

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	CHARACTERISTICS, CONSEQUENCES AND PREVENTION OF FALLS IN INSTITUTIONALISED OLDER ADULTS IN THE PROVINCE OF MALAGA (SPAIN): A PROSPECTIVE COHORT MULTICENTRE STUDY.
AUTHORS	Aranda-Gallardo, Marta; Miguel Morales-Asencio, Jose; Enriquez de Luna-Rodriguez, Margarita; Vazquez-Blanco, Maria Jose; Morilla-Herrera, Juan Carlos; Rivas-Ruiz, Francisco; Toribio-Montero, Juan Carlos; Canca-Sanchez, Jose Carlos

VERSION 1 – REVIEW

REVIEWER	Rosie Cooper NHS Grampian Scotland
REVIEW RETURNED	06-Nov-2017

GENERAL COMMENTS	<p>Thank you for the opportunity to review your valuable work in this important field.</p> <p>1) Is the research question or study objective clearly defined? More clarity is required in defining the objective - "profile & consequence" are broad terms.</p> <p>3) Is the study design appropriate to answer the research question? The design limits the characteristics of the profile of the institutionalised individuals to age, sex, etc and equally the circumstances to the fall location, when/where it occurred etc and consequences to immediate harm. As there are wider profiles & consequences to consider the research question should be narrower or the consequences be broadened.</p> <p>4. Are the methods described sufficiently to allow the study to be repeated? More clarity re the specifics / classification of the physical restraints is required to be able to repeat reliably - operational definitions required.</p> <p>6. Are the outcomes clearly defined? While outcomes are defined there is scope to expand the cross reference of serious injuries such as fracture & internal bleeding with low falls rate areas- for example Bed Rails used at night which "protected against nocturnal falls". We don't know whether the more severe consequences such as a fracture or internal bleeding were predominant in these cohorts where the falls numbers were low.</p> <p>9. Do the results address the research question or objective? Results are focused on immediate physical harm and while the aim sets out to describe "potential consequences" the wider consequences such as increasing dependency, fear of further falls,</p>
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	<p>reduction in activity levels, hospital admissions, low mood, death have not been explored and as such should perhaps have been highlighted in the "limitation" section (12) so defining the scope of "consequences" being explored.</p> <p>10. Are they presented clearly? While the results are clear is there opportunity to display them more visually?</p> <p>A valuable piece of work in this complex and growing field which warrants publishing. Thank you for the insight into institutionalised care in Andalusia, a good opportunity to share learning across different systems & countries - challenging opinion.</p> <p>- The author also provided a marked copy with additional comments. Please contact the publisher for full details.</p>
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REVIEWER	Catherine Bailey Northumbria University Newcastle upon Tyne UK
REVIEW RETURNED	17-Nov-2017

GENERAL COMMENTS	<p>Given that falls in older people in residential settings are common, can have serious human and economic consequences and that falls prevention needs to be better understood from within this setting, then this prospective cohort study is timely.</p> <p>This is a well executed large study that within this paper, is clearly described in terms of its design, sampling, recruitment, data collection and analysis and its results. Whilst the sample of included older people (896) across 37 nursing homes in the study location in southern Spain, is large, this was also contextualised from within the overall nursing home population (2,541 people within 68 nursing homes) for that location. Given that the focus is on older people I was a little surprised that the inclusion criteria stipulated being over 16 years, though not that most of the respondents who fell were women with I believe, an average age of 82 years.</p> <p>The nine month follow up period is also a strength of the study. That a validated definition of a fall (!) is given is pleasing (sometime omitted) as is the three pronged approach to evaluation: analysing nursing home records,, verifying these with appropriate care staff and if possible, with the resident involved. Ethical approval is declared and descriptive statistical analyses seem adequate. Limitations are also considered.</p> <p>Whilst falls injuries were mostly minor or moderate, that during nine months, 411 falls, affecting 213 residents across the included 37 nursing homes and with an approximate 5% fracture rate, is of course cause for concern, even if in range of that reported in published literature. That falls prevention seems to encompass use of bed rails, physical restraint and in some cases, it seems, suspension of psychotropic drugs is worrying, especially as the authors point out that physical restraint might in and of itself, cause injuries. The authors do cite the Spanish Bioethics Committee to suggest that the use of physical restraint is more common in Spain than elsewhere, citing other European countries and the USA.</p>
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	<p>A moral conundrum is posed wherein whilst future studies might develop physical constraint protocols that attend to the Spanish Bioethics Committee recommendations, including issues of consent, evaluation and specialised nursing care, the authors note that physical constraint may be employed to prevent falls, even though research suggests such a measures may increase incidence of falls. It may be, that alongside the protocol development, there is need to consider nursing home staff moral dilemmas alongside professional development.</p> <p>In my opinion this article is in scope for BMJ Open readership and in relation to adding to the evidence base about falls prevention in nursing homes, I would very much welcome seeing this in print.</p>
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VERSION 1 – AUTHOR RESPONSE

Dear Editor,

The manuscript has been revised in accordance with the reviewers and editorial recommendations. I've submitted a new version of the manuscript (Main Manuscript R1) which contains the modifications required. I redacted this reponse letter giving a point-by-point response to the concerns.

Editor Comments to Author:

- Please edit the title so that it only contains one sentence, and contains the study design (cohort study) and location.
 - The title has been changed according to your recommendations: "Characteristics, consequences and prevention of falls in institutionalised older adults in the province of Malaga (Spain): a prospective cohort multicentre study."
- The Strengths and Limitations section should include at least one limitation.
 - This limitation has been added: "The results are focused on the immediate physical harms resulting from falls. Wider consequences were not explored."

Reviewer(s)' Comments to Author:

Reviewer: 1

1) Is the research question or study objective clearly defined?

More clarity is required in defining the objective - "profile & consequence" are broad terms.

- The term "profile" has been replaced by "characteristics". "Consequences" has been replaced by "physical harms".

3) Is the study design appropriate to answer the research question?

The design limits the characteristics of the profile of the institutionalised individuals to age, sex, etc and equally the circumstances to the fall location, when/where it occurred etc and consequences to immediate harm. As there are wider profiles & consequences to consider the research question should be narrower or the consequences be broadened.

- The aim of the study has been more detailed: "The aim of this study was to determine the characteristics (age, sex, level of consciousness) of institutionalised elderly persons who suffer falls, their circumstances (date, place, performed activity and presence or not of other people during the fall) and the physical harms resulting from this event."

4. Are the methods described sufficiently to allow the study to be repeated?

More clarity re the specifics / classification of the physical restraints is required to be able to repeat reliably - operational definitions required.

The definition of "bed rail" and "physical restraint" has been added into the methods section: "Bed rails were considered as side bars that prevent, limit or restrict the movements of a person, such as getting out of bed. Physical restraint was any device (wrist strap, abdominal belt or ankle brace) that attached or tied to the resident's body limits the free movement of all or a part of the body."

6. Are the outcomes clearly defined?

While outcomes are defined there is scope to expand the cross reference of serious injuries such as fracture & internal bleeding with low falls rate areas- for example Bed Rails used at night which "protected against nocturnal falls". We don't know whether the more severe consequences such as a fracture or internal bleeding were predominant in these cohorts where the falls numbers were low.

In the results section we explain that no relation was found between the use of bed rails and fall-related injuries (including fractures): "An analysis was performed to determine whether any of the prevention measures adopted were related to injuries due to falls. In this respect, no significant relationship was observed between fall-related injuries and the use of bed rails or the suspension of psychotropic medication." and "None of the preventive measures examined were related to the occurrence of fractures following a fall."

There was only one case of internal bleeding, so it was ruled out to perform any analysis in this regard.

9. Do the results address the research question or objective?

Results are focused on immediate physical harm and while the aim sets out to describe "potential consequences" the wider consequences such as increasing dependency, fear of further falls, reduction in activity levels, hospital admissions, low mood, death have not been explored and as such should perhaps have been highlighted in the "limitation" section (12) so defining the scope of "consequences" being explored.

The aim of the study has been modified and any allusion to the "consequences" of falls has been replaced for "physical harm" or "immediate harm" resulting from falls in the manuscript. This text has been added as a limitation: "Results are focused on immediate physical harm but the wider consequences such as increasing dependency, fear of further falls, reduction in activity levels, hospital admissions, low mood or death have not been explored."

10. Are they presented clearly?

While the results are clear is there opportunity to display them more visually?

A graph has been introduced (figure 2) with the relationship between injuries due to falls and the type of preventive measure adopted.

A valuable piece of work in this complex and growing field which warrants publishing. Thank you for the insight into institutionalised care in Andalusia, a good opportunity to share learning across different systems & countries - challenging opinion.

Reviewer: 2

Given that falls in older people in residential settings are common, can have serious human and economic consequences and that falls prevention needs to be better understood from within this setting, then this prospective cohort study is timely.

This is a well executed large study that within this paper, is clearly described in terms of its design, sampling, recruitment, data collection and analysis and its results. Whilst the sample of included older people (896) across 37 nursing homes in the study location in southern Spain, is large, this was also contextualised from within the overall nursing home population (2,541 people within 68 nursing homes) for that location. Given that the focus is on older people I was a little surprised that the inclusion criteria stipulated being over 16 years, though not that most of the respondents who fell were women with I believe, an average age of 82 years.

The Spanish legislation establishes in 16 years the majority of age for the decision making for sanitary purposes. Although the majority of people institutionalized in nursing homes are older than 65 years, sometimes people under this age but with great physical or neurological impairment are institutionalized in these centers. This is due to the deficiencies of our social-health system to house these cases.

The nine month follow up period is also a strength of the study. That a validated definition of a fall (!) is given is pleasing (sometime omitted) as is the three pronged approach to evaluation: analysing nursing home records, verifying these with appropriate care staff and if possible, with the resident involved. Ethical approval is declared and descriptive statistical analyses seem adequate. Limitations are also considered.

Whilst falls injuries were mostly minor or moderate, that during nine months, 411 falls, affecting 213 residents across the included 37 nursing homes and with an approximate 5% fracture rate, is of course cause for concern, even if in range of that reported in published literature. That falls prevention seems to encompass use of bed rails, physical restraint and in some cases, it seems, suspension of psychotropic drugs is worrying, especially as the authors point out that physical restraint might in and of itself, cause injuries. The authors do cite the Spanish Bioethics Committee to suggest that the use of physical restraint is more common in Spain than elsewhere, citing other European countries and the USA.

A moral conundrum is posed wherein whilst future studies might develop physical constraint protocols that attend to the Spanish Bioethics Committee recommendations, including issues of consent, evaluation and specialised nursing care, the authors note that physical constraint may be employed to prevent falls, even though research suggests such a measures may increase incidence of falls. It may be, that alongside the protocol development, there is need to consider nursing home staff moral dilemmas alongside professional development.

This text has been added in the "Discussion" section according to your recommendations: "This moral dilemma should be taken into account in the realization of future protocols, reinforcing the training of staff in this regard."

In my opinion this article is in scope for BMJ Open readership and in relation to adding to the evidence base about falls prevention in nursing homes, I would very much welcome seeing this in print.

Thank you very much for your comments, they represent a positive reinforcement to our work.

VERSION 2 – REVIEW

REVIEWER	Rosie Cooper NHS Grampian, Scotland
REVIEW RETURNED	27-Dec-2017
GENERAL COMMENTS	Thank you for the opportunity to re-review this important study. All earlier comments have been addressed and I feel that the quality is

	good. It warrants publishing as adds valuable and relevant findings to the evidence base re falls & specific prevention measures in nursing homes. Well done
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