

BMJ Open Comparison of two skin protection regimes for the Prevention of Incontinence-associated Dermatitis in geriatric care (PID): a study protocol for an exploratory randomised controlled pragmatic trial

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ABSTRACT

Introduction The majority of aged long-term care receivers and patients in geriatric acute care are affected by some form of incontinence. These individuals are at risk of developing incontinence-associated dermatitis (IAD), a common type of irritant contact dermatitis caused by repeated and prolonged direct contact of the skin with urine and stool. The prevalence of IAD in these settings is high. Preventive measures include mild skin cleansing and the application of skin protecting leave-on products. Available evidence is weak regarding the comparative performance of different skin protection strategies and products due to a lack of confirmatory trials using relevant comparators and endpoints. Therefore, the overall aim of this exploratory trial is to compare the effects of three skin protection strategies to estimate effect sizes of the recently published core outcomes in IAD research.

Methods and analysis A pragmatic three-arm, assessor-blinded, randomised controlled, exploratory trial with parallel group design will be performed, comparing film-forming and lipophilic skin protecting leave-on products for IAD prevention with standard incontinence care alone. The trial will be conducted in geriatric nursing homes and geriatric acute care settings in the federal state of Berlin, Germany. A total of n=210 participants being incontinent of urine and stool will be included. Outcomes include IAD incidence, erythema, erosion, maceration, IAD-related pain, patient satisfaction, safety, feasibility and compliance. IAD incidence of the control and intervention groups will be compared to estimate effect sizes, and the procedural feasibility of the intervention will be tested to plan a possible subsequent confirmatory randomised controlled trial.

Ethics and dissemination The study received the approval of the ethics committee of Charité—Universitätsmedizin Berlin (EA4/043/22). Results will be disseminated through peer-reviewed open-access journals and international conferences.

Trial registration number ClinicalTrials.gov (NCT05403762) and German Clinical Trials Register

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This exploratory clinical trial compares the two most important skin protectant categories for the prevention of incontinence-associated dermatitis (IAD) in a direct head-to-head comparison, applying core outcomes in IAD research.
- ⇒ The recently developed IAD-specific Core Outcome Set will be applied for the first time in a clinical trial.
- ⇒ The pragmatic approach allows the integration of the study-related procedures into the regular care routine of the participants, providing realistic insights on how well the planned intervention can be implemented under real-life conditions in the geriatric population.
- ⇒ Results will be used to plan a possible confirmatory trial which is needed for the development of evidence-based prevention of IAD.
- ⇒ The follow-up time of 14 days is short compared with the long duration of being incontinent and thus being at IAD risk.

(Deutsches Register Klinischer Studien, or DRKS) (DRKS00028954).

INTRODUCTION

Background

Incontinence-associated dermatitis (IAD) is an inflammation of the skin caused by repeated or prolonged contact with urine and/or stool.^{1,2} Clinical signs of IAD include skin redness, vesicles, nodular thickening and maceration of the tissue as well as defects of the skin up to the loss of the upper skin layers. For those affected, this can be a great physical as well as psychological burden. In addition to pain, burning and itching, IAD is associated with an increased risk of

secondary infections and the development of pressure ulcers (PUs).^{3 4} As a result of these symptoms, affected individuals may also suffer from a reduced quality of life, for example, through a loss of independence, reduction of social activities, or poor sleep due to IAD-related pain or itch.^{5–7}

The prevalence of incontinence rises with increasing age⁸; therefore, IAD is more common in aged populations. With approximately 80%, the majority of residents in long-term care facilities, as well as a high proportion of geriatric patients in acute care settings, are affected by one form of incontinence and are therefore at potential risk of developing an IAD.^{9–11} The prevalence of IAD is 3%–23% in long-term geriatric care and 15%–40% in acute care settings.¹² A representative prevalence study in institutional long-term care facilities showed an IAD prevalence of 35.4% (95% CI 29.9% to 42.2%).¹³

If adequate preventive interventions are initiated at an early stage, the development of IAD might be prevented. However, the high prevalence of IAD in these settings indicates that current prevention strategies are not optimal. Current practices in the context of IAD prevention are largely influenced by individual traditions or personal preferences and might not be evidence based.¹⁴ At the same time, a clear need for support and assistance is expressed by nurses and other caregivers to perform efficient and effective IAD prevention.¹⁵ Therefore, it is important to close existing evidence gaps in this research area.

State-of-the-art interventions to prevent IAD should limit the exposure of the skin to urine and/or stool. This can be achieved by the use of absorbent incontinence products and structured skin care and protection regimens. The implementation of standardised skin care regimens, including the use of skin protection products, can help to prevent the development of IAD or at least reduce its severity.¹⁶ Based on the ingredients and the overall composition, there are two main categories of skin protectants: film-forming products (including polymers such as dimethicone, siloxane, cyanoacrylate) that build a protective layer on the skin surface; and lipophilic leave-on products (including petrolatum, waxes, paraffin) forming a hydrophobic physical barrier on the skin surface. Main working mechanisms include the inhibition of penetration, alteration of biochemistry of the irritant, irritant bonding and a moisture function.¹⁷ No barrier product offers universal protection^{18 19} and both categories of skin protectants have advantages and disadvantages.²⁰ However, there is no evidence that any specific skin protectant is superior to another.

This article describes the protocol of a pragmatic, three-arm, assessor-blinded, randomised controlled, exploratory trial with parallel group design, aiming to compare the two main categories of skin protectants for the prevention of IAD within a standardised skin cleansing regimen, with the standardised skin cleansing regimen alone; applying the recently published core outcomes in IAD research.²¹

Objectives

The primary research objective of this trial is to compare the incidence of IAD in the two intervention and the control groups to estimate effect sizes for a possible subsequent confirmatory randomised controlled trial (RCT). Another objective is to evaluate the feasibility of the planned interventional skin care regimen in geriatric acute and long-term care populations. Furthermore, the feasibility of the IAD-specific Core Outcome Set (CONSIDER)²¹ will be evaluated in the context of a clinical trial.

METHODS AND ANALYSIS

Study design and setting

This exploratory, three-arm, assessor blinded, randomised controlled, pragmatic parallel group trial will be conducted in geriatric hospitals, or geriatric wards of hospitals and institutional long-term care facilities of the federal state of Berlin, Germany. Because one aim of this trial is to assess the feasibility of conducting a future confirmatory RCT, this study might be also regarded as a feasibility trial according to Eldridge *et al.*²²

Eligibility criteria

The inclusion criteria for patients and residents are the following: (1) age of at least 65 years; (2) living/staying in a participating institution at the time of data collection and having a planned minimum length of stay of 14 days; (3) being incontinent of urine and stool; (4) presence of intact skin at the study area with no clinical signs of IAD or the presence of intact skin with early clinical signs of IAD (Ghent Global IAD categorisation tool (GLOBIAD) category 1A²³); (5) written informed consent (signed by the participant or a legal representative).

Residents/patients (1) at the end of life; (2) having IAD with signs of clinical infection in the IAD area; (3) with any skin condition or wounds (at investigational areas of the skin) requiring additional medical treatment (eg, PUs, intertrigo, infection); (4) with known hypersensitivity or allergy to silicones and/or topical leave-on products; and (5) having topical treatments in the IAD area will not be considered eligible.

The inclusion criteria at the institutional level are that participating nursing homes, geriatric hospitals or geriatric hospital ward(s) (1) are in the federal state of Berlin and express a clear commitment to apply the study-related procedures; (2) are willing to regularly allow study-related training (on-site at the nursing home/hospital (ward), conducted by study personnel) and to allow and ensure the participation by a sufficient number of employees; (3) agree that study-related documents, such as diaries, will be completed daily by involved caregivers to ensure compliance and that study personnel may review these documents on regular intervals; (4) commit to adhere to the trial procedures. Any circumstance that makes it unfeasible to conduct the study in the respective

institution in accordance to the study protocol will result in ineligibility.

Recruitment

Eligible local nursing homes, geriatric hospitals, or hospitals with geriatric wards will be contacted by letter, email, or phone and invited to participate in the study. For interested institutions, an initial in-person meeting is arranged at the facility. Within the meeting, the institutions will be informed about the aims and scope of the project. The recruitment of participants in the geriatric hospitals/wards and the nursing homes will be realised in close cooperation with the local responsible contact person on-site. This person will inform possible eligible residents/patients and hand out a first study information leaflet. Interested residents or their legal representatives will then be contacted by the study team in person. They will be informed about the conduct of the study and invited to participate.

Sequence generation, randomisation, allocation concealment and blinding

A computer-generated, block randomisation with 1:1:1 allocation ratio per trial arm will be used. In order to detect any possible sex-related differences or interactions,²⁴ the randomisation will be stratified according to males and females. Two independent randomisation lists will be generated according to the same principle, one for participants in the geriatric hospitals/wards and one for participants of the nursing homes. This is done to ensure that there is an equal distribution of allocation in both settings. The allocation sequence will be implemented by using numbered opaque sealed envelopes. The generation of allocation sequence and preparation of envelopes will be done by an employee who is not involved in the planning of the study, the associated data analysis or any further study-related procedures.

Due to the nature of the intervention, blinding of involved caregivers and participants is not possible. Visits will be performed by at least two investigators/assessors. For the team member who reviews the diaries and verifies the correct implementation of study-related procedures by nurses, blinding is also not possible as diaries and procedures provide information about the assignment. The skin condition-related assessments (including GLOBIAD IAD categorisation, visual inspection of erythema, erosion and maceration) will be done by the second member of the study team ('outcome assessor') who is blinded to the allocation. The data manager will be blinded throughout the period of data entry and verification until database closure. The trial statistician will be blinded during statistical analysis.

Interventions

Included participants of all three groups receive a standardised skin cleansing regimen consisting of cleansing of the skin with water and the addition of a mild cleansing product. Cleaning is done using disposable washing mitts.

To remove possible residual stool from the skin, an additional skin oil may be used. After subsequent gentle drying of the skin, elastic disposable breathable incontinence pants are put on. This is considered as 'standard incontinence care'. In order to ensure the greatest possible standardisation and uniformity, the same predefined procedures and product categories will be used for all participants. After informed consent and baseline visits, included residents/patients will be randomly assigned on day 0 to one of the following three study arms:

- ▶ Study arm 1 (experimental intervention I): standard incontinence care with additional daily topical application of a film-forming leave-on skin protectant that builds a protective layer on the surface of the skin. The skin protectant is applied once daily to dry skin after regular skin cleansing in the morning.
- ▶ Study arm 2 (experimental intervention II): standard incontinence care with additional daily topical application of a lipophilic leave-on skin protectant that forms a hydrophobic physical barrier on the skin. The skin protectant is applied twice daily to dry skin after regular skin cleansing in the morning and evening.
- ▶ Study arm 3 (control group): standard incontinence care alone, no additional skin protectant is applied in the control group.

A detailed description of interventions, according to the template for intervention description and replication (TIDieR) checklist,²⁵ is provided in [table 1](#).

Strategies to improve adherence to intervention protocol

Ongoing communication with managers and responsible staff of the nursing homes and hospitals will be maintained throughout the study to prevent premature loss of participants. Kick-off meetings in participating institutions will be held, study background and procedures will be explained as well as the importance of following the study protocol. The regular visits of study personnel at the institutions will be used to review diaries completed by the caregivers at least every second day. The high frequency of visits will increase the caregivers' attention of the study and provide the opportunity for regular communication between the caregivers and the study team. The investigators can immediately identify missing data and inconsistencies in the diaries and discuss and resolve any study-related procedures directly with the caregivers. This timely and prompt approach will significantly contribute to data quality and completeness. Likewise, caregivers are invited to discuss open questions with the study staff promptly at any time.

Initial educational sessions include explanation and demonstration of the product and its use. Then, nurses will apply the product under supervision during the first visit. During the regular study visits, the study personnel will periodically verify that the product is being applied correctly. After the initial training, nurses will be retrained after 3 and 6 months ([table 1](#)), and, if necessary, in individual additional meetings. In addition, providing

Table 1 Description of interventions according to the template for intervention description and replication²⁵

Item	Experimental intervention I	Experimental intervention II	Control group
1. Brief name	Film-forming leave-on skin protectant for IAD prevention	Hydrophobic leave-on skin protectant for IAD prevention	No skin protectant
2. Rationale	Film-forming topical leave-on products are widely used to protect the skin from irritants including urine and/or stool in incontinent patients. ⁴¹ ⁴² Whether film-forming products are better than hydrophobic ointments/emulsions or no skin protectants is unclear.	Monophasic or biphasic hydrophobic topical leave-on products are widely used to protect the skin from irritants including urine and/or stool in incontinent patients. ⁴¹ Whether hydrophobic leave-on products are better than film-forming products or no products is unclear.	Most incontinent patients do not receive any topical skin protectant when the skin is intact. The relative and absolute benefit of applying any skin protectant to intact skin of incontinent geriatric patients is unclear.
3. Materials	<ul style="list-style-type: none"> ▶ Skin will be cleansed with water and the addition of a mild cleanser (preferably non-alkaline skin cleansers with a pH range similar to normal skin and non-ionic surfactants, for example, Bübchen Creme Pflegebad, Nestlé Nutrition, Germany) using disposable wash mitts/cloths (eg, Waschhandschuh PLUS, Desomed, Germany). ▶ A skin oil (perfume-free, dye-free, for example, Baby Öl, Nestlé Nutrition, Germany) may be used in addition to removing stool. ▶ ESENTA Skin Barrier (ConvaTec, UK) will be applied on clean and dry skin exposed to urine and stool. After application, the solvent evaporates leaving a silicone film on the skin surface. ▶ Elastic disposable breathable incontinence pants are put on (eg, Seni active classic, TZMO Deutschland, Germany). 	<ul style="list-style-type: none"> ▶ Skin will be cleansed with water and the addition of a mild cleanser (preferably non-alkaline skin cleansers with a pH range similar to normal skin and non-ionic surfactants, for example, Bübchen Creme Pflegebad, Nestlé Nutrition, Germany) using disposable wash mitts/cloths (eg, Waschhandschuh PLUS, Desomed, Germany). ▶ A skin oil (perfume-free, dye-free, for example, Baby Öl, Nestlé Nutrition, Germany) may be used in addition to removing stool. ▶ Hydrophobes Basisgel DAC will be applied on clean and dry skin. It contains 95% paraffin oil and creates a hydrophobic layer on the skin surface.⁴³ ▶ Elastic disposable breathable incontinence pants are put on (eg, Seni active classic, TZMO Deutschland, Germany). 	<ul style="list-style-type: none"> ▶ Skin will be cleansed with water and the addition of a mild cleanser (preferably non-alkaline skin cleansers with a pH range similar to normal skin and non-ionic surfactants, for example, Bübchen Creme Pflegebad, Nestlé Nutrition, Germany) using disposable wash mitts/cloths (eg, Waschhandschuh PLUS, Desomed, Germany). ▶ A skin oil (perfume-free, dye-free, for example, Baby Öl, Nestlé Nutrition, Germany) may be used in addition to removing stool. ▶ Elastic disposable breathable incontinence pants are put on (eg, Seni active classic, TZMO Deutschland, Germany).
4. Procedures	After regular skin cleansing in the morning, the skin protectant is applied to dry skin.	After regular skin cleansing in the morning and evening, the skin protectant is applied to dry skin. In addition, the product is reapplied following the skin cleansing after a stool incontinence episode.	After regular skin cleansing, no additional skin protectant is applied.
	Prior to the beginning of the study, ward nurses are educated in interactive face-to-face meetings. Handouts will be provided and posters summarising the study procedures are placed on the wards. Refresher meetings are held every 3 months under the supervision of investigators.		
5. Who provides?	Ward nurses who participated in an educational session about this study and the procedures and thus have study-relevant knowledge.		

Continued

Table 1 Continued

Item	Experimental intervention I	Experimental intervention II	Control group
6. How	<ul style="list-style-type: none"> ▶ After removal of the incontinence briefs, the skin is cleansed and dried. ▶ An oil may be used to remove stool and/or residual products. ▶ The skin protectant is applied to dry skin. According to manufacturer instructions, the spray must be held approximately 10 cm away from the skin surface. A uniform layer of the product is applied using a sweeping motion over the area to be protected. The film must be completely dry before the person is turned onto their back, new incontinence materials are placed or clothing is put on. ▶ New incontinence pants are put on (if needed from the view of the nurses). 	<ul style="list-style-type: none"> ▶ After removal of the incontinence briefs, the skin is cleansed and dried. ▶ An oil may be used to remove stool and/or residual products. ▶ The skin protectant is applied to dry skin. ▶ New incontinence pants are put on (if needed from the view of the nurses). 	<ul style="list-style-type: none"> ▶ After removal of the incontinence briefs, the skin is cleansed and dried. ▶ An oil may be used to remove stool and/or residual products. ▶ New incontinence pants are put on (if needed from the view of the nurses).
7. Where	In the patient rooms, in or outside of the bed.		
8. When and how much	It is widely assumed that polymeric films protect the skin up to 72 hours. ⁴⁴ According to manufacturer instruction, reapplication of ESENTA Skin Barrier (ConvaTec, UK) is recommended every 12–72 hours. To ensure sufficient skin protection and to standardise application within this trial, the product will be applied once daily in the morning as a uniform film to cover the exposed skin area.	Because traditional lipophilic leave-on products do not adhere to the skin surface that strongly, it may be removed more easily. To ensure sufficient protection, the Hydrophobes Basisgel DAC will be applied twice daily (in the morning and evening) as a thin layer on the skin exposed to urine and stool.	Not applicable
9. Tailoring*	The frequency and intensity of skin cleansing and the application of new incontinence material will be based on the number and intensity of incontinence episodes.		
	Not applicable	The skin protectant will be reapplied in addition to after every stool removal from the skin.	Not applicable
11. How well*	Ward nurses are initially trained and retrained after 3 months, after 6 months and as needed at individual additional meetings. During the study, the nurses continuously document the study-related procedures performed (cleansing, use of leave-on products, used materials) in a resident/patient-specific diary. The study personnel check these diaries daily for completeness and consistency to ensure and improve compliance and adherence to the protocol.		

*Items 10 and 12 do not apply for study protocols and are therefore not listed in the table.
IAD, incontinence-associated dermatitis.

continence care and applying protective leave-on products are common in nursing practice.

To minimise the risk of confusion regarding the group assignment, patient-bound diaries with group-specific designs are used, and colour-coded participant cards are left in the patient's/resident's room. These cards contain an image of the product to be used and instructions for use. Clearly visible labels on the products indicate the number and timing of

daily applications. Only one resident/patient per room will be included in order to reduce the risk of contamination.

By keeping the documentation requirements to a minimum and using a pragmatic intervention approach that does not create additional workload but rather integrates into the usual daily care routine, the burden on caregivers is kept as low as possible and feasibility is improved.

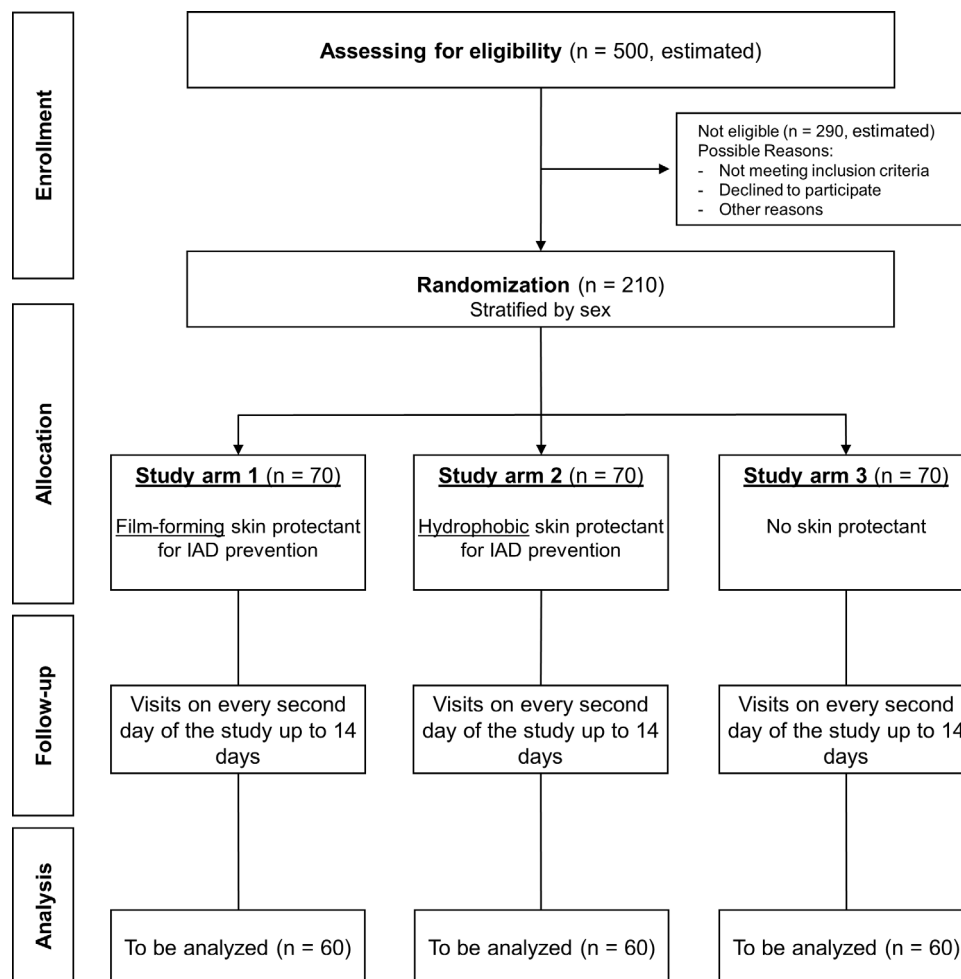


Figure 1 Overview of the planned trial flow. IAD, incontinence-associated dermatitis.

Participant timeline

After inclusion, residents will be followed up for 14 days. Written informed consent will be obtained prior to study participation or data collection by the residents/patients themselves or their legal representatives, if applicable. An overview of the planned trial flow is shown in [figure 1](#).

Outcomes

Due to the exploratory nature of the trial and according to methodological guidance for exploratory trials, a distinction between primary and secondary endpoints is not made.²² Because the aim is to prevent IAD, IAD incidence is the main clinical outcome in this trial. Further outcomes are classification and localisation of IAD, IAD-related itch and, according to CONSIDER,²¹ erythema, erosion, maceration, IAD-related pain, patient satisfaction, and safety. In total, eight study visits are planned. All outcomes will be measured at baseline (day 0) and at days 2, 4, 6, 8, 10, 12 and 14.

Feasibility outcomes include willingness to participate (measured as proportion of eligible patients/residents who were included in the trial), retention (measured as proportion of enrolled subjects who completed the trial), and adherence/compliance to prescribed intervention (measured by the proportion of group-specific

procedures performed correctly according to the diary). These feasibility outcomes will be measured every second day on-site during the study visits using the diaries. Through close monitoring and frequent attendance, we ensure that nurses remain aware of the study procedures and that documentation is made. [Table 2](#) shows the schedule of enrolment, visits, measurement time points, interventions, assessments and variables.

Skin assessment and measurements

The skin assessments will be performed by a blinded outcome assessor and include IAD categorisation (according to GLOBIAD²³), localisation, assessment of erythema (according to the item 'Redness' of Borchert *et al*²⁶), erosion (according to Nast *et al*²⁷) and maceration (according to Whitehead *et al*²⁸). Standardised erythema level measurements will be conducted in duplicates at the cranial end of the gluteal cleft. Erythema levels will be measured by using the Mexameter MX18 probe with MDD 4 device (Courage+Khazaka Electronic, Cologne, Germany²⁹). The probe measures the haemoglobin (erythema) components of the skin, which are mainly responsible for its colour, allowing to quantify skin redness. Measurement values are displayed in device-specific arbitrary units (AU) and range from 0 AU to 999

Table 2 Schedule of enrolment, visits, measurement time points, interventions, assessments and variables

	Days														Close-out		
	Enrolment	Allocation	Post-allocation														
Time point	-5 to 0	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Formal requirements and allocation																	
Eligibility screening	x																
Informed consent	x																
Randomisation and allocation		x															
Participant characteristics																	
Demographic variables (eg, age, sex, care level)		x															
Relevant medical diseases		x															
Relevant medication		x															
Physical function (Barthel Index)		x															
Cognitive status (MMSE)		x															
Incontinence characteristics		x															
Clinical outcomes																	
Ghent Global IAD categorisation		x		x	x		x	x	x	x		x	x				x
Erythema (visual inspection)		x		x	x		x	x	x	x		x	x				x
Erythema (instrumental measurement)		x		x	x		x	x	x	x		x	x				x
Erosion		x		x	x		x	x	x	x		x	x				x
Maceration		x		x	x		x	x	x	x		x	x				x
IAD-related pain (NRS or PAINAD-G)		x		x	x		x	x	x	x		x	x				x
IAD-related itch		x		x	x		x	x	x	x		x	x				x
Patient satisfaction (NRS)		x		x	x		x	x	x	x		x	x				x
(Serious) adverse events or incidents		x		x	x		x	x	x	x		x	x				x
Feasibility outcomes																	
Retention		x		x	x		x	x	x	x		x	x				x
Adherence/compliance to prescribed intervention		x		x	x		x	x	x	x		x	x				x
Interventions and study-related procedures																	
Study arm 1: conduction of the standardised skin cleansing regimen and application of the film-forming skin protectant																	
Study arm 2: conduction of the standardised skin cleansing regimen and application of the hydrophobic skin protectant																	
Study arm 3: conduction of the standardised skin cleansing regimen, no additional skin protectant																	

IAD, incontinence-associated dermatitis; MMSE, Mini-Mental State Examination; NRS, numerical rating scale; PAINAD-G, Pain Assessment in Advanced Dementia.

AU, whereby higher readings indicate more extreme erythema. Empirical evidence supports the reliability of this measurement at this skin area.^{30 31}

Baseline data and assessments

Demographic, health and care-specific data are collected for all participants. Demographic variables (including age,

sex, care level, body height and weight, skin photo type), relevant medical diagnoses and relevant medication will be obtained from institutions' records. Functional assessments using the Barthel Index³² and the Mini-Mental State Examination (MMSE)³³ will be conducted, if assessment scores are not already present in the records. The Barthel Index measures physical function related to the daily activities using 10 items (eg, washing and toilet use, eating and mobility or incontinence). Scores range from 0 (very dependent) to 100 (not dependent). The MMSE will be used to measure possible cognitive impairments. It has a maximum score of 30, whereby lower scores indicating a more severe impairment. A score of 24 or higher indicates normal cognition. The assessment includes categories regarding orientation, attention or memory.

Participant-reported outcome measures

Participants will be asked about the presence of IAD-related itch. Patient satisfaction is assessed by a numerical rating scale (NRS) from 0 (dissatisfied) to 10 (very satisfied) for patients/residents with MMSE³³ scores of 24 or higher. IAD-related pain will be assessed with an NRS from 0 (no pain) to 10 (worst possible pain) in patients/residents without cognitive impairment (scores of 24 or higher according to MMSE³³). For patients/residents with dementia (scores of <24 according to MMSE³³), the Pain Assessment in Advanced Dementia^{34 35} scale will be used. These outcomes will be assessed by the unblinded study assistant.

In addition, qualitative interviews will be conducted with n=12 participants to explore the patient perspectives and preferences regarding IAD prevention. To consider possible sex-related differences, an equal number of male and female participants will be included per group. To be eligible, patients need to have an MMSE score of 24 or higher. Results of a previous clinical study that we conducted in the geriatric acute care setting indicate a proportion of cognitively impaired patients of approximately 50%.³⁶ Because cognitively impaired geriatric patients or nursing home residents are often affected by incontinence, they are at particularly high risk of developing IAD. Therefore, it was explicitly decided to include this target group. Because not all subjects will be cognitively impaired, it will be possible to gather the patient's perspective and preferences using qualitative interviews. Interviews will be transcribed verbatim and qualitative content analyses conducted.

Sample size

Due to the exploratory nature of the trial, a formal sample size calculation is not applicable.²² The trial has three study arms and is stratified by sex (male and female) and kind of setting (geriatric hospitals/wards and nursing homes). Following the recommendations for exploratory trials,³⁷ a sample size of n=60 participants per group is considered feasible and sufficient to describe group differences. In order to compensate a possible loss to follow-up, n=70 patients per group will be included.

From the patients included in the trial, n=12 participants (four participants per study arm) will be invited to participate in a qualitative interview. This number is based on the recommendations for doing qualitative research in feasibility studies for RCTs.³⁸

Statistical methods

All statistical evaluations will be conducted using the statistical programming language R and IBM SPSS statistics V.28.0 (IBM Corporation). Variables will be described for each setting (geriatric hospitals/hospital wards and nursing homes) and individual level on an intention-to-treat basis. Outcomes will be described using means, medians, proportions (including the cumulative incidence) and corresponding spread estimates per group. Mean differences between groups and time points will be calculated. In addition, we will provide Kaplan-Meier curves for the time from inclusion in the study to the onset of IAD in the three study groups. The observations are censored if patients withdraw from the study before the onset of an IAD or if the study is terminated before the onset of an IAD. Because this is an exploratory trial, no group comparisons using formal statistical tests will be performed. However, two-sided 95% CIs for all means and proportions and for the differences in means and proportions between the three study groups will be calculated. All statistical analyses will be performed for the whole sample and for both sex strata and settings separately.

Data collection methods

All data collectors will be trained regarding accurate and reproducible data collection. Demographic characteristics and basic medical information such as main medical diagnoses and regular medication will be extracted from institutions' documentation. The skin assessments will be performed by trained blinded experienced and qualified members of the study team. Using typical IAD images, the agreement for assessing erythema (yes/no), erosion (yes/no) and maceration (yes/no) between raters will be measured. An error proportion of less than 5% is targeted. These tests will be done before data collection and regularly during the trial. Other assessments and skin measurements will be conducted in duplicate measurements by trained members of the study team, which will not be involved in the skin condition assessments.

During the study, the nurses continuously document the study-related procedures performed (cleansing, use of leave-on products, used materials) in a subject-specific diary. The study personnel checks these diaries regularly for completeness and consistency to ensure and improve compliance and adherence to the protocol. Involved nurses will participate in an interactive face-to-face educational session about the study and its associated procedures and documentation to ensure that they have study-relevant knowledge.

Data management

A paper source data file will be used for the study (online supplemental file 1). Data (informed consent process and consent retrieval, demographics, medical history, skin assessments, skin measurements, clinical scores, rating scales) will be collected during the study visits in written form. An electronic case report form (eCRF) will be developed and provided by the Clinical Trial Office (CTO) at the Charité–Universitätsmedizin Berlin. Data management, handling and storage will be conducted in accordance with the trial-specific data management plan and the International Council for Harmonisation (ICH) guidelines.

Data entry will be performed by the trial site personnel. Validation and data queries will be handled by the data management team of the study. According to a predefined query process, changes to data entries in the eCRF (if any) will be made by qualified trial site personnel. The eCRF will have an audit trail with appropriate functionality for data capture, tracking and documentation of any queries or changes. Electronic signatures will be used to verify the data and identify the person entering or changing the data (SecuTrial).

Monitoring

Monitoring of the study will be conducted by the CTO. The monitor is responsible for reviewing the study progress, verifying the adherence to the study protocol as well as the compliance to ICH-Good Clinical Practice. The monitor will visit the centre before, during and after completion of the study to ensure that the study is conducted, recorded and reported according to the protocol.

Harms

The skin-protecting product ‘ESENTA Hautschutz Spray’ (PZN: 16866747) to be used in study arm 1 is CE marked in accordance with Article 20 (1) of the European Union (EU) Medical Device Regulation (MDR) 2017/745. The investigational product is used and evaluated within its defined intended purpose in the context of the planned clinical trial. The use is considered to be safe. The skin-protecting product ‘Hydrophobes Basisgel DAC’ (study arm 2) is regarded as a cosmetic product according to the EU Regulation No 1223/2009 on cosmetic products. Because long-term care residents and patients in acute care are affected by a variety of diseases and health problems, the adverse events (AEs) and serious AEs terminology (according to EU MDR 2017/745 Article 2 (57) and (58)) will be adopted for this trial and will be used for the documentation throughout the study.

Patient and public involvement

Patient involvement was implemented by having the study protocol reviewed and advised by the German incontinence support group of affected individuals. This cooperation will continue throughout the duration of the study including the interpretation of study results in the

final report. Geriatric patients were actively involved in the development of the IAD-specific Core Outcome Set,²¹ which will be evaluated within this trial. This supports the relevance of the outcomes to be measured in this trial. As part of this trial, semistructured interviews with trial participants will be conducted to explore the views of the care receivers.

DISCUSSION

To the best of our knowledge, this exploratory trial will be the first with a head-to-head comparison of the two most important skin protector categories and applying the core outcomes in IAD research. One of the major objectives is to compare the IAD incidences of the control and intervention groups to estimate realistic effect sizes to be used for a formal sample size calculation and hypothesis testing. Furthermore, as the study procedures are integrated into the participants’ regular care, this pragmatic approach will provide insights on the feasibility of the planned interventions under real-life conditions in the geriatric acute and long-term care populations. This trial will also provide evidence regarding the feasibility of measuring the previously identified IAD-specific core outcomes. The results of the aforementioned parameters will serve as a basis to plan a possible subsequent confirmatory trial, which is eventually required for the development of evidence-based IAD prevention.

An important part of this trial is the consideration of the patient perspective. This is taken into account by the use of the IAD-specific Core Outcome Set, which was co-developed by geriatric patients; also, patient interviews with study participants will be conducted. Furthermore, this trial was developed with, and will be regularly reviewed and advised by, a German incontinence support group. The results of the qualitative part of the trial will give the opportunity to gain insight and to understand whether the delivered intervention is acceptable and feasible, from the (geriatric) patient’s point of view.

This trial will benefit patients individually as well as aged long-term care residents and patients in acute geriatric care in general. Results will provide evidence regarding effects of skin protection products for IAD prevention, which will be relevant to multiple settings and populations affected by incontinence. Due to age-related functional changes, the risk of incontinence increases, explaining its high prevalence in the geriatric population. Since treatment of the underlying incontinence is often not possible, the prevention of avoidable consequences, such as the development of IAD, is of particular importance. Improvement of prevention will contribute to a reduction of subsequent complications of IAD like secondary infections and development of PUs, leading to enhanced patient safety and improved quality of life.

The study is limited by the follow-up period of 14 days; this time might be too short to observe outcomes in subjects who are at much longer IAD risk. The follow-up time is limited by the geriatric acute care setting, as the

length of stay is between 2 and 3 weeks until discharge. We were involved in a previous trial for IAD treatment in the same acute care setting (ClinicalTrials.gov: NCT03298113); the median follow-up time was 10 days (IQR 8–15 days) and results indicate that this duration was appropriate to document clinically relevant endpoints towards healing. Because this is an IAD prevention trial, the non-occurrence of IAD and related endpoints are considered as clinically relevant as well. A study in nursing homes showed that of the residents who developed IAD, 89% did so within the first 14 days of the onset of incontinence,³⁹ suggesting that this period of time is sufficient to observe outcomes for the majority of the study population. The presence of a combined faecal and urinary incontinence as an inclusion criterion could limit the number of eligible subjects and may result in prolonged recruitment times. Although it is very important to obtain data from the patient's perspective, no qualitative data will be collected from individuals with an MMSE score of less than 24. Due to the assumption that IAD prevention measures are routine practice, qualitative data from a nursing perspective are also not collected.

ETHICS AND DISSEMINATION

The ethics committee (EC) of the Charité–Universitätsmedizin Berlin approved this study (EA4/043/22). Substantial amendments to the protocol will be submitted to the EC. The investigator will inform the EC of all problems involving risks to participants. If changes in the informed consent form (ICF) or study information become necessary, these documents will also be submitted to the EC. Prior to inclusion into the study, verbal and written study information will be provided to residents/patients and, if applicable, their legal representatives. Informed consent for each participating subject will be obtained on a written ICF approved by the EC. The information and consent procedure will be conducted by the investigator and qualified members of the study team delegated by the investigator. If during the trial one of the interventions is evidently leading to more IAD cases, this will not cause harm, because as soon as IAD develops the trial endpoint is reached and targeted interventions can be implemented.

The trial was registered on 13 June 2022, at the German Clinical Trials Register (Deutsches Register Klinischer Studien (DRKS)) (DRKS00028954) and on 3 June 2022 at ClinicalTrials.gov (NCT05403762).

After study completion, results will be uploaded at ClinicalTrials.gov and the DRKS, and published in international journals and at least in one German journal (eg, 'Pfleger'). All articles will be published open access. Results will be further presented at national and international conferences. To support dissemination of the trial results for subsequent research purposes (eg, individual patient data (IPD) meta-analyses or secondary analyses), we will provide access to anonymised IPD from this trial according to the recommendations of the International

Committee of Medical Journal Editors.⁴⁰ It is planned to share the data at zenodo.org supported by the European Commission.

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