

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

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| <b>TITLE (PROVISIONAL)</b> | Association of fear of falling with performance-based physical function and low back pain in older adults: A Cross-Sectional Study in Iran |
| <b>AUTHORS</b>             | Khodadadi, Zeinab; ShahAli, Shabnam; Hejazi, Anahita; Shanbehzadeh, Sanaz  |

### VERSION 1 – REVIEW

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| <b>REVIEWER</b>        | Al Zoubi, Fadi<br>The Hong Kong Polytechnic University Faculty of Health and Social Sciences, Department of Rehabilitation Sciences |
| <b>REVIEW RETURNED</b> | 23-Apr-2024   |

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| <b>GENERAL COMMENTS</b> | <p>The abstract mentions that the authors considered demographics as covariates. Clearly defining the demographics and their treatment as confounders, moderators, mediators, etc. is crucial.</p> <p>Page 4 (lines 69–71): The authors mentioned that older adults are predominantly having sedentary physical function. However, this is not true for all communities or countries. In addition, the two references (7 and 8) do not support the author's argument.</p> <p>On page 5, line 101, it seems like this is a case-control study, but it is clearly described in this direction.</p> <p>The authors mentioned on page 6, line 105, that pain was measured using VAS between 20 and 70/100, and then on the same page, line 115, &gt;3 to VAS. I'm not sure if this is also on a scale of 0–10 or the same scale as 0-100.</p> <p>The authors mentioned on page 9 (lines 189–190) that "data were normally distributed" without specifying which variables were meant by this statement.</p> <p>There was no mention of any significant differences between the two groups. This should be added to the results and Table 1.</p> <p>The authors discussed how having lower extremity pain might affect their estimates. I am wondering why you did not consider that during data collection.</p> <p>What are the cut-off points for the bivariate correlations for low, moderate, and strong?</p> <p>The study's objective does not align with the design.</p> |
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| <b>REVIEWER</b>        | Saadat, Maryam<br>Ahvaz Jundishapur University of Medical Sciences |
| <b>REVIEW RETURNED</b> | 03-Jun-2024  |

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| <b>GENERAL COMMENTS</b> | write conclusion in abstract based on finding this study and state intervention as suggestion<br>Does mild pain in other parts of the body $\leq 3$ could affect on physical function and fear of falling?<br>in limitation: "study participants were older adults with no or mild disability" . include disability of two groups in demogeraphic table. |
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| <b>REVIEWER</b>        | Bagheri , Rasool<br>Semnan University |
| <b>REVIEW RETURNED</b> | 08-Jun-2024                           |

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| <b>GENERAL COMMENTS</b> | <p>Introduction:<br/>In this section you stated that a possible association might be existed between fear and low back pain. However, you did not explain which type of low back pain (chronic or acute, specific or non-specific) is considered for this correlation. This issue should be added in the introduction.<br/>Introduction should be finalized with a study question or hypothesis.</p> <p>Method:<br/>Please state that specific or non-specific LBP included in your study?<br/>Please state about the eligibility criteria, and the sources and methods of selection of participants in your study according to the STROBE checklist.<br/>Another issue in your study is the control group. You included 70 participants over 60 years old. In this age, you may have a challenge with selecting healthy control group for matching. A major concern about your study is that the control group who matched with LBP group may have not really healthy condition. What did you resolve this issue in your study? Please state.<br/>Please state the manufacture name for the G*power software.</p> <p>Results:<br/>Please delete preceding zero from P values in all tables.</p> |
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| <b>REVIEWER</b>        | Khanmohammadi, Roya<br>Tehran University of Medical Sciences |
| <b>REVIEW RETURNED</b> | 09-Jun-2024  |

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| <b>GENERAL COMMENTS</b> | <p>Introduction</p> <ul style="list-style-type: none"> <li>• It is suggested to merge the following two sentences and provide a more comprehensive sentence.<br/>"The experience of a fall can lead some older adults to disengage from physical activity (1). The disengagement could be caused by fear of falling which is recognized as a psychological factor that contributes to avoiding physical activity and influencing clinical outcomes in older adults (2, 3)."</li> <li>• Include the background of previous studies in this field, highlighting the implementation limitations or contradictory results. Also, discuss how you have addressed these aspects in your study to clarify the necessity of conducting it.</li> </ul> <p>Method</p> <ul style="list-style-type: none"> <li>• Why were individuals with moderate to high disability (Oswestry Disability Index scores &gt; 25) excluded from the study, despite their</li> </ul> |
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|  | <p>higher susceptibility to fear of movement? This exclusion might explain why back pain did not show a significant relationship with fear, as the participants did not experience severe back pain.</p> <ul style="list-style-type: none"> <li>• Given that pain in other joints significantly affects the results, why wasn't it measured to control for its effects as a confounding factor? To address this issue, the following study is suggested. Gonçalves TR, Cunha DB, Mediano MFF, Wanigatunga AA, Simonsick EM, Schrack JA. Association of non-chronic low back pain with physical function, endurance, fatigability, and quality of life in middle- and older-aged adults: Findings from Baltimore Longitudinal Study of Aging. PloS one. 17:e0277083, 2022; 10.1371/journal.pone.0277083</li> <li>• In defining LBP as an independent variable, participants were asked if they had experienced LBP in the past 12 months. However, the inclusion criteria specified a history of LBP lasting more than 3 months. Please clarify this discrepancy.</li> <li>• Given that the data had a normal distribution, why was Pearson correlation coefficient not used?</li> </ul> <p>Results</p> <ul style="list-style-type: none"> <li>• Given that the inclusion criteria were based on back pain, it would be more appropriate to organize Table 1 accordingly, rather than by gender.</li> <li>• In addition, include the pain intensity (VAS) and disability level (ODI) of the participants in Table 1 to better clarify the demographic characteristics of the participants.</li> <li>• The results suggest a positive relationship between fear of falling and walking speed. Does this mean that the greater the fear, the faster the walking speed?</li> <li>• What does "direct effect" and "inverse effect" mean in the following sentence?<br/>"Gender had a direct effect on fear of falling, and the 30s-STST test had an inverse effect."</li> <li>• It seems that "30s-STST test" is redundant in the following sentence.<br/>"In addition, the 30s-STST test and gender (model 2) explained 31.5% of the variance score on the fear of falling"</li> </ul> <p>Discussion</p> <ul style="list-style-type: none"> <li>• It is recommended to emphasize the participants' pain intensity and disability characteristics when explaining the absence of a relationship between back pain and fear.</li> </ul> |
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## VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Dr. Fadi Al Zoubi, The Hong Kong Polytechnic University Faculty of Health and Social Sciences

1. COMMENT: The abstract mentions that the authors considered demographics as covariates. Clearly defining the demographics and their treatment as confounders, moderators, mediators, etc. is crucial.

RESPONSE: Thank you for this valuable comment. In this study, demographic variables including age, gender, and BMI were considered as covariates since they were related to the dependent variable and were included in the analysis to account for their potential influence on the dependent variable. This was performed to increase the precision and accuracy of estimates by reducing the error variance. Including demographics as a covariate is also seen in similar studies:

- Camacho-Soto A, Sowa GA, Perera S, Weiner DK. Fear avoidance beliefs predict disability in older adults with chronic low back pain. *Pm r.* 2012;4(7):493-7.
- Donath L, Faude O, Bridenbaugh SA, Roth R, Soltermann M, Kressig RW, Zahner L. Transfer effects of fall training on balance performance and spatiotemporal gait parameters in healthy community-dwelling older adults: a pilot study. *J Aging Phys Act.* 2014 Jul;22(3):324-33.
- Morelhão PK, Gobbi C, Christofaro DGD, Damato TM, Grande GD, Frange C, Andersen ML, Tufik S, Franco MR, Pinto RZ. Bidirectional Association Between Sleep Quality and Low Back Pain in Older Adults: A Longitudinal Observational Study. *Arch Phys Med Rehabil.* 2022 Aug;103(8):1558-1564.

#### CORRECTION:

Abstract: Demographic variables including age, gender, and BMI were considered as potential covariates.

2. COMMENT: Page 4 (lines 69–71): The authors mentioned that older adults are predominantly having sedentary physical function. However, this is not true for all communities or countries. In addition, the two references (7 and 8) do not support the author's argument.

RESPONSE: Thanks for this point. Based on this comment, the text and references were revised:

CORRECTION: Despite the positive effects of physical function, most older adults do not meet recommended physical function levels (7, 8).

References:

7. Wingood M, Bonnell L, LaCroix AZ, Rosenberg D, Walker R, Bellettiere J, et al. Community-Dwelling Older Adults and Physical Activity Recommendations: Patterns of Aerobic, Strengthening, and Balance Activities. *J Aging Phys Act.* 2022;30(4):653-65.

8. Bauman A, Merom D, Bull FC, Buchner DM, Fiatarone Singh MA. Updating the Evidence for Physical Activity: Summative Reviews of the Epidemiological Evidence, Prevalence, and Interventions to Promote "Active Aging". *Gerontologist.* 2016;56 Suppl 2:S268-80.

3. COMMENT: On page 5, line 101, it seems like this is a case-control study, but it is clearly described in this direction.

RESPONSE: Thank you for your insightful comment. The text is revised as follows:

CORRECTION: One hundred forty subjects over 60 years, with and without LBP were recruited.

4. The authors mentioned on page 6, line 105, that pain was measured using VAS between 20 and 70/100, and then on the same page, line 115, >3 to VAS. I'm not sure if this is also on a scale of 0–10 or the same scale as 0-100.

RESPONSE: Thank you for pointing this out. We apologize for any confusion this may have caused. We revise the manuscript using a single scale to maintain consistency and avoid confusion.

CORRECTION: ... pain score  $\geq 30$  mm according to VAS in any part of the body other than the lower back (neck, hips, knees, etc.),

5. The authors mentioned on page 9 (lines 189–190) that "data were normally distributed" without specifying which variables were meant by this statement.

RESPONSE: Thank you for this valuable comment. The text is revised as follows:

CORRECTION:

Statistical analysis: ... The normality of the data was assessed using a combination of the Shapiro-Wilks test, histograms, and skew/kurtosis.

Results: ... All variables except age followed an approximately normal distribution.

6. There was no mention of any significant differences between the two groups. This should be added to the results and Table 1.

RESPONSE: Thank you for this point. As you rightly pointed out in the comments, the method of reporting had caused inconsistency regarding the study design. Since the study aimed to evaluate the

association between LBP and level of physical performance with fear of falling in older adults, the design was considered cross-sectional. In this study comparing individuals with and without LBP was not the main purpose. We revised Table 1, groups were removed and data were reported as a whole in Table 1. Reporting data as a whole (in Table 1) is also seen in similar studies:

- Fernandes SG, Sales WB, Tavares DV, Pereira DDS, Nóbrega PVN, Holanda CMA, et al. Relationship between Pain, Fear of Falling and Physical Performance in Older People Residents in Long-Stay Institutions: A Cross-Sectional Study. *Int J Environ Res Public Health*. 2022;19(19).

- Morelhão PK, Gobbi C, Christofaro DGD, Damato TM, Grande GD, Frange C, et al. Bidirectional Association Between Sleep Quality and Low Back Pain in Older Adults: A Longitudinal Observational Study. *Arch Phys Med Rehabil*. 2022;103(8):1558-64.

Moreover, LBP, age, and gender were added in Table 2 (Bivariate correlation analysis).

CORRECTION: Bivariate analysis revealed a significant correlation between fear of falling and physical function tests (TUG, gait speed, Open/Close Eyes SLS, and 30s-STs), LBP, and Gender ( $P < .05$ ). According to Spearman's rho coefficient, there was a positive and moderate correlation between fear of falling and TUG, gait speed and female gender, positive and weak correlation with age, and also a negative and moderate correlation with Open/Close Eyes SLS, 30s-STs and not having LBP (Table 2).

7. The authors discussed how having lower extremity pain might affect their estimates. I am wondering why you did not consider that during data collection.

RESPONSE: Thank you for this comment. Pain at multiple regional sites is common among older adults. One way to exclude or control it as a confounding variable is restriction (Pourhoseingholi MA, Baghestani AR, Vahedi M. How to control confounding effects by statistical analysis. *Gastroenterol Hepatol Bed Bench*. 2012;5(2):79-83). In this study, we included people with a maximum pain intensity of 10 or 20 mm according to VAS in other body parts other than the lower back. Also, subjects with ambulatory limitations caused by persistent lower-extremity pain and rheumatoid arthritis were excluded from the study which may control confounding by the number of painful sites/joints. Moreover, the discussion is revised as follows:

CORRECTION: According to the results of the present study, having or not having LBP was not an indicator of fear of falling. Including older adults with moderate pain and low levels of disability may have resulted in this insignificant finding. Fear of falling may be more pronounced in older adults with LBP, suffering from greater pain and disability. Older adults with severe pain and higher disability levels might experience greater functional limitations and psychological distress, which could increase their fear of falling (48, 49). Thus, extrapolation of the results to older adults with severe LBP and moderate to high disability should be undertaken with caution. Different results may emerge with those having severe pain intensity or moderate to high disability levels.

8. What are the cut-off points for the bivariate correlations for low, moderate, and strong?

RESPONSE: Thank you for this valuable comment. Based on this comment, the following explanations were added to the text:

CORRECTION: Correlation coefficient values were considered very weak (0–0.19), weak (0.20–0.39), moderate (0.40–0.69), strong (0.70–0.89), and very strong (0.90–1) (42).

9. The study's objective does not align with the design.

RESPONSE: Thank you for this valuable comment. Since the study aimed to evaluate the association between LBP and level of physical performance with fear of falling in older adults, the design was considered cross-sectional. In this study comparing individuals with and without LBP was not the main purpose. We assumed strict restrictions for eligibility criteria to evaluate whether having or not having LBP is related to higher levels of fear of falling, with considering physical function and female gender.



A previous systematic review has mentioned physical function and female gender as the main contributing factors associated with a higher fear of falling in older adults (Denkinger MD, Lukas A, Nikolaus T, Hauer K. Factors associated with fear of falling and associated activity restriction in community-dwelling older adults: a systematic review. *Am J Geriatr Psychiatry*. 2015;23(1):72-86). In the present study in addition to the previous factors, LBP was also considered as well. Previous studies have evaluated the effect of the presence of pain in any part of the body as a factor, whereas the specific association between LBP and fear of falling considering the level of physical function hasn't been evaluated.

Also, according to comment 5, we revised the text (method, participants) and tables to fix the inconsistency regarding the study design.

Reviewer 2: Dr. Maryam Saadat, Ahvaz Jundishapur University of Medical Sciences

1. COMMENT: write conclusion in abstract based on finding of this study and state intervention as suggestion.

RESPONSE: Thank you for this valuable comment. The text is revised as follows:

CORRECTION: Conclusion: Fear of falling was significantly associated with lower extremity muscle function, measured by the 30s-STS test and female gender. Older adults with fear of falling could benefit from interventions that improve lower extremity muscle function. Also, the observed association between the fear of falling and the female sex confirms the need for effective interventions to reduce the fear of falling among older women.

2. Does mild pain in other parts of the body  $\leq 3$  could affect on physical function and fear of falling?

RESPONSE: Thank you for this comment. Pain at multiple regional sites is common among older adults. One way to exclude or control it as a confounding variable is restriction (Pourhoseingholi MA, Baghestani AR, Vahedi M. How to control confounding effects by statistical analysis. *Gastroenterol Hepatol Bed Bench*. 2012;5(2):79-83). In this study, we included people with a maximum pain intensity of 10 or 20 mm according to VAS in other body parts other than the lower back. Also, subjects with ambulatory limitations caused by persistent lower-extremity pain and rheumatoid arthritis were excluded from the study which may control confounding by the number of painful sites/joints. Moreover, the discussion is revised as follows:

CORRECTION: According to the results of the present study, having or not having LBP was not an indicator of fear of falling. Including older adults with moderate pain and low levels of disability may have resulted in this insignificant finding. Fear of falling may be more pronounced in older adults with LBP, suffering from greater pain and disability. Older adults with severe pain and higher disability levels might experience greater functional limitations and psychological distress, which could increase their fear of falling (48, 49). Thus, extrapolation of the results to older adults with severe LBP and moderate to high disability should be undertaken with caution. Different results may emerge with those having severe pain intensity or moderate to high disability levels.

3. in limitation: "study participants were older adults with no or mild disability". include disability of two groups in the demographic table.

RESPONSE: Thank you for this valuable comment. Based on this comment, we added the descriptive data for disability to Table 1. According to reviewer 1 comment, the method of reporting had caused inconsistency regarding the study design. Since the study aimed to evaluate the association between LBP and level of physical performance with fear of falling in older adults, the design was considered cross-sectional. In this study comparing individuals with and without LBP was not the main purpose. We revised Table 1, groups were removed and data were reported as a whole in Table 1. Reporting data as a whole (in Table 1) is also seen in similar studies:

- Fernandes SG, Sales WB, Tavares DV, Pereira DDS, Nóbrega PVN, Holanda CMA, et al. Relationship between Pain, Fear of Falling and Physical Performance in Older People Residents in Long-Stay Institutions: A Cross-Sectional Study. *Int J Environ Res Public Health*. 2022;19(19).

- Morelhão PK, Gobbi C, Christofaro DGD, Damato TM, Grande GD, Frange C, et al. Bidirectional Association Between Sleep Quality and Low Back Pain in Older Adults: A Longitudinal Observational Study. *Arch Phys Med Rehabil.* 2022;103(8):1558-64.

Moreover, LBP, age, and gender were added in Table 2 (Bivariate correlation analysis).

Reviewer 3: Dr. Rasool Bagheri, Semnan University

1. COMMENT: Introduction: In this section, you stated that a possible association might exist between fear and low back pain. However, you did not explain which type of low back pain (chronic or acute, specific or non-specific) is considered for this correlation. This issue should be added in the introduction.

RESPONSE: Thank you for pointing this out. We appreciate the reviewer's comment. In the context of older adults, the classification of low back pain as specific or non-specific is challenging due to the high prevalence of degenerative joint disease (DJD) changes in the spine. DJD changes, such as osteoarthritis, degenerative disc disease, and facet joint osteoarthritis, are common in the aging population and can contribute to low back pain (Hicks GE, Morone N, Weiner DK. Degenerative lumbar disc and facet disease in older adults: prevalence and clinical correlates. 2009., Kalichman L, Hunter DJ. Lumbar facet joint osteoarthritis: a review. *Semin Arthritis Rheum.* 2007).

These changes are often part of the normal aging process and are not always indicative of a specific pathological condition. The classification of low back pain in older adults is further complicated by the fact that pain perception and reporting can be influenced by various factors, including age-related changes in pain processing and perception. Older adults may have a higher pain threshold or may underreport their pain due to a belief that pain is a normal part of aging. Additionally, older adults may have multiple comorbidities that can contribute to or exacerbate low back pain (Weiner DK, Haggerty CL, Kritchevsky SB, et al. How does low back pain impact physical function in independent, well-functioning older adults? Evidence from the Health ABC Cohort and implications for the future. *Pain Med.* 2003).

Given these complexities, we did not classify low back pain in our study as specific or non-specific, recognizing the multifactorial nature of pain in older adults with DJD changes.

In the present study, similar to previous studies that assessed older adults with LBP, in the baseline survey, participants were asked if they had experienced chronic LBP lasting more than 3 months in the past year or recurrent LBP for at least two episodes of pain, lasting two consecutive days in the past year. Also, according to the exclusion criteria, subjects with specific pathology (such as congenital spinal malformation, or scoliosis, ambulatory limitation caused by persistent lower-extremity pain) were excluded from the study.

2. Introduction should be finalized with a study question or hypothesis.

RESPONSE: Thanks for this valuable comment. The hypotheses were added to the text.

CORRECTION: The study hypotheses were: (a) a high fear of falling is associated with lower levels of physical function, and (b) a fear of falling is positively associated with having LBP.

3. Method: Please state that specific or non-specific LBP included in your study?

RESPONSE: Thank you for your insightful comment.

Causes of LBP in older adults may differ from those in a younger population. Aside from nonspecific or mechanical LBP, older people may experience LBP secondary to osteoporotic spine or degenerative radiological changes (e.g., disc space narrowing and osteophytes). Imperatively, since degenerative changes are inevitable in older adults, most studies on older adults use the terms chronic and recurrent LBP instead of non-specific LBP, and Potential "red flags" (such as congenital spinal malformation, or scoliosis, ambulatory limitation caused by persistent lower-extremity pain) are considered as exclusion criteria to rule out specific pathology.

(-Wong CKW, Mak RYW, Kwok TSY, Tsang JSH, Leung MYC, Funabashi M, et al. Prevalence, Incidence, and Factors Associated With Non-Specific Chronic Low Back Pain in Community-Dwelling

Older Adults Aged 60 Years and Older: A Systematic Review and Meta-Analysis. The Journal of Pain. 2022;23(4):509-34.

-Grooten WJA, Boström C, Dederling Å, Halvorsen M, Kuster RP, Nilsson-Wikmar L, et al. Summarizing the effects of different exercise types in chronic low back pain - a systematic review of systematic reviews. BMC Musculoskelet Disord. 2022;23(1):801

In the present study, similar to previous studies that assessed older adults with LBP, in the baseline survey, participants were asked if they had experienced chronic LBP lasting more than 3 months in the past year or recurrent LBP for at least two episodes of pain, lasting two consecutive days in the past year. Also, according to the exclusion criteria, subjects with specific pathology (such as congenital spinal malformation, or scoliosis, ambulatory limitation caused by persistent lower-extremity pain) were excluded from the study.

CORRECTION: Independent variable, LBP- In the baseline survey, participants were asked if they had experienced chronic LBP lasting more than 3 months in the past year or recurrent LBP for at least two episodes of pain, lasting two consecutive days in the past year.

4. Please state about the eligibility criteria, and the sources and methods of selection of participants in your study according to the STROBE checklist.

RESPONSE: Thanks for this comment. In accordance with the STROBE checklist, we provide the following information regarding the eligibility criteria, and the sources and methods of selection of participants in our study:

-This cross-sectional study is reported according to Strengthening the Reporting of Cross-sectional Observational Studies (STROBE) and was conducted in the physiotherapy department of the Iran University of Medical Sciences laboratory between March 2022 and April 2023.

-The study recruited older adults with LBP from Iran University orthopedic and/or physiotherapy outpatient clinics.

Eligibility Criteria:

Older adults with a history of LBP lasting more than 3 months in the past year, recurrent LBP for at least two episodes of pain, lasting two consecutive days in the last year (29), and with a pain score between 30 and 70 mm on a Visual Analog Scale (VAS) (30) were included.

The other group consisted of older adults without LBP recruited through advertisements at the University and in the local community. The inclusion criteria for the non-LBP group were no LBP in the previous year or back pain lasting more than one week in the previous year (31). One physiotherapist checked the eligibility criteria of the participants and conducted the assessments. Both groups were matched based on demographic characteristics.

Exclusion criteria for both groups were: pelvic or spinal surgery, congenital spinal malformation or scoliosis, degenerative neurologic disease, severe labyrinthitis; history of dizziness and use of medicine affecting balance, history of foot, knee, and hip surgery, chronic cardiovascular or respiratory diseases, rheumatoid arthritis, falls in the past year, Mini-Mental State Examination score <21 and Oswestry Disability Index scores > 25, pain score ≥ 30 mm according to VAS in any part of the body other than the lower back (neck, hips, knees, etc.), and ambulatory limitation caused by persistent lower-extremity pain.

We hope that these details provide a clear understanding of the eligibility criteria and the sources and methods of selection of participants in our study, as required by the STROBE checklist. Revisions are highlighted in the text.

CORRECTION: This cross-sectional study is reported according to Strengthening the Reporting of Cross-sectional Observational Studies (STROBE) and was conducted in the physiotherapy department of the Iran University of Medical Sciences laboratory between March 2022 and April 2023.



- One physiotherapist checked the eligibility criteria of the participants and conducted the assessments.

5. Another issue in your study is the control group. You included 70 participants over 60 years old. In this age, you may have a challenge with selecting healthy control group for matching. A major concern about your study is that the control group who matched with the LBP group may have not really healthy condition. What did you resolve this issue in your study? Please state.

RESPONSE: We appreciate the reviewer's concern regarding the control group. Given the challenges in selecting a truly healthy control group among older adults, we employed several strategies to address this issue:

- Inclusion Criteria: We included participants aged 60 and older in both groups. This approach helped mitigate the effects of age-related changes on physical function and fear of falling.

- Health Screening: All participants in the control group underwent a health screening to exclude individuals with significant health issues that could impact physical function (Exclusion criteria for both groups were: pelvic or spinal surgery, congenital spinal malformation or scoliosis, degenerative neurologic disease, severe labyrinthitis; history of dizziness and use of medicine affecting balance, history of foot, knee, and hip surgery, chronic cardiovascular or respiratory diseases, rheumatoid arthritis, falls in the past year, Mini-Mental State Examination score <21 and Oswestry Disability Index scores > 25, pain score  $\geq 30$  mm according to VAS in any part of the body other than the lower back (neck, hips, knees, etc.), and ambulatory limitation caused by persistent lower-extremity pain. This screening included assessments of comorbidities, medication use, and self-reported health status.

- We considered demographic characteristics (age, gender, BMI) as covariates. since they were related to the dependent variable and were included in the analysis to account for their potential influence on the dependent variable. This was performed to increase the precision and accuracy of estimates by reducing the error variance. Overall, while selecting a truly healthy control group among older adults can be challenging, we believe that our approach helped minimize the risk of bias and ensure the comparability of the control group with the LBP group in our study.

6. Please state the manufacturer name for the G\*power software.

RESPONSE: Thank you for this point. It is added to the text.

CORRECTION: The sample size was calculated with G\*Power, version 3.1.9.2 (Heinrich-Heine-Universität, Düsseldorf, Germany) for a linear multiple regression model.

7. Results: Please delete the preceding zero from P values in all tables.

RESPONSE: Thank you for this suggestion. We revised the text and tables based on this comment. Revisions are highlighted in the text and Tables.

Reviewer 4: Dr. Roya Khanmohammadi, Tehran University of Medical Sciences

1. COMMENT: It is suggested to merge the following two sentences and provide a more comprehensive sentence. "The experience of a fall can lead some older adults to disengage from physical activity (1). The disengagement could be caused by fear of falling which is recognized as a psychological factor that contributes to avoiding physical activity and influencing clinical outcomes in older adults (2, 3)."

RESPONSE: Thank you for this valuable comment. Based on this comment, we revised the text as follows:

CORRECTION: The experience of a fall can lead some older adults to disengage from physical activity due to fear of falling, which is recognized as a psychological factor that contributes to avoiding physical activity and influencing clinical outcomes in older adults (1-3).

2. COMMENT: Include the background of previous studies in this field, highlighting the implementation limitations or contradictory results. Also, discuss how you have addressed these aspects in your study to clarify the necessity of conducting it.

RESPONSE: Thank you for this valuable comment. Based on this comment, the following explanations were added to the text:

CORRECTION: Extensive studies on the fear of falling have been done in previous research, particularly on its association with sociodemographics and health-related factors (23-25). Also, previous studies have shown older adults with fear of falling had poorer physical activity levels (26, 27), balance, and lower muscle strength (4) than those without. Moreover, in the study of well-functioning elderly individuals, those who reported some fear of falling, but had no criteria of frailty, had similar gait performance as those with one or more frailty criteria and no fear of falling (28). Overall, previous studies demonstrate that fear of falling is common among older adults and is associated with numerous negative outcomes. Although the association of fear of falling with many risk factors has been widely explored, few have explored other influencing factors such as LBP, and physical function status. It is unclear which factors (LBP, and physical function) could be a stronger indicator of fear of falling in older adults. Understanding the association of fear of falling with performance-based physical function and LBP, can be helpful to develop interventions that aim to modify these determinants in older adults.

3. COMMENT: Why were individuals with moderate to high disability (Oswestry Disability Index scores > 25) excluded from the study, despite their higher susceptibility to fear of movement? This exclusion might explain why back pain did not show a significant relationship with fear, as the participants did not experience severe back pain.

RESPONSE: Thank you for this valuable comment. Considering the age of participants and preventing them from losing balance or aggravating LBP symptoms during performance-based physical function tests (especially during single leg stance with open and closed eyes) we included older adults with low disability.

Based on this comment, the following explanations were added to the limitations:

CORRECTION:

...Fourth, the study included older adults with no or low disability to minimize safety concerns during performance-based physical function tests. Therefore, results cannot be generalized to those with moderate or severe disability.

4. COMMENT: Given that pain in other joints significantly affects the results, why wasn't it measured to control for its effects as a confounding factor? To address this issue, the following study is suggested.

RESPONSE: Thank you for pointing this out. Confounders must meet two criteria to be considered potential confounders: Criterion 1 is that potential confounders must be known risk factors for the health outcome. A risk factor is any variable that is:

1. Already known to be "causally related" to the health outcome or disease (though not necessarily a direct cause) AND
2. Antecedent to the health outcome or disease based on substantive knowledge or theory, or based on previous research findings.

The confounding factor must be predictive of the health outcome or disease occurrence apart from its association with exposure; that is, among unexposed individuals, the potentially confounding factor should be related to the health outcome or disease. Demographic data such as age, and gender, for example, are widely considered risk factors for the fear of falling. Only one study reported a correlation between high painful joint count and fear of falling among subjects with rheumatoid arthritis (Fessel KD, Nevitt MC. Correlates of fear of falling and activity limitation among persons with rheumatoid arthritis. *Arthritis Care Res.* 1997;10(4):222-8). However, the "number of painful sites/joints" is not considered a risk factor for the fear of falling in other previous studies.

In a population-based pain study, the distribution of the number of painful sites in the body shows that pain at multiple regional sites is common with no clear distinction between single and multiple site syndromes (Hunt IM, Silman AJ, Benjamin S, et al. The prevalence and associated features of chronic widespread pain in the community using the 'Manchester' definition of chronic widespread pain. *Rheumatology* 1999; 38: 275–279). Also, as pointed out by Grimby-Ekman et al, identifying the number of painful sites may have advantages in epidemiological studies but lacks validity in a clinical setting (Grimby-Ekman A, Gerdle B, Bjork J, Larsson B. Comorbidities, intensity, frequency and duration of pain, daily functioning and health care seeking in local, regional, and widespread pain – a descriptive population-based survey (SwePain). *BMC Musculoskelet Disord*. 2015;16:165).

Moreover, one way to exclude or control confounding variables is restriction. Restriction eliminates variation in the confounder (Pourhoseingholi MA, Baghestani AR, Vahedi M. How to control confounding effects by statistical analysis. *Gastroenterol Hepatol Bed Bench*. 2012;5(2):79-83). In this study, we included people with a maximum pain intensity of 10 or 20 mm according to VAS in other body parts other than the lower back. Also, subjects with ambulatory limitations caused by persistent lower-extremity pain and rheumatoid arthritis were excluded from the study which may control confounding by the number of painful sites/ joints.

In the Gonçalves et al. study (the study you mentioned) the association of non-chronic low back pain with physical function, and endurance ... was assessed. Subjects with low back pain have an increased likelihood of co-occurring pain elsewhere in the spine, extremities, or multi-site pain, so they considered the number of painful sites as a covariate. In this study, we investigated the association of fear of falling with performance-based physical function and low back pain. As explained earlier, the number of painful sites/ joints is not considered a risk factor for fear of falling in other studies.

5. COMMENT: In defining LBP as an independent variable, participants were asked if they had experienced LBP in the past 12 months. However, the inclusion criteria specified a history of LBP lasting more than 3 months. Please clarify this discrepancy.

RESPONSE: Thank you for this point. Based on this comment, we revised the independent variable/ LBP, as follows:

CORRECTION:

In the baseline survey, participants were asked if they had experienced LBP lasting more than 3 months in the past year or recurrent LBP for at least two episodes of pain, lasting two consecutive days in the past year.

6. COMMENT: Given that the data had a normal distribution, why was Pearson correlation coefficient not used?

RESPONSE: Thank you for this valuable comment. Age had a non-normal distribution: The text is revised as follows:

CORRECTION:

Statistical analysis: ... The normality of the data was assessed using a combination of the Shapiro-Wilks test, histograms, and skew/kurtosis.

Results: ... All variables except age followed an approximately normal distribution.

7. COMMENT: Given that the inclusion criteria were based on back pain, it would be more appropriate to organize Table 1 accordingly, rather than by gender. In addition, include the pain intensity (VAS) and disability level (ODI) of the participants in Table 1 to better clarify the demographic characteristics of the participants.

RESPONSE: Thank you for this suggestion. According to reviewer 1 comment, the method of reporting had caused inconsistency regarding the study design. Since the study aimed to evaluate the association between LBP and level of physical performance with fear of falling in older adults, the design was considered cross-sectional. In this study comparing individuals with and without LBP was not the main purpose. We revised Table 1, groups were removed and data were reported as a whole in Table 1. Reporting data as a whole (in Table 1) is also seen in similar studies:

- Fernandes SG, Sales WB, Tavares DV, Pereira DDS, Nóbrega PVN, Holanda CMA, et al. Relationship between Pain, Fear of Falling and Physical Performance in Older People Residents in Long-Stay Institutions: A Cross-Sectional Study. *Int J Environ Res Public Health*. 2022;19(19).

- Morelhão PK, Gobbi C, Christofaro DGD, Damato TM, Grande GD, Frange C, et al. Bidirectional Association Between Sleep Quality and Low Back Pain in Older Adults: A Longitudinal Observational Study. *Arch Phys Med Rehabil*. 2022;103(8):1558-64.

Moreover, LBP, age, and gender were added in Table 2 (Bivariate correlation analysis).

Also, the descriptive data for pain intensity and disability was added to Table 1. Revisions are highlighted in Table 1.

8. COMMENT: The results suggest a positive relationship between fear of falling and walking speed. Does this mean that the greater the fear, the faster the walking speed?

Response: Many thanks for your comment. The results indicated an inverse relationship between fear of falling and the time to complete the walking speed test. The time that participants walked an 8-meter distance was measured in seconds rather than meters per second. Specifically, participants with lower levels of fear of falling demonstrated faster walking speeds, as evidenced by their shorter completion time for the test. This finding suggests that a greater fear of falling is associated with slower walking speeds. We apologize for any confusion that may have led to the misunderstanding that a higher fear of falling corresponds to faster walking speeds.

9. COMMENT: What does "direct effect" and "inverse effect" mean in the following sentence? "Gender had a direct effect on fear of falling, and the 30s-STST test had an inverse effect."

Response: Thank you for this point. Based on this comment, we revised the text as follows:

CORRECTION: Table 3 shows a significant direct association between gender as a covariate and fear of falling, with women reporting higher fears. Also, there was a significant indirect association between the 30s-STST test results and fear of falling; participants with a higher fear of falling performed fewer test repetitions.

10. COMMENT: It seems that "30s-STST test" is redundant in the following sentence.

"In addition, the 30s-STST test and gender (model 2) explained 31.5% of the variance score on the fear of falling"

Response: Many thanks for this point. Based on this comment, we revised the text as follows:

CORRECTION: The results of stepwise regression analysis revealed that the 30s-STST test (model 1) accounted for 17.8% of the variance score of the fear of falling. Further, adding gender to the model, as a covariate (model 2), increased the explained variance score to 31.5% (Table 4).

11. COMMENT: It is recommended to emphasize the participants' pain intensity and disability characteristics when explaining the absence of a relationship between back pain and fear.

RESPONSE: Thank you for this valuable comment. Based on this comment, the following explanations were added to the text:

CORRECTION: According to the results of the present study, having or not having LBP was not an indicator of fear of falling. Including older adults with moderate pain and low levels of disability may have resulted in this insignificant finding. Fear of falling may be more pronounced in older adults with LBP, suffering from greater pain and disability. Older adults with severe pain and higher disability levels might experience greater functional limitations and psychological distress, which could increase their fear of falling (47, 48). Thus, extrapolation of the results to older adults with severe LBP and moderate to high disability should be undertaken with caution. Different results may emerge with those having severe pain intensity or moderate to high disability levels.

## VERSION 2 – REVIEW

|                         |   |
|-------------------------|---|
| <b>REVIEWER</b>         | Khanmohammadi, Roya<br>Tehran University of Medical Sciences                                |
| <b>REVIEW RETURNED</b>  | 12-Jul-2024   |
| <b>GENERAL COMMENTS</b> | Congratulations, the comments are well applied and I recommend the article for publication. |