Received: 12 July 2020 | Revised: 17 May 2021 | Accepted: 1 June 2021

DOI: 10.1111/opn.12402

International Journal of Older People Nursing

WILEY

ORIGINAL ARTICLE

The relationship between common foot problems with falls and quality of life in older people

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Funding information
This study has been supported by Rehabilitation Research Center, Iran University of Medical Sciences, Tehran, Iran [grant number: 96-02-125-31475].

Abstract

Objectives: To evaluate the relationship between a number of prevalent foot problems in older people and their history of falls and quality of life. To examine the relationship between timed up and go (TUG) test time and ankle muscles' strength.

Method: In this cross-sectional observational study on a convenient sample of 350 people 65 years and older, direct logistic and hierarchical regressions were used to assess the relation of self-reported falls and quality of life with hallux valgus, oedema, sensory loss and callus. The correlation coefficients were calculated to measure the relationship between TUG test time and ankle muscle strength.

Results: Moderate negative correlations were measured between ankle muscles' strength and TUG time ($r_{Dorsiflexors} = -0.42$ $p = 0.000$, $r_{Plantar\ flexors} = -0.45$ $p = 0.000$). The odds ratio extracted from logistic regression for foot pain was 3.05 ($p = 0.000$, 95% CI: 1.8–5.1). The results of the hierarchical regression showed that oedema had the highest contribution to depicting the quality of life (standardised B = −0.22, $p = 0.001$), followed by foot pain (beta = −0.178, $p = 0.004$) and plantar sensory loss (beta = −0.143, $p = 0.019$).

Conclusion: The results of this study highlight the importance of foot problems in older people. Foot pain showed relationship with self-reported fall experience. Oedema and foot pain had negative impact on quality of life. Ankle muscles' strength may affect balance in older people. However, because of the small effects sizes and wide confidence intervals, the results should be interpreted cautiously.

KEYWORDS

falls, foot pain, oedema, older people, quality of life

1 | INTRODUCTION

The high prevalence of foot problems among older people and their destructive effects on independence and quality of life are among significant issues in geriatrics (Menz, 2008). Foot problems decrease mobility in older people and are considered important risk factors for falls. Impaired foot protective sensation (Chaiwanichsiri et al., 2009), foot pain, hallux valgus and deformities of the lesser toes (Awale et al., 2017; Menz et al., 2018) have been indicated to have relationships with falls in older people. In addition, reduced range of motion of the ankle joint and reduced strength of the toe flexors have been identified as risk factors for falls in older people (Menz et al., 2006).

The ability to carry out daily activities independently and painlessly has a determining effect on the older people's health-related quality of life. Musculoskeletal problems are among the main causes of disability and reduced quality of life in older people (Jover et al., 2015; Minetto et al., 2020). Studies indicate that foot problems have

deleterious effects on different aspects of quality of life in older people. Based on previous research, conditions such as oedema (Cooper-Stanton, 2018; Mercier et al., 2019), foot pain (López-López et al., 2018), hallux valgus (Hogea et al., 2017), callus and deformities of lesser toes (Lopez-Lopez, Martinez-Vazquez, et al., 2018; Lopez-Lopez, Painceira-Villar, et al., 2018) adversely affect the quality of life in older people. This study was conducted to evaluate the relationship between a number of prevalent foot problems in older people and their history of falls and quality of life in Tehran, Iran.

What does this research add to existing knowledge in gerontology?

- This research emphasises the importance of care about foot problems in older people.
- Foot pain and oedema affect quality of life in older people and foot pain may be associated with fall experience.

What are the implications of this new knowledge for nursing care with older people?

- More attention should be paid to foot diseases and deformities in older people.
- Management of foot problems may improve health-related quality of life in older people.
- Including foot and especially ankle muscles' strength, training exercises may benefit older people, since moderate significant correlations were seen between timed up and go test and ankle muscles' strength.

How could the findings be used to influence policy or practice or education?

- Regular foot and ankle clinical examinations should be emphasised in recommendations and educations for those who provide health care for older people.
- Implementing appropriate on time actions when older people are diagnosed with any foot and ankle problems should be highlighted.
- In order to assess risk of falls in older people, nurses should be trained to evaluate common foot problems.

2 | METHODOLOGY

This was a cross-sectional observational study conducted with the participation of people 65 years and above, with Abbreviated Mental Test Scores (AMTS) higher than 6 (Foroughan et al., 2017), living in Tehran and not confined to the bed or wheelchair. The target population in this study was all community-dwelling older people living in Tehran city. In this regard, Tehran city was divided into four regions as strata, and then, samples were selected from each region using the convenience sampling method. Sampling was mainly performed in places with high gathering rates for older people, such as parks and cultural centres from September 2017 to November 2019. Finally, 350 volunteered older people were entered to the study. It should be noted that we considered the number of population of each region proportionally in sample selection. It means that more samples were selected from more populous regions. Institutionalised people were not included in the study. The sample size was estimated based on the prevalence of bunion reported in a previous study (Dunn et al., 2004) using the formula for cross-sectional studies:

$$n = \frac{z^2 P(1-P)}{d^2}$$

Where n is sample size, z is corresponding to confidence level (z = 1.96 for 95% CI), P is expected prevalence (p = 37% obtained from the above-mentioned study), and d is precision (5%). The calculated sample size was 359.

All assessments and data gatherings were done by three trained examiners with academic backgrounds in musculoskeletal education. The ethics committee of the Iran University of Medical Sciences approved the study protocol (No: IR.IUMS.REC. 1396.31475). Written informed consent was obtained from all participants.

2.1 | Assessments and data gathering

The participants' health status and medications in use, employment status and their routine activities were inquired from them and recorded in the evaluation form. The Persian version of the AMTS was used for cognitive assessment. This rapid, brief test includes ten simple questions. The total Cronbach's α coefficient of the Persian version of AMTS was 0.90. Validation study on the Persian version showed that the scores 6 and 7 showed the optimum balance between sensitivity (99% and 94%, respectively) and specificity (85% and 86%, respectively) (Foroughan et al., 2017). Foot skin and toenails were assessed by inspection and palpation in search of conditions such as dry or fissured skin, thick, ingrown and discoloured nails. First metatarsophalangeal (MP) joint range of dorsiflexion was evaluated by goniometer and categorised into normal (more than 50 degrees in non-weight-bearing position), restricted (hallux limitus) and hallux rigidus (less than 10 degrees) (Coughlin & Shurnas, 2003; Scott et al., 2007). Hallux valgus was classified based on the Manchester scale to normal, mild, moderate and severe grades (Garrow et al., 2001). Toe flexor muscles' strength was measured using the paper grip test for greater and lesser toes separately (de Win et al., 2002). Strength of ankle plantar and dorsiflexors were manually tested (Menz, 2004). Corns and calluses were assessed by observation and palpation.

Plantar sensation was evaluated using a 10 g monofilament in four regions of the plantar surface including heel, forefoot (medial and lateral) and greater toe with the eyes closed. The inability to sense each of the true tests or responding positive to a sham test

was considered as impaired sensation (Dunn et al., 2004). Foot and ankle oedema was assessed by the examiner through observation and palpation, and the extremity oedema was graded as 'none', 'visually swollen', 'pitting' or 'marked' (massive swelling and pitting). Oedema graded as pitting or marked was considered to be clinically significant. (Dunn et al., 2004). Participants were questioned regarding foot pain of any severity in the last four weeks, and the region and duration of pain were also recorded. The range of motion of ankle dorsiflexion was evaluated using the weight-bearing Lunge test (Menz, 2004). The Persian version of the Short Form Health Survey (SF-36) questionnaire was given to the participants (Montazeri et al., 2005). If self-administration was not feasible for the participant due to the inability to read and write or having trouble completing the form because of conditions such as visual impairment or hand tremor, the interviewer completed the questionnaire. The participants' history of falls and also the number of falls during the past year were inquired and recorded. The mobility was evaluated using the timed up and go (TUG) test, and the cut-off point of 13.5 seconds was considered for risk of fall (Shumway-Cook et al., 2000). TUG is a simple clinical performance-based measure of lower extremity function, mobility and fall risk. High inter-rater reliability in community-dwelling older people (ICC = 0.98), 87% specificity and sensitivity in identifying fallers and non-fallers (Shumway-Cook et al., 2000), and high test–retest reliability (Steffen et al., 2002) of this test have been reported previously. TUG test is identified frequently for the evaluation of gait and balance deficits in falls screening in the clinical practice guidelines for the prevention of falls in older people published by the American Geriatrics Society and the British Geriatrics Society (Summary of the Updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons, 2011).

2.2 | Statistical analyses

To compare the quality of life in males and females, the Mann–Whitney non-parametric statistical test was conducted. The relationship between muscle strength and TUG test time was evaluated using the Spearman correlation coefficient. Logistic regression was used to evaluate the relationship between falls and foot problems, and the relationship between quality of life and foot problems was evaluated by hierarchical regression. To examine the loading of the pain items on the subscales and total score of SF-36, the Spearman correlation coefficient was used.

3 | RESULTS

Three hundred and fifty participants (215 females and 135 males) took part in this study. Table 1 represents the demographic characteristics of the participants. In some of the following tables, the total number is less than 350, which is due to missing data. The sum of percentages might reach approximately 100% since number has been rounded.

Thick nail was the most prevalent toenail problem (14.2%). 20.5% of the participants had more than one toenail problem. Dry skin (30.9%) and fissured skin (30.8%) were common skin problems. Based on the Manchester scale (Table 2), 69.9% of the participants had hallux valgus. Mild hallux valgus was the most prevalent type of the deformity (36.6%). Pitting and marked oedema were seen in 26.5% of the participants (Table 2). In 42.3% of the participants, the first MP joint range of motion was decreased. The prevalence of hallux rigidus was 10.7% in the sample evaluated (Table 2). Eighty-nine of the participants showed loss of plantar sensation at least at one region. Regions with sensation loss are shown in Table 2. Sensory loss in more than one region was seen in 55.1%. Among those with sensation disorder only in one region, the most prevalent region was the heel area (area with the thickest skin).

Based on the manual muscle testing and six-point scale, the muscle strength of the ankle plantar and dorsiflexors was categorised into normal, good, fair, poor, trace and zero. The strength of ankle plantar flexor muscles was normal in 46.4% (160 persons) and good in 23.5% (81 persons). 30.2% of the participant had plantar flexor strength of grade fair or less. Ankle dorsiflexor muscles' strength was normal in 59.1% (204 persons) and good in 22.6% (78 persons). Ankle dorsiflexor strength was graded fair or less in 18.2% of the participants.

The toe flexor strength was reported as reduced or normal based on the paper grip test. The toe flexor strength in 35.9% of the participants was decreased (Table 2). Ankle joint dorsiflexion range of motion was categorised as normal and reduced based on the lunge test (Table 2). In 45% of the participants evaluated, the ankle joint did not have adequate flexibility to do the lunge movement, and they were considered to have reduced range of motion.

Based on the information available related to pain from 338 participants, 44.1% of them (149 individuals) reported pain in their feet. Among these, 50 individuals (33.5%) had foot pain in more than one region.

Forty-four participants (12.8%) reported more than one fall event in the last year. One hundred and eighteen participants (34.4%) remembered at least one fall in the last year. One hundred and eighty-one individuals (52.7%) reported no history of fall during

TABLE 1 Demographic characteristics of the subjects

	BMI[a] (kg/m^2)	Weight (kg)	Height (cm)	Age (yrs)	Number
27.4 ± 4.1	68.3 ± 9.8	158.4 ± 6.1	68.5 ± 6	215	Female
25.6 ± 2.9	75.4 ± 10.7	171.4 ± 7	70.5 ± 6.6	135	Male
26.7 ± 3.7	71.1 ± 10.7	163.5 ± 7	63.5 ± 6.3	350	Total

[a]Body Mass Index.

TABLE 2 Frequency of oedema, first MP range of motion, sensory loss, toe flexor strength, ankle flexibility and SF-36 mean scores

Oedema	Number (Percentage of total number)
None and visually swollen	253 (73.5%)
Pitting and marked	91 (26.5%)
Total	344 (100%)
1st MP ROM	Number (Percentage of total number)
Normal	199 (57.7%)
Hallux Limitus	109 (31.6%)
Hallux Rigidus	37 (10.7%)
Total	345 (100%)
Sensory Loss	Number (Percentage of sensory loss)
Heel	31 (34.8%)
Forefoot (medial and lateral)	7 (7.9%)
Hallux	2 (2.2%)
More than one zone	49 (55.1%)
Total	89 (100%)
Toe flexor strength	Number (Percentage of total number)
Normal	220 (63.8%)
Reduced	124 (35.9%)
Total	345(100%)
Ankle Flexibility	Number (Percentage of total number)
Normal	188(55%)
Reduced	154(45%)
Total	342(100%)
Hallux Valgus	Number (Percentage of total number)
Normal	104(30.1%)
Mild	127(36.6%)
Moderate	94(27.2%)
Severe	20(5.8%)
Total	343(100%)
SF36	Mean Score
Physical component subscale	56.22±22.34
Mental component subscale	62.84±21.11
Total	60.04±22.04

the past year. Data regarding the history of fall were unavailable in seven cases.

The mean and standard deviation of the TUG test time for the study participants were 11.61 ± 4.1 seconds. Eighty-five of the participants (24.2%) had a TUG test time of more than 13.5 seconds and were at risk of fall.

The Persian version of quality of life questionnaire (SF-36) was used to evaluate the quality of life (Table 2).

To examine the relationship between the TUG test time and ankle muscles' strength, the Spearman correlation coefficient was calculated (Table 3). Moderate negative Spearman's correlation coefficients were measured between ankle dorsi/plantar flexor strength and TUG time ($r_{Dorsiflexors} = -0.42$ $p = 0.000$, $r_{Plantar\ flexors} = -0.45$ $p = 0.000$).

The relationship between falls and foot problems was tested. Direct logistic regression was performed to assess the impact of a number of factors on the likelihood that respondents would have experienced one or more falls (Table 4). The model contained five independent variables (pain, hallux valgus, oedema, sensory loss and callus). The full model containing all predictors was statically significant, X2 (4, N = 290) = 26.86 $p = 0.000$, indicating that the model was able to distinguish between those who have experienced falls and those who have not. Overall, the model explained between 8.8% (Cox and Snell *R*-squared) and 12% (Nagelkerke *R*-squared) of the variance in fall history and correctly classified 67.2% of the cases. As shown in Table 4, only one of the independent variables (pain) made a statistically significant contribution to the model. The odds ratio of 3.05 indicates greater odds of association between foot pain and fall experience.

Hierarchical multiple regression was used to assess the ability of five control measures (pain, oedema, sensation, hallux valgus and callus) to predict the level of quality of life (SF-36 total) after controlling for the influence of gender (Table 5). Preliminary analyses were conducted to ensure no violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Gender was entered at step one, explaining 9.2% of the variance in SF-36 total. After entry of other variables at step two, the total variance explained by the model as a whole was 19.9% $F(6, 227) = 9.382$, $p < 0.001$. The five control measures explained an additional 10.6% of the variance in quality of life, after controlling for gender, *R*-squared change = 0.106, *F* change (5, 227) = 6.032, $p < 0.001$. In the final model, three control measures were statistically significant, the oedema (beta = −0.200, $p = 0.001$), the pain (beta = −0.178, $p = 0.004$) and the plantar sensation (beta = −0.143, $p = 0.019$).

The correlation of the pain item with the subscales of the SF-36 was also examined. The Spearman correlation coefficients between pain item and SF-36 total score was 0.71 $p = 0.000$, between pain item and SF-36 physical component score was 0.62 $p = 0.000$, and between pain item and SF-36 mental component score was 0.72 $p = 0.000$.

4 | DISCUSSION

This study was conducted with the aim of assessing common foot problems and evaluating their relationship with fall and quality of life in an older people population. In this study, the odds of having a history of fall were three times greater in individuals with foot pain. Although the full model was able to distinguish between fallers and non-fallers, it explained at most 12% of the variance of fall history. Higher percentages of explained variance would indicate stronger

TABLE 3 The association between ankle muscles' strength, ankle joint flexibility, toe flexor strength and TUG test time

Ankle flexibility	Toe flexor strength	Dorsiflexor strength	Plantar flexor strength	
0.27	0.11	−0.42	−0.45	Spearman's rho
0.000*	0.05	0.000*	0.000*	Sig. (2-tailed)

*Significance level: 0.05.

TABLE 4 Logistic regression predicting likelihood of fall history

95% Confidence Interval for OR	Odds Ratio (OR)	Sig	Df	Wald	SE	B	
0.431–1.315	0.753	0.318	1	0.997	0.285	−0.284	Hallux Valgus
0.971–2.934	1.688	0.064	1	3.443	0.282	0.523	Oedema
0.306–1.027	0.561	0.061	1	3.506	0.309	−0.578	Sensory loss
1.828–5.094	3.052	0.000*	1	18.217	0.261	1.116	Foot Pain
	0.447	0.002*	1	9.581	0.260	−0.804	Constant

*Significance level: 0.05.

strength of associations, and we could make better predictions. So, interpreting the findings should be done cautiously, despite their accordance with previous literature. The same should be considered for the relationship between SF-36 and foot problems. Oedema of the feet and ankle was an important parameter related to reduced quality of life in this population followed by foot pain and lack of sensation. The fact that the coefficients for pain, sensation and oedema are negative indicates that having each of these foot problems is associated with decrease in quality of life. However, the wide confidence intervals and weak effect sizes raised questions about the generalisability of these results. Plantar and dorsiflexor muscles' strength indicated a moderately negative and significant relationship with TUG test time.

In this study, more than 50% of the participants reported foot pain, indicating different results from some previous studies. In an epidemiologic survey conducted in a small town in Italy on 495 people above 65 years of age, 22% of the study population had reported foot pain (Benvenuti et al., 1995). The Cheshire foot pain and disability survey in people 65 years and above reported approximately 13% foot pain. However, in this research, participants were required to report at least one month of foot pain and one item in the Manchester foot pain and disability index. Thus, it is probable that fewer people satisfied these criteria, or people with more severe pain entered the study (Garrow et al., 2004). Both studies indicated less prevalence of foot problems compared to the current study. Nevertheless, in a study conducted in 1968 in the United States, 74% reported having foot pain (Helfand, 2004), which is much higher than that reported in this study. Each of the studies provides their definitions of foot pain or different methods for recording foot pain. Some are based on the patient's own report, while others are based on clinical examination, and comparison of them is quite challenging. In addition, the prevalence of foot problems and the attention to foot pain in older people in various societies are quite different. Different sample sizes and methods of sampling may be other factors in obtaining different results. Participants of the current study were selected randomly from the community, which is a positive feature of the sampling. An attempt was also made to have participants from different regions of the city.

Nevertheless, the high prevalence of foot pain in the current study and the relationship that foot pain (for any reason) has with a history of falls is quite remarkable, indicating the significance of identifying foot problems and resolving them. In the regression model, pain was shown to have the greatest role in depicting quality of life after oedema, which reveals the significant impact of foot pain on quality of life. In the study by Hill, participants who had foot pain obtained a lower score in all domains of the SF-36 questionnaire (Hill et al., 2008). This indicates that foot pain not only has a physical dimension but also has a significant psychological effect on the individual's life.

The variable that had the greatest relationship with the quality of life score in the current study was foot oedema. Oedema can result in limited range of motion in the ankle, reduced movement and increased risk of falls. Oedema makes it difficult for the individual to find the appropriate footwear (Noble-Jones & Rowley, 2016). Other studies have also reported the reduced quality of life in individuals with oedema. Chronic oedema results in functional impairment, anxiety, depression, social problems and clinical symptoms such as pain and discomfort (Mercier et al., 2019). After oedema, pain had the greatest relationship with quality of life. The pain item also showed to have strong correlations with the SF-36 total score and mental component. Also, a moderate correlation ($r = 0.62$) was seen between pain and physical component. Foot pain has shown to have negative impact on quality of life (Lopez-Lopez, Martinez-Vazquez, et al., 2018). Foot pain was shown to be one of the significant predictors for SF-36 physical component (Chen et al., 2003). All pain types and sources have detrimental effects on all aspects of health-related quality of life in all age groups (Katz, 2002). Despite being in line with other studies, the results of the current study should be interpreted cautiously because of small effect sizes and wide confidence intervals.

Overall, foot problems are observed in about 30% of older people across the world (Benvenuti et al., 1995; Gorter et al., 2000), and a resultant decrease in the speed of walking leads to difficulty in performing daily routines (Leveille et al., 1998). Also, balance and functional abilities in older people have shown relationships with

TABLE 5 Hierarchical regression results (relationship between foot problems and quality of life)

Coefficients													
		Unstandardised Coefficients		Standardised Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model		B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	41.007	4.154		9.872	0.000	32.822	49.191					
	Sex	13.733	2.829	0.304	4.855	0.000	8.160	19.306	0.304	0.304	0.304	1.000	1.000
2	(Constant)	50.328	4.905		10.260	0.000	40.663	59.994					
	Sex	12.067	2.729	0.267	4.422	0.000	6.690	17.444	0.304	0.282	0.263	0.969	1.032
	HV	0.881	2.928	0.018	.301	0.764	−4.889	6.652	−0.035	0.020	0.018	0.947	1.056
	callus	0.974	2.711	0.022	.359	0.720	−4.367	6.316	−0.042	0.024	0.021	0.952	1.051
	Oedema	−9.965	3.016	−0.200	−3.304	0.001	−15.909	−4.021	−0.259	−0.214	−0.196	0.966	1.035
	Sensation	−7.039	2.980	−0.143	−2.362	0.019	−12.910	−1.167	−0.165	−0.155	−0.140	0.969	1.032
	pain	−7.900	2.716	−0.178	−2.909	0.004	−13.251	−2.548	−0.247	−0.190	−0.173	0.940	1.063

Dependent variable: SF-36 total.
All the variables were entered the model as categorical ones.

foot problems, while foot problems have been identified as risk factors for falls (Menz & Lord, 2001). In their study in 2005, Menz et al. identified the toe flexor strength, foot sole sensation and ankle flexibility as predictors of balance (Menz et al., 2005). In the current study, flexor strength of the toes was decreased in about 36% of participants; however, no relationship was observed between the strength of the toe flexors and TUG test time as a functional test. Ankle muscles' strength showed a moderately significant relationship with TUG test results. This test is one of the clinical mobility tests that can be used for predicting risk of falls. In previous studies, the strength of plantar flexors of the ankle was considered an important factor in preventing falls (based on Limit of Stability and postural tests) compared to that of dorsiflexors, and it has been recommended that ankle muscle strength training be included in prevention programmes for falls in older people (Melzer et al., 2009). A more important role of plantar flexors compared to dorsiflexors is the control of balance that has also been referred to in other studies (Bok et al., 2013). However, a study has shown the improvement of balance to be in line with the improvement in ankle dorsiflexor strength in older people (Shehab Mahmoud Abd El- Kader & Ashmawy, 2014). In the current study, the relationship between plantar and dorsiflexor strength and TUG test time were extremely close. However, in a very recent study by Porto et al. (Porto et al., 2020), lower limb muscle strength (including plantar and dorsiflexors) was not directly related to the occurrence of the first fall among older people.

In spite of the results obtained in other studies, this study revealed neither a significant effect of hallux valgus on quality of life nor a relationship with falls.

This study also faced some limitations, including the fact that history of falls was recorded based on the participants' self-reports, and many older people are likely to report falls when they experienced post-fall pain or injury (Boongird & Ross, 2017). Another limitation was that the severity of pain was not inquired upon. In addition, the footwear of the study participants was not evaluated, and problems related to footwear were also not inquired upon. Direct estimates of inter-rater reliability were not made prior to this study. The authors are also aware of the possibility of a biased sample. Because of the recruitment strategy, older people with more frailty or mobility impairments may have less likely been captured. The results of the current study are recommended to interpret cautiously despite their consistency with other studies. A study on a greater sample size may be more trustable. Future prospective studies on the effects of managing foot problems especially pain and oedema on fall occurrence and quality of life in older people could confirm the results more firmly.

5 | CONCLUSION

Despite the limitations, the results of this study highlight the importance of foot problems in older people. The relationships between foot pain and fall experience were significant. Oedema and foot pain also showed significant relationship with quality of life. Moderate

negative correlations were seen between TUG time and ankle muscles' strength. Based on the TUG time, 24.2% of the participants were at risk of falls. However, these results should be interpreted cautiously.

ACKNOWLEDGEMENTS

The authors would like to thank Rehabilitation Research Center of Iran University of Medical Sciences for the financial support of this study [grant number: 96-02-125-31475]. All the participants are appreciated for their presence and patience. The authors would also like to acknowledge Mr Habib Ejrai and Mr Abolfazl Rajabi Moghadam for their help in preparing the proposal. Dr Masoumeh Bagherzadeh Cham is also appreciated for providing opportunities of data gathering.

CONFLICT OF INTEREST

The Authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTIONS

Maryam Jalali supervised the project, designed the analyses, wrote the grant proposal, planned and supervised data collection, performed the analyses, interpreted the results and wrote the paper. Parviz Mozhgani contributed to sampling and data acquisition, contributed to the results interpretation, drafted and provided critical revision of the paper. Hasan Saeedi contributed to the design and implementation of the research. Fatemeh Azadinia contributed to the design and implementation of the research, and contributed to the grant proposal writing. Maryam Niksolat contributed to the design and implementation of the research, and contributed substantially to sampling and data acquisition. Faezeh Ghorbani contributed to the grant proposal writing, organised data collection and contributed substantially in data collection process.

IRB APPROVAL NUMBER

The ethics committee of Iran University of Medical Sciences approved the study protocol (No: IR.IUMS.REC 1396.31475).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, [MN], or first author [MJ] upon reasonable request.

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How to cite this article: Jalali, M., Mojgani, P., Saeedi, H., Azadinia, F., Niksolat, M., & Ghorbani, F. (2021). The relationship between common foot problems with falls and quality of life in older people. *International Journal of Older People Nursing*, 00, e12402. https://doi.org/10.1111/opn.12402