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Predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes: A cross-sectional survey

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ABSTRACT

Objectives: To assess the prevalence of frailty and identify predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

Design: A cross-sectional design.

Setting: Two community health centers in central China.

Participants: 291 community-dwelling older adults aged ≥ 65 years with type 2 diabetes.

Main outcome measures: Data were collected via face-to-face interviews, anthropometric measurements, laboratory tests and community health files. The main outcome measure was frailty assessed by the frailty phenotype criteria. The multivariate logistic regression model was used to identify the predictors of frailty.

Results: The prevalence of frailty was 19.2% for community-dwelling older adults with type 2 diabetes. The significant predictors of frailty included alcohol drinking (non-current drinker) (OR = 4.374, 95% CI 1.547 to 12.366), glycated hemoglobin (HbA1c) (OR = 1.374, 95% CI 1.105 to 1.709), nutritional status (malnutrition risk/malnutrition) (OR = 3.612, 95% CI 1.553 to 8.402), depression (OR = 1.141, 95% CI 1.008 to 1.291), exercise (OR = 0.886, 95% CI 0.823 to 0.953), and foot self-care behavior (OR = 0.891, 95% CI 0.815 to 0.975).

Conclusions: A high prevalence of frailty was found among older adults with type 2 diabetes in the Chinese community. Frailty identification and multi-faceted interventions should be developed with the consideration of proper glycemic control, nutritional instruction, depressive symptoms improvement, and self-care behaviors enhancement in this population.

ARTICLE SUMMARY

Strengths and limitations of this study

- This is the first study to explore the predictors of frailty among the community-dwelling older adults with type 2 diabetes in China.
- The study examined which domains of diabetes self-care behaviors were preferentially associated with frailty among diabetic older adults.
- The study is a cross-sectional study so the causal relationship of the associated factors with frailty could not be established.
- The study was conducted in one city of China, which may affect the generalizability of the findings.

KEYWORDS

Community-dwelling older adults; frailty; predictors; type 2 diabetes.

INTRODUCTION

Across the world, the estimated number of people aged 65–99 years with diabetes was 136 million (19.3%) in 2019, and this number will keep increasing to 195 million in 2030 and 276 million in 2045.[1] China has the world's largest number of adults with diabetes[1] and the prevalence of older Chinese adults with diabetes aged above 60 years was 20.2% in the latest national survey.[2] The elderly with type 2 diabetes are at risk for developing frailty,[3] a geriatric syndrome manifesting as reduced strength, endurance, and physiologic function that increases vulnerability for developing increased dependency and death.[4] Older people with diabetes were more likely to be frail than their non-diabetes counterparts.[5 6] This close relationship could be explained as the diabetes impairs the skeletal muscle function, vascular function, and hormonal milieu, as well as accelerates the sarcopenia providing the basis of frailty.[3 7 8]

Frailty is associated with higher disability, mortality, cardiovascular events and healthcare utilization among the older adults with type 2 diabetes.[9 10] Identifying the associated factors for frailty among older adults with diabetes may help to improve their health outcomes. A few studies have examined some influencing factors of frailty among diabetic older adults, primarily including sociodemographic, physical, and biological factors. Chhetri *et al*[5] identified that female, urban living, older age, comorbidity, high waist circumference, less house work, and not receiving medical consultation regularly were independent risk factors of frailty in Chinese community-dwelling pre-diabetic and diabetic population. Additionally, systolic blood pressure, albumin, glycated hemoglobin (HbA1c), high-density lipoprotein cholesterol, total cholesterol, triglycerides, bodyweight, and abdominal obesity contributed to

the development of frailty in the diabetic elderly.[6 11 12] Until now, the important but modifiable factors, including nutritional status, psychological and self-care behavioral factors, were rarely studied among the community-dwelling diabetic older adults.

Based on the model of cycle of frailty,[13] malnutrition plays an important role in the progression of frailty. The association between malnutrition and frailty has been established among community-dwelling older adults.[14 15] Two-thirds of malnourished older adults were physically frail, whereas approximately 10% of the physically frail population was malnourished.[14] Many older adults with diabetes are at risk of malnutrition, which may stem from an inappropriate diet or overly strict diet control.[16] Depression is another common factor for frailty among the elderly.[17 18] A systematic review showed that the elderly with depression had a higher risk of developing frailty (odds ratio [OR] = 4.07, 95% confidence interval [CI] 1.93 to 8.55).[19] There is a lack of understanding of the impact of malnutrition and depression on frailty among the diabetic older people. Knowledge of these associations is useful for designing optimum strategies for frailty prevention in those population.

Self-care behaviors were preventive factors for frailty, especially for the older adults who were able to acquire and maintain appropriate health management methods or strengthen their support system.[20] Diabetes self-care behaviors should be adopted by diabetic older adults to control their disease, referring to proper diet, regular exercise, self-monitoring blood glucose, checking one's foot, and taking medicine on time.[21] However, there is a dearth of studies on which domains of diabetes self-care behaviors are preferentially associated with frailty. Examining the associations is important for developing specific interventions focusing on self-management behaviors to reduce the risk of frailty.

There is a common sense among key stakeholders including the older adults and health care practitioners that it is impossible to prevent frailty.[22] In fact, frailty can be reversible or attenuated by appropriate interventions.[4] In China, there are more older people with type 2 diabetes living in the community, and the health management of diabetic elderly is the focus of community health services, which still do not include frailty screening and management.[23] Little is known about the frailty status among the community-dwelling older adults with type 2 diabetes in China. Therefore, the purposes of this study were to assess the prevalence of frailty and explore the predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

METHODS

Study design and setting

A cross-sectional design was used. The participants were recruited from two community health centers of Xianning City of Hubei Province in China from June to October 2019. Both community health centers provided primary health care services for older people in urban and rural communities.

Participants

Older adults with type 2 diabetes were identified from the electronic community health files of the two community health centers. The inclusion criteria of this study were people who were: (1) 65 years old or above and living in the community; (2) diagnosed with type 2 diabetes confirmed by the physician based on the World Health Organization diagnostic criteria, 1999; (3) with 6 months or longer for duration of diabetes after diagnosed; and (4)

able to walk independently. The diabetic older adults were excluded if they: (1) were unable to communicate with the investigators; (2) had dementia or mental health disorders; and (3) had acute diabetic complications.

The sample size was calculated using the formula for cross-sectional studies,[24] $n = \frac{Z^2P(1-P)}{d^2}$. Where n is the sample size, Z is the statistic corresponding to level of confidence, P is expected prevalence, and d is precision. Hence, we assumed a confidence level of 95.0%, expected frailty prevalence of 20.0% for community-dwelling older adults with type 2 diabetes (determined by the presurvey), and precision of 5.0%, at least 246 participants were needed for this study.

Survey instrument

The self-designed personal information questionnaire was used to collect the participants' characteristics. The sociodemographic characteristics included age, gender, living place, education level, marital status, living status, working status, personal monthly income, and medical insurance; the lifestyle and clinical characteristics contained smoking, alcohol drinking, sleep duration at night, self-rated quality of sleep, duration of diabetes, number of comorbidities, polypharmacy, body mass index (BMI), waist circumference, and HbA1c. Polypharmacy was defined as concurrent use of 5 or more drugs. BMI was calculated by weight (kg)/ [height (m)] ^{2} and classified as underweight, normal, overweight, and obesity (< 18.5, 18.5-23.9, 24.0-27.9, and ≥ 28.0 kg/m^2), and high waist circumference was defined as ≥ 85 cm in men and ≥ 80 cm in women.[25]

Frailty was measured using the modified frailty phenotype criteria, which was based on the phenotypic criteria proposed by Fried *et al*.[13] Participants meeting 3 or more of the following

5 criteria were identified as frailty: (1) Unintentional weight loss: weight loss ≥ 4.5kg in the past year, not due to dieting and exercise; (2) Exhaustion: It was identified based on a response of "3-4 days or most of the time a week" to either of the two questions: "I felt that everything I did was an effort" and "I could not get going"; (3) Slowness: average walking speed was tested by asking the participants to walk 6 meters for twice with usual pace. Slowness was identified by walking speed for men (≤ 0.89m/s) and women (≤ 0.79m/s)[26]; (4) Weakness: grip strength was measured with a dynamometer three times on each hand, and the maximum of the readings was used. Weakness was judged by grip strength for men (≤ 28kg) and women (≤ 18kg)[26]; and (5) Low physical activity: the Chinese version of Physical Activity Scale for the Elderly (PASE)[27] was used to assess participants' physical activity level in the past week. Low physical activity was classified by PASE score for men (≤ 56.4) and women (≤ 58.8).[26]

Mini-Nutritional Assessment (MNA) was used to assess the nutritional status of older adults.[28] It consists of 18 items grouped into four parts: anthropometric assessment, general assessment, dietary assessment and self-assessment. The total score ranges from 0 to 30 and is used to classify the elderly as well-nourished (≥ 24), at risk of malnutrition (17–23.5), or malnourished (< 17). The Chinese version of MNA has been proven to be reliable and valid in community-dwelling older population.[29]

Geriatric Depression Scale-15 (GDS-15) was used to evaluate the depressive symptoms of older adults.[30] The scale contains 15 items that require the subjects to answer with "yes" or "no". The maximum score of the scale is 15 and a higher score indicates more severe

depressive symptoms. The Chinese version of GDS-15 is a reliable and valid screening tool for assessing geriatric depression in Chinese population.[31]

The Chinese version of Summary of Diabetes Self-Care Activities (SDSCA)[32] was used to measure self-care behaviors of the older adults with type 2 diabetes, which was modified from the original SDSCA.[21] It is a brief self-report questionnaire that includes 11 items assessing the following aspects: general diet, specific diet, exercise, blood-glucose testing, foot care, and medication care in the past week. The total score of this scale ranges from 0 to 77 and a higher score indicates better diabetes self-care behaviors. It showed good validity and test-retest reliability in Chinese patients with type 2 diabetes.[32]

Anthropometric measurements, including height or knee height, weight, mid-arm circumference, calf circumference and waist circumference, were measured strictly adhering to the measurement manual by the trained investigators. The knee height was measured and converted to the estimated height with specific equations[33] for the older adults with severe spinal curvature. HbA1c measurement was administered by the laboratory in the community health centers.

Data collection and ethical considerations

Ethical Approval was obtained prior to data collection. The researcher contacted the directors of two community health centers and explained the aims of this study. After permission was granted, the public health nurses and physicians were invited to assist with data collection. They helped to recruit participants mainly through a phone call, informing the eligible diabetic older adults of the study purpose, and then invited the older adults to the community health centers to complete the survey if consented to participate. In addition, when older

adults with type 2 diabetes went to the community health centers for physical check-up, follow-up blood glucose monitoring or health education, they were also invited to participate in this study if eligible. Once the written informed consent was obtained from each participant, the survey was administered by trained investigators. The information in this survey was obtained from the participants' self-reporting, anthropometric measurements and laboratory test results, supplemented by the community health files.

Data analysis

The SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Frailty was defined as the dependent variable with 1 = frail (≥ 3 on the frailty phenotype criteria) and 0 = non-frail (< 3). Sociodemographic, lifestyle and clinical characteristics, malnutrition, depression, and diabetes self-care behaviors were considered potential factors for frailty. Raw data were evaluated for normality and multi-collinearity before data analysis. Data were described as n (%) for categorical variables and median (P_{25}–P_{75}) or mean ± SD for continuous variables. To test the statistic difference between frail and non-frail group, univariate analyses were conducted using chi-square test for categorical variables and Mann-Whitney U test for continuous variables. Binary logistic regression with the Wald method of backward elimination was performed to identify the predictors of frailty. The statistical significance was set at $P < 0.05$ for all tests. Variables with a value of $P < 0.05$ in the univariate analyses were included in the logistic regression.

Patient and public involvement

Patients were not involved in the development of research question or the design of the study. Anthropometric measurements and HbA1c test results were provided to the participants, community physicians and nurses.

RESULTS

As shown in figure1, a total of 302 eligible older adults consented to participate in this study. Eleven participants did not complete the questionnaires due to temporary issues and limited time, so the final sample consisted of 291 participants. Among these participants, 235 (80.8%) were non-frail and 56 (19.2%) were frail.

Characteristics of the participants

The median age of participants was 69 years (interquartile range [IQR] 67-72), with a range from 65 to 85 years. The majority of the participants were female (52.9%), living in urban area (84.5%), had junior high school or higher education (63.9%), had a spouse (80.1%), living with others (86.9%), retired (73.9%), with a personal monthly income below 3000 yuan (66.3%) and had urban employees' insurance (58.1%) (table 1).

Regarding the lifestyle characteristics, most of the participants were non-current smokers (87.3%), non-current drinkers (73.2%), with 5-8 h sleep duration at night per day (66.0%), and had good/very good sleep quality (61.2%) (table 2). Considering clinical characteristics, the median duration of diabetes and median number of comorbidities was 10 years (IQR 4-16) and 5 (IQR 3-6), respectively. Of the participants, 29.6% had polypharmacy; 43.6% with normal BMI; and 17.5% with normal waist circumference. The median score of HbA1c was 6.66% (IQR 5.87-7.47) (table 2).

Malnutrition, depression, and diabetes self-care behaviors

Of the participants, 96 (33.0%) were at risk of malnutrition, 6 (2.1%) were malnourished and 189 (64.9%) were nourished. The median score of depression was 3 (IQR 1-5). The total score of diabetes self-care behaviors ranged from 12 to 70, with an average of 40.25 ± 10.08. Among the 6 sub-dimensions of diabetes self-care behaviors, the two dimensions with the lowest level were blood-glucose testing (0 [0-2]) and foot care (0 [0-7]) (table 3).

Univariate analyses for influencing factors of frailty

Significant sociodemographic differences within groups (non-frail vs. frail) were found for education level ($p = 0.010$), working status ($p < 0.001$), personal monthly income ($p = 0.007$), and medical insurance ($p = 0.013$) (table 1). Regarding the lifestyle and clinical characteristics, significant group differences included alcohol drinking ($p = 0.002$), sleep duration at night ($p = 0.029$), self-rated sleep quality ($p = 0.039$), comorbidities ($p = 0.040$), polypharmacy ($p = 0.036$), and HbA1c ($p = 0.031$) (table 2). As shown in table 3, significant group differences were noted for malnutrition risk/malnutrition ($p < 0.001$), depression ($p < 0.001$), exercise ($p < 0.001$), foot care ($p = 0.004$), and medication care ($p = 0.026$).

Predictors of frailty

The multiple logistic regression revealed six predictors of frailty for older adults with type 2 diabetes in this study, including alcohol drinking (non-current drinker) (OR = 4.374, 95% CI 1.547 to 12.366), HbA1c (OR = 1.374, 95% CI 1.105 to 1.709), nutritional status (malnutrition risk/malnutrition) (OR = 3.612, 95% CI 1.553 to 8.402), depression (OR = 1.141, 95% CI 1.008 to 1.291), exercise (OR = 0.886, 95% CI 0.823 to 0.953), and foot care (OR = 0.891, 95% CI 0.815 to 0.975) (table 4). The model achieved overall significance (X^2

(6) = 83.286, p < 0.001) and had an overall classification accuracy of 83.5%. The Hosmer and Lemeshow test showed the model fit the data well (X^2 (8) = 4.898, p = 0.768).

DISCUSSION

This is the first study to explore the predictors of frailty among the community-dwelling older adults with type 2 diabetes in China. This study found that alcohol drinking, HbA1c, nutritional status, depression, exercise and foot self-care behavior were significant predictors of frailty in community-dwelling diabetic older adults.

The prevalence of frailty was 19.2% among this population by using the Fried frailty phenotype criteria, which focused on physical frailty. Our result was comparable with the Beijing study,[5] which showed the community-dwelling diabetic population had the prevalence (19.32%) of frailty. The Beijing study applied the accumulation of deficits method (Frailty Index ≥ 0.25) to measure frailty among the diabetic people aged ≥ 55 years.[5] By using the Fried frailty phenotype for assessing frailty, the prevalence of frailty in people with diabetes older than 65 years were 25.0%-32.0% as reported in the American studies.[13 34] However, the studies conducted in Singapore and Spain showed lower frailty prevalence of 8.2% and 11.2%, respectively.[6 10] These differences in prevalence of frailty can be explained by that the two Western studies recruited younger diabetic older adults, who may be in a better physical condition.

Alcohol drinking was one predictor of frailty among the diabetic older adults, and the frailty risk was significantly higher among non-current drinkers. Surprisingly, alcohol use had a negative association with physical frailty, which has been reported among older adults

in previous studies.[6 35-37] This association could be explained by the "sick quitter" effect. The diabetic older adults in poor health may reduce alcohol consumption or quit drinking, so the ex-drinker group may contain people who were previous alcoholism or with a poor health condition, while current drinker group may include healthier individuals.[38] Nevertheless, a recent study demonstrated moderate alcohol consumption may protect against frailty through an anti-inflammatory mechanism, which elucidated C-reactive protein level partially mediated the relationship between moderate alcohol use and physical frailty.[39]

Elevated HbA1c was associated with an increased risk of physical frailty among community-dwelling diabetic older adults, which was consistent with the previous study in diabetic older people.[6] Hyperglycemia could contribute to physical frailty through several potential mechanisms, such as increasing microvascular damage[40] or causing skeletal muscle mitochondrial dysfunction.[41] In contrast, Yanagita *et al*[11] reported low level of HbA1c was associated with frailty measured by the Clinical Frailty Scale (CFS) among the diabetic older adults. Zaslavsky *et al*[42] found a U-shaped relationship between glucose levels and physical frailty in older adults with diabetes, with the lowest risk of frailty at HbA1c levels of 7.6%. Overall, poor glucose control with hyperglycemia or hypoglycemia may increase the risk of frailty. Therefore, optimal glycemic control needs to be individually determined for older adults with type 2 diabetes.[43]

Malnutrition led to physical frailty among community-dwelling older adults with type 2 diabetes, which was comparable with the findings of a Spanish study.[12] In this study, 35.1% of our participants were at risk of malnutrition or malnourished and 52.6% of them were overweight or obesity. However, 39 (38.2%) of participants who had malnutrition risk or with

malnutrition in this study were classified as either overweight or obesity. This result suggests that the diabetic elderly can suffer from malnutrition status even if they are overweight or obesity. Malnutrition is prevalent in diabetic older adults[44 45] due to various reasons, such as ageing-related appetite reductions, swallowing difficulties, limited mobility, and overly dietary restrictions.[16] We found that 45.4% of the diabetic older adults scored 0 point on the item of protein intake in this study, indicating that those people might be in insufficient protein intake. Although malnutrition and physical frailty share some common screening items and physiology, they are not interchangeable syndromes, and community-dwelling diabetic older people with malnutrition were more prone to be physically frail. It would be effective to prevent the physical frailty by screening the nutritional status of the diabetic older adults and providing them appropriate dietary instructions in community.

Consistent with previous studies among older population,[17 18] this study highlighted the significant impact of depression on frailty among the diabetic elderly. Recent evidence showed a reciprocal interaction between depression and frailty in older adults.[19] Depression contributes to physical frailty due to the decrease in physical activities or weight loss, and in turn, physical frailty may cause functional dependence or disability, and thus leads to depression. Diabetes can cause depression, which is a common condition in the people with type 2 diabetes, especially in the elderly.[46 47] Therefore, appropriate management of depressive symptoms should be an urgent need to help slow the progression of physical frailty in the elderly with type 2 diabetes in the community.

We found exercise and foot self-care behavior were protective factors for frailty among community-dwelling diabetic older adults. A higher score of exercise behavior was

associated with a lower risk of physical frailty. Exercise can help reduce frailty through mechanisms of decreasing muscle inflammation, promoting anabolism, and increasing muscle protein synthesis.[48] The education programs for exercise training were effective to improve frailty in the elderly.[49] Pariser *et al*[50] conducted a diabetes self-management education program, comprising ten weeks aerobic and resistance exercise training, which effectively reduced the HbA1c and frailty in diabetic older adults. In this study, most of the participants adhered to oral medication or insulin injection every day in the past week, while most of them did not attach importance to blood glucose monitoring and foot care. It is interesting that foot self-care behavior was a predictor of frailty in this study. It can be explained by that the participants with a higher score on foot care were more likely to be active in self-management for complications prevention and concerned about their own health, contributing to reduce the risk of frailty. In addition, the adherence to medication among the non-frail participants was better than those with frailty, and a significant group difference was found in this study. The association between frailty and medication care may be explained by that the adherence to medication is directly associated with the control of blood glucose, which has an impact on the progression of frailty.

This study has several limitations. First, this study is a cross-sectional study so the causal relationship of the associated factors with frailty could not be established. Second, information such as the older adults' physical activities and self-care behaviors were self-reported, so it may be subjected to potential recall bias. Third, we excluded the older adults who could not walk independently, and with severe vision and hearing problems, so findings may not be generalizable to a more heterogeneous population. The effect of factors on frailty

among the community-dwelling diabetic older adults should be explored using prospective longitudinal design with a larger sample size in the future.

CONCLUSIONS

The older adults with type 2 diabetes are at a high risk of frailty in the community of China. Being a non-current alcohol drinker, a higher level of HbA1c, malnutrition, and more depressive symptoms were risk factors of frailty among the community-dwelling diabetic older adults; exercise and foot self-care behavior were protective factors of frailty. The findings of this study could facilitate future studies to implement targeted and suitable interventions for frailty among community-dwelling diabetic older adults.

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Author Contributions

LK, JL and JM designed the study. LK, HZ and QW collected and managed the data. LK and JF completed the data analysis. LK and JL drafted the manuscript. JB checked and revised the manuscript. All the authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent for publication

Obtained.

Ethics approval

This study was approved by the Medical Ethics Committee of Huazhong University and Science and Technology (No. 2019–S941).

Data availability statement

Data are available from the first author upon reasonable request. All data relevant to this study are included in the article.

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Table 1 Sociodemographic characteristics of the participants

Variables	Total (n=291) N (%)	Non-frail (n=235) N (%)	Frail (n=56) N (%)	P value
Age (years)				0.679
65-69	154 (52.9)	126 (53.6)	28 (50.0)	
70-74	91 (31.3)	74 (31.5)	17 (30.4)	
≥75	46 (15.8)	35 (14.9)	11 (19.6)	
Gender				0.110
Male	137 (47.1)	116 (49.4)	21 (37.5)	
Female	154 (52.9)	119 (50.6)	35 (62.5)	
Living place				0.336
Urban	246 (84.5)	201 (85.5)	45 (80.4)	
Rural	45 (15.5)	34 (14.5)	11 (19.6)	
Education level				***0.010***
Illiterate	42 (14.4)	26 (11.1)	16 (28.6)	
Elementary school	63 (21.6)	52 (22.1)	11 (19.6)	
Junior high school	95 (32.6)	77 (32.8)	18 (32.1)	
Senior high school	55 (18.9)	47 (20.0)	8 (14.3)	
College or over	36 (12.4)	33 (14.0)	3 (5.4)	
Marital status				0.421
Spouse	233 (80.1)	186 (79.1)	47 (83.9)	
No spouse	58 (19.9)	49 (20.9)	9 (16.1)	
Living status				0.456
Living with others	253 (86.9)	206 (87.7)	47 (83.9)	
Living alone	38 (13.1)	29 (12.3)	9 (16.1)	
Working status				***<0.001***
Retired	215 (73.9)	182 (77.4)	33 (58.9)	
Currently employed	23 (7.9)	21 (8.9)	2 (3.6)	
Unemployed	53 (18.2)	32 (13.6)	21 (37.5)	
Personal monthly income (RMB)				***0.007***
<1000	43 (14.8)	27 (11.5)	16 (28.6)	
1000-1999	50 (17.2)	41 (17.4)	9 (16.1)	
2000-2999	100 (34.4)	81 (34.5)	19 (33.9)	
≥3000	98 (33.7)	86 (36.6)	12 (21.4)	
Medical insurance				***0.013***
Urban residential insurance	79 (27.1)	59 (25.1)	20 (35.7)	
Urban employees' insurance	169 (58.1)	146 (62.1)	23 (41.1)	
New rural cooperative medical insurance	43 (14.8)	30 (12.8)	13 (23.2)	

RMB, Ren Min Bi.

Table 2 Lifestyle and clinical characteristics of the participants

Variables	Total (n=291)	Non-frail (n=235)	Frail (n=56)	P value
	N (%)/Median (IQR)			
Smoking				0.344
Non-smoker/ Ex-smoker	254 (87.3)	203 (86.4)	51 (91.1)	
Current smoker	37 (12.7)	32 (13.6)	5 (8.9)	
Alcohol Drinking				***0.002***
Non-drinker/ Ex-drinker	213 (73.2)	163 (69.4)	50 (89.3)	
Current drinker	78 (26.8)	72 (30.6)	6 (10.7)	
Sleep duration at night (hours)				***0.029***
<5	75 (25.8)	53 (22.6)	22 (39.3)	
5-8	192 (66.0)	163 (69.4)	29 (51.8)	
>8	24 (8.2)	19 (8.1)	5 (8.9)	
Self-rated sleep quality				***0.039***
Very good	33 (11.3)	31 (13.2)	2 (3.6)	
Good	145 (49.8)	121 (51.5)	24 (42.9)	
Bad	89 (30.6)	66 (28.1)	23 (41.1)	
Very bad	24 (8.2)	17 (7.2)	7 (12.5)	
Duration of diabetes (years)	10 (4-16)	10 (5-16)	7 (4-13)	0.133
Number of comorbidities	5 (3-6)	4 (3-6)	5 (4-7)	***0.040***
Polypharmacy				***0.036***
No	205 (70.4)	172 (73.2)	33 (58.9)	
Yes	86 (29.6)	63 (26.8)	23 (41.1)	
BMI (kg/m^2)				0.498
<18.5	11 (3.8)	8 (3.4)	3 (5.4)	
18.5-23.9	127 (43.6)	102 (43.4)	25 (44.6)	
24-27.9	114 (39.2)	96 (40.9)	18 (32.1)	
≥28	39 (13.4)	29 (12.3)	10 (17.9)	
Waist circumference				0.213
Normal	51 (17.5)	38 (16.2)	13 (23.2)	
High	240 (82.5)	197 (83.8)	43 (76.8)	
HbA1c (%)	6.66 (5.87-7.47)	6.55 (5.86-7.24)	6.97 (5.95-8.42)	***0.031***

IQR, interquartile range; BMI, body mass index; HbA1c, glycated hemoglobin.

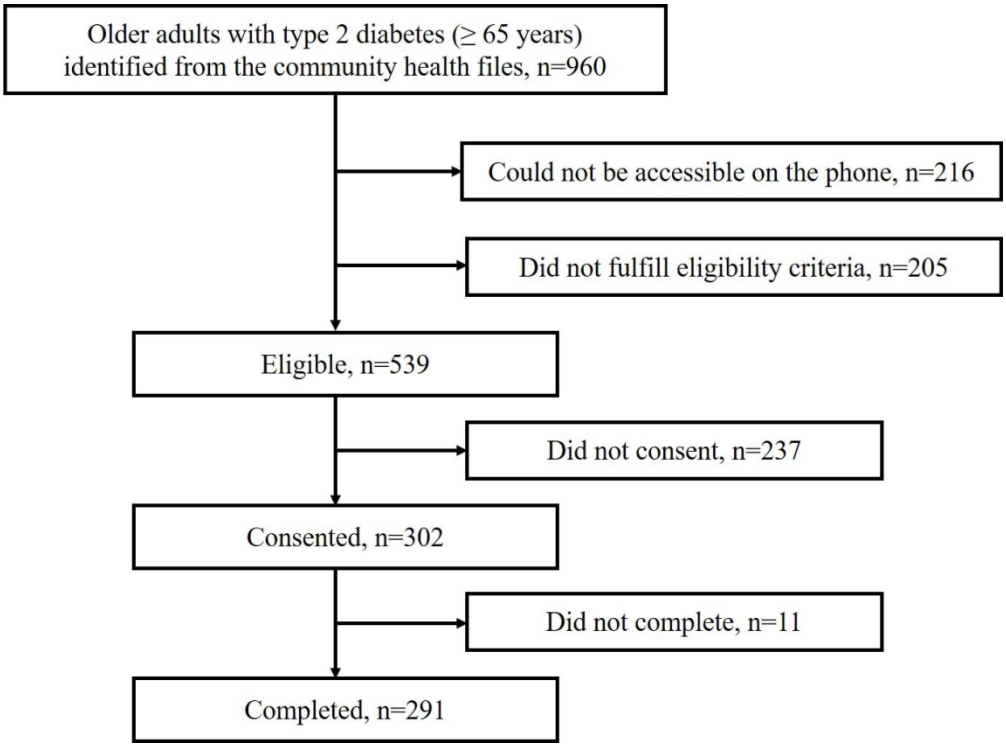
Table 3 Malnutrition, depression and diabetes self-care behaviors of the participants

Variables	Possible range	Actual range	Total (n=291)	Non-frail (n=235)	Frail (n=56)	P value
			N (%)/Median (IQR)			
Malnutrition risk/malnutrition						***<0.001***
No			189 (64.9)	172 (73.2)	17 (30.4)	
Yes			102 (35.1)	63 (26.8)	39 (69.6)	
Depression	0-15	0-15	3 (1-5)	2 (1-4)	5 (4-8)	***<0.001***
Diabetes self-care behaviors						
General diet	0-14	0-14	14 (10-14)	14 (10-14)	14 (10-14)	0.223
Specific diet	0-14	0-14	8 (7-12)	8 (7-12)	7 (7-12)	0.637
Exercise	0-14	0-14	7 (7-14)	12 (7-14)	7 (0-7)	***<0.001***
Blood-glucose testing	0-14	0-14	0 (0-2)	0 (0-2)	0 (0-1)	0.066
Foot care	0-14	0-14	0 (0-7)	0 (0-7)	0 (0-0)	***0.004***
Medication care	0-7	0-7	7 (7-7)	7 (7-7)	7 (7-7)	***0.026***

IQR, interquartile range.

Table 4 Logistic regression model of predictors for frailty

	B	SE	Wald X^2	P value	OR	95% CI
Alcohol Drinking						
Non-drinker/Ex-drinker	1.476	0.530	7.746	0.005	4.374	1.547 to 12.366
Current drinker	-	-	-	-	1	-
HbA1c	0.318	0.111	8.167	0.004	1.374	1.105 to 1.709
Malnutrition risk/Malnutrition						
No	-	-	-	-	1	-
Yes	1.284	0.431	8.888	0.003	3.612	1.553 to 8.402
Depression	0.132	0.063	4.358	0.037	1.141	1.008 to 1.291
Exercise	-0.121	0.037	10.547	0.001	0.886	0.823 to 0.953
Foot care	-0.115	0.046	6.358	0.012	0.891	0.815 to 0.975
Constant	-4.840	1.073	20.368	<0.001	0.008	



Flow chart of inclusion of participants

234x173mm (300 x 300 DPI)

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

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 9-10
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6-7, 9-10
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10
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	7-9
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	11
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	12
		(*b*) Report category boundaries when continuous variables were categorized	25-26
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
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	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
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	18

*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.

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Predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes: A cross-sectional survey

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ABSTRACT

Objectives: To assess the prevalence of frailty and identify predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

Design: A cross-sectional design.

Setting: Two community health centers in central China.

Participants: 291 community-dwelling older adults aged ≥ 65 years with type 2 diabetes.

Main outcome measures: Data were collected via face-to-face interviews, anthropometric measurements, laboratory tests, and community health files. The main outcome measure was frailty, as assessed by the frailty phenotype criteria. The multivariate logistic regression model was used to identify the predictors of frailty.

Results: The prevalence of pre-frailty and frailty were 51.5% and 19.2%, respectively. The significant predictors of frailty included alcohol drinking (ex-drinker) (OR = 4.461, 95% CI 1.079 to 18.438), glycated hemoglobin (HbA1c) (OR = 1.434, 95% CI 1.045 to 1.968), nutritional status (malnutrition risk/malnutrition) (OR = 8.062, 95% CI 2.470 to 26.317), depression (OR = 1.438, 95% CI 1.166 to 1.773), and exercise behavior (OR = 0.796, 95% CI 0.716 to 0.884).

Conclusions: A high prevalence of frailty was found among older adults with type 2 diabetes in the Chinese community. Frailty identification and multi-faceted interventions should be developed for this population, taking into consideration proper glycemic control, nutritional instruction, depressive symptoms improvement, and enhancement of self-care behaviors.

ARTICLE SUMMARY

Strengths and limitations of this study

- The study evaluated an extensive list of sociodemographic factors, lifestyle and clinical characteristics, nutritional status, depression, and diabetes self-care behaviors that could influence the frailty status of community-dwelling older adults with type 2 diabetes.
- The study examined which domains of diabetes self-care behaviors were associated with frailty among diabetic older adults.
- The study is a cross-sectional study, so a causal relationship between factors associated with frailty could not be established.
- The study was conducted in one city of China, which may affect the generalizability of the findings.

KEYWORDS

Community-dwelling older adults; frailty; predictors; type 2 diabetes.

INTRODUCTION

Across the world, the estimated number of people aged 65–99 years with diabetes was 136 million (19.3%) in 2019, and this number is estimated to increase to 195 million in 2030 and 276 million in 2045.[1] China had the world's largest number of adults with diabetes,[1] and the prevalence of older Chinese adults with diabetes over the age of 60 was 20.2% in the latest national survey.[2] Elderly people with type 2 diabetes are at risk for developing frailty,[3] a geriatric syndrome manifesting as a reduction in one's physical strength, endurance, and physiologic function that increases the likelihood of developing functional dependency and death.[4] Diabetic people are more likely to be frail than their non-diabetic counterparts.[5 6] This relationship between diabetes and frailty may be explained by the fact that diabetes impairs skeletal muscle function, vascular function, and hormonal milieu, as well as accelerates sarcopenia, thereby leading to increased frailty.[3 7 8]

Frailty is associated with higher disability, mortality, cardiovascular events, and healthcare utilization among older adults with type 2 diabetes.[9 10] Identifying the associated factors for frailty among older adults with diabetes may help to improve their health outcomes. A few studies have shown that sociodemographic factors (e.g., age, education level), [6 11] physical factors (e.g., systolic blood pressure, bodyweight, abdominal obesity), [6 11 12] and biological factors (e.g., glycated hemoglobin [HbA1c], albumin, high-density lipoprotein cholesterol) [6 11] were associated with frailty in diabetic older adults. Until now, important, modifiable factors such as nutritional status, psychological well-being, and self-care behavioral factors were rarely studied among community-dwelling diabetic older adults.

The association between malnutrition and frailty has been established among community-dwelling older adults.[13 14] Depression is another common factor associated with frailty among the elderly.[15 16] However, there is a lack of understanding of the impact of malnutrition and depression on frailty among the specific diabetic older population. Diabetic older adults should adopt numerous diabetes self-care behaviors to control their disease; these behaviors include proper diet, regular exercise, self-monitoring of blood glucose, proper foot care, and strict adherence to prescribed medications.[17] Nevertheless, there is a dearth of studies on which domains of diabetes self-care behaviors are preferentially associated with frailty. Examining these associations is important for developing specific interventions to reduce the risk of frailty for diabetic older people.

In China, there is an increasing number of older people with type 2 diabetes living in the community, and the health management of the diabetic elderly population is the focus of many community health services; however, frailty is not among the physical conditions that is routinely screened for in this population.[18] Little is known about the frailty status among the community-dwelling older adults with type 2 diabetes in China. To our knowledge, only one study reported the prevalence of frailty in a community-dwelling diabetic population in mainland China; however, that study included a sample of diabetic people aged 55 years and older, identifying the risk factors of frailty among an elevated blood glucose (pre-diabetes and diabetes) population.[5] Therefore, the aims of this study were to assess the prevalence of frailty and explore the predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

METHODS

Study design and setting

A cross-sectional design was used. The participants were recruited from two community health centers of Xianning City of Hubei Province in China from June to October 2019. Both community health centers provided primary health care services for older people in urban and rural communities.

Data collection and ethical considerations

Ethical Approval was obtained from the Medical Ethics Committee of Huazhong University and Science and Technology (No. 2019–S941) prior to data collection. The researcher contacted the directors of two community health centers and explained the aims of this study. After permission was granted, the public health nurses and physicians were invited to assist with data collection. Health center staff helped to recruit participants by phone, informing the eligible diabetic older adults of the study purpose. Eligible individuals were then invited to the community health centers to complete the survey if they consented to participate. As another means of recruitment, when older adults with type 2 diabetes went to the community health centers for a physical check-up, follow-up blood glucose monitoring, or health education, they were also invited to participate in this study, if eligible. Once the written informed consent was obtained from each participant, the survey was administered by trained investigators. The information in this survey was obtained from the participants' self-reporting, anthropometric measurements, and laboratory test results, which were supplemented by the community health files.

Participants

Older adults with type 2 diabetes were identified from the electronic files of the two community health centers. The inclusion criteria of this study were as follows: (1) at least 65 years old and living in the community; (2) diagnosed with type 2 diabetes, as confirmed by a physician based on the World Health Organization diagnostic criteria, 1999; (3) received their diagnosis at least 6 months prior to joining the study. The diabetic older adults were excluded if they: (1) could not walk independently; (2) had severe vision and hearing problems; (3) were unable to communicate with the investigators; (4) had dementia or mental health disorders; and (5) had acute diabetic complications.

The sample size was calculated using the formula for cross-sectional studies,[19] $n = \frac{Z^2P(1-P)}{d^2}$. Where n is the sample size, Z is the statistic corresponding to level of confidence, P is expected prevalence, and d is precision. We assumed a confidence level of 95.0%, expected frailty prevalence of 20.0% for community-dwelling older adults with type 2 diabetes (determined by the pre-survey), and precision of 5.0%, indicating that at least 246 participants were needed for this study.

Survey instrument

The personal information questionnaire was used to collect the participants' characteristics. The sociodemographic characteristics included age, gender, living place, education level, marital status, living status, working status, personal monthly income, and medical insurance; the lifestyle and clinical characteristics included smoking, alcohol drinking, sleep duration at night, self-rated quality of sleep, duration of diabetes, number of comorbidities, polypharmacy, body mass index (BMI), waist circumference, and HbA1c. Smoking status was categorized as current smoker (having smoked at least one cigarette per day), ex-smoker

(having stopped smoking at least one year before the survey) and non-smoker (having never smoked in one's lifetime). Alcohol drinking status was categorized into current drinker (someone who reported consuming alcohol currently), ex-drinker (someone who had quitted drinking at least one year prior to the survey), and non-drinker (someone who reported never consuming alcohol). Polypharmacy was defined as concurrent use of 5 or more drugs. BMI was calculated by weight (kg)/ [height (m)] ^{2} and classified as underweight, normal, overweight, and obese (< 18.5, 18.5-23.9, 24.0-27.9, and ≥ 28.0 kg/m^2), and high waist circumference was defined as ≥ 85 cm in men and ≥ 80 cm in women.[20]

Frailty was measured using the modified frailty phenotype criteria, which was based on the phenotypic criteria proposed by Fried *et al*.[21] The criteria included five components: (1) Unintentional weight loss: weight loss ≥ 4.5kg in the past year, not due to dieting and exercise; (2) Exhaustion: It was identified based on a response of "3-4 days or most of the time" during the week to either of the two questions: "I felt that everything I did was an effort" and "I could not get going"; (3) Slowness: average walking speed was tested by asking the participants to walk 6 meters at their usual pace, at total of two times. Slowness was identified by walking speed for men (≤ 0.89m/s) and women (≤ 0.79m/s)[22]; (4) Weakness: grip strength was measured with a dynamometer three times on each hand, and the maximum of the readings was used. Weakness was judged by grip strength for men (≤ 28kg) and women (≤ 18kg)[22]; and (5) Low physical activity: the Chinese version of Physical Activity Scale for the Elderly (PASE)[23] was used to assess participants' physical activity level in the past week. Low physical activity was classified by PASE score for men (≤ 56.4) and women (≤ 58.8).[22] One point was assigned for the presence of each component, and the

summed score was used to classify participants as robust (score = 0), pre-frail (score = 1-2) and frail (score = 3-5).

Mini-Nutritional Assessment (MNA) was used to assess the nutritional status of older adults.[24] It consists of 18 items grouped into four parts: anthropometric assessment, general assessment, dietary assessment, and self-assessment. The total score ranges from 0 to 30 and is used to classify the elderly as well-nourished (≥ 24), at risk of malnutrition (17–23.5), or malnourished (< 17). The Chinese version of MNA has been proven to be reliable and valid in the community-dwelling older population.[25]

Geriatric Depression Scale-15 (GDS-15) was used to evaluate the depressive symptoms of older adults.[26] The scale contains 15 items that require the subjects to answer with “yes” or “no”. The maximum score of the scale is 15, and a higher score indicates more severe depressive symptoms. The Chinese version of GDS-15 is a reliable and valid screening tool for assessing geriatric depression in the Chinese population.[27]

The Chinese version of Summary of Diabetes Self-Care Activities (SDSCA)[28] was used to measure self-care behaviors of the older adults with type 2 diabetes; this instrument was modified from the original SDSCA.[17] It is a brief self-report questionnaire that includes 11 items assessing the following aspects: general diet, specific diet, exercise, blood-glucose testing, foot care, and medication care in the past week. The total score of this scale ranges from 0 to 77, and a higher score indicates better diabetes self-care behaviors. It showed good validity and test-retest reliability in Chinese patients with type 2 diabetes.[28]

Anthropometric measurements, including height or knee height, weight, mid-arm circumference, calf circumference, and waist circumference, were measured by the trained

investigators according to the measurement manual. Knee height was measured and converted to the estimated height using specific equations[29] for the older adults with severe spinal curvature. All the HbA1c measures were obtained after the participants were recruited into the study. The blood collection and HbA1c measurements were administered by the community health center laboratories when the participants came to the centers for this survey.

Data analysis

The SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Frailty was defined as the dependent variable with 1= robust (0 on the frailty phenotype criteria), 2 = pre-frail (1-2), 3 = frail (≥ 3). Sociodemographic, lifestyle and clinical characteristics, malnutrition, depression, and diabetes self-care behaviors were considered potential factors for frailty. Raw data were evaluated for normality and multi-collinearity before data analysis. Data were described as n (%) for categorical variables and median (interquartile range [IQR]) or mean ± SD for continuous variables. To test the statistical difference among groups, univariate analyses were conducted using chi-square test for categorical variables and Kruskal-Wallis H test for continuous variables. Variables that showed statistical significance of $P < 0.1$ in the univariate analyses were included in the multinomial logistic regression, which estimated the prevalence odds ratio (OR) for pre-frail relative to robust and for frail relative to robust. The statistical significance was set at $P < 0.05$ for the logistic regression.

Patient and public involvement

Patients were not involved in the development of research question or the design of the study. Anthropometric measurements and HbA1c test results were provided to the participants, community physicians and nurses.

RESULTS

As shown in figure 1, a total of 302 eligible older adults consented to participate in this study. Eleven participants did not complete the questionnaires due to temporary issues and limited time, so the final sample consisted of 291 participants. Among these participants, 85 (29.2%) were robust, 150 (51.5%) were pre-frail, and 56 (19.2%) were frail.

Characteristics of the participants

The median age of participants was 69 years (IQR 67-72), with a range from 65 to 85 years. Among the participants, 154 (52.9%) were female. The majority of the participants were living in urban areas (84.5%), had junior high school or higher education (63.9%), had a spouse (80.1%), lived with others (86.9%), were currently not working (92.1%), had a personal monthly income below 3000 yuan (66.3%), and had urban employees' insurance (58.1%) (table 1).

Regarding the lifestyle characteristics, most of the participants were non-smokers (63.6%), non-drinkers (57.4%), with 5-8 h sleep duration at night per day (66.0%), and had good/very good sleep quality (61.2%) (table 2). Considering clinical characteristics, the median duration of diabetes was 10 years (IQR 4-16), and the median number of comorbidities was 5 (IQR 3-6). Among all participants, 29.6% had polypharmacy, 43.6% had normal BMI, and 17.5% had a normal waist circumference. The median score of HbA1c was 6.66% (IQR 5.87-7.47) (table 2).

Malnutrition, depression, and diabetes self-care behaviors

Of all participants, 96 (33.0%) were at risk of malnutrition, 6 (2.1%) were malnourished, and 189 (64.9%) were nourished. The median score of depression was 3 (IQR 1-5). The total score for diabetes self-care behaviors ranged from 12 to 70, with an average of 40.25 ± 10.08. Among the 6 sub-dimensions of diabetes self-care behaviors, the two dimensions with the lowest level were blood-glucose testing (0 [0-2]) and foot care (0 [0-7]) (table 3).

Univariate analyses for influencing factors of frailty

Univariate analyses were conducted to explore the associated factors for frailty according to the criterion of inclusion ($p < 0.10$). Significant sociodemographic differences among groups were found for education level ($p = 0.077$), personal monthly income ($p = 0.026$), and medical insurance ($p = 0.034$) (table 1). Regarding the lifestyle and clinical characteristics, significant group differences included alcohol drinking ($p = 0.004$), sleep duration at night ($p = 0.046$), self-rated sleep quality ($p = 0.065$), duration of diabetes ($p = 0.036$), comorbidities ($p = 0.030$), polypharmacy ($p = 0.025$), and HbA1c ($p = 0.055$) (table 2). As shown in table 3, significant group differences were noted for malnutrition risk/malnutrition ($p < 0.001$), depression ($p < 0.001$), exercise ($p < 0.001$), foot care ($p = 0.007$), and medication care ($p = 0.060$).

Predictors of frailty

The predictors of pre-frailty for older adults with type 2 diabetes in this study included alcohol drinking (ex-drinker) ($p = 0.017$), malnutrition risk/malnutrition ($p = 0.026$), depression ($p = 0.003$), and exercise ($p = 0.008$) (table 4). The following predictors were found for the condition of frailty: alcohol drinking (ex-drinker) ($p = 0.039$), HbA1c ($p =$

0.026), malnutrition risk/malnutrition (p = 0.001), depression (p = 0.001), and exercise (p < 0.001) (table 4).

DISCUSSION

In this study, we assessed frailty status and its associated factors among Chinese community-dwelling older adults with type 2 diabetes. We found the prevalence of pre-frailty and frailty were 51.5% and 19.2%, respectively. Our result was comparable with the Beijing study (the prevalence of frailty was 19.32%),[5] however, the Beijing study applied the accumulation of deficits method (Frailty Index ≥ 0.25) to measure frailty among diabetic people aged ≥ 55 years. By using the Fried frailty phenotype for assessing frailty, the prevalence of frailty in people with diabetes aged 65 and older was 25.0%-32.0%, as reported in the American studies.[21 30] In addition, studies conducted in Singapore and Spain showed lower frailty prevalence of 8.2% and 11.2%, respectively,[6 10] but, these two studies also recruited younger diabetic adults (i.e. younger than 65 years). The explanation for the wide variation in the prevalence of frailty in community-dwelling diabetic elderly populations is probably related to frailty instrument differences, sample difference, and socioeconomic differences among the studies.

Alcohol drinking was one predictor of frailty and pre-frailty among the diabetic older adults, and the frailty risk was significantly higher among ex-drinkers compared with non-drinkers. This association could be explained by the "sick quitter" effect. The diabetic older adults in poor health may reduce alcohol consumption or quit drinking, so the ex-drinker group may contain people with previous alcoholism or with a poor health condition.[31] In our study, it is interesting that current drinking status showed a protective effect (OR = 0.266, p =

0.055) on frailty compared with non-drinkers, although this factor didn't satisfy the statistical significance in the logistic regression. Previous studies indicated alcohol use (especially moderate drinking) had a negative association with physical frailty. [32-34] Moreover, a recent study demonstrated moderate alcohol consumption may protect against frailty through an anti-inflammatory mechanism, which indicated that C-reactive protein level partially mediated the relationship between moderate alcohol use and physical frailty.[35]

Elevated HbA1c was associated with an increased risk of frailty among community-dwelling diabetic older adults, which was consistent with the previous study in diabetic older people.[6] Hyperglycemia could contribute to physical frailty through several potential mechanisms, such as increasing microvascular damage[36] or causing skeletal muscle mitochondrial dysfunction.[37] In contrast, Yanagita *et al*[11] reported low level of HbA1c was associated with frailty measured by the Clinical Frailty Scale (CFS) among diabetic older adults. Zaslavsky *et al*[38] found a U-shaped relationship between glucose levels and physical frailty in older adults with diabetes, with the lowest risk of frailty at HbA1c levels of 7.6%. Overall, poor glucose control with hyperglycemia or hypoglycemia may increase the risk of frailty. Therefore, optimal glycemic control needs to be individually determined for older adults with type 2 diabetes.[39] The global guideline for managing type 2 diabetes in older adults recommended that a HbA1c target up to 8.5% may be appropriate for frail diabetic elderly persons with functional dependency.[40] Recently, an international position statement on the management of frailty in diabetes mellitus patients recommended a HbA1c target range of 7.0%-8.0% for mild to moderate frail diabetic older adults, and 7.5%-8.5% for those with severe frailty.[41]

Malnutrition led to pre-frailty and frailty among community-dwelling older adults with type 2 diabetes, which was comparable with the findings of a Spanish study.[12] In the current study, 35.1% of our participants were at risk for malnutrition or were malnourished, and 52.6% of them were overweight or obese. However, 39 (38.2%) of the participants who had malnutrition risk or were malnourished in this study were classified as either overweight or obese. This result suggests that the diabetic elderly can suffer from malnutrition status even if they are overweight or obese. Malnutrition is prevalent in diabetic older adults[42 43] due to various reasons, such as ageing-related appetite reductions, swallowing difficulties, limited mobility, and overly dietary restrictions.[44] We found that 45.4% of the diabetic older adults scored 0 points on the item of protein intake in this study, indicating that those people might have insufficient protein intake. Although malnutrition and physical frailty share some common screening items and physiology, they are not interchangeable syndromes, and community-dwelling diabetic older people with malnutrition were more prone to be physically frail. Screening the nutritional status of diabetic older adults and providing them with appropriate dietary instructions would be an effective method for preventing physical frailty within this population.

Consistent with previous studies among older populations,[15 16] this study highlighted the significant impact of depression on pre-frailty and frailty among the diabetic elderly. Recent evidence showed a reciprocal interaction between depression and frailty in older adults.[16] Depression contributes to physical frailty due to the decrease in physical activities or weight loss, and in turn, physical frailty may cause functional dependence or disability, thus leading to depression. Diabetes can contribute to depression, which is a common condition in

people with type 2 diabetes, especially in the elderly.[45 46] Therefore, there is an urgent need for appropriate management of depressive symptoms in elderly diabetic adults in order to help slow the progression of physical frailty in this population.

We found exercise behavior was a protective factor for frailty among community-dwelling diabetic older adults. A higher score of exercise behavior was associated with a lower risk of pre-frailty and frailty. Exercise can help reduce frailty through mechanisms of decreasing muscle inflammation, promoting anabolism, and increasing muscle protein synthesis.[47] Education programs for exercise training have shown to be effective at improving frailty in the elderly.[48] Pariser *et al*[49] conducted a diabetes self-management education program comprised of ten weeks of aerobic and resistance exercise training, which effectively reduced HbA1c and frailty in diabetic older adults. In addition, the three different frailty groups (i.e. robust, pre-frail, and frail) differed significantly in terms of medication care and foot self-care behaviors in this study. The association between medication care behavior and frailty may be explained by the fact that adherence to medication is directly associated with the control of blood glucose, which has an impact on the progression of frailty. The association between foot self-care behavior and frailty could be explained by the observation that the participants with a higher score on foot care were more likely to be active in self-management for complications prevention and concerned about their own health, contributing to a reduced risk of frailty.

This study has several limitations. First, this study is a cross-sectional study, therefore the causal relationship of the associated factors with frailty could not be established. Second, information such as the older adults' physical activities and self-care behaviors were self-

reported, so it may be subject to potential recall bias. Third, we excluded older adults who could not walk independently, as well as those with severe vision and hearing problems, so findings may not be generalizable to a more heterogeneous population. Fourth, the data collected from one city would likely not reflect the nation-wide prevalence of frailty. Fifth, information such as the amount of alcohol consumed weekly for current drinkers and the date of drinking cessation, as well as the amount of previous alcohol consumption for ex-drinkers was not collected in this study. Future studies on the relationship between alcohol consumption and frailty in this population are warranted. Finally, future studies should explore the effects of clinical and behavioral factors on frailty among community-dwelling diabetic older adults using a prospective longitudinal design and a larger sample size.

CONCLUSIONS

Older adults with type 2 diabetes are at a high risk of frailty in Chinese elderly populations. Being an ex-drinker, having a higher level of HbA1c, experiencing malnutrition risk/malnutrition, and suffering from depressive symptoms were risk factors of frailty among the community-dwelling diabetic older adults; exercise self-care behavior was found to be a protective factor for frailty. The findings of this study could help guide future studies to implement targeted and suitable interventions for preventing frailty among community-dwelling diabetic older adults.

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Author Contributions

LK, JL and JM designed the study. LK, HZ and QW collected and managed the data. LK and JF completed the data analysis. LK and JL drafted the manuscript. JB checked and revised the manuscript. All the authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent for publication

Obtained.

Ethics approval

This study was approved by the Medical Ethics Committee of Huazhong University and Science and Technology (No. 2019–S941).

Data availability statement

Data are available from the first author upon reasonable request. All data relevant to this study are included in the article.

Figure 1. Flow chart of inclusion of participants.

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Table 1 Sociodemographic characteristics of the participants by different frailty statuses

Variables	Total (n=291) N (%)	Robust (n=85) N (%)	Pre-frail (n=150) N (%)	Frail (n=56) N (%)	P value
Age (years)					0.295
65-69	154 (52.9)	52 (61.2)	74 (49.3)	28 (50.0)	
70-74	91 (31.3)	25 (29.4)	49 (32.7)	17 (30.4)	
≥75	46 (15.8)	8 (9.4)	27 (18.0)	11 (19.6)	
Gender					0.270
Male	137 (47.1)	41 (48.2)	75 (50.0)	21 (37.5)	
Female	154 (52.9)	44 (51.8)	75 (50.0)	35 (62.5)	
Living place					0.434
Urban	246 (84.5)	75 (88.2)	126 (84.0)	45 (80.4)	
Rural	45 (15.5)	10 (11.8)	24 (16.0)	11 (19.6)	
Education level					***0.077***
Illiterate	42 (14.4)	8 (9.4)	18 (12.0)	16 (28.6)	
Elementary school	63 (21.6)	18 (21.2)	34 (22.7)	11 (19.6)	
Junior high school	95 (32.6)	27 (31.8)	50 (33.3)	18 (32.1)	
Senior high school	55 (18.9)	19 (22.4)	28 (18.7)	8 (14.3)	
College or over	36 (12.4)	13 (15.3)	20 (13.3)	3 (5.4)	
Marital status					0.658
Spouse	233 (80.1)	66 (77.6)	120 (80.0)	47 (83.9)	
No spouse	58 (19.9)	19 (22.4)	30 (20.0)	9 (16.1)	
Living status					0.279
Living with others	253 (86.9)	71 (83.5)	135 (90.0)	47 (83.9)	
Living alone	38 (13.1)	14 (16.5)	15 (10.0)	9 (16.1)	
Currently working					0.197
Yes	23 (7.9)	10 (11.8)	11 (7.3)	2 (3.6)	
No	268 (92.1)	75 (88.2)	139 (92.7)	54 (96.4)	
Personal monthly income (Chinese Yuan)					***0.026***
<1000	43 (14.8)	7 (8.2)	20 (13.3)	16 (28.6)	
1000-1999	50 (17.2)	14 (16.5)	27 (18.0)	9 (16.1)	
2000-2999	100 (34.4)	34 (40.0)	47 (31.3)	19 (33.9)	
≥3000	98 (33.7)	30 (35.3)	56 (37.3)	12 (21.4)	
Medical insurance					***0.034***
Urban residential insurance	79 (27.1)	17 (20.0)	42 (28.0)	20 (35.7)	
Urban employees' insurance	169 (58.1)	56 (65.9)	90 (60.0)	23 (41.1)	
New rural cooperative medical insurance	43 (14.8)	12 (14.1)	18 (12.0)	13 (23.2)	

Table 2 Lifestyle and clinical characteristics of the participants by different frailty statuses

Variables	Total (n=291)	Robust (n=85)	Pre-frail (n=150)	Frail (n=56)	P value
	N (%)/Median (IQR)				
Smoking					0.612
Non-smoker	185 (63.6)	54 (63.5)	93 (62.0)	38 (67.9)	
Ex-smoker	69 (23.7)	17 (20.0)	39 (26.0)	13 (23.2)	
Current smoker	37 (12.7)	14 (16.5)	18 (12.0)	5 (8.9)	
Alcohol Drinking					***0.004***
Non-drinker	167 (57.4)	50 (58.8)	76 (50.7)	41 (73.2)	
Ex-drinker	46 (15.8)	7 (8.2)	30 (20.0)	9 (16.1)	
Current drinker	78 (26.8)	28 (32.9)	44 (29.3)	6 (10.7)	
Sleep duration at night (hours)					***0.046***
<5	75 (25.8)	14 (16.5)	39 (26.0)	22 (39.3)	
5-8	192 (66.0)	64 (75.3)	99 (66.0)	29 (51.8)	
>8	24 (8.2)	7 (8.2)	12 (8.0)	5 (8.9)	
Self-rated sleep quality					***0.065***
Very good	33 (11.3)	14 (16.5)	17 (11.3)	2 (3.6)	
Good	145 (49.8)	44 (51.8)	77 (51.3)	24 (42.9)	
Bad	89 (30.6)	24 (28.2)	42 (28.0)	23 (41.1)	
Very bad	24 (8.2)	3 (3.5)	14 (9.3)	7 (12.5)	
Duration of diabetes (years)	10 (4-16)	9 (4-16)	11 (5-16)	7 (4-13)	***0.036***
Number of comorbidities	5 (3-6)	4 (3-6)	5 (3-6)	5 (4-7)	***0.030***
Polypharmacy					***0.025***
No	205 (70.4)	68 (80.0)	104 (69.3)	33 (58.9)	
Yes	86 (29.6)	17 (20.0)	46 (30.7)	23 (41.1)	
BMI (kg/m^2)					0.321
<18.5	11 (3.8)	0 (0)	8 (5.3)	3 (5.4)	
18.5-23.9	127 (43.6)	37 (43.5)	65 (43.3)	25 (44.6)	
24-27.9	114 (39.2)	38 (44.7)	58 (38.7)	18 (32.1)	
≥28	39 (13.4)	10 (11.8)	19 (12.7)	10 (17.9)	
Waist circumference					0.285
Normal	51 (17.5)	11 (12.9)	27 (18.0)	13 (23.2)	
High	240 (82.5)	74 (87.1)	123 (82.0)	43 (76.8)	
HbA1c (%)	6.66 (5.87-7.47)	6.74 (5.96-7.20)	6.48 (5.72-7.26)	6.97 (5.95-8.42)	***0.055***

IQR, interquartile range; BMI, body mass index; HbA1c, glycated hemoglobin.

Table 3 Malnutrition, depression and diabetes self-care behaviors of the participants by different frailty statuses

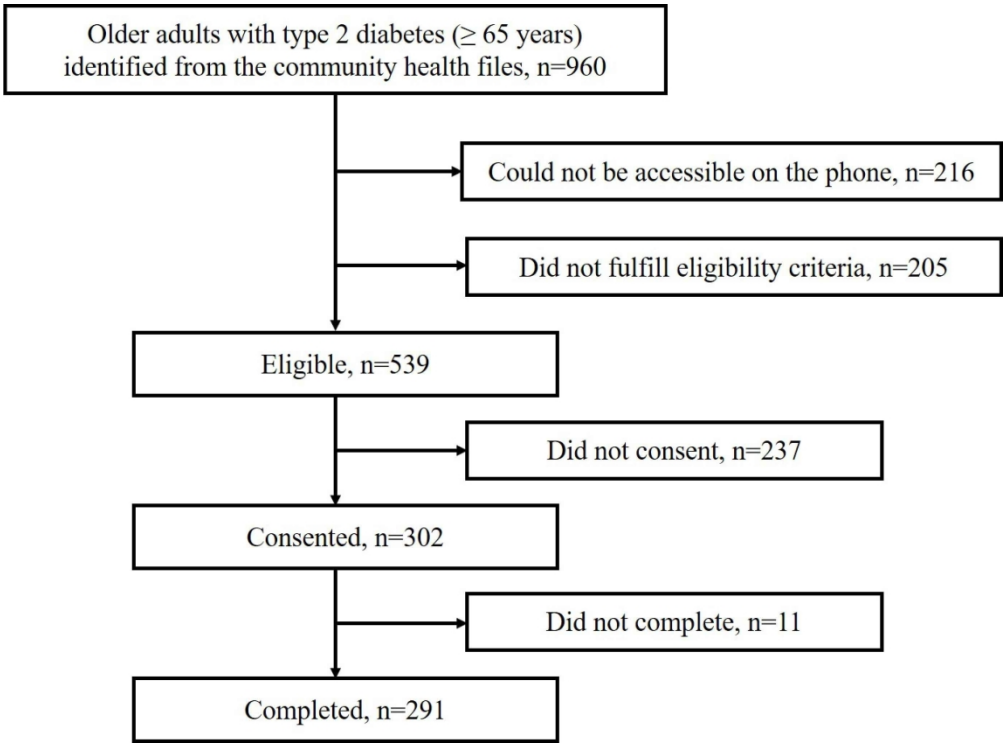
Variables	Possible range	Actual range	Total (n=291)	Robust (n=85)	Pre-frail (n=150)	Frail (n=56)	P value
			N (%)/Median (IQR)				
Malnutrition risk/malnutrition							***<0.001***
No			189 (64.9)	76 (89.4)	96 (64.0)	17 (30.4)	
Yes			102 (35.1)	9 (10.6)	54 (36.0)	39 (69.6)	
GDS-15 score	0-15	0-15	3 (1-5)	1 (0-3)	3 (1-5)	5 (4-8)	***<0.001***
SDSCA score							
General diet score	0-14	0-14	14 (10-14)	14 (10-14)	14 (10-14)	14 (10-14)	0.465
Specific diet score	0-14	0-14	8 (7-12)	10 (7-13)	7 (7-12)	7 (7-12)	0.131
Exercise score	0-14	0-14	7 (7-14)	14 (7-14)	7 (7-14)	7 (0-7)	***<0.001***
Blood-glucose testing score	0-14	0-14	0 (0-2)	0 (0-2)	0 (0-2)	0 (0-1)	0.183
Foot care score	0-14	0-14	0 (0-7)	0 (0-7)	0 (0-7)	0 (0-0)	***0.007***
Medication care score	0-7	0-7	7 (7-7)	7 (7-7)	7 (7-7)	7 (7-7)	***0.060***

IQR, interquartile range; GDS-15, Geriatric Depression Scale-15; SDSCA, Summary of Diabetes Self-Care Activities.

Table 4 Logistic regression model of predictors for pre-frailty and frailty

	Pre-frail			Frail		
	OR	**95% CI**	**P value**	**OR**	**95% CI**	**P value**
Alcohol Drinking						
Ex-drinker	3.664	1.260 to 10.653	***0.017***	4.461	1.079 to 18.438	***0.039***
Current drinker	1.416	0.680 to 2.950	0.353	0.266	0.069 to 1.026	0.055
Non-drinker	1	-	-	1	-	-
HbA1c	0.830	0.644 to 1.071	0.152	1.434	1.045 to 1.968	***0.026***
Malnutrition risk/Malnutrition						
Yes	2.806	1.133 to 6.950	***0.026***	8.062	2.470 to 26.317	***0.001***
No	1	-	-	1	-	-
GDS-15 score	1.285	1.087 to 1.520	***0.003***	1.438	1.166 to 1.773	***0.001***
Exercise score	0.906	0.843 to 0.974	***0.008***	0.796	0.716 to 0.884	***<0.001***

GDS-15, Geriatric Depression Scale-15.



Flow chart of inclusion of participants

234x173mm (300 x 300 DPI)

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

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10
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	7-10
Bias	9	Describe any efforts to address potential sources of bias	9-10
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	11
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	12
		(*b*) Report category boundaries when continuous variables were categorized	26-27
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
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	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
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	18

*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.

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Predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes: A cross-sectional survey

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ABSTRACT

Objectives: To assess the prevalence of frailty and identify predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

Design: A cross-sectional design.

Setting: Two community health centers in central China.

Participants: 291 community-dwelling older adults aged ≥ 65 years with type 2 diabetes.

Main outcome measures: Data were collected via face-to-face interviews, anthropometric measurements, laboratory tests, and community health files. The main outcome measure was frailty, as assessed by the frailty phenotype criteria. The multivariate logistic regression model was used to identify the predictors of frailty.

Results: The prevalence of pre-frailty and frailty were 51.5% and 19.2%, respectively. The significant predictors of frailty included alcohol drinking (ex-drinker) (OR = 4.461, 95% CI 1.079 to 18.438), glycated hemoglobin (HbA1c) (OR = 1.434, 95% CI 1.045 to 1.968), nutritional status (malnutrition risk/malnutrition) (OR = 8.062, 95% CI 2.470 to 26.317), depressive symptoms (OR = 1.438, 95% CI 1.166 to 1.773), and exercise behavior (OR = 0.796, 95% CI 0.716 to 0.884).

Conclusions: A high prevalence of frailty was found among older adults with type 2 diabetes in the Chinese community. Frailty identification and multi-faceted interventions should be developed for this population, taking into consideration proper glycemic control, nutritional instruction, depressive symptoms improvement, and enhancement of self-care behaviors.

ARTICLE SUMMARY

Strengths and limitations of this study

- The study evaluated an extensive list of sociodemographic factors, lifestyle and clinical characteristics, nutritional status, depressive symptoms, and diabetes self-care behaviors that could influence the frailty status of community-dwelling older adults with type 2 diabetes.
- The study examined which domains of diabetes self-care behaviors were associated with frailty among diabetic older adults.
- The study is a cross-sectional study, so a causal relationship between factors associated with frailty could not be established.
- The study was conducted in one city of China, which may affect the generalizability of the findings.

KEYWORDS

Community-dwelling older adults; frailty; predictors; type 2 diabetes.

INTRODUCTION

Across the world, the estimated number of people aged 65–99 years with diabetes was 136 million (19.3%) in 2019, and this number is estimated to increase to 195 million in 2030 and 276 million in 2045.[1] China had the world's largest number of adults with diabetes,[1] and the prevalence of older Chinese adults with diabetes over the age of 60 was 20.2% in the latest national survey.[2] Elderly people with type 2 diabetes are at risk for developing frailty,[3] a geriatric syndrome manifesting as a reduction in one's physical strength, endurance, and physiologic function that increases the likelihood of developing functional dependency and death.[4] Diabetic people are more likely to be frail than their non-diabetic counterparts.[5 6] This relationship between diabetes and frailty may be explained by the fact that diabetes impairs skeletal muscle function, vascular function, and hormonal milieu, as well as accelerates sarcopenia, thereby leading to increased frailty.[3 7 8]

Frailty is associated with higher disability, mortality, cardiovascular events, and healthcare utilization among older adults with type 2 diabetes.[9 10] Identifying the associated factors for frailty among older adults with diabetes may help to improve their health outcomes. A few studies have shown that sociodemographic factors (e.g., age, education level), [6 11] physical factors (e.g., systolic blood pressure, bodyweight, abdominal obesity), [6 11 12] and biological factors (e.g., glycated hemoglobin [HbA1c], albumin, high-density lipoprotein cholesterol) [6 11] were associated with frailty in diabetic older adults. Until now, important, modifiable factors such as nutritional status, psychological well-being, and self-care behavioral factors were rarely studied among community-dwelling diabetic older adults.

The association between malnutrition and frailty has been established among community-dwelling older adults.[13 14] Depression is another common factor associated with frailty among the elderly.[15 16] However, there is a lack of understanding of the impact of malnutrition and depression on frailty among the specific diabetic older population. Diabetic older adults should adopt numerous diabetes self-care behaviors to control their disease; these behaviors include proper diet, regular exercise, self-monitoring of blood glucose, proper foot care, and strict adherence to prescribed medications.[17] Nevertheless, there is a dearth of studies on which domains of diabetes self-care behaviors are preferentially associated with frailty. Examining these associations is important for developing specific interventions to reduce the risk of frailty for diabetic older people.

In China, there is an increasing number of older people with type 2 diabetes living in the community, and the health management of the diabetic elderly population is the focus of many community health services; however, frailty is not among the physical conditions that is routinely screened for in this population.[18] Little is known about the frailty status among the community-dwelling older adults with type 2 diabetes in China. To our knowledge, only one study reported the prevalence of frailty in a community-dwelling diabetic population in mainland China; however, that study included a sample of diabetic people aged 55 years and older, identifying the risk factors of frailty among an elevated blood glucose (pre-diabetes and diabetes) population.[5] Therefore, the aims of this study were to assess the prevalence of frailty and explore the predictors of frailty among Chinese community-dwelling older adults with type 2 diabetes.

METHODS

Study design and setting

A cross-sectional design was used. The participants were recruited from two community health centers of Xianning City of Hubei Province in China from June to October 2019. Both community health centers provided primary health care services for older people in urban and rural communities.

Data collection and ethical considerations

Ethical Approval was obtained from the Medical Ethics Committee of Huazhong University and Science and Technology (No. 2019–S941) prior to data collection. The researcher contacted the directors of two community health centers and explained the aims of this study. After permission was granted, the public health nurses and physicians were invited to assist with data collection. Health center staff helped to recruit participants by phone, informing the eligible diabetic older adults of the study purpose. Eligible individuals were then invited to the community health centers to complete the survey if they consented to participate. As another means of recruitment, when older adults with type 2 diabetes went to the community health centers for a physical check-up, follow-up blood glucose monitoring, or health education, they were also invited to participate in this study, if eligible. Once the written informed consent was obtained from each participant, the survey was administered by trained investigators. The information in this survey was obtained from the participants' self-reporting, anthropometric measurements, and laboratory test results, which were supplemented by the community health files.

Participants

Older adults with type 2 diabetes were identified from the electronic files of the two community health centers. The inclusion criteria of this study were as follows: (1) at least 65 years old and living in the community; (2) diagnosed with type 2 diabetes, as confirmed by a physician based on the World Health Organization diagnostic criteria, 1999; (3) received their diagnosis at least 6 months prior to joining the study. The diabetic older adults were excluded if they: (1) could not walk independently; (2) had severe vision and hearing problems; (3) were unable to communicate with the investigators; (4) had dementia or mental health disorders; and (5) had acute diabetic complications.

The sample size was calculated using the formula for cross-sectional studies,[19] $n = \frac{Z^2P(1-P)}{d^2}$. Where n is the sample size, Z is the statistic corresponding to level of confidence, P is expected prevalence, and d is precision. We assumed a confidence level of 95.0%, expected frailty prevalence of 20.0% for community-dwelling older adults with type 2 diabetes (determined by the pre-survey), and precision of 5.0%, indicating that at least 246 participants were needed for this study.

Survey instrument

The personal information questionnaire was used to collect the participants' characteristics. The sociodemographic characteristics included age, gender, living place, education level, marital status, living status, working status, personal monthly income, and medical insurance; the lifestyle and clinical characteristics included smoking, alcohol drinking, sleep duration at night, self-rated quality of sleep, duration of diabetes, number of comorbidities, polypharmacy, body mass index (BMI), waist circumference, and HbA1c. Smoking status was categorized as current smoker (having smoked at least one cigarette per day), ex-smoker

(having stopped smoking at least one year before the survey) and non-smoker (having never smoked in one's lifetime). Alcohol drinking status was categorized into current drinker (someone who reported consuming alcohol currently), ex-drinker (someone who had quitted drinking at least one year prior to the survey), and non-drinker (someone who reported never consuming alcohol). Polypharmacy was defined as concurrent use of 5 or more drugs. BMI was calculated by weight (kg)/ [height (m)] ^{2} and classified as underweight, normal, overweight, and obese (< 18.5, 18.5-23.9, 24.0-27.9, and ≥ 28.0 kg/m^2), and high waist circumference was defined as ≥ 85 cm in men and ≥ 80 cm in women.[20]

Frailty was measured using the modified frailty phenotype criteria, which was based on the phenotypic criteria proposed by Fried *et al*.[21] The criteria included five components: (1) Unintentional weight loss: weight loss ≥ 4.5kg in the past year, not due to dieting and exercise; (2) Exhaustion: It was identified based on a response of "3-4 days or most of the time" during the week to either of the two questions: "I felt that everything I did was an effort" and "I could not get going"; (3) Slowness: average walking speed was tested by asking the participants to walk 6 meters at their usual pace, at total of two times. Slowness was identified by walking speed for men (≤ 0.89m/s) and women (≤ 0.79m/s)[22]; (4) Weakness: grip strength was measured with a dynamometer three times on each hand, and the maximum of the readings was used. Weakness was judged by grip strength for men (≤ 28kg) and women (≤ 18kg)[22]; and (5) Low physical activity: the Chinese version of Physical Activity Scale for the Elderly (PASE)[23] was used to assess participants' physical activity level in the past week. Low physical activity was classified by PASE score for men (≤ 56.4) and women (≤ 58.8).[22] One point was assigned for the presence of each component, and the

summed score was used to classify participants as robust (score = 0), pre-frail (score = 1-2) and frail (score = 3-5).

Mini-Nutritional Assessment (MNA) was used to assess the nutritional status of older adults.[24] It consists of 18 items grouped into four parts: anthropometric assessment, general assessment, dietary assessment, and self-assessment. The total score ranges from 0 to 30 and is used to classify the elderly as well-nourished (≥ 24), at risk of malnutrition (17–23.5), or malnourished (< 17). The Chinese version of MNA has been proven to be reliable and valid in the community-dwelling older population.[25]

Geriatric Depression Scale-15 (GDS-15) was used to evaluate the depressive symptoms of older adults.[26] The scale contains 15 items that require the subjects to answer with "yes" or "no". The maximum score of the scale is 15, and a higher score indicates more severe depressive symptoms. The Chinese version of GDS-15 is a reliable and valid screening tool for assessing geriatric depressive symptoms in the Chinese population.[27]

The Chinese version of Summary of Diabetes Self-Care Activities (SDSCA)[28] was used to measure self-care behaviors of the older adults with type 2 diabetes; this instrument was modified from the original SDSCA.[17] It is a brief self-report questionnaire that includes 11 items assessing the following aspects: general diet, specific diet, exercise, blood-glucose testing, foot care, and medication care in the past week. The total score of this scale ranges from 0 to 77, and a higher score indicates better diabetes self-care behaviors. It showed good validity and test-retest reliability in Chinese patients with type 2 diabetes.[28]

Anthropometric measurements, including height or knee height, weight, mid-arm circumference, calf circumference, and waist circumference, were measured by the trained

investigators according to the measurement manual. Knee height was measured and converted to the estimated height using specific equations[29] for the older adults with severe spinal curvature. All the HbA1c measures were obtained after the participants were recruited into the study. The blood collection and HbA1c measurements were administered by the community health center laboratories when the participants came to the centers for this survey.

Data analysis

The SPSS version 21.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis. Frailty was defined as the dependent variable with 1= robust (0 on the frailty phenotype criteria), 2 = pre-frail (1-2), 3 = frail (≥ 3). Sociodemographic, lifestyle and clinical characteristics, malnutrition, depressive symptoms, and diabetes self-care behaviors were considered potential factors for frailty. Raw data were evaluated for normality and multi-collinearity before data analysis. Data were described as n (%) for categorical variables and median (interquartile range [IQR]) or mean ± SD for continuous variables. To test the statistical difference among groups, univariate analyses were conducted using chi-square test for categorical variables and Kruskal-Wallis H test for continuous variables. Variables that showed statistical significance of $P < 0.1$ in the univariate analyses were included in the multinomial logistic regression, which estimated the prevalence odds ratio (OR) for pre-frail relative to robust and for frail relative to robust. The statistical significance was set at $P < 0.05$ for the logistic regression.

Patient and public involvement

Patients were not involved in the development of research question or the design of the study. Anthropometric measurements and HbA1c test results were provided to the participants, community physicians and nurses.

RESULTS

As shown in figure 1, a total of 302 eligible older adults consented to participate in this study. Eleven participants did not complete the questionnaires due to temporary issues and limited time, so the final sample consisted of 291 participants. Among these participants, 85 (29.2%) were robust, 150 (51.5%) were pre-frail, and 56 (19.2%) were frail.

Characteristics of the participants

The median age of participants was 69 years (IQR 67-72), with a range from 65 to 85 years. Among the participants, 154 (52.9%) were female. The majority of the participants were living in urban areas (84.5%), had junior high school or higher education (63.9%), had a spouse (80.1%), lived with others (86.9%), were currently not working (92.1%), had a personal monthly income below 3000 yuan (66.3%), and had urban employees' insurance (58.1%) (table 1).

Regarding the lifestyle characteristics, most of the participants were non-smokers (63.6%), non-drinkers (57.4%), with 5-8 h sleep duration at night per day (66.0%), and had good/very good sleep quality (61.2%) (table 2). Considering clinical characteristics, the median duration of diabetes was 10 years (IQR 4-16), and the median number of comorbidities was 5 (IQR 3-6). Among all participants, 29.6% had polypharmacy, 43.6% had normal BMI, and 17.5% had a normal waist circumference. The median score of HbA1c was 6.66% (IQR 5.87-7.47) (table 2).

Malnutrition, depressive symptoms, and diabetes self-care behaviors

Of all participants, 96 (33.0%) were at risk of malnutrition, 6 (2.1%) were malnourished, and 189 (64.9%) were nourished. The median score of depressive symptoms was 3 (IQR 1-5). The total score for diabetes self-care behaviors ranged from 12 to 70, with an average of 40.25 ± 10.08. Among the 6 sub-dimensions of diabetes self-care behaviors, the two dimensions with the lowest level were blood-glucose testing (0 [0-2]) and foot care (0 [0-7]) (table 3).

Univariate analyses for influencing factors of frailty

Univariate analyses were conducted to explore the associated factors for frailty according to the criterion of inclusion ($p < 0.10$). Significant sociodemographic differences among groups were found for education level ($p = 0.077$), personal monthly income ($p = 0.026$), and medical insurance ($p = 0.034$) (table 1). Regarding the lifestyle and clinical characteristics, significant group differences included alcohol drinking ($p = 0.004$), sleep duration at night ($p = 0.046$), self-rated sleep quality ($p = 0.065$), duration of diabetes ($p = 0.036$), comorbidities ($p = 0.030$), polypharmacy ($p = 0.025$), and HbA1c ($p = 0.055$) (table 2). As shown in table 3, significant group differences were noted for malnutrition risk/malnutrition ($p < 0.001$), depressive symptoms ($p < 0.001$), exercise ($p < 0.001$), foot care ($p = 0.007$), and medication care ($p = 0.060$).

Predictors of frailty

The predictors of pre-frailty for older adults with type 2 diabetes in this study included alcohol drinking (ex-drinker) ($p = 0.017$), malnutrition risk/malnutrition ($p = 0.026$), depressive symptoms ($p = 0.003$), and exercise ($p = 0.008$) (table 4). The following predictors

were found for the condition of frailty: alcohol drinking (ex-drinker) (p = 0.039), HbA1c (p = 0.026), malnutrition risk/malnutrition (p = 0.001), depressive symptoms (p = 0.001), and exercise (p < 0.001) (table 4).

DISCUSSION

In this study, we assessed frailty status and its associated factors among Chinese community-dwelling older adults with type 2 diabetes. We found the prevalence of pre-frailty and frailty were 51.5% and 19.2%, respectively. Our result was comparable with the Beijing study (the prevalence of frailty was 19.32%),[5] however, the Beijing study applied the accumulation of deficits method (Frailty Index ≥ 0.25) to measure frailty among diabetic people aged ≥ 55 years. By using the Fried frailty phenotype for assessing frailty, the prevalence of frailty in people with diabetes aged 65 and older was 25.0%-32.0%, as reported in the American studies.[21 30] In addition, studies conducted in Singapore and Spain showed lower frailty prevalence of 8.2% and 11.2%, respectively,[6 10] but, these two studies also recruited younger diabetic adults (i.e. younger than 65 years). The explanation for the wide variation in the prevalence of frailty in community-dwelling diabetic elderly populations is probably related to frailty instrument differences, sample difference, and socioeconomic differences among the studies.

Alcohol drinking was one predictor of frailty and pre-frailty among the diabetic older adults, and the frailty risk was significantly higher among ex-drinkers compared with non-drinkers. This association could be explained by the “sick quitter” effect. The diabetic older adults in poor health may reduce alcohol consumption or quit drinking, so the ex-drinker group may contain people with previous alcoholism or with a poor health condition.[31] In our

study, it is interesting that current drinking status showed a protective effect (OR = 0.266, p = 0.055) on frailty compared with non-drinkers, although this factor didn't satisfy the statistical significance in the logistic regression. Previous studies indicated alcohol use (especially moderate drinking) had a negative association with physical frailty. [32-34] Moreover, a recent study demonstrated moderate alcohol consumption may protect against frailty through an anti-inflammatory mechanism, which indicated that C-reactive protein level partially mediated the relationship between moderate alcohol use and physical frailty.[35]

Elevated HbA1c was associated with an increased risk of frailty among community-dwelling diabetic older adults, which was consistent with the previous study in diabetic older people.[6] Hyperglycemia could contribute to physical frailty through several potential mechanisms, such as increasing microvascular damage[36] or causing skeletal muscle mitochondrial dysfunction.[37] In contrast, Yanagita *et al*[11] reported low level of HbA1c was associated with frailty measured by the Clinical Frailty Scale (CFS) among diabetic older adults. Zaslavsky *et al*[38] found a U-shaped relationship between glucose levels and physical frailty in older adults with diabetes, with the lowest risk of frailty at HbA1c levels of 7.6%. Overall, poor glucose control with hyperglycemia or hypoglycemia may increase the risk of frailty. Therefore, optimal glycemic control needs to be individually determined for older adults with type 2 diabetes.[39] The global guideline for managing type 2 diabetes in older adults recommended that a HbA1c target up to 8.5% may be appropriate for frail diabetic elderly persons with functional dependency.[40] Recently, an international position statement on the management of frailty in diabetes mellitus patients recommended a HbA1c target

range of 7.0%-8.0% for mild to moderate frail diabetic older adults, and 7.5%-8.5% for those with severe frailty.[41]

Malnutrition led to pre-frailty and frailty among community-dwelling older adults with type 2 diabetes, which was comparable with the findings of a Spanish study.[12] In the current study, 35.1% of our participants were at risk for malnutrition or were malnourished, and 52.6% of them were overweight or obese. However, 39 (38.2%) of the participants who had malnutrition risk or were malnourished in this study were classified as either overweight or obese. This result suggests that the diabetic elderly can suffer from malnutrition status even if they are overweight or obese. Malnutrition is prevalent in diabetic older adults[42 43] due to various reasons, such as ageing-related appetite reductions, swallowing difficulties, limited mobility, and overly dietary restrictions.[44] We found that 45.4% of the diabetic older adults scored 0 points on the item of protein intake in this study, indicating that those people might have insufficient protein intake. Although malnutrition and physical frailty share some common screening items and physiology, they are not interchangeable syndromes, and community-dwelling diabetic older people with malnutrition were more prone to be physically frail. Screening the nutritional status of diabetic older adults and providing them with appropriate dietary instructions would be an effective method for preventing physical frailty within this population.

Consistent with previous studies among older populations,[15 16] this study highlighted the significant impact of depressive symptoms on pre-frailty and frailty among the diabetic elderly. Recent evidence showed a reciprocal interaction between depression and frailty in older adults.[16] Depression contributes to physical frailty due to the decrease in physical

activities or weight loss, and in turn, physical frailty may cause functional dependence or disability, thus leading to depression. Diabetes can contribute to depression, which is a common condition in people with type 2 diabetes, especially in the elderly.[45 46] Therefore, there is an urgent need for appropriate management of depressive symptoms in elderly diabetic adults in order to help slow the progression of physical frailty in this population.

We found exercise behavior was a protective factor for frailty among community-dwelling diabetic older adults. A higher score of exercise behavior was associated with a lower risk of pre-frailty and frailty. Exercise can help reduce frailty through mechanisms of decreasing muscle inflammation, promoting anabolism, and increasing muscle protein synthesis.[47] Education programs for exercise training have shown to be effective at improving frailty in the elderly.[48] Pariser *et al*[49] conducted a diabetes self-management education program comprised of ten weeks of aerobic and resistance exercise training, which effectively reduced HbA1c and frailty in diabetic older adults. In addition, the three different frailty groups (i.e. robust, pre-frail, and frail) differed significantly in terms of medication care and foot self-care behaviors in this study. The association between medication care behavior and frailty may be explained by the fact that adherence to medication is directly associated with the control of blood glucose, which has an impact on the progression of frailty. The association between foot self-care behavior and frailty could be explained by the observation that the participants with a higher score on foot care were more likely to be active in self-management for complications prevention and concerned about their own health, contributing to a reduced risk of frailty.

This study has several limitations. First, this study is a cross-sectional study, therefore the causal relationship of the associated factors with frailty could not be established. Second, information such as the older adults' physical activities and self-care behaviors were self-reported, so it may be subject to potential recall bias. Third, we excluded older adults who could not walk independently, as well as those with severe vision and hearing problems, so findings may not be generalizable to a more heterogeneous population. Fourth, the data collected from one city would likely not reflect the nation-wide prevalence of frailty. Fifth, information such as the amount of alcohol consumed weekly for current drinkers and the date of drinking cessation, as well as the amount of previous alcohol consumption for ex-drinkers was not collected in this study. Future studies on the relationship between alcohol consumption and frailty in this population are warranted. Finally, future studies should explore the effects of clinical and behavioral factors on frailty among community-dwelling diabetic older adults using a prospective longitudinal design and a larger sample size.

CONCLUSIONS

Older adults with type 2 diabetes are at a high risk of frailty in Chinese elderly populations. Being an ex-drinker, having a higher level of HbA1c, experiencing malnutrition risk/malnutrition, and suffering from depressive symptoms were risk factors of frailty among the community-dwelling diabetic older adults; exercise self-care behavior was found to be a protective factor for frailty. The findings of this study could help guide future studies to implement targeted and suitable interventions for preventing frailty among community-dwelling diabetic older adults.

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Author Contributions

LK, JL and JM designed the study. LK, HZ and QW collected and managed the data. LK and JF completed the data analysis. LK and JL drafted the manuscript. JB checked and revised the manuscript. All the authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent for publication

Obtained.

Ethics approval

This study was approved by the Medical Ethics Committee of Huazhong University and Science and Technology (No. 2019–S941).

Data availability statement

Data are available from the first author upon reasonable request. All data relevant to this study are included in the article.

Figure 1. Flow chart of inclusion of participants.

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Table 1 Sociodemographic characteristics of the participants by different frailty statuses

Variables	Total (n=291) N (%)	Robust (n=85) N (%)	Pre-frail (n=150) N (%)	Frail (n=56) N (%)	P value
Age (years)					0.295
65-69	154 (52.9)	52 (61.2)	74 (49.3)	28 (50.0)	
70-74	91 (31.3)	25 (29.4)	49 (32.7)	17 (30.4)	
≥75	46 (15.8)	8 (9.4)	27 (18.0)	11 (19.6)	
Gender					0.270
Male	137 (47.1)	41 (48.2)	75 (50.0)	21 (37.5)	
Female	154 (52.9)	44 (51.8)	75 (50.0)	35 (62.5)	
Living place					0.434
Urban	246 (84.5)	75 (88.2)	126 (84.0)	45 (80.4)	
Rural	45 (15.5)	10 (11.8)	24 (16.0)	11 (19.6)	
Education level					***0.077***
Illiterate	42 (14.4)	8 (9.4)	18 (12.0)	16 (28.6)	
Elementary school	63 (21.6)	18 (21.2)	34 (22.7)	11 (19.6)	
Junior high school	95 (32.6)	27 (31.8)	50 (33.3)	18 (32.1)	
Senior high school	55 (18.9)	19 (22.4)	28 (18.7)	8 (14.3)	
College or over	36 (12.4)	13 (15.3)	20 (13.3)	3 (5.4)	
Marital status					0.658
Spouse	233 (80.1)	66 (77.6)	120 (80.0)	47 (83.9)	
No spouse	58 (19.9)	19 (22.4)	30 (20.0)	9 (16.1)	
Living status					0.279
Living with others	253 (86.9)	71 (83.5)	135 (90.0)	47 (83.9)	
Living alone	38 (13.1)	14 (16.5)	15 (10.0)	9 (16.1)	
Currently working					0.197
Yes	23 (7.9)	10 (11.8)	11 (7.3)	2 (3.6)	
No	268 (92.1)	75 (88.2)	139 (92.7)	54 (96.4)	
Personal monthly income (Chinese Yuan)					***0.026***
<1000	43 (14.8)	7 (8.2)	20 (13.3)	16 (28.6)	
1000-1999	50 (17.2)	14 (16.5)	27 (18.0)	9 (16.1)	
2000-2999	100 (34.4)	34 (40.0)	47 (31.3)	19 (33.9)	
≥3000	98 (33.7)	30 (35.3)	56 (37.3)	12 (21.4)	
Medical insurance					***0.034***
Urban residential insurance	79 (27.1)	17 (20.0)	42 (28.0)	20 (35.7)	
Urban employees' insurance	169 (58.1)	56 (65.9)	90 (60.0)	23 (41.1)	
New rural cooperative medical insurance	43 (14.8)	12 (14.1)	18 (12.0)	13 (23.2)	

Table 2 Lifestyle and clinical characteristics of the participants by different frailty statuses

Variables	Total (n=291)	Robust (n=85)	Pre-frail (n=150)	Frail (n=56)	P value
	N (%)/Median (IQR)				
Smoking					0.612
Non-smoker	185 (63.6)	54 (63.5)	93 (62.0)	38 (67.9)	
Ex-smoker	69 (23.7)	17 (20.0)	39 (26.0)	13 (23.2)	
Current smoker	37 (12.7)	14 (16.5)	18 (12.0)	5 (8.9)	
Alcohol Drinking					***0.004***
Non-drinker	167 (57.4)	50 (58.8)	76 (50.7)	41 (73.2)	
Ex-drinker	46 (15.8)	7 (8.2)	30 (20.0)	9 (16.1)	
Current drinker	78 (26.8)	28 (32.9)	44 (29.3)	6 (10.7)	
Sleep duration at night (hours)					***0.046***
<5	75 (25.8)	14 (16.5)	39 (26.0)	22 (39.3)	
5-8	192 (66.0)	64 (75.3)	99 (66.0)	29 (51.8)	
>8	24 (8.2)	7 (8.2)	12 (8.0)	5 (8.9)	
Self-rated sleep quality					***0.065***
Very good	33 (11.3)	14 (16.5)	17 (11.3)	2 (3.6)	
Good	145 (49.8)	44 (51.8)	77 (51.3)	24 (42.9)	
Bad	89 (30.6)	24 (28.2)	42 (28.0)	23 (41.1)	
Very bad	24 (8.2)	3 (3.5)	14 (9.3)	7 (12.5)	
Duration of diabetes (years)	10 (4-16)	9 (4-16)	11 (5-16)	7 (4-13)	***0.036***
Number of comorbidities	5 (3-6)	4 (3-6)	5 (3-6)	5 (4-7)	***0.030***
Polypharmacy					***0.025***
No	205 (70.4)	68 (80.0)	104 (69.3)	33 (58.9)	
Yes	86 (29.6)	17 (20.0)	46 (30.7)	23 (41.1)	
BMI (kg/m^2)					0.321
<18.5	11 (3.8)	0 (0)	8 (5.3)	3 (5.4)	
18.5-23.9	127 (43.6)	37 (43.5)	65 (43.3)	25 (44.6)	
24-27.9	114 (39.2)	38 (44.7)	58 (38.7)	18 (32.1)	
≥28	39 (13.4)	10 (11.8)	19 (12.7)	10 (17.9)	
Waist circumference					0.285
Normal	51 (17.5)	11 (12.9)	27 (18.0)	13 (23.2)	
High	240 (82.5)	74 (87.1)	123 (82.0)	43 (76.8)	
HbA1c (%)	6.66 (5.87-7.47)	6.74 (5.96-7.20)	6.48 (5.72-7.26)	6.97 (5.95-8.42)	***0.055***

IQR, interquartile range; BMI, body mass index; HbA1c, glycated hemoglobin.

Table 3 Malnutrition, depressive symptoms and diabetes self-care behaviors of the participants by different frailty statuses

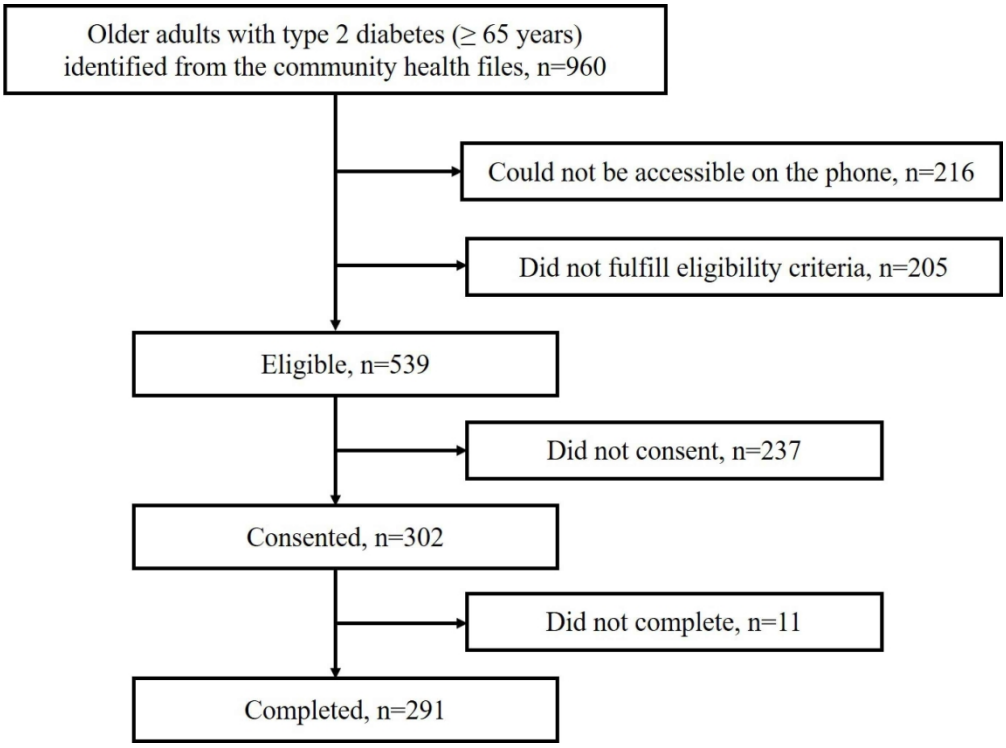
Variables	Possible range	Actual range	Total (n=291)	Robust (n=85)	Pre-frail (n=150)	Frail (n=56)	P value
			N (%)/Median (IQR)				
Malnutrition risk/malnutrition							***<0.001***
No			189 (64.9)	76 (89.4)	96 (64.0)	17 (30.4)	
Yes			102 (35.1)	9 (10.6)	54 (36.0)	39 (69.6)	
GDS-15 score	0-15	0-15	3 (1-5)	1 (0-3)	3 (1-5)	5 (4-8)	***<0.001***
SDSCA score							
General diet score	0-14	0-14	14 (10-14)	14 (10-14)	14 (10-14)	14 (10-14)	0.465
Specific diet score	0-14	0-14	8 (7-12)	10 (7-13)	7 (7-12)	7 (7-12)	0.131
Exercise score	0-14	0-14	7 (7-14)	14 (7-14)	7 (7-14)	7 (0-7)	***<0.001***
Blood-glucose testing score	0-14	0-14	0 (0-2)	0 (0-2)	0 (0-2)	0 (0-1)	0.183
Foot care score	0-14	0-14	0 (0-7)	0 (0-7)	0 (0-7)	0 (0-0)	***0.007***
Medication care score	0-7	0-7	7 (7-7)	7 (7-7)	7 (7-7)	7 (7-7)	***0.060***

IQR, interquartile range; GDS-15, Geriatric Depression Scale-15; SDSCA, Summary of Diabetes Self-Care Activities.

Table 4 Logistic regression model of predictors for pre-frailty and frailty

	Pre-frail			Frail		
	OR	**95% CI**	**P value**	**OR**	**95% CI**	**P value**
Alcohol Drinking						
Ex-drinker	3.664	1.260 to 10.653	***0.017***	4.461	1.079 to 18.438	***0.039***
Current drinker	1.416	0.680 to 2.950	0.353	0.266	0.069 to 1.026	0.055
Non-drinker	1	-	-	1	-	-
HbA1c	0.830	0.644 to 1.071	0.152	1.434	1.045 to 1.968	***0.026***
Malnutrition risk/Malnutrition						
Yes	2.806	1.133 to 6.950	***0.026***	8.062	2.470 to 26.317	***0.001***
No	1	-	-	1	-	-
GDS-15 score	1.285	1.087 to 1.520	***0.003***	1.438	1.166 to 1.773	***0.001***
Exercise score	0.906	0.843 to 0.974	***0.008***	0.796	0.716 to 0.884	***<0.001***

GDS-15, Geriatric Depression Scale-15.



Flow chart of inclusion of participants

234x173mm (300 x 300 DPI)

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

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10
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	7-10
Bias	9	Describe any efforts to address potential sources of bias	9-10
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	11
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	11-12
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	11
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	12-13
		(*b*) Report category boundaries when continuous variables were categorized	26-27
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
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	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
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	18

*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.