Coleman et al., 2013). Während einer verlängerten Phase der Immobilität kommt es zur Kompression und Deformation der Haut sowie der darunterliegenden Strukturen (Gefen et al., 2021). An den Prädilektionsstellen Ferse und Sakrum sind in Rückenlage bereits nach kurzer Zeit Veränderungen hautphysiologischer Parameter nachweisbar (Pfannes et al., 2018). Entzündungsprozesse können durch eine Anhäufung von Abbauprodukten oder Änderungen im Stoffwechsel entstehen und langfristig zu Schädigungen der Haut und des darunterliegenden Gewebes führen (Agam & Gefen, 2007). Sobald durch mechanische Deformation die physiologische Widerstandskraft überschritten wird, können Dekubitus entstehen. Bei älteren und pflegebedürftigen Menschen ist die interne Widerstandsfähigkeit aufgrund altersbedingter Veränderungen reduziert. Präventive Maßnahmen umfassen neben adäquaten Maßnahmen zu Hautschutz und Hautpflege sowie einer patientenadaptierten Risikoanalyse auch individuell angepasste Mobilisierungs- und Lagerungsmaßnahmen (EPUAP/NPUAP/PPPIA, 2019b). Die Verwendung geeigneter Anti-Dekubitusmatratzen, als zusätzliche präventive Maßnahme, hilft hautphysiologische Reaktionen an Dekubitus-Prädilektionsstellen nach längerer Liegedauer zu reduzieren (Tomova-Simitchieva et al., 2018).

Akute Verletzungen der Haut, wie Skin Tears (Hautrisse), treten insbesondere bei älteren und mobilitätseingeschränkten Personen mit fragiler Haut auf (Benbow, 2017). Die Prävalenz liegt in stationären Pflegeeinrichtungen zwischen 5 % und 15 % (Rayner et al., 2015; Skiveren et al., 2017; Woo & LeBlanc, 2018). Vorausgegangene Skin Tears erhöhen das Risiko. Präventiv kann ein adäquater Hautschutz durch die Applikation topischer Produkte zum Verbleib auf der Haut Anwendung finden (Fastner et al., 2023).

Geeignete Maßnahmen zur Förderung der Hautintegrität minimieren das Risiko Hautschäden zu entwickeln. Die gezielte Förderung der Hautgesundheit in Langzeitpflegeeinrichtungen wird durch den direkten und regelmäßigen Zugang des Pflegepersonals zu den Bewohnerinnen und Bewohnern gewährleistet. Pflegerische Interventionen, wie die Unterstützung bei der Körperpflege, das Wundmanagement oder

die Inkontinenzversorgung, ermöglichen die Anwendung regelmäßiger und gezielter Präventions- und Pflegemaßnahmen. Diesbezüglich existiert eine Vielzahl von Standards und Leitlinien. Jedoch konzentrieren sich diese Empfehlungen auf die Prävention einzelner und spezifischer Hautschäden wie zum Beispiel Maßnahmen zur Dekubitusprävention (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2017). Es gab bis zum Jahr 2022 keine evidenzbasierte Leitlinie zur allgemeinen Hautpflege, welches zu einer großen Heterogenität in der Pflegepraxis führt (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2023). Durch ein Überangebot krankheitsspezifischer Pflegeleitlinien stehen die Pflegeeinrichtungen vor der Herausforderung einzelne auszuwählen und anzuwenden. Dabei ist die Unterscheidung zwischen essentiellen und weniger erforderlichen pflegerischen Interventionen herausfordernd (Cowdell et al., 2020). Dieses kann zu einer fragmentierten Pflegepraxis führen, und gemeinsame Präventions- und Behandlungsprinzipien zur Verbesserung der Hautgesundheit oder evidenzbasierte Pflegestrategien werden möglicherweise nicht umgesetzt. Eine Vernachlässigung der Schnittpunkte von Ätiologie, Pathogenese und Prävention ist unter diesen Umständen die Folge.

Hinsichtlich der beschriebenen Versorgungslücke wurde ein ebensolcher Hautpflegealgorithmus entwickelt. Dieser verfolgt das Ziel, einzelne pflegerische Interventionen zusammen zu fassen und in der Praxis bedarfsorientiert anzuwenden (Lichterfeld et al., 2015). Voraussetzung ist ein umfassendes Hautassessment, um mögliche Indikationen einer spezifischen Hautpflege, z.B. trockene oder fragile Haut, Inkontinenz oder reibende Hautstellen, zu erkennen. Der anschließende, individuelle Hautpflegeprozess wird in reinigende Maßnahmen, das Entfernen von Schmutz und anderen Stoffen, und in Hautpflege/Hautschutz, das Auftragen von Produkten zum Verbleib auf der Haut, eingeteilt. Zusätzliche Interventionen bei immobilen Patienten, wie beispielsweise spezielle Anti-Dekubitusmatratzen, sollen darüber hinaus individuell Anwendung finden (Lichterfeld-Kottner, El Genedy, et al., 2020).

Dieser Hautpflegealgorithmus wurde, in adaptierter Form, im Rahmen einer pragmatischen, randomisierten, kontrollierten Studie in der geriatrischen Langzeitpflege implementiert (Kottner et al., 2019). Durch die Anpassung der Pflegeroutine über einen Zeitraum von sechs Monaten konnten Effekte auf die Hautgesundheit und die Umsetzbarkeit in der Praxis untersucht werden.

1.2 Forschungsfragen

Wie ist die Prävalenz der häufigsten pflegerelevanten Hautschäden in der stationären Langzeitpflege? Gibt es Assoziationen zwischen einzelnen Hautschäden oder mit soziodemographischen und funktionellen Faktoren?
(Teilprojekt 1, Publikation 1: Prävalenzanalyse (Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Sill, et al., 2023))

Hat die Implementierung eines strukturierten und evidenzbasierten Hautpflegealgorithmus einen Einfluss auf die Entstehung von Inkontinenz-assoziierter Dermatitis, Skin Tears, Dekubitus, Intertrigo sowie die Intensität von trockener Haut? Gibt es Veränderungen von Schmerz, Juckreiz oder Lebensqualität?
(Teilprojekt 1, Publikation 2: Analyse der Intervention (Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Hillmann, et al., 2023))

Welchen Effekt hat eine zweistündige Liegedauer auf einer Standardschaummatratze auf hautphysiologische Parameter am Sakral- und Fersenbereich? Gibt es Assoziationen zwischen hautphysiologischen Veränderungen und mechanischer Deformation der Haut?
(Teilprojekt 2, Publikation 3: Sekundärdatenanalyse (Völzer & Kottner, 2022))

2 Methodik

Die vorliegende Dissertation gliedert sich in zwei Teilprojekte, welche nachfolgend beschrieben sind.

2.1 Teilprojekt 1 (Prävalenzanalyse und Analyse der Intervention)

Im Rahmen des ersten Teilprojektes wurde eine klinische Studie in stationären Langzeitpflegeeinrichtungen durchgeführt. Diese setzt sich mit der Epidemiologie und den Assoziationen der häufigsten pflegerelevanten Hautschäden (Publikation 1: (Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Sill, et al., 2023)) sowie möglichen Effekten der Implementierung eines evidenzbasierten Hautpflegealgorithmus auseinander (Publikation 2: (Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Hillmann, et al., 2023)).
Beide Publikationen wurden 2023 im „International Journal of Nursing Studies“ veröffentlicht.

2.1.1 Studiendesign und Setting

Es wurde eine explorative, clusterrandomisierte, pragmatische Studie mit dem Titel „Enhancing SKIN health and safety in aged CARE: an exploratory cluster-randomized pragmatic trial in aged nursing home residents (SKINCARE)“ in 17 Pflegeheimen im Bundesland Berlin von April 2019 (first patient in) bis Juni 2021 (last patient out) durchgeführt.
Die Ethikkommission der Charité Universitätsmedizin Berlin hat das Vorhaben im Vorfeld zustimmend bewertet (EA1/243/18). Die Studie wurde vorab in der Datenbank ClinicalTrials.gov. registriert (NCT03824886). Das Studienprotokoll wurde publiziert (Kottner et al., 2019).

2.1.2 Studienpopulation

Einschlusskriterien auf Ebene der Pflegeheime waren: (I) Lokalisation im Bundesland Berlin mit (II) mindestens 70 Bewohnendenplätzen sowie (III) die Anwendung eines gültigen Standards zur Dekubitusprophylaxe.

Einschlusskriterien auf Ebene der Bewohnerinnen und Bewohner waren: (I) erhöhte Pflegebedürftigkeit (mindestens Pflegegrad 2 nach dem Sozialgesetzbuch XI) und (II) ein Mindestalter von 65 Jahren. Bewohnende mit Palliativversorgung oder mit vorliegenden Hautschäden welche eine weiterführende Behandlung erforderten wurden nicht in die Studie eingeschlossen. Die Teilnehmenden oder die gesetzliche Vertretung wurden schriftlich und mündlich durch das wissenschaftliche Personal über Inhalt, Ablauf und Risiken der Studie aufgeklärt und mussten vorab schriftlich ihre Einwilligung zur Studienteilnahme geben.

2.1.3 Intervention

In den Pflegeheimen der Interventionsgruppe wurde ein evidenzbasierter Hautpflegealgorithmus für die Dauer von sechs Monaten implementiert. Dieser ergänzte die bestehende Standardversorgung und wurde durch das Pflegepersonal umgesetzt. Zur Unterstützung des Implementierungsprozesses fanden regelmäßig Schulungen, Absprachen und Studienbesuche vor Ort statt. Abhängig vom Ergebnis der Randomisierung erhielt das Pflegepersonal aller teilnehmenden Pflegeeinrichtungen vor Studienbeginn eine gruppenspezifische Schulung durch das Studienpersonal.
Die Schulung für das Pflegepersonal der Interventionsgruppe umfasste eine Dauer von 45 bis 60 Minuten. Schwerpunkte waren die Anatomie der Haut, mit den Besonderheiten älterer Haut, sowie die häufigsten pflegerelevanten Hautschäden, wie Hauttrockenheit, Inkontinenz-assoziierte Dermatitis, Skin Tears, Dekubitus und Intertrigo. Eine tägliche Hautinspektion zur Feststellung potentieller Hautveränderungen und zur Identifikation unerwünschter Einflussfaktoren, wie beispielsweise Inkontinenz, Übergewicht oder reibende Hautstellen, wurde als essentieller Bestandteil jeder strukturierten Hautpflegeroutine vorangestellt. Zur Vermeidung von Hautschäden wurde auf die schonende Hautreinigung und die anschließende Pflege der Haut mittels der Applikation topischer Produkte zum Verbleib auf der Haut hingewiesen. Trockene Hautstellen sollten einmal täglich oder seltener gereinigt werden. Nach der Reinigung wurde an trockenen Hautarealen und insbesondere an den Extremitäten die zweimalige tägliche Anwendung von lipophilen Produkten empfohlen. Wenn die von den Bewohnenden bereits verwendeten Produkte den Kriterien geeigneter Pflegeprodukte entsprachen (lipophil und ein hautfreundlicher pH-Wert) konnten diese weiterverwendet werden. Bei Bedarf wurde eine lipophile Emulsion zur Verfügung gestellt (Lipophile Harnstoff-Creme 5 %,

NRF 11.129). Bei vorliegender Inkontinenz sollte die Haut im betroffenen Bereich mit milden Reinigungsmitteln gereinigt werden. Es wurde die Empfehlung gegeben, im Anschluss ein Hautschutzprodukt aufzutragen. Dieses wurde im Bedarfsfall zur Verfügung gestellt (Weiche Zinkpaste DAB, NRF 11.21). Aufeinanderliegende Hautstellen und Hautfalten, zum Beispiel axillär oder inguinal, sollten sauber und trocken gehalten werden. Reibung in diesem Bereich sowie das Auftragen zusätzlicher Produkte zum Verbleib auf der Haut sollten vermieden werden. Es wurde darauf hingewiesen, medizinische Expertise bei unklaren Hauterscheinungen hinzuzuziehen. Abschließender Bestandteil jeder durchgeführten Schulung für das Pflegepersonal der Interventionsgruppe war die Besprechung und Diskussion von Fallbeispielen.

Für den Zeitraum der Studie wurde eine Zusammenfassung des Hautpflegealgorithmus an jedem Bettplatz der teilnehmenden Bewohnerinnen und Bewohner der Interventionsgruppe aufgestellt (Abb. 1).

Das Pflegepersonal der Kontrollgruppe erhielt vor Studienbeginn eine circa 30-minütige Schulung durch das Studienpersonal. Im Vordergrund standen Klinik und Diagnostik der häufigsten pflegerelevanten Hautschäden: Hauttrockenheit, Inkontinenz-assoziierte Dermatitis, Skin Tears, Dekubitus und Intertrigo. Es wurden keine weiterführenden Empfehlungen zu Hautreinigung oder Hautpflege gegeben, d.h. die pflegerischen Interventionen wurden durch das Pflegepersonal gemäß der Standardversorgung ausgeführt.

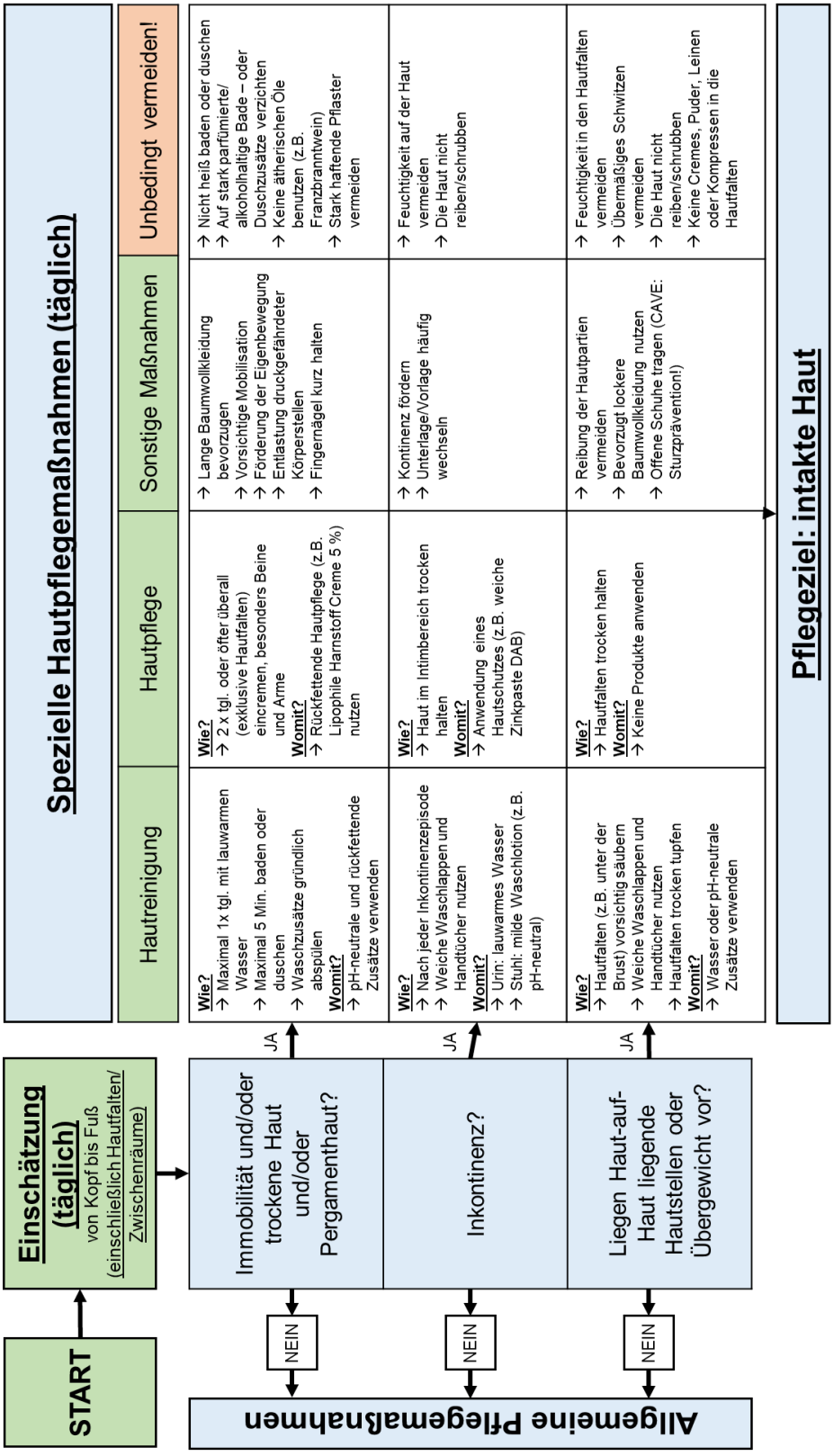

Abbildung 1. Hautpflegealgorithmus

Quelle: Modifiziert nach: Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Hillmann, et al., 2023.

2.1.4 Stichprobengröße

Zum Zeitpunkt der Studienentwicklung 2017 gab es in Berlin 288 geriatrische Langzeitpflegeeinrichtungen mit insgesamt 28.299 Plätzen. Es wurde von einer durchschnittlichen Anzahl von Bewohnenden von 100 Personen je Pflegeheim und einer Studienbeteiligung von 25 % ausgegangen. Aufgrund des explorativen Studiendesigns wurde eine Gesamtanzahl von 500 Bewohnenden bei 20 teilnehmenden Einrichtungen geplant. Berücksichtigt man ein Dropout von 8 % ergibt das eine geplante Gesamtanzahl von insgesamt 460 teilnehmenden Pflegeheimbewohnerinnen und -bewohnern.

2.1.5 Randomisierung und Verblindung

Die Randomisierung der Cluster (Pflegeheime) basierte auf einer einfachen, computergenerierten 1:1 Zuteilung in Interventions- oder Kontrollgruppe. Sowohl die Generierung als auch die Erstellung blickdichter Umschläge wurde durch ein unabhängiges Datenmanagement ausgeführt. Nach Abschluss der ersten Studienvisite (Baselinevisite) in einem Pflegeheim öffnete die Projektleitung den zugehörigen Randomisierungsumschlag und teilte die Einrichtung der Interventions- oder der Kontrollgruppe zu. Die Studienleitung und ein Teil des Studienteams waren nicht verblindet und übernahmen die Kommunikation und die Schulungen in den teilnehmenden Pflegeheimen. Eine zweite und unabhängige Gruppe des Studienteams war verblindet und führte die dermatologischen Untersuchungen der Studienteilnehmenden durch. Das Datenmanagement war während der gesamten Datenerhebung verblindet.

2.1.6 Endpunkte und Variablen

2.1.6.1 Klinische Parameter

Soziodemographische und medizinische Parameter (z. B. Alter, Medikamentengebrauch, Vorerkrankungen, Pflegegrad) wurden vor der ersten Studienvisite aus den Akten der Teilnehmenden durch das Studienpersonal extrahiert.

Die Diagnose von Xerosis cutis, Inkontinenz-assoziierter Dermatitis, Skin Tears, Dekubitus und Intertrigo wurde von Fach- oder Assistenzärztinnen und -ärzten für Dermatologie innerhalb der Studienvisiten gestellt. Die einzelnen Lokalisationen und die Ausprägung der Hautschäden wurden angegeben. An allen drei Messzeitpunkten

(Baseline, Follow-up nach drei Monaten, End-of-Study nach sechs Monaten) wurden diese Ergebnisse durch das Studienpersonal in standardisierten Datenerhebungsbögen dokumentiert.

Die Intensität trockener Haut wurde mittels des Overall Dry Skin Score (ODS) an Rumpf, Gesicht und den Extremitäten bewertet (Kang et al., 2014). Die Einteilung umfasst fünf Kategorien: der ODS Score 0 beschreibt keine Anzeichen trockener Haut und der ODS Score 4 umschreibt das Hautareal als sehr rau mit großen Hautschuppen, Entzündungen oder Rissen (Serup, 1995).

Die Diagnose und der Schweregrad der Inkontinenz-assoziierten Dermatitis wurden anhand des Ghent Global Incontinence-associated Dermatitis Categorisation Tool (GLOBIAD) bewertet. Bei einer Hautschädigung mit vorliegender Urin- und/oder Stuhlinkontinenz wurde eine klinisch diagnostizierte Inkontinenz-assoziierte Dermatitis in Kategorie 1 (A, B) oder 2 (A, B) eingeteilt sowie eine Differenzierung zwischen ventraler und dorsaler Lokalisation vorgenommen (Beeckman et al., 2018; Van den Bussche et al., 2018).

Der Schweregrad von Skin Tears wurde klinisch anhand des International Skin Tear Advisory Panel (ISTAP) eingeteilt. Abhängig vom Ausmaß der Hautverletzung ist eine Unterteilung von Typ I bis III möglich; zusätzlich wurde die Lokalisation dokumentiert (LeBlanc et al., 2013; Van Tiggelen et al., 2020).

Diagnostizierte Dekubitus wurden ausgehend vom Ausmaß der Schädigung anhand des National Pressure Ulcer Advisory Panel / European Pressure Ulcer Advisory Panel in sechs Kategorien (Kategorie I bis IV, tiefe Gewebsschädigung / deep tissue injury und nicht klassifizierbar/unstageable) eingeteilt (EPUAP/NPUAP/PPPIA, 2014).

Die Intertrigo wurde klinisch anhand der International Classification of Diseases (ICD)-11 diagnostiziert (World Health Organization, 2022). Die Lokalisation wurde dokumentiert.

2.1.6.2 Bewohnendespezifische Parameter

Ausgehend von den kognitiven Fähigkeiten der Teilnehmenden wurden verschiedene Erhebungsinstrumente angewendet, um Schmerz, Juckreiz und Lebensqualität zu erheben. Die Schwere einer möglichen kognitiven Einschränkung wurde vorab mit der Global Deterioration Scale (GDS) beurteilt (Reisberg et al., 1982). Die verwendete Skala beschreibt sieben Stadien kognitiver Leistungsfähigkeit. Im ersten Stadium (GDS Stufe 1) liegen keine kognitiven Einschränkungen vor, das höchste Stadium (GDS Stufe 7) ist durch schwerwiegende kognitive Defizite gekennzeichnet.

Mittels der numerischen Schmerzskala (Numeric Rating Scale, NRS) wurde bei Teilnehmenden ohne kognitive Defizite (GDS 1) die Schmerzintensität beurteilt. Bei dem Vorliegen einer leichten, mittelschweren oder schweren Demenz (GDS 2 bis 7) wurde die Schmerzintensität mit einer verbalen Messskala (Verbal Rating Scale, VRS) beurteilt (Williamson & Hoggart, 2005).

Um die Intensität des Juckreizes zu bestimmen wurde der 5-D Itch Fragebogen bei Teilnehmenden ohne kognitive Defizite verwendet (GDS 1) (Elman et al., 2010). Die Juckreizintensität wurde mittels einer Punktezahl ermittelt (0-25 Punkte), wobei ein Wert von 25 Punkten den maximalen Juckreiz beschreibt.

Die Lebensqualität wurde mittels des WHO-Five Well-Being Index bei Teilnehmenden ohne kognitive Defizite (GDS 1) erhoben. Der maximal erreichbare Wert liegt bei 25 Punkten, welches umgerechnet 100 % entspricht (Allgaier et al., 2013). Bei Teilnehmenden mit leichten bis mittelschweren kognitiven Defiziten (GDS 2 bis 6) wurde der Qualidem (37 Items) verwendet (Dichter et al., 2016). Bei schwerwiegender Demenz (GDS 7) wurde der Qualidem (18 Items) angewendet (Arons et al., 2017; Dichter et al., 2013).

Die Mobilität wurde mittels des Barthel Indexes erhoben (Mahoney & Barthel, 1965; Wade & Collin, 1988). Dieses Bewertungsverfahren erfasst grundlegende Alltagsfunktionen, wie Körperpflege, Kontinenz und Mobilität. Es findet hauptsächlich in der Geriatrie Anwendung. Die maximale Punktzahl bei uneingeschränkter Mobilität und Selbstständigkeit im Alltag liegt bei 100 Punkten.

Das Dekubitusrisiko wurde unter Zuhilfenahme der Braden-Skala beurteilt. Die Einschätzung entsteht durch die Beurteilung verschiedener Risikofaktoren, wie Mobilität, Sensorik, Ernährung und Hautfeuchtigkeit (Bergstrom et al., 1987; Kottner & Dassen, 2008). Ein Wert von unter 13 von möglichen 23 Punkten wird als geringes Dekubitusrisiko gewertet.

2.1.7 Statistische Methoden

Alle Bewohnenden der randomisierten Pflegeheime, welche schriftlich der Studienteilnahme zugestimmt hatten, den Einschlusskriterien entsprachen und die erste Studienvisite erhielten, wurden in die Datenanalyse eingeschlossen (Intention-to-treat, ITT).

Bei metrischen Variablen wurden Mittelwerte (Standardabweichung, SD) und Medianwerte (Interquartilsabstände, IQR) berechnet. Für kategoriale Variablen wurden Proportionen und Odds Ratios (OR) einschließlich des 95 % Konfidenzintervalls (KI) berechnet.

Unter Einbeziehung von Stichprobenmerkmalen wurden Gruppenvergleiche zwischen Personen mit und ohne Inkontinenz-assoziierter Dermatitis, Skin Tears, Dekubitus und Intertrigo erstellt. Ein Gruppenvergleich zu Xerosis cutis entfiel, da nahezu alle Teilnehmenden trockene Haut aufwiesen. Gruppenunterschiede mit einem p-Wert von unter 5 % wurden als mögliche Prädiktoren für ein anschließendes allgemeines Schätzmodell (General Estimating Equation Model, GEE) verwendet. GEE-Modelle liefern robuste Standardfehler für Schätzungen von Regressionskoeffizienten in geclusterten Stichproben. Die Modelle wurden für das Vorhandensein von Skin Tears und Dekubitus angefertigt, da für diese Hautschäden klinisch und statistisch relevante Assoziationen mit Stichprobenmerkmalen ermittelt wurden.

Um Effekte des eingeführten Hautpflegealgorithmus aufzuzeigen wurde die kumulative Inzidenz mit multipler Imputation (ITT) für das erstmalige Auftreten von Hautschäden (Inkontinenz-assoziierte Dermatitis, Skin Tears, Dekubitus, Intertrigo) nach drei und sechs Monaten berechnet. In diese Berechnung wurden nur jene Fälle einbezogen, bei denen diese spezifischen Hautschäden zu Studienbeginn noch nicht vorlagen. Die kumulative Inzidenz nach drei Monaten beinhaltet neu aufgetretene Hautschäden innerhalb dieses Zeitraumes. Die kumulative Inzidenz nach sechs Monaten impliziert alle neu aufgetretenen Hautschäden über den gesamten Studienzeitraum von sechs Monaten.

Alle Berechnungen wurden mit IBM SPSS Statistics Version 27, sowie mit der R Version 4.1.1. (R package gee version 4.13) für die GEE-Modelle durchgeführt.

2.2 Teilprojekt 2 (Sekundärdatenanalyse)

Das zweite Teilprojekt ist eine Sekundärdatenanalyse einer klinischen Studie. In diesem Kontext wurden die Auswirkungen einer verlängerten Liegedauer auf hautphysiologische Parameter untersucht und mögliche Assoziationen analysiert. Die Ergebnisse wurden 2022 im “Journal of Tissue Viability” publiziert (Publikation 3: (Völzer & Kottner, 2022)).

2.2.1 Studiendesign und Setting

Es wurde eine Sekundärdatenanalyse einer randomisierten, kontrollierten, exploratorischen Studie mit Crossover-Design durchgeführt. Die Studie “Comparing the effects of 3 different pressure ulcer prevention support surfaces on the structure and function of heel and sacral skin: an exploratory cross-over trial” wurde im Vorfeld durch die Ethikkommission der Charité Universitätsmedizin genehmigt (EA1/270/15) und bei ClinicalTrials.gov registriert (NCT02930590). Untersucht wurden in vivo Veränderungen hautphysiologischer Parameter nach verlängerter Liegedauer (Rückenlage) bei Frauen zwischen 60 und 80 Jahren im Sakral- und Fersenbereich auf drei verschiedenen Matratzen.
In der Sekundärdatenanalyse wurden ausschließlich Auswirkungen der Liegedauer auf der Standardschaummatratze ausgewertet.

2.2.2 Studienpopulation

Einschlusskriterien für diese ambulant durchgeführte Studie waren das weibliche Geschlecht (I), ein Lebensalter zwischen 60 und 80 Jahren (II) und Rauchfreiheit seit mindestens einem Jahr (III). Es durften an den Untersuchungsgebieten Ferse und Sakrum keine Hautschäden oder Narben bestehen (IV). Zwölf Stunden vor den Messungen war es nicht gestattet topische Produkte zum Verbleib auf der Haut aufzutragen (V). Vorab musste eine schriftliche Einverständniserklärung vorliegen (VI).

2.2.3 Intervention

Zu Beginn wurden hautphysiologische Parameter am Sakral- und Fersenbereich gemessen. Danach mussten die Teilnehmerinnen zwei Stunden bewegungslos in Rückenlage auf den Matratzen liegen. Als zusätzliche Auflage auf der Matratze wurde

ein Baumwolllaken verwendet, mit welchem die Haut der Probandinnen direkt in Berührung kam. Sofort im Anschluss wurden die Messungen an Sakrum und Ferse wiederholt.

2.2.4 Endpunkte und Variablen

Zu den erhobenen hautphysiologischen Parametern gehören Messungen von Hautfeuchtigkeit, Hauttemperatur, Hautrötung, Hautelastizität und Topographie der Haut. Die Messungen waren nicht invasiv und wurden zweimal durchgeführt, um die Messreliabilität zu erhöhen (Elban et al., 2020; Kottner & Blume-Peytavi, 2021).

Die Beurteilung der Hautfeuchtigkeit umfasste die Messungen des transepidermalen Wasserverlustes (transepidermal water loss, TEWL), der Stratum corneum Hydratation (SCH) und der epidermalen Hydratation.

Die Stratum corneum Hydratation wurde mit dem Corneometer CM 825 (Courage+Khazaka electronic GmbH, Köln, Deutschland) gemessen. Dabei wird der Feuchtigkeitsgehalt der obersten Hautschicht (Hornzellenschicht, Stratum corneum) erfasst (Berardesca et al., 1997; du Plessis et al., 2013). Die Werte werden in einer dimensionslosen Einheit (Arbitrary Unit, AU) angegeben und reichen von 0 AU bis maximal 120 AU. Höhere Werte beschreiben eine erhöhte SCH; Werte unter 40 AU werden – in Abhängigkeit vom Körperareal – als ein Hinweis für trockene Haut gewertet (Heinrich et al., 2003; Kottner et al., 2013).

Der transepidermale Wasserverlust wurde mit dem Tewameter TM 300 (Courage+Khazaka, electronic GmbH, Köln, Deutschland) gemessen. Mittels Sensoren für Temperatur und relative Feuchtigkeit misst die Sonde indirekt die Wasserabdampfungsrate der Haut durch das Prinzip einer sogenannten „offenen Kammer“ (Hohlzylinder) (Rogiers & Group, 2001). Die Messeinheit der Wasserabdampfungsrate ist $g/h/m^2$, wobei höhere Werte einen größeren transepidermalen Wasserverlust beschreiben (Akdeniz et al., 2018).

Die epidermale Hydratation beschreibt prozentual den Wassergehalt im Gewebe (0 - 100 %) in 0,5 mm Tiefe und wurde mit dem MoistureMeterEpiD (Delfin Technologies Ltd, Kuopio, Finnland) gemessen (Kottner & Blume-Peytavi, 2021).

Die Temperatur der Hautoberfläche wurde in Grad Celsius (°C) mit dem Skin-Thermometer ST 500 (Courage+Khazaka, electronic GmbH, Köln, Deutschland) gemessen und basiert auf dem Prinzip einer berührungslosen Infrarotmessung.

Die Rötung der Haut (Erythem) wurde mit dem Mexameter MX 18 (Courage+Khazaka electronic GmbH, Köln, Deutschland) gemessen. Die Messung basiert auf dem Prinzip der Reflexion und Absorption von Melanin und Hämoglobin, der beiden Hauptfarbkomponenten der Haut. Die Maßeinheit ist eine dimensionslose Einheit und liegt zwischen 0 AU und 999 AU (Clarys et al., 2000).
Die Widerstandsfähigkeit der Haut (structural skin stiffness) und Elastizität der Haut (skin elasticity) wurden mit dem Cutometer MPA 580 (Courage+Khazaka electronic GmbH, Köln, Deutschland) gemessen (Monteiro Rodrigues et al., 2020). Das Prinzip dieser Messung unterliegt einer Saugwirkung, bei dem die Haut mechanisch durch einen negativen Druck auseinandergezogen wird. Die Verformung der Haut und die Fähigkeit sich wieder zusammenzuziehen werden graphisch als Kurve dargestellt (Tiefe in Millimeter je Zeit). Die Berechnung der Hautelastizität wurde für folgende weitere Parameter genutzt: elastische Eigenschaft (elastic function, Ur/Ue in Prozent), Verformbarkeit (extensibility, Uf in Millimeter) und elastische Rückverformung (elastic recovery Ur/Uf in Prozent). Zusätzlich wurde ein Bild der Hautoberfläche an beiden Messarealen mit der Visioscan VC 98 (Courage+Khazaka electronic GmbH, Köln, Deutschland) aufgenommen. Anhand des Bildmaterials wurde die Topographie der Hautoberfläche (skin roughness, Rz) in Mikrometer (µm) gemessen (Mercurio et al., 2013; Trojahn et al., 2015).

2.2.5 Statistische Methoden

Die Datenanalyse erfolgte deskriptiv durch die Berechnung von Mittelwerten (Standardabweichungen, SD) und Medianwerten (Interquartilsabstände, IQR). Zusätzlich wurden die Differenzen der Mittelwerte (Deltawerte) aller Messvariablen zwischen der ersten und zweiten Messung an beiden Studienarealen berechnet. Assoziationen wurden mit dem Korrelationskoeffizienten nach Spearman (r_s) aufgezeigt. Werte zwischen $r_s \geq 0{,}5$ und $r_s \leq -0{,}5$ zeigen moderate Korrelationen zwischen den einzelnen Parametern (Mukaka, 2012). Aufgrund des explorativen Designs und der geringen Stichprobengröße wurden die p-Werte nicht berücksichtigt.
Für alle Berechnungen wurde die IBM SPSS Statistics Version 27 verwendet.

3 Ergebnisse

3.1 Teilprojekt 1 (Prävalenzanalyse)

3.1.1 Studienpopulation

An der Studie haben 17 Pflegeheime teilgenommen und 314 Bewohnerinnen und Bewohner haben eine Baselinevisite erhalten. Die Mehrheit der Teilnehmenden war weiblich (68,8 %) und das Durchschnittsalter lag bei 85,4 (SD 7,1) Jahren. Die durchschnittliche bisherige Aufenthaltsdauer im Pflegeheim betrug 30,4 (SD 31,4) Monate und die Pflegegrade II (31,5 %) und III (36,6 %) waren vorherrschend. Der überwiegende Anteil der Teilnehmenden war von Inkontinenz betroffen (79,0 %). Ungefähr die Hälfte der Teilnehmenden wies kognitive Einschränkungen auf (49,5 %). Weitere Stichprobenmerkmale und die Prävalenz der häufigsten pflegerelevanten Hautschäden sind nachfolgend in Tabelle 1 aufgeführt.

Tabelle 1. Stichprobenmerkmale und Prävalenz pflegerelevanter Hautschäden

Stichprobenmerkmale (n = 314)	
Alter in Jahren; Mittelwert (SD)[1]	85,4 (7,1)
Weibliches Geschlecht; %	68,8
Body-Mass-Index in kg/m²; Mittelwert (SD)	26,2 (5,2)
Urin- und/oder Stuhlinkontinenz; %	79,0
Barthel Index; Mittelwert (SD)	45,2 (24,0)
Braden Scale Score; Mittelwert (SD)	16,5 (3,2)
Global Deterioration Scale 2-7; %	49,4
Prävalenz	
Xerosis cutis; % (95 % KI)[2]	95,9 (93,6 – 97,8)
Inkontinenz-assoziierte Dermatitis; % (95 % KI)	21,0 (15,6 – 26,3)
Skin Tears; % (95 % KI)	10,5 (7,3 – 13,8)
Dekubitus; % (95 % KI)	8,0 (5,1 – 10,8)
Intertrigo; % (95 % KI)	35,0 (30,0 – 40,1)

[1] Standardabweichung
[2] Konfidenzintervall

Quelle: Eigene Darstellung (Bettina Völzer)

3.1.2 Hauptergebnisse

Xerosis cutis konnte bei nahezu allen Teilnehmenden an mindestens einer Körperstelle (überwiegend an den Extremitäten) festgestellt werden (Prävalenz 95,9 %, 95 % KI 93,6 bis 97,8). Die Prävalenz von Intertrigo betrug 35,0 % und die am häufigsten betroffenen Körperareale waren Regio inguinalis, Rumpf und Füße. Die Diagnose war mit einem erhöhten Body-Mass-Index (Mittelwertdifferenz -2,9; 95 % KI -4,1 bis -1,8) und einer längeren bisherigen Aufenthaltsdauer im Pflegeheim (Mittelwertdifferenz -8,4; 95 % KI - 16,9 bis -0,7) assoziiert. Bei den von Inkontinenz betroffenen Teilnehmenden lag bei 21,0 % eine Inkontinenz-assoziierte Dermatitis vor. Diese war assoziiert mit einem kürzeren bisherigen Aufenthalt im Pflegeheim (Mittelwertdifferenz in Monaten 11,1; 95 % KI 3,9 bis 18,3). Skin Tears wurden bei 10,5 % der Bewohnenden, insbesondere an den Extremitäten, diagnostiziert. Dieser Befund war assoziiert mit einem höheren Lebensalter (Mittelwertdifferenz -3,1; 95 % KI -5,3 bis -0,8), einem niedrigeren Body-Mass-Index (Mittelwertdifferenz 2,4; 95 % KI 0,7 bis 4,0) und einer demenziellen Erkrankung (OR 3,8; 95 % KI 1,8 bis 8,7). Zudem konnten Einschränkungen der Mobilität mit dem Auftreten von Skin Tears in Zusammenhang gebracht werden (Barthel Index Mittelwertdifferenz 13,4; 95 % KI 4,5 bis 21,2). Die Prävalenz von Dekubitus betrug 8,0 % und der Sakralbereich war mit 74,1 % am häufigsten betroffenen. Assoziationen mit dem männlichen Geschlecht (OR 0,3; 95 % KI 0,1 bis 0,7), einer längeren bisherigen Aufenthaltsdauer im Pflegeheim (Mittelwertdifferenz -11,6; 95 % KI -22,6 bis -0,5) sowie Harn und/oder Stuhlinkontinenz (OR 7,0; 95 % KI 1,7 bis 10,3) wurden festgestellt. Zusätzlich wiesen die betroffenen Personen Einschränkungen hinsichtlich Mobilität und Transfer auf (Barthel Index Item ‚Transfer': Mittelwertdifferenz 3,6; 95 % KI 1,9 bis 5,2). Ein Zusammenhang mit einem erhöhten pflegerischen Unterstützungsbedarf wurde konstatiert (OR 3,3; 95 % KI 1,4 bis 8,4).

Für das Auftreten von Skin Tears und Dekubitus wurden klinisch relevante Assoziationen mit soziodemographischen und funktionellen Stichprobenmerkmalen aufgezeigt. Daraus resultierend wurden GEE-Modelle für geclusterte Stichproben berechnet. Statistisch signifikante Prädiktoren für das Vorhandensein von Skin Tears waren Einschränkungen der Mobilität und des Transfers sowie ein höheres Lebensalter. Adjustiert wurde für Alter, Übergewicht, Demenz und Mobilität.

Statistisch signifikante Prädiktoren für das Vorhandensein von Dekubitus waren männliches Geschlecht, eingeschränkte Mobilität sowie die Notwendigkeit der

Unterstützung bei der Körperpflege. Urininkontinenz war der größte klinisch relevante Prädiktor, wenn auch nicht statistisch signifikant. Das GEE-Modell für Dekubitus wurde adjustiert für Geschlecht, bisherige Aufenthaltsdauer im Pflegeheim, Inkontinenz, Mobilität, Selbstständigkeit bei der Körperpflege und die Nutzung von Anti-Dekubitusmatratzen.

Nahezu alle Teilnehmenden (97,8 %) waren von mindestens einem pflegerelevanten Hautschaden betroffen. Insgesamt hatten 46,8 % der Pflegeheimbewohnenden zwei oder mehrere pflegerelevante Hautschäden gleichzeitig. Das Vorhandensein von Xerosis cutis, Inkontinenz-assoziierter Dermatitis, Skin Tears, Dekubitus und Intertrigo war nicht miteinander assoziiert.

3.2 Teilprojekt 1 (Analyse der Intervention)

3.2.1 Studienpopulation

Insgesamt wurden neun Pflegeheime mit 165 Teilnehmenden der Interventionsgruppe und acht Pflegeheime mit 149 Teilnehmenden der Kontrollgruppe zugeordnet. Relevante Stichprobencharakteristika sowie die Prävalenz pflegerelevanter Hautschäden von Interventions- und Kontrollgruppe sind nachfolgend Tabelle 2 zu entnehmen. Hinsichtlich soziodemographischer und funktioneller Parameter sind Interventions- und Kontrollgruppe vergleichbar. In der Interventionsgruppe wurde eine höhere Prävalenz für Intertrigo, Skin Tears und Dekubitus festgestellt. Vergleichbare Werte wurden für Xerosis cutis und Inkontinenz-assoziierte Dermatitis erhoben.

Tabelle 2. Stichprobenmerkmale und Prävalenz pflegerelevanter Hautschäden im Gruppenvergleich

Stichprobenmerkmale	**Interventionsgruppe (n = 165)**	**Kontrollgruppe (n = 149)**
Alter in Jahren; Mittelwert (SD)[1]	85,2 (7,3)	85,6 (6,9)
Weibliches Geschlecht; %	67,9	69,8
Body-Mass-Index in kg/m^2; Mittelwert (SD)	26,6 (5,0)	25,9 (5,4)
Urin- und/oder Stuhlinkontinenz; %	75,2	82,6
Barthel Index; Mittelwert (SD)	46,9 (22,5)	43,2 (25,4)
Braden Scale Score; Mittelwert (SD)	16,8 (3,0)	16,2 (3,4)
Global Deterioration Scale 2-7	50,9	47,7
Prävalenz		
Xerosis cutis; % (95 % KI)[2]	95,2 (91,5 – 98,2)	96,6 (93,6 – 99,3)
IAD[3]; % (95 % KI)	20,8 (13,3 – 28,7)	21,1 (13,9 – 29,3)
Skin Tears; % (95 % KI)	12,1 (7,3 – 17,4)	8,7 (4,3 – 13,7)
Dekubitus; % (95 % KI)	10,9 (6,4 – 16,0)	4,7 (1,5 – 8,6)
Intertrigo; % (95 % KI)	38,2 (41,4 – 46,3)	31,5 (24,2 – 38,9)

[1] Standardabweichung
[2] Konfidenzintervall
[3] Inkontinenz-assoziierte Dermatitis

Quelle: Eigene Darstellung (Bettina Völzer)

3.2.2 Hauptergebnisse

Die kumulative Inzidenz der häufigsten pflegerelevanten Hautschäden (ITT), drei Monate (Follow-up) und sechs Monate (End-of-Study) nach Studienbeginn, ist nachfolgend tabellarisch abgebildet (Tabelle 3).

Die höchste kumulative Inzidenz wurde in der Kontrollgruppe für Intertrigo (37,8 %; 95 % KI 27,5 bis 49,5) und Skin Tears (27,2 %; 95 % KI 19,3 bis 36,9) festgestellt. Die kumulative Inzidenz für Skin Tears, Dekubitus und Intertrigo war sowohl nach drei als auch nach sechs Monaten in der Kontrollgruppe höher als in der Interventionsgruppe.

Die kumulative Inzidenz der Inkontinenz-assoziierten Dermatitis hingegen war an beiden Messzeitpunkten in der Interventionsgruppe höher als in der Kontrollgruppe.

Tabelle 3. Kumulative Inzidenz pflegerelevanter Hautschäden im Gruppenvergleich

	Kumulative Inzidenz; % (95 % KI)[1]			
	Follow-up		End-of-Study	
	Interventionsgruppe	Kontrollgruppe	Interventionsgruppe	Kontrollgruppe
Inkontinenz-assoziierte Dermatitis	17,1 (10,3 – 27,0)	12,0 (6,1 – 22,2)	26,3 (17,9 – 36,8)	23,1 (14,6 – 34,5)
Skin Tears	11,4 (6,4 – 19,5)	18,9 (12,5 – 27,6)	19,2 (12,8 – 27,8)	27,2 (19,3 – 36,9)
Dekubitus	8,6 (4,3 – 16,4)	11,1 (6,2 – 19,1)	13,6 (8,1 – 21,9)	16,9 (10,6 – 25,9)
Intertrigo	11,2 (5,6 – 21,0)	19,7 (12,3 – 29,9)	27,0 (18,4 – 37,7)	37,8 (27,5 – 49,4)

[1] Konfidenzintervall

Quelle: Eigene Darstellung (Bettina Völzer)

Die Anteile von Xerosis cutis waren in Interventions- und Kontrollgruppe im Studienverlauf vergleichbar. Die höchsten Werte des Overall Dry Skin Score wurden während der ersten Studienvisite an den Extremitäten (Median 1,0; IQR 1,0 bis 1,0) sowie den Füßen (Median 1,0; IQR 1,0 bis 1,4) ermittelt. Diese Werte verringerten sich im Mittel nach sechs Monaten bei den Teilnehmenden der Interventionsgruppe an den unteren Extremitäten und dem Rumpf. Insgesamt wurde im Studienverlauf eine hohe Variabilität des Overall Dry Skin Score festgestellt.

In der Interventionsgruppe verbesserten sich bei den Teilnehmenden Lebensqualität und Schmerzintensität minimal. Zudem waren am Studienende in der Interventionsgruppe prozentual weniger Teilnehmende von Juckreiz betroffen. Die Intensität des Juckreizes war darüber hinaus geringer.

Detaillierte Ergebnisse aller erhobenen Variablen sind der Publikation zu entnehmen (Völzer, El Genedy-Kalyoncu, Fastner, Tomova-Simitchieva, Neumann, Hillmann, et al., 2023).

3.3 Teilprojekt 2 (Sekundärdatenanalyse)

3.3.1 Studienpopulation

An der Untersuchung nahmen 15 gesunde Frauen mit einem Durchschnittsalter von 66,2 (SD 3,6) Jahren und einem Body-Mass-Index von durchschnittlich 24,7 (SD 2,0) kg/m^2 teil.

3.3.2 Hauptergebnisse

Am Sakralbereich konnte nach zweistündiger Liegedauer eine Zunahme von transepidermalem Wasserverlust (TEWL), Stratum corneum Hydratation (SCH) und epidermaler Hydratation sowie ein Anstieg der Hauttemperatur und eine Verstärkung der Hautrötung (Erythem) festgestellt werden. Ebenso vergrößerten sich die Verformbarkeit (Uf) und die Topographie der Haut (Rz), während die elastische Eigenschaft (Ur/Ue) und die elastische Rückverformung (Ur/Uf) abnahmen. Die stärksten positiven Assoziationen wurden hinsichtlich Hautelastizität zwischen Ur/Ue und Ur/Uf (r_s = 0,854) sowie zwischen SCH und epidermaler Hydratation (r_s = 0,702) aufgezeigt. Die stärksten negativen Assoziationen wurden zwischen TEWL und Rz (r_s = -0,492) festgestellt. Der Anstieg der Hauttemperatur sowie die Zunahme des Erythems waren am Sakralbereich nicht miteinander oder weiteren Parametern assoziiert.

An der Ferse wurde eine Zunahme von TEWL, SCH und epidermaler Hydratation festgestellt. Insbesondere der Anstieg des TEWL war größer als am Sakrum. Ebenfalls konnten eine Verstärkung des Erythems, eine Erhöhung der lokalen Hauttemperatur sowie eine Vergrößerung der Verformbarkeit (Uf) gemessen werden. Die stärksten positiven Assoziationen traten hinsichtlich der Hautelastizität zwischen Ur/Uf und Ur/Ue (r_s = 0,907) auf. Eine mäßig positive Assoziation konnte zwischen epidermaler Hydratation und SCH gezeigt werden (r_s = 0,458). Die stärksten negativen Assoziationen wurden für Ur/Ue und Uf (r_s = -0,721) und Ur/Uf und Uf (r_s = -0,639) festgestellt. Die Verstärkung des Erythems war ebenfalls negativ mit einer erhöhten Hauttemperatur assoziiert (r_s = -0,525).

Die Abbildungen 2 und 3 geben einen Überblick über moderate Assoziationen hautphysiologischer Parameter an Sakrum und Ferse ($r_s \geq 0,5$ oder $r_s \leq -0,5$). Detaillierte Ergebnisse der Veränderungen hautphysiologischer Parameter sowie aller Assoziationen können der Publikation entnommen werden (Völzer & Kottner, 2022).

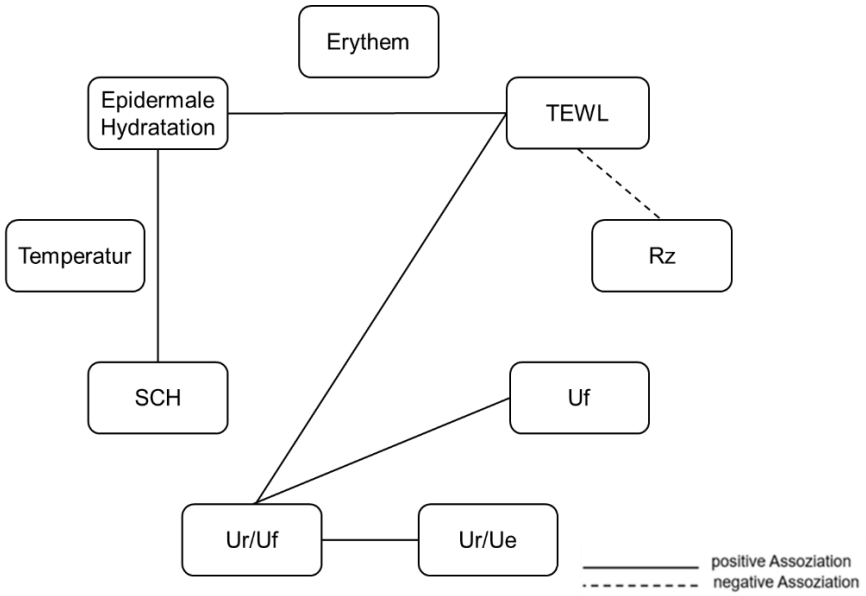

Abbildung 2. Assoziationen hautphysiologischer Parameter am Sakralbereich

Quelle: Modifiziert nach: Völzer & Kottner, 2022.

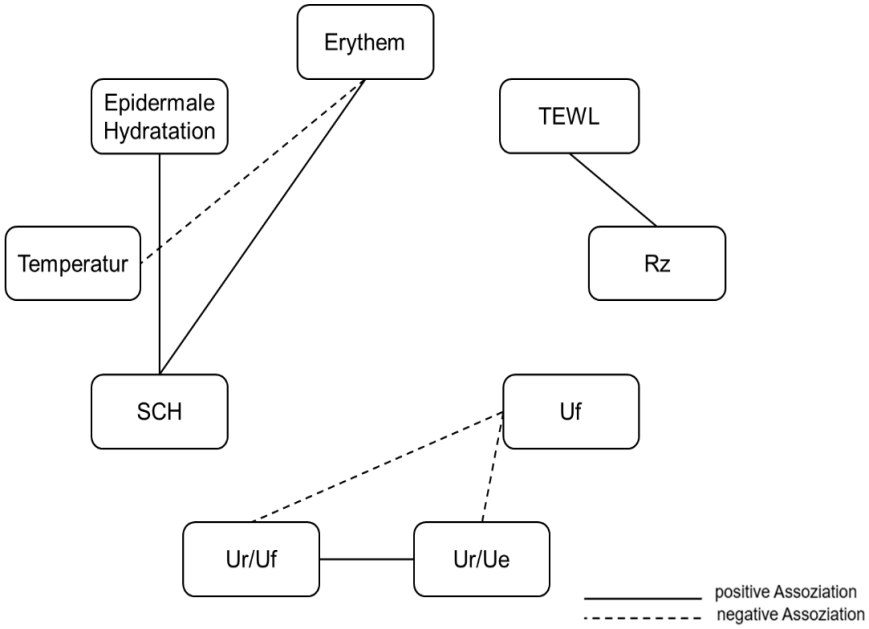

Abbildung 3. Assoziationen hautphysiologischer Parameter an der Ferse

Quelle: Modifiziert nach: Völzer & Kottner, 2022.

4 Diskussion

4.1 Kurze Zusammenfassung der Ergebnisse

Die Untersuchung von insgesamt 314 Pflegeheimbewohnenden in Berliner Langzeitpflegeeinrichtungen zeigte eine hohe Prävalenz pflegerelevanter Hautschäden. Nahezu alle Teilnehmenden waren von Xerosis cutis (95,9 %; 95 % KI 93,6 bis 97,8) und mehr als ein Drittel von Intertrigo betroffen (35,0 %; 95 % KI 30,0 bis 40,1). Die Prävalenz Inkontinenz-assoziierter Dermatitis betrug 21,0 % (95 % KI 15,6 bis 26,3), von Skin Tears 10,5 % (95 % KI 7,3 bis 13,8) und von Dekubitus 8,0 % (95 % KI 5,1 bis 10,8). Assoziationen zwischen einzelnen pflegerelevanten Hautschäden und eingeschränkter Mobilität, reduzierter Kognition sowie erhöhter Pflegebedürftigkeit wurden festgestellt.

Nach Einführung eines strukturierten und evidenzbasierten Hautpflegealgorithmus mit vorausgehendem Hautassessment für einen Zeitraum von sechs Monaten war die kumulative Inzidenz der häufigsten pflegerelevanten Hautschäden in der Interventionsgruppe überwiegend geringer als in der Kontrollgruppe, welche die Standardversorgung nicht veränderte. Eine Abweichung wurde hinsichtlich der Inkontinenz-assoziierten Dermatitis festgestellt, da sowohl nach drei, als auch nach sechs Monaten die kumulative Inzidenz in der Interventionsgruppe höher war als bei den Teilnehmenden der Kontrollgruppe. Eine leichte Verbesserung von Schmerz, Juckreiz und Lebensqualität konnte bei den Teilnahmenden der Interventionsgruppe festgestellt werden.

Bei gesunden Frauen über 65 Jahre führte eine 120-minütige Liegedauer auf einer Standardschaummatratze an Ferse und Sakrum zu einem Anstieg von Hautfeuchtigkeit, Hauttemperatur und einer verstärkten Hautrötung. Messungen der Hautelastizität waren an beiden Messpunkten positiv miteinander assoziiert (elastische Eigenschaft und Rückverformung, r_s Sakralbereich = 0,854 und r_s Ferse = 0,907). Am Sakrum zeigte sich die stärkste Assoziation zwischen Stratum corneum Hydratation und epidermaler Hydratation (r_s = 0,702). Die Verstärkung von Erythem und Temperatur waren an diesem Messareal mit keinen weiteren Parametern assoziiert. An der Ferse konnte eine negative Korrelation zwischen Temperatur- und Erythemverstärkung festgestellt werden.

4.2 Interpretation und Einbettung der Ergebnisse in den bisherigen Forschungsstand

4.2.1 Prävalenzanalyse

Die dermatologische Untersuchung von Bewohnerinnen und Bewohnern über 65 Jahre in geriatrischen Langzeitpflegeeinrichtungen ergab eine hohe Prävalenz pflegerelevanter Hautschäden. Dieses macht die Dringlichkeit für die Prävention ebensolcher Hautschäden in dem beschriebenen Setting deutlich.

Mit einer Prävalenz von 95,9 % wurde bei nahezu allen Teilnehmenden eine Xerosis cutis diagnostiziert. Dieses Ergebnis ist vergleichbar mit einer vorausgegangenen Studie, in welcher die Prävalenz 99,1 % betrug (Hahnel, Blume-Peytavi, Trojahn, Dobos, Jahnke, et al., 2017). Eine deutlich niedrigere Prävalenz in Höhe von 41,2 % wurde, bei vergleichbarem Setting und vergleichbarer Population, durch die Einschätzung der Haut durch das Pflegepersonal erhoben (Lechner et al., 2019). Dahingehend kann interpretiert werden, dass sich die Beurteilung von Hauttrockenheit durch Pflegekräfte, ärztliches Personal oder andere geschulte Beurteilende unterscheidet. Ausgehend von dieser Diskrepanz erscheint es denkbar, dass das Pflegepersonal möglicherweise erste Anzeichen von Hauttrockenheit übersieht. Die Ausbildung und Schulung hinsichtlich der Identifizierung erster Anzeichen von Xerosis cutis könnte demzufolge noch spezifischer angepasst und intensiviert werden. Mit dem Ziel Schäden der Haut zu vermeiden sei die Notwendigkeit eines korrekt ausgeführten Hautassessments, gefolgt von einer individualisierten und evidenzbasierten Pflegeroutine, noch einmal hervorgehoben (Kottner, 2023).

Die Prävalenz der Inkontinenz-assoziierten Dermatitis betrug 21,0 %. Dieser Wert liegt im Mittel vorheriger Studienergebnisse aus geriatrischen Langzeitpflegeeinrichtungen, welche Werte zwischen 6,1 % und 35,4 % beschrieben (Hahnel, Blume-Peytavi, Trojahn, & Kottner, 2017; Kottner et al., 2014). Eine Assoziation mit einem kürzeren Aufenthalt in einer Pflegeeinrichtung wurde in der SKINCARE-Studie festgestellt und hebt die Wirksamkeit spezifischer Hautpflegemaßnahmen durch geschultes Pflegepersonal hervor. Die Bedeutung einer dauerhaften und sofort nach einer stationären Aufnahme beginnenden Hautpflege durch qualifiziertes Pflegepersonal konnte in einer vorausgegangenen Studie eruiert werden (Kennedy et al., 2018). Eine zusätzliche Analyse der Baselinedaten der SKINCARE-Studie zeigte zudem, dass die vom Pflegepersonal durchgeführte Körperpflege, im Vergleich zu der von den Bewohnenden

selbstständig durchgeführten Pflege, mit einer besseren Hautgesundheit in Zusammenhang steht. Das bedeutet, dass pflegerische Maßnahmen des Pflegepersonals adäquater, verglichen mit alleiniger pflegerischer Versorgung durch die Bewohnenden, sind (Amin et al., 2023).

Die Prävalenz für Skin Tears beträgt in der im Rahmen der Dissertation vorgestellten SKINCARE-Studie 11 % und erscheint hoch – verglichen mit Werten zwischen 3,0 % und 4,6 % aus früheren europäischen Untersuchungen (Skiveren et al., 2017; Van Tiggelen et al., 2019). Kanadische Studienergebnisse zeigen hingegen Prävalenzwerte von 14,7 % bis 20,8 % in einem vergleichbaren Setting (LeBlanc et al., 2021; Woo & LeBlanc, 2018). Assoziationen mit höherem Lebensalter, niedrigem Body-Mass-Index, sowie physischen und kognitiven Einschränkungen, konnten identifiziert werden und stützen bestehende Forschungsergebnisse (Rayner et al., 2015; Strazzieri-Pulido et al., 2017).

Die vorliegenden Studienergebnisse zeigen eine Prävalenz von Dekubitus der Kategorien 1 und 2 nach NPUAP/EPUAP Klassifikation zu Studienbeginn von 8 %. Dieses Ergebnis ist konform mit den Ergebnissen eines Systematic Review europäischer Daten (Moore et al., 2019). Es wurden Assoziationen mit Urin- und/oder Stuhlinkontinenz, männlichem Geschlecht, erhöhter Pflegebedürftigkeit sowie funktionellen und kognitiven Einschränkungen festgestellt. Bei Bewohnenden mit Dekubitus wurden häufiger spezielle Anti-Dekubitusunterlagen verwendet, welches eine angemessene Pflegeroutine aufzeigt.

Die Prävalenz für Intertrigo beträgt in der SKINCARE-Studie 35,0 % und ist damit doppelt so hoch im Vergleich mit einer früheren Studie in Berliner Langzeitpflegeeinrichtungen, welche eine Prävalenz von 16,1 % konstatierte (Gabriel et al., 2019). Zusätzlich zeigen die vorliegenden Ergebnisse, dass ungefähr die Hälfte der Teilnehmenden mehr als eine intertriginöse Hautstelle aufwies. Eine Assoziation mit erhöhtem Body-Mass-Index lässt sich in Erkenntnisse bestehender Literatur einordnen (J. Kottner et al., 2020; Romanelli et al., 2023).

4.2.2 Analyse der Intervention

Durch die Einführung eines strukturierten Hautpflegealgorithmus konnten positive Effekte hinsichtlich der Prävention pflegerelevanter Hautschäden, wie Skin Tears, Dekubitus, Intertrigo sowie der Intensität von Xerosis cutis, erzielt werden.

Xerosis cutis wurde bei nahezu allen Bewohnerinnen und Bewohnern zu Studienbeginn diagnostiziert, wodurch eine Erfassung der kumulativen Inzidenz im Studienverlauf nicht

möglich war. Durchschnittlich wurde eine leichte Reduktion der Intensität trockener Haut an allen Messarealen in der Interventionsgruppe nach sechs Monaten erreicht. Die Wirksamkeit einer regelmäßigen Applikation topischer Hautpflegeprodukte wird unterstützt durch eine Sekundäranalyse der Studiendaten: Hierbei konnte gezeigt werden, dass ältere Pflegeheimbewohnerinnen und -bewohner mit trockener Haut seltener Hautpflegeprodukte verwendeten als jene mit weniger intensiv ausgeprägter Hauttrockenheit. Ausgehend von dem hohen Anteil von Xerosis cutis lassen die Ergebnisse jedoch bislang auf eine noch unzureichende Applikation topischer Produkte zum Verbleib auf der Haut schließen (Amin et al., 2023). Eine weitere Sekundärdatenanalyse zeigte zudem, dass die Standardversorgung aus einer täglichen Waschroutine, wöchentlichem Duschen sowie täglicher Applikation topischer Produkte auf dem Gesicht und wöchentlich auf dem gesamten Körper besteht (Amin et al., 2024). Ausgehend von der hohen Prävalenz von Xerosis cutis kann vermutet werden, dass die aktuelle Standardversorgung in stationären Langzeitpflegeeinrichtungen noch nicht ausreichend ist Hautschäden zu vermeiden und die Hautgesundheit zu verbessern. Hahnel et al. publizierten in einer früheren Untersuchung die Wirksamkeit einer strukturierten Hautpflege mit zweimaliger Applikation topischer Produkte zum Verbleib auf der Haut. Die Verbesserung von Hauttrockenheit in der geriatrischen Langzeitpflege konnte gezeigt werden und deckt sich mit den positiven Effekten der implementierten Hautpflegeroutine innerhalb der SKINCARE-Studie (Hahnel, Blume-Peytavi, Trojahn, Dobos, Stroux, et al., 2017).

Sechs Monate nach Studienbeginn wurde in der Interventionsgruppe eine kumulative Inzidenz für Skin Tears in Höhe von 19,2 % und in der Kontrollgruppe in Höhe von 27,2 % festgestellt. Verglichen mit einer kanadischen Studie und einer aufgezeigten Inzidenz von 18,9 % innerhalb von vier Wochen sind die erhobenen Werte der SKINCARE-Studie augenscheinlich höher, jedoch war der Beobachtungszeitraum mit sechs Monaten deutlich länger (LeBlanc et al., 2020). Carville et al. konnten in einem RCT zeigen, dass die zweimalige tägliche Applikation topischer Pflegeprodukte zum Verbleib auf der Haut das Auftreten von Skin Tears bei Bewohnenden geriatrischer Langzeitpflegeeinrichtungen um fast 50 % reduzieren konnte (Carville et al., 2014). Die vergleichbare Intervention zur Prävention von Skin Tears in einem ähnlichen Setting unterstützt die Wirksamkeit der Applikation topischer Produkte zum Verbleib auf der Haut. Zusätzlich lässt sich daraus ableiten, dass die Verwendung adäquater Hautpflegeprodukte als präventive Maßnahme zur Vermeidung von Xerosis cutis und

Skin tears positive Effekte zeigt und der Hautpflegealgorithmus die Prävention verschiedener Hautschäden parallel adressiert.

Hinsichtlich der Entstehung einer oder mehrerer intertriginöser Hautareale ist festzustellen, dass die kumulative Inzidenz mit 27,0 % in der Interventionsgruppe deutlich geringer ist als in der Kontrollgruppe mit 37,8 %. Durch eine vorausgegangene Randomisierung konnten mögliche Gruppenunterschiede aufgrund des BMI reduziert werden und der Einfluss des Körpergewichtes erscheint hinsichtlich dieser Interpretation marginal. Der präventive Effekt des eingeführten Hautpflegealgorithmus verdeutlicht die Relevanz eines strukturierten Hautassessments und einer darauf abgestimmten individuellen Pflegeroutine. Ein positiver Effekt vorsichtiger Hautreinigung mit dem Ziel trockener und nicht reibender Hautstellen ist damit erkennbar. Unabhängig davon erscheint das Vorkommen von Intertrigo in der vorgelegten SKINCARE-Studie hoch. Vergleichbare Studien existieren jedoch nur unzureichend und es finden sich keine Erhebungen mit einem analogen Beobachtungszeitraum hinsichtlich des Neuauftretens einer Intertrigo (Romanelli et al., 2023). Mit einer Beobachtungsdauer von im Median fünf Tagen zeigt eine spanische Studie eine Inzidenz von 15,9 % bei älteren Patientinnen und Patienten auf einer Intensivstation und liefert damit nur bedingt vergleichbare Ergebnisse (Valls-Matarin et al., 2017).

Mit einer kumulativen Inzidenz von 26,3 % in der Interventionsgruppe verglichen mit 23,1 % in der Kontrollgruppe wurde ein unerwartet höherer Anteil von Inkontinenz-assoziierter Dermatitis in der Interventionsgruppe festgestellt. Auch wenn die Differenzen zwischen den beiden Gruppen gering sind, so wurden diese bereits nach dem dreimonatigen Beobachtungszeitraum deutlich (Interventionsgruppe 17,1 % vs. Kontrollgruppe 12,0 %). Dies kann darauf hindeuten, dass die Standardversorgung zur Vermeidung von Hautschäden durch Inkontinenz bereits auf eine schonende Hautreinigung und -trocknung mit anschließender Applikation eines Hautschutzproduktes fokussiert. Weitere Erklärungsansätze können individuelle Unterschiede zwischen Interventions- und Kontrollgruppe hinsichtlich Intensität, Dauer und Art der einwirkenden Exposition sein. Denn der Kontakt mit Stuhlgang oder rezidivierende Durchfallerkrankungen können, verglichen mit einer ausschließlichen Exposition mit Urin, aufgrund von Fäkalenzymen und -bakterien zu einer erhöhten Anfälligkeit von Hautschäden führen (Beeckman et al., 2009). Zusätzliche Faktoren, wie beispielsweise Beschaffenheit und Tragedauer des Inkontinenzmaterials, können die Ergebnisse darüber hinaus beeinflusst haben (Cardozo et al., 2023). Eine allgemeine Betrachtung

der kumulativen Inzidenz lässt auf Parallelen mit einer Erhebung in belgischen Pflegeeinrichtungen schließen. Hier wurde nach einem vierwöchigen Beobachtungszeitraum bei Standardversorgung mit milder Reinigung und topischer Applikation eines Hautschutzes bei beginnenden Hautveränderungen eine Inzidenz von 30,0 % festgestellt (Van Damme et al., 2017). Die Ergebnisse deuten darauf hin, dass hinsichtlich der Prävention Inkontinenz-assoziierter Dermatitis noch weitere Maßnahmen zur Förderung der Kontinenz, Expositionsreduktion und der Anwendung von adäquatem Hautschutz umgesetzt werden sollten (El Genedy-Kalyoncu et al., 2022).

Die kumulative Inzidenz von Dekubitus betrug in der Interventionsgruppe 13,6 % und war damit im Vergleich zur Kontrollgruppe, in welcher diese 16,9 % betrug, etwas geringer. Maßnahmen der Implementierung fokussierten neben regelmäßigen Hautassessments und individueller Hautpflege auf der Förderung von Mobilität, entlastender Lagerung druckgefährdeter Körperbereiche oder der Verwendung spezieller Anti-Dekubitusmatratzen. Die schnelle Entwicklung von Dekubitus und die daraus resultierende Belastung von Bewohnerinnen und Bewohnern in Pflegeheimen spiegelt sich auch in belgischen Studienergebnissen wieder: Diese zeigen eine Inzidenz von 8,4 % innerhalb der ersten 14 Tage des Beobachtungszeitraumes bei Anwendung evidenzbasierter Maßnahmen zur Dekubitusprävention (Anrys et al., 2019).

Zusätzlich zum Auftreten der häufigsten pflegerelevanten Hautprobleme wurden auch Veränderungen von Schmerz, Juckreiz und Lebensqualität aus Perspektive der Bewohnenden erhoben. Unabhängig vom kognitiven Zustand der Teilnehmenden konnte eine Reduzierung der Schmerzen in Interventions- und Kontrollgruppe über den Studienverlauf festgestellt werden. Die Variabilität der erhobenen Daten ist jedoch sehr hoch und zusätzliche Einflussfaktoren bleiben gegebenenfalls unentdeckt (McAuliffe et al., 2009). Hinsichtlich des Juckreizes konnte in der SKINCARE-Studie im Durchschnitt eine leichte Abnahme der Intensität in der Interventionsgruppe, verglichen mit der Kontrollgruppe, ermittelt werden. Zudem waren nach sechs Monaten insgesamt weniger Teilnehmende der Interventionsgruppe von Juckreiz betroffen (19,7 % verglichen mit 34,5 % Kontrollgruppe). Es ist davon auszugehen, dass die Effekte der Implementierung des Hautpflegealgorithmus sich positiv auf die Reduzierung von Hauttrockenheit und möglichen verbundenen Folgen, wie beispielsweise Juckreiz, ausgewirkt haben. Durch die Applikation lipophiler Produkte zur Pflege und zum Schutz der Haut konnten Hauttrockenheit und daraus resultierender Juckreiz vermindert werden. Gleichzeitig soll angemerkt werden, dass weitere Einflussfaktoren, wie beispielsweise Medikamente oder

systemische Erkrankungen, die Entstehung und Intensität von Juckreiz darüber hinaus beeinflussen können (Weisshaar & Mettang, 2018).

Zusätzlich zu den klinischen Ergebnissen und Erhebungen wurden zu Studienbeginn und am Studienende die hautphysiologischen Parameter Stratum corneum Hydratation und Transepidermaler Wasserverlust sowie der pH-Wert der Hautoberfläche an den Extremitäten gemessen. Diese waren im Studienverlauf vergleichbar mit vorausgegangenen Erhebungen in einem äquivalenten Setting (Hahnel, Blume-Peytavi, Trojahn, & Kottner, 2017). Nach sechsmonatiger Intervention zeigten sich im Gruppenvergleich nur wenige Unterschiede der gemessenen hautphysiologischen Parameter. Gleichzeitig kam es aber zu einer Verbesserung klinischer Zeichen von Hauttrockenheit in der Interventionsgruppe. In einer Sekundärdatenanalyse der SKINCARE-Daten konnte gezeigt werden, dass Bewohnerinnen und Bewohner mit moderater bis schwerwiegender Xerosis cutis zu Studienbeginn eine geringere Stratum corneum Hydratation und einen höheren pH-Wert der Haut aufwiesen. Dieses kann als möglicher Hinweis auf eine gestörte Hautbarriere gedeutet werden (Amin et al., 2023). Eine Studie von Hahnel et al. zur Beurteilung der Hautgesundheit älterer Menschen in Pflegeheimen konnte nur wenige Zusammenhänge zwischen hautphysiologischen Messungen und dem Auftreten von Hauttrockenheit, Dekubitus, Skin Tears und Inkontinenz-assoziierter Dermatitis feststellen und sprach Messungen hautphysiologischer Parameter nur einen begrenzten diagnostischen Mehrwert zu (Hahnel, Blume-Peytavi, Trojahn, & Kottner, 2017). In diesem Zusammenhang soll die Relevanz der klinischen Einschätzung der Haut im Pflegealltag hervorgehoben werden, da eine standardisierte Messung unter klinischen Bedingungen in stationären Langzeitpflegeeinrichtungen nur unzureichend umzusetzen ist. In diesem Setting sollte daher eine klinische Einschätzung der Hautbeschaffenheit die priorisierte Herangehensweise darstellen.

4.2.3 Sekundärdatenanalyse

Bei der Untersuchung zur Veränderung der Hautphysiologie an Sakrum und Ferse in Rückenlage zeigte sich eine deutliche Veränderung der Messergebnisse nach 120 - minütiger Liegedauer bei gesunden Frauen über 65 Jahre.

Eine Zunahme der Hautfeuchtigkeit (SCH, TEWL und epidermale Hydratation) wurde an Sakrum und Ferse festgestellt. Ebenso konnten positive Assoziationen zwischen epidermaler Hydratation und SCH an beiden Messarealen aufgezeigt werden.
Während des Liegens kommt es zu einer Okklusion zwischen Haut und Auflagefläche, welches zu einer Akkumulation von Feuchtigkeit führt und die obersten Hautschichten beeinflusst (Lachenbruch et al., 2015). Durch diese Veränderungen des umgebenden Mikroklimas konnte bereits in einer früheren Studie eine Zunahme der Hautfeuchtigkeit nach verlängerter Liegedauer an der Ferse durch eine erhöhte Stratum corneum Hydratation bei in vitro Modellen konstatiert werden (Rawlings et al., 1995). Ebenfalls wurde gezeigt, dass sich der TEWL, als Anzeichen einer gestörten Hautbarriere, durch eine längere Liegedauer erhöht (Denzinger et al., 2019). Der Anstieg unterschiedlicher Parameter zur Messung der Hautfeuchtigkeit war gegenwärtig auf der Standardschaummatratze, verglichen mit speziellen Anti-Dekubitusmatratzen, am deutlichsten. Dies hebt noch einmal die Relevanz der Nutzung adäquater Matratzen bei gegebener Indikation hervor (Denzinger et al., 2019; Tomova-Simitchieva et al., 2018).
Die Zunahme des Erythems war an beiden Messarealen vergleichbar. Auch in diesem Zusammenhang zeigten spezielle Matratzen oder Unterlagerungen, zusammen mit Unterbrechungen der Druckeinwirkung, einen präventiven Effekt (Borzdynski et al., 2021; Finestone et al., 1991; Tomova-Simitchieva et al., 2018). Des Weiteren wurde an beiden Messarealen festgestellt, dass es keine Assoziation zwischen einem Temperaturanstieg und einer Zunahme der Hautfeuchtigkeit gibt. Am Sakralbereich konnte keine Assoziation zwischen der Verstärkung des Erythems und weiteren Parametern eruiert werden. Hingegen ergab die Analyse an der Ferse eine negative Assoziation zwischen Temperaturanstieg und einer Zunahme des Erythems. Goller et al. haben zuvor die fehlende Verbindung zwischen Temperatur und Erythem dahingehend diskutiert, dass die Hautrötung abhängig vom Sauerstoffgehalt des Blutes und dem Kapillarvolumen ist, während die Hauttemperatur durch den Blutfluss und die Beschaffenheit der Arteriolen entsteht (Goller et al., 1971). Dies lässt darauf schließen, dass das Erythem als Folge des einwirkenden Druckes und Teil der mechanischen Deformation entsteht. Damit bildet sich das Erythem unabhängig von Veränderungen des Mikroklimas und damit einer Zunahme von Hautfeuchtigkeit und Temperatur.

4.3 Stärken und Schwächen der Studien

Die SKINCARE-Studie (Publikationen 1 und 2) wurde zwischen 2019 und 2021 während der SARS-CoV-2 Pandemie in stationären Langzeitpflegeeinrichtungen durchgeführt. Der Einschluss von ursprünglich geplanten 500 Bewohnerinnen und Bewohnern aus insgesamt 20 Pflegeheimen konnte durch die Verbreitung des Coronavirus und den daraus resultierenden starken Kontaktbeschränkungen gegenüber vulnerablen Personengruppen, insbesondere im Bereich der Langzeitpflege, nicht erreicht werden. Damit einhergehend bedeuteten vermehrt krankheits- und isolationsbedingte Personalausfälle sowie zusätzlich auferlegte Hygienevorschriften einen veränderten Fokus für das Pflegepersonal. Ein möglicher Einfluss auf die pflegerischen Tätigkeiten und die Umsetzung des Hautpflegealgorithmus kann dahingehend nicht ausgeschlossen werden.

Trotz der beschriebenen Herausforderungen konnten insgesamt 17 Pflegeheime mit 314 Bewohnerinnen und Bewohnern randomisiert werden. Diese Stichprobe wird als ausreichend angesehen, um Punktschätzungen mit angemessenen Konfidenzintervallen zu berechnen. Durch die Generierung umfangreicher biographischer und funktioneller Daten, sowie durch eingehende dermatologische Untersuchungen des gesamten Körpers an drei Untersuchungszeitpunkten, wurde eine umfassende Analyse des Hautzustandes mit potentiellen Einflussvariablen ermöglicht. Bei der Berechnung von Assoziationen zwischen soziodemographischen und funktionellen Parametern und der Prävalenz einzelner Hautschäden können aufgrund der Querschnittsdatenauswertung zu Studienbeginn jedoch keine kausalen Beziehungen geschlussfolgert werden.

Eine standardisierte Datenerhebung in Papier- und elektronischer Form sowie ein externes Monitoring sicherten die Datenvalidität. Das longitudinale Studiendesign über einen Zeitraum von sechs Monaten ist vergleichsweise lang und besonders positiv hervorzuheben, da es eine Auswertung möglicher Effekte der Intervention zulässt.

Eine Verzerrung hinsichtlich der allgemeinen Teilnahmebereitschaft an der Studie, seitens der Pflegeeinrichtungen, als auch seitens der Bewohnenden, muss bedacht werden (selection bias / volunteer bias). Bei den eingeschlossenen Pflegeheimen sind zudem, trotz erfolgter Randomisierung, Unterschiede hinsichtlich Größe, Personalschlüssel oder Trägerschaft denkbar. Dabei kann ein unterschiedlicher Pflegestandard nicht ausgeschlossen werden. Mögliche Effekte der Implementierung des Hautpflegealgorithmus sind daraus resultierend nicht ausschließlich auf diese

zurückzuführen. Eine Vergleichbarkeit der Gruppen konnte durch die Auswertung funktioneller und demographischer Eigenschaften der Teilnehmenden bestätigt werden. Bei der Erhebung dieser Daten mussten bei vorliegenden kognitiven Einschränkungen einzelne Informationen von Angehörigen oder dem Pflegepersonal erhoben werden (response bias). Ebenfalls kann bei der Befragung der Studienteilnehmenden eine Verzerrung des Erinnerungsvermögens nicht ausgeschlossen werden (recall bias).

In die Studie zur Evaluation hautphysiologischer Parameter nach 120-minütiger Liegedauer auf einer Standardschaummatratze (Sekundärdatenanalyse, Publikation 3) wurden ausschließlich gesunde Frauen über 65 Jahre eingeschlossen. Dieses kann eine verminderte Vergleichbarkeit mit multimorbiden oder pflegeabhängigen Personen zur Folge haben. Ebenso ist die Übertragung der Ergebnisse auf männliche Personen nur bedingt möglich, wobei jedoch der Einfluss des biologischen Geschlechtes bei der Entstehung von Dekubitus nicht eindeutig geklärt ist (Lichterfeld-Kottner, Lahmann, & Kottner, 2020). Des Weiteren ist eine Liegedauer von zwei Stunden eine kurze Zeitspanne und somit sind nur bedingt Rückschlüsse auf langfristige Auswirkungen bei immobilen und pflegeabhängigen Personen möglich. Dennoch ist diese Zeitspanne mit den Lagerungsempfehlungen für Erwachsene in der Akut- und Langzeitpflege vergleichbar (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2017). Zudem werden Veränderungen des Gewebes, die zu einer Entstehung von Dekubitus führen können, bereits innerhalb der ersten Minuten vermutet. Bei anhaltender Belastung und in Abhängigkeit individueller und äußerer Faktoren können diese jedoch erst nach Stunden klinisch sichtbar werden (Gefen et al., 2021). In der vorgestellten Studie wurde die Druckintensität auf den Fersen- und Sakralbereich und eine mögliche Auswirkung auf Gewebedeformationen in der Tiefe vernachlässigt, da diese von den persönlichen Voraussetzungen der Teilnehmerinnen abhängig waren. Es ist somit aber nicht auszuschließen, dass der Einfluss des Körpergewichtes das Ergebnis individuell beeinflusst hat – jedoch ist diese Störgröße unter realen Pflegebedingungen ebenfalls präsent.

4.4 Implikationen für Praxis und/oder zukünftige Forschung

Die diskutierten Ergebnisse ermöglichen den Rückschluss, dass ein standardisiertes Hautassessment mit anschließenden individuellen Pflegemaßnahmen die Hautgesundheit älterer Menschen in Langzeitpflegeeinrichtungen verbessern kann.

Die Studienergebnisse zeigten eine hohe Prävalenz pflegerelevanter Hautschäden in der stationären Langzeitpflege. Zusätzlich konnte ermittelt werden, dass nur unzureichend pflegerische Maßnahmen zum Hautschutz und zur Förderung der Hautgesundheit angewendet werden, welches ebenfalls die Relevanz einer umfassenden und evidenzbasierten Hautpflege unterstützt (Amin et al., 2024).

Durch die Implementierung eines evidenzbasierten Hautpflegealgorithmus konnten die häufigsten pflegerelevanten Hautschäden, wie Hauttrockenheit, Skin Tears, Dekubitus und Intertrigo, gemessen als kumulative Inzidenz nach sechs Monaten oder Intensität, reduziert werden. Dadurch wurde gezeigt, dass die Anwendung einer standardisierten Hautpflegeroutine positive Effekte auf die Prävention von Hautschäden hat. Daraus resultierend ist es denkbar, den beschriebenen Hautpflegealgorithmus in einer weiteren Studie in der pflegeintensiven Akutversorgung (Intensivstation oder geriatrische Normalstation) zu implementieren sowie die Umsetzbarkeit und mögliche Effekte zu untersuchen. Darauf aufbauend wäre es empfehlenswert eine konfirmatorische Studie durchzuführen, um konkrete Aussagen zur Wirksamkeit der evidenzbasierten und strukturierten Hautpflege in der Praxis treffen zu können. Die Wirksamkeit könnte dann zusätzlich in der pflegerischen Versorgung in weiteren Ländern überprüft werden.

Das deutsche Netzwerk für Qualitätsentwicklung in der Pflege hat zu eben dieser Thematik, unter Einbeziehung zahlreicher Experten und Expertinnen, kürzlich den Expertenstandard zur Erhaltung und Förderung der Hautintegrität herausgegeben (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2023). Dieser beschreibt die pflegeberufliche Hautpflege zum Erhalt und zur Förderung der Hautgesundheit hinsichtlich pflegerelevanter Hautschäden. Die Relevanz zur Etablierung eines Hautassessments, gefolgt von evidenzbasierter und individueller Hautpflege, wird damit auf pflegewissenschaftlicher Ebene noch einmal verdeutlicht. Zusätzlich haben die Studienergebnisse gezeigt, dass ein ebensolcher Hautpflegalgorithmus in der Praxis umsetzbar ist (Charité - Universitätsmedizin Berlin, 2023).

Obwohl sich der implementierte Hautpflegealgorithmus auf Verfahren zur Hautreinigung und Hautpflege fokussierte, konnte ebenfalls ein positiver Effekt hinsichtlich der

Vermeidung von Dekubitus erzielt werden. Ein Zusammenhang zwischen einer verbesserten Hautintegrität und zugleich erhöhter Widerstandsfähigkeit gegenüber mechanischer Deformation kann aus diesen Resultaten abgeleitet werden. Gleichzeitig wurde auf die Verwendung spezieller Anti-Dekubitusmatratzen, sowie Mobilisierungs- und Lagerungsmaßnahmen hingewiesen, welches zu einer Verstärkung dieses positiven Effektes führte.

Die Ergebnisse der Sekundärdatenanalyse zeigten, dass eine Liegedauer von 120 Minuten bei gesunden Probandinnen bereits zu einer Erhöhung von Hautfeuchtigkeit, Hauttemperatur, Erythem und mechanischer Deformation der oberflächlichen Strukturen der Haut führt. Diese Veränderungen waren deutlicher auf einer Standardschaummatratze, verglichen mit speziellen Anti-Dekubitusmatratzen. Darauf aufbauende Studien mit männlichen Studienteilnehmenden oder in einem Setting der stationären Langzeitversorgung würden zusätzliche Erkenntnisse liefern. Diese könnten dazu beitragen, konkrete präventive Maßnahmen zur Vermeidung von Hautschäden abzuleiten und Möglichkeiten zur Verbesserung des Hautschutzes bei der Dekubitusprävention zu erkennen und nachfolgend zu etablieren.

5 Schlussfolgerungen

I. Die Prävalenz von Xerosis cutis, Inkontinenz-assoziierter Dermatitis, Skin Tears, Dekubitus und Intertrigo in stationären Langzeitpflegeeinrichtungen ist hoch. Nahezu alle Studienteilnehmenden waren von pflegerelevanten Hautschäden betroffen. Einschränkungen von Mobilität und Kognition sowie ein höheres Lebensalter wirkten sich risikohaft auf die Hautgesundheit aus. Die Ergebnisse deuten darauf hin, dass Xerosis cutis, Inkontinenz-assoziierte Dermatitis, Skin Tears, Dekubitus und Intertrigo jedoch unabhängig voneinander vorliegen. Es ist denkbar, dass adäquate pflegerische Intervention, wie eine individuelle Hautpflege, Lagerung und Mobilisierung die Hautgesundheit unterstützen.

II. Die Implementierung eines strukturierten Hautpflegealgorithmus über einen Zeitraum von sechs Monaten war in der stationären Langzeitpflege umsetzbar und zeigte präventive Effekte hinsichtlich der Entstehung von Xerosis cutis, Skin Tears, Dekubitus und Intertrigo. Weitere Maßnahmen zur Vermeidung einer Inkontinenz-assoziierten Dermatitis erscheinen notwendig. Adäquate Pflegemaßnahmen helfen die Hautintegrität zu verbessern und wirken sich positiv auf Schmerz, Juckreiz und Lebensqualität aus.

III. Eine Liegedauer von zwei Stunden auf einer Standardschaummatratze führte am Sakral- und Fersenbereich zu einer mechanischen Deformation der Haut sowie zu einer Erhöhung von Hautfeuchtigkeit, Hauttemperatur und einer verstärkten Erythembildung. Die Korrelationsanalyse zeigte, dass eine Zunahme von Hautrötung und Hauttemperatur nicht miteinander oder weiteren Parametern assoziiert ist. Dieses bedeutet, dass, unabhängig von der Okklusion und einer Veränderung des Mikroklimas, die Erythembildung als Folge mechanischer Deformation durch Druckeinwirkung aufgetreten ist.

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Eidesstattliche Versicherung

„Ich, Bettina Völzer, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: „Epidemiologie und Prävention pflegerelevanter Hautschäden in der stationären Langzeitpflege“ (Epidemiology and prevention of care-related adverse skin conditions in residential long-term care) selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.

Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren/innen beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet.

Ich versichere ferner, dass ich die in Zusammenarbeit mit anderen Personen generierten Daten, Datenauswertungen und Schlussfolgerungen korrekt gekennzeichnet und meinen eigenen Beitrag sowie die Beiträge anderer Personen korrekt kenntlich gemacht habe (siehe Anteilserklärung). Texte oder Textteile, die gemeinsam mit anderen erstellt oder verwendet wurden, habe ich korrekt kenntlich gemacht.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.org) zur Autorenschaft eingehalten. Ich erkläre ferner, dass ich mich zur Einhaltung der Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis verpflichte.

Weiterhin versichere ich, dass ich diese Dissertation weder in gleicher noch in ähnlicher Form bereits an einer anderen Fakultät eingereicht habe.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst.“

Datum Unterschrift

Anteilserklärung an den erfolgten Publikationen

Bettina Völzer hatte folgenden Anteil an folgenden Publikationen:

Publikation 1

Völzer, B., El Genedy-Kalyoncu, M., Fastner, A., Tomova-Simitchieva, T., Neumann, K., Sill, J., Balzer, K., & Kottner, J. (2023). Prevalence and associations of xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo in aged nursing home residents: A representative prevalence study. Int J Nurs Stud, 141, 104472. doi: 10.1016/j.ijnurstu.2023.104472

Beitrag im Einzelnen:
Beteiligung an der Rekrutierung von Pflegeeinrichtungen sowie der teilnehmenden Bewohner und Bewohnerinnen der zugrundeliegenden Studie, Durchführung einer wesentlichen Anzahl von Studienvisiten, wesentliche Mitarbeit bei der Datenerhebung, Datenextraktion und Datenaufbereitung, hauptsächliche Durchführung der statistischen Auswertung und wesentliche Beteiligung bei der Interpretation der Daten, Federführung beim Schreiben der Publikation und dem Erstellen sämtlicher Inhalte inklusive aller Tabellen und Abbildungen (im Manuskript und im zugehörigen Anhang) sowie beim Einreichen und der Revision des Manuskriptes

Publikation 2

Völzer, B., El Genedy-Kalyoncu, M., Fastner, A., Tomova-Simitchieva, T., Neumann, K., Hillmann, K., Blume-Peytavi, U., Hahnel, E., Sill, J., Balzer, K., & Kottner, J. (2023). Enhancing skin health and safety in aged care (SKINCARE trial): A cluster-randomised pragmatic trial. Int J Nurs Stud, 149, 104627. doi: 0.1016/j.ijnurstu.2023.104627

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Beteiligung an der Rekrutierung von Pflegeeinrichtungen sowie der teilnehmenden Bewohner und Bewohnerinnen, Durchführung von Studienvisiten, wesentliche Mitarbeit bei der Datenerhebung, Datenextraktion und Datenaufbereitung, wesentliche Beteiligung bei der statistischen Auswertung und der Interpretation der Daten, Federführung beim Schreiben der Publikation und dem Erstellen sämtlicher Inhalte, inklusive aller

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Prevalence and associations of xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo in aged nursing home residents: A representative prevalence study

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ABSTRACT

Background: The number of elderly and care-dependent people is increasing, leading to increased risks of adverse skin conditions. Skin care, including prevention and treatment of vulnerable skin, is an essential part of daily nursing practice in long-term residential settings. For many years, the research focus has been on individual skin problems including xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo, although people may be affected by several at the same time.
Objectives: Aim of the present study was to describe the prevalence and associations of skin conditions relevant to nursing practice in aged nursing home residents.
Design: Analysis of baseline data of a cluster-RCT in long-term residential settings.
Setting: The study was conducted in a representative sample of n = 17 nursing homes in the federal state of Berlin, Germany.
Participants: Care dependent nursing home residents being 65 + years.
Methods: A random sample of all eligible nursing homes was drawn. Demographic and health characteristics were collected and head-to-toe skin examinations conducted by dermatologists. Prevalence estimates and intracluster correlation coefficients were calculated, and group comparisons conducted.
Results: Three hundred fourteen residents with a mean age of 85.4 (SD 7.1) years were included. The majority was affected by xerosis cutis (95.9%, 95% CI 93.6 to 97.8), followed by intertrigo 35.0% (95% CI 30.0 to 40.1), incontinence-associated dermatitis 21.0% (95% CI 15.6 to 26.3), skin tears 10.5% (95% CI 7.3 to 13.8), and pressure ulcers 8.0% (95% CI 5.1 to 10.8). In total, more than half of the nursing home residents were affected by two or more skin conditions at the same time. Several associations between skin conditions and mobility, care dependency, or cognitive impairment were observed. There were no associations between xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers or intertrigo.
Conclusions: The adverse skin and tissue conditions xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers and intertrigo are very common in long-term residential settings, placing a high burden on this population. Although care receivers share similar risk factors and may be affected by several skin conditions at the same time, there are no associations indicating separate aetiological pathways.
Registration: This study is registered at the German Clinical Trials Register (registration number: DRKS00015680; date of registration: January 29th, 2019) and ClinicalTrials.gov (NCT03824886; date of registration: January 31st, 2019).

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What is already known

- The number of care-dependent people, who are affected by physical and cognitive impairments is increasing.
- Skin care is a key activity in daily nursing practice in long-term residential settings.

What this paper adds

- More than half of the nursing home residents were diagnosed with more than one adverse skin condition at the same time.
- Dry skin, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo seem not to be associated with each other.
- Adverse skin conditions are associated with higher care dependency, and physical and cognitive impairments.

1. Introduction

Worldwide, and especially in industrialised nations, the population is growing and ageing. The proportion of people over 65 years is supposed to double within the upcoming 30 years up to 16% globally (Department of Economic and Social Affairs, 2020). In Europe, the need for professional long-term care increases, as the number of people over 65 years is supposed to rise substantially until 2050. Currently, 30.9% in this generation are in need of long-term residential care (Social Protection Committee and the European Commission, 2021). By nature, the process of ageing is associated with the development of chronic diseases, functional impairments, or care dependency. In particular, older people are at risk for a loss of intrinsic capacity and functional decline (Beard et al., 2019; World Health Organization, 2015).

Skin health and skin integrity may be regarded as a result of an intact cutaneous structure and a functional capacity that is high enough to protect it (Kottner et al., 2020a). However, ageing also leads to a decline of the functional capacity of the skin resulting in a higher susceptibility of dryness and itching, infections, skin tears, or pressure-induced ulcerations. In addition to the reduction of the skins' functional capacity, personal lifestyles (including smoking, and repeated damaging hygiene behaviours), and environmental factors (chronic sun exposure, air pollution) may impair skin integrity (Blume-Peytavi et al., 2016; Sena et al., 2016). Overall, skin health is affected by chronic diseases (including diabetes mellitus), medication (including diuretics), functional impairments (including limited mobility), or nutrition. The prevalence of skin conditions, such as xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo is substantial and plays a clinically relevant role in daily nursing practice in long-term care (Cowdell et al., 2020; Hahnel et al., 2017). Skin care is a fundamental part of nursing practice, and nursing interventions may therefore have a substantial impact on skin health (Kieft et al., 2017).

Throughout the development of adverse skin conditions, there seem to be overlaps in terms of risks, causal factors, and treatments (Kottner et al., 2019). Especially the influence of co-morbidities, medication, and polypharmacy is discussed widely (Sgonc and Gruber, 2013; Jaul et al., 2018). Additionally, it has been proposed that there might be differences regarding the individual susceptibility to develop adverse skin conditions, but empirical evidence is lacking so far (Hahnel et al., 2017).

Moreover, research mostly concentrates on single skin conditions when describing epidemiology, risks, and treatments. Hahnel et al. conducted a prevalence study in a geriatric population, but these results were based on a small sample (n = 223) and a study design to document all dermatological conditions in an unstructured way (Hahnel et al., 2017).

Therefore, the objective of this study was to measure the prevalence and the severity of the five most important skin conditions relevant for nursing practice in long-term residential settings at the same time. Furthermore, possible associations among each other, and with demographic and functional characteristics were examined.

2. Methods

2.1. Study design

Baseline secondary data was analysed from a representative sample of long-term residential care facilities. The baseline secondary data was anlaysed prior to the randomisation of these facilities into an exploratory cluster RCT to evaluate the effects of the implementation of an evidence-based skin care and prevention package (ClinicalTrials.gov Identifier: NCT03824886 (Kottner et al., 2019)). The study was approved by the ethics committee at the Charité Universitätsmedizin Berlin, Germany (approval number: EA1/243/18).

2.2. Setting

The study was conducted in the federal state of Berlin, Germany, from April 2019 to June 2021 in long-term care facilities. Two hundred eighty-eight nursing homes were assessed for eligibility, and invited following a simple randomisation scheme. In case of non-responding, the next randomly chosen nursing home was contacted. After the recruitment of nursing homes and residents and receiving informed consent, the study visits were performed at the facilities.

2.3. Participants

Inclusion criteria at the nursing home level were: (1) location in the federal state of Berlin, (2) at least n = 70 nursing home beds, and (3) the presence of a pressure ulcer prevention standard in the institution. Eligibility criteria at the resident level were: (1) living in the nursing home at time of data collection independently from the duration of residency, (2) being 65 years of age and older, (3) being substantially care dependent according to the German Code Book XI, (4) written informed consent. Being at least substantially care dependent was considered necessary to estimate the possible impact of nursing care on the skin conditions of interest. A possible impact of the length of stay on the presence of xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo was considered in the statistical analyses. Due to ethical reasons residents at the end of life were excluded. We also excluded residents in need of special dermatological treatments, to avoid possible contaminations between medical treatments and nursing interventions.

2.4. Variables

2.4.1. Demographic characteristics

Sex (male, female), age (years), body mass index (BMI in kg/m^2), the duration of residency in the care facility (months), if applicable, the type of incontinence (urinary, faecal or double), and the presence of diarrhoea were extracted from the medical records. We used the ICD-11 definition of incontinence. Urinary incontinence is defined as the loss of voluntary control of the bladder with involuntary passage of urine, and faecal incontinence with the loss of voluntary control of the anal sphincters with leakage of faeces and flatus. Diarrhoea is described with a high frequency and reduced consistency of bowel movements, which can occur acute or chronic (World Health Organization, 2022). The German care levels (level II to V) were used to indicate the overall degree of mobility, cognitive ability, and activities of daily living. Higher care levels indicate higher care dependency (Bundesministerium für Gesundheit, 2021). Smoking status, pack-years, and the highest educational level were assessed. Comparable to previous studies (Sinikumpu et al., 2020), the individual education and qualification level was classified based on the highest degree achieved: no professional qualification (subjects having no school qualification or a degree at primary school), vocational training (subjects having a degree at secondary and grammar school or vocational training) and university degree. The variable 'outdoor occupation' was assessed to describe possible influences of

continuous sun exposure (Modenese et al., 2018), and applies to residents having worked outside at least one year during life.

2.4.2. Health characteristics

To measure cognitive function, the Global Deterioration Scale (GDS) was used, and the subjects were assigned to seven possible stages. Stage 1 is described as having no cognitive impairments or memory deficits and stage 7 as having severe cognitive decline and being highly care-dependent. This instrument was selected as an easy to use and fast way to classify study participants. The validity and reliability of this instruments is supported by previous research and there is a high correlation between the GDS and the Mini-Mental State Examination (Choi et al., 2003; Reisberg et al., 1982).

To evaluate itch, the 5-D itch scale was applied to residents with GDS Stage 1, who were affected by itching skin. The 5-D itch scale is a multidimensional instrument to measure itch (Ständer et al., 2013), and because it is completed by the respondent via self-report, we included only residents without cognitive limitations (Elman et al., 2010). The values range from 5 to 25, whereas higher values are indicating severe pruritus.

'Quality of Life' was assessed using the WHO-Five Well-Being Index in residents with GDS 1, as it is described as a valid instrument with high sensitivity for depression and/or well-being in patients without cognitive limitations (Allgaier et al., 2013). A maximum score of 25 could have been achieved. In residents with a GDS 2 to 6, quality of life was measured using the Qualidem 37 according to the recommendation for its use in people with mild to moderate dementia (Dichter et al., 2016), while the Qualidem 18 was used with regard to Dichter et al. in severe dement participants (GDS 7) (Arons et al., 2017; Dichter et al., 2013).

Medical diagnoses were extracted from medical files and transformed into the ICD-11 classification system by research associates, whereas diseases were ordered by body organs and systems (Jakob, 2018; World Health Organization, 2022). Pharmaceuticals were transformed into Anatomical Therapeutic Chemical Codes (Delvaux et al., 2020). The term 'Polypharmacy' was defined as the intake of five or more medications per day of different pharmaceutical agents (Masnoon et al., 2017). The variable 'Cortisone intake' refers to subjects, who have a daily oral intake of medication containing cortisone or an affiliating derivate in order to investigate a possible systemic influence on the skin. Residents using cortisone applied locally on only parts of the body were excluded from that calculation, because a substantial systemic effect was considered unlikely.

The pressure ulcer risk was measured by the study staff using the Braden Scale Score (Bergstrom et al., 1987). Reliability of the German version of this instrument in the long-term care setting was supported by Kottner and Dassen (Kottner and Dassen, 2008). The highest possible score is 23, indicating minimal risk. Because the total score only provides approximate information about pressure ulcer risk the items 'Mobility' and 'Activity' were analysed separately. The item 'Mobility' describes the patients' possibility to change body positions with or without assistance and ranges from 1 (= immobile) to 4 (= without limitations). The item 'Activity' specifies the state of physical impairment from being bedfast (= 1) to regular walking abilities (= 4). Both items are key predictors when measuring pressure ulcer risk (Coleman et al., 2014; Lahmann and Kottner, 2011).

The Barthel-Index was measured to describe the overall functional status, whereas a maximal score of 100 could have been achieved indicating independence in their 'Activities of Daily Living' (Wade and Collin, 1988; Mahoney and Barthel, 1965). The items 'Standing-up and Mobility' and 'Transfer' were considered separately to investigate the influence of the nursing home residents' ability to conduct repositioning in order to prevent pressure-related injuries. 'Standing-up and Mobility' describes the ability to stand up and walk, or the independent use of a wheelchair and can vary between 0 (= completely dependent) and 15 (= standing up and walking at least 50 m without help). 'Transfer' refers to the subjects' ability to move from bed to chair and back and ranges from 0 (= being bedfast) to 15 (= being completely independent). Skin self-care ability was assessed as 'fully independent', 'need some assistance', and 'dependent'.

Numeric rating scales in residents with GDS 1 and verbal rating scales in residents with GDS 2–7 were used to measure pain (Williamson and Hoggart, 2005). Numeric rating scales ranged from 0 to 10, whereas 10 was the strongest pain imaginable. The verbal rating scale described six grading of pain in words, which were transformed into numbers equivalent to the numeric rating scale.

2.4.3. Skin conditions

Xerosis cutis was classified using the Overall Dry Skin Score, whose reliability is supported by Kang (Kang et al., 2014). The Overall Dry Skin Score ranges from category 0 (no skin dryness) to 4 (advanced skin roughness, large scales, inflammation, and cracks) (Serup, 1995).

Incontinence-associated dermatitis was classified according to the Ghent Global Incontinence-Associated Dermatitis Categorisation Tool (GLOBIAD) in urinary and/or faecal incontinent subjects as 1A, 1B, 2A, and 2B (Beeckman et al., 2018; Van den Bussche et al., 2018). A distinction was made between intact and eroded skin to distinguish between moderate and severe incontinence-associated dermatitis according to the GLOBIAD, and affected skin areas were described. The validity and reliability including the German version of this classification is supported by Beeckman et al., and compared to other classifications the GLOBIAD is currently supported by the best available evidence (Beeckman et al., 2018).

Skin tears were classified according to the International Skin Tear Advisory Panel in three types (Type I-III) (LeBlanc et al., 2013). Compared to other available skin tear classifications the International Skin Tear Advisory Panel classification is supported by highest reliability and validity (Van Tiggelen et al., 2020). The type, affected skin areas and number of skin tears in total per area were documented.

Pressure ulcers were classified according to the NPUAP/EPUAP classification (National Pressure Ulcer Advisory Panel European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance, 2014) in six categories (Category I-IV and unstageable) as recommended by the latest International Guideline 2019 (European Pressure Ulcer Advisory Panel, 2019). The location was specified and presented using the number of pressure ulcers in total per skin area.

Intertrigo was diagnosed according to ICD-11 as EK02.20: 'Intertriginous dermatitis due to friction, sweating or contact with body fluids' (World Health Organization, 2022). The location and the total number of intertrigo lesions per skin fold were documented.

Diagnoses and classifications of these skin conditions were based on clinical appearances and descriptions and were performed by trained dermatologists.

2.4.4. Health services utilisation

The last visit by medical specialty during the last twelve months was extracted from the medical files in the nursing home, and the five most often named medical specialists are provided. Skin and pressure ulcer risk assessments and the use of incontinence skin care products in residents having a urinary and/or faecal incontinence were documented. Information about the procedure in the nursing homes regarding the use of special support surfaces and repositioning of the residents, as well as the process of off-loading of their heels was obtained from direct observation and the nursing staff.

2.5. Data sources and measurement

Demographic and health data were extracted from the medical records by researchers and study assistants, and the residents were interviewed. The medical records were the primary source of data. In case of missing information, especially in cognitive limited participants, nursing staff or family members were interviewed, or the data was considered as missing data. A head-to-toe skin examination was conducted

by trained dermatologists who had expertise in geriatric dermatology. All study visits were performed by a team of trained dermatologists, research associates, and study nurses, and the data was documented in standardised written data collection forms.

2.6. Bias

To ensure external validity, a random sample of all available nursing homes in the federal state of Berlin, Germany, was drawn. All residents in participating institutions were invited to take part. To increase internal validity, standardised data collection forms and definitions were used for all variables. Skin conditions were diagnosed and classified by trained dermatologists. External monitoring was conducted by the Charité Coordination Center for Clinical Trials at the Charité Universitätsmedizin Berlin following the 'Guideline for good clinical practice E6 (R2)' (Committee for Human Medicinal Products, 2018) to increase accuracy during the whole data collection process, and to ensure a correct study implementation in adherence to the study protocol.

2.7. Study size

Because of the exploratory study design a formal sample size determination was not applicable. It was decided to include n = 20 nursing homes out of n = 288 eligible nursing homes. Assuming on average n = 100 residents per nursing home and a participation rate of 25%, the expected number of participating subjects per facility was n = 25 resulting in an expected sample size of n = 500.

2.8. Quantitative variables

2.8.1. Demographic characteristics

The BMI was categorised into underweight (BMI < 18.5 kg/m^2) and overweight (BMI > 25.0 kg/m^2) according to the World Health Organization recommendation (Hajek et al., 2015). Nursing home residents having smoked at least once during their lifetime, or residents who were still smoking, were categorised as smokers/former smokers, and the pack-years were calculated by multiplying the number of cigarette packs smoked per day by the number of years having smoked.

2.8.2. Health characteristics

From the ICD-11 coding of medical diseases, the first three letters were used for the statistical analysis to present the five most frequent diseases. To describe the most frequently consumed medication the Anatomical Therapeutic Chemical Classification was used. These codes consist of up to seven letters and numbers. The first three letters refer to the main active ingredient or substance, and were therefore used to describe the medications.

The severity of itch was shown by mean values and affected skin areas. Pain was displayed by means. Mean values of the Qualidem 18 and 37 were calculated. The result of the WHO-Five Well-Being Index is presented as mean value. According to the user instructions the mean value was multiplied by '4' to resemble a percentage. The highest percentage that can be achieved is 100% and indicates best well-being.

2.8.3. Skin conditions relevant to nursing practice

If at least one skin area was affected by dry skin of category 1 according to the Overall Dry Skin Score, the subject was counted as prevalent case. Regarding extremities, at least one side must have been graded with Overall Dry Skin Score 1 or higher. In addition, means and medians were used to present dry skin severity per affected skin area. For all other skin conditions of interest proportions were calculated.

2.9. Statistical methods

Metric variables were described using mean and standard deviation or median and interquartile range. For categorical variables, frequency and proportion of each level is given. Prevalence estimates are reported with two-sided 95% confidence intervals (95% CI) using the bootstrap technique. For each prevalence estimate the intracluster correlation coefficient was calculated, using the ANOVA estimate to measure the heterogeneity of the nursing homes.

Demographic, health, and functional characteristics of residents with and without incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo were compared using mean differences or odds ratios, and corresponding 95% CIs. The group comparison was not conducted for subjects with dry skin, because nearly every participant was affected. Group differences with a p-value below 5% (two-sided) were considered as possible predictors for a subsequent general estimating equation (GEE) model with logistic link function. GEE models give robust standard errors for estimates of regression coefficients in clustered samples. GEE models were performed for skin tears and pressure ulcers, because several associations with demographic, health and functional characteristics were observed for these two skin conditions only. Predictors were selected based on clinical relevance and group differences.

Missing data was labelled in the tables and excluded from the analyses. All calculations were conducted with IBM SPSS Statistics Version 27 and R version 4.1.1. For general estimating equation model analyses we used the R package gee version 4.13.

3. Results

3.1. Participants

In total, n = 17 nursing homes with n = 314 nursing home residents participated. On average, n = 18 participants per institution were included (Fig. 1).

3.2. Descriptive data

Resident characteristics are shown in Table 1. The majority of the participants was female (68.8%), the mean age was 85.4 (SD 7.1) years. More than half of the residents were overweight (57.6%). The duration of residency was median 22.0 (IQR 8.0 to 42.3) months. An outdoor occupation was performed by 8.3% at least once during their professional life, and 45.6% were (former) smokers.

Approximately 80% of nursing home residents were incontinent. Diseases of the cardiovascular system, dementia, renal failure, and diabetes mellitus were most frequent, and 87.3% received five or more pharmaceuticals. The median Barthel Index was 45.0 (IQR 25.0 to 65.0), and half of the nursing home residents showed Global Deterioration Scale (GDS) Stage 1, indicating no cognitive impairment.

3.3. Main results

Prevalence estimates of adverse skin conditions are shown in Table 2. The highest prevalence was observed for xerosis cutis (95.9%; 95% CI 93.6 to 97.8), and most severely affected skin area were feet (Overall Dry Skin Score median 1.0; IQR 1.0 to 2.0).

The prevalence of incontinence-associated dermatitis was 21.0% (95% CI 15.6 to 26.3), and the predominant category was 1A (78.2%). The genital skin area was most often affected (70.9%).

The prevalence of skin tears was 10.5% (95% CI 7.3 to 13.8). The majority of skin tears was classified as Type 1 (74.5%). In total, n = 47 skin tears were found, most affected skin areas were arms (38.8%), legs (27.7%) and feet (21.3%).

Pressure ulcers were found in n = 25 residents (8.0%; 95% CI 5.1 to 10.8). From n = 27 pressure ulcers in total, n = 13 were classified into Category I (48.1%) and n = 14 were classified into Category II (55.6%). The most often affected area was the sacrum (74.1%).

Intertrigo was diagnosed in n = 110 residents with a prevalence of 35.0% (95% CI 30.0 to 40.1). In total, n = 170 intertrigo lesion were

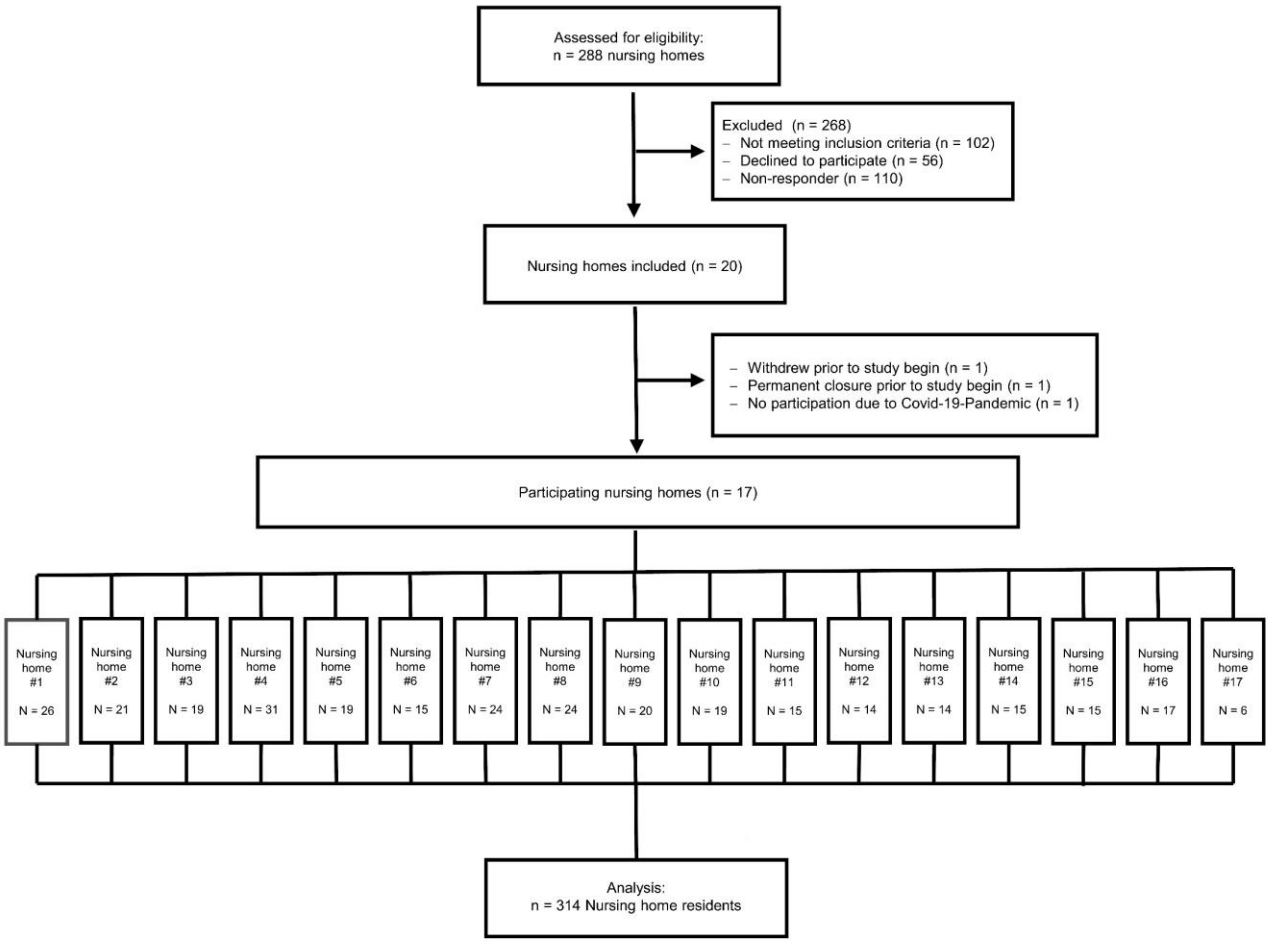

Fig. 1. Flow chart of nursing homes and participants.

found, and the genital area (32.9%), trunk (30.6%) and feet (28.2%) were most often affected.

For all skin conditions, the intracluster correlation coefficients ranged from 0.024 for xerosis cutis and incontinence-associated dermatitis to 0.105 for pressure ulcers. Overall, 56.6% of the nursing home residents were affected by two or more adverse skin conditions at the same time.

3.4. Other analyses

Differences between incontinent residents with and without an incontinence-associated dermatitis are shown in the Online Appendix. A shorter duration of residency (mean difference 11.1; 95% CI 3.9 to 18.3) was associated with the occurrence of incontinence-associated dermatitis. Odds ratios for the appearance of incontinence-associated dermatitis and faecal or double incontinence were 1.4 (95% CI 0.8 to 2.9), and 1.5 (95% CI 0.8 to 2.7), respectively.

Skin tears were associated with higher age (mean difference −3.1; 95% CI −5.3 to −0.8), a lower BMI (mean difference 2.4; 95% CI 0.7 to 4.0), and dementia (OR 3.8; 95% CI 1.8 to 8.7). Residents with skin tears had higher mobility impairments according to the Braden Scale score item 'Mobility' (mean difference 0.3; 95% CI 0.0 to 0.6) and lower Barthel Index scores (mean difference 13.4; 95% CI 4.5 to 21.2) including differences regarding the item 'Transfer' (Online Appendix).

Differences between residents with and without a pressure ulcer are shown in the Online Appendix. Strongest associations were observed with male sex (OR 0.3; 95% CI 0.1 to 0.7), and a longer length of stay in the nursing home (mean difference −11.6; 95% CI −22.6 to −0.5). All types of incontinences were associated with the presence of a pressure ulcer (OR 7.0; 95% CI 1.7 to 10.3). Residents with pressure ulcer showed higher functional impairments regarding Braden Scale scores (mean difference 2.5; 95% CI 1.5 to 3.5), the Barthel Index (mean difference 20.2; 95% CI 12.2 to 28.6), and in particular with limitations regarding transfer (mean difference 3.6; 95% CI 1.9 to 5.2). Moreover, being dependent on nursing staff regarding skin care was associated with the presence of pressure ulcers (OR 3.3; 95% CI 1.4 to 8.4).

The presence of intertrigo was associated with a higher BMI (mean difference −2.9; 95% CI −4.1 to −1.8), as well as a longer duration of residency (mean difference −8.4; 95% CI −16.9 to −0.7). Residents with intertrigo were more likely to be (former) smokers (OR 0.6; 95% CI 0.4 to 1.0) (Online Appendix).

Because of the high number of clinical relevant associations, GEE model analysis with logistic link function was conducted for the appearance of skin tears and pressure ulcers.

The logistic GEE model for skin tears is shown in Online Appendix, and is adjusted for age, overweight, dementia, and mobility. To avoid interaction between measurements of mobility, the Barthel Index item 'Transfer' was finally selected. Statistically significant predictors were impaired mobility (impaired transfer), and higher age.

The logistic GEE model for pressure ulcers is shown in Online Appendix and is adjusted for sex, length of stay in the nursing home, incontinence, mobility, skin self-care abilities, and the use of special support surfaces. The Braden item score 'Activity', and urinary incontinence showed highest group differences. Therefore these two variables were

Table 1
Demographic and health characteristics of nursing home residents (n = 314).

		Missing, n
Demographic characteristics		
Female, n (%)	216 (68.8)	
Age (years)		
Mean (SD)	85.4 (7.1)	
Median (IQR)	86.0 (80.0 to 91.0)	
BMI (kg/m²)		
Mean (SD)	26.2 (5.2)	
Median (IQR)	25.9 (22.5 to 29.1)	
Underweight (BMI < 18.5), n (%)	13 (4.1)	
Overweight (BMI > 25.0), n (%)	181 (57.6)	
Care level, n (%)		
II	99 (31.5)	
III	115 (36.6)	
IV	74 (23.6)	
V	26 (8.3)	
Duration of residency (months)		
Mean (SD)	30.4 (31.4)	
Median (IQR)	22.0 (8.0 to 42.3)	
Smoker/former smoker, n (%)	129 (45.6)	31
Pack-years, Mean (SD)	17.6 (17.1)	212
Education, n (%)		
No professional qualification	37 (11.8)	
Vocational training	203 (64.6)	
University degree	31 (9.9)	
No information	43 (13.7)	
Outdoor occupation, n (%)	26 (8.3)	
Incontinence type, n (%)		
Urinary incontinence	247 (78.7)	
Faecal incontinence	121 (38.5)	
Double incontinence	120 (38.2)	
Diarrhoea	1 (0.3)	
Urinary and/or faecal incontinence and/or double incontinence and/or diarrhoea	248 (79.0)	
Health characteristics		
Most frequent medical diagnoses, n (%)		
Hypertension	235 (74.8)	
Dementia	101 (32.2)	
Renal failure	99 (31.5)	
Diabetes mellitus	88 (28.0)	
Heart arrhythmia	72 (22.9)	
Most frequent medication, n (%)		
Antithrombotic medication	198 (63.1)	
Beta-adrenoreceptor antagonists	173 (55.1)	
Diuretics	170 (54.1)	
Medication influencing the renin-angiotensin system	162 (51.6)	
Psychoanaleptics	144 (45.9)	
Polypharmacy (≥5 medications), n (%)	274 (87.3)	
Cortisone intake, n (%)	14 (4.5)	
Braden Scale Score		
Mean (SD)	16.5 (3.2)	
Median (IQR)	17.0 (15.0 to 19.0)	
Mobility Score		
Mean (SD)	2.5 (0.7)	
Median (IQR)	3.0 (2.0 to 3.0)	
Activity Score		
Mean (SD)	2.7 (0.9)	
Median (IQR)	3.0 (2.0 to 3.0)	
Global Deterioration Scale (Stages), n (%)		
1	159 (50.6)	
2	55 (17.5)	
3	19 (6.1)	
4	18 (5.7)	
5	32 (10.2)	
6	21 (6.7)	
7	10 (3.2)	
Barthel Index		
Mean (SD)	45.2 (24.0)	
Median (IQR)	45.0 (25.0 to 65.0)	
Standing up and mobility		
Mean (SD)	7.6 (4.7)	
Median (IQR)	10.0 (5.0 to 10.0)	
Transfer		
Mean (SD)	9.7 (4.8)	
Median (IQR)	10.0 (5.0 to 15.0)	
Skin self-care ability, n (%)		
Fully independent	10 (3.2)	
Need some assistance	198 (63.1)	
Dependent	106 (33.8)	
Itch (5-D itch scale; residents with GDS 1)		
Itch reported, n (%)	76 (48.1)	1
Mean (SD)	11.3 (2.5)	
Median (IQR)	10.5 (9.0 to 12.8)	
Most affected skin areas, n (%)		
Back	36/76 (47.4)	
Head/scalp	27/76 (35.5)	
Forearms	25/76 (32.9)	
Upper arms	22/76 (28.9)	
Lower legs	18/76 (23.7)	
Pain scales		
Numeric Rating Scales (residents GDS 1), n (%)	159 (100)	
Mean (SD)	1.6 (2.7)	
Median (IQR)	0.0 (0.0 to 2.0)	
Verbal Rating Scales (residents GDS 2–7), n (%)	139 (89.7)	16
Mean (SD)	1.1 (2.1)	
Median (IQR)	0.0 (0.0 to 2.0)	
Quality of Life		
WHO-Five Well-Being Index, n (%) (residents with GDS 1)	157 (98.7)	2
Mean (SD)	15.6 (5.4)	
Median (IQR)	17.0 (12.0 to 19.0)	
Percentage (%)	62.4	
Qualidem 37 (residents GDS 2–6), n (%)	135 (93.1)	10
Mean (SD)	144.4 (28.2)	
Median (IQR)	145.0 (124.0 to 167.0)	
Qualidem 18 (residents GDS 7), n (%)	10 (100)	
Mean (SD)	69.5 (21.9)	
Median (IQR)	74.5 (53.3 to 87.0)	
Health services utilisation		
Last visit by specialty, n (%)	129 (41.1)	
Neurologist	37 (11.8)	
Ear, nose and throat specialist	32 (10.2)	
Orthopaedist	29 (9.2)	
Dermatologist	28 (8.9)	
Dentist	14 (4.5)	
Skin care		
Documentation of skin assessment, n (%)	232 (73.9)	
Documentation of pressure ulcer risk, n (%)	263 (83.8)	
Use of incontinence skin care products, n (%)	62/248 (25.0)	
Pressure ulcer prevention, n (%)		
Use of special support surfaces	160 (51.0)	
Repositioning	60 (38.5)	158
Off-loading of heels	45 (28.8)	158

selected for the multivariate model. Urinary incontinence was the strongest predictor for pressure ulcers, although not statistically significant. Statistically significant predictors were male sex, as well as impaired mobility and skin self-care ability.

4. Discussion

4.1. Key results

Results of this representative sample indicate that nearly every nursing home resident was affected by mild to moderate signs of dry skin. At least every fifth nursing home resident showed signs of incontinence-associated dermatitis, mostly classified as erythema without eroded skin. The prevalence of skin tears was 10.5%, and the majority was classified as Type I indicating that the skin tear could be repositioned to cover the wound bed. The prevalence of pressure ulcers was 8% and all were non-blanchable erythema or superficial skin loss. More than one-third of the nursing home residents were affected by intertrigo at the trunk, feet, and genital area.

Table 2
Skin conditions relevant to nursing practice in nursing home residents (n = 314).

		Missing, n
Xerosis cutis		
Prevalence, n (%)	301 (95.9)	
95% CI	93.6 to 97.8	
ICC (ANOVA) estimate[a]	0.024	
Skin areas and classification according to the ODS[b]		
Face (≥ODS 1), n (%)	182 (58.1)	1
Mean (SD)	1.04 (0.21)	
Median (IQR)	1.0 (1.0 to 1.0)	
Trunk (≥ODS 1), n (%)	161 (51.4)	1
Mean (SD)	1.10 (0.32)	
Median (IQR)	1.0 (1.0 to 1.0)	
Arms (one or both arms ≥ ODS 1), n (%)	255 (81.5)	1
Mean (SD)	1.18 (0.43)	
Median (IQR)	1.0 (1.0 to 1.0)	
Legs (one or both legs ≥ ODS 1), n (%)	269 (85.9)	1
Mean (SD)	1.23 (0.46)	
Median (IQR)	1.0 (1.0 to 1.0)	
Feet (one or both feet ≥ ODS 1), n (%)	269 (86.5)	3
Mean (SD)	1.29 (0.48)	
Median (IQR)	1.0 (1.0 to 2.0)	
Incontinence-associated dermatitis		
Prevalence, n (%)	52/248 (21.0)	
95% CI	15.6 to 26.3	
ICC (ANOVA) estimate	0.024	
Number of IADs (total)[c]	55	
Classification according to GLOBIAD, n (%)		
IAD 1A	43/55 (78.2)	
IAD 1B	5/55 (9.1)	
IAD 2A	5/55 (9.1)	
IAD 2B	0/55 (0.0)	
Missing, n	3/55 (5.5)	
Skin areas, n (%)		
Genital area	39/55 (70.9)	
Sacral area	15/55 (27.3)	
Missing, n	1/55 (1.8)	
Skin tears		
Prevalence, n (%)	33 (10.5)	
95% CI	7.3 to 13.8	
ICC (ANOVA) estimate	0.030	
Number of skin tears (total)	47	
Classification according to ISTAP, n (%)		
Type 1	35/47 (74.5)	
Type 2	4/47 (8.5)	
Type 3	2/47 (4.3)	
Unknown	6/47 (12.8)	
Number of skin tears per skin area, n (%)		
Head	1/47 (2.1)	
Arms	18/47 (38.3)	
Hands	3/47 (6.4)	
Sacrum	1/47 (2.1)	
Legs	13/47 (27.7)	
Feet	10/47 (21.3)	
Unknown	1/47 (2.1)	
Pressure ulcer		
Prevalence, n (%)	25 (8.0)	
95% CI	5.1 to 10.8	
ICC (ANOVA) estimate	0.105	
Number of pressure ulcers (total)	27	
Classification acc. to NPUAP/EPUAP, n (%)		
Category I	13/27 (48.1)	
Category II	14/27 (55.6)	
Category III	0 (0.0)	
Category IV	0 (0.0)	
Category V (deep tissue injury)	0 (0.0)	
Unstageable	0 (0.0)	
Number of pressure ulcers per skin area, n (%)		
Trunk	2/27 (7.4)	
Arm	1/27 (3.7)	
Sacrum	20/27 (74.1)	
Feet	4/27 (14.8)	
Intertrigo		
Prevalence, n (%)	110 (35.0)	
95% CI	30.0 to 40.1	
ICC (ANOVA) estimate	0.059	
Number of intertrigo (total)	170	
Number of intertrigo per skin area, n (%)		
Trunk	52/170 (30.6)	
Arms	3/170 (1.8)	
Genital area	56/170 (32.9)	
Sacral area	10/170 (5.9)	
Feet	48/170 (28.2)	
Unknown	1/170 (0.6)	
Numbers of skin conditions, n (%)		
0	7 (2.2)	
1	140 (44.6)	
2	118 (37.6)	
3	44 (14.0)	
4	5 (1.6)	

[a] Intracluster correlation coefficient.
[b] Overall Dry Skin Score.
[c] Incontinence-associated dermatitis.

The occurrence of these adverse skin conditions was associated with impaired mobility, and care dependency. Moreover, the length of stay in the facility, as well as being affected by incontinence or cognitive limitations, seem to have an impact on the presence of single skin conditions. More than half of the nursing home residents were diagnosed with more than one adverse skin condition at once. However, xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo were not associated with each other.

4.2. Limitations

The anticipated sample size of n = 20 nursing homes with n = 500 residents participating was not achieved. After the start of the study in April 2019, the Covid-19-Pandemic began in March 2020. This resulted in substantial recruitment problems of nursing homes and residents. However, the achieved sample size is considered sufficient to generate point estimates with reasonable error margins.

Due to the cross-sectional study design, no causal relationships between skin conditions and associated factors could have been made. The GEE models included statistically significant associations, but many more parameters, which were not considered in the present study, can have an impact on the occurrence of adverse skin conditions.

The presence of a pressure ulcer prevention standard was considered as one inclusion criterion to enhance comparability of care processes within nursing homes. However, we did not analyse these standards in detail but described process variables such as the use of special support surfaces. In addition, the institutional impact was taken into account while presenting the intracluster correlation coefficients.

A recall bias cannot be excluded, especially for the variables smoking and pack-years, education or outside working activities. Moreover, cognitive limitations of residents resulted in missing data or assessing information by proxy, which may also have influenced the study results.

If possible we used measuring instruments with supported by evidence regarding validity and reliability of the German translations. In case of unavailability, English versions were applied.

4.3. Interpretation

Compared to previous studies, the prevalence of the investigated skin conditions xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo was high. The proportions of subjects with skin dryness were more than double as high as in recent investigations in a similar setting, where trained nurses collected the data (Lechner et al., 2019). Still, studies applying similar data collection procedures by trained dermatologists reported a likewise high

prevalence of skin dryness (Hahnel et al., 2017). This indicates that early signs of skin dryness might be overlooked by nurses in long-term residential settings. The majority of nursing home residents presents Overall Dry Skin Score 1, showing, as described by Serup, signs of faint scaling and roughness at the skin (Serup, 1995). Xerosis cutis is widely regarded as a predictor for further skin diseases (Augustin et al., 2018). However, our results show no relationship between dry skin and the other investigated adverse skin conditions, which might be explained by the fact that nearly every resident was affected by skin dryness. The intracluster correlation coefficient for xerosis cutis was 0.024 and thereby the lowest value in this study. This leads to the assumption that the impact of a specific nursing home, care or resident characteristics was rather low regarding xerosis cutis.

The prevalence of incontinence-associated dermatitis in our study was 21% and is comparable to previous research, reporting prevalence between 3.1% and 11.2% (Kottner et al., 2014), and 30.0% in older people in long-term residential care facilities (Van Damme et al., 2017). The genital skin area was most often affected, which is also supported by previous research. Contrary to existing evidence (Lichterfeld-Kottner et al., 2020; Beeckman et al., 2016), the overall proportion of incontinent subjects receiving skin protection products was low. On the other hand, subjects with incontinence-associated dermatitis received slightly more often incontinence skin care products compared to incontinent participants without an incontinence-associated dermatitis. This indicates that the presence of incontinence-associated dermatitis seems to trigger preventive or therapeutic skin care. Similar findings were reported previously (Jacobson and Wright, 2015; Lichterfeld et al., 2015). Although there is no clear recommendation and superiority of a care procedure or topical product, there is evidence that mild skin cleansing and the application of a skin protecting leave-on product is helpful (Lichterfeld-Kottner et al., 2020). For the presence of incontinence-associated dermatitis, our results show a clinical relevant association with a shorter duration of residency. However, based on the cross-sectional nature of our data this finding is difficult to interpret. Possibly, living for a longer period in a facility may help to provide more adequate skin care over time (Kennedy et al., 2018). The intracluster correlation coefficient for incontinence-associated dermatitis was 0.024, indicating that the impact of the nursing home, the applied care, or the residents' characteristics were rather minor.

The proportion of skin tears in the present study was 11%. In contrast, a previous study in Germany revealed a lower prevalence of 6.3% in a similar setting but with fewer participants and a different study focus (Hahnel et al., 2017). The prevalence of skin tears in Belgium was likewise lower, with only 3.0% in long-term care settings (Van Tiggelen et al., 2019), whereas Canadian studies report an occurrence between 14.7% (Woo and LeBlanc, 2018) and 20.8% (LeBlanc et al., 2021). In the present sample, skin tears were associated with higher age, lower weight, and physical and cognitive impairments, which is supported by previous findings (Strazzieri-Pulido et al., 2017; Rayner et al., 2015). In general, age-related skin changes, as well as sensory deficits, predispose to the development of wounds (Serra et al., 2018). The intracluster correlation coefficient for skin tears was 0.030 indicating that institutional influences were minor.

The prevalence of pressure ulcers was 8% and thereby similar to previous findings, as for example Hahnel et al. reported a prevalence of 9.0% in a comparable setting (Hahnel et al., 2017). Pressure ulcers were primarily assigned to the first two categories of NPUAP/EPUAP classification, and our findings are in accordance with data from the International Pressure Ulcer Prevalence Study regarding prevalence and staging (Kayser et al., 2018). Special support surfaces were used more often in residents with pressure ulcers, supporting an appropriate treatment. Pressure ulcers were more likely in male and incontinent residents, who showed a functional decline and a loss of intrinsic capacity. This complex interplay is supported by the latest pressure ulcer risk model (Coleman et al., 2013). The intracluster correlation coefficient of 0.1 for pressure ulcer prevalence was the highest value in the present study, indicating strong institutional effects (Killip et al., 2004). The calculated intracluster correlation coefficient is comparable to previous findings (Wilborn et al., 2010) and may be associated with differences regarding pressure ulcer prevention practice, as for example distinct organisation, attitude or implementation in nursing routine (Balzer and Kottner, 2015).

More than one-third of the nursing home residents were affected by intertrigo. This proportion is higher, compared to previous estimates in long-term residential settings of 6.7% in the Netherlands (Kottner et al., 2020b) and 16.1% in Germany (Gabriel et al., 2019). The number of intertrigo lesions was n = 170 in total, representing that more than half of the affected nursing home residents had more than one intertriginous skin area. Associations between the presence of intertrigo and a higher BMI, a (former) smoking status, and a longer duration of residency were observed. Overweight (Kottner et al., 2020b; García Hidalgo, 2002), and a higher age (Gabriel et al., 2019) are widely seen as influencing factors. The intracluster correlation coefficient for intertrigo was 0.059, indicating heterogeneity between the nursing homes.

The investigated skin conditions xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo were not associated with each other. Irrespectively from this finding, our results indicate that adverse skin conditions appeared foremost in older and care-dependent residents, who were limited in their mobility. Moreover, our analysis revealed that the occurrence of adverse skin conditions was not influenced by the presence of other skin conditions, diseases, or the intake of pharmaceuticals. These results support the understanding of intrinsic capacity while distancing from a model of disease-based ageing. The patients' disease status seems to be less important than the overall mental or functional status (World Health Organization, 2015).

For the first time, the present study investigated several skin conditions relevant to nursing practice at the same time, as well as their interaction and relationship with functional and biographic aspects. Comparable examinations of the whole body by dermatologists in long-term residential settings are rare, but an important requirement in future research regarding prevention and treatment of adverse skin conditions in long-term care settings (Schulz et al., 2021).

4.4. Generalisability

To avoid a selection bias, the nursing homes were randomly chosen from a list of all available nursing homes and every resident was eligible. Care dependency, cognitive and physical impairment, taken together as 'Care level' are similar to the countries' average (Destatis, 2020). Moreover, demography is comparable to previous German studies within a similar setting regarding age, sex, and the prevalence of investigated skin conditions (Bohnet-Joschko et al., 2021; Hahnel et al., 2017).

Further European studies in long-term care facilities show comparable results regarding demography of participants, as a Danish study indicates a median age of 84 years and 63% participation rate of women (Lundby et al., 2020); and a study conducted in Spain found mean age of 86.8 years and a participation rate of 63.8% women (Cadenas et al., 2021).

5. Conclusion

The prevalence of xerosis cutis, incontinence-associated dermatitis, skin tears, pressure ulcers and intertrigo in long-term residential settings is high, indicating a substantial burden in this population. Although there are comparable causal factors, these five skin conditions seem to occur independently from each other. At the same time, adverse skin conditions could largely be prevented by nursing interventions, including skin assessments, evidence-based and individually tailored skin care.

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CRediT authorship contribution statement

Bettina Völzer: Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Monira El Genedy-Kalyoncu:** Validation, Investigation, Data curation, Writing – review & editing, Project administration. **Alexandra Fastner:** Validation, Investigation, Data curation, Writing – review & editing. **Tsenka Tomova-Simitchieva:** Validation, Investigation, Writing – review & editing. **Konrad Neumann:** Formal analysis, Writing – review & editing. **Janna Sill:** Validation, Investigation, Writing – review & editing. **Katrin Balzer:** Conceptualization, Methodology, Writing – review & editing, Project administration, Funding acquisition. **Jan Kottner:** Conceptualization, Methodology, Formal analysis, Investigation, Resources, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Data availability

Anonymised data will be shared after completion of data analysis.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2023.104472.

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Enhancing skin health and safety in aged care (SKINCARE trial): A cluster-randomised pragmatic trial

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ABSTRACT

Background: Older nursing home residents are prone to develop different skin conditions at the same time, including xerosis cutis, skin tears, pressure ulcers, incontinence-associated dermatitis or intertrigo. Guidelines and recommendations mainly address these skin conditions separately. The overall aim of this study was to measure the effects of the implementation of a skincare and prevention package.
Trial design: A two-arm cluster-randomised controlled trial was conducted.
Methods: In nursing homes being assigned to the intervention group, an evidence-based and structured skincare and prevention programme was implemented for six months. Nursing home residents in the control group received standard care as usual. Blinded dermatologists conducted head-to-toe skin assessments, and the researchers assessed skin barrier parameters including stratum corneum hydration and transepidermal water loss at the upper and lower extremities after three and six months. Outcomes included the cumulative incidence of incontinence-associated dermatitis, skin tears, pressure ulcers and intertrigo, and were presented as intention-to-treat and per protocol analysis. Skin dryness and resident-reported outcomes (pain, itch, quality of life) were assessed.
Results: A random sample of 17 nursing homes in the federal state of Berlin, Germany, was drawn and randomised in intervention (n = 9) and control groups (n = 8). In total, 165 participants were allocated to the intervention, and 149 participants were allocated to the control group. The cumulative incidence of skin tears (19.2 %, 95 % CI 12.8–27.8), pressure ulcers (13.6 %, 95 % CI 8.1–21.9) and intertrigo (27.0 %, 95 % CI 18.4–37.7) was lower in the intervention compared to the control group, with cumulative incidences of 27.2 % (95 % CI 19.3–36.9) for skin tears, 16.9 % (95 % CI 10.6–25.9) for pressure ulcer, and 37.8 % (95 % CI 27.5–49.4) for intertrigo. The incidence of incontinence-associated dermatitis was higher in the intervention group (26.3 %, 95 % CI 17.9–36.8) compared to the control group (23.1 %; 95 % CI 14.6–34.5). Mean skin dryness was lower in the intervention group but showed variation. The impact on pain, itch, and quality of life was trivial.
Conclusions: The present study results indicate that the implementation of tailored and evidence-based nursing routines improves skin health and safety in residential long-term care. Evidence suggests that multiple adverse skin conditions can be prevented by regular skin assessments and individually tailored skincare routines. Positive effects on skin dryness were observed, but skin physiology parameters did not indicate changes of the skin barrier function.
Trial registration: This study is registered at the German Clinical Trials Register (registration number: DRKS00015680; date of registration: January 29th, 2019) and ClinicalTrials.gov (NCT03824886; date of registration: January 31st, 2019).

What is already known

- The skin of older and care dependent people is susceptible of developing adverse skin conditions, including incontinence-associated dermatitis, skin tears, pressure ulcers, intertrigo and xerosis cutis.

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- There are a number of guidelines and good practice recommendations addressing skin conditions separately.
- An evidence-based skincare regimen addressing several skin conditions simultaneously might be effective in residential long-term care.

What this paper adds

- The implementation of a skincare and prevention programme might reduce the incidence of skin tears, pressure ulcers and intertrigo in residential long-term care.
- The severity of skin dryness can be decreased by adequate skin assessments and individually tailored skincare routines.
- The implementation of specific skincare activities seemed to have no impact on skin barrier characteristics, pain and itch.

1. Introduction

Worldwide the population is getting older, and the proportion of older people increases continuously (United Nations Department of Economic and Social Affairs, 2022). Besides, the impact of age-related diseases, combined with care dependency, is substantial (World Health Organization, 2015; Social Protection Committee and the European Commission, 2021). In Germany, approximately five million people are currently in need of nursing care – a number that has more than doubled over the past ten years (Destatis, 2022). Residents living in long-term care facilities are in particular affected by reduced mobility and cognitive impairments. Additionally, they are at risk to develop a wide range of adverse skin conditions (Hahnel et al., 2017a). For example, the prevalence of incontinence-associated dermatitis in residential care facilities is up to 30 % (Van Damme et al., 2017), and the prevalence of pressure ulcers ranges from 3.4 to 32.4 % (Anthony et al., 2019). The prevalence of intertrigo and skin tears is up to 16 % (Gabriel et al., 2019), and 21 % (Woo and LeBlanc, 2018), respectively.

In long-term residential settings, the nursing staff plays a key role in terms of prevention and treatment of skin conditions. Available guidelines and good practice recommendations usually address the aforementioned skin conditions individually, and implementing different guidelines separately might be challenging (Carthey et al., 2011). High numbers of recommended skincare interventions might be time-consuming, and may lead to situations, in which it is no longer possible to distinguish between essentially important and rather insignificant skincare practices in daily nursing routines (Cowdell et al., 2020). Therefore, skincare interventions in general should focus on structured assessments, clear care goals, and tailored interventions (Kottner and Surber, 2016). Many skin conditions relevant for nursing practice show similarities in terms of risk factors, aetiology, prevention and treatment (Campbell et al., 2016; Kottner et al., 2019). For example, the use of lipophilic leave-on-products reduces signs of xerosis cutis and helps to prevent skin tears (Lichterfeld-Kottner et al., 2020; Fastner et al., 2023). Mild skin cleansing is the cornerstone of preventing dry skin, incontinence-associated dermatitis and intertrigo (Dissemond et al., 2021; Lichterfeld-Kottner et al., 2020). Because of the overlaps of basic skincare principles, a comprehensive, evidence-based skincare and prevention algorithm was developed recently (Lichterfeld et al., 2015). Still, effects of implementing this algorithm are unknown.

Apart from evaluating clinical signs of impaired skin, skin physiological measurements are common in scientific investigations. Skin barrier characteristics stratum corneum hydration, transepidermal water loss and skin surface pH have been used previously to show changes of skin integrity during skincare interventions in residential long-term care, and to give an insight into the development of adverse skin conditions (Hahnel et al., 2017b).

The overall aim of this study was to measure and evaluate possible effects of the implementation of an evidence-based skincare programme to prevent and treat common adverse skin conditions in residential long-term care. The specific research questions were as follows:

(1) Does the implementation of the skincare programme reduce the incidence of incontinence-associated dermatitis, skin tears, pressure ulcers, intertrigo, and the severity of dry skin?
(2) How does the skincare programme affect the skin barrier characteristics skin surface pH, stratum corneum hydration and transepidermal water loss?
(3) Does the implementation of the skincare programme reduce itch and pain, and improve quality of life?
(4) What are the effect sizes and intracluster correlation coefficients of the outcomes?

2. Methods

2.1. Trial design

An investigator-blinded, exploratory cluster randomised controlled trial (ClinicalTrials.gov Identifier: NCT03824886; date of registration: January 31st 2019) was conducted in institutional long-term care facilities in the federal state of Berlin, Germany, from April 2019 to June 2021. A study protocol was published (Kottner et al., 2019), and the study was approved by the ethics committee at the Charité Universitätsmedizin Berlin, Germany (approval number: EA1/243/18).

2.2. Participants

Eligibility criteria at the nursing home level were: (1) being located in the federal state of Berlin with (2) at least 70 residents, and (3) the application of a standard pressure ulcer prevention programme in the institution. Inclusion criteria at the resident level were: (1) living in the nursing home, (2) being 65 years or older, (3) having a substantial care need (classified at least as care level II out of V according to the German healthcare system/German Code Book XI), and (4) written informed consent by themselves or legal representatives in case of cognitive impairments. Nursing home residents being at the end of life or having skin conditions that needed further dermatological treatment were excluded from the study.

2.3. Interventions

In the nursing homes being assigned to the intervention group, a skincare and prevention programme was implemented in combination with present care routines and delivered by the nursing staff (including registered nurses and nursing assistants) on site (Supplementary material, Table 1 'TIDieR checklist'). Recommended skincare interventions were provided for a study period of six months. The Normalization Process Theory (Johnson and May, 2015) was applied, which is an effective guidance for implementation in nursing practice (May et al., 2014), and the four-phase model established by the German Network for Quality Improvement (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege (DNQP), 2015). Additionally, research evidence on useful strategies to facilitate practice changes in institutionalised care was taken into account (Weening-Verbree et al., 2013; Vlaeyen et al., 2017). Throughout the trial, continuous meetings and study visits supported the implementation process, and a daily hotline in the study centre on workdays was available for further questions.

After the nursing homes expressed their commitment to take part, a skincare project team with a key project leader was appointed by the institution to ensure continuous communication with the study team. The skincare team in the nursing home consisted of three to four persons (e.g., quality manager, wound manager, senior charge nurse). Together with the key project leader and the study team, representatives of each nursing home were identified, and possible barriers and facilitators for the implementation of the skincare programme, as well as the

continuation of existing guidelines and standards, were discussed. Additionally, study information, such as background, aim and study flow, was explained to all participating institutions. Moreover, posters for the wards and leaflets, informing nursing home residents and their relatives or visitors about the project, were provided.

For the implementation of the skincare and prevention programme in the intervention, group training courses for the nursing staff were conducted, which lasted approximately 45 to 60 min. The trainings were directed face-to-face by the research team, though in one case (during the SARS-CoV-2 pandemic) it was provided as an online course. A self-directed learning package for the nurses and other caregivers was delivered. Follow-up trainings for the ward nurses were offered and conducted as needed. The education programme focussed on basics of preventive skincare in residential long-term care settings. Main topics were skin anatomy, characteristics of ageing skin, and care related skin problems, containing skin dryness, skin tears, pressure ulcers, incontinence-associated dermatitis, and intertrigo. Moreover, basic skin assessments and care routines including cleansing, and the adequate selection and application of leave-on products, were presented. Each training course in the intervention group finished with the presentation and discussion of case studies and an assessment of learning progress (15 questions). A summary of these specific skincare activities was placed near the bedside of each participant in the intervention group (Supplementary material, Fig. 1). Based on a daily assessment, the nursing staff was asked to assess factors, such as immobility, skin dryness, incontinence, obesity or moist skinfolds, and thereafter to evaluate the skin, followed by tailored skincare interventions. Recommendations for cleansing and applying leave-on products were provided, including frequencies of application and desired product characteristics. For example, dry skin areas were supposed to be cleansed once daily or less often. Personal products were continued to be used when meeting the criteria of adequate product characteristics, such as being lipophilic and having a skin friendly pH value. These decisions were made by the nursing staff. Bathing or showering should last not more than 5 min, and washing should be performed with lukewarm water. After cleansing, the application of lipophilic leave-on products including humectants at least twice daily, especially at the extremities, was recommended. A lipophilic emulsion (Lipophile Harnstoff-Creme 5 %, NRF 11.129) was offered if products were not available onsite. Skin areas of incontinent residents exposed to urine and/or stool were expected to be cleansed using mild cleansers, and a skin protection product should be applied. In case skin protection products were not available, a zinc containing product was offered (Weiche Zinkpaste DAB, NRF 11.21). These products were purchased by the researchers from the hospital pharmacy.

Incontinence material should be changed frequently. Skin folds in general were recommended to keep as clean and dry as possible, and soft wipes and towels should have been used. Skin-on-skin friction should be avoided and residents were advised to wear long cotton clothing. Applying leave-on-products in skin folds, as well as rubbing/scrubbing the skin should have been avoided. Strategies, such as repositioning, off-loading, and safe transfer techniques, were highlighted. Clear guidance was provided when to involve medical experts.

The control group received no further skincare instruction, and the skincare practice in the institutions was continued as usual. An education programme of approximately 30 min for the nursing staff in the control group was conducted, focussing on the identification of common adverse skin conditions in long-term care. No case studies were discussed, and information about skincare assessments or the application of adequate products was omitted.

During the study period, the nursing staff in the intervention and control groups documented the provided skincare activities in resident diaries in a daily manner. The study staff checked these diaries frequently for completeness and consistency, and assisted in case of questions. Throughout the trial, continuous meetings and study visits supported the implementation process; the frequency of the meetings was based on the need of the skincare project team in the respective nursing home and on the availability of the nursing staff. Independent of these actions, a comprehensive process evaluation took place.

2.4. Sample size

At the time the study design was developed, there were 288 nursing homes with 28.299 residents in the federal state of Berlin, Germany. A mean of 100 residents per institution and a participation rate of 25 were assumed, leading to a sample size estimation of 500 nursing home residents in 20 nursing homes in total. A drop-out of 8 % was considered, leading to a participation rate of 23 residents per institution, and 460 in total. Due to the exploratory design of the study, it was planned to include ten nursing homes in each arm with an assumed intracluster correlation coefficient of 0.02 (Wilborn et al., 2010), and an incidence of adverse skin conditions of 29.3 % in six months in the control group. A level of $\alpha = 0.05$ for the two-sided Z-test for difference in proportions was taken with a power of more than 80 %, if in the intervention group skin conditions worsen in less than 16.2 % in six months. The method used for power calculation for the clustered binary outcome was used as described in Ahn et al. (2015).

2.5. Randomisation

A 1:1 simple random generation of the allocation sequence of nursing homes to the intervention or control group was conducted. An independent data manager prepared a computer-generated random-list and opaque envelopes containing the random numbers. After the baseline visits were completed, the principle investigator opened the envelopes, which contained the group assignment, and assigned the nursing homes to either the intervention or control group.

2.6. Blinding

A blinded group of outcome assessors, including trained dermatologists/residents of dermatology, research associates and study nurses, completed the examinations and assessments of the follow-up and end-of-study visits. The trial statistician, as well as the data manager, were blinded during data management and the statistical analysis.

2.7. Outcomes

2.7.1. Clinical outcomes

The presence, location and severity of incontinence-associated dermatitis, skin tears, pressure ulcers, intertrigo, and xerosis cutis were assessed at all three study visits by trained dermatologists or residents of dermatology. In order to reduce a possible rater-related bias in diagnosing and classifying the skin conditions of interest, established standardised classifications including images were used.

Incontinence-associated dermatitis was categorised in accordance with the Ghent Global Incontinence-Associated Dermatitis Categorisation Tool (GLOBIAD) in urinary and/or faecal incontinent subjects in categories 1 (A, B) and 2 (A, B) (Beeckman et al., 2018; Van den Bussche et al., 2018), and the localisation was differentiated between genital and sacral areas. Skin tears were categorised according to the International Skin Tear Advisory Panel (ISTAP) in Types I to III (LeBlanc et al., 2013; Van Tiggelen et al., 2020). Pressure ulcers were categorised according to the National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel/Pan Pacific Pressure Injury Alliance classification in categories I to IV, deep tissue injury (V), and unstageable (VI) (NPUAP/EPUAP/PPPIA, 2014; European Pressure Ulcer Advisory Panel, 2019). Intertrigo was diagnosed according to ICD-11 as an irritant contact dermatitis of the skin folds caused by repetitive shearing forces of skin on skin due to friction, sweating or contact with body fluids (World Health Organization, 2022). The Overall Dry Skin Score (ODS) was used to evaluate severity of skin dryness at different body parts (Kang et al., 2014). The score has five categories ranging from 0 (no skin dryness) to 4 (advanced skin roughness, large scales, inflammation and cracks) (Serup, 1995).

2.7.2. Skin parameters

Stratum corneum hydration, transepidermal water loss and skin surface pH were measured during all three study visits. The skin measurements were performed in duplicate, and conducted on the lateral right lower leg and right midvolar forearm. If measurements were not possible to conduct at these skin areas (e.g., due to amputation or wounds), they were performed on contralateral skin areas. To ensure standardisation, measurements were conducted according to manufacturers' instructions and standard operating procedures, and devices were calibrated prior to the first measurement of the day. Participants were not allowed to consume caffeinated beverage, or use any kind of leave-on products at the day of the measurements.

The stratum corneum hydration was measured using the Corneometer CM 825 (Courage + Khazaka, Cologne, Germany). This measurement is based on the differences of the dielectric constant of water and other substances. With this device, the moisture content in the stratum corneum is measured (Berardesca et al., 1997). Values are given in arbitrary units (AU), and range from 0 to 120, whereas higher readings indicate higher stratum corneum hydration. Reliability of this parameter in long-term care settings was supported previously (Elban et al., 2020).

Transepidermal water loss was measured with the Tewameter TM 300 (Courage + Khazaka, Cologne, Germany). The probe captures the constant permeation of water through the stratum corneum in gramme per hour per m^2 (Rogiers and Group, 2001). The measuring probe contains a pair of sensors that are located in different distances to the skin surface to determine temperature and relative humidity above the skin surface. The humidity gradient between both sensors is used for calculating the transepidermal water loss, and the measurements are reliable to describe the water skin barrier in this setting (Elban et al., 2020). Higher values indicate a higher transepidermal water loss (Akdeniz et al., 2018).

Skin surface pH was measured with the Skin-pH-Meter® PH 905 (Courage + Khazaka, Cologne, Germany), a planar glass electrode. The pH is a measure of acidity and alkalinity, and indicates the concentration of hydrogen ions in an aqueous solution (Parra et al., 2003). Reference values of human skin range from 4 to 7 (du Plessis et al., 2018).

2.7.3. Resident-reported outcomes

To identify residents who were cognitively able to provide self-report information, we first applied the Global Deterioration Scale (GDS) to measure the severity of cognitive impairments (Reisberg et al., 1982). Stage 1 describes no cognitive impairments or memory deficits and stage 7 describes severe cognitive decline. This instrument is easy to use and was a pragmatic way to classify participating nursing home residents according to their ability to give self-reports. Residents were asked directly regarding pain, itch, and quality of life, if being assigned to GDS stage 1.

To evaluate the intensity of itch, the 5-D itch scale was used in residents with GDS stage 1, which describes itching body areas (Elman et al., 2010). The instrument is multidimensional (Ständer et al., 2013), and the highest value indicating severe pruritus is 25.

Quality of life was measured using the WHO-Five Well-Being Index in residents with GDS 1, whereas a maximum of 25 can be achieved. The instrument has a high sensitivity for well-being in patients without cognitive impairments (Allgaier et al., 2013). In residents with a GDS 2 to 6, the Qualidem 37 was used according to the recommendation to apply this instrument in people with mild to moderate dementia (Dichter et al., 2016). According to Dichter et al., the Qualidem 18 was applied for residents with severe dementia (GDS 7) (Dichter et al., 2013; Arons et al., 2017).

To measure pain, a numeric rating scale (NRS) was used in residents with GDS 1, and the verbal rating scale (VRS) was used in residents with GDS 2 to 7 (Williamson and Hoggart, 2005). Numeric rating scales ranged from 0 (no pain) to 10 (strongest pain imaginable). The verbal rating scale described six categories of pain in words and was transformed into numbers equivalent to the numeric rating scale.

2.7.4. Harms

In the present study the definition of undesirable effects and serious undesirable effects was chosen, because it was neither a drug nor a medical device study. The provided skincare products were regarded, according the EU Regulation No 1223/2009, as cosmetic products. An undesirable effect was defined as an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product. A serious undesirable effect was defined as temporary or permanent functional incapacity, disability, hospitalisation, congenital abnormality or an immediate vital risk or death (The European Parliament and the Council of the European Union, 2009). It was planned to document the nature, intensity, duration, and actions taken.

2.8. Statistical methods

All randomised nursing homes were included in the statistical analysis at the cluster level. At the individual level, all nursing home residents, who met the eligibility criteria, gave informed consent, and completed the baseline visit, were included. The data was analysed descriptively. Mean values (standard deviation), median values (interquartile ranges) and intracluster correlation coefficients were calculated. The 95 % confidence intervals were presented, if applicable. Main clinical outcomes were presented as corrected cumulative incidence using the intention-to-treat principle with multiple imputation.

Cumulative incidence of incontinence-associated dermatitis, skin tears, pressure ulcers, and intertrigo at follow-up and end-of-study was calculated. Only subjects without any of the respective skin conditions of interest at baseline (absence of incontinence-associated dermatitis, skin tears, pressure ulcers, or intertrigo) were included in the calculation (denominator). Cumulative incidence after three months shows newly developed specific adverse skin conditions over the course of three months. Cumulative incidence after six months includes all newly developed skin damages after three and six months together, and is presented as intention-to-treat and per protocol analysis.

Mean Overall Dry Skin Scores were calculated per group and time points. Means of the right and left leg, arm and foot were calculated, and mean (standard deviation) and median (interquartile ranges) values of all body areas are given. Means (standard deviations) and medians (interquartile ranges) of stratum corneum hydration, transepidermal water loss and skin surface pH are presented.

Missing data was labelled in the tables and excluded from the analyses.

3. Results

3.1. Participant flow

In total, 17 nursing homes participated in the study. Nine nursing homes were allocated to the intervention group, and eight nursing homes to the control group. Baseline visits included 314 nursing home residents, and 299 were included in the follow-up visits after three months, although only 231 residents were directly assessed. Due to SARS-CoV-19 restrictions, 68 residents still took part, but could not be visited. After six months, 240 participants received the end-of-study visits (Fig. 1). Approximately 18 nursing home residents per institution participated (Völzer et al., 2023).

3.2. Recruitment

In total, 207 nursing homes were contacted between November 2018 and July 2020. In case of non-responding or declining, the next randomly chosen nursing home was invited to participate. Reasons

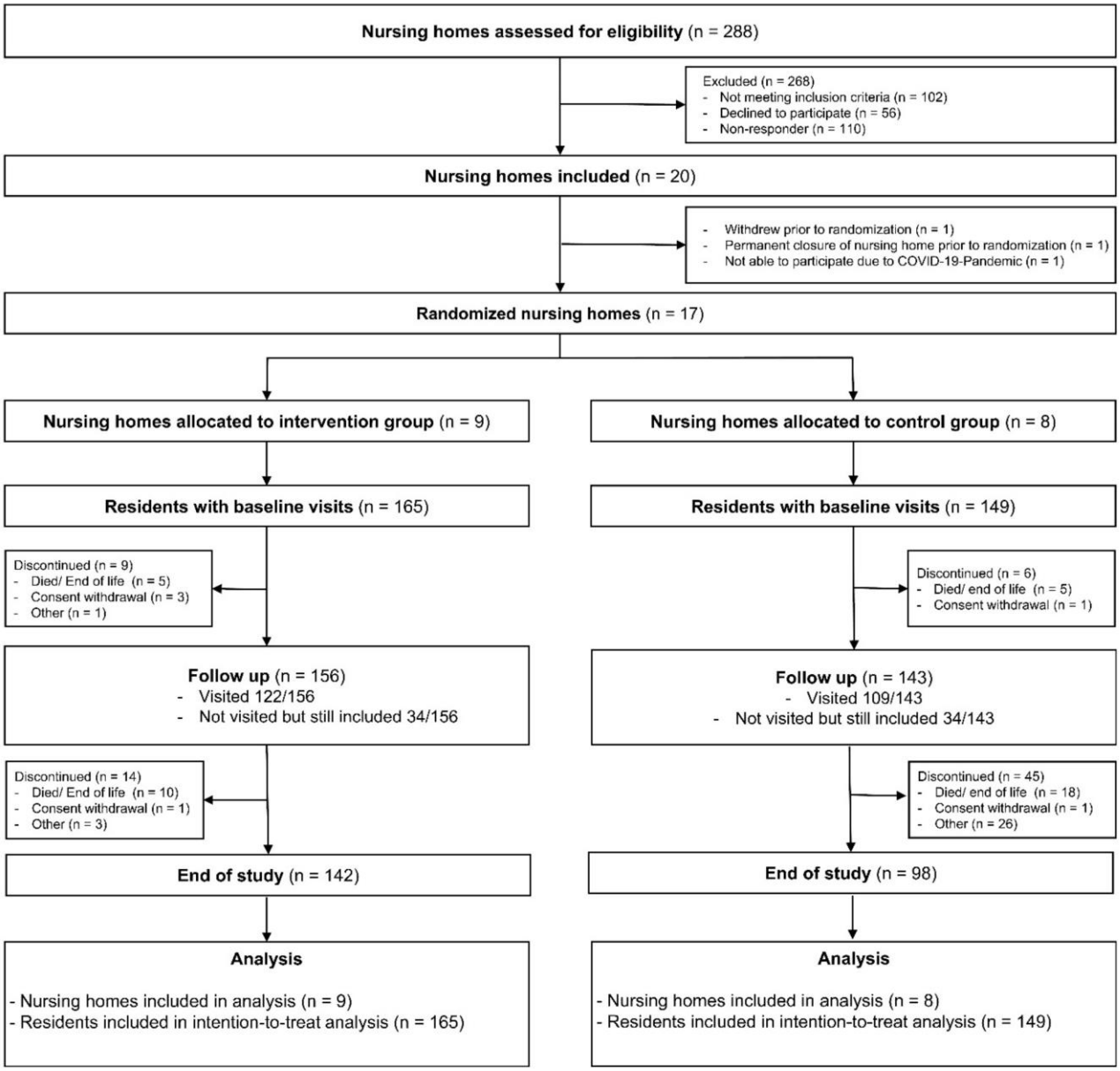

Fig. 1. Flow chart of nursing homes and participants.

of refusal were no interest, no capacity or the expected effort being too high.

3.3. Baseline data

In total, nine nursing homes allocated to the intervention group (with 165 participants), and eight nursing homes (with 149 participants) allocated to the control group, were analysed. A total of 314 subjects, who had a baseline visit, was analysed following the intention-to-treat principle. In parallel, per protocol analyses were conducted including those residents, who were present at the respective visits.

Baseline characteristics of the sample are presented in Table 1, and had been published in detail previously (Völzer et al., 2023). Mean age was 85.2 (SD 7.3) years in the intervention and 85.6 (SD 6.9) years in the control group. The majority in both groups was female. Mean Body Mass Index was 26.6 (SD 5.0) kg/m^2 in the intervention and 25.9 (SD 5.4) kg/m^2 in the control group. Minor differences in the proportions of care levels between both groups were recognised, but in both groups most nursing home residents had a care level III. More than three quarters of the participants were urinary and/or faecal incontinent.

Baseline proportions of intertrigo, pressure ulcers, and skin tears were higher in the intervention group. Proportions of incontinence-associated dermatitis, and mean and median values of severity of dry skin were comparable between groups. An overview of all affected skin areas and classification of each skin condition is displayed in the Supplementary material (Supplementary material, Table 2).

3.4. Clinical outcomes

Cumulative incidence at follow-up (after three months) and end-of-study visits (after six months) of both groups is displayed in Table 2. The

Table 1
Baseline characteristics.

	Intervention group (n = 165)	Control group (n = 149)
Demographic characteristics		
Female, n (%)	112 (67.9)	104 (69.8)
Age (years)		
Mean (SD)	85.2 (7.3)	85.6 (6.9)
Median (IQR)	85.0 (81.0–91.0)	86.0 (80.0–91.0)
BMI (kg/m^2)		
Mean (SD)	26.6 (5.0)	25.9 (5.4)
Median (IQR)	26.1 (23.2–29.8)	25.4 (22.0–28.7)
Care level, n (%)		
II	49 (29.7)	50 (33.6)
III	63 (38.2)	52 (34.9)
IV	41 (24.8)	33 (22.1)
V	12 (7.3)	14 (9.4)
Global Deterioration Scale, n (%)		
Stage 1	81 (49.1)	78 (52.3)
Stage 2	32 (19.4)	23 (15.4)
Stage 3	13 (7.9)	6 (4.0)
Stage 4	10 (6.1)	8 (5.4)
Stage 5	18 (10.9)	14 (9.4)
Stage 6	8 (4.8)	13 (8.7)
Stage 7	3 (1.8)	7 (4.7)
Education, n (%)		
No professional qualification	23 (13.9)	14 (9.4)
Vocational training	106 (64.2)	97 (65.1)
University degree	22 (13.3)	9 (6.0)
No information	14 (8.5)	29 (19.5)
Smoker/former smoker, n (%)	66 (40.0)	63 (42.3)
Pack-years, mean (SD)	18.1 (16.9)	17.0 (17.4)
Incontinence type, n (%)		
Urinary incontinence	124 (75.2)	123 (82.6)
Faecal incontinence	59 (35.8)	62 (41.6)
Skin conditions		
Incontinence-associated dermatitis		
Proportion, n (%)	26/125 (20.8)	26/123 (21.1)
Skin tears		
Proportion, n (%)	20/165 (12.1)	13/149 (8.7)
Pressure ulcer		
Proportion, n (%)	18/165 (10.9)	7/149 (4.7)
Intertrigo		
Proportion, n (%)	63/165 (38.2)	47/149 (31.5)
Overall Dry Skin Score		
Face		
Mean (SD)	0.67 (0.56)	0.54 (0.51)
Median (IQR)	1.00 (0.00–1.00)	1.00 (0.00–1.00)
Trunk		
Mean (SD)	0.65 (0.63)	0.47 (0.54)
Median (IQR)	1.00 (0.00–1.00)	0.00 (0.00–1.00)
Arms		
Mean (SD)	1.04 (0.65)	0.88 (0.53)
Median (IQR)	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Legs		
Mean (SD)	1.07 (0.67)	1.04 (0.54)
Median (IQR)	1.00 (1.00–1.00)	1.00 (1.00–1.00)
Feet		
Mean (SD)	1.09 (0.61)	1.12 (0.64)
Median (IQR)	1.00 (1.00–1.00)	1.00 (1.00–1.38)

intention-to-treat analysis shows that after six compared to three months the cumulative incidence for incontinence-associated dermatitis, skin tears, pressure ulcers and intertrigo increased (Fig. 2). The highest incidence was observed for intertrigo (37.8 %; 95 % CI 27.5 to 49.4) and skin tears (27.2 %; 95 % CI 19.3 to 36.9). After three and six months, the incidence of incontinence-associated dermatitis was higher in the intervention compared to the control group. The incidence of pressure ulcers, intertrigo and skin tears was lower after three and six months compared to the control group. The per protocol analyses showed similar results in terms of group differences. Intracluster correlation coefficients ranged from 0.03 for incontinence-associated dermatitis (after three and six months) to 0.17 for intertrigo.

Xerosis cutis was diagnosed in 95.2 % of the participants in the intervention group, and in 96.6 % of the participants in the control group at baseline. The highest Overall Dry Skin Scores were observed at the legs and feet. After three and six months, the Overall Dry Skin Score was lower in the intervention compared to the control group at the arms, trunk, legs and feet (Supplementary material, Table 3). Irrespective of these group differences there was variation between time points.

3.5. Skin parameters

The skin barrier characteristics transepidermal water loss, skin surface pH, stratum corneum hydration and skin temperature are shown in Table 4 in the Supplementary material. Group differences were trivial and showed variability between time points and skin areas.

3.6. Resident-reported outcomes

Resident-reported outcomes quality of life, itch and pain are displayed in Table 3. Results indicate a small increase of the quality of life after six months in both groups. Pain assessments showed a slight decrease of pain in intervention and control groups. After six months, the proportion of subjects who reported itch was lower in the intervention compared to the control groups.

3.7. Harms

During the study no undesirable effects or serious undesirable effects occurred.

4. Discussion

The intention-to-treat, as well as the per-protocol analyses, indicates that the implemented skincare programme helped to prevent the new development of skin tears, pressure ulcers and intertrigo during the duration of the study. Results also indicate a positive effect regarding skin dryness after three months, and a small effect after six months. The skincare programme seemed to have no influence in reducing the incidence of incontinence-associated dermatitis. Intervention related undesirable effects did not occur. Overall, these results seem to indicate that the proposed skincare programme improves skin health in older nursing home residents.

One underlying assumption of the skincare programme was, that there are overlaps regarding the preventive effects of basic skincare interventions, which address different adverse skin conditions simultaneously (Kottner et al., 2019). This is supported by the results, as for example in the intervention group skin dryness and skin tear occurrence were reduced. Though the focus was on topical skincare interventions, a positive effect on pressure ulceration was observed. Associations between skin properties and pressure ulcer risks are widely known, and it can be assumed that improving the skin condition increases the internal resistance to mechanical deformation (Lechner et al., 2017; European Pressure Ulcer Advisory Panel, 2019).

An unexpected higher increase of incontinence-associated dermatitis was observed in the intervention compared to control group after three months. However, group differences after six months were very small. Probably, the provided guidance was insufficient to improve care, or other factors had a stronger influence on incontinence-associated dermatitis occurrence than the skincare interventions.

Irrespective of these observations, there was a substantial increase of the incidences of all skin conditions (except xerosis cutis). This is illustrated by the fact that nearly half of the residents of the control group developed an intertrigo, and one third skin tears within six months. These numbers are higher compared to a Canadian study, showing an incidence of 18.9 % for skin tears (LeBlanc et al., 2021). Skin tear development in a Japanese study showed a cumulative incidence of 13.5 %, but findings were limited to the documentation of wounds at the

Table 2
Cumulative incidence at follow-up and end-of-study visit.

	Follow-up (3 months)		End-of-study (6 months)	
	Intervention group	Control group	Intervention group	Control group
Incontinence-associated dermatitis				
Cumulative incidence (PP), n (%)	13/76 (17.1)	7/73 (9.6)	21/75 (28.0)	14/61 (23.0)
Cumulative incidence (ITT), % (95 % CI)	17.1 (10.3–27.0)	12.0 (6.1–22.2)	26.3 (17.9–36.8)	23.1 (14.6–34.5)
ICC ANOVA estimate	0.030		0.030	
Skin tears				
Cumulative incidence (PP), n (%)	9/108 (8.3)	19/101 (18.8)	18/104 (17.3)	25/61 (30.1)
Cumulative incidence (ITT), % (95 % CI)	11.4 (6.4–19.5)	18.9 (12.5–27.6)	19.2 (12.8–27.8)	27.2 (19.3–36.9)
ICC ANOVA estimate	0.150		0.150	
Pressure ulcer				
Cumulative incidence (PP), n (%)	6/106 (5.7)	10/105 (9.5)	12/104 (11.5)	13/81 (16.0)
Cumulative incidence (ITT), % (95 % CI)	8.6 (4.3–16.4)	11.1 (6.2–19.1)	13.6 (8.1–21.9)	16.9 (10.6–25.9)
ICC ANOVA estimate	0.156		0.156	
Intertrigo				
Cumulative incidence (PP), n (%)	7/76 (9.2)	16/74 (21.6)	21/76 (27.6)	28/60 (46.7)
Cumulative incidence (ITT), % (95 % CI)	11.2 (5.6–21.0)	19.7 (12.3–29.9)	27.0 (18.4–37.7)	37.8 (27.5–49.4)
ICC ANOVA estimate	0.149		0.168	

PP, per protocol; ITT, intention-to-treat; ICC, intracluster correlation coefficient.

forearms only (Minematsu et al., 2021). Cumulative incidence of pressure ulcers was investigated in nursing homes in Belgium with 8.4 % within the first 14 days (Anrys et al., 2019). Though the follow-up time was different in that study, especially the fast development of pressure ulcers indicates a substantial burden in this population, pointing out the need to reduce unwanted skin conditions using appropriate interventions. To prevent the development of incontinence-associated dermatitis, evidence for mild skin cleansing and the application of skin protectants exists (Fastner et al., 2023). However, the close contact between the skin, irritants, and absorbent hygiene products cannot be avoided completely. Moreover, the application of any leave-on product or incontinence material, as well as duration of wearing these,

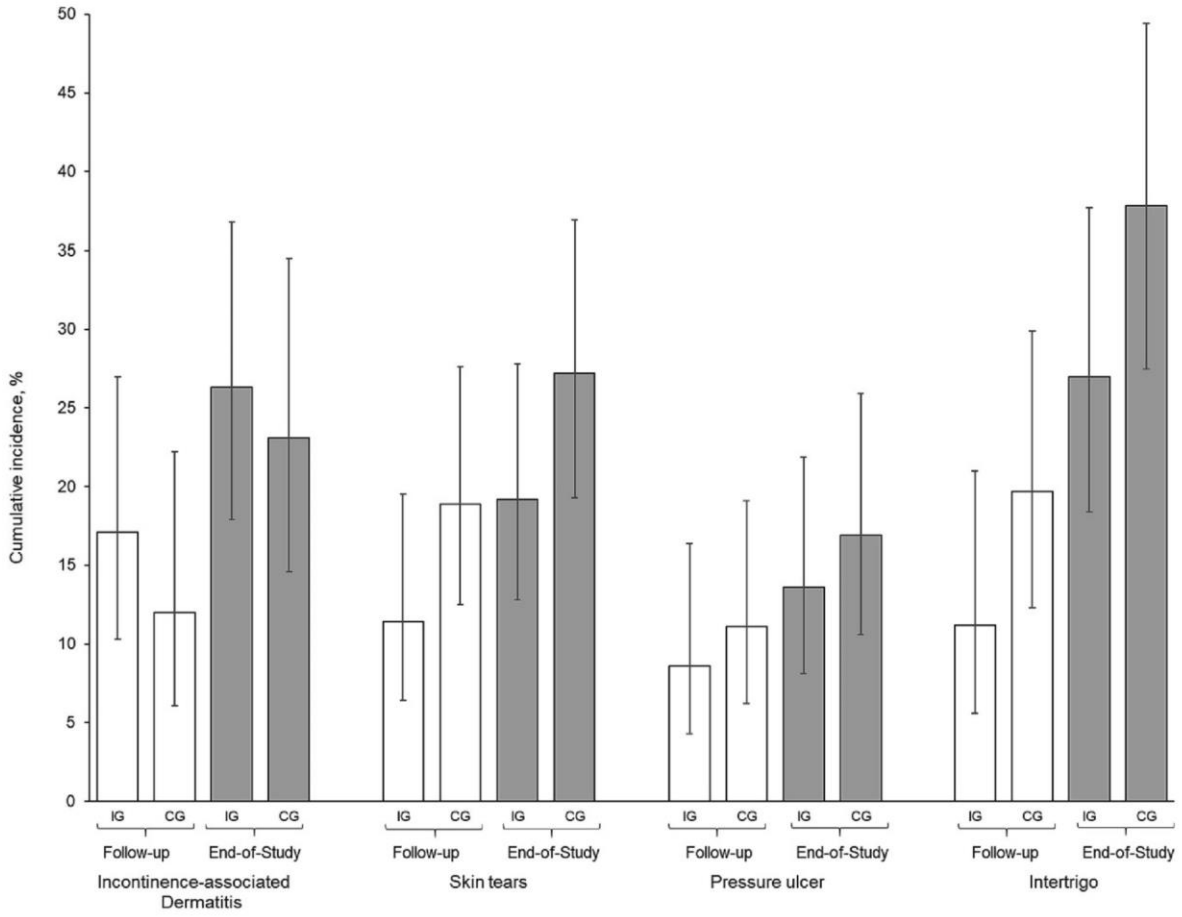

Fig. 2. Cumulative incidence (95 % CI; intention-to-treat analysis) at follow-up (after 3 months) and end-of-study visits (after 6 months) in intervention (IG) and control groups (CG).

Table 3
Comparisons of quality of life, itch and pain at baseline, follow-up, and end-of-study.

	Baseline		Follow-up (after 3 months)		End-of-study (after 6 months)	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Quality of life						
WHO-Five Well-Being (Global Deterioration Scale 1)	n = 79/81	n = 78/78	/[a]	/	n = 66/66	n = 55/55
Mean (SD)	15.2 (5.9)	16.0 (4.8)	/	/	16.7 (5.5)	17.3 (5.5)
Median (IQR)	17.0 (12.0–19.0)	17.0 (13.0–19.0)	/	/	18.0 (14.0–21.0)	18.0 (15.0–21.0)
Qualidem 37 (Global Deterioration Scale 2–6)	n = 76/81	n = 59/64	/	/	n = 64/72	n = 34/37
Mean (SD)	145.0 (27.2)	143.6 (29.7)	/	/	163.5 (32.1)	159.5 (32.9)
Median (IQR)	145.0 (124.0–170.0)	147.0 (124.0–167.0)	/	/	165.5 (144.5–188.0)	156.5 (141.0–190.3)
Qualidem 18 (Global Deterioration Scale 7)	n = 3/3	n = 7/7	/	/	n = 2/4	n = 6/6
Mean (SD)	76.3 (8.7)	66.6 (25.6)	/	/	82.0 (7.1)	67.7 (21.0)
Median (IQR)	74.0 (69.0–n.a.)	75.0 (48.0–90.0)	/	/	82.0 (77.0–n.a.)	70.5 (47.5–81.3)
Pain assessment						
Numeric Rating Scale (Global Deterioration Scale 1)	n = 81/81	n = 78/78	n = 47/47	n = 61/61	n = 65/66	n = 55/55
Mean (SD)	1.8 (1.9)	1.4 (1.5)	1.5 (2.6)	0.9 (1.9)	1.0 (2.1)	1.1 (2.3)
Median (IQR)	0.0 (0.0–4.5)	0.0 (0.0–2.0)	0.0 (0.0–4.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
Verbal Rating Scale (Global Deterioration Scale 2–7)	n = 76/84	n = 63/71	n = 69/75	n = 39/48	n = 69/76	n = 33/43
Mean (SD)	1.1 (2.2)	1.1 (1.9)	0.6 (1.4)	0.5 (1.3)	0.7 (1.5)	0.5 (1.6)
Median (IQR)	0.0 (0.0–2.0)	0.0 (0.0–2.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
Itch assessment (Global Deterioration Scale 1)						
Itch present, n (%)	n = 37/81 (45.7)	n = 39/78 (50.0)	n = 12/47 (25.5)	n = 24/61 (39.3)	n = 13/66 (19.7)	n = 19/55 (34.5)
Mean (SD)	11.6 (3.2)	11.1 (1.7)	10.6 (2.5)	10.1 (2.0)	10.8 (2.5)	11.2 (2.6)
Median (IQR)	10.0 (9.0–14.0)	11.0 (10.0–12.0)	10.0 (9.0–11.0)	10.0 (9.0–11.0)	10.0 (9.0–13.5)	10.0 (9.0–13.0)

[a] Was not assessed at follow-up.

influences the skins' microclimate and may to some extent explain the comparable incidence of incontinence-associated dermatitis in the intervention and control groups (Bender et al., 2017; Kottner et al., 2018). Stricter reductions of the exposure to urine and stool might be needed, and could be promoted by using high absorbency incontinence products (Cardozo et al., 2023) or other forms of continence promotion (Registered Nurses' Association of Ontario, 2020).

Considering skin tears, pressure ulcers and incontinence-associated dermatitis, the intracluster correlation coefficients did not change during the study period. The values indicate heterogeneity of the sample, as well as strong institutional effects, which were highest for intertrigo at the end-of-study. Compared to the estimated intracluster correlation coefficient for the sample size calculation, the calculated values of the sample were higher, indicating a higher variability within the clusters.

The skin barrier characteristics stratum corneum hydration, transepidermal water loss, and skin surface pH are comparable to previous estimates in this population (Akdeniz et al., 2018; Hahnel et al., 2017b; Kottner et al., 2013b). The recommendations for a twice daily application of lipophilic leave-on-products to dry skin areas seemed to have no effect on skin barrier characteristics. Group differences of skin physiology measurements between intervention and control groups were very small, though a clinical improvement in the assessment of the severity of skin dryness occurred. This is in accordance with previous findings of a comparable study investigating the effectiveness of a standardised skincare regimen on skin dryness in residential long-term care (Hahnel et al., 2017b). Although skin barrier characteristics play an important role in skin research, effects are more likely to be observed in highly controlled experimental conditions. Given the substantial heterogeneity of biophysical and clinical outcomes in skin research (Kottner et al., 2013a; Amin et al., 2021), it seems that clinical outcomes are more relevant (Fastner et al., 2023).

The implemented skin care process seems to have only slightly influenced the assessed resident-reported outcomes pain, itch and quality-of-life. There was a comparable proportion of nursing home residents with itching body areas at the beginning of the study in intervention and control groups. After six months, the number of residents being affected by itch was reduced in the intervention group to a greater extent. Since itch is closely associated with dry skin (Valdes-Rodriguez et al., 2015), it can be assumed that the applied skincare had a positive effect. However, many other causes of itch, including systemic diseases or medication exist, but were not taken into account in this trial (Ständer et al., 2007; Weisshaar and Mettang, 2018). Results of a study, which focussed on associations between itch and skin dryness, skincare and well-being (Hahnel et al., 2019), indicate an unclear effect of skincare activities. It was shown that there were no associations between skin dryness, well-being and itch in a comparable setting. These findings are partly supported by the present study, as the trial results regarding quality of life and pain are inconclusive, and the skincare programme had no clear measurable impact on these resident-reported outcomes. Additionally, it should be taken into account that multiple factors influence quality of life, itch and pain in older nursing home residents (Pinter et al., 2021; Ausín et al., 2020).

To ensure external validity, a random sample of all eligible nursing homes in the federal state of Berlin, Germany, was drawn, and all eligible residents in the institutions were invited to participate. Nursing home residents of intervention and control groups showed comparable demographic characteristics, which are representative of a nursing home population (Hahnel et al., 2017c; Cadenas et al., 2021). In addition, the study followed a highly pragmatic approach. The actual implementation of the skincare programme was performed in the nursing homes under normal daily practice conditions. Thus, the observed effects seem to be realistic. Finally, there is no 100 % certainty that skin care interventions were performed exactly as prescribed. Overall, there was agreement between the documentation in the diaries and the skincare algorithm provided, and study results indicate that a behaviour change took place. The results of the process evaluation accompanying the trial will be published elsewhere.

4.1. Limitations

Due to restrictions in the context of the Covid-19-Pandemic, the anticipated sample size could not have been achieved. Although 20 nursing homes were recruited and agreed to participate, three had to be excluded afterwards. Reasons were permanent closure, withdrawal of participation, and restrictions due to the Covid-19-Pandemic prior to randomisation. Due to infection control measures, follow-up visits could not take place in two institutions of the intervention and control groups. However, since this was an exploratory trial, the sample is considered sufficient to describe incidence estimates per group with reasonable 95 % confidence intervals. The sample size further decreased, because residents, who were already affected by specific adverse skin

conditions at baseline and/or follow-up, had to be excluded from incidence analysis.

It is also likely that the pandemic event had an impact on the actual implementation of the skincare programme or on skin and hygiene activities in general. Caregivers had to implement restrictive hygiene rules in a short period of time and the life of nursing home residents was massively affected.

Due to the high proportion of subjects with cognitive impairments, it was impossible to obtain patient-reported data directly from approximately half of all included residents. Using verbal rating scales for the pain assessment of cognitively impaired subjects may also led to biased results.

Finally, only a small proportion of residents from all residents per nursing home were included, which may have led to selection bias. Although resident characteristics were similar in the intervention and control groups, there were substantial baseline differences regarding the proportion of subjects with skin tears and pressure ulcers. However, regarding the calculation of cumulative incidence the denominator included only subjects being free from incontinence-associated dermatitis, skin tears, pressure ulcers or intertrigo, and a bias is therefore unlikely.

5. Conclusion

In summary, results of this exploratory trial show beneficial effects of implementing a comprehensive skincare programme and guidance on the prevention of skin tears, pressure ulcers, and intertrigo, and the improvement of dry skin and itch in residential long-term care, while at the same time high institutional effects persisted. The impact on quality of life and pain seems to be weak. Furthermore, study results indicate that adequate nursing interventions are powerful to improve skin health and safety. These exploratory trial results are useful for larger confirmatory trial planning to demonstrate the impact of comprehensive skincare programmes and standards.

6. Other information

6.1. Registration

The study was registered at the German Clinical Trials Register (DRKS-ID: DRKS00015680; date of registration: January 29th 2019) and ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT03824886; date of registration: January 31st 2019).

6.2. Protocol

The study protocol has been published in Trials on May 29th 2019 (https://doi.org/10.1186/s13063-019-3375-7).

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CRediT authorship contribution statement

Bettina Völzer: Writing – review & editing, Writing – original draft, Visualization, Validation, Investigation, Formal analysis, Data curation. **Monira El Genedy-Kalyoncu:** Writing – review & editing, Validation, Project administration, Investigation, Data curation. **Alexandra Fastner:** Writing – review & editing, Validation, Investigation, Data curation. **Tsenka Tomova-Simitchieva:** Writing – review & editing, Validation, Investigation. **Konrad Neumann:** Writing – review & editing, Formal analysis. **Kathrin Hillmann:** Writing – review & editing, Validation, Investigation. **Ulrike Blume-Peytavi:** Writing – review & editing. **Elisabeth Hahnel:** Writing – review & editing, Validation, Project administration, Investigation. **Janna Sill:** Writing – review & editing, Validation, Investigation. **Katrin Balzer:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization. **Jan Kottner:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Data availability

Anonymised data will be shared after completion of data analysis.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2023.104627.

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Associations between skin structural and functional changes after loading in healthy aged females at sacral and heel skin: A secondary data analysis

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ABSTRACT

Aim of the study: Mechanical loading causes skin occlusion and deformation, which influences structural and functional skin properties. Aims of the study were to measure structural and functional skin parameters after loading at the sacral and heel skin and to describe possible associations.
Material and methods: A secondary data analysis based on a clinical trial with n = 15 aged women was conducted. Changes of transepidermal water loss, stratum corneum hydration, epidermal hydration, erythema, temperature, structural stiffness, elastic recovery, elastic function, and mean roughness after 120 min loading were described and compared. Spearman's rho (r_s) was used to estimate possible associations.
Results: Loading caused an increase of transepidermal water loss, stratum corneum and epidermal hydration, erythema and temperature at sacral and heel skin. There was a decrease of median roughness at the heel skin surface (-8.5 (IQR -10.5 to 5.5) μm). Strongest positive associations were observed between changes of elastic function and elastic recovery ($r_s = 0.9$ at heel and sacral skin) and between changes of epidermal and stratum corneum hydration at both skin areas ($r_s = 0.7$ at sacral skin and $r_s = 0.5$ at the heel).
Conclusion: Two hours loading on a standard foam mattress leads to skin occlusion at the skin surface and mechanical deformation. Skin occlusion seems primarily to increase temperature, stratum corneum and epidermal hydration that may affect mechanical skin properties. Mechanical deformation seems to be responsible for the erythematous response of the dermal skin layer.

1. Introduction

A pressure ulcer (PU) is defined as locally injured skin and/or underlying tissue. It is usually located above anatomic rigid structures (bones or tendons) and occurs due to pressure or pressure in combination with shear [1]. Predominant predilection sites are heel, ischial and sacral skin [2,3]. PUs can lead to reduced quality of life and care dependence, as well as pain, increased mortality and high costs [4].

In long-term care, PU prevalence ranges from 3.4 to 32.4% [5]; the International Pressure Ulcer Prevalence Study suggests a prevalence at an average of 7% [6] and an European systematic review reports a median prevalence of 10.8% across all settings [7]. Despite the heterogeneity of methods and reporting, the PU prevalence estimates clearly indicate the need to further improvement of PU prevention [8].

PUs develop due to pressure combined with shear between external surfaces and stiff internal body structures. Long periods of loading may lead to a direct deformation damage and compression of blood vessels causing localized ischemia [9]. Waste products accumulate, lymphatic flow is impaired and direct cell death may occur [10]. As a consequence, an inflammatory process is initiated and the interstitial fluid, which has also been described as subepidermal moisture, increases [9,11]. This situation could be further enhanced due to reperfusion which may intensify the inflammatory process leading to visible skin and tissue damage [12,13].

During mechanical loading, there is a direct contact between the skin and external objects such as textiles, mattresses, cushions or medical devices. This leads to deformation of anatomical structures and to an occlusive environment between the skin and external surfaces affecting the skin microclimate. This interaction between temperature, humidity and airflow can be seen as an indirect PU risk factor, as increasing

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hydration and skin temperature are linked with soft tissue deformation and the development of PUs [14]. Since loading generally is associated with occlusive effects, skin temperature and stratum corneum hydration (SCH) increase through the accumulation of heat and humidity. Changes of local skin temperature and increased water loss through the stratum corneum have been shown previously [15,16]. A mathematical model also supports a decrease of the tolerance threshold of skin with increasing temperature and humidity [17].

Irrespectively of these well-known effects of loading, the interaction between different skin properties is largely unknown. Recently, Pfannes et al. showed a positive association at the sacral skin area between mean roughness (Rz) and erythema and a negative association between changes of structural stiffness and transepidermal water loss (TEWL) during loading. At the heel skin, a positive association between TEWL and stiffness change was demonstrated [18]. Empirical evidence further indicates positive associations of increasing skin temperature with erythema and SCH [19].

For early detection of PU development, disentangling the effects of occlusion and deformation on the skin structure and function is important. Associations among skin parameters, which appear at the same time, are largely unknown. Recent studies mostly concentrate on changes of skin parameters after loading [20] rather than demonstrating associations between them. Therefore, the aim of this study was to describe the direction, strength and interaction between various skin properties during loading.

2. Material and Methods

2.1. Design

A secondary data analysis was conducted using clinical trial data [21]. A randomised, controlled, exploratory trial (RCT) with crossover design was conducted from 2016 to 2017 (approved by the Ethics Committee of the Charité Universitätsmedizin Berlin EA1/270/15) and the effects of loading on skin properties using different types of mattresses were investigated. This secondary data analysis focuses on possible associations of skin parameters at heel and sacral skin after loading on a basic foam mattress. This is the most common standard support surface in healthcare settings and because the material is stiffer compared to specialized support surfaces, stronger skin changes could have been observed [21].

2.2. Participants

15 healthy women, aged 60–72 years (mean age 66.2, SD 3.6), with a mean Body-Mass-Index (BMI) of 24.7 kg/m^2 (SD 2.0) and a phototype I-III according to Fitzpatrick [22], were included.

2.3. Interventions

Before laying down on the basic foam mattress for 2 h, skin physiological baseline measurements at the sacral and heel skin areas were conducted. After a period of 2 h in supine position, the measurements were repeated [21].

2.4. Variables and measurements

Non-invasive measurements to evaluate skin parameters using well-established devices were performed. All measurements were done twice to increase reliability [23,24].

TEWL was measured with the Tewameter TM 300 (Courage + Khazaka electronic GmbH, Cologne, Germany), an open-chamber device, and is displayed in g/h/m^2. The measurement was performed according to current guidelines [25,26]. TEWL characterizes the skin barrier function, whereas increasing values can be seen as an indicator of impaired skin function [27]. TEWL reference estimates depend on the skin areas [28].

Skin surface temperature was measured in °C with the Skin-Thermometer ST 500 (Courage + Khazaka, electronic GmbH, Cologne, Germany), based on a relative infrared testing method.

The erythema index was measured with the Mexameter MX 18 (Courage + Khazaka electronic GmbH, Cologne, Germany). The measurement is based on reflection and absorption of melanin and haemoglobin and is displayed in arbitrary units (AU).

SCH was measured with the Corneometer CM 825 (Courage + Khazaka electronic GmbH, Cologne, Germany). Values are expressed in AU and range from 0 to 120, whereas values under 40 AU are often interpreted as sign for dry skin [29]. It displays the hydration of the stratum corneum via measurements of a very small depth of 10–20 μm to exclude the impact of deeper skin layers. The measurement is based on differences in the dielectric constants of water and other substances [25].

Epidermal hydration represents the percentage of tissue water (0–100%) in 0.5 mm depth and was measured with the MoistureMeterEpiD (Delfin Technologies Ltd, Kuopio, Finland).

An image of the skin surface was taken by the Visioscan VC 98 (Courage + Khazaka electronic GmbH, Cologne, Germany). Based on the images, Rz was displayed in μm [30]. Empirical evidence supports the validity of this parameter [31].

The structural skin stiffness and elasticity was measured with the Cutometer MPA 580 (Courage + Khazaka electronic GmbH, Cologne, Germany) [32]. Using a suction method, the skin is distorted mechanically by negative pressure. The skin deformation and ability to return are displayed as a curve (depth in mm in time). Calculations of skin elasticity and deformability were used for this reanalysis in terms of elastic function (Ur/Ue in %), extensibility (Uf in mm) and elastic recovery (Ur/Uf in %).

2.5. Statistical methods

Descriptive data analysis was used to calculate means, standard deviations (SD), medians and interquartile ranges (IQR) for all parameters. Means of the two duplicate measurements for all parameters at baseline and after 120 min loading at the sacral and the right heel skin area were computed. Delta values were presented as mean and median differences between both points in time per skin area. Differences between delta values between both skin areas were also calculated. To show possible associations, delta values of all skin parameters were correlated with each other using Spearman's rho (r_s). Results are displayed as a correlation matrix. Based on Burnand et al. and Mukaka, thresholds of $r_s \geq 0.30$ or ≤ -0.30 can be used to demonstrate low correlations [33,34]. In this analysis, thresholds of $r_s \geq 0.50$ or ≤ -0.50 are applied to demonstrate moderate correlations among skin properties [34].

Selected scatter-plots of paired comparisons are displayed in the manuscript, all scatter-plots can be found in the appendix. All calculations were conducted with IBM SPSS Statistics Version 27. Due to the exploratory nature and the small sample size of n = 15, p-values were not considered.

3. Results

3.1. Descriptive data

Results of the descriptive analysis of skin parameters at the sacral and right heel skin are shown in Table 1. At the sacral skin area, an increase of TEWL, temperature, SCH, epidermal hydration and erythema after 2 h of loading was observed. Furthermore, an increase of Uf along with Rz occurred. In contrast, a decrease of Ur/Ue, as well as of Ur/Uf were found.

At the heel, an increase of TEWL, temperature, SCH, epidermal hydration, erythema, Uf, as well as of Ur/Ue was observed. Opposite to that, a decrease of Rz and Ur/Uf could have been shown.

Table 1
Mean (SD) and median (IQR) of skin parameters at sacral and heel skin.

	Sacrum			Right heel			Difference heel (delta value) –sacrum (delta value)
	Baseline	After 2 h	Difference (Delta value)	Baseline	After 2 h	Difference (Delta value)	
TEWL [g/m²/h]							
Mean (SD)	7.7 (1.7)	15.5 (7.1)	7.9 (6.9)	9.9 (3.6)	25.9 (11.3)	16.0 (8.8)	8.1 (6.3)
Median (IQR)	7.1 (6.8–8.8.)	14.5 (9.3–20.5)	6.2 (2.6–12.6)	8.6 (7.4–12.1)	28.4 (15.9–32.3)	17.6 (8.1–20.4)	9.5 (4.8–13.0)
Temperature [°C]							
Mean (SD)	28.8 (1.4)	31.8 (0.6)	3.0 (1.1)	24.1 (2.8)	26.8 (1.5)	2.7 (2.8)	−0.3 (2.8)
Median (IQR)	29.1 (28.1–29.8)	32.0 (31.3–32.2)	3.1 (2.3–3.8)	24.3 (23.3–25.4)	26.6 (25.5–27.3)	1.7 (1.1–3.4)	−0.5 (−2.4–0.4)
SCH [AU]							
Mean (SD)	29.2 (8.5)	34.0 (12.3)	4.8 (9.4)	14.7 (8.1)	20.6 (8.3)	5.8 (4.2)	1.0 (9.0)
Median (IQR)	27.5 (25.1–36.2)	31.6 (26.1–42.5)	3.0 (−1.6–5.8)	12.9 (8.7–17.8)	20.2 (14.5–24.6)	5.9 (2.5–9.3)	2.5 (−0.9–5.0)
Epidermal hydration [%]							
Mean (SD)	42.7 (5.1)	45.0 (5.5)	2.3 (5.9)	24.8 (5.3)	29.1 (5.6)	4.3 (5.1)	2.0 (6.7)
Median (IQR)	41.0 (39.0–47.0)	43.5 (41.0–49.5)	1.0 (−0.5–5.0)	24.0 (21.5–27.5)	28.0 (27.0–31.5)	3.5 (0.5–6.5)	1.5 (−3.5–6.5)
Erythema [AU]							
Mean (SD)	180 (48.8)	241.8 (72.3)	61.9 (54.5)	182.2 (57.4)	240.7 (75.7)	58.4 (46.8)	−3.5 (57.6)
Median (IQR)	167.2 (150.5–193.7)	235.9 (191.3–275.2)	60.7 (16.6–104.2)	186.2 (116.7–234.7)	225.2 (183.5–290.5)	45.7 (21.7–93.5)	−1.5 (−44.1–22.5)
Rz [μm]							
Mean (SD)	36.7 (7.4)	38.7 (5.9)	2.1 (6.4)	58.2 (24.2)	54.6 (18.5)	−3.6 (9.3)	−5.6 (10.4)
Median (IQR)	34.0 (32.0–41.5)	39.5 (34.0–44.0)	2.5 (−2.5–5.0)	51.5 (34.5–72.0)	51.0 (39.5–70.5)	−8.5 (−10.5–5.5)	−7.0 (−17.0–2.5)
Uf [mm]							
Mean (SD)	0.31 (0.04)	0.34 (0.06)	0.03 (0.05)	0.09 (0.02)	0.10 (0.04)	0.01 (0.03)	−0.02 (0.06)
Median (IQR)	0.32 (0.28–0.33)	0.35 (0.32–0.37)	0.03 (0.01–0.05)	0.09 (0.07–0.10)	0.10 (0.07–0.12)	0.02 (−0.00–0.04)	−0.01 (−0.05–0.01)
Ur/Ue [%]							
Mean (SD)	0.80 (0.21)	0.72 (0.21)	−0.07 (0.11)	0.74 (0.15)	1.10 (1.53)	0.37 (1.55)	0.44 (1.57)
Median (IQR)	0.80 (0.66–0.97)	0.65 (0.56–0.90)	−0.10 (−0.15–0.02)	0.68 (0.62–0.85)	0.70 (0.62–0.81)	−0.02 (−0.17–0.15)	0.10 (−0.13–0.24)
Ur/Uf [%]							
Mean (SD)	0.55 (0.14)	0.51 (0.15)	−0.03 (0.08)	0.37 (0.06)	0.38 (0.07)	0.00 (0.06)	0.04 (0.10)
Median (IQR)	0.56 (0.43–0.66)	0.44 (0.42–0.64)	−0.03 (−0.11–0.01)	0.35 (0.33–0.43)	0.38 (0.32–0.42)	−0.03 (−0.04–0.06)	0.04 (−0.03–0.11)

TEWL increases were substantially higher at the heel (mean 16.0 (SD 8.8) g/m²/h) compared to the sacral skin (mean 7.9 (SD 6.9) g/m²/h). The increase of stratum corneum and epidermal hydration was also higher at the heel skin. The last column of Table 1 illustrates the comparisons between changes of skin properties at heel and sacral skin.

3.2. Correlation analysis

The correlation matrix of the delta values for all measured skin parameters is presented in Table 2. At the sacral skin area, the highest positive associations were found between Ur/Ue and Ur/Uf ($r_s = 0.854$), and between SCH and epidermal hydration ($r_s = 0.702$). Highest negative associations were observed between TEWL and Rz ($r_s = -0.492$) and Rz and Ur/Ue ($r_s = -0.329$). Increases of erythema and temperature were unrelated to any other cutaneous parameters. Scatter-plots are provided to demonstrate the relation between SCH and epidermal hydration ($r_s = 0.702$), TEWL and epidermal hydration ($r_s = 0.487$), as well as TEWL and Ur/Uf ($r_s = 0.514$) in Fig. 1.

At the right heel the highest positive correlation was observed between Ur/Uf and Ur/Ue ($r_s = 0.907$). Highest negative associations were observed between Ur/Ue and Uf ($r_s = -0.721$) and between Ur/Uf and Uf ($r_s = -0.639$). The erythema increase was negatively associated with temperature increase and positively with SCH increase. A moderate positive correlation between epidermal hydration and SCH ($r_s = 0.458$), as well as a moderate negative correlation between erythema and temperature ($r_s = -0.525$) can be seen in the scatter-plots (Fig. 2).

Table 2
Correlation matrix (Spearman's rho) of all skin parameters at sacral and heel skin.

		Heel								
		TEWL delta	Temp delta	SCH delta	Erythema delta	Ep. hydr. delta	Rz delta	Uf delta	Ur/Ue delta	Ur/Uf delta
Sacrum	TEWL delta	–	0.361	0.414	0.118	0.446	**0.463**[a]	0.196	−0.286	−0.189
	Temp delta	0.171	–	−0.389	**−0.525**	0.227	0.020	0.054	−0.318	−0.114
	SCH delta	0.343	−0.054	–	**0.471**	**0.458**	0.279	−0.046	−0.043	−0.118
	Erythema delta	−0.111	−0.218	0.104	–	0.125	0.295	−0.021	0.289	0.332
	Ep. hydr. delta	**0.487**	0.224	**0.702**	−0.073	–	0.336	0.308	−0.202	−0.224
	Rz delta	**−0.492**	−0.211	−0.021	0.241	0.039	–	−0.048	0.093	0.222
	Uf delta	0.379	−0.021	0.425	0.250	0.376	0.039	–	**−0.721**	**−0.639**
	Ur/Ue delta	0.418	0.196	0.054	−0.193	0.109	−0.329	0.107	–	**0.907**
	Ur/Uf delta	**0.514**	0.061	0.371	−0.268	0.328	−0.231	**0.461**	**0.854**	–

[a] Bold indicates $r_s \geq 0.50$ or ≤ -0.50.

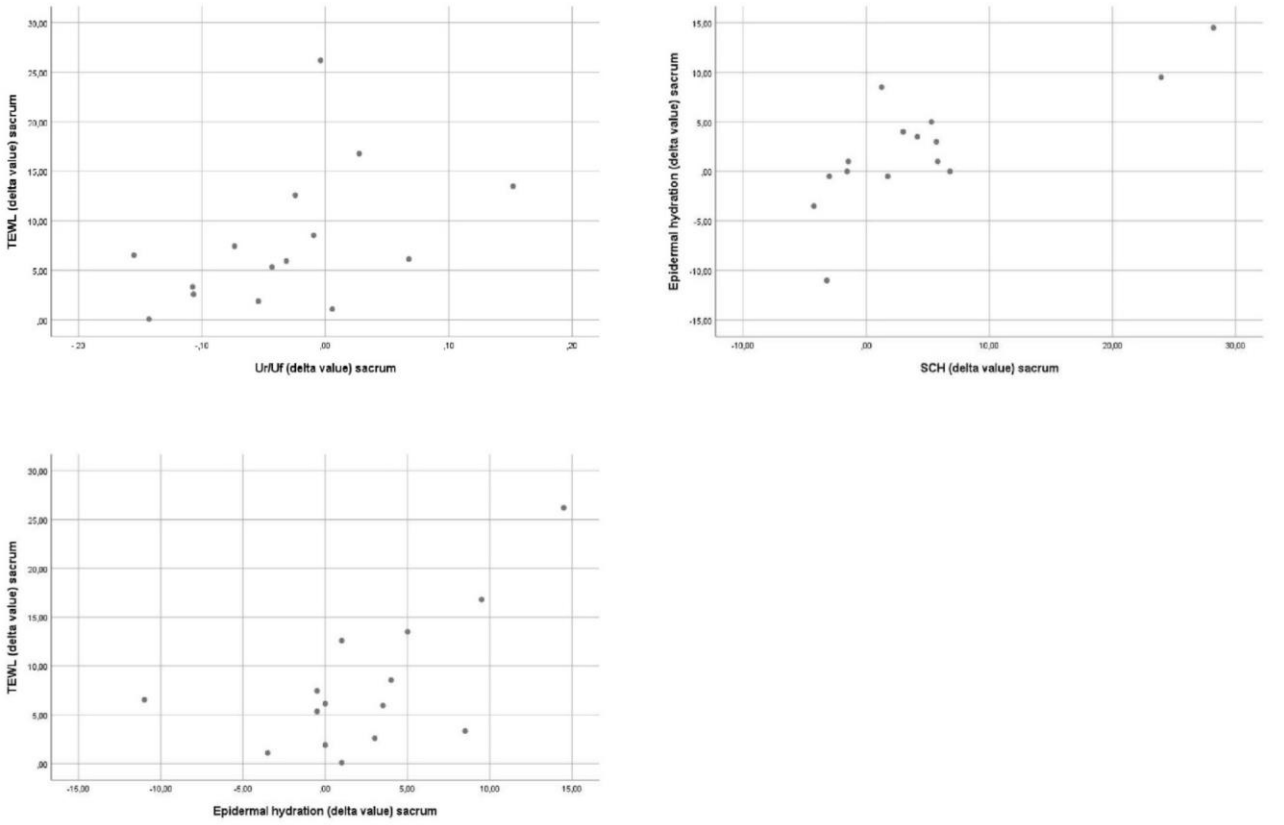

Fig. 1. Selected scatter-plots demonstrating associations at the sacral skin.

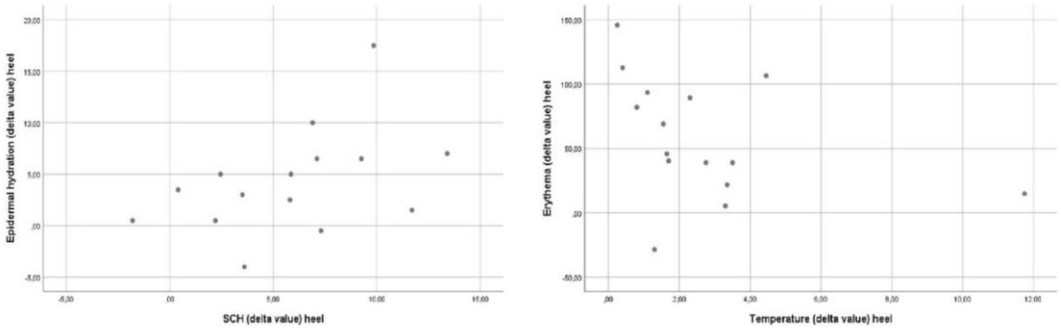

Fig. 2. Selected scatter-plots demonstrating associations at the right heel.

Figs. 3 and 4 provide a summary of the findings and show associations of $r_s \geq 0.50$ or $r_s \leq -0.50$. Black lines were used for positive and dashed lines for negative associations.

4. Discussion

At sacral and heel skin, TEWL, skin surface temperature, SCH, epidermal hydration, Uf and erythema increased, and Ur/Uf decreased after 120 min in supine position on a basic foam mattress. During loading, skin occlusion occurs, leading to an accumulation of heat and humidity and affecting the uppermost skin layers [35–37]. This occlusive effect seems to be particular strong on standard hospital matresses compared to special surfaces used in PU prevention [21].

Increasing values of TEWL and SCH during loading could have been shown previously in supine position at the sacral and heel skin, as well as on the gluteal area during sitting [20,38]. At the heel skin, changes of both parameters were substantially higher compared to the sacral skin area in the present investigation, as well as in previous research. In addition, the increase of the skin surface temperature during loading is in accordance with recent studies including human subjects, as well as in vitro models [39–41].

Moreover, our study results show an elevated erythema index after loading. Erythema increases were similar at heel and sacral skin which may indicate comparable degrees of mechanical deformation of the dermal tissue. Loading intensity is supposed to be directly associated with reactive hyperaemia. Special surfaces, as well as brief interruptions during loading seem to be responsible for modified increases of erythema [21,42].

Concerning the skin structure, site-specific changes occurred. A decrease of Rz at the heel, but not at the sacral skin area could be shown.

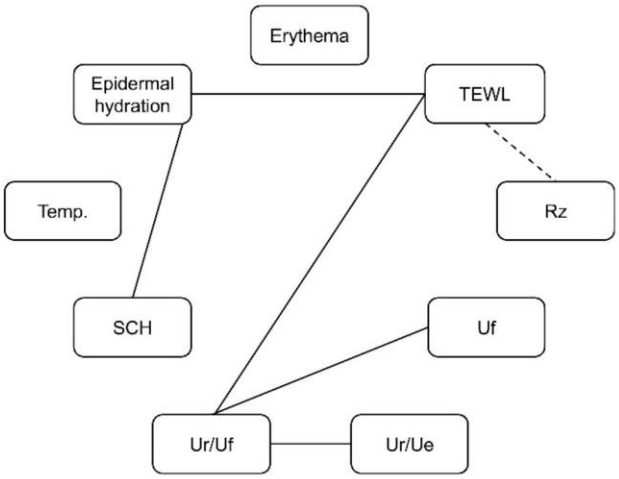

Fig. 3. Associations of skin parameters on the sacral skin area.

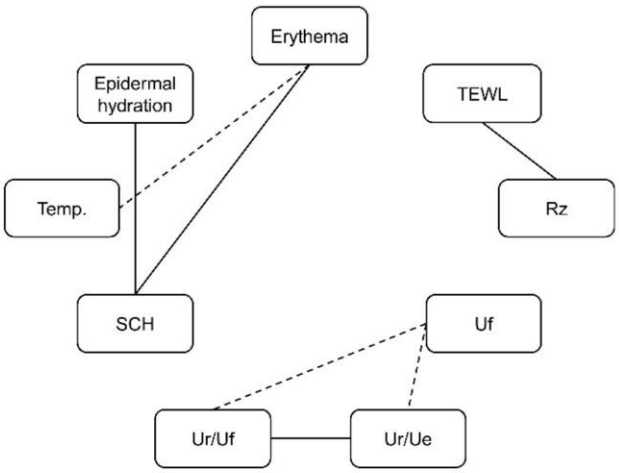

Fig. 4. Associations of skin parameters on the heel skin area.

Similar observations have been made previously and may be explained by different anatomical structures of heel and sacral skin [43]. As the stratum corneum of the heel is much thicker, without hair follicles and during loading a higher hydration occurred, Rz at the heel decreases, indicating a flattening of the skin [44].

After 120 min loading, highest associations at both skin areas have been shown between changes of Ur/Ue and Ur/Uf. Because both are measures of related mechanical properties, this positive association was expected and has been shown before [18].

At the sacral skin area (Fig. 3), positive correlations with respect to increased humidity were displayed between SCH, epidermal hydration and TEWL. Mechanical influence during loading may also impact the barrier function of the SC and is therefore connected with changes of TEWL [26]. Moreover, the association of increased hydration, skin stiffness and elasticity was obvious. Increasing Uf indicates that the skin above the sacrum after loading is less stiff. This effect may have been intensified by an increasing value of SCH, and led over the course to reductions of Ur/Ue and Ur/Uf.

An unexpected observation was the absence of interactions between erythema and temperature and other skin parameters at the sacral skin area. Because an erythema can be interpreted as an indicator of the degree of previous mechanical deformation [42], results suggest that this occurred independently from occlusion. The erythema response seems to be mostly affected by pressure and is independent from microclimate. The absence of correlations between erythema and temperature was shown previously in spinal cord injured subjects in a sitting position [45], during loading in a supine position [18], as well as after locally applied pressure on the skin surface [46].

At the heel skin (Fig. 4), correlations between SCH, TEWL and epidermal hydration were shown. These results are comparable with interactions found at the sacral skin, though the increase of TEWL was much higher. Especially increases of epidermal hydration affected the skin surface topography and structural stiffness. The much thicker and stiffer heel SC seems to be much more sensitive to occlusion during loading. The positive correlation between TEWL, epidermal hydration and Rz may indicate that the degree of mechanical loading might influence the epidermal structure and function via humidity much more, compared to the sacral skin.

Regarding the erythema, the elevation was associated with increases of SCH. Moreover, a negative correlation between erythema and temperature was shown, which supports the findings at the sacral skin and aforementioned study results. Goller et al. suppose that no association between erythema and temperature can exist, as the skin colour is dependent on the blood oxygenation and volume in the capillaries and the skin surface temperature contributes to the blood flow and condition of the arterioles [46].

4.1. Limitations and generalisability

The RCT investigated the effect of mechanical loading on various skin properties at sacral and heel skin in healthy aged women. Therefore, the generalisability to elderly population at PU risk is limited. To reduce variance due to sex, only females were included. As sex is not associated with PU prevalence, a generalisation of the results independent from this aspect can be supposed [2].

The data was taken from a study where a relative short loading phase was investigated. Therefore, long-term effects of loading on the skin properties are unknown.

Moreover, the intensity of the mechanical load and thus resulting tissue deformation was not measured. Possibly, the body weight deformed unequally the tissues above sacrum or calcaneus and may have influenced the results of this study [47].

5. Conclusion

Two hours loading on a standard foam mattress leads to occlusion and mechanical deformation. Occlusion seems to primarily increase the SC and epidermal hydration and temperature that may affect mechanical skin properties. On the other hand, mechanical deformation seems to be primarily responsible for the erythematous response of the dermal skin layer. Further in vivo research with extended loading times is needed to measure long term effects of microclimate changes on skin structure and function.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtv.2022.01.010.

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Lebenslauf

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

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Originalarbeiten (chronologisch)

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Amin, R., **Völzer, B.**, Genedy-Kalyoncu, M. E., Blume-Peytavi, U., & Kottner, J. (2023). The prevalence and severity of dry skin and related skin care in older adult residents in institutional long-term care: A cross-sectional study. Geriatr Nurs, 54, 331-340. doi: 10.1016/j.gerinurse.2023.10.032

Amin, R., **Völzer, B.**, El Genedy-Kalyoncu, M., Blume-Peytavi, U., & Kottner, J. (2024). Skin care types, frequencies and products: A cross-sectional study in German institutional long-term care. J Tissue Viability. doi: 10.1016/j.jtv.2024.02.005

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Völzer, B., El Genedy-Kalyoncu, M., Fastner, A., Kottner, J. 2022. Prevalence and associations of common adverse skin conditions in aged nursing home residents – a representative prevalence study. Student Free Paper Session: Clinical science. The 22nd Annual Meeting of the European Pressure Ulcer Advisory Panel (14-16 September 2022 Prague, Czech Republic)

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Völzer, B. Fastner, A., El Genedy-Kalyoncu, M., Kottner, J. Enhancing skin health and safety in the care of older people: an exploratory cluster-randomised pragmatic trial. Conference abstract, Journal of Wound Care, 32(9). doi: 10.12968/jowc.2023.32.9.558

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