

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The prevalence and associated factors of skin diseases in aged nursing home residents: a multicentre prevalence study.
AUTHORS	Hahnel, Elisabeth; Blume-Peytavi, Ulrike; Trojahn, Carina; Dobos, Gabor; Jahnke, Irina; Kanti, Vera; Richter, Claudia; Lichterfeld-Kottner, Andrea; Garcia Bartels, Natalie; Kottner, Jan

VERSION 1 – REVIEW

REVIEWER	Flora Balieva Stavanger University Hospital, Norway
REVIEW RETURNED	30-Jul-2017

GENERAL COMMENTS	This is an interesting and relevant topic. The paper is well written and clear. The diagnostic codes are sometimes somewhat imprecise. I have corrected several. Please check thoroughly. Please also comment how diagnoses were registered? Eg Only a main diagnosis or secondary diagnosis. Was xerosis cutis and perhaps accompanying pruritus registered as 2 diagnoses? Or only xerosis?/only pruritus if this was the main symptom? The authors make many good points and have a good conclusion. Some small spelling mistakes should be corrected.
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REVIEWER	Jo Middleton (Research Fellow) Department of Primary Care and Public Health, Brighton & Sussex Medical School, UK
REVIEW RETURNED	01-Aug-2017

GENERAL COMMENTS	<p>1 GENERAL POINTS</p> <p>1.1 STRUCTURE The paper is well structured throughout, and conforms to the STROBE checklist (which is attached).</p> <p>1.2 STYLE, VOICE, AND LEXICAL CONCERNS Overall the paper is very well written, in a clear manner and consistent voice.</p> <p>1.2.1 (!!) Title and throughout, 'nursing homes'</p>
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	<p>Whilst I am very familiar with residential care for the elderly in my own country, I am not familiar with the structure of the sector in Germany, as I also imagine many international readers may not be. I mention this as residential care for the elderly differs markedly between countries. In the UK for example the majority of long term care facilities for the elderly are 'residential care', staffed by relatively basically trained staff, only a minority are 'nursing homes', with registered nurses in attendance. In the UK there is a substantial difference re co-morbidities etc. between those who live in 'residential care' and those in 'nursing homes'. As this study states it is the largest randomised prevalence study of skin disease carried out by dermatologists in this setting, more detail on what the setting is would be helpful. Specifically, in Germany are all care homes for the elderly with nursing? (there is no mention in the article of any other type of care facility). If so it would be helpful contextual detail for readers to ascertain (i) generalisability to patient groups in their own countries, (ii) relevance of training recommendations for the non-defined 'healthcare providers in the nursing homes' (p15, 52-53)/'caregivers' (p15, 59). I suspect it isn't, but if 'nursing homes' is being used to mean also homes without qualified nurses, I would suggest for international readers 'long-term care facility for the elderly' may be a more appropriate label. Overall though, a bit more contextual detail on the study setting would be helpful.</p> <p>1.2.2 (!) p4, 20: 'PU'. First usage, please put in full (presumably 'Pressure Ulcer').</p> <p>1.2.3 (!) p6, 58; throughout (inc. tables): 'gender' The paper uses 'gender' when I presume it means 'sex'. The demographic information collected seems to be biological sex - male/female (i.e. P15, 23-34: male gender, biological characteristics; P31, Table S2: Gender (0=male, 1=female) - not gender. I cannot find BMJ guidance on this but the most up to date author guidance from The Lancet is below. Clarity here is important as the article mentions specific claims about biological sex based associations with disease prevalence ('The association of male gender [sic] and androgenetic alopecia and actinic keratosis may be explained by genetic and biological processes', p15, 23-41). 'For all study types, we encourage correct use of the terms sex (when reporting biological factors) and gender (when reporting identity, psychosocial, or cultural factors). Where possible, report the sex and/or gender of study participants, and describe the methods used to determine sex and gender. Separate reporting of data by demographic variables, such as age and sex, facilitates pooling of data for subgroups across studies and should be routine, unless inappropriate. Discuss the influence or association of variables, such as sex and/or gender, on your findings, where appropriate, and the limitations of the data' [www.thelancet.com/pb/assets/raw/Lancet/authors/tlo-information-for-authors.pdf]</p> <p>1.2.4 (!) p9, 43-45; 'A vocational training was the highest educational degree [my emphasis] for the majority (48.9%)' I suggest changing 'degree' to 'level' as use of 'degree' here could be incorrectly read as referring to University education (which can include vocational training, nurses etc.)</p> <p>1.3 ETHICS Details ethical approval and gives details of where study protocol was published.</p> <p>1.3.1 (!!) p9, 31: '252 residents (31.1%) provided written informed consent and n=233 were included' This is inaccurate, unless all participants gave consent themselves,</p>
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	<p>rather than were brought into the study following consultation with their legal representatives (as per P5, line 36). I suggest clarifying with the number of residents who provided written consent, and the number who participated on the basis of recommendation from their legal representatives. This should also be reflected in the associated cohort diagram.</p> <p>1.3.2 (!) p6, 36: 'written informed consent given personally or by legal representative'.</p> <p>Across multiple jurisdictions one of the barriers to research in this setting has been the legal implications of research participation by those lacking capacity to consent due to dementia and associated cognitive impairments. I have checked the pre-published protocol for this study and no more detail is given about this aspect. The authors may feel the mention given is sufficient as it is not the topic of the paper. However given at least part of the readership will be those concerned with carrying out research in this setting the authors may like to give some more detail about: (i) how they determined that individual residents lacked capacity to consent to this particular piece of research, or, if it was instead done on the authority of a pre-existing decision what it was and who conveyed it to the research team, (ii) if in Germany 'legal representatives' have power to consent others into research participation IN ADDITION to medical care. This may all be relatively simple in Germany, but it is not elsewhere and even a small amount of detail on this aspect would aid international readers.</p> <p>The following papers address this issue and will explain to the authors why this may be worth addressing for international readers. I worked on the study on scabies outbreaks in care homes that triggered this discussion, but am NOT an author on any of the ethics papers below and only have co-authors on one of them (the last in the list).</p> <p>Power of Attorney for Research: The Need for a Clear Legal Mechanism. Public Health Ethics. DOI: https://doi.org/10.1093/phe/phw035</p> <p>Is Anticipated Consent an Acceptable Model for a Unique Cohort of Research Participants? Commentary on Case Study of Scabies in Nursing Homes. Public Health Ethics. DOI: https://doi.org/10.1093/phe/phw022</p> <p>Researching Scabies Outbreaks among People in Residential Care and Lacking Capacity to Consent: A Case Study. Public Health Ethics. DOI: https://doi.org/10.1093/phe/phv011</p> <p>2 ABSTRACT No concerns, except my point above re 'Nursing Homes' (1.2.1)</p> <p>3 ARTICLE SUMMARY No concerns.</p> <p>4 INTRODUCTION Good overview of the topic. However, could do with more contextual detail re care sector in Germany and clarification re 'nursing homes' (1.2.1).</p> <p>5 METHODS 5.1 QUALITY OF DATA SOURCES AND METHODS</p>
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	<p>The study method is appropriate, and it is especially pleasing to see the home selection followed randomisation and home level demographics compared to national demographics for this setting.</p> <p>5.1.1 (!!) p6, 53-55: 'Concomitant disease...and medications were extracted from the medical records.'</p> <p>What medical records these exactly are is not stated, it would be helpful to state the data source, primary care?, nursing home records? This is worth stating for clarity, but also as from my experience the latter are not always reliable and would, in a UK context at least, be a potential limitation worth stating.</p> <p>5.2 SPECIFIC ISSUES WITH METHODS</p> <p>5.2.1 (!) p6, 53-55. Medical history of participants was collected from records, and it is not stated whether the examining clinicians had access to this data prior to or during examinations. Either way this should be stated. If the data had already been collected and the clinicians were not blinded to it this could have biased detection and would be worth considering listing under limitations.</p> <p>5.2.2 (!) p6, 37-38: 'Residents at the end of life were not considered eligible.'</p> <p>I commend the authors for listing this in limitations (P12, 45-46: 'We also excluded residents at the end of life which may have led to selection bias.'), but it would also be good to explicitly say in methods WHY end of life residents were not considered eligible. I can make my own guess, but I might be wrong.</p> <p>5.2.3 (!) I don't know if dermatoscopes were used during examinations, but if they were this should be stated, including type/model.</p> <p>6 RESULTS</p> <p>Clear and well presented, but see re Gender/Sex reporting (1.2.3).</p> <p>7 DISCUSSION</p> <p>7.1 KEY RESULTS</p> <p>Good summary, no concerns.</p> <p>7.2 LIMITATIONS</p> <p>Good honest summary, no concerns (but see 5.2.1).</p> <p>7.3 INTERPRETATION</p> <p>Well written, with a logical flow of argument and referencing relevant literature which is up-to-date. I agree with their conclusion that an algorithm to guide diagnosis, care, and referrals for skin disease in this sector is needed, and this recommendation does seem supported by their wider argument and the study data.</p> <p>7.3.1 GENERALISABILITY</p> <p>Good to see this clear statement which does support the generalisability of study, though see my concerns re international readers and 'nursing homes' (1.2.1).</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1: This is an interesting and relevant topic. The paper is well written and clear. The diagnostic codes are sometimes somewhat imprecise. I have corrected several. Please check thoroughly. Please also comment how diagnoses were registered? Eg Only a main diagnosis or secondary diagnosis. Was xerosis cutis and perhaps accompanying pruritus registered as 2 diagnoses? Or only xerosis?/only pruritus if this was the main symptom?

The authors make many good points and have a good conclusion.

Some small spelling mistakes should be corrected.

Response: Thank you very much for this comment. Please find our point-by-point responses below.

Comment 1: Is this completely true? A seborrheic keratosis is probably not so adverse? You make a point later on how not all conditions require care or specialized interventions. Perhaps omit, or use other adjective? (Page 2, line 38: Conclusion)

Response: Thank you for your comment and we agree. We toned down the wording accordingly.

Changes to the manuscript:

Page 2, section: 'Abstract' (Conclusion):

'Study results indicate, that almost every resident living in residential care has at least on dermatological diagnosis.'

Comment 2: An overview of the number not eligible should be given as well in order to show how representative for the whole nursing population the population observed is. Perhaps comment on possible skin conditions that thus may have been missed eg. decubitus in non-mobile patients could be higher? (Page 6, line 38: Participants)

Response: We agree that this information is very important. According to STROBE the section 'Participants' describes the in- and exclusion criteria. We reworded the sentence and added some explanations to make this clearer. We do not have any data about persons who refused consent. According to the applicable laws this is only allowed after consent. Persons at the end of life, persons who did not want to participate were not seen. Therefore we are not able to give an overview of the characteristics of residents not participating. We just have the information, that from the n = 811 nursing home residents living in the nursing home at time of data collection, n = 39 were younger than 65 years old (which was an exclusion criterion), and n = 520 do not want to participate. Later, in the Generalizability section we expand the discussion about possible non-response bias.

Changes to the manuscript:

Page 6, section 'Participants':

'The exclusion criteria was residents at the end of life to avoid unnecessary burden due to the examinations. All residents (or their legal representatives) living in the residential care facility at time of data collection were invited to participate.'

Page 17, section 'Generalisability':

'However, a systematic exclusion of for instance highly care depended residents who might also been at higher PU risk may have introduced non-response bias.'

Comment 3: Are all nursing homes very alike in Berlin? Public vs private? Perhaps mention if there is any difference or not between nursing homes in the Berlin area. You mention this briefly in limitations, but perhaps elaborate as to how much the study group is in reality representable. (Page 7, line 46: Bias)

Response: Nursing homes in Berlin vary in terms of size, ownership etc. In order to reduce selection bias we applied the random sampling of all nursing homes. We added explanations in the methods section ('Setting' and 'Bias').

Changes to the manuscript:

Throughout the manuscript: Rewording of the term 'nursing home'.

Page 6, section 'Setting' (Materials and Methods):

'In Germany, institutional long-term care facilities or residential care facilities are full-time

accommodations with professional care. The staff is a mix between registered nurses and nursing assistants. Using computer generated random numbers, institutional long-term care facilities from a list of all existing facilities (n = 291) in the federal state of Berlin, Germany were contacted.'

Page 8, section 'Bias' (Materials and Methods):

'Institutional long-term care facilities in the state of Berlin differ in terms of ownership, size, and specialization. In order to reduce selection bias institutions were randomly selected from all facilities of the state of Berlin.'

Comment 4: How was significance calculated? (Page 8, line 49: Statistical methods)

Response: We added the explanation in the methods section accordingly.

Changes to the manuscript:

Page 9, section 'statistical methods' (Materials and Methods):

'95% confidence intervals of the odds ratios excluding 1 were considered to be statistically significant'

Comment 5: Please comment whether the participants can be seen as completely representative for the whole population when nursing home characteristics differ and less than 50% participated. (Page 9, line 19: Participants)

Response: We agree that the low-response rate may have introduced bias. We expanded the discussion under the heading 'generalisability' on page 17.

Changes to the manuscript:

Page 17, section 'Generalisability':

'Despite a response rate of 27.5% of residents living in the residential care facilities at time of data collection, demographic data like (...).'

Comment 6: Is this a significant OR? Especially since the CI is below 1? The other ORs are also quite low. Perhaps formulate differently? Is there truly an association? (Page 10, line 25: main results)

Response: Thank you for detecting this error. Because the 95% CI includes 1 it is not statistically significant. We corrected this in table 2 and deleted the result in the text accordingly.

Changes to the manuscript:

Page 11, section 'main results':

'(...) and intertrigo (OR = 1.052, 95% 1.004 to 1.102).'

Page 13, section 'key results':

'Increasing age leads to increased risks of seborrheic keratosis and intertrigo and to decreased risks of having seborrheic dermatitis.'

Please find the correction in table 2 (Bold type and underlining of the OR was deleted)

Comment 7: It is probably redundant to mention this as a significant result since this is predominantly a male condition and is very rare in females, you would have to weight the cases or adjust somehow for presenting the expected vs seen results. Perhaps not present this data in this way, but instead comment that this is expected or confirmed to be as in the normal population, i.e. as in not nursing home population. (Page 10, line 30: main results).

Response: We totally agree that this condition is predominantly seen in males but females especially in advanced aged are affected as well (female pattern hair loss). We feel that it is appropriate to present the results as they are in the Results section. We discuss possible sex differences in the Discussion part.

Changes to the manuscript:

Page 16, section 'Interpretation':

'The association of male sex and androgenetic alopecia was expected, because in the Caucasian population the prevalence increases with age in men up to 80% and in women up to 42%.⁴⁶ This may be also associated with actinic keratosis. Because men have a greater incidence higher prevalence of pattern baldness, there is a reduced natural UV protection on the scalp skin which caused a higher occurrence of actinic keratosis.'

Comment 8: Some could be pooled - eg. Aphtha, mucosal and Oral aptha. Tear of skin, abrasion, skin injury might also belong in the same group. Perhaps even some of the others (Eczema craquele and xerosis, nummulat eczema and sepcified or not-specified eczemas could perhaps be pooled) - gives a better overview of the represented conditions. (Page 12, line 10: Key results)

Response: Thank you for your comment. We checked and discussed the supplementary table again with the dermatologists. We pooled Aphta mucosal and oral aphtosis as well as xerosis and eczema craquelé. We corrected this in the manuscript file under the headings 'abstract', 'key results', 'main results' and in the supplementary table S1 accordingly.

Changes to the manuscript:

Page 2, section 'Abstract':

'In total, 60 dermatological diseases were diagnosed.'

Page 11, section 'Main results':

'In total, 60 dermatological diseases were diagnosed.'

Page 13, section 'Key results':

'In total, 60 dermatological diseases were diagnosed, which was unexpectedly high.'

Page 14, section 'Interpretation':

'We diagnosed a broad spectrum of dermatological conditions in our study population with a total number of 60 diagnoses, which is unexpectedly high.'

Comment 9: This is somewhat diffuse as the statistics were not so strong. See also comment in table. (Page 10, line 24: key results)

Response: We agree that despite statistical significance the odds ratios were near 1. We extended the interpretation of the size and direction in the Discussion. In the section 'Main results' we feel that it is appropriate to present the results as they are.

Changes to the manuscript:

Page 13, section 'key results':

'In the majority the strengths of associations were small.'

Comment 10: Should an apostrophy be used here? The same is used other places. Please check if this is correct. (Page 13, line 21: Interpretation)

Response: Thank you for your comment. We deleted the apostrophes.

Throughout the manuscript: Rewording 'prevalence's' to 'prevalences'.

Comment 11: How did patients with PU in your study differ from the patients in the ither studies?

Age? Or did patients with PU agree more often to participate compared to non-participants? What is expected in form of prevlence if life-support patients also were examined? (Page 13, line 23: Interpretation)

Response: In this manuscript we did not analyse the group of PU patients separately. Therefore we are unable to do this comparison here. Whether this high proportion can be explained by response bias is difficult to explain. What is very well in institutional long-term care is underreporting during routine data collections, audits or chart reviews. The head-to-toe skin examination is likely to increase the internal validity and thus the accuracy of the estimates. We added this thought to the discussion.

Changes to the manuscript:

Page 14, section 'Interpretation':

'The PU prevalence of 9% was substantially higher compared to previous studies^{30, 31} of the German long-term care setting. The main reason for this finding is unclear. Underreporting is a well-known phenomenon in epidemiological PU research.^{32, 33} The full head-to-toe skin examination supports the internal validity and the accuracy of this point estimate. This indicates that PUs are a substantial problem in German long-term care settings.'

Comment 12: How do you define intertrigo? See comment in table - candida ICD-10 is used. (Page

13, line 52: Interpretation)

Response: Thank you for your comment. We corrected the ICD 10 code for intertrigo accordingly. We define intertrigo (L30.4) as an inflammation of the body folds caused by warm, moist skin areas. Candida (Candidiasis (B 37.9) in the Table) differ from that diagnosis and is defined as a candida infection of the skin. We critically reviewed concepts and ICD 10 codes throughout the manuscript and discussed these with the dermatologists. We aspired to make the codes as precise as possible. Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 13: How does this apply if patients no longer work. If not other comment that these occupational dermatoses are expected to be lower, less prevalent, or get better. You would also need to describe if these occupations were very represented in the study population. (Page 15, line 12: Interpretation)

Response: Thank you very much for this comment. We assume that the life-time exposure plays a role in developing hand eczema or contact dermatitis. We agree, that this might be confusing for the reader, because we do not show data about the occupational past of the residents. Therefore we decided to delete this sentence.

Changes to the manuscript:

Page 16, section 'Interpretation':

Following sentence was deleted:

'Furthermore, work in metal industry or exposures to wet trades, for example hairdressers or medical professions can play a role in the development of hand eczema^{43, 44} or contact dermatitis.^{45, 46}'

Comment 14: I would say that androgenetic alopecia most certainly is explained by this, not may be. I understand you mean that the higher prevalence of AGA may be the reason for higher AK, but it reads as if AGA may be higher in men because they are men... Reformulate? (Page 15, line 23: Interpretation)

Response: We reworded the sentence accordingly and added more explanations.

Changes to the manuscript:

Page 16, section 'Interpretation':

'The association of male sex and androgenetic alopecia was expected, because in the Caucasian population the prevalence increases with age in men up to 80% and in women up to 42%.⁴⁶ This may be also associated with actinic keratosis. Because men have a higher prevalence of pattern baldness, there is a reduced natural UV protection on the scalp skin which caused a higher occurrence of actinic keratosis.'

Comment 15: I think you could comment in more detail. You only give an example on sex, but present a lot of patient characteristics (age, education and so on...). Also the low participation rate as to generalisability should be commented, including the patients not eligible or not included. Eg: how many were on life support? (Page 16, line 30: Generalisability)

Response: Thank you for your comment. We added more comments. We agree that it is interesting to know, why residents declined participation. Due to the data protection regulations, we were not allowed to collect any data of the residents not included. We added a comment regarding the low participation rate.

Changes to the manuscript:

Page 17, section 'Generalisability':

'In comparison to the German care statistics, the participating institutional long-term care facilities were more private owned (60% vs. 40.8% in the German care statistic) and there were less non-profit institutions (30% vs. 55.8% in the German care statistic) which may limit the generalisability of results.⁵³ Despite a response rate of 27.5% of residents living in the residential care facilities at time of data collection, demographic data like age, sex and care dependency are well comparable with the general German (...)'

Comment 16: Could you comment on possible explanations for not giving consent? 1. Did the residents perhaps have problems understanding? Not able to give consent (eg because of dementia?) or speculate whether patients could have a skin condition, embarrassment of being seen. The latter could potentially lead to underdiagnostic. (Page 22, Flow-Chart)

Response: Thank you for your comment. We did not systematically collect data of residents or their legal representatives not giving consent. The procedure of recruitment was to hand out flyers and posters onsite the residential care facilities. The director/senior nurse of the institutions additionally send letters to all residents and relatives to inform about the study and invited all interested residents/relatives to kick-off meetings (due to data protection regulations we were not allowed to send the letters by our self). Via these meetings we informed personally all residents/relatives about the conduct of the study. Finally, we invited residents personally on the wards. We assume that main reasons for not responding was low interest of the residents or the legal representatives. We added the non-response discussion to the limitations and generalisability sections and updated the Flow-Chart with all information we have.

Changes to the manuscript:

Page 13, section 'Limitations':

'In total, n = 559/811 residents living in the institutional long-term care at time of data collection did not responded which may had led to a possible selection bias.'

Page 17, section 'Generalisability':

'A response bias due to the informed consent procedure cannot be excluded as well.'

Please find the corrections in the Flow-Chart on Page 24.

Comment 17: How was statistical significance defined? CI95% is from lower than 1 to above 1. I may not have understood the performed tests correctly but if 95% of values are within this interval they could easily be mostly equal to 1. If I am wrong please explain so other readers like me also can understand. Sometimes using age groups could give more clear results, eg. 65-75 years and 75 and above, then age differences are easier to register. Just a suggestion. (Page 24, Table 2)

Response: Thank you very much for your comment. P-values of <0.05 were considered to be statistically significant which corresponds to 95% CIs excluding 1. We added an explanation in the methods section accordingly. We used the biserial correlation (Spearman rho correlation coefficient) to examine the strengths of associations between skin diseases and demographic and medical variables. We agree that age groups may enhance contrasts but dichotomization or categorization always reduces statistical power. Because of the sample size we would prefer to treat age as continuous variable. The 95% CI for neoplasm range from 0.999 to 1.134, and therefore it is not statistically significant. We corrected that in Table 2 and in the main results, key results section accordingly.

Changes to the manuscript:

Page 9, section 'statistical methods' (Materials and Methods):

'95% confidence intervals of the odds ratios excluding 1 were considered to be statistically significant'

Page 11, section 'main results':

'(...) and intertrigo (OR = 1.052, 95% 1.004 to 1.102).'

Page 13, section 'key results':

'A university qualification may be protective against xerosis cutis. Increasing age leads to increased risks of seborrheic keratosis and intertrigo and to decreased risks of having seborrheic dermatitis.'

Please find the correction in table 2 (Bold type and underlining of the OR was deleted)

Comment 18: ICD 10? Perhaps L30.8? (Page 29, Table S1)

Response: Thank you for that important comment. An ICD 10 code for IAD does not exist. This was discussed internationally already in the context of the new ICD-11. In the Beta-draft version online it will be named 'Irritant contact dermatitis due to incontinence'. We added this information in the methods section accordingly to make this clear.

Changes to the manuscript:

Page 7, section 'Variables' (Materials and Methods):

'(...) with the exception of IAD and skin tears. IAD was diagnosed according to the IAD-IT classification of Junkin 200816.'

Comment 19: L30.4B37.2 is a candidal infection? Was this the case? Or any intertrigo? Then use L30.4 (Page 29, Table S1)

Response: We agree and corrected the ICD 10 code in the supplementary table S1.

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 20: Acrochordon. ICD10 L91.8? (Page 29, Table S1)

Response: Thank you for your comment. We agree and corrected the diagnosis and ICD 10 code in the supplementary table S1.

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 21: Is this not the same as superficial injury and open wounds? Or T14.8? Or pool together? Will rank higher, end is perhaps more correct with patients having more problems with small traumatic wounds and tears. Just a suggestion. (Page 29, Table S1)

Response: Thank you for your comment. Skin tears are caused by shear, friction and/or blunt force causing the separation of the layers of the skin (partial or full thickness wound) most common on the extremities (LeBlanc, 2011). We added an explanation in the method section, because we think that skin tears are a distinct diagnostic category. Skin tears were diagnosed based on an international consensus.

Changes to the manuscript:

Page 6, section 'Variables' (Materials and Methods):

'According to an international consensus skin tears are caused by shear, friction and/or blunt force causing the separation of the layers of the skin (partial or full thickness wound) most common on the extremities.17 Skin tears were recorded as present/absent. '

Comment 22: L40.- is probably more correct here. Or did the patients only have flexural psoriasis? In this case change to Flexural psoriasis. PS: in this case, how was this differentiated from intertrigo? (Page 29, Table S1)

Response: We agree and corrected the ICD 10 into L40.-.

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 23: See the one before the last, repetition (Page 29, Table S1)

Response: It is a repetition indeed. The ICD code K12.0 was in total in 2/223 cases. We corrected this in the supplementary table S1 accordingly.

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 24: A form of Tinea corporis? (Page 30, Table S1)

Response: Pytirisias versicolor is a separate diagnosis. It is also a fungal infection of the skin with spots or patches of white, pink, red or brown skin colors which can be lighter or darker than the skin around. The spots can occur anywhere on the body, but are most common on the neck, check, back and arms. Because this differs from tinea corporis we would like to have this as additional code.

Changes to the manuscript:

No changes were made.

Comment 25: Isn't this the serious form of Xerosis cutis? (Page 30, Table S1)

Response: We agree totally that Eczema craquelé is a severe subcategory of xerosis cutis and occurs as a result of very dry skin. We deleted Eczema craquelé as a separate diagnosis in the supplementary table S1.

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Comment 26: Already given as Aphtha, mucosal. Same à patient or 2 patients? (Page 30, Table S1)

Response: We agree, and corrected that in the supplementary table S1 (please see also the comment 23.)

Changes to the manuscript:

Please find the correction in the supplementary table S1.

Reviewer #2: The prevalence and associated factors of skin diseases in aged nursing home residents: a multicentre prevalence study. BMJ Open Congratulations to the authors on a valuable piece of research on a relatively understudied population. As someone who has worked on a multi-centre skin disease study in care homes for elderly I can imagine how logistically difficult this research was to carry out, and commend the study team for successfully collecting the reported data. There are no major methodological or reporting errors and I recommend publication with minor revisions. I am happy to review the paper again if helpful. I have flagged my queries and suggestions for improvements as (!) for the least serious, and (!!) for the more serious.

Response: Thank you very much for your encouraging comments and the opportunity to improve this manuscript for publication. Please find our point by point responses below.

Comment 1: 1 GENERAL POINTS

1.1 STRUCTURE

The paper is well structured throughout, and conforms to the STROBE checklist (which is attached).

Response: Thank you very much.

Comment 2: 1.2 STYLE, VOICE, AND LEXICAL CONCERNS

Overall the paper is very well written, in a clear manner and consistent voice.

1.2.1 (!!) Title and throughout, 'nursing homes'

Whilst I am very familiar with residential care for the elderly in my own country, I am not familiar with the structure of the sector in Germany, as I also imagine many international readers may not be. I mention this as residential care for the elderly differs markedly between countries. In the UK for example the majority of long term care facilities for the elderly are 'residential care', staffed by relatively basically trained staff, only a minority are 'nursing homes', with registered nurses in attendance. In the UK there is a substantial difference re co-morbidities etc. between those who live in 'residential care' and those in 'nursing homes'. As this study states it is the largest randomised prevalence study of skin disease carried out by dermatologists in this setting, more detail on what the setting is would be helpful. Specifically, in Germany are all care homes for the elderly with nursing? (there is no mention in the article of any other type of care facility). If so it would be helpful contextual detail for readers to ascertain (i) generalisability to patient groups in their own countries, (ii) relevance of training recommendations for the non-defined 'healthcare providers in the nursing homes' (p15, 52-53)/'caregivers' (p15, 59). I suspect it isn't, but if 'nursing homes' is being used to mean also homes without qualified nurses, I would suggest for international readers 'long-term care facility for the elderly' may be a more appropriate label. Overall though, a bit more contextual detail on the study setting would be helpful.

Response: Thank you for your comment. We added an explanation in the methods section

accordingly. In Germany 'nursing homes' are long-term care institutions providing professional care by registered nurses and nursing assistants. In most cases the percentage of assistants is higher than of RNs. Based on the comments we feel indeed that the term 'institutional long-term care facility' may be more suitable in the international context. We reworded this term accordingly.

Changes to the manuscript:

Throughout the manuscript: Rewording of the term 'nursing home'.

Page 6, section 'Setting' (Materials and Methods):

'In Germany, institutional long-term care facilities or residential care facilities are full-time accommodations with professional care. The staff is a mix between registered nurses and nursing assistants. Using computer generated random numbers, institutional long-term care facilities from a list of all existing facilities (n = 291) in the federal state of Berlin, Germany were contacted.'

Comment 3: 1.2.2 (!) p4, 20: 'PU'.

First usage, please put in full (presumably 'Pressure Ulcer').

Response: Thank you. Pressure ulcer was first mentioned and the abbreviation given on page 4, line 20.

Comment 4: 1.2.3 (!) p6, 58; throughout (inc. tables): 'gender'

The paper uses 'gender' when I presume it means 'sex'. The demographic information collected seems to be biological sex - male/female (i.e. P15, 23-34: male gender, biological characteristics; P31, Table S2: Gender (0=male, 1=female) - not gender. I cannot find BMJ guidance on this but the most up to date author guidance from The Lancet is below. Clarity here is important as the article mentions specific claims about biological sex based associations with disease prevalence ('The association of male gender [sic] and androgenetic alopecia and actinic keratosis may be explained by genetic and biological processes', p15, 23-41).

'For all study types, we encourage correct use of the terms sex (when reporting biological factors) and gender (when reporting identity, psychosocial, or cultural factors). Where possible, report the sex and/or gender of study participants, and describe the methods used to determine sex and gender. Separate reporting of data by demographic variables, such as age and sex, facilitates pooling of data for subgroups across studies and should be routine, unless inappropriate. Discuss the influence or association of variables, such as sex and/or gender, on your findings, where appropriate, and the limitations of the data' [www.thelancet.com/pb/assets/raw/Lancet/authors/tlo-information-for-authors.pdf]

Response: Thank you very much for this very important comment and for sharing the reference. We totally agree that the term 'sex' is more appropriate. We reworded this throughout the manuscript.

Changes to the manuscript:

Page 7, section 'variables' (Materials and Methods):

'Demographic variables of the nursing home residents (e.g. age, sex) were collected.'

Page 8, section 'data sources and measurement':

'Demographic characteristics (e.g. age, sex) (...)'

Page 11, section 'main results':

'Female sex showed (...)'

Page 16, section 'Interpretation':

'Male sex was strongly associated (...)'

Page 17, section 'Generalisability':

'(...) demographic data like age, sex and care dependency are (...)'

Comment 5: 1.2.4 (!) p9, 43-45; 'A vocational training was the highest educational degree [my emphasis] for the majority (48.9%)'

I suggest changing 'degree' to 'level' as use of 'degree' here could be incorrectly read as referring to University education (which can include vocational training, nurses etc.)

Response: We reworded 'degree' into 'level' accordingly.

Changes to the manuscript:

Page 10, section 'descriptive data':

'A vocational training was the highest educational level for the majority (48.9 %).'

Comment 6: 1.3 ETHICS

Details ethical approval and gives details of where study protocol was published.

Response: Thank you very much.

Comment 7: 1.3.1 (!) p9, 31: '252 residents (31.1%) provided written informed consent and n=233 were included'

This is inaccurate, unless all participants gave consent themselves, rather than were brought into the study following consultation with their legal representatives (as per P5, line 36). I suggest clarifying with the number of residents who provided written consent, and the number who participated on the basis of recommendation from their legal representatives. This should also be reflected in the associated cohort diagram.

Response: Thank you very much for your comment. We checked our data and added this information in the manuscript and updated the Flow-Chart.

Changes to the manuscript:

Page 10, section 'Participants' (Results):

'In total, n = 811 long-term care residents were assessed for eligibility, n = 58 residents (23%) provided written informed consent by themselves and for n = 194 residents (77%) the legal representative gave consent for participation. In total n = 29 residents declined participation prior examination resulting in n = 223 included long-term care residents (Fig. 1).'

Please find the corrections in the Flow-Chart on Page 24.

Comment 8: 1.3.2 (!) p6, 36: 'written informed consent given personally or by legal representative'.

Across multiple jurisdictions one of the barriers to research in this setting has been the legal implications of research participation by those lacking capacity to consent due to dementia and associated cognitive impairments. I have checked the pre-published protocol for this study and no more detail is given about this aspect. The authors may feel the mention given is sufficient as it is not the topic of the paper. However given at least part of the readership will be those concerned with carrying out research in this setting the authors may like to give some more detail about: (i) how they determined that individual residents lacked capacity to consent to this particular piece of research, or, if it was instead done on the authority of a pre-existing decision what it was and who conveyed it to the research team, (ii) if in Germany 'legal representatives' have power to consent others into research participation IN ADDITION to medical care. This may all be relatively simple in Germany, but it is not elsewhere and even a small amount of detail on this aspect would aid international readers.

The following papers address this issue and will explain to the authors why this may be worth addressing for international readers. I worked on the study on scabies outbreaks in care homes that triggered this discussion, but am NOT an author on any of the ethics papers below and only have co-authors on one of them (the last in the list).

Power of Attorney for Research: The Need for a Clear Legal Mechanism. Public Health Ethics. DOI: <https://doi.org/10.1093/phe/phw035>

Is Anticipated Consent an Acceptable Model for a Unique Cohort of Research Participants?

Commentary on Case Study of Scabies in Nursing Homes. Public Health Ethics. DOI:

<https://doi.org/10.1093/phe/phw022>

Researching Scabies Outbreaks among People in Residential Care and Lacking Capacity to Consent: A Case Study. Public Health Ethics. DOI: <https://doi.org/10.1093/phe/phv011>

Response: Thank you very much for that much important comment and the references. We did not determine whether the individual resident lacked capacity to consent. The procedure of recruitment was to hand out flyers and posters onsite the residential care facilities. The director/senior nurse of the institutions send letters to the all legal representatives to inform about the study and invited all interested residents/relatives to kick-off meetings and study participation. Due to the data protection regulations we were not allowed to approach the residents by ourselves. The procedure to gather written informed consent in that way was approved by the local ethics committee (Charité-Universitätsmedizin Berlin (EA1/190/14)). In case that a legal representative was existing, this person signed the informed consent form on behalf of the resident. If the resident declined participation verbally prior or during the examination we respect that of course, even if the legal representative signed the ICF (in total n =6, please see that information in the Flow-Chart). In Germany legal representatives have the power to consent for participation in clinical research. We agree that research in that field is highly challenging and added some more explanations in the methods and discussion.

Changes to the manuscript:

Page 6, section 'Participants' (Materials and Methods):

'Only residents being able to give informed consent by themselves or having a legal representative who decided on behalf of the resident took part in this study.'

Page 14, section 'Interpretation':

'Research in this setting is challenging due to difficulties of gathering written informed consent (e.g. due to dementia and associated cognitive impairments).²³ Irrespectively from that, besides a study published (...).'

Page 17, section 'Generalisability':

'A response bias due to the informed consent procedure cannot be excluded as well.'

Comment 9: 2 ABSTRACT

No concerns, except my point above re 'Nursing Homes' (1.2.1)

Response: Thank you very much. We reworded this term accordingly (please see comment 2).

Comment 10: 3 ARTICLE SUMMARY

No concerns.

Response: Thank you very much.

Comment 11: 4 INTRODUCTION

Good overview of the topic. However, could do with more contextual detail re care sector in Germany and clarification re 'nursing homes' (1.2.1).

Response: Thank you for your comment. We added details in the introduction and methods setting.

Changes to the manuscript:

Page 4, section 'Introduction':

'According to the latest statistics there are 800.000 residents living in 13.600 long-term care institutions in Germany¹⁵ and these figures are expected to increase. At the same time the prevalence of skin diseases in this care setting is largely unknown.'

Page 6, section 'Setting' (Materials and Methods):

'In Germany, institutional long-term care facilities or residential care facilities are full-time accommodations with professional care. The staff is a mix between registered nurses and nursing assistants.'

Comment 12: 5 METHODS

5.1 QUALITY OF DATA SOURCES AND METHODS

The study method is appropriate, and it is especially pleasing to see the home selection followed randomisation and home level demographics compared to national demographics for this setting.

Response: Thank you very much.

Comment 13: 5.1.1 (!) p6, 53-55: 'Concomitant disease...and medications were extracted from the medical records.'

What medical records these exactly are is not stated, it would be helpful to state the data source, primary care?, nursing home records? This is worth stating for clarity, but also as from my experience the latter are not always reliable and would, in a UK context at least, be a potential limitation worth stating.

Response: Records in the long-term care setting consist of nursing documentation and medical documentation. The GPs are responsible for completing the medical records which also includes prescriptions and other medical issues. We added explanations in the text. Of course there may be limitations regarding documentation quality. We added this to the limitations.

Changes to the manuscript:

Page 7, section 'Variables' (Materials and Methods):

'Concomitant diseases (ICD 10 classification level 1) and medications were extracted from the medical records. These contain documentation of anamnesis, diagnoses, examination results, therapies and results, interventions, consents and medical letters.'

Page 13, section 'Limitations':

'We also had no control over the documentation quality of the medical records.'

Comment 14: 5.2 SPECIFIC ISSUES WITH METHODS

5.2.1 (!) p6, 53-55. Medical history of participants was collected from records, and it is not stated whether the examining clinicians had access to this data prior to or during examinations. Either way this should be stated. If the data had already been collected and the clinicians were not blinded to it this could have biased detection and would be worth considering listing under limitations.

Response: The trained study assistants collected the data from the records. The board certified dermatologists had no access to the medical history prior and during the examinations. We added this to the manuscript.

Changes to the manuscript:

Page 8, section 'Bias' (Materials and Methods):

'The board certified dermatologists had no access to medical history data of the residents prior and during examinations to reduce the risk of detection bias.'

Comment 15: 5.2.2 (!) p6, 37-38: 'Residents at the end of life were not considered eligible.'

I commend the authors for listing this in limitations (P12, 45-46: 'We also excluded residents at the end of life which may have led to selection bias.'). but it would also be good to explicitly say in methods WHY end of life residents were not considered eligible. I can make my own guess, but I might be wrong.

Response: We excluded residents at the end of life (dying persons) for ethical reasons. We decided to avoid unnecessarily burden due to the examinations. We examine the residents from head to toe, therefore we have to assist to undress, to reposition the residents and that might be too much physical and psychological stress for the resident.

Changes to the manuscript:

Page 6, section 'Participants' (Materials and Methods):

'The exclusion criteria was residents at the end of life to avoid unnecessarily burden due to the examinations'

Comment 16: 5.2.3 (!) I don't know if dermatoscopes were used during examinations, but if they were this should be stated, including type/model.

Response: Dermatoscopes were used during examinations. We added this in the manuscript.

Changes to the manuscript:

Page 7, section 'data sources and measurement' (Materials and Methods):

'Examinations were done by clinical evaluation and using dermatoscopes (Dermogenius basic, DermoScan GmbH, Germany).'

Comment 17: 6 RESULTS

Clear and well presented, but see re Gender/Sex reporting (1.2.3).

Response: Thank you, we reworded the gender/sex reporting (please see the response to 1.2.3 above).

Comment 18: 7 DISCUSSION

7.1 KEY RESULTS

Good summary, no concerns.

Response: Thank you very much.

Comment 19: 7.2 LIMITATIONS

Good honest summary, no concerns (but see 5.2.1).

Response: Thank you very much (please see the response to 5.2.1 above).

Comment 20: 7.3 INTERPRETATION

Well written, with a logical flow of argument and referencing relevant literature which is up-to-date. I agree with their conclusion that an algorithm to guide diagnosis, care, and referrals for skin disease in this sector is needed, and this recommendation does seem supported by their wider argument and the study data.

Response: Thank you very much for your comment.

Comment 21: 7.3.1 GENERALISABILITY

Good to see this clear statement which does support the generalisability of study, though see my concerns re international readers and 'nursing homes' (1.2.1).

Response: Thank you for your comment and please find our response regarding 1.2.1 above.

VERSION 2 – REVIEW

REVIEWER	Flora Balieva Department of Dermatology, Stavanger University Hospital Norway
REVIEW RETURNED	15-Aug-2017

GENERAL COMMENTS	Thank you for the revision of the paper. On page 15 near the end you write that systemic diseases were not further specified and in the next sentence that this permits detailed analysis.. Do you mean the opposite?
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REVIEWER	Jo Middleton Research Fellow, Department of Primary Care and Public, Brighton and Sussex Medical School, UK
REVIEW RETURNED	21-Aug-2017

GENERAL COMMENTS	The authors have responded to my previous reviewer comments, making sufficient changes, and adding detail where required. No clear errors or causes for concern have been inserted in updating the manuscript.
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	I congratulate the authors on their revisions. Skin disease in the residential and nursing care population is relatively understudied, and so I am glad to now be able to recommend publication of this useful article without any further revisions.
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VERSION 2 – AUTHOR RESPONSE

Reviewer # 1:

Comment 1: Thank you for the revision of the paper.

On page 15 near the end you write that systemic diseases were not further specified and in the next sentence that this permits detailed analysis. Do you mean the opposite?

Response: Thank you very much for your comment. You are absolutely right, we meant the opposite. We reworded the sentence accordingly.

Changes to the manuscript:

Page 15, section 'Limitations':

'This restricts detailed analyses of possible associations.'

Reviewer # 2:

Comment 1: The authors have responded to my previous reviewer comments, making sufficient changes, and adding detail where required. No clear errors or causes for concern have been inserted in updating the manuscript.

I congratulate the authors on their revisions. Skin disease in the residential and nursing care population is relatively understudied, and so I am glad to now be able to recommend publication of this useful article without any further revisions.

Response: Thank you very much again for your thoughtful comments of the first revision. We would like to thank you for your recommendation of publication.