

PEER REVIEW HISTORY

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ARTICLE DETAILS

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| TITLE (PROVISIONAL) | Incidence and risk factors for falls among community dwelling elderly subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala, India |
| AUTHORS | Sasidharan, Divyamol; Vijayakumar, Priya; Raj, Manu; Soman, Sumi; Antony, Libin; Sudhakar, Abish; Kabali, Conrad |

VERSION 1 – REVIEW

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| REVIEWER | Jennifer Davis UBC Canada |
| REVIEW RETURNED | 17-Oct-2019 |

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| GENERAL COMMENTS | <p>Thank you for the opportunity to review this manuscript on an important area of research examining the incidence and risk factors among community dwelling elders adults. I have the following comments/questions details below by manuscript section.</p> <p>General Comment:</p> <ol style="list-style-type: none">1) The manuscript would benefit from editing. For example, there are use of capitals mid-sentence.2) Ensure consistent wording (i.e., 12 months versus 1 year) throughout the manuscript.3) There was not a STROBE checklist included. <p>Abstract</p> <ol style="list-style-type: none">1) There is a wealth of information on falls and risk of falls; agreeably this is limited in low and middle income countries. Can the authors please provide some rationale to explain how they think low/middle income countries may have different risk factors and epidemiology? This would be helpful in placing the objective in context.2) Please include study time horizon of 12 months in first sentence and in the title.3) Instead of using 90 day intervals, suggest 3-month internals.4) Methods should state study location.5) Please state loss to followup and % missing data in the abstract. <p>Introduction</p> <ol style="list-style-type: none">1) It will be helpful to reframe the introduction to focus the reader on your rationale for why you believe risk factors for falls and falls epidemiology among low or middle income countries may be different. A paragraph devoted to this would be helpful.2) The epidemiology of falls more broadly is well establishes, and as such the first paragraph epidemiology can be condensed. <p>Methods</p> <ol style="list-style-type: none">1) What is meant by comprehensive skills? What level was considered comprehensive? |
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| | <p>2) For the inclusion criteria, please add how this was assessed with a reference where possible.</p> <p>3) Statistics: Please describe % missing data and methods conducted to deal with missing data. Multiple imputation is an approach commonly used, but will depend on whether the assumptions of MCAR are met.</p> <p>4) For the statistics section; please comment on why negative binomial regression was not used.</p> <p>5) For all modeling, please describe your dependent and independent variables of interest for all models.</p> <p>6) Please give more details of how falls were collected. Did all participants use a falls diary? Were they required to return it? Was it reviewed? If so at what frequency was it reviewed?</p> <p>Results</p> <p>1) Please explain why a followup time of 100 follow years was chosen as compared with using 1000 person years etc...</p> <p>2) Please report the ratio of women to men in the first line of the results.</p> <p>Conclusion</p> |
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| REVIEWER | Dr Alex Joseph School of Public Health, SRM Institute of Science and Technology, Kattankulathur, Tamilnadu , India |
| REVIEW RETURNED | 01-Nov-2019 |

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| GENERAL COMMENTS | Well written manuscript, May kindly include operational definitions for the study variables. |
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VERSION 1 – AUTHOR RESPONSE

| Reviewer Number | Original comments of the reviewer | Reply by the author(s) | Changes done on page number and line number |
|-----------------|---|---|---|
| 1.1 | The manuscript would benefit from editing. For example, there are use of capitals mid-sentence. | The manuscript was edited and identified errors were corrected. | |
| 1.2 | Ensure consistent wording (i.e., 12 months versus 1 year) throughout the manuscript. | The suggested change is made in the revised version. | |
| 1.3 | There was not a STROBE checklist included | included | |
| 1.4 | There is a wealth of information on falls and risk of falls; agreeably this is limited in low and middle income countries. Can the authors please provide some rationale to explain how they think low/middle income countries may have different risk factors and epidemiology? This would be helpful in placing the objective in context. | Correction made | Page 4, Line 53-55 |

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| 1.5 | Please include study time horizon of 12 months in first sentence and in the title. | Correction made in the title | Page4, Line 49-50 |
| 1.6 | Instead of using 90 day intervals, suggest 3-month internals. | Correction made | Page 4, Line 57 |
| 1.7 | Methods should state study location. | Correction made | Page 4, Line 59-60 |
| 1.8 | Please state loss to followup and % missing data in the abstract. | There was no missing data as all subjects who failed to respond to phone calls were visited by study personnel and their data were collected from home visits. We didn't mention missingness as there was no missing data. This information is added to statistical analysis paragraph in the revised manuscript. | Page 7 &8, Line 168-169 |
| 1.9 | It will be helpful to reframe the introduction to focus the reader on your rationale for why you believe risk factors for falls and falls epidemiology among low or middle income countries may be different. A paragraph devoted to this would be helpful. | Reframed introduction as suggested | Page 5, Line 97-103 |
| 1.10 | The epidemiology of falls more broadly is well establishes, and as such the first paragraph epidemiology can be condensed. | Condensed as suggested | |
| 1.11 | What is meant by comprehensive skills? What level was considered comprehensive? | We meant simple comprehension (working knowledge) of either English or Malayalam as some residents in the state are now migrant workers who may not understand both languages in which the questionnaire was available. The related sentence is modified in the revised version to avoid confusion. | Page 7, line 148-149 |
| 1.12 | For the inclusion criteria, please add how this was assessed with a reference where possible. | Explained in the revised version | Page 7, Line 146-149 |
| 1.13 | Statistics: Please describe % missing data and methods conducted to deal with missing data. Multiple imputation is an approach commonly used, but will depend on whether the assumptions of MCAR are met. | There was no missing data as all patients who didn't respond to phone call based follow up were visited at home by the study personnel. This information is added to the methods | Page 8, Line 174-176 |

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| | | section of the revised manuscript. | |
| 1.14 | For the statistics section; please comment on why negative binomial regression was not used. | We checked for over-dispersion using the Pearson and deviance methods. The tests did not detect over-dispersion in our data so we proceeded with a logistic regression. We have added a line mentioning the selection of logistic regression in the statistical analysis section of the revised manuscript. | Page 8, Line 185-186 |
| 1.15 | For all modeling, please describe your dependent and independent variables of interest for all models. | We have two models in the manuscript on for falls and another for recurrent falls. We selected those variables who showed a significant association with the dependent variable (falls or recurrent falls) on univariate comparisons with a p value cut-off of 0.02 We have added the suggested details of the variables in the paragraph describing this model in the revised version. | Page 10-11 Line 259-264, Line 272-274 |
| 1.16 | Please give more details of how falls were collected. Did all participants use a falls diary? Were they required to return it? Was it reviewed? If so at what frequency was it reviewed? | All subjects were requested to keep a falls diary and enter details when a fall occurred. The diary was reviewed by the research team if they reported a fall. This review was done when the researchers visited the same cluster to collect data from those subjects who didn't respond to phone based follow up. Such visits happened every three months for all clusters as each cluster would have some subjects not responding to phone calls during all four rounds of | Page 8, Line 173-176 |

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| | | follow up calls. The same info is added to the methods section of the revised version. | |
| 1.17 | Please explain why a follow up time of 100 follow years was chosen as compared with using 1000 person years etc... | We used a follow up denominator of 100 person years as the incidence rate was large enough (double digits). We hope this is acceptable when the incidence of the disease under study is high as is our case. | |
| 1.18 | Please report the ratio of women to men in the first line of the results. | included | Page 9, Line 201-202 |
| Reviewer Number | Original comments of the reviewer | Reply by the author(s) | Changes done on page number and line number |
| 2.1 | include operational definitions for the study variables. | included | Page 7, Line 151-154 |
| 2.2 | Remove Background: -On the Abstract section, please remove Background to comply with the Journal's structured abstract format. | Correction made | |
| 2.3 | Please provide an 'Article summary' section consisting of the heading: 'Strengths and limitations of this study'. Please note that 'Strengths and limitations of this study' should consist of 3-5 bullet points. | included | Page 5, Line 79-88 |
| 2.4 | Please provide figure legend/caption Please include figure legends at the end of your main manuscript. | included | Page 18, Line 471 |
| 2.5 | We have noticed that you have uploaded the file "consent 1.pdf" under 'supplementary file'. However, we can't see any citation for this file within the main text. If this file needs to be published as supplementary file, please cite it as 'supplementary file' in the main text. Otherwise, kindly change its file designation to 'Supplementary file for editors only'. | It is a supplementary file for editors only. Changes made. | |

VERSION 2 – REVIEW

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| REVIEWER | Jennifer Davis Canada, University of British Columbia |
| REVIEW RETURNED | 29-Jan-2020 |

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| GENERAL COMMENTS | <p>Thank you for the opportunity to review this manuscript addressing an important topic for older adults in all communities. I have the following suggestions.</p> <p>General comment: It is unclear if this is a study protocol or if this is a publication of interim findings.</p> <p>Title: Please state the time horizon of the prospective cohort?</p> <p>Abstract: Please explain the rationale behind why the authors believe the difference in falls and consequences of fall related injuries is related to falls risk factors in low and middle income countries. Key elements of the structures abstract are missing. What type of study design was this? What is the following duration? Is the a longitudinal prospective cohort study? It might be useful to report the IRR for falls in person years rather than followup years.</p> <p>Introduction The definition of falls, risk factors for falls and incidence of falls are quite well established in the literature. Given the focus of this study is to better understand differences in low and middle income countries, I think it would be helpful for the authors to consider reframing the introduction to: 1) Compare fall incident rates in low, med and high income countries, 2) compare fall risk factors in low, med and high income countries answering the question for 1 & 2- are they different and 3) then justify the rationale was to why the authors believe risk factor and incidence rates differ.</p> <p>Methods The term interventions is used. Given this is a prospective cohort study, please explain what intervention was delivered and to whom.</p> <p>Statistical Analysis Please describe dependent and independent variables for all analyses. Also, please list all categorical variables? Continuous variables should be used in the regression analyses where possible. Logistic regression should be selected for dichotomous outcomes. Continuous data can be transformed if the assumption of normality is not met. Continuous variables such as age do not need to be dichotomized.</p> <p>Discussion In the discussion, the following statement does not align with the sample size of 201 reported for the results “The strengths of the current study include; prospective cohort study design, large sample size (n=1000),</p> |
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VERSION 2 – AUTHOR RESPONSE

| Reviewer Number | Original comments of the reviewer | Reply by the author(s) | Changes done on page number and line number |
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| 1 | It is unclear if this is a study protocol or if this is a publication of interim findings. | This was a prospective cohort study conducted over a period of 1 year. | |
| 2 | Please state the time horizon of the prospective cohort? | The time horizon of “One year” was added to the title as per the suggestion of the previous reviewer | Page 2 Line 50-51 |
| 3 | Please explain the rationale behind why the authors believe the difference in falls and consequences of fall related injuries is related to falls risk factors in low and middle income countries. | The rationale is explained with supporting literature in the revised version of the manuscript. | Page4 Lines 93-103 |
| 4 | Key elements of the structures abstract are missing. What type of study design was this? What is the following duration? Is the a longitudinal prospective cohort study? | Abstract has been modified completely | Page 2-3 Lines 53-73 |
| 5 | It might be useful to report the IRR for falls in person years rather than follow up years | The suggested change has been made in the revised manuscript. (we regret to inform that the value was based on person years but we quoted them as follow up years in the earlier version. We are sorry for this confusion). | Page 3 line 62 Page 8 lines 223, 226 |
| 6 | The definition of falls, risk factors for falls and incidence of falls are quite well established in the literature. Given the focus of this study is to better understand differences in low and middle income countries, I think it would be helpful for the authors to consider reframing the introduction to: 1) Compare fall incident rates in low, med and high income countries, 2) compare fall risk factors in low, med and high income countries | The introduction is revised to include this suggestion from the reviewer. | Page 4 Line 96-102 |

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| | answering the question for 1 & 2- are they different and 3) then justify the rationale was to why the authors believe risk factor and incidence rates differ. | | |
| 7 | The term interventions is used. Given this is a prospective cohort study, please explain what intervention was delivered and to whom. | The term intervention was in the title of the paragraph by mistake. However, the same has been now removed from the revised version as no interventions were done in this study | Page 6 Line 162 |
| 8 | Please describe dependent and independent variables for all analyses. Also, please list all categorical variables? Continuous variables should be used in the regression analyses where possible. Logistic regression should be selected for dichotomous outcomes. Continuous data can be transformed if the assumption of normality is not met. Continuous variables such as age do not need to be dichotomized. | We have described all the independent variables for the two predictor models (one for falls and another for recurrent falls) presented in the revised version of the manuscript. We dichotomized age after a discussion with clinicians as to how they would like to see the risk from age represented in the final model. Unfortunately, age didn't show a statistical significance to be presented as a predictor. We request the reviewer to permit us in presenting the two regression models in the current version. We acknowledge that dichotomizing continuous variables can result in some loss of information. | Page 9-10 Lines 265-270 Lines 278-280 |
| 9 | In the discussion, the following statement does not align with the sample size of 201 reported for the results "The strengths of the current study include; prospective cohort study design, large sample size (n=1000), | Please note that the sample size is 1000 and the number of people who experienced a fall during the follow up period of one year is 201. | |

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| REVIEWER | Jennifer Davis University of British Columbia |
| REVIEW RETURNED | 16-Mar-2020 |

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| GENERAL COMMENTS | <p>The authors have conducted an interesting study examining the incident and risk factors for falls in a specific population of older adults.</p> <p>I have the following suggestions:</p> <p>General comment: 1) The manuscript needs editing for clarity of writing, grammar, spacing and spelling errors. 2) Could the authors please explain why data from 2017 was not published closer to the date of collection?</p> <p>Abstract: Methods: "Prospective cohort study with stratified random cluster sampling" Please state how the clusters were defined. Conclusion: "Interventions targeting falls among elderly need to focus on modifiable risk factors like living alone during daytime, movement disorders, arthritis and dependence on basic activities of daily living." Please refine the conclusion to highlight how the findings of this study impact future intervention strategies for individuals in Kerala.</p> <p>Introduction: Line 112- The reference for Lord should appear after his name and same comment for Deandrea.</p> <p>Methods Page 6: Please describe if the study questionnaire was derived from any validated questionnaires.</p> <p>Table 4: The title should explain that this is the adjusted model and should also state the sample size of the model.</p> |
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VERSION 3 – AUTHOR RESPONSE

| General comment | Original comments of the reviewer | Reply by the author(s) | Changes done on page number and line number |
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| 1. | 1) The manuscript needs editing for clarity of writing, grammar, spacing and spelling errors. | We have done a thorough language editing via a professional editor. | |
| 2. | Could the authors please explain why data from 2017 was not published closer to the date of collection? | The principal investigator had to take a break due to a health-related reason (pregnancy) and was also out of the country to attend | |

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| | | to some other personal matters. The manuscript preparation was delayed by a year due to this reason. Please excuse us for the delay from our part. | |
| Editorial Comments | | | |
| 1. | Abstract: Methods: "Prospective cohort study with stratified random cluster sampling" Please state how the clusters were defined. | This has been explained in the main text due to the word limit of the abstract. | Page 5, lines 144-149 |
| 2. | Conclusion: "Interventions targeting falls among elderly need to focus on modifiable risk factors like living alone during daytime, movement disorders, arthritis and dependence on basic activities of daily living." Please refine the conclusion to how light how the findings of this study impact future intervention strategies for individuals in Kerala. | We have modified the discussion and the conclusion section to focus more on Kerala. The revised section states why intervention studies targeting falls are more relevant to the state. | Page 12-13, Lines 362-365 |
| 3. | Introduction: Line 112- The reference for Lord should appear after his name and same comment for Deandrea. | Changes have been made as suggested | Page 4, Line 115,118 |
| 4. | Methods Page 6: Please describe if the study questionnaire was derived from any validated questionnaires. | Study questionnaire was freshly prepared by us after a vast literature review. | Page 6, Line 167-168 |
| 5. | Table 4: The title should explain that this is the adjusted model and should also state the sample size of the model. | Changes have been made as suggested | Page 18, Line 501,502 |