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Incidence and risk factors for falls among community dwelling elderly subjects - A prospective cohort study from Ernakulam, Kerala, India

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Contributors

1. Divyamol K Sasidharan, MD (Geriatric Medicine), jisbbb87@gmail.com
2. Priya Vijayakumar, MD (General Medicine), divz64@gmail.com
3. Manu Raj, DNB (Pediatric Cardiology), drmanuraj@gmail.com
4. Sumi Soman, MSc Nursing, sumisoman90@gmail.com
5. Libin Antony P F, Msc Nursing, libinantony.antony@gmail.com
6. Abhish Sudhakar, MA Sociology, abishsudhakar@aims.amrita.edu
7. Conrad Kabali, PhD Biostatistics, ckabali@gmail.com

Department(s) and institution(s): Department of Geriatric Medicine, Amrita Vishwa Vidyapeetham

Corresponding Author:

Name : Priya Vijayakumar
Address : Clinical Professor
Department of Geriatric Medicine
Amrita Institute of Medical Sciences, Kochi
Phone numbers : 9995653009
E-mail address : divz64@gmail.com

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Title:**Incidence and risk factors for falls among community dwelling elderly subjects - A prospective cohort study from Ernakulam, Kerala, India****Abstract*****Background & Objectives:***

Purpose: There is limited knowledge regarding epidemiology and risk of falls in elderly living in low and middle income countries. The primary objective was to report the incidence of falls in community dwelling elderly population aged 65 years and above from Ernakulam, Kerala, India.

Methods: The study was a prospective cohort with stratified random cluster sampling. We collected information via house visits using a questionnaire. The subjects were followed up prospectively for 12 months by phone at 90 day intervals and missing subjects by house visits.

Participants: Community dwelling elderly above 65years of age.

Findings: We recruited a total of 1000 participants. A total of 201(20.1%) subjects reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow-up years. Female sex (OR 1.48, 95% CI 1.05, 2.10, $p = 0.027$), movement disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, $p=0.048$), arthritis (OR 1.48, 95% CI 1.05, 2.09, $p=0.026$), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09, $p<0.001$), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, $p=0.012$), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, $p=0.001$) and a history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, $p<0.001$) predicted a fall in the following year.

Interpretation & Conclusions: One in five community dwelling elderly fall annually and one in four who fall are prone to fall again in the next year. 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.

Keywords: Falls, Elderly, Community based study, Cohort Study, Kerala

Strengths and limitations of this study

The strengths of the current study include a prospective cohort study design, large sample size (n=1000), representative urban and rural population components, inclusion of participants from different SES levels, no participants lost to follow up and use of a fall diary to avoid recall bias. The limitations include data from a single study site and a short period of follow up (one year).

Introduction

Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent of the total population.¹ This geriatric population is expected to double by 2050 to 2.1 billion.¹ Unintentional injuries are reported to be the fifth leading cause of death globally in this population and falls constitute two out of every three deaths in this category.² The Kellogg International Working Group that was constituted to focus on the prevention of elderly falls defined a fall as 'unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.³

Many prospective population-based studies have examined the epidemiology of falls in the community dwelling elderly across different settings. The reported incidence rates show wide variability from as low as 29% to as high as 40% in this population.⁴⁻⁹ Various studies done in India have reported the prevalence of falls in community dwelling elderly ranging from 13-53%.¹⁰⁻¹³ The incidence of recurrent falls (more than two episodes per calendar year) was reported to be 11 to 21% by Lord et al.⁴

The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven major categories.⁴ These include socio-demographic factors, balance and mobility factors, sensory and neuromuscular factors, psychological factors, medical factors, medication use, and environmental factors.⁴ A recent meta-analysis by Deandrea et al pooled data from 74 prospective cohort studies that reported risk factors for prospective falls among community dwelling elders.¹⁴ A prior history of falls, gait problems, walking aid use, vertigo, Parkinson

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3 disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age
4 group.¹⁴
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7 The primary objective of our study was to report the incidence of falls in community
8 dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective
9 follow up schedule. The secondary objective was to identify factors that can predict a risk for
10 future fall in community dwelling elders.
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20 **Methods:**

21 *Selection and Description of participants:*

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23 **Design & Setting:** The current study is a community based prospective cohort study that was
24 conducted in an area within 10 km radius from the study centre (Amrita Institute of Medical
25 Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of 3
26 years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, 4 municipalities
27 and 1 corporation. The study area comes under Ernakulam district of Kerala, South India.
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34 We calculated the sample size using a previously published study by Mitchell-Fearson et al
35 which reported a 21.7% prevalence for falls in the elderly.¹⁵ We selected an alpha of 0.05 and
36 an allowable error of 20% giving us a minimum sample size of 347 subjects. The design
37 effect for the sampling method (multistage stratified random cluster sampling) was calculated
38 using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC)
39 of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We
40 enrolled a total of 1000 participants anticipating significant sub group differences within the
41 study sample.
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49 **Participants:** We used stratified random cluster sampling method to select the participants.
50 The sample was stratified at two levels, rural urban (level 1) and at the level of individual
51 local self-governing units (LSGs, level 2). A total of 40 clusters using Probability
52 proportional to size technique were selected randomly from the list of all available clusters
53 within the defined geographical area. Each cluster was from an individual electoral ward
54 within the LSGs. We selected 25 participants from each cluster. In each cluster, a random
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3 starting point was selected and households were visited in a sequential manner by the
4 principal investigator and staff till 25 subjects were recruited. A flowchart on the study
5 design used in the present study is shown in figure.1. The inclusion criteria included (i)
6 minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the
7 study area of a minimum of 12 months after assessment and (iv) comprehensive skills in
8 English/Malayalam language. The exclusion criteria included complete dependence for day
9 to day activities.
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16 **Patient and public involvement:** Patients and the public were not specifically involved in
17 the planning and execution of this study. However, they were informed of the need of the
18 study and quarterly follow up was done telephonically.
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22 ***Technical Information and Interventions:***

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24 A study questionnaire was prepared after a detailed literature review of studies related to falls
25 in the elderly. The study questionnaire included questions relating to the socio-demographic
26 profile, comorbidities, physical activity, medication use and environmental assessment. This
27 questionnaire was initially piloted over a small number of patients (n=50) and redundant
28 questions were either removed or modified. The modified questionnaire was reviewed by
29 subject experts and was approved for use in the full study.
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36 All initial assessments were done at the participant's home. The research team (PI, two
37 nurses) visited all recruited subjects at their home premises. The study questionnaire was
38 administered by the PI by means of a face to face interview during house visits. In addition,
39 height, weight and blood pressure readings were taken by the trained staff (nurses) that
40 accompanied the PI. All subjects were advised to keep a diary in which they should note
41 down and incidence of fall along with the date and time of fall, what the patient was doing
42 when he fell, what caused the fall, whether it was witnessed fall or not and whether the fall
43 had any consequences or complications. Three monthly follow up was done by telephonic
44 conversation with enrolled subjects. Those who were not available over the phone were
45 revisited via house visits. The data collection period was from August 2015 to April 2017.
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54 ***Statistics:***

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56 We summarized demographic and social-economic variables to characterize the study
57 population (Table 1). We presented the mean and standard deviation for normally distributed
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3 continuous variables. Values are expressed in number and percentages. We used Chi square
4 test to examine the association of categorical risk factors with prospective falls. All individual
5 factors with a p value of <0.2 for association on bivariate analysis was selected for
6 multivariate analysis. Multiple binary logistic regression was used to construct the prediction
7 model for prospective falls. The cut-off point for statistical significance was set at an α -level
8 of 5%. We reported the adjusted Odds Ratios (aOR) with 95% confidence intervals.
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10 Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago,
11 USA).

17 ***Ethical approval:***

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20 We collected written informed consent from the consenting subjects before recruitment to the
21 study and the same was documented for future reference. The consent contained the title,
22 purpose, methods employed in the study, benefits to the subject as well as family and the
23 interest of the respondent to participate on a voluntary basis to the study. The confidentiality
24 of the study during the analysis was also mentioned in the consent. The consent process and
25 study protocol was approved by the Institutional Ethics Committee (Institutional Ethics
26 Committee Registration Number: ECR/129/Inst/KL/2013).

33 **Results**

34 ***Baseline Characteristics of the study population***

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36 We recruited a total of 1000 participants from 40 individual pre-designated clusters spread
37 across a circular geographical area with the study institution as the centre point. The
38 distribution of gender, age categories, weight status, education level, household living pattern
39 and area of domicile are presented in Table 1. The mean age of the study subjects was
40 72.7(7.2) years. Among study participants, 568 (56.8%) were female, 87.4% were literate
41 and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or
42 obese as per Asian Criteria of BMI classification.¹⁶ The morbidity profile of the study
43 population was published earlier.¹⁷ The self-reported prevalence of diabetes(DM), coronary
44 artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3%
45 respectively. Among study subjects, 768 (76.8%) were hypertensive as documented either by
46 high values on house visit measurement or by current treatment for hypertension. Among
47 hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and
48 remaining 240(31.2%) were newly detected during the baseline evaluation of the study.
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Incidence of falls in the study population

A total of 201(20.1%) subjects reported a fall during the prospective follow up period of 12 months. The total fall episodes during the follow up period were 301. The overall incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 follow up years. The corresponding figures for elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6, 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85 were 27.4, 36.8 and 41.1 per 100 follow up years respectively. Among participants, more women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period, compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls) during the follow up.

Factors associated with prospective falls.

The association of baseline factors with a prospective history of falls during the follow up period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline variables, only gender and living arrangement showed a significant association with a prospective history of falls on bivariate comparisons. Females had a higher risk of fall when compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during daytime also had a higher risk of falls when compared to those living with family/caretaker (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors affecting locomotion was explored by bivariate analysis and is presented in **Table 3**. Among the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010), vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed significant associations with prospective falls on bivariate comparisons. A history of falls in the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p <0.001).

Among baseline factors only gender showed an association with recurrent falls on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion

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3 dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. $p < 0.001$),
4 dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. $p = 0.038$)
5 and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 $p < 0.001$) showed an
6 association with recurrent falls on bivariate comparisons.
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11 In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%)
12 reported taking anti diabetic medications and 69(6.9%) reported taking either
13 benzodiazepines or other sedative drugs. There was no significant association for prospective
14 falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, $p = 0.104$), anti-
15 diabetic medications (OR 1.14, 95% CI 0.81, 1.60, $p = 0.446$) or benzodiazepines/sedatives
16 (OR 1.56, 95% CI 0.90, 2.72, $p = 0.110$) in bivariate comparisons.
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23 ***Independent Risk Factors for prospective falls***

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25 The final adjusted model with independent predictors of prospective falls in the elderly is
26 presented as Table 4. Among the factors examined in the logistic regression model, female
27 sex (OR 1.48, 95% CI 1.05, 2.10, $p = 0.027$), parkinsonism (OR 2.26, 95% CI 1.00, 5.05,
28 $p = 0.048$), arthritis (OR 1.48, 95% CI 1.05-2.09, $p = 0.026$), dependence in basic activities of
29 daily living (OR 3.49, 95% CI 2.00, 6.09, $p < 0.001$), not using antihypertensive medications
30 (OR 1.53, 95% CI 1.10-2.13, $p = 0.012$), living alone during the daytime (OR 3.27, 95% CI
31 1.59-6.71, $p = 0.001$) and history of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58,
32 $p < 0.001$) were found to be significantly associated with falls. The independent predictors for
33 recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, $p = 0.031$), dependence in basic
34 activities of daily living (OR 3.63, 95% CI 1.71, 7.70, $p = 0.001$), and history of falls in the
35 previous year (OR 3.39, 95% CI 1.89, 6.05, $p < 0.001$).
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45 **Discussion**

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47 This community based prospective cohort study provides details of 301 fall episodes
48 experienced by 201 elderly subjects during a follow up period of one year from Ernakulam,
49 Kerala, India. Approximately one in five elderly subjects in this age group reported a fall
50 during the study period. There appears to be a sex based difference in the proportion that fell
51 with one in four elderly women falling compared to one in six men during follow up. The
52 results also suggest a dose response relationship between age and falls with more subjects
53 falling in older age groups compared to relatively younger groups. In addition, every fourth
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3 person who fell reported one or more falls following the index fall episode during the study
4 period. The independent predictors for falls in the elderly included female sex, parkinsonism
5 and related movement disorders, arthritis, dependence in basic activities of daily living, not
6 using antihypertensive medicines, living alone during daytime and a history of fall in the
7 preceding year. The corresponding predictors for recurrent falls included female sex,
8 dependence in basic activities of daily living and a history of fall in the preceding year. To
9 our knowledge, this is the only prospective cohort study done in India that focussed on falls
10 in free living elderly who were assessed in the community setting.

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12 The incidence of falls in the elderly from our study appears to be at the lower end of the
13 spectrum as reported by western studies (29% to 40%).⁴⁻⁹ Interestingly, our results are more
14 similar to that reported by a prospective study among community dwelling elderly Chinese
15 subjects.¹⁸ The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-
16 years for all elderly, women and men respectively. The proportion with recurrent falls in this
17 study was also similar to our study (4.75% v/s 5.3%).

18
19 The risk factors for prospective falls in community dwelling elderly was examined by a
20 recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.¹⁴ Most of the
21 prospective studies in the meta-analysis suggested that community dwelling elderly women
22 are at higher risk for falls compared to their male counterparts. The pooled estimates for falls
23 (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-
24 analysis are in agreement with the current study.

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26 Several prospective studies have reported higher risk for falls among elderly patients with
27 Parkinsonism and/or related movement disorders similar to the current study. The meta-
28 analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI,
29 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't
30 report any positive association between Parkinson's disease and recurrent falls, probably due
31 to the small number of recurrent fallers (5.3%) in the cohort.

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33 Our finding of high risk for falls among those elderly with arthritis is in concordance with
34 several other studies.¹⁹⁻²² Together these studies suggest that elderly with arthritis and/or
35 chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence
36 of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis
37 free peers.²²

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6 Several studies have reported that living alone during the daytime is a risk factor for falls in
7 the elderly as suggested by the current study.¹⁴ The meta-analysis is also in agreement with
8 this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that
9 examined the same.
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13 Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated
14 with falls in the elderly.²³ Yokoya et al recently concluded that higher frequency of leaving
15 home, higher exercise levels and presence of interest in activities (e.g., meeting friends,
16 shopping, working in the garden) were associated with a reduced risk for fall in community
17 dwelling elders.²³ Maintaining and enhancing physical functions, principally walking ability
18 and walking speed are critical for fall prevention among elderly.^{24,25} Age appropriate
19 exercises including those enhancing muscle strength and improving balance can probably
20 reduce the incidence of falls among elderly.²⁵
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24 A history of falls in the previous year appears to be the most consistent risk factor across
25 several studies.^{14,25,26} Pooled data from several studies in the recent meta-analysis puts the
26 risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for
27 recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).¹⁴ Suzuki et al
28 reported that five out of six elderly with a history of falls were anxious about another fall and
29 one in three said that they did not venture out again due to fear of another fall.²⁵
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33 One notable finding in our study was the lack of association for falls with medication use for
34 most groups of medications except for antihypertensive medications. This is in contrast to a
35 meta-analysis of the impact of medication classes on falls in elderly.²⁷ Woolcott et al reported
36 an OR of 1.41 (95% CrI, 1.20-1.71) for falls among elderly with benzodiazepine use.²⁷ The
37 lack of association between sedatives use and falls in our study is probably due to the limited
38 number of subjects reporting the use of the same (6.9%). We saw an inverse association
39 between falls and the use of antihypertensive drug use in the current study. One probable
40 reason could be the high proportion of uncontrolled hypertensives in the study population.
41 This finding needs to be explored further in future studies.
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Conclusion

One in five community dwelling elderly citizens fall on an annual basis and one in four of those who fall are prone to fall again in the same calendar year. Female sex, movement disorders including parkinsonism, arthritis, dependence in basic activities of daily living, living alone during daytime and a history of falls in the previous year appear to predict a fall in the following year. Any intervention targeting a reduction in falls among the elderly need to focus on the modifiable risk factors like living alone at home during daytime, movement disorders and arthritis. We need to encourage mechanisms that may reduce dependence of elderly on basic activities of daily living. Attention should also be given to encourage both physical activity and interests in social activities among elderly subjects.

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)
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Gender	Male	432(43.2)
	Female	568(56.8)
Age group	65-75	648(64.8)
	75-85	262(26.2)
	>85	90(9.0)
Weight Status(BMI)	Underweight(<18.5)	124(12.4)
	Normal(18.5-22.9)	340(34.0)
	Overweight(23-24.9)	188(18.8)
	Pre Obese(25-29.9)	264(26.4)
	Obese(>30)	84(8.4)
Education	Graduate and above	132(13.2)
	Diploma / Pre-degree	85(8.5)
	Middle class / Primary	657(65.7)
	Illiterate	126(12.6)
House Hold	Living with family / caretaker	820 (82.0)
	Living alone during daytime	145 (14.5)
	Living alone	35 (3.5)
Domicile	Urban	700(70.0)
	Rural	300(30.0)

Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors	Prospective falls		OR (95% CI)	P value
	No Fall	Fall		

	n(%)	n (%)	n (%)		
Gender					
Men [432(43.2)]		365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women [568(56.8)]		434(76.4)	134(23.6)		
Age Group in years					
65-75 [648(64.8)]		528(81.5)	120(18.5)		
75-85 [262(26.2)]		208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 [90(9.0)]		63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]					
No		532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes		267(78.1)	75(21.9)		
Hypertension (768(76.8))					
No		181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes		618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))					
No		622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes		177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))					
No		639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes		160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))					
No		762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes		37(69.8)	16(30.2)		
Alcohol (177(17.7))					
No		654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
Yes		145(81.9)	32(18.1)		
Smoking (178(17.8))					
No		652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
Yes		147(82.6)	31(17.4)		
Living Arrangement					
Living with family/caretaker (820(82))		669(81.6)	151(18.4)		
Living alone during daytime (145(14.5))		109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone (35(3.5))		21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	Prospective falls	OR (95% CI)	P value
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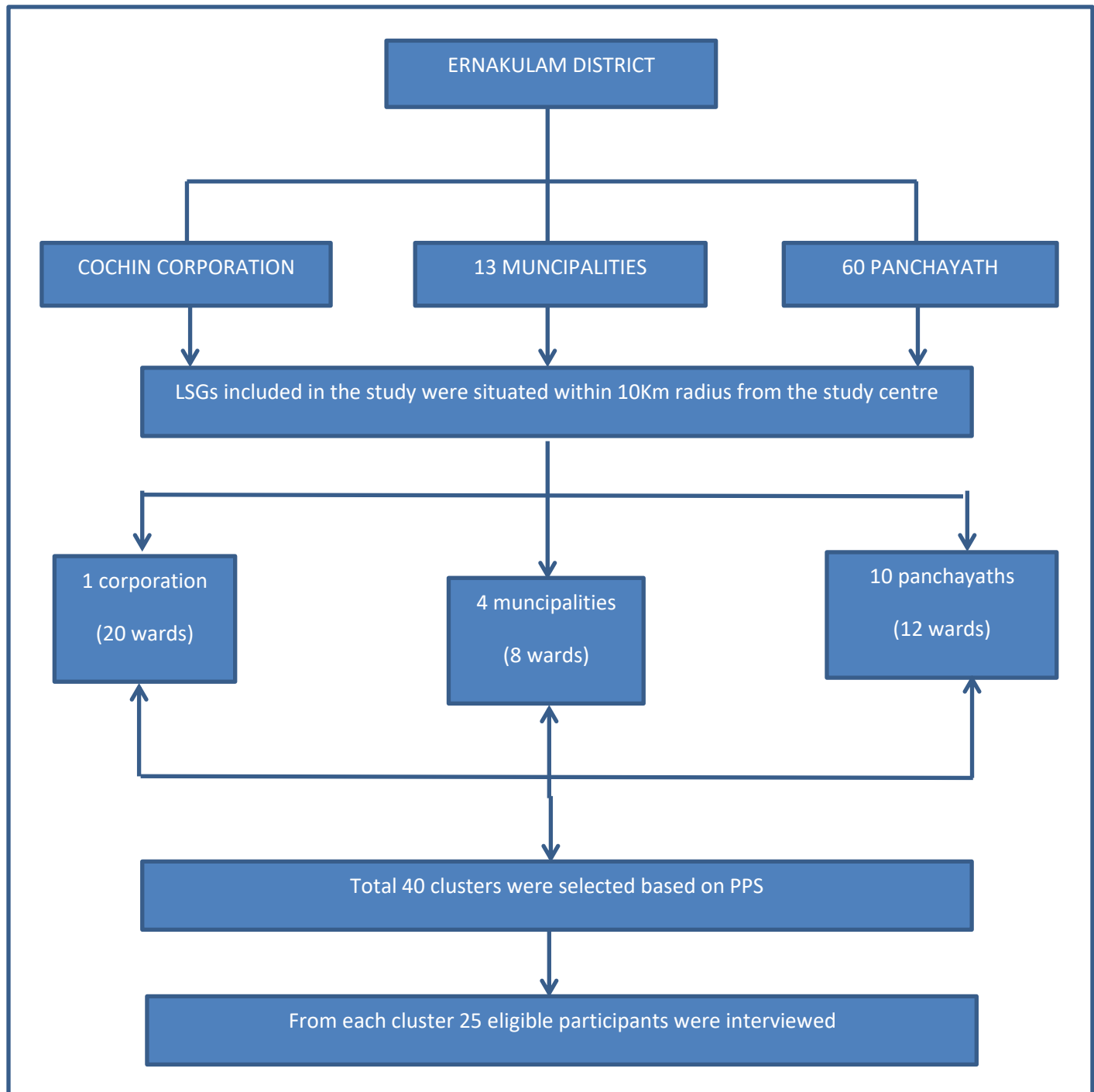
		No Fallers n (%)	Fallers n (%)		
Parkinsonism(28(2.8))	No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
	Yes	17(60.7)	11(39.3)		
Vertigo(388(38.8))	No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))	No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))	No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))	No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))	No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)	75(23.7)		
Visual impairment (594(59.4))	No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
	Yes	473(79.6)	121(20.4)		
Not independent in Basic Activities of daily living (59(5.9))	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

Table 4 Risk factors of falls in community dwelling elderly subjects

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure

Fig.1 Flowchart of the Study Design



APPENDIX IV

INFORMED CONSENT

Introduction: Falls are a very common and often devastating problem in the elderly population. Most of these patients, who fall, end up getting injured, needing hospitalization or even surgical procedures. The prevalence of falls in the elderly is high and debilitating to the patients. However this aspect of health care is mostly neglected in our setup unless and until a person reports after a fall. Hence I feel this study will help us to assess the risk of fall in our population.

Name of project: A PROSPECTIVE STUDY TO ASSESS THE PREVALENCE OF FALLS IN ELDERLY IN ERNAKULAM DISTRICT AND ITS ASSOCIATED RISK FACTORS OVER 1 YEAR

Co coordinating center: Geriatric department, Amrita Institute of medical sciences, Kochi

Name of respondent.....

Address.....

Invitation and Purpose of the study:

We are conducting a study in which we are trying to understand the prevalence of fall in elderly in Kochi, Kerala, India and to find out the factors associated with these falls, with your permission, we would like to conduct this study. Please go through the details of the project below

Do I have to take part in this study?

Your participation in this study is voluntary. It is up to you to decide whether to participate in this study. If you change your mind, you are free to withdraw from the study at any time and without giving a reason. Refusal to participate will not involve any penalty or loss.

What do I have to do in this study? What is being studied?

If you agree to participate in this study, a questionnaire containing questions on environmental and lifestyle factors under study will be used to collect data. Trained investigators with the assistance of translators will administer the questionnaire. You will have to give answers to the questions asked. Follow up shall be done over phone where you have to say if you have fallen during the study period and the details of falls.

A Prospective Study to Assess the Prevalence of Falls in the Elderly Living in Thrissur District and its Associated Risk Factors

What are the Methods employed in the study?

A questionnaire containing questions on environmental and lifestyle factors under study. Basic physical parameters will be assessed, like height, weight, BMI and blood pressure. Memory status and depression status will be assessed using MMSE and GDS tools.

What are the risks in taking part in this study?

There are no risks in taking part in the study.

What are the Benefits?

The study will not provide you with any direct benefits. This study will put some light to the extent of this unrecognized problem. This information will help in prevention of such falls in elderly.

Is participation compulsory?

No. Taking part in this study is on a voluntary basis. If you have any doubt please do not hesitate to ask.

How will the information collected in the study be used?

The information collected will be kept completely confidential. At no point will we reveal the identity of the respondents when we analyze the data. Your information will be archived in a coded form. Your permission to the investigator to use this information does not automatically end at a particular time.

However your details will be released to any regulatory authorities if requested for legal/auditing purpose.

Problems or Questions:

If you have any question about the study, you may contact your investigator, whose details will be provided to you. You will also be asked to provide your address and contact details as we need to contact you during the study.

Name and Contact Details of the Investigator - Dr. Divyamol Sasidharan

Mob. No. 9995653009

email:divz64@gmail.com

Geriatrics Department

ADMS, Kochi-682041

Name and contact details of local/Central ethics committee chairperson/member -

Dr. Santhi Kumar Nair, ADMS, Kochi-682041

A Prospective Study to Assess the Prevalence of Falls in the Elderly Living in Ernakulam District and its Associated Risk Factors

I confirm that I have read the written information for study, "Prevalence of falls in elderly in Ernakulam district and its associated risk factors over 1 year in Kochi, Kerala, India", and confirm that

- I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.
- I understand that I grant access to data to authorized persons described in the information sheet have been given time and opportunity to consider taking part in this study.
- I understand my participation is voluntary and that I am free to withdraw at any time, without giving reason
- I agree to take part in this study.

I confirm that I have been informed by my investigator that the information collected from me will be used for presentation /scientific publication and research analysis. I understand that such use is for advancement of further medical knowledge. I voluntarily agree to such use. I also understand that my identity will not be revealed in such presentation I express my willingness to the same. Having understood all the facts and the conditions stated above I accept and agree and hereby express my free and voluntary consent to Dr. Divyamol Sasidharam and his associates to participate in the study.

I understand that I have not given up any of my rights by signing this form. I will receive the full copy of the informed consent referred to above, including this signed statement with my signature below:

Signature of respondent:

Address:

Date:

Signature of witness:

Name of witness:

Address:

Date:

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6 *A Prospective Study to Assess the Prevalence of Falls in the Elderly Living in Transjordan District and its Associated Risk Factors*
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8 I have explained and made Mr. /Mrs. understand
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10 the above mentioned details of the study. -
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15 Signature of investigator:

16 Name:

17 Address:

18 Date:
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033691.R1
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Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Epidemiology, Public health
Keywords:	Falls, Elderly, Community based study, Cohort Study, Kerala

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1 **Type of article:** Original

2 **Title of the article:** Incidence and risk factors for falls among community dwelling
3 elderly subjects on a one year follow up - A prospective cohort study from Ernakulam,
4 Kerala, India

5 **Running title :** Risk factors for falls among community dwelling elderly subjects in Kerala

6 **Contributors**

- 7 1. Divyamol K Sasidharan, MD (Geriatric Medicine), jisbbb87@gmail.com, Geriatric
8 Medicine Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 9 2. Priya Vijayakumar, MD (General Medicine), divz64@gmail.com, Geriatric Medicine
10 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 11 3. Manu Raj, DNB (Pediatric Cardiology), drmanuraj@gmail.com, Public Health
12 Research Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 13 4. Sumi Soman, MSc Nursing, sumisoman90@gmail.com, Public Health Research
14 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 15 5. Libin Antony P F, Msc Nursing, libinantony.antony@gmail.com, Public Health
16 Research Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 17 6. Abish Sudhakar, MA Sociology, abishsudhakar@aims.amrita.edu, Paediatric
18 Cardiology, Amrita Institute of Medical Science, Kochi, Kerala, India
- 19 7. Conrad Kabali, PhD Biostatistics, ckabali@gmail.com, Division of
20 Epidemiology, University of Toronto Dalla Lana School of Public
21 Health, Toronto, Ontario, Canada

22
23 **Department(s) and institution(s):** Department of Geriatric Medicine, Public Health
24 Research Department, Amrita Institute of Medical Science, Kochi, Kerala, India

25
26 **Corresponding Author:**

27 Name : Priya Vijayakumar

28 Address : Clinical Professor

29 Department of Geriatric Medicine

30 Amrita Institute of Medical Sciences, Kochi

1
2
3
4 31 Phone numbers : 9995653009
5
6 32 E-mail address : divz64@gmail.com

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40 49 **Title:**

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42 50 **Incidence and risk factors for falls among community dwelling elderly subjects on a one**
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44 51 **year follow up - A prospective cohort study from Ernakulam, Kerala, India**

45
46 52 **Abstract**

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48 53 **Purpose :** There is limited data regarding epidemiology and risk of falls in elderly in low
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50 54 middle income countries probably due to lack of awareness regarding the factors leading to
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52 55 falls and the consequences of fall related injuries in old in these countries.

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54 56 **Participants :** Community dwelling elderly above 65years of age.

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58 58 **Findings to date :** We recruited a total of 1000 participants. A total of 201(20.1%) subjects
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4 59 reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per
5 60 100 follow-up years. Female sex (OR 1.48, 95% CI 1.05, 2.10, $p = 0.027$), movement
6 61 disorders including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, $p=0.048$), arthritis (OR 1.48,
7 62 95% CI 1.05, 2.09, $p=0.026$), dependence in basic activities of daily living (OR, 3.49, 95%
8 63 CI 2.00, 6.09, $p<0.001$), not using antihypertensive medications (OR, 1.53, 95% CI 1.10,
9 64 2.13, $p=0.012$), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, $p=0.001$) and a
10 65 history of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, $p<0.001$) predicted a fall
11 66 in the following year.

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19 68 **Future plans:** The Cohort is being followed up to study falls and its relation to mortality.
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25 71 **Keywords:** Falls, Elderly, Community based study, Cohort Study, Kerala

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28 72 **Strengths and limitations of this study:**

- 29 73
- 30 74 • The study was a prospective cohort study design with large sample size ($n=1000$).
 - 31 75 • The study population represented both urban and rural population from different
 - 32 76 Socio Economic Scale levels.
 - 33 77 • None of the participants were lost to follow up and a fall diary was used to avoid
 - 34 78 recall bias.
 - 35 79 • The data is from a single study setting.
 - 36 80 • The study has a short period of follow up (one year).
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45 82 **Introduction**

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48 83 Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent
49 84 of the total population.¹ Unintentional injuries are reported to be the fifth leading cause of
50 85 death globally in this population and falls constitute two out of every three deaths in this
51 86 category.² The Kellogg International Working Group defined a fall as ‘unintentionally
52 87 coming to the ground or some lower level and other than as a consequence of sustaining a
53 88 violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic
54 89 seizure’.³

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3 90 Many prospective population-based studies have examined the epidemiology of falls in the
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5 91 community dwelling elderly across different settings. Environmental factors have been
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7 92 considered as having an association with falls in low middle income countries. Nutrition is
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9 93 not that well addressed among the elders in developing countries. Poor nutrition is a risk
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11 94 factor that could be contributing to the increase in falls in low middle income countries.
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13 95 Interventions that prevent falls are not accessible to a majority of elder population in such
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15 96 countries. Fall preventing interventions are not that freely available in many part of such
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17 97 countries.⁴

17 98 The reported incidence rates show wide variability from as low as 29% to as high as 40% in
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19 99 this population.⁵⁻¹⁰ Various studies done in India have reported the prevalence of falls in
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21 100 community dwelling elderly ranging from 13-53%.¹¹⁻¹⁴ The incidence of recurrent falls (more
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23 101 than two episodes per calendar year) was reported to be 11 to 21% by Lord et al.⁵

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25 102 The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven
26
27 103 major categories.⁵ These include socio-demographic factors, balance and mobility factors,
28
29 104 sensory and neuromuscular factors, psychological factors, medical factors, medication use,
30
31 105 and environmental factors.⁵ A recent meta-analysis by Deandrea et al pooled data from 74
32
33 106 prospective cohort studies that reported risk factors for prospective falls among community
34
35 107 dwelling elders.¹⁵ A prior history of falls, gait problems, walking aid use, vertigo, parkinson
36
37 108 disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age
38
39 109 group.¹⁵

39 110 The primary objective of our study was to report the incidence of falls in community
40
41 111 dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective
42
43 112 follow up schedule. The secondary objective was to identify factors that can predict a risk for
44
45 113 future fall in community dwelling elders.

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48 49 115 **Methods:**

50 51 116 *Selection and Description of participants:*

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53
54 117 **Design & Setting:** The current study is a community based prospective cohort study that was
55
56 118 conducted in an area within 10 km radius from the study centre (Amrita Institute of Medical
57
58 119 Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of

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2
3 120 three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, four
4
5 121 municipalities and one corporation. The study area comes under Ernakulam district of Kerala,
6
7 122 South India.

8
9 123 We calculated the sample size using a previously published study by Mitchell-Fearson et al
10
11 124 which reported 21.7% prevalence for falls in the elderly.¹⁶ We selected an alpha of 0.05 and
12
13 125 an allowable error of 20% giving us a minimum sample size of 347 subjects. The design
14
15 126 effect for the sampling method (multistage stratified random cluster sampling) was calculated
16
17 127 using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC)
18
19 128 of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We
20
21 129 enrolled a total of 1000 participants anticipating significant sub group differences within the
22
23 130 study sample.

24 131 **Participants:** We used stratified random cluster sampling method to select the participants.
25
26 132 The sample was stratified at two levels, rural urban (level 1) and at the level of individual
27
28 133 local self-governing units (LSGs, level 2). A total of 40 clusters using Probability
29
30 134 proportional to size technique were selected randomly from the list of all available clusters
31
32 135 within the defined geographical area. Each cluster was from an individual electoral ward
33
34 136 within the LSGs. We selected 25 participants from each cluster. In each cluster, a random
35
36 137 starting point was selected and households were visited in a sequential manner by the
37
38 138 principal investigator and staff till 25 subjects were recruited. A flowchart on the study
39
40 139 design used in the present study is shown in figure.1. The inclusion criteria included (i)
41
42 140 minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the
43
44 141 study area for a minimum of one year after assessment and (iv) ability to communicate in
45
46 142 English/Malayalam language. The exclusion criteria included complete dependence for day
47
48 143 to day activities.

47 144 **Operational definitions:**

48
49 145 Fall was defined as suggested by The Kellogg International Working Group as mentioned in
50
51 146 the introduction.³

52
53
54 147 A recurrent fall was defined as fall of two or more times during the follow up period of one
55
56 148 year.⁵

1
2
3 149 **Patient and public involvement:** Patients and the public were not specifically involved in
4
5 150 the planning and execution of this study. However, they were informed of the need of the
6
7 151 study and quarterly follow up was done telephonically.
8

9 152 ***Technical Information and Interventions:***

10
11 153 A study questionnaire was prepared after a detailed literature review of studies related to falls
12
13 154 in the elderly. The study questionnaire included questions relating to the socio-demographic
14
15 155 profile, comorbidities, physical activity, medication use and environmental assessment. This
16
17 156 questionnaire was initially piloted over a small number of patients (n=50) and redundant
18
19 157 questions were either removed or modified. The modified questionnaire was reviewed by
20
21 158 subject experts and was approved for use in the full study.
22

23 159 All initial assessments were done at the participant's home. The research team (PI, two
24
25 160 nurses) visited all recruited subjects at their home premises. The study questionnaire was
26
27 161 administered by the PI by means of a face to face interview during house visits. In addition,
28
29 162 height, weight and blood pressure readings were taken by the trained staff (nurses) that
30
31 163 accompanied the PI. All subjects were advised to keep a fall diary in which they should note
32
33 164 down and incidence of fall along with the date and time of fall, what the patient was doing
34
35 165 when he fell, what caused the fall, whether it was witnessed fall or not and whether the fall
36
37 166 had any consequences or complications. Three monthly follow up was done by telephonic
38
39 167 conversation with enrolled subjects for one year from first visit. Those who were not
40
41 168 available over the phone were revisited via house visits by the research staff and hence no
42
43 169 missing data was encountered in the study. In addition, the fall diaries of those who reported
44
45 170 a fall from the same cluster were reviewed during these house visits. The data collection
46
47 171 period was from August 2015 to April 2017.

48
49 172 ***Statistics:***

50
51 173 We summarized demographic and social-economic variables to characterize the study
52
53 174 population (Table 1). We presented the mean and standard deviation for normally distributed
54
55 175 continuous variables. Values are expressed in number and percentages. We used Chi square
56
57 176 test to examine the association of categorical risk factors with prospective falls. All individual
58
59 177 factors with a p value of <0.2 for association on bivariate analysis was selected for
60
178 multivariate analysis. Multiple binary logistic regression was used to construct the prediction

1
2
3 179 model for prospective falls. We selected Logistic regression after verifying lack of over-
4
5 180 dispersion using the Pearson and deviance methods. The cut-off point for statistical
6
7 181 significance was set at an α -level of 5%. We reported the adjusted Odds Ratios (aOR) with
8
9 182 95% confidence intervals. We encountered no missing data in the study. Statistical analysis
10
11 183 was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago, USA).

12 13 184 ***Ethical approval:***

14
15 185 We collected written informed consent from the consenting subjects before recruitment to the
16
17 186 study and the same was documented for future reference. The consent contained the title,
18
19 187 purpose, methods employed in the study, benefits to the subject as well as family and the
20
21 188 interest of the respondent to participate on a voluntary basis to the study. The confidentiality
22
23 189 of the study during the analysis was also mentioned in the consent. The consent process and
24
25 190 study protocol was approved by the Institutional Ethics Committee of Amrita Institute of
26
27 191 Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number:
28
29 192 ECR/129/Inst/KL/2013).

30 193 **Results**

31 32 194 ***Baseline Characteristics of the study population***

33
34 195 We recruited a total of 1000 participants from 40 individual pre-designated clusters spread
35
36 196 across a circular geographical area with the study institution as the centre point of which 568
37
38 197 (56.8%) were female. The distribution of gender, age categories, weight status, education
39
40 198 level, household living pattern and area of domicile are presented in Table 1. The mean age
41
42 199 of the study subjects was 72.7(7.2) years. Among study participants, 568 (56.8%) were
43
44 200 female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%)
45
46 201 were either pre-obese or obese as per Asian Criteria of BMI classification.¹⁷ The morbidity
47
48 202 profile of the study population was published earlier.¹⁸ The self-reported prevalence of
49
50 203 diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were
51
52 204 34.2%, 20.1%&5.3% respectively. Among study subjects, 768 (76.8%) were hypertensive as
53
54 205 documented either by high values on house visit measurement or by current treatment for
55
56 206 hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking
57
58 207 treatment for hypertension and remaining 240(31.2%) were newly detected during the
59
60 208 baseline evaluation of the study.

209 ***Incidence of falls in the study population***

210 A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one
211 year. The total fall episodes during the follow up period were 301. The overall incidence rate
212 of falls was 31 (95% CI 27.7, 34.6) per 100 follow up years. The corresponding figures for
213 elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6,
214 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85
215 were 27.4, 36.8 and 41.1 per 100 follow up years respectively. Among participants, more
216 women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified
217 groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period,
218 compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years
219 group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls)
220 during the follow up.

221 ***Factors associated with prospective falls.***

222 The association of baseline factors with a prospective history of falls during the follow up
223 period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline
224 variables, only gender and living arrangement showed a significant association with a
225 prospective history of falls on bivariate comparisons. Females had a higher risk of fall when
226 compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during
227 daytime also had a higher risk of falls when compared to those living with family/caretaker
228 (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors
229 affecting locomotion was explored by bivariate analysis and is presented in **Table 3**. Among
230 the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010),
231 vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p
232 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence
233 in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in
234 instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed
235 significant associations with prospective falls on bivariate comparisons. A history of falls in
236 the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p
237 <0.001).

238
239 Among baseline factors only gender showed an association with recurrent falls on bivariate
240 comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion

1
2
3 241 dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001),
4
5 242 dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038)
6
7 243 and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an
8
9 244 association with recurrent falls on bivariate comparisons.

10
11 245

12 246 In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%)
13
14 247 reported taking anti diabetic medications and 69(6.9%) reported taking either
15
16 248 benzodiazepines or other sedative drugs. There was no significant association for prospective
17
18 249 falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-
19
20 250 diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives
21
22 251 (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

23 252 ***Independent Risk Factors for prospective falls***

24
25 253 The final adjusted model with independent predictors of prospective falls in the elderly is
26
27 254 presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis
28
29 255 with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary
30
31 256 symptoms, constipation, knee pain, paresthesia of feet, history of fall in the previous year,
32
33 257 dependence in basic and instrumental activities of daily living, use of assistive devices for
34
35 258 movement, cognitive impairment, depression, use of antihypertensive medications and
36
37 259 benzodiazepines. The same were included in the final model construction. Among the factors
38
39 260 examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p =
40
41 261 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI
42
43 262 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00,
44
45 263 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13,
46
47 264 p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history
48
49 265 of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be
50
51 266 significantly associated with falls.

52
53 267 The factors included to assess the independent risk factors of recurrent falls were, female sex,
54
55 268 vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily
56
57 269 living and history of falls in the previous year. From the above, the independent predictors for
58
59 270 recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic
60
271 activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the
272 previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

273 Discussion

274 This community based prospective cohort study provides details of 301 fall episodes
275 experienced by 201 elderly subjects during a follow up period of one year from Ernakulam,
276 Kerala, India. Approximately one in five elderly subjects in this age group reported a fall
277 during the study period. There appears to be a sex based difference in the proportion that fell
278 with one in four elderly women falling compared to one in six men during follow up. The
279 results also suggest a dose response relationship between age and falls with more subjects
280 falling in older age groups compared to relatively younger groups. In addition, every fourth
281 person who fell reported one or more falls following the index fall episode during the study
282 period. The independent predictors for falls in the elderly included female sex, parkinsonism
283 and related movement disorders, arthritis, dependence in basic activities of daily living, not
284 using antihypertensive medicines, living alone during daytime and a history of fall in the
285 preceding year. The corresponding predictors for recurrent falls included female sex,
286 dependence in basic activities of daily living and a history of fall in the preceding year. To
287 our knowledge, this is the only prospective cohort study done in India that focussed on falls
288 in free living elderly who were assessed in the community setting.

289 The incidence of falls in the elderly from our study appears to be at the lower end of the
290 spectrum as reported by western studies (29% to 40%).⁵⁻¹⁰ Interestingly, our results are more
291 similar to that reported by a prospective study among community dwelling elderly Chinese
292 subjects.¹⁹ The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-
293 years for all elderly, women and men respectively. The proportion with recurrent falls in this
294 study was also similar to our study (4.75% v/s 5.3%).

295 The risk factors for prospective falls in community dwelling elderly was examined by a
296 recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.¹⁵ Most of the
297 prospective studies in the meta-analysis suggested that community dwelling elderly women
298 are at higher risk for falls compared to their male counterparts. The pooled estimates for falls
299 (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-
300 analysis are in agreement with the current study.

301 Several prospective studies have reported higher risk for falls among elderly patients with
302 Parkinsonism and/or related movement disorders similar to the current study. The meta-
303 analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI,

1
2
3 304 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't
4
5 305 report any positive association between Parkinson's disease and recurrent falls, probably due
6
7 306 to the small number of recurrent fallers (5.3%) in the cohort.
8

9
10 307 Our finding of high risk for falls among those elderly with arthritis is in concordance with
11
12 308 several other studies.²⁰⁻²³ Together these studies suggest that elderly with arthritis and/or
13
14 309 chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence
15
16 310 of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis
17
18 311 free peers.²³
19

20
21 313 Several studies have reported that living alone during the daytime is a risk factor for falls in
22
23 314 the elderly as suggested by the current study.¹⁵ The meta-analysis is also in agreement with
24
25 315 this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that
26
27 316 examined the same.

28
29 317 Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated
30
31 318 with falls in the elderly.²⁴ Yokoya et al recently concluded that higher frequency of leaving
32
33 319 home, higher exercise levels and presence of interest in activities (e.g., meeting friends,
34
35 320 shopping, working in the garden) were associated with a reduced risk for fall in community
36
37 321 dwelling elders.²⁴ Maintaining and enhancing physical functions, principally walking ability
38
39 322 and walking speed are critical for fall prevention among elderly.^{25,26} Age appropriate
40
41 323 exercises including those enhancing muscle strength and improving balance can probably
42
43 324 reduce the incidence of falls among elderly.²⁶

44
45 325 A history of falls in the previous year appears to be the most consistent risk factor across
46
47 326 several studies.^{15,26,27} Pooled data from several studies in the recent meta-analysis puts the
48
49 327 risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for
50
51 328 recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).¹⁵ Suzuki et al
52
53 329 reported that five out of six elderly with a history of falls were anxious about another fall and
54
55 330 one in three said that they did not venture out again due to fear of another fall.²⁶

56
57 331 One notable finding in our study was the lack of association for falls with medication use for
58
59 332 most groups of medications except for antihypertensive medications. This is in contrast to a
60
333 meta-analysis of the impact of medication classes on falls in elderly.²⁸ Woolcott et al reported

1
2
3 334 an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.²⁸ The
4
5 335 lack of association between sedatives use and falls in our study is probably due to the limited
6
7 336 number of subjects reporting the use of the same (6.9%). We saw an inverse association
8
9 337 between falls and the use of antihypertensive drug use in the current study. One probable
10
11 338 reason could be the high proportion of uncontrolled hypertensives in the study population.
12 339 This finding needs to be explored further in future studies.

13
14 340 The strengths of the current study include; prospective cohort study design, large sample size
15
16 341 (n=1000), representative urban and rural population components, inclusion of participants
17
18 342 from different Socioeconomic levels, no participants lost to follow up and use of a fall diary
19
20 343 to avoid recall bias. However, the study included participants from a limited geographical
21
22 344 setting and was able to follow up only for a shorter period (one year) and hence the
23 345 generalisation of the study findings is limited.

24
25 346

26
27 347

28
29 348 ***Funding:***

30
31 349

32 350 This research received no specific grant from any funding agency in the public, commercial
33
34 351 or not-for-profit sectors.

35
36 352

37 353 **Conclusion**

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39 354

40 355 One in five community dwelling elderly citizens fall on an annual basis and one in four of
41
42 356 those who fall are prone to fall again in the same calendar year. Female sex, movement
43
44 357 disorders including parkinsonism, arthritis, dependence in basic activities of daily living,
45
46 358 living alone during daytime and a history of falls in the previous year appear to predict a fall
47
48 359 in the following year. Any intervention targeting a reduction in falls among the elderly need
49
50 360 to focus on the modifiable risk factors like living alone at home during daytime, movement
51
52 361 disorders and arthritis. We need to encourage mechanisms that may reduce dependence of
53
54 362 elderly on basic activities of daily living. Attention should also be given to encourage both
55
56 363 physical activity and interests in social activities among elderly subjects.

57 364

58 365 **Competing Interests:** Authors have no competing interests.

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3 **367 References:**

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)
Gender	
Male	432(43.2)
Female	568(56.8)
Age group	
65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)
Living alone	35 (3.5)
Domicile	

Urban	700(70.0)
Rural	300(30.0)

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Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors n(%)	Prospective falls		OR (95% CI)	P value
	No Fall n (%)	Fall n (%)		
Gender				
Men [432(43.2)]	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women [568(56.8)]	434(76.4)	134(23.6)		
Age Group in years				
65-75 [648(64.8)]	528(81.5)	120(18.5)	1.14 (0.80-1.64)	0.468
75-85 [262(26.2)]	208(79.4)	54(20.6)		
>85 [90(9.0)]	63(70.0)	27(30.0)		
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))				
No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes	37(69.8)	16(30.2)		

Alcohol (177(17.7))	No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
	Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))	No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
	Yes	147(82.6)	31(17.4)		
Living Arrangement					
Living with family/caretaker (820(82))		669(81.6)	151(18.4)		
Living alone during daytime (145(14.5))		109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone (35(3.5))		21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

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Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	Prospective falls		OR (95% CI)	P value
	No Fallers n (%)	Fallers n (%)		
Parkinsonism(28(2.8))	No	782(80.5)	2.663(1.23-5.78)	0.010
	Yes	17(60.7)		
Vertigo(388(38.8))	No	505(82.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)		
Arthritis(281(28.1))	No	591(82.2)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)		
Knee pain (565(56.5))	No	356(81.8)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)		
Numbness and paraesthesia of feet(475(47.5))	No	432(82.3)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)		
Urinary symptoms (316(31.6))	No	558(81.6)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)		
Visual impairment (594(59.4))	No	326(80.3)	1.04(0.76-1.43)	0.796
	Yes	473(79.6)		

16

Not independent in Basic Activities of daily living (59(5.9))	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

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Table 4 Risk factors of falls in community dwelling elderly subjects

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

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Figure legends

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4 471 Fig.1 Flowchart of the study design

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13 477 **Contributorship statement** :-

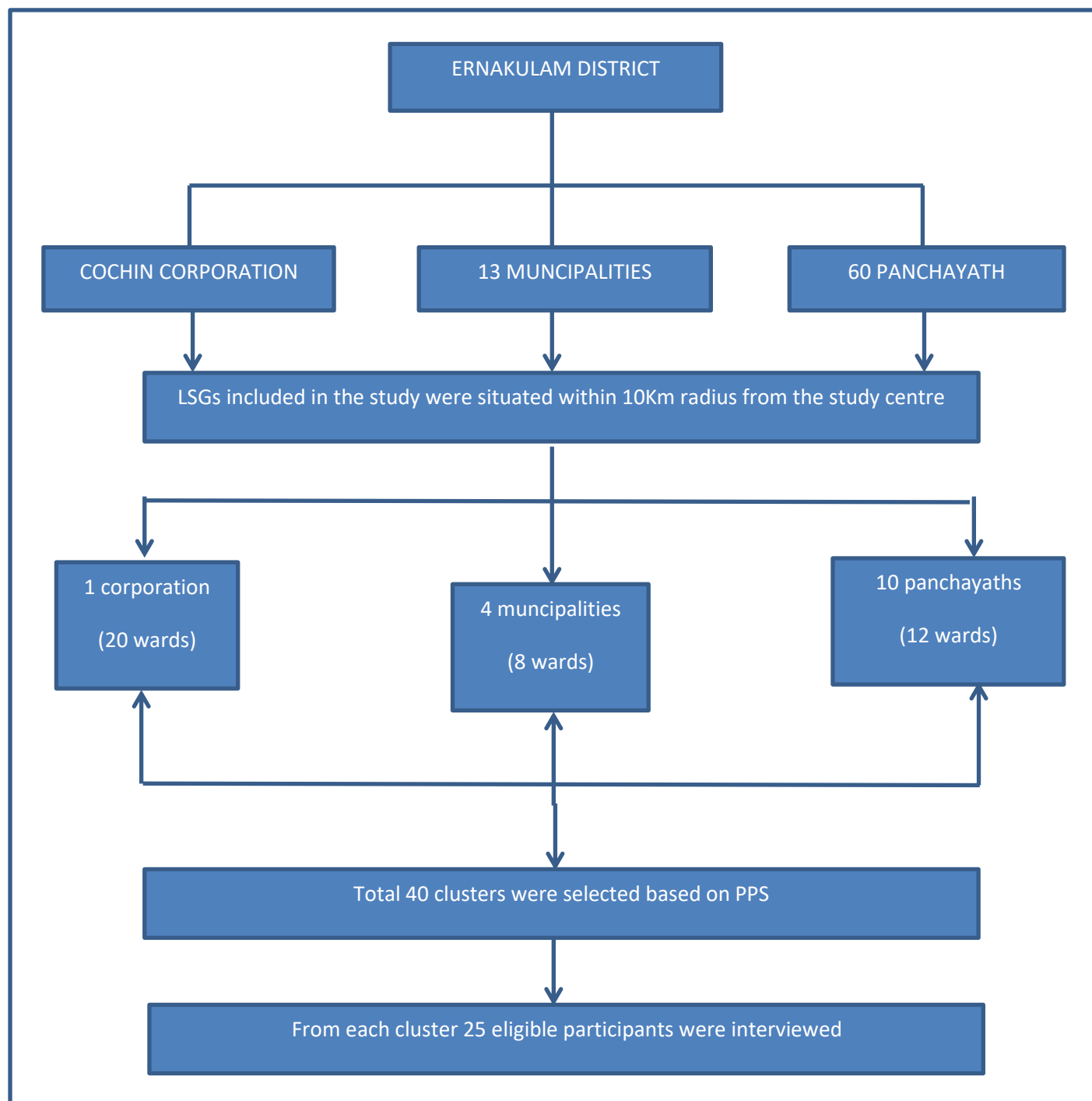
14 478 Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and
15
16 479 Manu Raj did review of literature and planned, conducted analysed and prepared manuscript
17
18 480 of the research work. Priya Vijayakumar supervised the experiment and in final editing of the
19
20 481 article. Sumi Soman and Libin Antony was involved in data acquisition and analysis. Abish
21
22 482 Sudhakar and Conrad Kabali derived the models and analysed the data.
23

24 483 **Data availability statement** :-

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26 484 All data relevant to the study are included in the article or uploaded as supplementary information.
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Figure

Fig.1 Flowchart of the Study Design



1 STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

		Recommendation	Action taken
2			
3			
4	Title and abstract	1 (a) Indicate the study's design with a commonly used term in the title or the abstract	Page 4, Line 50 & 51
5		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 4-5, Line 53-78
6			
7			
8			
9	Introduction		
10	Background/rationale	2 Explain the scientific background and rationale for the investigation being reported	Page 5, Line 92-95 & 100-106
11	Objectives	3 State specific objectives, including any prespecified hypotheses	Page 6, Line 119-122
12			
13			
14			
15			
16	Methods		
17	Study design	4 Present key elements of study design early in the paper	Page 6, Line 126
18	Setting	5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6, Line 117-138
19			
20			
21			
22	Participants	6 (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 6&7, Line 139-151
23		(b) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
24			
25			
26			
27			
28	Variables	7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 7, Line 154-165
29			
30			
31			
32	Data sources/measurement	8* For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 7, Line 160-177
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36			
37	Bias	9 Describe any efforts to address potential sources of bias	Page 7, Line 147-151&170-174
38			
39			
40	Study size	10 Explain how the study size was arrived at	Page 6&7, Line 131-138
41	Quantitative variables	11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8, Line 180-190
42			
43			
44			
45	Statistical methods	12 (a) Describe all statistical methods, including those used to control for confounding	Page 8, Line 181-186
46		(b) Describe any methods used to examine subgroups and interactions	Not done
47		(c) Explain how missing data were addressed	No missing data was encountered
48		(d) If applicable, explain how loss to follow-up was addressed	No Loss to follow up was reported
49		(e) Describe any sensitivity analyses	Not Applicable
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55	Results		
56	Participants	13 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 9, Line 201-203 Refer Fig 1
57		(b) Give reasons for non-participation at each stage	Not Applicable
58			
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		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9, Line 201-214
	*	(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 8, Line 173-176
Outcome data	15	Report numbers of outcome events or summary measures over time	Page 9, Line 216-226
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 10, Line 228-257
		(b) Report category boundaries when continuous variables were categorized	Not applicable
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11, Line 259-278
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 11-12, Line 280-300
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 13, Line 349-351
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 12&13, Line 301-343
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 346-349
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 14, Line 356-357

BMJ Open

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

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Secondary Subject Heading:	Epidemiology, Public health
Keywords:	Falls, Elderly, Community based study, Cohort Study, Kerala

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5 2 **Title of the article:** **Incidence and risk factors for falls among community dwelling elderly**
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8
9 4 **India**

10
11 5 **Running title :** Risk factors for falls among community dwelling elderly subjects in Kerala

12
13 6 **Contributors**

- 14
15 7 1. Divyamol K Sasidharan, MD (Geriatric Medicine), jisbbb87@gmail.com, Geriatric
16 8 Medicine Department, Amrita Institute of Medical Science, Kochi, Kerala, India
17
18 9 2. Priya Vijayakumar, MD (General Medicine), divz64@gmail.com, Geriatric Medicine
19 10 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
20
21 11 3. Manu Raj, DNB (Pediatric Cardiology), drmanuraj@gmail.com, Public Health Research
22 12 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
23
24 13 4. Sumi Soman, MSc Nursing, sumisoman90@gmail.com, Public Health Research
25 14 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
26
27 15 5. Libin Antony P F, Msc Nursing, libinantony.antony@gmail.com, Public Health Research
28 16 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
29
30 17 6. Abish Sudhakar, MA Sociology, abishsudhakar@aims.amrita.edu, Paediatric
31 18 Cardiology, Amrita Institute of Medical Science, Kochi, Kerala, India
32
33 19 7. Conrad Kabali, PhD Biostatistics, ckabali@gmail.com, Division of
34 20 Epidemiology, University of Toronto Dalla Lana School of Public Health, Toronto, Ontario,
35 21 Canada
36
37
38
39
40
41
42
43

44 23 **Department(s) and institution(s):** Department of Geriatric Medicine, Public Health
45 24 Research Department, Amrita Institute of Medical Science, Kochi, Kerala, India
46
47
48
49

50 26 **Corresponding Author:**

51 27 Name : Priya Vijayakumar
52
53 28 Address : Clinical Professor
54
55 29 Department of Geriatric Medicine
56
57 30 Amrita Institute of Medical Sciences, Kochi
58
59
60

1
2
3
4 31 Phone numbers : 9995653009
5
6 32 E-mail address : divz64@gmail.com

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35
36 47 analysis stage.

37
38 48

39
40 49 **Title:**

41
42 50 **Incidence and risk factors for falls among community dwelling elderly subjects on a one**
43
44 51 **year follow up - A prospective cohort study from Ernakulam, Kerala, India**

45
46 52 **Abstract**

47
48 53 **Objectives:** There is limited knowledge regarding epidemiology and risk of falls in elderly
49
50 54 living in low and middle income countries. The current study aims to report the incidence of
51
52 55 falls among free living elderly population from Kerala, India.

53
54 56 **Design:** Prospective cohort study with stratified random cluster sampling.

55
56 57 **Setting:** The study location was Ernakulam, Kerala, India. We collected information via
57
58 58 house visits using a questionnaire. The subjects were followed up prospectively for one year
59
60 59 by phone at three monthly intervals and missing subjects by house visits.

60 **Participants:** Community dwelling elderly above 65years of age.

61 **Results:** We recruited a total of 1000 participants. A total of 201(20.1%) subjects reported a
62 fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per 100 person
63 years. Female sex (OR 1.48, 95% CI 1.05, 2.10, $p = 0.027$), movement disorders including
64 parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, $p=0.048$), arthritis (OR 1.48, 95% CI 1.05, 2.09,
65 $p=0.026$), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00, 6.09,
66 $p<0.001$), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13, $p=0.012$),
67 living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, $p=0.001$) and a history of falls in
68 the previous year (OR, 2.25, 95% CI 1.60, 3.15, $p<0.001$) predicted a fall in the following
69 year.

70 **Conclusions:** One in five community dwelling elderly fall annually and one in four who fall
71 are prone to fall again in the next year. Interventions targeting falls among elderly need to
72 focus on modifiable risk factors like living alone during daytime, movement disorders,
73 arthritis and dependence on basic activities of daily living.

74 **Keywords:** Falls, Elderly, Community based study, Cohort Study, Kerala

75 **Strengths and limitations of this study:**

- 76
- 77 • The study was a prospective cohort study design with large sample size (n=1000).
- 78 • The study population represented both urban and rural population from different
79 Socio Economic Scale levels.
- 80 • None of the participants were lost to follow up and a fall diary was used to avoid
81 recall bias.
- 82 • The data is from a single study setting.
- 83 • The study has a short period of follow up (one year).
- 84

85 **Introduction**

86 Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent
87 of the total population.¹ Unintentional injuries are reported to be the fifth leading cause of
88 death globally in this population and falls constitute two out of every three deaths in this
89 category.² The Kellogg International Working Group defined a fall as ‘unintentionally

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2
3 90 coming to the ground or some lower level and other than as a consequence of sustaining a
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5 91 violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic
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7 92 seizure'.³
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9 93 Already over 70 % of the world's older population live in developing countries. The
10
11 94 proportion will increase in coming decades due to increasing longevity in all regions of the
12
13 95 world.⁴The incidence of falls as well as the consequences of falls have been higher in lower
14
15 96 and middle income countries as compared to high income countries.⁵⁻⁷ Each year an estimated
16
17 97 646 000 individuals die from falls globally of which over 80% are in low- and middle-income
18
19 98 countries.⁵ In 2010, for example, years lived with disability (YLDs) due to reported falls were
20
21 99 631.2 per 100,000 (population) in India and 674.4 per 100,000 in China, compared with 472.2
22
23 100 per 100,000 in the United States.⁶ In that year, the global share of YLDs due to falls in adults
24
25 101 aged 50 to 59 years was 66 % in developing countries and 34 % in high income developed
26
27 102 countries.⁷ Fall preventing interventions are not that freely available in many parts of low and
28
29 103 middle income countries.⁸
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31 104
32 105 Many prospective population-based studies have examined the epidemiology of falls in the
33
34 106 community dwelling elderly across different settings. The reported incidence rates show wide
35
36 107 variability from as low as 29% to as high as 40% in this population.⁹⁻¹⁴ Various studies done
37
38 108 in India too have reported the prevalence of falls in community dwelling elderly ranging from
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40 109 13-53%.¹⁵⁻¹⁸ The incidence of recurrent falls (more than two episodes per calendar year was
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42 110 reported to be 11 to 21% by Lord et al.⁹
43

44 111
45 112 The risk factors for falls in the elderly as reported by Lord et al can be grouped into seven
46
47 113 major categories.⁹These include socio-demographic factors, balance and mobility factors,
48
49 114 sensory and neuromuscular factors, psychological factors, medical factors, medication use,
50
51 115 and environmental factors.⁹ A recent meta-analysis by Deandrea et al pooled data from 74
52
53 116 prospective cohort studies that reported risk factors for prospective falls among community
54
55 117 dwelling elders.¹⁹ A prior history of falls, gait problems, walking aid use, vertigo, parkinson
56
57 118 disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age
58
59 119 group.¹⁹
60

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3 120 The primary objective of our study was to report the incidence of falls in community
4
5 121 dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective
6
7 122 follow up schedule. The secondary objective was to identify factors that can predict a risk for
8
9 123 future fall in community dwelling elders.

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13 **Methods:**

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15 126 ***Selection and Description of participants:***

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18 127 **Design & Setting:** The current study is a community based prospective cohort study that was
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20 128 conducted in an area within 10 km radius from the study centre (Amrita Institute of Medical
21
22 129 Sciences and Research Centre, Kochi, Kerala). The study was conducted over a period of
23
24 130 three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats, four
25
26 131 municipalities and one corporation. The study area comes under Ernakulam district of Kerala,
27
28 132 South India.

29 133 We calculated the sample size using a previously published study by Mitchell-Fearson et al
30
31 134 which reported 21.7% prevalence for falls in the elderly.²⁰ We selected an alpha of 0.05 and
32
33 135 an allowable error of 20% giving us a minimum sample size of 347 subjects. The design
34
35 136 effect for the sampling method (multistage stratified random cluster sampling) was calculated
36
37 137 using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC)
38
39 138 of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We
40
41 139 enrolled a total of 1000 participants anticipating significant sub group differences within the
42
43 140 study sample.

44 141 **Participants:** We used stratified random cluster sampling method to select the participants.
45
46 142 The sample was stratified at two levels, rural urban (level 1) and at the level of individual
47
48 143 local self-governing units (LSGs, level 2). A total of 40 clusters using Probability
49
50 144 proportional to size technique were selected randomly from the list of all available clusters
51
52 145 within the defined geographical area. Each cluster was from an individual electoral ward
53
54 146 within the LSGs. We selected 25 participants from each cluster. In each cluster, a random
55
56 147 starting point was selected and households were visited in a sequential manner by the
57
58 148 principal investigator and staff till 25 subjects were recruited. A flowchart on the study
59
60 149 design used in the present study is shown in figure.1. The inclusion criteria included (i)

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2
3 150 minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the
4 151 study area for a minimum of one year after assessment and (iv) ability to communicate in
5 152 English/Malayalam language. The exclusion criteria included complete dependence for day
6 153 to day activities.

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11 154 **Operational definitions:**

12
13 155 Fall was defined as suggested by The Kellogg International Working Group as mentioned in
14 156 the introduction.³

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16
17 157 A recurrent fall was defined as fall of two or more times during the follow up period of one
18 158 year.⁹

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20
21
22 159 **Patient and public involvement:** Patients and the public were not specifically involved in
23 160 the planning and execution of this study. However, they were informed of the need of the
24 161 study and quarterly follow up was done telephonically.

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28 162 ***Technical Information:***

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31 163 A study questionnaire was prepared after a detailed literature review of studies related to falls
32 164 in the elderly. The study questionnaire included questions relating to the socio-demographic
33 165 profile, comorbidities, physical activity, medication use and environmental assessment. This
34 166 questionnaire was initially piloted over a small number of patients (n=50) and redundant
35 167 questions were either removed or modified. The modified questionnaire was reviewed by
36 168 subject experts and was approved for use in the full study.

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41 169 All initial assessments were done at the participant's home. The research team (PI, two
42 170 nurses) visited all recruited subjects at their home premises. The study questionnaire was
43 171 administered by the PI by means of a face to face interview during house visits. In addition,
44 172 height, weight and blood pressure readings were taken by the trained staff (nurses) that
45 173 accompanied the PI. All subjects were advised to keep a fall diary in which they were
46 174 instructed to note down any incidence of fall along with the date and time of fall, what the
47 175 patient was doing when he fell, what caused the fall, whether it was a witnessed fall or not
48 176 and whether the fall had any consequences or complications. A three monthly follow up was
49 177 done by telephonic conversation with enrolled subjects for one year from first visit. Those
50 178 who were not available over the phone were revisited via house visits by the research staff

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3 179 and hence no missing data were encountered in the study. In addition, the fall diaries of those
4
5 180 who reported a fall from the same cluster were reviewed during these house visits. The data
6
7 181 collection period was from August 2015 to April 2017.

8 9 182 ***Statistics:***

10
11 183 We summarized demographic and social-economic variables to characterize the study
12
13 184 population (Table 1). We presented the mean and standard deviation for normally distributed
14
15 185 continuous variables. All categorical variables are expressed in number and percentages. We
16
17 186 used Chi square test to examine the association of categorical risk factors with prospective
18
19 187 falls. All individual factors with a p value of <0.2 for association on bivariate analysis was
20
21 188 selected for multivariate analysis. Multiple binary logistic regression was used to construct
22
23 189 the prediction model for prospective falls. We selected Logistic regression after verifying
24
25 190 lack of over-dispersion using the Pearson and deviance methods. The cut-off point for
26
27 191 statistical significance was set at an α -level of 5%. We reported the adjusted Odds Ratios
28
29 192 (aOR) with 95% confidence intervals. We encountered no missing data in the study.
30
31 193 Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago,
32
33 194 USA).

33 195 ***Ethical approval:***

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35
36 196 We collected written informed consent from the consenting subjects before recruitment to the
37
38 197 study and the same was documented for future reference. The consent contained the title,
39
40 198 purpose, methods employed in the study, benefits to the subject as well as family and the
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42 199 interest of the respondent to participate on a voluntary basis to the study. The confidentiality
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44 200 of the study during the analysis was also mentioned in the consent. The consent process and
45
46 201 study protocol was approved by the Institutional Ethics Committee of Amrita Institute of
47
48 202 Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number:
49
50 203 ECR/129/Inst/KL/2013).

50 204 **Results**

51 205 ***Baseline Characteristics of the study population***

52
53 206 We recruited a total of 1000 participants from 40 individual pre-designated clusters spread
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55 207 across a circular geographical area with the study institution as the centre point of which 568
56
57 208 (56.8%) were female. The distribution of gender, age categories, weight status, education
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3 209 level, household living pattern and area of domicile are presented in Table 1. The mean age
4 210 of the study subjects was 72.7(7.2) years. Among study participants, 568 (56.8%) were
5 211 female, 87.4% were literate and 82% lived with family or caretakers. A total of 348 (34.8%)
6 212 were either pre-obese or obese as per Asian Criteria of BMI classification.²¹ The morbidity
7 213 profile of the study population was published earlier.²² The self-reported prevalence of
8 214 diabetes(DM), coronary artery diseases(CAD) and cerebrovascular accidents (CVA) were
9 215 34.2%, 20.1%&5.3% respectively. Among study subjects, 768 (76.8%) were hypertensive as
10 216 documented either by high values on house visit measurement or by current treatment for
11 217 hypertension. Among hypertensives, a total of 528 subjects (68.8%) reported taking
12 218 treatment for hypertension and remaining 240(31.2%) were newly detected during the
13 219 baseline evaluation of the study.

220 *Incidence of falls in the study population*

221 A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one
222 year. The total fall episodes during the follow up period were 301. The overall incidence rate
223 of falls was 31 (95% CI 27.7, 34.6) per 100 person years. The corresponding figures for
224 elderly men and women separately were 21.2 (95% CI 18.5, 24.2) & 38.3 (95% CI, 34.6,
225 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85
226 were 27.4, 36.8 and 41.1 per 100 person years respectively. Among participants, more
227 women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified
228 groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period,
229 compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years
230 group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls)
231 during the follow up.

232 *Factors associated with prospective falls.*

233 The association of baseline factors with a prospective history of falls during the follow up
234 period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline
235 variables, only gender and living arrangement showed a significant association with a
236 prospective history of falls on bivariate comparisons. Females had a higher risk of fall when
237 compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during
238 daytime also had a higher risk of falls when compared to those living with family/caretaker
239 (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors

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3 240 affecting locomotion was explored by bivariate analysis and is presented in **Table 3**. Among
4
5 241 the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010),
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7 242 vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p
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9 243 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence
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11 244 in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in
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13 245 instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed
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15 246 significant associations with prospective falls on bivariate comparisons. A history of falls in
16
17 247 the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p
18
19 248 <0.001).

20
21 250 Among baseline factors only gender showed an association with recurrent falls on bivariate
22
23 251 comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting locomotion
24
25 252 dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p <0.001),
26
27 253 dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p = 0.038)
28
29 254 and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001) showed an
30
31 255 association with recurrent falls on bivariate comparisons.

32
33 256
34 257 In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%)
35
36 258 reported taking anti diabetic medications and 69(6.9%) reported taking either
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38 259 benzodiazepines or other sedative drugs. There was no significant association for prospective
39
40 260 falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-
41
42 261 diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives
43
44 262 (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

263 ***Independent Risk Factors for prospective falls***

264 The final adjusted model with independent predictors of prospective falls in the elderly is
265 presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis
266 with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary
267 symptoms, constipation, knee pain, paraesthesia of feet, history of fall in the previous year,
268 dependence in basic and instrumental activities of daily living, use of assistive devices for
269 movement, cognitive impairment, depression, use of antihypertensive medications and
270 benzodiazepines. The same were included in the final model construction. Among the factors
271 examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, p =

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3 272 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, p=0.048), arthritis (OR 1.48, 95% CI
4 273 1.05-2.09, p=0.026), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00,
5 274 6.09, p<0.001), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13,
6 275 p=0.012), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, p=0.001) and history
7 276 of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, p<0.001) were found to be
8 277 significantly associated with falls.

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14 278 The factors included to assess the independent risk factors of recurrent falls were, female sex,
15 279 vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily
16 280 living and history of falls in the previous year. From the above, the independent predictors for
17 281 recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, p = 0.031), dependence in basic
18 282 activities of daily living (OR 3.63, 95% CI 1.71, 7.70, p = 0.001), and history of falls in the
19 283 previous year (OR 3.39, 95% CI 1.89, 6.05, p<0.001).

24 284 **Discussion**

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28 285 The current study provides details of fall episodes experienced by free living elderly from
29 286 Kerala, India during a prospective follow up of one year. Approximately one in five elderly
30 287 subjects in this age group reported a fall during the study period. There appears to be a sex
31 288 based difference in the proportion that fell with one in four elderly women falling compared
32 289 to one in six men during follow up. The results also suggest a dose response relationship
33 290 between age and falls with more subjects falling in older age groups compared to relatively
34 291 younger groups. In addition, every fourth person who fell reported one or more falls
35 292 following the index fall episode during the study period.

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43 293 The independent predictors for falls in the elderly included female sex, parkinsonism and
44 294 related movement disorders, arthritis, dependence in basic activities of daily living, not using
45 295 antihypertensive medicines, living alone during daytime and a history of fall in the preceding
46 296 year. The corresponding predictors for recurrent falls included female sex, dependence in
47 297 basic activities of daily living and a history of fall in the preceding year. To our knowledge,
48 298 this is the only prospective cohort study done in India that focussed on falls in free living
49 299 elderly who were assessed in the community setting.

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56 300 The incidence of falls in the elderly from our study appears to be at the lower end of the
57 301 spectrum as reported by western studies (29% to 40%).⁹⁻¹⁴ Interestingly, our results are more

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3 302 similar to that reported by a prospective study among community dwelling elderly Chinese
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5 303 subjects.²³ The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-
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7 304 years for all elderly, women and men respectively. The proportion with recurrent falls in this
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9 305 study was also similar to our study (4.75% v/s 5.3%).

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11 306 The risk factors for prospective falls in community dwelling elderly was examined by a
12
13 307 recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.¹⁹ Most of the
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15 308 prospective studies in the meta-analysis suggested that community dwelling elderly women
16
17 309 are at higher risk for falls compared to their male counterparts. The pooled estimates for falls
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19 310 (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-
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21 311 analysis are in agreement with the current study.

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23 312 Several prospective studies have reported higher risk for falls among elderly patients with
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25 313 Parkinsonism and/or related movement disorders similar to the current study. The meta-
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27 314 analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for falls and 2.84 (95% CI,
28
29 315 1.77, 4.58) for recurrent falls from five studies that looked for the same. Our study didn't
30
31 316 report any positive association between Parkinson's disease and recurrent falls, probably due
32
317 to the small number of recurrent fallers (5.3%) in the cohort.

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34 318 Our finding of high risk for falls among those elderly with arthritis is in concordance with
35
36 319 several other studies.²⁴⁻²⁷ Together these studies suggest that elderly with arthritis and/or
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38 320 chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence
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40 321 of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis
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42 322 free peers.²⁷

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45 324 Several studies have reported that living alone during the daytime is a risk factor for falls in
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47 325 the elderly as suggested by the current study.¹⁹ The meta-analysis is also in agreement with
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49 326 this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that
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51 327 examined the same.

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53 328 Reduced BADL(Basic Activities of Daily Living) capability is also reported to be associated
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55 329 with falls in the elderly.²⁸ Yokoya et al recently concluded that higher frequency of leaving
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57 330 home, higher exercise levels and presence of interest in activities (e.g., meeting friends,
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59 331 shopping, working in the garden) were associated with a reduced risk for fall in community
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3 332 dwelling elders.²⁸ Maintaining and enhancing physical functions, principally walking ability
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5 333 and walking speed are critical for fall prevention among elderly.^{29,30} Age appropriate
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7 334 exercises including those enhancing muscle strength and improving balance can probably
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9 335 reduce the incidence of falls among elderly.³⁰

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11 336 A history of falls in the previous year appears to be the most consistent risk factor across
12
13 337 several studies.^{19,30,31} Pooled data from several studies in the recent meta-analysis puts the
14
15 338 risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for
16
17 339 recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).¹⁹ Suzuki et al
18
19 340 reported that five out of six elderly with a history of falls were anxious about another fall and
20
21 341 one in three said that they did not venture out again due to fear of another fall.³⁰

22
23 342 One notable finding in our study was the lack of association for falls with medication use for
24
25 343 most groups of medications except for antihypertensive medications. This is in contrast to a
26
27 344 meta-analysis of the impact of medication classes on falls in elderly.³² Woolcott et al reported
28
29 345 an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.³² The
30
31 346 lack of association between sedatives use and falls in our study is probably due to the limited
32
33 347 number of subjects reporting the use of the same (6.9%). We saw an inverse association
34
35 348 between falls and the use of antihypertensive drug use in the current study. One probable
36
37 349 reason could be the high proportion of uncontrolled hypertensives in the study population.
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39 350 This finding needs to be explored further in future studies.

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41 351 Several studies have earlier suggested that the prevalence of falls in low and middle income
42
43 352 countries are higher than that reported from high income countries.⁴⁻⁶ The morbidity from
44
45 353 falls and related events too appear to be higher in low and middle income countries compared
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47 354 to high income countries like US.⁴⁻⁶ There appears to be low awareness about the
48
49 355 consequences of falls in low and middle income countries. This could probably be due to the
50
51 356 lack of data regarding falls reported from these regions. It is expected that the awareness
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53 357 related to falls will improve with dissemination of data from the current study as well as
54
55 358 similar studies from this region. The same may also stimulate research into the interventional
56
57 359 options to reduce fall related mortality and morbidity.

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59 360 The strengths of the current study include; prospective cohort study design, large sample size
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361 (n=1000), representative urban and rural population components, inclusion of participants
362 from different Socioeconomic levels, no participants lost to follow up and use of a fall diary

363 to avoid recall bias. However, the study included participants from a limited geographical
364 setting and was able to follow up only for a shorter period (one year) and hence the
365 generalisation of the study findings is limited.

366

367 **Conclusion**

368

369 One in five community dwelling elderly citizens fall on an annual basis and one in four of
370 those who fall are prone to fall again in the same calendar year. Female sex, movement
371 disorders including parkinsonism, arthritis, dependence in basic activities of daily living,
372 living alone during daytime and a history of falls in the previous year appear to predict a fall
373 in the following year. Any intervention targeting a reduction in falls among the elderly need
374 to focus on the modifiable risk factors like living alone at home during daytime, movement
375 disorders and arthritis. We need to encourage mechanisms that may reduce dependence of
376 elderly on basic activities of daily living. Attention should also be given to encourage both
377 physical activity and interests in social activities among elderly subjects.

378

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380

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383 or not-for-profit sectors.

384

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Tables

26 476 **Table 1. Baseline Details of the study population.**

Demographic factors	n (%)
Gender	
Male	432(43.2)
Female	568(56.8)
Age group	
65-75	648(64.8)
75-85	262(26.2)
>85	90(9.0)
Weight Status(BMI)	
Underweight(<18.5)	124(12.4)
Normal(18.5-22.9)	340(34.0)
Overweight(23-24.9)	188(18.8)
Pre Obese(25-29.9)	264(26.4)
Obese(>30)	84(8.4)
Education	
Graduate and above	132(13.2)
Diploma / Pre-degree	85(8.5)
Middle class / Primary	657(65.7)
Illiterate	126(12.6)
House Hold	
Living with family / caretaker	820 (82.0)
Living alone during daytime	145 (14.5)

	Living alone	35 (3.5)
Domicile	Urban	700(70.0)
	Rural	300(30.0)

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Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors n(%)	Prospective falls		OR (95% CI)	P value
	No Fall n (%)	Fall n (%)		
Gender				
Men [432(43.2)]	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women [568(56.8)]	434(76.4)	134(23.6)		
Age Group in years				
65-75 [648(64.8)]	528(81.5)	120(18.5)	1.14 (0.80-1.64)	0.468
75-85 [262(26.2)]	208(79.4)	54(20.6)		
>85 [90(9.0)]	63(70.0)	27(30.0)		
Diabetes [342(34.2)]				
No	532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes	267(78.1)	75(21.9)		
Hypertension (768(76.8))				
No	181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes	618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))				
No	622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes	177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))				
No	639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes	160(79.6)	41(20.4)		
Cerebrovascular Disease				

(53(5.3))	No	762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
	Yes	37(69.8)	16(30.2)		
Alcohol (177(17.7))	No	654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
	Yes	145(81.9)	32(18.1)		
Smoking (178(17.8))	No	652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
	Yes	147(82.6)	31(17.4)		
Living Arrangement					
Living with family/caretaker (820(82))		669(81.6)	151(18.4)		
Living alone during daytime (145(14.5))		109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone (35(3.5))		21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

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Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons

Risk factors	Prospective falls		OR (95% CI)	P value	
	No Fallers n (%)	Fallers n (%)			
Parkinsonism(28(2.8))	No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
	Yes	17(60.7)	11(39.3)		
Vertigo(388(38.8))	No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))	No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))	No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))	No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))	No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)	75(23.7)		

Visual impairment (594(59.4))	No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
	Yes	473(79.6)	121(20.4)		
Not independent in Basic Activities of daily living (59(5.9))	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

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498 **Table 4 Risk factors of falls in community dwelling elderly subjects**

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		
Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

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Figure legends

Fig.1 Flowchart of the study design

Contributorship statement :-

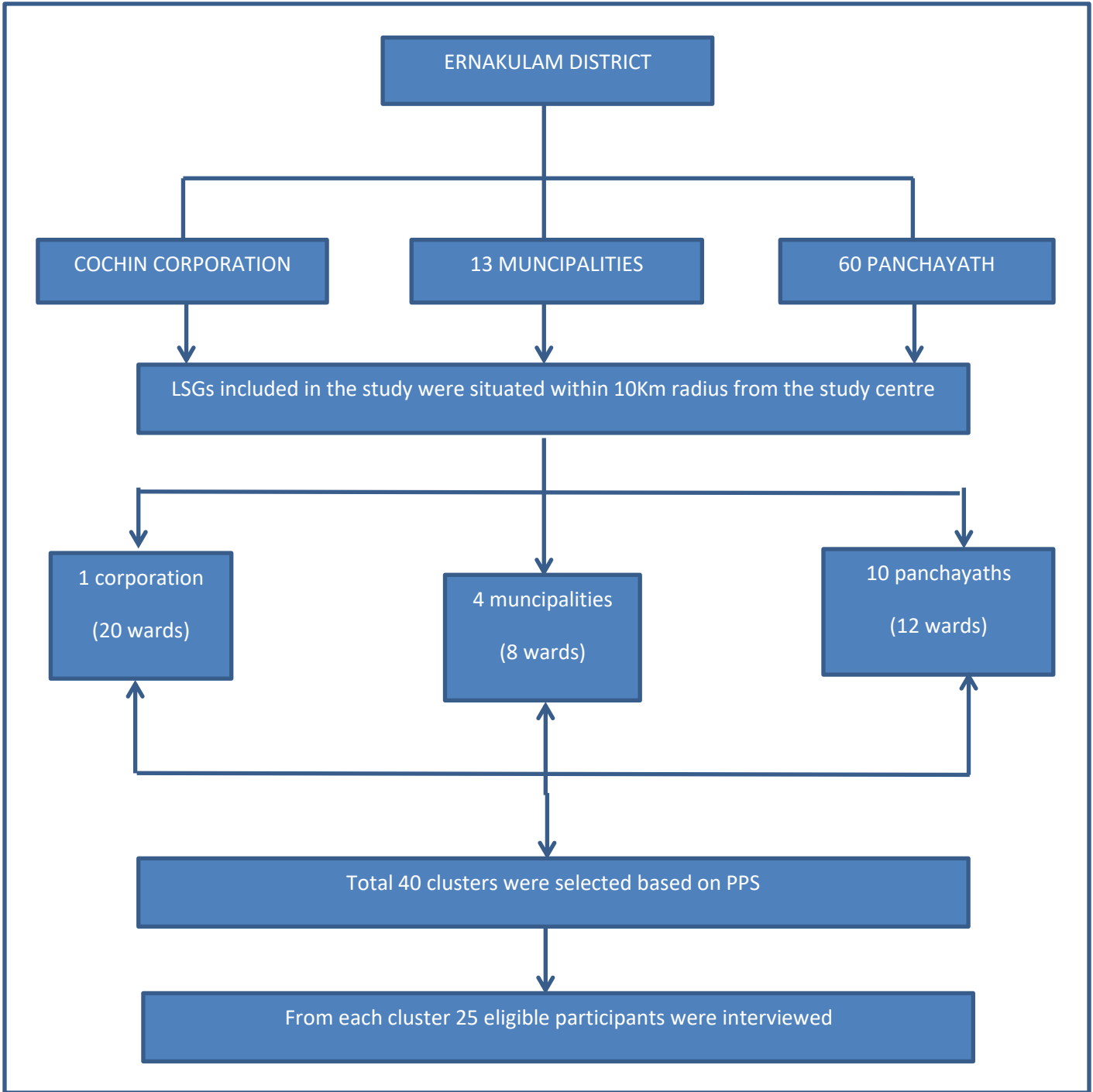
512 Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and
513 Manu Raj did review of literature and planned, conducted analysed and prepared manuscript
514 of the research work. Priya Vijayakumar supervised the experiment and in final editing of the
515 article. Sumi Soman and Libin Antony was involved in data acquisition and analysis. Abish
516 Sudhakar and Conrad Kabali derived the models and analysed the data.

Data availability statement :-

518 All data relevant to the study are included in the article or uploaded as supplementary information.
519
520
521
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523
524

Figure

Fig.1 Flowchart of the Study Design



STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

		Recommendation	Action taken
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 2, Line 50 & 51
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2-3, Line 53-73
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4, Line 86-103
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 5, Line 120-123
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5, Line 127
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, Line 128-132
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5-6, Line 141-153
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6, Line 154-158
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6-7, Line 163-181
Bias	9	Describe any efforts to address potential sources of bias	Page 6-7, Line 173-176, 177-179
Study size	10	Explain how the study size was arrived at	Page 5, Line 133- 140
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7, Line 183-194
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 7, Line 183-194
		(b) Describe any methods used to examine subgroups and interactions	Not done
		(c) Explain how missing data were addressed	No missing data was encountered
		(d) If applicable, explain how loss to follow-up was addressed	No Loss to follow up was reported
		(e) Describe any sensitivity analyses	Not Applicable
Results			
Participants	13	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 8, Line 206-208 Refer Fig 1
		(b) Give reasons for non-participation at each stage	Not Applicable

		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 8, Line 207-219
	*	(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 6-7, Line 176-177
Outcome data	15	Report numbers of outcome events or summary measures over time	Page 8, Line 221-231
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 8-9, Line 232-262
		(b) Report category boundaries when continuous variables were categorized	Not applicable
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 09, Line 263-283
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 10, Line 286-292
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 13, Line 363-365
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11-12, Line 300-359
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 363-365
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 13, Line 369-370

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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

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3 **subjects on a one year follow up - A prospective cohort study from Ernakulam, Kerala,**
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5 **Running title :** Risk factors for falls among community dwelling elderly subjects in Kerala

6 **Contributors**

- 7 1. Divyamol K Sasidharan, MD (Geriatric Medicine), jisbbb87@gmail.com, Geriatric
8 Medicine Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 9 2. Priya Vijayakumar, MD (General Medicine), divz64@gmail.com, Geriatric Medicine
10 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 11 3. Manu Raj, DNB (Pediatric Cardiology), drmanuraj@gmail.com, Public Health Research
12 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 13 4. Sumi Soman, MSc Nursing, sumisoman90@gmail.com, Public Health Research
14 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 15 5. Libin Antony P F, Msc Nursing, libinantony.antony@gmail.com, Public Health Research
16 Department, Amrita Institute of Medical Science, Kochi, Kerala, India
- 17 6. Abish Sudhakar, MA Sociology, abishsudhakar@aims.amrita.edu, Paediatric
18 Cardiology, Amrita Institute of Medical Science, Kochi, Kerala, India
- 19 7. Conrad Kabali, PhD Biostatistics, ckabali@gmail.com, Division of
20 Epidemiology, University of Toronto Dalla Lana School of Public Health, Toronto, Ontario,
21 Canada

22
23 **Department(s) and Institution(s):** Department of Geriatric Medicine, Public Health
24 Research Department, Amrita Institute of Medical Science, Kochi, Kerala, India

25
26 **Corresponding Author:**

27 Name : Priya Vijayakumar

28 Address : Clinical Professor

29 Department of Geriatric Medicine

30 Amrita Institute of Medical Sciences, Kochi

1
2
3
4 31 Phone numbers : 9995653009
5
6 32 E-mail address : divz64@gmail.com

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31
32 47 analysis stage.

33
34 48

35
36 49 **Title:**

37
38 50 **Incidence and risk factors for falls among community dwelling elderly subjects on a one**
39
40 51 **year follow up - A prospective cohort study from Ernakulam, Kerala, India**

41
42 52 **Abstract**

43
44
45 53 **Objectives:** There is limited knowledge regarding epidemiology and risk of falls among the
46 54 elderly living in low and middle income countries. In this situation, the current study aims to
47 55 report the incidence of falls and associated risk factors among free living elderly population
48
49 56 from Kerala, India.

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51
52 53 **Design:** Prospective cohort study with stratified random cluster sampling.

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55 54 **Setting:** The study location was Ernakulam, Kerala, India, and we collected information via
56
57 59 house visits using a questionnaire. During the research, the subjects were followed up

60 prospectively for one year by phone at intervals of three months and missing subjects were
61 contacted by house visits.

62 **Participants:** Community dwelling elderly above 65years of age.

63 **Results:** We recruited a total of 1000 participants out of which a total of 201(20.1%) subjects
64 reported a fall during follow-up. The incidence rate of falls was 31 (95% CI 27.7, 34.6) per
65 100 person years. Female sex (OR 1.48, 95% CI 1.05, 2.10, $p = 0.027$), movement disorders
66 including parkinsonism (OR 2.26, 95% CI, 1.00, 5.05, $p=0.048$), arthritis (OR 1.48, 95% CI
67 1.05, 2.09, $p=0.026$), dependence in basic activities of daily living (OR, 3.49, 95% CI 2.00,
68 6.09, $p<0.001$), not using antihypertensive medications (OR, 1.53, 95% CI 1.10, 2.13,
69 $p=0.012$), living alone during daytime (OR 3.27, 95% CI 1.59, 6.71, $p=0.001$) and a history
70 of falls in the previous year (OR, 2.25, 95% CI 1.60, 3.15, $p<0.001$) predicted a fall in the
71 following year.

72 **Conclusions:** One in five community dwelling senior citizen fall annually and one in four
73 who fall are prone to fall again in the following year. Interventions targeting falls among the
74 elderly need to focus on modifiable risk factors such as living alone during daytime,
75 movement disorders, arthritis and dependence on basic activities of daily living.

76 **Keywords:** Falls, Elderly, Community based study, Cohort Study, Kerala

77 **Strengths and limitations of this study:**

- 79 • The study has a prospective cohort study design with a large sample size ($n=1000$).
- 80 • The study population represented both urban and rural population from different
81 Socio Economic Scale levels.
- 82 • None of the participants were lost to follow up and a fall diary was used to avoid
83 recall bias.
- 84 • The data are from a single study setting.
- 85 • The study has a short period of follow up (one year).

87 **Introduction**

88 Globally, there are an estimated 962 million people aged 60 or over, comprising 13 per cent
89 of the total population.¹ In this segment of the population, unintentional injuries are reported

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3 90 to be the fifth leading cause of death globally and falls constitute two out of every three
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5 91 deaths in this category.² A fall is defined by The Kellogg International Working Group as
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7 92 ‘unintentionally coming to the ground or some lower level and other than as a consequence of
8
9 93 sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an
10
11 94 epileptic seizure’.³

12
13 95 The incidence of falls and the consequences of falls have been higher in lower and middle
14
15 96 income countries as compared to high income countries⁴⁻⁶ mainly because fall preventing
16
17 97 interventions are not that freely available in many parts of these countries.⁷ Each year an
18
19 98 estimated 646 000 individuals die from falls globally of which over 80% are in low- and
20
21 99 middle-income countries.⁴ In 2010, for example, years lived with disability (YLDs) due to
22
23 100 reported falls were 631.2 per 100,000 (population) in India and 674.4 per 100,000 in China,
24
25 101 compared with 472.2 per 100,000 in the United States.⁵ In that year, the global share of YLDs
26
27 102 due to falls in adults aged 50 to 59 years was 66 % in developing countries and 34 % in high
28
29 103 income developed countries.⁶ Clearly, the situation needs to be addressed urgently as already
30
31 104 over 70 % of the world’s older population live in developing countries and the proportion is
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33 105 likely to increase in the coming decades due to increasing longevity in all the regions of the
34
35 106 world.⁸

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37 107
38 108 Many prospective population-based studies have examined the epidemiology of falls in the
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40 109 community dwelling elderly across different settings. The reported incidence rates show wide
41
42 110 variability from as low as 29% to as high as 40% in this population.⁹⁻¹⁴ Furthermore, various
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44 111 studies done in India too have reported the prevalence of falls in community dwelling elderly
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46 112 ranging from 13-53%.¹⁵⁻¹⁸ The incidence of recurrent falls (more than two episodes per
47
48 113 calendar year was reported to be 11 to 21% by Lord et al.⁹

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50 114
51 115 The risk factors for falls in the elderly as reported by Lord et al⁹ can be grouped into seven
52
53 116 major categories: socio-demographic factors, balance and mobility factors, sensory and
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55 117 neuromuscular factors, psychological factors, medical factors, medication use, and
56
57 118 environmental factors.⁹ A recent meta-analysis by Deandrea et al¹⁹ pooled data from 74
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59 119 prospective cohort studies that reported risk factors for prospective falls among community
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120 dwelling elders. A prior history of falls, gait problems, walking aid use, vertigo, parkinson

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3 121 disease and anti-epileptic drug use were the dominant reasons for prospective falls in this age
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5 122 group.¹⁹
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7

8 123 The primary objective of our study was to report the incidence of falls in community
9 124 dwelling elderly population from Ernakulam, Kerala, India through a year-long prospective
10 125 follow up schedule, and the secondary objective was to identify factors that can predict a risk
11 126 for future falls in community dwelling elderly.
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15 127

17 128 **Methods:**

19 129 *Selection and Description of participants:*

21
22 130 **Design & Setting:** The current study is a community based prospective cohort study that was
23 131 conducted in an area within a radius of ten kilometres from the study centre (Amrita Institute
24 132 of Medical Sciences and Research Centre, Kochi, Kerala). The study was conducted over a
25 133 period of three years (Nov 2014 to Nov 2017). This circular area included 12 panchayats,
26 134 four municipalities and one corporation. The study area comes under
27 135 Ernakulam district of Kerala, South India.
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33 136 We calculated the sample size using a previously published study by Mitchell-Fearson et al
34 137 which reported 21.7% prevalence for falls in the elderly.²⁰ We selected an alpha of 0.05 and
35 138 an allowable error of 20% giving us a minimum sample size of 347 subjects. The design
36 139 effect for the sampling method (multistage stratified random cluster sampling) was calculated
37 140 using a pilot of ten clusters (cluster size k=25) that provided an Intra Class Correlation (ICC)
38 141 of 0.023. The sample size adjusted for design effect was 539 (inflation factor of 1.552). We
39 142 enrolled a total of 1000 participants anticipating significant sub group differences within the
40 143 study sample.
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48 144 **Participants:** We used stratified random cluster sampling method to select the participants.
49 145 The sample was stratified at two levels, rural urban (level 1) and at the level of individual
50 146 local self-governing units (LSGs, level 2). A total of 40 clusters using Probability
51 147 proportional to size technique were selected randomly from the list of all available clusters
52 148 within the defined geographical area. Each cluster was from an individual electoral ward
53 149 within the LSGs. We selected 25 participants from each cluster. In each cluster, a random
54 150 starting point was selected and households were visited in a sequential manner by the
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3 151 principal investigator and staff till 25 subjects were recruited. A flowchart on the study
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5 152 design used in the present study is shown in figure.1. The inclusion criteria were: (i)
6
7 153 minimum age of 65 years or more (ii) ambulant physical status (iii) intention to stay in the
8
9 154 study area for a minimum of one year after assessment and (iv) ability to communicate in
10
11 155 English/Malayalam language. The exclusion criteria included complete dependence for day-
12
13 156 to-day activities.

14
15 157 **Operational definitions:**

16
17 158 A fall was defined as suggested by The Kellogg International Working Group as mentioned
18
19 159 in the introduction.³

20
21 160 A recurrent fall was defined as falling of two or more times during the follow up period of
22
23 161 one year.⁹

24
25 162 **Patient and public involvement:** Patients and the public were not specifically involved in
26
27 163 the planning and execution of this study. However, they were informed of the need of the
28
29 164 study and quarterly follow up which was to be done telephonically.

30
31 165 ***Technical Information:***

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33
34 166 A study questionnaire was prepared after a detailed review of the literature on studies related
35
36 167 to falls in the elderly; however, the questionnaire was freshly prepared by us and not derived
37
38 168 from other studies. The study questionnaire included questions relating to the socio-
39
40 169 demographic profile, comorbidities, physical activity, medication use and environmental
41
42 170 assessment. This questionnaire was initially piloted over a small number of patients (n=50)
43
44 171 and the redundant questions were either removed or modified. The modified questionnaire
45
46 172 was reviewed by subject experts and was approved for use in the full study.

47 173 All initial assessments were done at the participant's home. The research team (PI, two
48
49 174 nurses) visited all the recruited subjects at their home premises. The study questionnaire was
50
51 175 administered by the PI by means of a face-to-face interview during house visits. In addition,
52
53 176 height, weight and blood pressure readings were taken by the trained staff (nurses) that
54
55 177 accompanied the PI. All subjects were advised to keep a fall diary in which they were
56
57 178 instructed to note down any incident of fall along with the date and time of the fall, what the
58
59 179 patient was doing when he fell, what caused the fall, whether it was a witnessed fall or not
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2
3 180 and whether the fall had any consequences or complications. A three monthly follow up was
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5 181 done by telephonic conversation with the enrolled subjects for one year from the first visit.
6
7 182 Those who were not available over the phone were contacted via house visits by the research
8
9 183 staff and hence no missing data were encountered in the study. In addition, the fall diaries of
10
11 184 those who reported a fall from the same cluster were reviewed during these house visits. The
12
13 185 data collection period was from August 2015 to April 2017.

14 186 ***Statistics:***

17 187 We summarized demographic and social-economic variables to characterize the study
18
19 188 population (Table 1). We presented the mean and standard deviation for normally distributed
20
21 189 continuous variables. All categorical variables are expressed in number and percentages. We
22
23 190 used Chi square test to examine the association of categorical risk factors with prospective
24
25 191 falls. All individual factors with a p value of <0.2 for association on bivariate analysis was
26
27 192 selected for multivariate analysis. Multiple binary logistic regression was used to construct
28
29 193 the prediction model for prospective falls. We selected Logistic regression after verifying
30
31 194 lack of over-dispersion using the Pearson and deviance methods. The cut-off point for
32
33 195 statistical significance was set at an α -level of 5%. We reported the adjusted Odds Ratios
34
35 196 (aOR) with 95% confidence intervals. We encountered no missing data in the study.
36
37 197 Statistical analysis was done using IBM SPSS Statistics 20 Windows (SPSS Inc., Chicago,
38
39 198 USA).

38 199 ***Ethical approval:***

41 200 We collected written informed consent from the consenting subjects before recruitment to the
42
43 201 study and the same was documented for future reference. The consent contained the title,
44
45 202 purpose, methods employed in the study, benefits to the subject as well as to their families. It
46
47 203 was also made clear that participation in this research is purely voluntary. The confidentiality
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49 204 of the study during the analysis was also mentioned in the consent. The consent process and
50
51 205 study protocol was approved by the Institutional Ethics Committee of Amrita Institute of
52
53 206 Medical Sciences and Research centre. (Institutional Ethics Committee Registration Number:
54
55 207 ECR/129/Inst/KL/2013).

55 208 **Results**

57 209 ***Baseline Characteristics of the study population***

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3 210 We recruited a total of 1000 participants from 40 individual pre-designated clusters spread
4
5 211 across a circular geographical area with the study institution as the centre point. The
6
7 212 distribution of gender, age categories, weight status, education level, household living pattern
8
9 213 and area of domicile are presented in Table 1. The mean age of the study subjects was
10
11 214 72.7(7.2) years. Among the study participants, 568 (56.8%) were female, 87.4% were literate
12
13 215 and 82% lived with family or caretakers. A total of 348 (34.8%) were either pre-obese or
14
15 216 obese as per Asian Criteria of BMI classification.²¹ The morbidity profile of the study
16
17 217 population was published earlier.²² The self-reported prevalence of diabetes(DM), coronary
18
19 218 artery diseases(CAD) and cerebrovascular accidents (CVA) were 34.2%, 20.1%&5.3%
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21 219 respectively. Among the study subjects, 768 (76.8%) were hypertensive as documented either
22
23 220 by high values on house visit measurement or by current treatment for hypertension. Among
24
25 221 hypertensives, a total of 528 subjects (68.8%) reported taking treatment for hypertension and
26
27 222 remaining 240(31.2%) were newly detected during the baseline evaluation of the study.

26 223 ***Incidence of falls in the study population***

28
29 224 A total of 201(20.1%) subjects reported a fall during the prospective follow up period of one
30
31 225 year. The total fall episodes during the follow up period were 301. The overall incidence rate
32
33 226 of falls was 31 (95% CI 27.7, 34.6) per 100 person years. The corresponding figures for
34
35 227 elderly men and women separately were 21.2 (95% CI 18.5, 24.2) and 38.3 (95% CI, 34.6,
36
37 228 42.3) respectively. The stratified incidence rates for age groups 65-75, 75-85 & more than 85
38
39 229 were 27.4, 36.8 and 41.1 per 100 person years respectively. Among the participants, more
40
41 230 women reported a fall compared to men (23.6% v/s 15.5%, p, 0.002). In the age stratified
42
43 231 groups, 27(30.0%) subjects in the age group >85 years reported a fall in the follow up period,
44
45 232 compared to 54(20.6%) in the age group 75-85 years and 120(18.5%) in the 65-75 years
46
47 233 group. (p 0.038). In addition, 53 (5.3 %) people sustained recurrent falls (two or more falls)
48
49 234 during the follow up.

48 235 ***Factors associated with prospective falls.***

50
51 236 The association of baseline factors with a prospective history of falls during the follow up
52
53 237 period is presented in **Table 2** as unadjusted bivariate comparisons. Among all baseline
54
55 238 variables, only gender and living arrangement showed a significant association with a
56
57 239 prospective history of falls on bivariate comparisons. Females had a higher risk of fall when
58
59 240 compared to males (OR 1.68, 95% CI, 1.21, 2.33. p 0.002). Those living alone during
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3 241 daytime also had a higher risk of falls when compared to those living with family/caretaker
4 242 (OR 2.95, 95% CI, 1.47, 5.94. p 0.002). The association of prospective falls with factors
5 243 affecting locomotion was explored by bivariate analysis and is presented in **Table 3**. Among
6 244 the factors affecting locomotion, only parkinsonism (OR 2.66, 95% CI, 1.23, 5.78. p 0.010),
7 245 vertigo (OR 1.51, 95% CI, 1.10, 2.06. p 0.010), arthritis (OR 1.62, 95% CI, 1.17, 2.25. p
8 246 0.004), numbness and paraesthesia of feet (OR 1.37, 95% CI, 1.00, 1.86. p 0.048) dependence
9 247 in basic activities of daily living (OR 3.45, 95% CI, 2.01, 5.92. p <0.001) and dependence in
10 248 instrumental activities of daily living (OR 1.63, 95% CI, 1.18, 2.25. p 0.003) showed
11 249 significant associations with prospective falls on bivariate comparisons. A history of falls in
12 250 the preceding year also had a higher risk for prospective falls (OR 2.59, 95% CI, 1.87, 3.58. p
13 251 <0.001).

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25 253 Furthermore, among baseline factors only gender showed an association with recurrent falls
26 254 on bivariate comparisons (OR 2.44, 95% CI, 1.29, 4.63. p 0.005). Among factors affecting
27 255 locomotion, dependence in basic activities of daily living (OR 5.00, 95% CI, 2.38, 10.10. p
28 256 <0.001), dependence in instrumental activities of daily living (OR 1.79, 95% CI, 1.03, 3.12. p
29 257 = 0.038) and a history of falls in the preceding year (OR 4.20, 95% CI, 2.38, 7.39 p <0.001)
30 258 showed an association with recurrent falls on bivariate comparisons.

31 259

32 260 In the study population, 474(47.4%) subjects reported taking anti-hypertensives, 277(27.7%)
33 261 reported taking anti diabetic medications and 69(6.9%) reported taking either
34 262 benzodiazepines or other sedative drugs. There was no significant association for prospective
35 263 falls with use of anti-hypertensive medications (OR 0.77, 95% CI 0.57, 1.06, p = 0.104), anti-
36 264 diabetic medications (OR 1.14, 95% CI 0.81, 1.60, p=0.446) or benzodiazepines/sedatives
37 265 (OR 1.56, 95% CI 0.90, 2.72, p=0.110) in bivariate comparisons.

266 ***Independent Risk Factors for prospective falls***

267 The final adjusted model with independent predictors of prospective falls in the elderly is
268 presented as Table 4. The variables found to be significant(P value <0.2) in bivariate analysis
269 with falls were age, sex, living arrangement, vertigo, parkinsonism, arthritis, urinary
270 symptoms, constipation, knee pain, paraesthesia of feet, history of fall in the previous year,
271 dependence in basic and instrumental activities of daily living, use of assistive devices for
272 movement, cognitive impairment, depression, use of antihypertensive medications and

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3 273 benzodiazepines. The same were included in the final model construction. Among the factors
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5 274 examined in the logistic regression model, female sex (OR 1.48, 95% CI 1.05, 2.10, $p =$
6
7 275 0.027), parkinsonism (OR 2.26, 95% CI 1.00, 5.05, $p=0.048$), arthritis (OR 1.48, 95% CI
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9 276 1.05-2.09, $p=0.026$), dependence in basic activities of daily living (OR 3.49, 95% CI 2.00,
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11 277 6.09, $p<0.001$), not using antihypertensive medications (OR 1.53, 95% CI 1.10-2.13,
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13 278 $p=0.012$), living alone during the daytime (OR 3.27, 95% CI 1.59-6.71, $p=0.001$) and history
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15 279 of falls in the previous year (OR 2.59, 95% CI 1.87, 3.58, $p<0.001$) were found to be
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17 280 significantly associated with falls.

18 281 The factors included to assess the independent risk factors of recurrent falls were, female sex,
19
20 282 vertigo, parkinsonism, arthritis and dependence in basic and instrumental activities of daily
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22 283 living and history of falls in the previous year. From the above, the independent predictors for
23
24 284 recurrent falls were female sex (OR 2.05, 95% CI 1.07, 3.95, $p = 0.031$), dependence in basic
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26 285 activities of daily living (OR 3.63, 95% CI 1.71, 7.70, $p = 0.001$), and history of falls in the
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28 286 previous year (OR 3.39, 95% CI 1.89, 6.05, $p<0.001$).

29 287 **Discussion**

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31 288 The current study provides details of fall episodes experienced by free living elderly from
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33 289 Kerala, India during a prospective follow up of one year. Approximately one in five elderly
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35 290 subjects in this age group reported a fall during the study period. There appears to be a sex
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37 291 based difference in the proportion that fell with one in four elderly women falling compared
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39 292 to one in six men during follow up. The results also suggest a dose response relationship
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41 293 between age and falls with more subjects falling in older age groups compared to relatively
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43 294 younger groups. In addition, every fourth person who fell reported one or more falls
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45 295 following the index fall episode during the study period.

46 296 The independent predictors for falls in the elderly included female sex, parkinsonism and
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48 297 related movement disorders, arthritis, dependence in basic activities of daily living, not using
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50 298 antihypertensive medicines, living alone during daytime and a history of fall in the preceding
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52 299 year. The corresponding predictors for recurrent falls included female sex, dependence in
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54 300 basic activities of daily living and a history of fall in the preceding year. To our knowledge,
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56 301 this is the only prospective cohort study done in India that focussed on falls in free living
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58 302 elderly who were assessed in the community setting.

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3 303 The incidence of falls in the elderly from our study appears to be at the lower end of the
4 spectrum as reported by western studies (29% to 40%).⁹⁻¹⁴ Interestingly, our results are more
5 304 similar to that reported by a prospective study among community dwelling elderly Chinese
6 subjects.²³ The incidence rate of falls in this study were 27.0, 32.4 and 22.0 per 100 person-
7 305 years for all elderly, women and men respectively. The proportion with recurrent falls in this
8 306 study was also similar to our study (4.75% v/s 5.3%).
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14 309 The risk factors for prospective falls in community dwelling elderly was examined by a
15 recent meta-analysis by Deandrea et al that pooled 74 prospective cohorts.¹⁹ Most of the
16 310 prospective studies in the meta-analysis suggested that community dwelling elderly women
17 311 are at higher risk for falls compared to their male counterparts. The pooled estimates for falls
18 312 (OR 1.30, 95% CI, 1.18, 1.42) and recurrent falls (OR 1.34, 95% CI, 1.12, 1.60) in this meta-
19 313 analysis are in agreement with the current study.
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25 315 Similar to the current study, several prospective studies have reported higher risk for falls
26 316 among elderly patients with Parkinsonism and/or related movement disorders similar to the
27 317 current study. The meta-analysis suggested an adjusted OR of 2.71 (95% CI, 1.08, 6.84) for
28 318 falls and 2.84 (95% CI, 1.77, 4.58) for recurrent falls from five studies that looked for the
29 319 same. Our study didn't report any positive association between Parkinson's disease and
30 320 recurrent falls, probably due to the small number of recurrent fallers (5.3%) in the cohort.
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37 321 Our finding of high risk for falls among those elderly with arthritis is in concordance with
38 322 several other studies.²⁴⁻²⁷ Together these studies suggest that the elderly with arthritis and/or
39 323 chronic pain have a higher risk for falls. The GLOW cohort also reported a higher incidence
40 324 of falls and fractures in postmenopausal women with osteoarthritis compared to osteoarthritis
41 325 free peers.²⁷
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48 327 Several studies have reported that living alone during the daytime is a risk factor for falls in
49 328 the elderly as suggested by the current study.¹⁹ The meta-analysis is also in agreement with
50 329 this observation (OR 1.33, 95% CI, 1.21, 1.45) after looking at data from 11 studies that
51 330 examined the same.
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56 331 Reduced capability for BADL(Basic Activities of Daily Living) is also reported to be
57 332 associated with falls in the elderly.²⁸ Yokoya et al recently concluded that higher frequency
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3 333 of leaving home, higher exercise levels and presence of interest in activities (e.g., meeting
4 334 friends, shopping, working in the garden) were associated with a reduced risk for fall in
5 335 community dwelling elders.²⁸ Therefore, maintaining and enhancing physical functions,
6 336 principally walking ability and walking speed are critical for fall prevention among the
7 337 elderly.^{29,30} Age appropriate exercises including those enhancing muscle strength and
8 338 improving balance can probably reduce the incidence of falls among the elderly.³⁰

13
14 339 A history of falls in the previous year appears to be the most consistent risk factor across
15 340 several studies.^{19,30,31} Pooled data from several studies in the recent meta-analysis puts the
16 341 risk at an OR of 2.77 (95% CI, 2.37, 3.25) for falls and an OR of 3.46 (95%CI, 2.85, 4.22) for
17 342 recurrent falls, in agreement with the current study (2.59 & 3.39 respectively).¹⁹ Suzuki et al
18 343 reported that five out of six elderly with a history of falls were anxious about another fall and
19 344 one in three said that they did not venture out again due to fear of another fall.³⁰

23
24 345 One notable finding in our study was the lack of association for falls with medication use for
25 346 most groups of medications except for antihypertensive medications. This is in contrast to a
26 347 meta-analysis of the impact of medication classes on falls in elderly.³² Woolcott et al reported
27 348 an OR of 1.41 (95% CI, 1.20-1.71) for falls among elderly with benzodiazepine use.³² The
28 349 lack of association between sedatives use and falls in our study is probably due to the limited
29 350 number of subjects reporting the use of the same (6.9%). We saw an inverse association
30 351 between falls and the use of antihypertensive drug use in the current study. One probable
31 352 reason could be the high proportion of uncontrolled hypertensives in the study population.
32 353 This finding needs to be explored further in future studies.

33 354 Several studies have earlier suggested that the prevalence of falls in low and middle income
34 355 countries is higher than that reported from high income countries.⁴⁻⁶ The morbidity from falls
35 356 and related events too appear to be higher in low and middle income countries compared to
36 357 high income countries like the US.⁴⁻⁶ There appears to be low awareness about the
37 358 consequences of falls in low and middle income countries. This could probably be due to the
38 359 lack of data regarding falls reported from these regions. It is expected that the awareness
39 360 related to falls will improve with dissemination of data from the current study as well as
40 361 similar studies from this region. The same may also stimulate research into the interventional
41 362 options to reduce fall related mortality and morbidity. Interventional studies to prevent falls
42 363 in the elderly are very relevant to the state of Kerala as it has the maximum proportion of

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3 364 elderly (12.6%) in India as per 2011 census.³³ This is much higher than the national average
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5 365 of 8.6%, making Kerala more appropriate for future intervention studies in this area.
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8 366 The strengths of the current study include the following; prospective cohort study design,
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10 367 large sample size (n=1000), representative urban and rural population components, inclusion
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12 368 of participants from different socioeconomic levels, no participants lost to follow up and use
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14 369 of a fall diary to avoid recall bias. However, the study included participants from a limited
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16 370 geographical setting and was able to follow up only for a short period (one year), and hence
17
18 371 the generalisation of the study findings is limited.
19

372 373 **Conclusion**

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22 375 One in five community dwelling elderly citizens fall on an annual basis and one in four of
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24 376 those who fall are prone to fall again in the same calendar year. Female sex, movement
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26 377 disorders including parkinsonism, arthritis, dependence in basic activities of daily living,
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28 378 living alone during daytime and a history of falls in the previous year appear to predict a fall
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30 379 in the following year.
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33 381 Any future intervention program targeting a reduction in falls among the elderly in India
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35 382 should start in Kerala due to the high proportion of elderly in the state and extend to similar
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37 383 states later. Such studies should focus on the modifiable risk factors such as living alone at
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39 384 home during daytime, movement disorders and arthritis as identified by the current study. We
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41 385 need to encourage mechanisms that may reduce dependence of the elderly for basic activities
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43 386 of daily living. Attention should also be given to encourage both physical and social activities
44
45 387 among elderly subjects.
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47 388
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49

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53
54 393 or not-for-profit sectors.
55

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Tables

Table 1. Baseline Details of the study population.

Demographic factors	n (%)	
Gender	Male	432(43.2)
	Female	568(56.8)
Age group		

	65-75	648(64.8)
	75-85	262(26.2)
	>85	90(9.0)
Weight Status(BMI)		
	Underweight(<18.5)	124(12.4)
	Normal(18.5-22.9)	340(34.0)
	Overweight(23-24.9)	188(18.8)
	Pre Obese(25-29.9)	264(26.4)
	Obese(>30)	84(8.4)
Education		
	Graduate and above	132(13.2)
	Diploma / Pre-degree	85(8.5)
	Middle class / Primary	657(65.7)
	Illiterate	126(12.6)
House Hold		
	Living with family / caretaker	820 (82.0)
	Living alone during daytime	145 (14.5)
	Living alone	35 (3.5)
Domicile		
	Urban	700(70.0)
	Rural	300(30.0)

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Table.2. Association of falls with baseline variables – bivariate comparisons

Risk factors	Prospective falls		OR (95% CI)	P value
	No Fall n (%)	Fall n (%)		
Gender				
Men [432(43.2)]	365(84.5)	67(15.5)	1.68(1.21-2.33)	0.002
Women [568(56.8)]	434(76.4)	134(23.6)		

Age Group in years					
65-75 [648(64.8)]		528(81.5)	120(18.5)		
75-85 [262(26.2)]		208(79.4)	54(20.6)	1.14 (0.80-1.64)	0.468
>85 [90(9.0)]		63(70.0)	27(30.0)	1.89 (1.15 -3.09)	0.012
Diabetes [342(34.2)]					
No		532(80.9)	126(19.1)	1.19(0.86-1.63)	0.298
Yes		267(78.1)	75(21.9)		
Hypertension (768(76.8))					
No		181(78.0)	51(22.0)	0.86(0.60-1.23)	0.414
Yes		618(80.5)	150(19.5)		
Asthma or COPD (225(22.5))					
No		622(80.3)	153(19.7)	1.10(0.77-1.59)	0.600
Yes		177(78.7)	48(21.3)		
Coronary Artery Disease (201(20.1))					
No		639(80.0)	160(20.0)	1.02(0.69-1.50)	0.906
Yes		160(79.6)	41(20.4)		
Cerebrovascular Disease (53(5.3))					
No		762(80.5)	185(19.5)	1.78(0.97-3.27)	0.060
Yes		37(69.8)	16(30.2)		
Alcohol (177(17.7))					
No		654(79.5)	169(20.5)	0.85(0.56-1.30)	0.460
Yes		145(81.9)	32(18.1)		
Smoking (178(17.8))					
No		652(79.3)	170(20.7)	0.81(0.53-1.23)	0.324
Yes		147(82.6)	31(17.4)		
Living Arrangement					
Living with family/caretaker (820(82))		669(81.6)	151(18.4)		
Living alone during daytime (145(14.5))		109(75.2)	36(24.8)	2.95(1.47-5.94)	0.002
Living alone(35(3.5))		21(60.0)	14(40.0)	1.46(0.97-2.22)	0.073

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506 **Table 3. Association of falls with factors affecting locomotion – Bivariate comparisons**

Risk factors	Prospective falls		OR (95% CI)	P value
	No Fallers n (%)	Fallers n (%)		
Parkinsonism(28(2.8))				
No	782(80.5)	190(19.5)	2.663(1.23-5.78)	0.010
Yes	17(60.7)	11(39.3)		

Vertigo(388(38.8))	No	505(82.5)	107(17.5)	1.51(1.10-2.06)	0.010
	Yes	294(75.8)	94(24.2)		
Arthritis(281(28.1))	No	591(82.2)	128(17.8)	1.62(1.17-2.25)	0.004
	Yes	208(74.0)	73(26.0)		
Knee pain (565(56.5))	No	356(81.8)	79(18.2)	1.24(0.91-1.70)	0.179
	Yes	443(78.4)	122(21.6)		
Numbness and paraesthesia of feet(475(47.5))	No	432(82.3)	93(17.7)	1.37(1.00-1.86)	0.048
	Yes	367(77.3)	108(22.7)		
Urinary symptoms (316(31.6))	No	558(81.6)	126(18.4)	1.38(0.99-1.90)	0.051
	Yes	241(76.3)	75(23.7)		
Visual impairment (594(59.4))	No	326(80.3)	80(19.7)	1.04(0.76-1.43)	0.796
	Yes	473(79.6)	121(20.4)		
Not independent in Basic Activities of daily living (59(5.9))	Yes	766(81.4)	175(18.6)	3.45(2.01-5.92)	<0.001
	No	33(55.9)	26(44.1)		
Not independent in Instrumental activities of daily living (306(30.6))	Yes	572(82.4)	122(17.6)	1.63(1.18-2.25)	0.003
	No	227(74.2)	79(25.8)		
Regular exercise or Yoga (342(34.2))	Yes	281(82.2)	61(17.8)	1.25(0.89-1.74)	0.198
	No	518(78.7)	140(21.3)		
History of falls in the previous 1 year (269(26.9))	Yes	182(67.7)	87(32.3)	2.59 (1.87 – 3.58)	<0.001
	No	617(84.4)	114(15.6)		

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510 **Table 4 Adjusted model for risk factors of falls in community dwelling elderly**511 **subjects(n=1000)**

Risk Factors	Odds Ratio (95% CI)	P value
All Falls		

Females	1.48 (1.05, 2.10)	0.027
Movement disorders / Parkinson's Disease	2.26 (1.00, 5.05)	0.048
Arthritis	1.48 (1.05, 2.09)	0.026
Dependence in basic activities of daily living	3.49 (2.00, 6.09)	<0.001
Not using antihypertensive medications	1.53 (1.10, 2.13)	0.012
Living alone during daytime	3.27 (1.59, 6.71)	0.001
History of falls in the previous year	2.25 (1.60, 3.15)	<0.001
Recurrent Falls		
Females	2.05 (1.07, 3.95)	0.031
Dependence in basic activities of daily living	3.63 (1.71, 7.70)	0.001
History of falls in previous year	3.39 (1.89, 6.05)	<0.001

Figure legends

Fig.1 Flowchart of the study design

Contributorship statement :-

Divyamol K S and Priya Vijayakumar conceptualised the original idea. Divyamol K S and Manu Raj did review of literature and planned, conducted analysed and prepared manuscript of the research work. Priya Vijayakumar supervised the experiment and the final editing of the article. Sumi Soman and Libin Antony were involved in data acquisition and analysis. Abish Sudhakar and Conrad Kabali derived the models and analysed the data.

Data availability statement :-

All data relevant to the study are included in the article or uploaded as supplementary information.

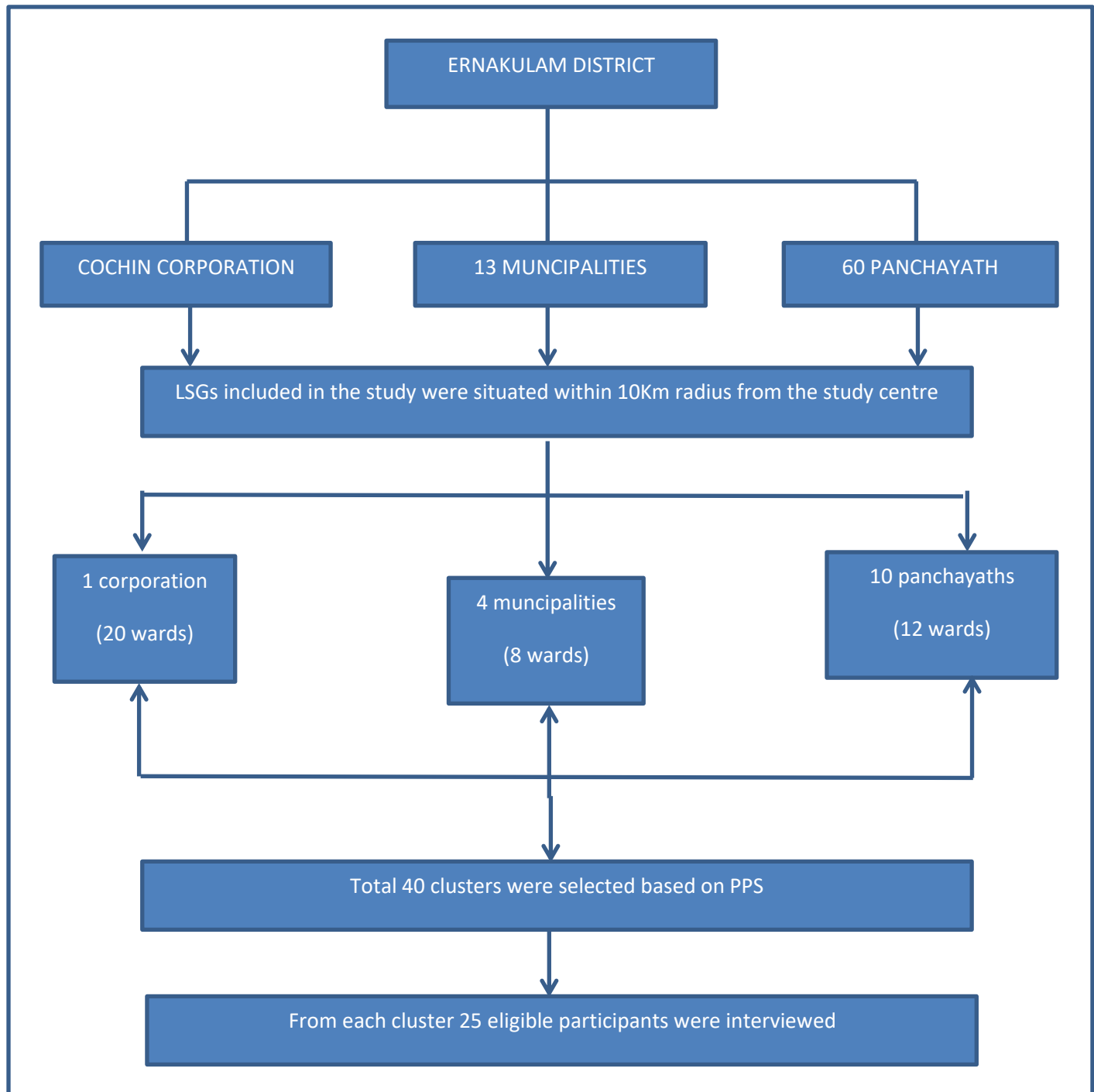
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Figure

Fig.1 Flowchart of the Study Design



1 STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

		Recommendation	Action taken
4	Title and abstract	1 (a) Indicate the study's design with a commonly used term in the title or the abstract	Page 2, Line 50 & 51
6		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2-3, Line 53-73
9	Introduction		
11	Background/rationale	2 Explain the scientific background and rationale for the investigation being reported	Page 4, Line 86-103
13	Objectives	3 State specific objectives, including any prespecified hypotheses	Page 5, Line 120-123
16	Methods		
17	Study design	4 Present key elements of study design early in the paper	Page 5, Line 127
18	Setting	5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 5, Line 128-132
22	Participants	6 (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5-6, Line 141-153
26		(b) For matched studies, give matching criteria and number of exposed and unexposed	Not Applicable
28	Variables	7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6, Line 154-158
32	Data sources/measurement	8* For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6-7, Line 163-181
37	Bias	9 Describe any efforts to address potential sources of bias	Page 6-7, Line 173-176, 177-179
40	Study size	10 Explain how the study size was arrived at	Page 5, Line 133- 140
41	Quantitative variables	11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7, Line 183-194
45		Statistical methods	12 (a) Describe all statistical methods, including those used to control for confounding
47	(b) Describe any methods used to examine subgroups and interactions		Not done
49	(c) Explain how missing data were addressed		No missing data was encountered
51	(d) If applicable, explain how loss to follow-up was addressed		No Loss to follow up was reported
53	(e) Describe any sensitivity analyses		Not Applicable
55	Results		
57	Participants	13 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 8, Line 206-208 Refer Fig 1
59		(b) Give reasons for non-participation at each stage	Not Applicable

		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 8, Line 207-219
	*	(b) Indicate number of participants with missing data for each variable of interest	No missing data
		(c) Summarise follow-up time (eg, average and total amount)	Page 6-7, Line 176-177
Outcome data	15	Report numbers of outcome events or summary measures over time	Page 8, Line 221-231
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 8-9, Line 232-262
		(b) Report category boundaries when continuous variables were categorized	Not applicable
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 09, Line 263-283
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 10, Line 286-292
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 13, Line 363-365
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11-12, Line 300-359
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 13, Line 363-365
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 13, Line 369-370