

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

## Frailty and driving status associated with disability

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-042468
Article Type:	Original research
Date Submitted by the Author:	06-Jul-2020
Complete List of Authors:	Doi, Takehiko; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Tsutsumimoto, Kota; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Ishii, Hideaki; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Nakakubo, Sho; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Kurita, Satoshi; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Shimada, Hiroyuki; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science
Keywords:	GERIATRIC MEDICINE, EPIDEMIOLOGY, PUBLIC HEALTH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

**Frailty and driving status associated with disability**

Takehiko Doi PhD, PT<sup>a</sup>, Kota Tsutsumimoto PhD, PT<sup>a</sup>, Hideaki Ishii PhD, PT<sup>a</sup>, Sho Nakakubo PhD, PT<sup>a</sup>, Satoshi Kurita PhD<sup>a</sup>, Hiroyuki Shimada PhD, PT<sup>a</sup>

<sup>a</sup>Department of Preventive Gerontology, Center for Gerontology and Social Science, National Center for Geriatrics and Gerontology, Obu, Aichi, Japan.

**Corresponding author:**

Takehiko Doi, Department of Preventive Gerontology, Center for Gerontology and Social Science, National Center for Geriatrics and Gerontology, 7-430, Morioka, Obu, Aichi 474-8511, Japan

Tel: +81-562-44-5651

E-mail: [take-d@ncgg.go.jp](mailto:take-d@ncgg.go.jp)

**Abstract Word Count: 230, Main Word Count: 2340**

**Keywords:** physical function, traffic, functioning and disability

**Running Title:** Disability, frailty, and drivng status

1  
2  
3  
4  
5  
6 21 **ABSTRACT**

7  
8 22 **OBJECTIVES:** To examine the relationship of driving status and frailty with disability  
9  
10 23 in older adults.

11  
12 24 **DESIGN:** A prospective study.

13  
14 25 **SETTING AND PARTICIPANTS:** The study included 8,533 participants (mean age:  
15  
16 26  $72.0 \pm 6.1$  years [range: 60–98 years], women: 54.1%) in a community setting.

17  
18 27 **MEASURES:** Driving status and frailty were assessed at baseline. Clinical definition of  
19  
20 28 frailty was according to J-CHS index. Disability was prospectively determined using a  
21  
22 29 record of Japanese long-term care insurance (LTCI).

23  
24 30 **RESULTS:** During follow-up duration (mean: 23.5 months), 58 participants (0.7%)  
25  
26 31 were regarded as moving out, 80 participants (0.9%) had died, and 311 participants  
27  
28 32 (3.6%) were certified by LTCI. The proportion of disability was 1.3 % among not frail  
29  
30 33 group and 5.4% among frail group. The proportion of disability was 2.5 % in  
31  
32 34 participants who were currently driving and 7.7% in those not driving. Based on status  
33  
34 35 of frailty and driving, participants were further classified into four groups: not frail and  
35  
36 36 currently driving (n = 2905), not frail and not driving (n = 632), frail and currently  
37  
38 37 driving (n = 3543), frail and not driving (n = 1315). Compared to older adults who are  
39  
40 38 not frail and driving, the combined status of frail and not driving (adjusted HR: 2.28  
41  
42 39 [95%CI: 1.47-3.52]) and frail with driving (HR: 1.91 [1.30-2.81]) were risk factors for  
43  
44 40 disability.

45  
46 41 **CONCLUSIONS:** Not driving and frail was a risk of disability in community-dwelling  
47  
48 42 older adults.

49  
50 43

1  
2  
3  
4  
5  
6 44 **Article Summary**  
7

8 45 **Strengths and limitations of this study**  
9

10  
11 46 • From a large population study of over 8000 older adults, current not driving increased  
12

13  
14  
15 47 risk of disability incidence.  
16

17 48 • The effects of driving were observed among participants who were frail, while not  
18

19  
20  
21 49 driving did not increase the risk of disability among participants who were not frail.  
22

23  
24 50 • The primary limitations were a short follow-up duration.  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 51 INTRODUCTION

52 Extending healthy life expectancy and diminishing the duration of life with disability  
53 helps to decrease the health burden on society.[1] Frailty is regarded as a prodromal stage  
54 of disability and has a high risk of adverse health outcomes, including disability. Frailty  
55 is a reversible status; someone's health could become robust again.[2] Although frailty is  
56 a complex age-related clinical condition, adequate assessment of risk and preventive  
57 actions could help providers disrupt the progression from frail to disabled.[3]

58 Driving is a critical resource in supporting an active life style in older adults. In fact,  
59 driving cessation increases the risk of disability.[4, 5] However, whether the combined  
60 condition of not driving and being frail also elevated the risk of disability is unclear. More  
61 older adults are driving cars, but they are also having more accidents, especially in super-  
62 aged societies, like Japan.[6] Adequate evaluation of driving ability is required, but  
63 driving cessation with insufficient cause can potentially increase disability. Thus, our  
64 study aimed to elucidate how frailty and driving status affects disability risks.

## 65 **METHODS**

### 66 **Participants**

67 Participants in this study were from the National Center for Geriatrics and Gerontology –  
68 Study of Geriatric Syndromes[7], which aims to establish a screening system for geriatric  
69 syndromes and validate evidence-based interventions for preventing these syndromes.  
70 Participants were collected from surveys conducted in 2015–2017; 9,701 individuals aged  
71 60 years or over were eligible. The survey was regarded as the baseline and prospectively  
72 collected data was used for a follow-up duration of approximately two years (23.5  
73 months). Exclusion criteria included: diagnoses of dementia, stroke, and Parkinson’s  
74 disease; being unable to independently perform basic activities of daily living; being  
75 certified with long-term care insurance (LTCI) in Japan before the survey; and having  
76 missing values for analysis. All participants provided written informed consent, and the  
77 ethics committee of the National Center for Geriatrics and Gerontology approved this  
78 study (770, 791).

### 80 **Frailty**

81 The definition of frailty used in this study was the Japanese CHS (J-CHS) index,[8-10]  
82 according to CHS index criteria.<sup>[2]</sup> The components of frailty in the J-CHS index are same  
83 as the original CHS index: shrinking (weight loss), weakness, poor endurance  
84 (exhaustion), slowness, and low activity. Weight loss was collected by a question from  
85 the Kihon Checklist,[11] with the question “Have you lost 2 kg or more in the past six  
86 months?” A “yes” answer indicated that participants had experienced weight loss.  
87 Weakness was defined as low muscle strength based on grip strength, measured using a



## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 88 Smedley-type handheld dynamometer (Takei Ltd, Niigata, Japan). Sex-specific cut-offs  
7  
8 89 of low muscle strength were < 26 kg in men and < 18 kg in women.[8, 9, 12] Exhaustion  
9  
10 90 was assessed using a question from the Kihon Checklist:[11] a “yes” answer to the  
11  
12 91 question, “In the last two weeks, have you felt tired for no reason?” indicated that  
13  
14 92 participants had exhaustion or poor endurance. Slowness was defined as slow walking  
15  
16 93 speed under normal conditions. Participants were asked to walk on a straight, 6.4 m  
17  
18 94 walkway, on a flat floor with their usual gait speed. Gait time was measured over a 2.4 m  
19  
20 95 distance between marks at 2.0 m and 4.4 m from the start of the walkway, and the mean  
21  
22 96 gait speed (m/s) was calculated. The cut-off value of slowness was less than 1.0 m/s.[8,  
23  
24 97 9] Low activity level was also measured using the questionnaire and indicated through a  
25  
26 98 response of “no” to both: “Do you engage in moderate levels of physical exercise or sports  
27  
28 99 aimed at health?” and “Do you engage in low levels of physical exercise aimed at  
29  
30 100 health?”[8, 9] Based on the values of these five components (weight loss, weakness,  
31  
32 101 exhaustion, slowness, and low activity), our study assigned “frail” to values of 1 and over,  
33  
34 102 including pre-frailty and frailty.[8, 9]  
35  
36  
37  
38  
39  
40  
41  
42

### 104 **Driving status**

43  
44  
45 105 The survey asked participants about their driving status. To determine driving status,  
46  
47 106 current status of driving license (without license, surrendered, not renewed, has license  
48  
49 107 but not driving, and currently driving with license) was reviewed. In our study, the status  
50  
51 108 of currently driving with license was regarded as currently driving, and all other statuses  
52  
53 109 were regarded as not driving.  
54  
55  
56  
57  
58

### 111 **Disability**

## Disability, frailty, and driving status

1  
2  
3  
4  
5 112 LTCI certification in all participants was monitored throughout follow-up. LTCI certifies  
6  
7  
8 113 a person as “Support Level 1 or 2” if he or she needs support for daily activities or “Care  
9  
10 114 Level 1, 2, 3, 4, or 5” if they need continuous care.[13] Beneficiaries of the LTCI can use  
11  
12 115 multiple services for which they are eligible. They can use more services than are covered  
13  
14 116 if they pay all the costs for services beyond the maximum level.[13, 14] In our study,  
15  
16 117 becoming disabled was defined as a new LTCI certification at any level. If we were  
17  
18 118 unable to follow up and assess for incident disability, this was treated as censored data,  
19  
20 119 i.e., moving out of the other city and death. We monitored this information through  
21  
22 120 monthly updates. We defined the follow-up period as beginning at the time we conducted  
23  
24 121 the survey at baseline (mean follow-up duration: 23.5 months [max: 24.0 months]).  
25  
26  
27  
28  
29  
30

### 123 **Covariates**

31  
32  
33 124 To understand participants’ characteristics, demographic data, medical condition, and life  
34  
35 125 style were assessed. Regarding demographic data, age and sex were collected. For  
36  
37 126 medical condition, participants were interviewed about their medication use by well-  
38  
39 127 trained nurses or other medical staff, and medication numbers were collected. Cognitive  
40  
41 128 function was assessed through the Mini-Mental State Examination (MMSE).[15]  
42  
43 129 Depressive symptoms were assessed using the geriatric depression scale (15 items  
44  
45 130 version).[16] In addition, going out less frequently was assessed by a question from the  
46  
47 131 Kihon Checklist.[11]  
48  
49  
50

### 51 52 53 54 133 **Statistical Analysis**

55  
56  
57 134 Variables at baseline were compared between participants with and without disability  
58  
59  
60

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 135 during the follow-up duration, using an unpaired *t*-test or  $\chi^2$  test. Participants were  
7  
8 136 classified into four groups according to their baseline status of driving and frailty: not  
9  
10 137 frail and currently driving, not frail and not driving, frail and currently driving, frail and  
11  
12 138 not driving.

13  
14  
15 139 To examine the association of frailty and driving status with the risk of disability,  
16  
17 140 Kaplan–Meier survival risk assessments were used to plot cumulative survival function,  
18  
19 141 and the results for each group were compared using log rank tests. The objective variable  
20  
21 142 was set as incident disability and the explanatory variable was four groups based on frail  
22  
23 143 and driving. In addition, Cox proportional hazards regression models was used to test the  
24  
25 144 association. For incident disability, hazard ratios (HR) of the frail group compared to the  
26  
27 145 not frail group and the not driving group compared to the driving group were calculated  
28  
29 146 respectively. Four groups were also set as the explanatory variable, with the without frail  
30  
31 147 and currently driving group as reference. These analyses were conducted in crude and  
32  
33 148 adjusted models, including covariates. Each model in Cox proportional hazards  
34  
35 149 regression analysis calculated HR and 95% confidence intervals (CI). All analyses were  
36  
37 150 performed using SPSS statistics software, Version 20 (IBM Corp., Chicago, IL, USA).  
38  
39  
40  
41  
42 151 Statistical significance was set at  $p < 0.05$  in all analyses.  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

152 **RESULTS**

153 From 9,701 eligible participants, 8,533 participants (mean age:  $72.0 \pm 6.1$  years [age  
154 range: 60–98 years], women: 54.1%) were matched with criteria and analyzed in this  
155 study. During the follow-up duration, 58 participants (0.7%) were regarded as moving  
156 out, 80 participants (0.9%) died, and 311 participants (3.6%) were certified by LTCL.  
157 Participants with disability, compared to those without disability, were older, took more  
158 medications, went out less frequently, and had higher scores on the geriatric depression  
159 scale and lower scores on MMSE (Table 1, all  $p < 0.001$ ). In addition, participants with  
160 disabilities were more likely to be frail and less likely to be currently driving (both  $p <$   
161  $0.001$ ).

162  
163 Table 1. Characteristics of participants with disability and without during follow-up  
164 duration

Variables	Without disability (n = 8084)	With disability (n = 311)	<i>p</i> -value
Age, years	71.7 (5.9)	79.2 (6.3)	< 0.001
Sex (women), %	54.1	56.3	0.450
Medication numbers	2.7 (2.6)	3.8 (2.8)	< 0.001
Less frequent going out, %	13.2	33.5	< 0.001
Currently driving, %	77.8	51.8	< 0.001
Status of frailty			< 0.001
Robust, %	43.2	15.1	
Pre frailty, %	50.2	52.4	

## Disability, frailty, and driving status

Frailty, %	6.6	32.5	
Geriatric Depression Score, score	2.6 (2.5)	3.8 (2.7)	< 0.001
Mini-Mental State Examination, score	27.3 (2.4)	25.0 (3.6)	< 0.001

Note: Values are mean (standard deviations) or proportions. The total number of participants was 8533. Data in this Table excluded 138 participants (58 participants regarded as moving out and 80 participants died).

The proportion of incident disability during follow-up duration was dependent on status of frailty and driving (Figure 1). The proportion of participants with disability was 1.3% in the not frail group and 5.4% in the frail group. The proportion of participants with disability who were currently driving was 2.5%, and the proportion of participants who were not driving was 7.7%. Based on their status of frailty and driving, participants were further classified into four groups: not frail and currently driving ( $n = 2905$ ), not frail and not driving ( $n = 632$ ), frail and currently driving ( $n = 3543$ ), and frail and not driving ( $n = 1315$ ). According to four groups based on frailty and driving status, participants who were not frail and currently driving had lowest proportion of disability (1.2%) and participants in frail and not driving had highest proportion of disability (10.4%). Survival risk based on log-rank test did not show a difference between participants from the not frail and currently driving group and the not frail and not driving ( $p = 0.077$ ). There were also not significant differences between participants from not frail and not driving and from frail and currently driving, ( $p = 0.051$ ). Other intergroup results did show differences ( $p < 0.001$ ). From the analysis using Cox proportional hazards regression models, the frail group had an increased risk of disability (crude HR

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 185 4.15 [95%CI: 3.04-5.66]), as did not driving (crude HR 3.15 [95%CI: 2.52-3.93]). In  
7  
8 186 addition, compared to not frail and currently driving group, participants from frail and  
9  
10 187 currently driving ( $p = 0.001$ ), and participants from frail and not driving ( $p < 0.001$ ), had  
11  
12 188 an increased risk of incident disability (Table 2).  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

189 Table 2. Association of status in frailty and driving with disability

Variables	Unadjusted HR	(95% CI)	<i>p</i>	Adjusted HR	(95% CI)	<i>p</i>
Not frail and currently driving	Reference					
Not frail and not driving	1.77	(0.93-3.35)	0.081	1.09	(0.57-2.09)	0.802
Frail and currently driving	3.10	(2.12-4.52)	< 0.001	1.91	(1.30-2.81)	0.001
Frail and not driving	9.25	(6.35-13.47)	< 0.001	2.28	(1.47-3.52)	< 0.001
Age				1.14	(1.12-1.16)	< 0.001
Sex (reference: men)				0.89	(0.69-1.16)	0.392
Mini-Mental State Examination				0.89	(0.86-0.92)	< 0.001
Medication numbers				1.03	(0.99-1.07)	0.136
Less frequently going out (reference: yes)				0.66	(0.51-0.85)	0.001
Geriatric Depression Scale				1.05	(1.01-1.09)	0.018

190 HR: hazard ratio; CI: confidence interval. The total number of participants was 8533. Data in this Table excluded 138 participants (58  
 191 participants regarded as moving out and 80 participants died).

## 192 **DISCUSSION**

193 Our study examined the association of frailty and driving status with the risk of  
194 disability among older adults. The proportion of incident disability was higher among  
195 those whose status was frail and not driving. The effects of driving were observed  
196 among participants who were frail, while not driving did not increase the risk of  
197 disability among participants who were not frail. This result remained even after  
198 adjustment with covariates.

199 Our study revealed that being frail was a risk of incident disability, which is in  
200 line with previous research. Numerous studies have indicated that frailty caused  
201 disability and other adverse health outcomes.[2] When we studied data from another  
202 section of the NCGG-SGS in 2011-12 with a similar follow-up duration (about 2 years),  
203 we saw a similar risk for frailty to cause disability,[10] although the data in 2011-2012  
204 did not have detailed assessments regarding driving. Our study is in accordance with  
205 similar studies and expands the previous evidence regarding frailty. Driving status had  
206 been associated with a risk of disability, particularly amongst frail participants. Driving  
207 a motor vehicle has a beneficial role in maintaining life space and activities in older  
208 adults. In fact, having a valid driving license was associated with reduced hazard of life-  
209 space constriction[17] and not driving increased restriction of life-space restriction.[18]  
210 In addition, having a combined status of frail and not driving created a high risk of  
211 disability compared to the other status. Not driving also caused functional decline in  
212 older adults, particularly when driving ceased. A prospective study revealed that  
213 stopping driving or reducing the distance driven was related to several functional  
214 declines and a decline in instrumental activities of daily living.[19] Furthermore, not  
215 driving was associated with higher risk of mortality.[20, 21] O'Connor suggested the



1  
2  
3  
4  
5  
6 216 relationship may be explained by health difficulties in social, physical, and general  
7  
8 217 health to accompany or follow driving cessation.[20]  
9

10 218 The strength of this study was that it was conducted in a large population study  
11  
12 219 with a prospective design. Our study also had limitations. In this study, disability was  
13  
14 220 defined as certification of LTCI. LTCI could not distinguish causes for the disability  
15  
16  
17 221 certification systematically. For example, we could not objectively distinguish between  
18  
19 222 mobility and cognitive disabilities.  
20

21 223 In conclusion, frailty and not driving status were associated with the risk of  
22  
23 224 disability. Not driving increased the risk of disability, particularly among frail older  
24  
25  
26 225 adults. The status of driving should be considered to assess the risk of disability.  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6 226 **ACKNOWLEDGMENT**  
7

8 227 We thank the Obu city and Takahama city office for help with participant recruitment.  
9

10 228

11  
12  
13 229 **CONTRIBUTORSHIP**  
14

15 230 TD: acquisition of the data, statistical analysis, interpretation of the data, and drafting of

16 231 the manuscript. HS: study design and concept, and drafting and revising of the

17 232 manuscript. IH and KT: acquisition of the data, statistical analysis, interpretation of the

18 233 data, and drafting of the manuscript. NS and KS: acquisition and interpretation of the data

19 234 and drafting of the manuscript.  
20  
21  
22  
23  
24  
25  
26  
27  
28

235

29 236 **COMPETING INTERESTS**  
30

31 237 None of the authors have any financial, personal, or potential conflict of interest with the

32 238 material presented in this article.  
33  
34  
35  
36  
37  
38

239

39 240 **DATA AVAILABILITY STATEMENT**  
40

41 241 No data are available.  
42  
43  
44  
45

242

46 243 **FUNDING**  
47

48 244 This work was supported by AMED under Grant Number (15dk0207004h0203,

49 245 15dk0107003h0003); a Grant-in-Aid for Scientific Research (B) (grant number

50 246 23300205); the Funds of Obu City Local Government; and Research Funding for

51 247 Longevity Sciences (26-33, 29-31, 30-7) from the National Center for Geriatrics and

52 248 Gerontology, Japan.  
53  
54  
55  
56  
57  
58  
59  
60

249 **REFERENCES**

- 250 1 GBD 2017 DALYs and HALE Collaborators. Global, regional, and national  
251 disability-adjusted life-years (DALYs) for 359 diseases and injuries and healthy life  
252 expectancy (HALE) for 195 countries and territories, 1990-2017: a systematic analysis  
253 for the Global Burden of Disease Study 2017. *Lancet* 2018;392:1859-922. doi:  
254 10.1016/s0140-6736(18)32335-3
- 255 2 Fried LP, Tangen CM, Walston J, *et al.* Frailty in older adults: evidence for a  
256 phenotype. *J Gerontol A Biol Sci Med Sci* 2001;56:M146-56. doi:  
257 10.1093/gerona/56.3.M146
- 258 3 Hoogendijk EO, Afilalo J, Ensrud KE, *et al.* Frailty: implications for clinical practice  
259 and public health. *Lancet* 2019;394:1365-75. doi: 10.1016/s0140-6736(19)31786-6
- 260 4 Hirai H, Ichikawa M, Kondo N, *et al.* The risk of functional limitations after driving  
261 cessation among older Japanese adults: the JAGES cohort study. *J Epidemiol* 2019. doi:  
262 10.2188/jea.JE20180260
- 263 5 Shimada H, Makizako H, Tsutsumimoto K, *et al.* Driving and Incidence of  
264 Functional Limitation in Older People: A Prospective Population-Based Study.  
265 *Gerontology* 2016;62:636-43. doi: 10.1159/000448036
- 266 6 National Police Agency. The White Paper on Police 2019. doi:
- 267 7 Shimada H, Tsutsumimoto K, Lee S, *et al.* Driving continuity in cognitively impaired  
268 older drivers. *Geriatr Gerontol Int* 2016;16:508-14. doi: 10.1111/ggi.12504
- 269 8 Satake S, Shimada H, Yamada M, *et al.* Prevalence of frailty among community-  
270 dwellers and outpatients in Japan as defined by the Japanese version of the Cardiovascular  
271 Health Study criteria. *Geriatr Gerontol Int* 2017;17:2629-34. doi: 10.1111/ggi.13129
- 272 9 Shimada H, Makizako H, Doi T, *et al.* Incidence of Disability in Frail Older Persons

## Disability, frailty, and driving status

- 1  
2  
3  
4  
5 273 With or Without Slow Walking Speed. *J Am Med Dir Assoc* 2015;16:690-6. doi:  
6  
7 274 10.1016/j.jamda.2015.03.019  
8  
9  
10 275 10 Makizako H, Shimada H, Doi T, *et al.* Impact of physical frailty on disability in  
11  
12 276 community-dwelling older adults: a prospective cohort study. *BMJ Open* 2015;5:e008462.  
13  
14 277 doi: 10.1136/bmjopen-2015-008462  
15  
16  
17 278 11 Fukutomi E, Okumiya K, Wada T, *et al.* Relationships between each category of 25-  
18  
19 279 item frailty risk assessment (Kihon Checklist) and newly certified older adults under  
20  
21 280 Long-Term Care Insurance: A 24-month follow-up study in a rural community in Japan.  
22  
23 281 *Geriatr Gerontol Int* 2015;15:864-71. doi: 10.1111/ggi.12360  
24  
25  
26 282 12 Chen LK, Liu LK, Woo J, *et al.* Sarcopenia in Asia: consensus report of the Asian  
27  
28 283 Working Group for Sarcopenia. *J Am Med Dir Assoc* 2014;15:95-101. doi:  
29  
30 284 10.1016/j.jamda.2013.11.025  
31  
32  
33 285 13 Tsutsui T, Muramatsu N. Japan's universal long-term care system reform of 2005:  
34  
35 286 containing costs and realizing a vision. *J Am Geriatr Soc* 2007;55:1458-63. doi:  
36  
37 287 10.1111/j.1532-5415.2007.01281.x  
38  
39  
40 288 14 Tsutsui T, Muramatsu N. Care-needs certification in the long-term care insurance  
41  
42 289 system of Japan. *J Am Geriatr Soc* 2005;53:522-7. doi: 10.1111/j.1532-  
43  
44 290 5415.2005.53175.x  
45  
46  
47 291 15 Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for  
48  
49 292 grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.  
50  
51 293 doi: 0022-3956(75)90026-6  
52  
53  
54 294 16 Yesavage JA. Geriatric Depression Scale. *Psychopharmacol Bull* 1988;24:709-11.  
55  
56 295 doi:  
57  
58 296 17 Shah RC, Maitra K, Barnes LL, *et al.* Relation of driving status to incident life space  
59  
60

## Disability, frailty, and driving status

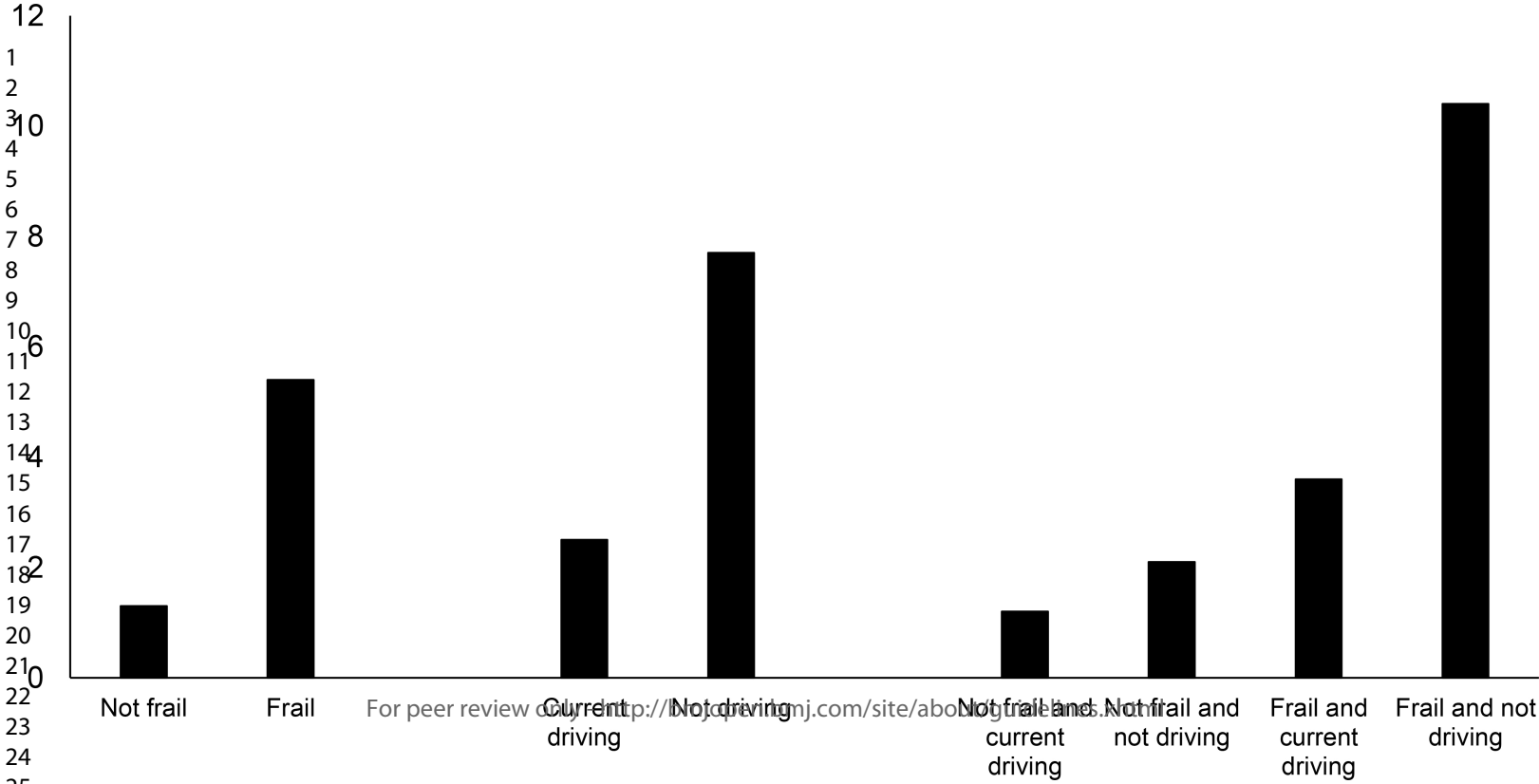
- 1  
2  
3  
4  
5  
6 297 constriction in community-dwelling older persons: a prospective cohort study. *J Gerontol*  
7  
8 298 *A Biol Sci Med Sci* 2012;67:984-9. doi: 10.1093/gerona/gls133  
9  
10 299 18 Tsuji T, Rantakokko M, Portegijs E, *et al.* The effect of body mass index, lower  
11  
12 300 extremity performance, and use of a private car on incident life-space restriction: a two-  
13  
14 301 year follow-up study. *BMC Geriatr* 2018;18:271. doi: 10.1186/s12877-018-0956-3  
15  
16  
17 302 19 Marie Dit Asse L, Fabrigoule C, Helmer C, *et al.* Automobile driving in older adults:  
18  
19 303 factors affecting driving restriction in men and women. *J Am Geriatr Soc* 2014;62:2071-8.  
20  
21 304 doi: 10.1111/jgs.13077  
22  
23  
24 305 20 O'Connor ML, Edwards JD, Waters MP, *et al.* Mediators of the association between  
25  
26 306 driving cessation and mortality among older adults. *J Aging Health* 2013;25:249s-69s.  
27  
28 307 doi: 10.1177/0898264313497796  
29  
30  
31 308 21 Edwards JD, Perkins M, Ross LA, *et al.* Driving status and three-year mortality  
32  
33 309 among community-dwelling older adults. *J Gerontol A Biol Sci Med Sci* 2009;64:300-5.  
34  
35 310 doi: 10.1093/gerona/gln019  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6 311 **LEGENDS**

7  
8 312 Figure 1. Proportion of disability compared between status of frail and  
9  
10  
11 313 driving.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

### Proportion of disability



**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

Section/Topic	Item #	Recommendation	Reported on page #
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
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	5-7
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	7-8
		(c) Explain how missing data were addressed	5
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	7-89
<b>Results</b>			



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	9-12
		(b) Give reasons for non-participation at each stage	9-12
		(c) Consider use of a flow diagram	9-12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-12
		(b) Indicate number of participants with missing data for each variable of interest	9-12
		(c) Summarise follow-up time (eg, average and total amount)	9-12
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-12
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	9-12
		(b) Report category boundaries when continuous variables were categorized	9-12
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	9-12
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	13
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
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	15

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## Frailty and driving status associated with disability: A 24-month follow-up longitudinal study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-042468.R1
Article Type:	Original research
Date Submitted by the Author:	19-Jan-2021
Complete List of Authors:	Doi, Takehiko; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Tsutsumimoto, Kota; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Ishii, Hideaki; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Nakakubo, Sho; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Kurita, Satoshi; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science Shimada, Hiroyuki; National Center for Geriatrics and Gerontology, Department of Preventive Gerontology, Center for Gerontology and Social Science
<b>Primary Subject Heading</b>:	Epidemiology
Secondary Subject Heading:	Geriatric medicine
Keywords:	GERIATRIC MEDICINE, EPIDEMIOLOGY, PUBLIC HEALTH

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3  
4  
5  
6 1 **Frailty and driving status associated with disability: A 24-month follow-up**  
7  
8 2 **longitudinal study**  
9

10 3  
11  
12 4  
13  
14 5 Takehiko Doi PhD, PT<sup>a</sup>, Kota Tsutsumimoto PhD, PT<sup>a</sup>, Hideaki Ishii PhD, PT<sup>a</sup>, Sho

16 6 Nakakubo PhD, PT<sup>a</sup>, Satoshi Kurita PhD<sup>a</sup>, Hiroyuki Shimada PhD, PT<sup>a</sup>

17  
18  
19 7 <sup>a</sup>Department of Preventive Gerontology, Center for Gerontology and Social Science,  
20  
21  
22 8 National Center for Geriatrics and Gerontology, Obu, Aichi, Japan.  
23  
24  
25 9

26 10 **Corresponding author:**

27  
28 11 Takehiko Doi, Department of Preventive Gerontology, Center for Gerontology and  
29  
30  
31 12 Social Science, National Center for Geriatrics and Gerontology, 7-430, Morioka, Obu,  
32  
33 13 Aichi 474-8511, Japan

34  
35 14 Tel: +81-562-44-5651

36  
37 15 E-mail: [take-d@ncgg.go.jp](mailto:take-d@ncgg.go.jp)  
38  
39  
40 16

41  
42 17 **Abstract Word Count:** 241, **Main Word Count:** 2821  
43  
44  
45 18

46  
47 19 **Keywords:** physical function, traffic, functioning and disability  
48  
49  
50 20

51 21 **Running Title:** Disability, frailty, and driving status  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

23 **ABSTRACT**

24 **OBJECTIVES:** To examine the relationship of driving status and frailty with disability  
25 in older adults.

26 **DESIGN:** A prospective study.

27 **SETTING AND PARTICIPANTS:** The study included 8,533 participants (mean age:  
28  $72.0 \pm 6.1$  years [range: 60–98 years], women: 54.1%) in a community setting.

29 **MEASURES:** Driving status and frailty were assessed at baseline. The clinical  
30 definition of frailty was used according to the J-CHS index. Disability was  
31 prospectively determined using a record of Japanese long-term care insurance (LTCI).

32 **RESULTS:** During the follow-up period (mean duration: 23.5 months), 58 participants  
33 (0.7%) were regarded as moving out of the city, 80 participants (0.9%) had died, and  
34 311 participants (3.6%) were certified by LTCI. The proportion of disability was 1.3%  
35 among the not-frail group and 5.4% among the frail group. The proportion of disability  
36 was 2.5% in participants who were currently driving and 7.7% in those not driving.

37 Based on frailty status and driving, participants were further classified into four groups:  
38 not frail and currently driving ( $n = 2905$ ), not frail and not driving ( $n = 632$ ), frail and  
39 currently driving ( $n = 3543$ ), and frail and not driving ( $n = 1315$ ). Compared to older  
40 adults who are not frail and driving, the combined status of frail and not driving  
41 (adjusted HR: 2.28 [95%CI: 1.47–3.52]) and frail and driving (HR: 1.91 [1.30–2.81])  
42 were risk factors for disability.

43 **CONCLUSIONS:** Not driving and frail were associated with a risk of disability in  
44 community-dwelling older adults.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

45 **Article Summary**

46 **Strengths and limitations of this study**

- 47 • This is a large population study including over 8,000 older adults.
- 48 • Frailty was defined by the J-CHS index.
- 49 • Incident disability was followed over time using data from long-term care insurance.
- 50 • The primary limitation was the short follow-up duration.
- 51 • Baseline data were collected from health checkups that had a selection bias.

## 52 INTRODUCTION

53 Extending healthy life expectancy and diminishing the duration of life with disability help  
54 to decrease health burdens on society.[1] Frailty is regarded as a prodromal stage of  
55 disability and has a high risk of adverse health outcomes, including disability. Frailty is a  
56 reversible status; someone's health could become robust again.[2] Although frailty is a  
57 complex age-related clinical condition, adequate assessment of risk and preventive  
58 actions could help providers disrupt the progression from frail to disabled.[3]

59 Driving is a critical resource in supporting an active lifestyle in older adults. In fact,  
60 driving cessation increases the risk of disability.[4, 5] However, whether the combined  
61 condition of not driving and being frail also elevates the risk of disability is unclear. More  
62 older adults are driving cars, but they are also having more accidents, especially in super-  
63 aged societies like Japan.[6] Adequate evaluation of driving ability is required, but  
64 driving cessation with insufficient cause can potentially increase disability. Thus, our  
65 study aimed to elucidate how frailty and driving status affect disability risks.

## 66 **METHODS**

### 67 **Participants**

68 Participants in this study were from the National Center for Geriatrics and Gerontology –  
69 Study of Geriatric Syndromes,[7] which aims to establish a screening system for geriatric  
70 syndromes and validate evidence-based interventions for preventing these syndromes.  
71 Participants were collected from surveys conducted in 2015–2017; 9,701 individuals aged  
72 60 years or over were eligible. The survey was regarded as the baseline and prospectively  
73 collected data was used for a follow-up duration of approximately two years (23.5  
74 months). Data to be certified with long-term care insurance (LTCI) were collected during  
75 the follow-up period. Other variables including frailty, driving status, and covariates were  
76 assessed at baseline. Exclusion criteria included diagnoses of dementia, stroke, and  
77 Parkinson’s disease; being unable to independently perform basic activities of daily  
78 living; being certified with LTCI in Japan before the survey; and having missing values  
79 for analysis. All participants provided written informed consent, and the ethics committee  
80 of the National Center for Geriatrics and Gerontology approved this study (770, 791).

### 82 **Frailty**

83 The definition of frailty used in this study was the Japanese CHS (J-CHS) index[8-10]  
84 according to CHS index criteria.[2] The components of frailty in the J-CHS index are the  
85 same as those in the original CHS index: shrinking (weight loss), weakness, poor  
86 endurance (exhaustion), slowness, and low activity. Weight loss was collected by a  
87 question from the Kihon Checklist[11] with the question “Have you lost 2 kg or more in  
88 the past six months?” A “yes” answer indicated that participants had experienced weight  
89 loss. The Kihon Checklist is a self-administered questionnaire to identify frail older adults



## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 90 who are at risk of being newly certified for LTCI in the near future consisting of 25 items  
7  
8 91 in the following categories: physical strength, nutritional status, oral function, cognitive  
9  
10 92 function, houseboundness, and depression risk.[11] Weakness was defined as low muscle  
11  
12 93 strength based on grip strength, measured using a Smedley-type handheld dynamometer  
13  
14 94 (Takei Ltd, Niigata, Japan). Sex-specific cut-offs of low muscle strength were < 26 kg in  
15  
16 95 men and < 18 kg in women.[8, 9, 12] Exhaustion was assessed using a question from the  
17  
18 96 Kihon Checklist:[11] a “yes” answer to the question “In the last two weeks, have you felt  
19  
20 97 tired for no reason?” indicated that participants had exhaustion or poor endurance.  
21  
22 98 Slowness was defined as slow walking speed under normal conditions. Participants were  
23  
24 99 asked to walk on a straight 6.4 m walkway on a flat floor with their usual gait speed. Gait  
25  
26 100 time was measured over a 2.4 m distance between marks at 2.0 m and 4.4 m from the start  
27  
28 101 of the walkway, and the mean gait speed (m/s) was calculated. The cut-off value of  
29  
30 102 slowness was less than 1.0 m/s.[8, 9] Low activity level was also measured using the  
31  
32 103 questionnaire and indicated through a response of “no” to both: “Do you engage in  
33  
34 104 moderate levels of physical exercise or sports aimed at health?” and “Do you engage in  
35  
36 105 low levels of physical exercise aimed at health?”[8, 9] Based on the values of these five  
37  
38 106 components (weight loss, weakness, exhaustion, slowness, and low activity), our study  
39  
40 107 assigned “frail” to values of 1 and over, including pre-frailty (1–2) and frailty (3 or  
41  
42 108 over).[8, 9]

109

110 **Driving status**

111 The survey asked participants about their driving status. To determine driving status,  
112 current status of driving license (without license [never having a license], surrendered  
113 license, license not renewed, has license but not driving, and currently driving with

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 114 license) was reviewed. In our study, the status of currently driving with license was  
7  
8 115 regarded as currently driving, and all other statuses were regarded as not driving.  
9

10  
11  
12 116

13 117 **Disability**

14  
15 118 LTCI certification in all participants was monitored throughout the follow-up period.

16  
17 119 LTCI certifies a person as “Support Level 1 or 2” if he or she needs support for daily  
18  
19 120 activities or “Care Level 1, 2, 3, 4, or 5” if they need continuous care.[13] Beneficiaries

20  
21 121 of the LTCI can use multiple services for which they are eligible. They can use more

22  
23 122 services than are covered if they pay all the costs for services beyond the maximum

24  
25 123 level.[13, 14] In our study, becoming disabled was defined as a new LTCI certification at

26  
27 124 any level. If we were unable to follow up and assess for incident disability (due to moving

28  
29 125 out of the city and death), this was treated as censored data. We monitored this

30  
31 126 information through monthly updates. We defined the follow-up period as beginning at

32  
33 127 the time we conducted the survey at baseline (mean follow-up duration: 23.5 months

34  
35 128 [max: 24.0 months]).  
36  
37  
38  
39

40  
41 129

42 130 **Covariates**

43  
44 131 To understand participants’ characteristics, demographic data, medical condition, and

45  
46 132 lifestyle were assessed. Regarding demographic data, age and sex were collected. For

47  
48 133 medical condition, participants were interviewed about their medication use by well-

49  
50 134 trained nurses or other medical staff and medication numbers were collected. Cognitive

51  
52 135 function was assessed through the Mini-Mental State Examination (MMSE).[15]

53  
54 136 Depressive symptoms were assessed using the geriatric depression scale (15 items

55  
56 137 version).[16] In addition, going out less frequently was assessed by a question from the  
57  
58  
59  
60

1  
2  
3  
4  
5 138 Kihon Checklist.[11]  
6  
7  
8 139  
9

10 140 **Statistical Analysis**  
11

12 141 Variables at baseline were compared between participants with and without disability  
13  
14 142 during the follow-up period using an unpaired *t*-test or  $\chi^2$  test. Participants were classified  
15  
16 143 into four groups according to their baseline status of driving and frailty: not frail and  
17  
18 144 currently driving, not frail and not driving, frail and currently driving, and frail and not  
19  
20 145 driving.  
21  
22

23  
24 146 To examine the association of frailty and driving status with the risk of disability,  
25  
26 147 Kaplan–Meier survival risk assessments were used to plot cumulative survival function,  
27  
28 148 and the results for each group were compared using log-rank tests. The objective variable  
29  
30 149 was set as incident disability, and the explanatory variable was four groups based on  
31  
32 150 frailty status and driving. In addition, Cox proportional hazards regression models were  
33  
34 151 used to test the association. For incident disability, hazard ratios (HR) of the frail group  
35  
36 152 compared to the not-frail group and the not-driving group compared to the driving group  
37  
38 153 were set respectively between models as well as in the same model. Four groups were  
39  
40 154 also set as the explanatory variable, with the not-frail and currently driving group as  
41  
42 155 reference. These analyses were conducted in crude and adjusted models, including  
43  
44 156 covariates. In addition, for a sensitivity analysis, Cox proportional hazards regression  
45  
46 157 analysis was also conducted to establish a different definition of disability. In the  
47  
48 158 sensitivity analysis, disability was defined to be certified as “Care Level 1 or higher,” and  
49  
50 159 other variables were set in the same manner. Each model in the Cox proportional hazards  
51  
52 160 regression analysis calculated HR and 95% confidence intervals (CI). All analyses were  
53  
54 161 performed using SPSS statistics software, Version 20 (IBM Corp., Chicago, IL, USA).  
55  
56  
57  
58  
59  
60

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 162 Statistical significance was set at  $p < 0.05$  in all analyses.  
7

8 163

9  
10 164 **Patient and Public Involvement**

11  
12 165 This study was conducted without patient or public involvement.  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

166 **RESULTS**

167 From 9,701 eligible participants, 8,533 participants (mean age:  $72.0 \pm 6.1$  years [age  
 168 range: 60–98 years], women: 54.1%) were matched with criteria and analyzed in this  
 169 study. During the follow-up period, 58 participants (0.7%) were regarded as moving out,  
 170 80 participants (0.9%) died, and 311 participants (3.6%) were certified by LTCL.  
 171 Participants with disability, compared to those without disability, were older, took more  
 172 medications, went out less frequently, and had higher scores on the geriatric depression  
 173 scale and lower scores on MMSE (Table 1, all  $p < 0.001$ ). In addition, participants with  
 174 disabilities were more likely to be frail and less likely to be currently driving (both  $p <$   
 175  $0.001$ ).

176

177 Table 1. Characteristics of participants with disability and without during the follow-up  
 178 period

Variables	Without disability (n = 8084)	With disability (n = 311)	<i>p</i> -value
Age, years	71.7 (5.9)	79.2 (6.3)	< 0.001
Sex (women), %	54.1	56.3	0.450
Medication numbers	2.7 (2.6)	3.8 (2.8)	< 0.001
Less frequent going out, %	13.2	33.5	< 0.001
Currently driving, %	77.8	51.8	< 0.001
Status of frailty			< 0.001
Robust, %	43.2	15.1	
Pre-frailty, %	50.2	52.4	

## Disability, frailty, and driving status

Frailty, %	6.6	32.5	
Geriatric Depression Score, score	2.6 (2.5)	3.8 (2.7)	< 0.001
Mini-Mental State Examination, score	27.3 (2.4)	25.0 (3.6)	< 0.001

Note: Values are means (standard deviations) or proportions. The total number of participants was 8,533. Data in this table excluded 138 participants (58 participants were regarded as moving out and 80 participants had died).

The proportion of incident disability during the follow-up period was dependent on the status of frailty and driving (Figure 1). The proportion of participants with disability was 1.3% in the not-frail group and 5.4% in the frail group. The proportion of participants with disability who were currently driving was 2.5%, and the proportion of participants who were not driving was 7.7%. Based on their status of frailty and driving, participants were further classified into four groups: not frail and currently driving (n = 2905), not frail and not driving (n = 632), frail and currently driving (n = 3543), and frail and not driving (n = 1315). Among those four groups, participants who were not frail and currently driving had the lowest proportion of disability (1.2%) and participants who were frail and not driving had the highest proportion of disability (10.4%). Survival risk based on log-rank test did not show a difference between participants from the not-frail and currently driving group and the not-frail and not-driving group ( $p = 0.077$ ). There were also no significant differences between participants from the not-frail and not-driving group and from the frail and currently driving group ( $p = 0.051$ ). Other intergroup results did show differences ( $p < 0.001$ ). From the analysis using Cox proportional hazards regression models, the frail group had an increased risk of disability (crude HR 4.15

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 199 [95%CI: 3.04–5.66]), as did not driving (crude HR 3.15 [95%CI: 2.52–3.93]). In the  
7  
8 200 model that set frailty and driving status together, similar results were shown for frailty  
9  
10 201 (HR 3.72 [95%CI: 2.72–5.07]) and not driving (HR 2.79 [95%CI: 2.23–3.49]). In addition,  
11  
12 202 compared to the not-frail and currently driving group, participants from the frail and  
13  
14 203 currently driving group ( $p = 0.001$ ), and those from the frail and not-driving group ( $p <$   
15  
16 204  $0.001$ ), had an increased risk of incident disability (Table 2). For a sensitivity analysis, a  
17  
18 205 different definition of disability (being certified as “Care Level 1 or higher”) was used.  
19  
20 206 Adjusted HR for incident disability was higher in the frail and not-driving group (HR 1.87  
21  
22 207 [95%CI: 1.06–3.31]), and other groups (not frail and not driving; frail and currently  
23  
24 208 driving) were not significantly associated with disability.  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Disability, frailty, and driving status

209 Table 2. Association of status in frailty and driving with disability

Variables	Unadjusted HR	(95% CI)	<i>p</i>	Adjusted HR	(95% CI)	<i>p</i>
Not frail and currently driving	Reference					
Not frail and not driving	1.77	(0.93-3.35)	0.081	1.09	(0.57-2.09)	0.802
Frail and currently driving	3.10	(2.12-4.52)	< 0.001	1.91	(1.30-2.81)	0.001
Frail and not driving	9.25	(6.35-13.47)	< 0.001	2.28	(1.47-3.52)	< 0.001
Age				1.14	(1.12-1.16)	< 0.001
Sex (reference: men)				0.89	(0.69-1.16)	0.392
Mini-Mental State Examination				0.89	(0.86-0.92)	< 0.001
Medication numbers				1.03	(0.99-1.07)	0.136
Less frequently going out (reference: yes)				0.66	(0.51-0.85)	0.001
Geriatric Depression Scale				1.05	(1.01-1.09)	0.018

210 HR: hazard ratio; CI: confidence interval. The total number of participants was 8533. Data in this Table excluded 138 participants (58  
 211 participants regarded as moving out and 80 participants died). The definition of frail for group classification was pre-frailty or frailty.



1  
2  
3  
4  
5  
6 212 **DISCUSSION**

7  
8 213 Our study examined the association of frailty and driving status with the risk of  
9  
10 214 disability among older adults. The proportion of incident disability was higher among  
11  
12 215 those with a status of frail and not driving. The effects of driving were observed among  
13  
14 216 participants who were frail, while not driving did not increase the risk of disability  
15  
16 217 among participants who were not frail. This result remained even after adjustment with  
17  
18 218 covariates.

19  
20  
21 219 Our study revealed that being frail was associated with a risk of incident  
22  
23 220 disability, which is in line with previous research. Numerous studies have indicated that  
24  
25 221 frailty caused disability and other adverse health outcomes.[2] When we studied data  
26  
27 222 from another section of the NCGG-SGS in 2011-12 with a similar follow-up duration  
28  
29 223 (about 2 years), we saw a similar risk for frailty to cause disability,[10] although the  
30  
31 224 data in 2011–2012 did not have detailed assessments regarding driving. Our study is in  
32  
33 225 accordance with similar studies and expands the previous evidence regarding frailty.  
34  
35 226 Driving status had been associated with a risk of disability, particularly among frail  
36  
37 227 participants. Driving a motor vehicle has a beneficial role in maintaining life space and  
38  
39 228 activities in older adults. In fact, having a valid driving license was associated with  
40  
41 229 reduced hazard of life-space constriction[17] and not driving increased the restriction of  
42  
43 230 life-space restriction.[18] In addition, having a combined status of frail and not driving  
44  
45 231 created a high risk of disability compared to the other statuses. Not driving also caused  
46  
47 232 functional decline in older adults, particularly when driving ceased. A prospective study  
48  
49 233 revealed that stopping driving or reducing the distance driven was related to several  
50  
51 234 functional declines and a decline in instrumental activities of daily living.[19]  
52  
53  
54 235 Furthermore, not driving was associated with a higher risk of mortality.[20, 21]  
55  
56  
57  
58  
59  
60

## Disability, frailty, and driving status

236 O'Connor suggested that the relationship may be explained by health difficulties in  
237 social, physical, and general health to accompany or follow driving cessation.[20]

238 Our results brought to light new ideas about the assessment of driving continuity  
239 in older adults. By engaging in several activities associated with driving, older adults  
240 may successfully age. The current system in Japan for adults aged 70 years or over,  
241 established by Japan's National Police Agency, requires individuals to attend a lecture  
242 on driving operation, undergo vision tests, attend an on-road lecture, and be screened for  
243 cognitive function.[22] If they are appropriately diagnosed as having dementia, they are  
244 unable to renew their licenses.[22] The evaluation of physical function (i.e., frailty)  
245 should be considered as part of the assessments used to renew licenses. Furthermore,  
246 age-related changes that affect driving skill are varied and occurred gradually. Thus,  
247 offering restricted licenses (e.g., restricting legal driving times to daylight or good  
248 weather) should be considered before cessation. To introduce such limited licenses may  
249 require detailed assessments in addition to the current system.

250 The strength of this study was that it was conducted in a large population study  
251 with a prospective design. Our study also has some limitations. In this study, disability  
252 was defined as certification of LTCI. LTCI cannot systematically distinguish causes for  
253 the disability certification. For example, we could not objectively differentiate between  
254 mobility and cognitive disabilities. In addition, LTCI has several levels (Support Level  
255 1–2, Care Level 1–5) based on the results of standardized assessments and a final  
256 decision from the expert board (Nursing Care Needs Certification Board).  
257 Characteristics of participants with disabilities are thus varied and depend on certified  
258 levels. Further study including more participants is required to compare the differences  
259 of each certified level. Furthermore, the data used in our study were derived from the

## Disability, frailty, and driving status

1  
2  
3  
4  
5  
6 260 NCGG-SGS database based on invitational health checkups among Japanese older  
7  
8 261 adults. Such checkups have a selection bias in that participants may have a higher health  
9  
10 262 literacy. Therefore, the results of our study are not easily generalizable. In addition, data  
11  
12 263 in this study could not clarify casual association between driving and disability. Reverse  
13  
14 264 causation (that functional decline with disability affects driving cessation) is also  
15  
16  
17 265 possible. To examine reverse causation, data regarding changes in function, incident  
18  
19 266 disability, and future driving cessation should be analyzed. Next, our study used the J-  
20  
21 267 CHS index to define frailty; using other criteria to define frailty may affect the results.  
22  
23  
24 268 Finally, detailed driving statuses (e.g., frequency, driving under specific conditions such  
25  
26 269 as at night and during bad weather) could not be considered in the analysis in this study  
27  
28 270 due to limitations in the data. Further studies with sufficient cohort data and  
29  
30  
31 271 intervention studies should be conducted in the future.

32  
33 272 In conclusion, frailty and driving status were found to be associated with the risk  
34  
35 273 of disability. Not driving increased the risk of disability, particularly among frail older  
36  
37 274 adults. The status of driving should be considered to assess the risk of disability.  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3  
4  
5  
6 275 **ACKNOWLEDGMENT**

7  
8 276 We thank the Obu city and Takahama city office for help with participant recruitment.  
9

10 277

11  
12 278 **CONTRIBUTORSHIP**

13  
14 279 TD: acquisition of the data, statistical analysis, interpretation of the data, and drafting of  
15  
16 the manuscript. HS: study design and concept, and drafting and revising of the  
17 280 manuscript. IH and KT: acquisition of the data, statistical analysis, interpretation of the  
18  
19 281 manuscript. IH and KT: acquisition of the data, statistical analysis, interpretation of the  
20  
21 282 data, and drafting of the manuscript. NS and KS: acquisition and interpretation of the data  
22  
23 283 and drafting of the manuscript.  
24

25  
26 284

27  
28 285 **COMPETING INTERESTS**

29  
30 286 None of the authors have any financial, personal, or potential conflict of interest with the  
31  
32 287 material presented in this article.  
33

34  
35 288

36  
37 289 **DATA AVAILABILITY STATEMENT**

38  
39 290 No data are available.  
40

41  
42 291

43  
44 292 **FUNDING**

45  
46 293 This work was supported by AMED under grant number (15dk0207004h0203,  
47  
48 294 15dk0107003h0003); a Grant-in-Aid for Scientific Research (B) (grant number  
49  
50 295 23300205); the Funds of Obu City Local Government; and Research Funding for  
51  
52 296 Longevity Sciences (26-33, 29-31, 30-7) from the National Center for Geriatrics and  
53  
54 297 Gerontology, Japan.  
55  
56  
57  
58  
59  
60

298 **REFERENCES**

- 299 1 Collaborators. GDaH. Global, regional, and national disability-adjusted life-years  
300 (DALYs) for 359 diseases and injuries and healthy life expectancy (HALE) for 195  
301 countries and territories, 1990–2017: a systematic analysis for the Global Burden of  
302 Disease Study 2017. *Lancet* 2018;392:1859-922. doi: 10.1016/s0140-6736(18)32335-3
- 303 2 Fried LP, Tangen CM, Walston J, *et al.* Frailty in older adults: evidence for a  
304 phenotype. *J Gerontol A Biol Sci Med Sci* 2001;56:M146-56. doi:  
305 10.1093/gerona/56.3.M146
- 306 3 Hoogendijk EO, Afilalo J, Ensrud KE, *et al.* Frailty: implications for clinical practice  
307 and public health. *Lancet* 2019;394:1365-75. doi: 10.1016/s0140-6736(19)31786-6
- 308 4 Hirai H, Ichikawa M, Kondo N, *et al.* The risk of functional limitations after driving  
309 cessation among older Japanese adults: the JAGES cohort study. *J Epidemiol* 2019. doi:  
310 10.2188/jea.JE20180260
- 311 5 Shimada H, Makizako H, Tsutsumimoto K, *et al.* Driving and incidence of functional  
312 limitation in older people: a prospective population-based study. *Gerontology*  
313 2016;62:636-43. doi: 10.1159/000448036
- 314 6 National Police Agency. The white paper on police 2019.
- 315 7 Shimada H, Tsutsumimoto K, Lee S, *et al.* Driving continuity in cognitively impaired  
316 older drivers. *Geriatr Gerontol Int* 2016;16:508-14. doi: 10.1111/ggi.12504
- 317 8 Satake S, Shimada H, Yamada M, *et al.* Prevalence of frailty among community-  
318 dwellers and outpatients in Japan as defined by the Japanese version of the Cardiovascular  
319 Health Study criteria. *Geriatr Gerontol Int* 2017;17:2629-34. doi: 10.1111/ggi.13129
- 320 9 Shimada H, Makizako H, Doi T, *et al.* Incidence of disability in frail older persons  
321 with or without slow walking speed. *J Am Med Dir Assoc* 2015;16:690-6. doi:

## Disability, frailty, and driving status

- 1  
2  
3  
4  
5  
6 322 10.1016/j.jamda.2015.03.019  
7  
8 323 10 Makizako H, Shimada H, Doi T, *et al.* Impact of physical frailty on disability in  
9  
10 324 community-dwelling older adults: a prospective cohort study. *BMJ Open* 2015;5:e008462.  
11  
12 325 doi: 10.1136/bmjopen-2015-008462  
13  
14 326 11 Fukutomi E, Okumiya K, Wada T, *et al.* Relationships between each category of 25-  
15  
16 327 item frailty risk assessment (Kihon Checklist) and newly certified older adults under  
17  
18 328 Long-Term Care Insurance: a 24-month follow-up study in a rural community in Japan.  
19  
20 329 *Geriatr Gerontol Int* 2015;15:864-71. doi: 10.1111/ggi.12360  
21  
22  
23  
24 330 12 Chen LK, Liu LK, Woo J, *et al.* Sarcopenia in Asia: consensus report of the Asian  
25  
26 331 Working Group for Sarcopenia. *J Am Med Dir Assoc* 2014;15:95-101. doi:  
27  
28 332 10.1016/j.jamda.2013.11.025  
29  
30  
31 333 13 Tsutsui T, Muramatsu N. Japan's universal long-term care system reform of 2005:  
32  
33 334 containing costs and realizing a vision. *J Am Geriatr Soc* 2007;55:1458-63. doi:  
34  
35 335 10.1111/j.1532-5415.2007.01281.x  
36  
37  
38 336 14 Tsutsui T, Muramatsu N. Care-needs certification in the long-term care insurance  
39  
40 337 system of Japan. *J Am Geriatr Soc* 2005;53:522-7. doi: 10.1111/j.1532-  
41  
42 338 5415.2005.53175.x  
43  
44  
45 339 15 Folstein MF, Folstein SE, McHugh PR. "Mini-mental state." A practical method for  
46  
47 340 grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.  
48  
49 341 doi: 0022-3956(75)90026-6  
50  
51  
52 342 16 Yesavage JA. Geriatric Depression Scale. *Psychopharmacol Bull* 1988;24:709-11.  
53  
54 343 doi:  
55  
56 344 17 Shah RC, Maitra K, Barnes LL, *et al.* Relation of driving status to incident life space  
57  
58 345 constriction in community-dwelling older persons: a prospective cohort study. *J Gerontol*  
59  
60

## Disability, frailty, and driving status

- 1  
2  
3  
4  
5 346 *A Biol Sci Med Sci* 2012;67:984-9. doi: 10.1093/gerona/gls133  
6  
7  
8 347 18 Tsuji T, Rantakokko M, Portegijs E, *et al.* The effect of body mass index, lower  
9  
10 348 extremity performance, and use of a private car on incident life-space restriction: a two-  
11  
12 349 year follow-up study. *BMC Geriatr* 2018;18:271. doi: 10.1186/s12877-018-0956-3  
13  
14 350 19 Marie Dit Asse L, Fabrigoule C, Helmer C, *et al.* Automobile driving in older adults:  
15  
16 351 factors affecting driving restriction in men and women. *J Am Geriatr Soc* 2014;62:2071-8.  
17  
18 352 doi: 10.1111/jgs.13077  
19  
20 353 20 O'Connor ML, Edwards JD, Waters MP, *et al.* Mediators of the association between  
21  
22 354 driving cessation and mortality among older adults. *J Aging Health* 2013;25:249s-69s.  
23  
24 355 doi: 10.1177/0898264313497796  
25  
26 356 21 Edwards JD, Perkins M, Ross LA, *et al.* Driving status and three-year mortality  
27  
28 357 among community-dwelling older adults. *J Gerontol A Biol Sci Med Sci* 2009;64:300-5.  
29  
30 358 doi: 10.1093/gerona/gln019  
31  
32 359 22 Cabinet Office. White paper on traffic safety in Japan, 2016.  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Disability, frailty, and driving status

360 **LEGENDS**

361 Figure 1. Proportion of disability between frailty and driving statuses.

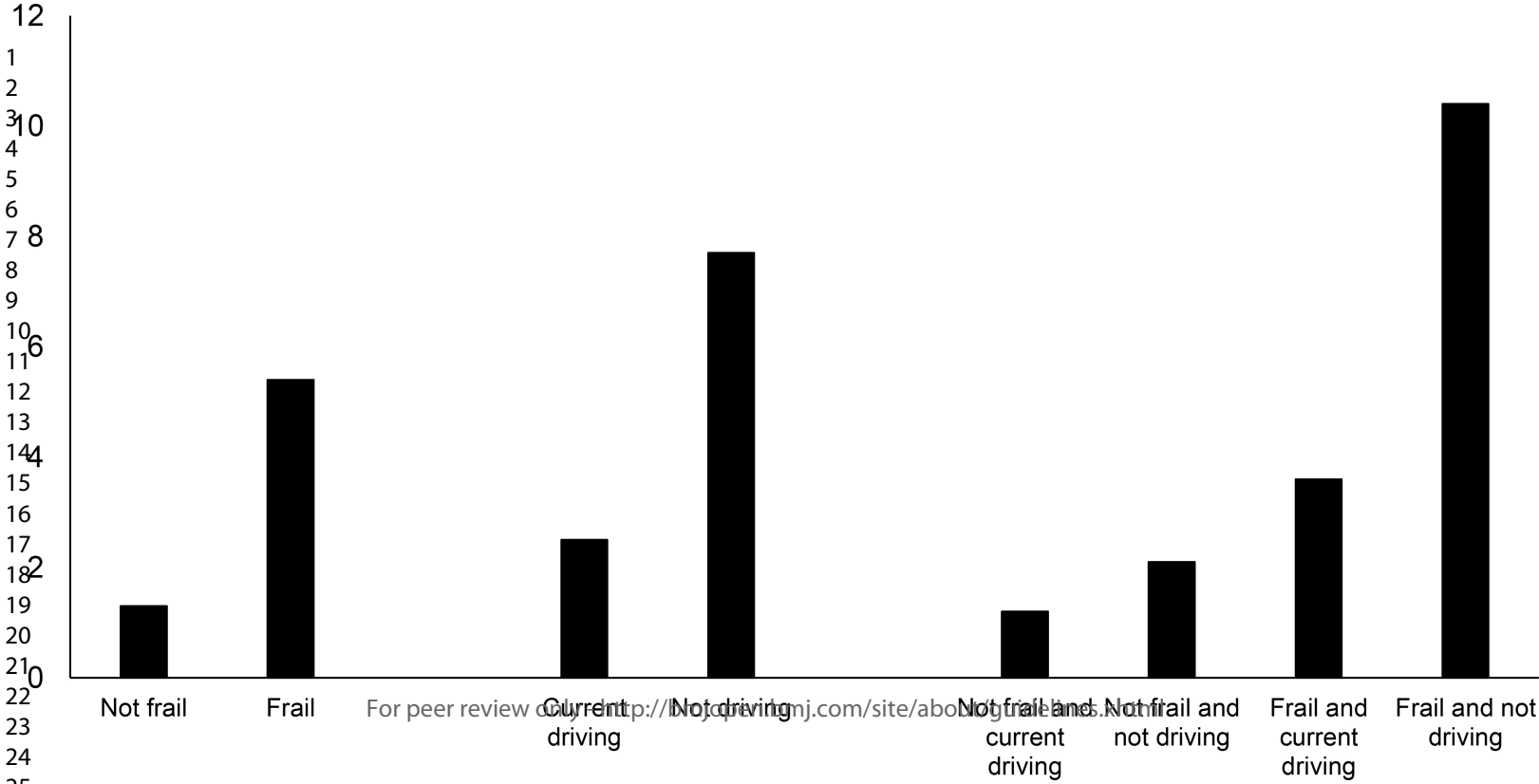
362

363 The definition of frail for classification into groups was pre-frailty or frailty.

For peer review only



# Proportion of disability



**STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies***

Section/Topic	Item #	Recommendation	Reported on page #
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-7
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	5-7
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	7-8
		(c) Explain how missing data were addressed	5
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	7-89
<b>Results</b>			

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	9-12
		(b) Give reasons for non-participation at each stage	9-12
		(c) Consider use of a flow diagram	9-12
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-12
		(b) Indicate number of participants with missing data for each variable of interest	9-12
		(c) Summarise follow-up time (eg, average and total amount)	9-12
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-12
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	9-12
		(b) Report category boundaries when continuous variables were categorized	9-12
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	9-12
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	13
<b>Limitations</b>			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
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	15

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).