

BMJ Open

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

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

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

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

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Association between DSHL and quality of life among elderly individuals with prediabetes in rural Hunan Province, China: A cross-sectional study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028648
Article Type:	Research
Date Submitted by the Author:	18-Dec-2018
Complete List of Authors:	Zhao, Hu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management lulu, Qin; School of Medicine, Hunan Normal University, Department of Social Medicine and Health Management Huilan, Xu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management
Keywords:	quality of life, health literacy, elderly, prediabetes

SCHOLARONE™
Manuscripts

1
2
3 Association between DSHL and quality of life among elderly individuals with prediabetes
4 in rural Hunan Province, China: A cross-sectional study
5
6

7 Zhao Hu¹, Lulu Qin², Huilan Xu^{1,*}

8 1 Department of Social Medicine and Health Management, Xiangya School of Public
9 Health, Central South University, Changsha, 410078, China(15200807487@163.com)

10 2 Department of Social Medicine and Health Management, School of Medicine, Hunan
11 Normal University, Changsha, 410013, China(qinlulu_1989@sina.com)

12 *Correspondence: Huilan Xu, E-mail: xhl6363@sina.com; Tel./Fax: +86-731-8480-5459

13 Word count: 4075, Tables: 4
14
15
16

17 **ABSTRACT**

18 **Objectives** To examine the association of diabetes-specific health literacy (DSHL) and
19 health-related quality of life (HRQoL) among elderly individuals with prediabetes in rural
20 China.
21

22 **Design, setting and participants** A cross-sectional study included 434 elderly individuals
23 with prediabetes from 42 villages in rural China.
24

25 **Main outcome measures** HRQoL was assessed using the Medical Outcomes Study
26 36-Item Short Form Health Survey (SF-36). DSHL was measured by a validated questionnaire
27 in China. Differences in HRQoL between groups with and without adequate DSHL were tested
28 by multivariate analysis of covariance (MANCOVA).
29

30 **Results** The prevalence of prediabetes was 21.5%. The average age of participants (n=434)
31 was 69.4±6.4 years, and 58.5% were female. The median DSHL score was 10.0 points, and
32 only 12.2% had adequate DSHL. Bivariate analysis showed that those with adequate DSHL
33 had increases of 2.9 points in the physical health component score (PCS) and 4.4 points in the
34 mental health component score (MCS) compared to those without. After adjustment for
35 confounders, a significant MANCOVA model (Wilks'λ=0.974, F=5.63, P=0.004) indicated
36 that individuals with prediabetes who had adequate DSHL reported higher MCS (M_{diff}=3.5,
37 95%CI: 1.8, 6.3, effect size=0.38). This remained significant across subscales: general health
38 (P=0.028), vitality (P=0.014), social functioning (P=0.017) and mental health (P=0.005).
39

40 **Conclusions** Low DSHL was associated with worsening HRQoL among elderly individuals
41 with prediabetes in rural China, particularly in the mental health components.
42

43 **Keywords** quality of life; health literacy; elderly; prediabetes
44

45 **Trial registration number** ChiCTR-IOR-15007033
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Article summary

Strengths and limitations of this study

- This is the first study to examine the association between health-related quality of life (HRQoL) and diabetes-specific health literacy among elderly individuals with pre-diabetes in rural China.
- The study provides valuable information on HRQoL among elderly with prediabetes in rural areas in China.
- The association between HRQoL and DSHL is analysed from eight domains, as well as from the physical health component and the mental health component, making the results more comprehensive.
- The cross-sectional study design makes causal relationships undeterminable. The study is limited by its self-reported design.

Introduction

Prediabetes describes individuals who have impaired fasting glucose (IFG) or/and impaired glucose tolerance (IGT)¹. Several studies have identified that individuals with prediabetes have a high risk of developing diabetes, and the occurrence increases with age^{2 3}. Approximately 5%–10% of people with prediabetes become diabetic annually, although the conversion rate varies by population and the definition of prediabetes^{4 5}. Therefore, people with prediabetes are an important target group for interventions intended to prevent diabetes.

Health-related quality of life (HRQoL) refers to how individuals subjectively assess their own well-being and their ability to perform physical, psychological and social functions⁶. Several studies have demonstrated that many risk factors, such as smoking, chronic diseases, poor diet, insufficient physical activity, and overweight, lead to lower HRQoL⁷⁻⁹. Studies have also found that the HRQoL score was relatively lower among individuals with IGT than among the healthy population; additionally, individuals progressing to prediabetes or diabetes suffer from greater loss in HRQoL than people with persistent normal glucose tolerance¹⁰⁻¹². Moreover, HRQoL affects both the entry and subsequent utilization of health services and the cost of health care in China^{13 14}. Thus, assessing HRQoL in the intermediate period between normal plasma glucose and diabetes enables us to investigate its influencing factors and consequently create interventions to improve it, especially by relieving pain, malaise and consequences of diseases¹⁵.

Health literacy (HL) is the degree to which individuals have the capacity to obtain, process and understand the basic health information and service need to make informed health decision¹⁶. Over the past decades, a growing body of research suggests that inadequate HL is associated with adverse health outcomes, such as poor self-rated health, misunderstandings about medical conditions and increased mortality risk¹⁷⁻¹⁹. Moreover, inadequate HL is common in individuals with type 2 diabetes and has been associated with diabetes outcomes, including worse glycemic control and increased risk for hypoglycemia^{20 21}. However, HL is arguably a broad multidimensional concept that serves as a bridge between literacy skills and abilities and the illness context in which individuals find themselves²². Clearly, some dimensions of literacy skills and abilities are generalizable across all health populations. However, in the presence of a specific illness context, some disease-specific HL would seem necessary for successful self-management of that disease. For example, diabetes-specific HL (DSHL) is particularly salient in the assessment of self-care for diabetes or prediabetes in older adults²³. Nevertheless, there is no clear definition of DSHL in the current literature. A study demonstrated that DSHL was positively associated with self-graded assessment of diabetes care²⁴. Some studies have indicated that DSHL is associated with diabetes-related knowledge, self-efficacy, diabetes-care behaviors and glycemic control^{25 26}.

Several studies have evaluated the association between HL and HRQoL among patients with type 2 diabetes²⁷, hypertension²⁸ and ischemic heart disease²⁹. A meta-analysis including 12,303 subjects indicated that the pooled correlation coefficient between HL and QoL was 0.35³⁰. Another study covering 1774 junior middle school students showed that students who were equipped with higher HL were associated with greater QoL³¹. However, few studies have investigated the relationship between specific HL and QoL, and almost no studies in the literature have explored the effect of diabetes-specific HL on HRQoL among elderly

1
2
3 individuals with prediabetes. Moreover, there is still a paucity of published studies on DSHL
4 and HRQoL among elderly individuals with prediabetes in rural areas in China.
5

6 Therefore, the purpose of our study was to investigate the situation of HRQoL and DSHL
7 among the elderly with prediabetes in rural areas in China. Moreover, we intended to explore
8 the association between DSHL and HRQoL. We hypothesized that elderly individuals with
9 prediabetes with sufficient DSHL would report higher HRQoL scores. We hope that this study
10 will contribute to the formulation of effective interventions to improve QoL and promote
11 diabetes prevention.
12
13

14 **Research design and methods**

15 **Study design**

16 This cross-sectional study was conducted in the rural areas of Yiyang City of Hunan Province
17 in China between April and July 2015. The study was registered at the Chinese Clinical Trial
18 Registry (trial registration number: ChiCTR-IOR-15007033). The study was approved by the
19 Medical Ethics Committee of Central South University (Changsha, China; Identification Code:
20 CTXY-150002-7; 27 February 2015). All participants signed the respective consent forms.
21
22

23 **Sample size**

24 Sample size was calculated using the formula for cross-sectional studies, as follows:
25

$$26 N = \frac{Z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

27 where $Z_{1-\alpha/2}^2=1.96$ when $\alpha=0.05$, p is the prevalence of prediabetes (which was 20% in this
28 study according to our presurvey), and d is an admissible error (which was 4%). According to
29 the formula, the theoretical sample size was 423, which included an extra 10% to allow for
30 subjects lost during the study.
31
32

33 **Participants**

34 Participants in this study were aged 60 years and older and were from the rural areas of
35 Yiyang City of Hunan Province. To select a representative sample of the elderly population
36 with prediabetes, a screening program was carried out among the elderly population in Yiyang
37 City. A multistage cluster randomized sampling method was used to select a representative
38 sample. In the first stage, two out of six counties were selected according to geographical
39 characteristics. In the second stage, 2 (Yangluozhou and Yinfengqiao) out of 11 townships and
40 2 (Qingshuzui and Maocaojie) out of 9 townships were randomly selected. In the third stage,
41 25% of the rural villages were randomly selected from each chosen township (each township
42 contains 30–50 villages). In the final stage, all households in each selected village with elderly
43 individuals who had lived in the area for 3 years or longer were eligible to participate in the
44 screening program. Those with severe physical and mental illness as well as diabetes were
45 excluded from the screening. An oral glucose tolerance test (OGTT) was used to distinguish
46 between prediabetes and normal plasma glucose. The diagnostic standards for prediabetes as
47 stated in the 1999 WHO criteria³² were (1) an IFG group with fasting plasma glucose of 6.1–
48 7.0 mmol/L and a 2-hour postglucose load of <7.8 mmol/L; (2) an IGT group with a 2-hour
49 postglucose load of 7.8–11.1 mmol/L and fasting plasma glucose of ≤6.1 mmol/L; and (3) an
50 IFG+IGT group.
51
52

53 More details of the study population and screening procedure have been published
54 elsewhere³³. In brief, 2144 elderly individuals took part in the screening program, and 461
55
56
57
58
59
60

1
2
3 elderly individuals had prediabetes. For various reasons, 21 of those with prediabetes
4 provided no response, and the response rate was 95.4%. Six more individuals had incomplete
5 data. Finally, a total of 434 individuals with prediabetes from 42 villages were included in this
6 study.
7

8 **Data collection**

9
10 Sociodemographic information was collected by trained staff using a set of structured
11 questionnaires, which included age, gender, education, marital status, presence of other
12 chronic diseases, history of hyperglycemia, family history of diabetes, physical activity,
13 smoking and alcohol drinking. Marital status was classified as married and nonmarried.
14 Nonmarried status included divorced, never married, lost a partner and living together
15 without a marriage certificate. Chronic diseases included hypertension, coronary heart disease,
16 dyslipidemia and others. History of hyperglycemia was defined as a situation of fasting
17 glucose >6.1 mmol/L or 2-hour glucose >7.8 mmol/L without a diagnosis of diabetes. Physical
18 activity was assessed using the International Physical Activity Questionnaire-long version
19 (IPAQ), and individuals who achieved ≥ 600 MET-min/week were categorized as active³⁴.
20 Smoking was defined as averaging one or more cigarettes in the last year. Alcohol drinking
21 was defined as drinking a glass of wine (approximately 250 mL beer or 100 mL sake or 20 mL
22 liquor).
23

24
25 Anthropometric measurements, including height, weight, blood pressure, waist
26 circumference and hip circumference, were assessed using a standard tool. The measurement
27 procedure was published in a previous study³⁵. Body mass index (BMI) was calculated using
28 the formula of weight in kilograms divided by height in m^2 (kg/m^2). The current Chinese
29 standard classification states that the cut-off values for normal weight, overweight and obesity
30 BMI are 18.5 kg/m^2 , 24.0 kg/m^2 and 28.0 kg/m^2 ³⁶, respectively. Hypertension was defined as
31 systolic blood pressure ≥ 140 mm Hg and/or diastolic blood pressure ≥ 90 mm Hg. The waist
32 to hip ratio (WHR) was calculated by dividing the waist circumference by the hip
33 circumference. A WHR >0.9 in men or >0.8 in women was defined as abnormal WHR³⁷.
34
35

36
37 DSHL was assessed using the Questionnaire of Health Literacy of Diabetes Mellitus of the
38 Public in China designed by the Chinese Center for Health Education³⁸. This questionnaire
39 has high reliability and validity, with a Cronbach's α of 0.866 ³⁵. The questionnaire is
40 organized into three main domains: diabetes-related knowledge, diabetes-related behavior,
41 and acquisition and utilization of diabetes information. The diabetes-related knowledge
42 section assessed attitudes toward diabetes, typical symptoms of diabetes, complications of
43 diabetes, factors conferring a high risk of developing diabetes and methods to prevent
44 diabetes. The diabetes-related behaviors included sitting time duration, physical exercise,
45 dietary pattern, physical examination, and smoking and alcohol drinking habits. In the part
46 about the acquisition and utilization of diabetes information, the participants were asked
47 about the method or way to find diabetes-related information, the degree of their acquisition
48 of diabetes-related information and their ability to identify the correctness of diabetes-related
49 information. An alternative classification was used where the scores 19.5 points and above
50 were classified as adequate DSHL and remaining classified as inadequate³⁸.
51
52

53
54 HRQoL was assessed using the Medical Outcomes Study 36-Item Short Form Health
55 Survey (SF-36). The SF-36 health survey questionnaire has been translated and validated in
56 Chinese, and the Chinese version has been proven to be reliable and valid in an elderly
57
58
59
60

population³⁹. This 36-item measure is organized into eight domains that constitute two main components: the physical health component and the mental health component. The physical health component includes four parts: physical functioning (PF), role physical (RP), bodily pain (BP) and general health (GH). Vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH) are included in the mental health component. The eight domains were scored from 0 to 100, indicating the worst to best possible health. Each domain score was further summarized and standardized into the physical component score (PCS) and the mental component score (MCS) according to American norms to allow for international comparisons⁴⁰.

Data analysis

Data were presented as n (%) for categorical variables and mean±SD or median (P₂₅-P₇₅) for numerical variables. Nonparametric tests were used because the distribution of the DSHL scores was non-Gaussian. The Mann-Whitney U test or Kruskal-Wallis test was used to identify the differences in total DSHL scores according to different variables. The *t*-test or one-way variance (ANOVA) was used to compare the differences in the scores for different domains of HRQoL. General linear models of multivariate analysis of covariance (MANCOVA) were used to test differences in HRQoL between the adequate DSHL group and the inadequate group. Sociodemographic and anthropometric variables were treated as possible covariates. A significant MANCOVA was followed by univariate *F*-tests using the Wilks' λ statistic. Linear independent pairwise comparisons were analyzed to examine the magnitude of the difference in the mean scores of the dependent variables. Effect sizes (*d*) were computed by dividing the difference in means between groups by the pooled SD and were interpreted as small ($d \leq 0.20$), medium ($0.2 < d \leq 0.50$) or large ($0.5 < d \leq 0.80$)⁴¹. The data were analyzed using SPSS Version.20.0 (SPSS/IBM, Armonk, New York, USA).

Results

DSHL score

A total of 461 elderly individuals had prediabetes, and the prevalence of prediabetes was 21.5% (461/2144) in rural areas of Yiyang City. In total, 434 elderly individuals with prediabetes were included in this study. The average age of all participants was 69.4±6.4 years. The average fasting plasma glucose was 5.9±0.5 mmol/L, and the average 2-hour plasma glucose load was 7.2±1.9 mmol/L. A majority of the subjects were female, had completed less than 6 years of education, smoked, drank no alcohol and had no hypertension. The characteristics of the study subjects are shown in Table 1.

The overall median DSHL score was 10.0 (IQR 7.0-13.0). A total of 53 (12.2%) subjects with prediabetes had adequate DSHL. Men had lower HL scores than women. Furthermore, married elderly individuals had higher DSHL scores than nonmarried individuals. Individuals with a history of hyperglycemia had a higher DSHL score than people with no history. Similarly, individuals with prediabetes who had completed 6 years or more of education had a higher score than those who had completed less than 6 years. The DSHL score according to different characteristics is presented in Table 1.

Table 1 The DSHL score according to different characteristics

Characteristics	n (%)	DSHL score [†]	P-value [‡]
Age			

60-70 years	239 (55.1)	10.0 (8.0-15.0)	0.461
70 years and older	195 (45.9)	10.0 (7.5-11.0)	
Gender			
Male	180 (41.5)	9.0 (7.0-12.0)	<0.001
Female	254 (58.5)	11.0 (8.0-13.0)	
Marital status			
Married	312 (71.9)	10.0 (7.0-13.0)	0.044
Nonmarried	122 (28.1)	9.0 (7.0-11.0)	
Education			
Less than 6 years	353 (83.3)	9.0 (6.5-12.0)	<0.001
6 years and more	81 (18.7)	12.0 (9.0-16.0)	
History of hyperglycemia			
Yes	28 (6.5)	12.5 (9.3-20.5)	0.001
No	406 (93.5)	9.0 (7.0-12.0)	
Family history of diabetes			
Yes	36 (8.3)	12.0 (7.0-13.8)	0.165
No	398 (91.7)	10.0 (7.0-12.0)	
Have other chronic disease			
Yes	176 (40.6)	10.0 (7.0-13.0)	0.544
No	258 (59.4)	10.0 (7.0-13.0)	
Physical activity			
Active	182 (41.9)	10.5 (8.0-13.5)	0.227
Inactive	252 (58.1)	9.5 (8.0-13.0)	
Smoking			
Yes	237 (54.6)	10.0 (8.0-12.0)	0.525
No	197 (45.4)	10.0 (8.0-13.0)	
Alcohol drinking			
Yes	98 (22.6)	10.0 (8.0-12.0)	0.308
No	336 (77.4)	10.0 (7.5-13.0)	
BMI			
Lean	17 (3.9)	9.0 (5.5-13.5)	0.547
Normal	233 (53.7)	9.0 (7.0-13.0)	
Overweight	129 (29.7)	10.0 (7.0-12.0)	
Obese	55 (12.7)	10.0 (7.0-13.0)	
Hypertension			
Yes	173 (39.9)	10.5 (8.5-13.0)	0.256
No	261 (61.1)	9.5 (8.0-12.0)	
WHR			
Normal	77 (17.7)	9.0 (7.0-12.0)	0.074
Abnormal	357 (82.3)	10.0 (7.0-13.0)	

DSHL, diabetes-specific health literacy

†Data are presented as the median (P₂₅-P₇₅)

*P value was determined by Kruskal-Wallis test or Mann-Whitney U test.

BMI, body mass index; WHR, waist to hip ratio

Health-related quality of life score

Individuals with prediabetes reported a PCS of 42.1 points (95%CI: 41.2, 43.1) and an MCS of 46.4 points (95%CI: 45.5, 47.1). The PCS of the four domains were 76.1±23.4, 71.4±42.4, 75.7±15.9 and 57.8±21.5, and the MCS of the four domains were 72.2±18.1, 79.7±17.1, 85.1±33.3 and 74.8±17.5. The means and their SDs for eight subscales of HRQoL scores according to different characteristics are shown in Table 2. Neither domain score showed a significant difference for the variables of gender, family history of diabetes or alcohol drinking (All $P > 0.05$). The BP and GH scores were lower among people aged 70 years and older. The MH score was lower among people who were not married. Individuals with prediabetes who had completed 6 years of education or more had higher SF and RE scores than people educated 1-6 years. Individuals who achieved active physical activity seemed to have higher scores in the PF, BP and GH domains. The RP, GH and RE scores were similarly higher among elderly people with normal BMI. Moreover, individuals with normal WHR had higher BP, SF and RE scores.

Table 2 HRQoL scores of eight domains measured by SF-36

Characteristics	Physical Health Components				Mental Health Components			
	PF	RP	BP	GH	VT	SF	RE	MH
Overall	76.1±23.4	71.4±42.4	75.7±15.9	57.8±21.5	72.2±18.1	79.7±17.1	85.1±33.3	74.8±17.5
Age								
60-70 years	76.9±23.5	74.1±41.6	77.4±16.6*	60.0±21.5*	72.9±17.7	80.5±16.6	87.2±31.1	75.7±17.4
70 years and older	74.9±23.1	67.2±43.4	73.1±14.4*	54.8±21.1*	71.1±18.8	78.5±17.8	82.0±36.3	73.4±17.7
Gender								
Male	75.8±23.4	73.3±41.4	74.9±16.5	58.5±20.7	72.5±18.3	80.7±16.3	86.0±32.3	74.2±18.5
Female	76.3±23.4	70.1±43.2	76.3±15.5	57.2±22.1	72.0±18.0	79.0±17.6	84.5±34.0	75.2±16.9
Marital status								
Married	75.6±23.9	73.2±42.2	75.3±16.3	58.8±21.6	73.0±18.1	79.7±16.9	85.4±33.2	76.0±16.9*
Nonmarried	77.5±21.8	66.6±42.9	76.7±14.9	54.9±20.8	69.9±18.1	79.8±17.7	84.4±33.6	71.4±18.8*
Education								
Less than 6 years	75.9±23.6	71.0±42.7	75.7±15.7	57.4±21.5	71.5±18.5	78.8±16.9*	83.1±34.9*	74.4±17.6
6 years and more	76.9±22.8	73.3±41.4	75.7±16.7	59.1±21.4	75.0±16.3	83.2±17.5*	93.1±24.5*	76.3±17.2
History of hyperglycemia								
Yes	75.9±23.5	67.9±43.3	73.2±12.9	51.2±30.1*	64.0±20.9*	76.0±17.3	80.9±36.6	69.2±19.9
No	77.2±22.5	71.9±42.3	76.0±16.2	58.5±20.3*	73.2±17.5*	80.2±17.0	85.7±32.9	75.5±17.1
Family history of diabetes								
Yes	75.7±23.9	72.9±42.3	75.2±16.2	58.4±21.9	72.7±18.2	79.5±16.8	84.5±34.0	75.6±17.2
No	77.2±22.1	67.5±42.5	77.1±15.0	55.9±20.3	70.8±17.8	80.3±17.9	86.8±31.4	72.6±18.4
Other chronic disease								
Yes	72.9±24.1*	72.0±42.6	71.7±16.2*	56.7±20.5	71.9±18.0	78.7±17.1	84.8±33.5	74.0±18.3
No	78.1±22.7*	71.1±42.4	78.1±15.2*	58.4±22.1	72.4±18.2	80.3±17.1	85.3±33.2	75.3±17.0
Physical activity								
Active	80.4±24.5*	72.9±42.8	78.5±17.2*	61.6±21.8*	73.8±16.4	80.9±18.3	90.1±28.0	76.3±16.4
Inactive	74.5±23.7*	70.9±42.3	74.6±15.3*	56.3±21.2*	71.6±18.7	79.2±16.6	83.3±34.9	74.2±17.9

Smoking								
Yes	76.2±24.2	70.1±43.2	75.3±16.3	57.2±21.4	71.9±18.1	78.1±17.8*	85.0±33.8	73.8±17.4
No	75.9±22.4	73.0±41.5	76.1±15.5	58.5±21.5	72.6±18.2	81.7±16.1*	85.4±32.8	75.9±17.7
Alcohol drinking								
Yes	76.3±23.1	71.1±42.7	75.3±15.7	57.7±21.4	72.7±18.0	79.6±16.9	84.0±34.5	74.8±17.4
No	75.4±24.5	72.4±41.5	76.8±16.7	57.9±21.7	70.4±18.6	80.1±17.9	89.1±28.6	74.5±18.0
BMI								
Lean	79.1±25.4	60.9±45.7*	73.9±13.4	53.7±23.5*	65.6±17.7	78.7±16.0	78.3±39.7*	69.2±20.7
Normal	76.7±22.8	77.0±39.6*	76.1±16.0	59.9±20.3*	73.7±18.0	81.2±17.1	89.2±28.5*	75.7±17.3
Overweight	75.1±24.5	76.6±39.2*	76.2±15.3	57.7±21.5*	70.7±18.8	78.7±17.5	82.6±36.2*	73.9±16.9
Obese	74.1±23.2	47.0±47.2*	73.9±17.4	51.6±23.9*	71.1±17.3	76.0±16.3	76.1±40.5*	74.4±18.0
Hypertension								
Yes	78.0±22.9*	66.9±44.4	75.3±17.1	55.5±23.8	71.0±18.7	77.8±17.5	78.5±38.0*	74.7±17.7
No	73.1±23.8*	74.3±40.9	75.9±15.1	59.2±19.8	73.0±17.9	80.9±16.7	89.4±29.2*	74.8±17.5
WHR								
Normal	77.3±23.5	72.8±41.6	78.4±17.1*	59.2±21.6	72.8±18.3	81.6±15.8*	88.1±29.8*	76.0±17.6
Abnormal	74.4±23.2	69.4±43.6	71.8±13.1*	55.8±21.2	71.4±17.8	76.9±18.4*	80.9±37.5*	73.1±17.4

Data are presented as the mean±SD, and analysis was performed using analysis of variance (ANOVA) or t-test. * $P<0.05$; PF, physical functioning; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health

Association between DSHL and HRQoL

Crude analysis indicated that when the eight subscales of HRQoL were placed as the dependent variables and DSHL (as a binary variable) was entered as the independent variable, the overall MANCOVA showed significant differences in the general health, vitality, social functioning and mental health scores between the two groups (Wilk's $\lambda=0.955$, $F=2.44$, $P=0.014$). After adjusting for other covariants, individuals with adequate DSHL reported higher scores on GH ($M_{diff}=6.8$, $P=0.028$), VT ($M_{diff}=6.6$, $P=0.014$), SF ($M_{diff}=6.0$, $P=0.017$) and MH ($M_{diff}=7.4$, $P=0.005$) than did those with inadequate DSHL. The associations between DSHL and different domains of HRQoL are shown in Table 3.

Crude analysis showed that with two components of HRQoL entered as dependent variables, the overall MANCOVA was significant (Wilks' $\lambda=0.965$, $F=7.87$, $P<0.001$). Individuals with adequate DSHL had higher PCS ($M_{diff}=2.9$, $ES=0.30$) and MCS ($M_{diff}=4.4$, $ES=0.47$) than those with inadequate HL after adjusting for age, gender, education, marital status, other chronic diseases, family history of diabetes, history of hyperglycemia, physical activity, hypertension, smoking, drinking, BMI and WHR. A linear independent pairwise comparison indicated that individuals with prediabetes who had higher DSHL reported higher MCS ($M_{diff}=3.5$, 95%CI: 1.8, 6.3) with a medium effect size ($ES=0.38$). The association between DSHL and HRQoL among elderly individuals with prediabetes is shown in Table 4.

Table 3 Association between DSHL and different subscales of HRQoL among elderly individuals with prediabetes

Sf-36 domains	Adequate DSHL		Inadequate DSHL		Difference		
	Mean	SE	Mean	SE	M_{diff} (95%CI)	ES(<i>d</i>)	<i>P</i> -value

Crude analysis (Wilk's $\lambda=0.955$, $F=2.44$, $P=0.014$)								
PF	80.0	3.2	75.5	1.2	4.6 (-2.3,11.2)	0.20	0.193	
RP	74.5	5.8	70.9	2.3	3.5 (-5.7,15.4)	0.08	0.224	
BP	78.9	2.2	75.2	0.8	3.7 (-1.8, 8.3)	0.23	0.110	
GH	64.5	2.9	56.8	1.1	7.6 (1.6,13.7)	0.38	0.013	
VT	78.9	2.5	71.3	0.9	7.5 (2.4,12.8)	0.42	0.004	
SF	86.0	2.3	78.8	0.9	7.2 (2.4,12.1)	0.43	0.001	
RE	91.2	4.6	84.3	1.7	6.9 (-2.7,16.5)	0.21	0.158	
MH	81.8	2.4	73.8	0.9	8.0 (3.0,13.0)	0.46	0.002	
Adjusted analysis (Wilk's $\lambda=0.958$, $F=2.31$, $P=0.019$) [†]								
PF	79.6	3.2	75.6	1.2	4.0 (-2.8,10.8)	0.17	0.252	
RP	73.1	5.9	71.2	2.1	1.9 (-6.7,14.2)	0.07	0.186	
BP	78.4	2.1	75.3	0.8	3.1 (-1.2,7.5)	0.19	0.161	
GH	63.7	2.9	56.9	1.1	6.8 (1.7,12.9)	0.33	0.028	
VT	78.0	2.5	71.4	0.9	6.6 (1.3,11.8)	0.37	0.014	
SF	84.9	2.3	79.0	0.9	6.0 (1.1,10.9)	0.36	0.017	
RE	88.0	4.6	84.7	1.7	3.4 (-6.2,12.9)	0.10	0.492	
MH	81.2	2.4	73.9	0.9	7.4 (2.3,12.5)	0.43	0.005	

DSHL, diabetes-specific health literacy; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

[†] Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

M_{diff}, mean difference; ES(d), mean difference/pooled SD.

Table 4 Association between DSHL and HRQoL among elderly individuals with prediabetes

Variables	Adequate DSHL		Inadequate DSHL		Difference		
	Mean	SE	Mean	SE	M _{diff} (95%CI)	ES (d)	P-value
Crude analysis (Wilks' $\lambda=0.965$, $F=7.87$, $P<0.001$)							
PCS	44.6	1.3	41.7	0.5	2.9 (1.4,5.7)	0.30	0.046
MCS	50.2	1.3	45.8	0.5	4.4 (1.7,7.1)	0.47	0.001
Adjusted analysis (Wilks' $\lambda=0.974$, $F=5.63$, $P=0.004$) [†]							
PCS	44.4	1.3	41.8	0.6	2.6 (-1.2,5.4)	0.27	0.067
MCS	49.4	1.3	45.9	0.7	3.5 (1.8, 6.3)	0.38	0.012

DSHL, diabetes-specific health literacy; M_{diff}, mean difference; ES (d), mean difference/pooled SD; PCS, physical component summary score; MCS, mental component summary score.

[†]Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

Discussion

This cross-sectional study showed a high prevalence (21.5%) of prediabetes among the elderly population in rural areas in China, which is similar to the findings of the earlier study⁴². The results, together with the large population living in rural areas, suggest that this serious public health problem in China requires better prevention.

1
2
3 Many studies have used general HL measurement instruments, such as REALM or
4 TOFHLA, which are not disease or condition-specific. However, the literature lacked valid
5 tools for the measurement of disease-specific HL. Fortunately, an increasing number of
6 studies have developed a series of new assessment instruments for DSHL^{43 44}. Therefore, our
7 study used a DSHL questionnaire with high reliability and validity that was designed by the
8 Chinese Center for Health Education. The questionnaire was able to effectively examine the
9 level of HL about diabetes knowledge, diabetes preventive behaviors and the acquisition and
10 utilization of diabetes information among individuals with prediabetes^{35 38}. The results of this
11 study indicated that the DSHL among elderly individuals with prediabetes in rural areas is
12 relatively low. Only 12.2% of subjects have sufficient DSHL, which was similar to the results
13 using the same questionnaire administered previously to 4282 residents aged 18–60 years in
14 China³⁸. Furthermore, based on the results of the univariate analysis, the DSHL score showed
15 significant differences in the variables of gender, education and history of hyperglycemia,
16 which are consistent with the findings of other studies^{45 46}.

17
18
19
20
21 Although the effect of HL on HRQoL has been widely discussed among some populations
22 in previous studies⁴⁷⁻⁴⁹, few studies have explored the association between HL and HRQoL
23 among individuals with prediabetes. There is also a lack of research probing the effect of
24 disease- or condition-specific HL on HRQoL. To our knowledge, this is the first study to
25 examine the relationship between DSHL and HRQoL among elderly individuals with
26 prediabetes. The results of this analysis partially support the research hypotheses. DSHL was
27 positively associated with mental well-being of HRQoL according to bivariate and
28 multivariate analyses. Compared with individuals with prediabetes with lower HL levels,
29 subjects with higher HL had better mental well-being (SF-36 MCS), especially in the VT, SF
30 and MH subscales. However, the relationship between HL levels and physical well-being
31 (SF36-PCS) was significant only in the bivariate model and became nonsignificant after
32 controlling for sociodemographic and somatometric covariates. More specifically, the elderly
33 with prediabetes who had sufficient diabetes-specific HL reported higher MCS scores
34 ($M_{diff}=3.5$, 95%CI: 1.8, 6.3) than did the participants with insufficient HL after controlling for
35 other confounders. These results are in concordance with those of previous studies that
36 targeted the relationship between general HL and HRQoL⁵⁰⁻⁵³. For instance, a cohort study
37 of type 2 diabetes demonstrated that patients with adequate HL had a 2.1-point increase in
38 PCS and a 3.1-point increase in MCS compared to those with inadequate HL⁵¹. In another
39 study, Jayasinghe and her colleagues found that HL accounted for 45% and 70% of the total
40 between-patient variance explained in PCS-12 and MCS-12, respectively⁷. Furthermore, a
41 study conducted in 605 patients with symptomatic heart failure (HF) showed that those with
42 adequate literacy had better HRQoL scores (mean difference=7.2, $P<0.01$) than did those with
43 low literacy⁵². A cross-sectional survey of 1841 cancer patients in Wisconsin also indicated
44 that higher HL was positively associated with the physical, functional, emotional, and social
45 well-being subscales of HRQoL⁵³. However, our results also contradict the findings of
46 previous studies that examined the association^{27-29 54-56}. Data from a clinical trial that included
47 154 predominantly white patients with type 2 diabetes who screened positive for depression
48 showed that the between-HL group difference in change over 1 year was only nonsignificant at
49 0.76 points for PCS and 0.56 points for MCS²⁷. In another study conducted among frequent
50 users of health care services, no association was found between HL and QoL on both PCS and
51
52
53
54
55
56
57
58
59
60

1
2
3 MCS⁵⁵. Two other studies^{29 54} demonstrated that HL was not significantly associated with
4 only the mental component of HRQoL. A prospective cohort study of 4278 older adults in the
5 UK showed that low HL significantly predicted declines in the physical, psychological and
6 environmental domains of QoL but not in the social relationship QoL⁵⁶. There are three
7 reasons for this variance. First, most studies pay attention to the impact of general HL rather
8 than specific HL on QoL. However, general HL includes the ability to obtain, process and
9 understand all basic health information, not just a specific disease. Secondly, the various
10 studies used different measurement tools of HL and HRQoL. Lastly, the contradictory results
11 were also likely due to differences in the study populations and sample size.

12
13
14
15 These results suggest that individuals with newly diagnosed prediabetes who have higher
16 levels of DSHL may have higher HRQoL, especially for the mental health component. A
17 potential explanation for the relationship between DSHL and the physical and mental
18 components of HRQoL may be that low DSHL limits individuals' understanding of complex
19 information about diabetes knowledge, prevention, diagnosis and treatment and thus
20 becomes a barrier to individuals' participation in medical processes. Moreover, people with
21 lower HL tend to have difficulty communicating, which prevents them from asking questions,
22 clearly expressing their concerns, emotions, and needs to providers and seeking additional
23 services, such as support for mental health^{50 53}. As we discussed previously, individuals with
24 inadequate DSHL may have difficulties obtaining or/and understanding diabetes knowledge,
25 be slower to adopt positive diabetes prevention behaviors and lack the approach of seeking
26 diabetes care information. Furthermore, as a previous study found that subjects with low
27 literacy were 3 times more likely to have depression⁵⁴, insufficient DSHL may further limit the
28 patient's ability to talk with their families and health care providers about difficult emotional
29 issues or abstract psychosocial implications of diabetes. Individuals with lower levels of DSHL
30 may not have knowledge of signs or symptoms of concern and may experience a psychological
31 panic, reducing the MCS of HRQoL. Furthermore, the finding that DSHL is associated with
32 changes in HRQoL outcomes in the prediabetes population raises the need for testing the
33 hypothesis of whether DSHL is a modifiable factor and, if so, considering whether
34 interventions aimed at improving DSHL through health education also lead to improvement
35 in HRQoL in this population. To date, there is no evidence on whether HL is a modifiable
36 factor, but many studies that address DSHL may play a key role in health promotion and
37 improve glycemia outcome⁵⁷.

38
39
40
41
42
43
44
45 Our study also revealed that individuals with prediabetes showed lower PCS than MCS,
46 and the mean scores of the four domains of the mental health components were likewise
47 higher than those of four subscales of the physical health components, which was consistent
48 with the findings of other studies^{58 59}. One explanation is that some elderly have difficulties in
49 physical activities due to illness. A study has also shown that chronic diseases have a stronger
50 effect on reducing physical function than psychological function⁶⁰. Similar to the results of our
51 study, elderly individuals with chronic disease, overweight or obesity and physical inactivity
52 have lower scores on the subscales of physical function, bodily pain and general health;
53 however, these domains are components of the physical health aspect of HRQoL.

54
55
56
57 Our study also has several limitations. First, its cross-sectional design did not permit
58 causal inferences. Furthermore, both cohort studies and randomized controlled trial designs
59 garner a deeper understanding of the relationship between DSHL and HRQoL. Second, HL
60

1
2
3 was measured using the public questionnaire of HL of diabetes mellitus. This may influence
4 the way in which our study may be compared to previous studies, the majority of which
5 measured multidimensional competences rather than a single competence of functional HL.
6 However, the definition and measurement of disease-specific HL are evolving and diverse
7 across countries. Third, self-administered questionnaires were used to assess HL and HRQoL.
8 Thus, inaccurate estimation and recall bias were inevitable. However, this limitation was
9 minimized because both instruments used in this study are valid and reliable. Lastly, the
10 effect size between HL and HRQoL may be underestimated due to the “over adjustment” for
11 confounders.
12
13

14 **Conclusions**

15
16 In summary, inadequate DSHL was associated with lower HRQoL among elderly
17 individuals with prediabetes in rural areas in China, particularly in mental health components,
18 although the difference could be considered small after accounting for sociodemographic and
19 anthropometric characteristics. These findings suggest that assessing and improving DSHL
20 may be important in individuals with prediabetes.
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Acknowledgements

We thank all the participants very much for their collaboration.

Author contributions

ZH and LQ completed the statistical analyses and drafted the manuscript. HLX checked and revised the manuscript. All authors read and approved the final manuscript.

Funding

This study was funded by the Teachers Research Found of Central South University (2013JSJJ034) and the Central South University Graduate Student Independent Exploration Innovation Project (NO.2013zzts286).

Competing interests

None declared.

Patient consent

Obtained.

Ethical approval

The study was approved by the Medical Ethics Committee of Central South University (Changsha, China; Identification Code: CTXY-150002-7; 27 February 2015).

Data sharing statement

No additional data are available.

References

1. Punthakee Z, Goldenberg R, Katz P. Definition, Classification and Diagnosis of Diabetes, Prediabetes and Metabolic Syndrome. *Canadian journal of diabetes* 2018;42 Suppl 1:S10-s15
2. Perreault L, Pan Q, Mather KJ, et al. Effect of regression from prediabetes to normal glucose regulation on long-term reduction in diabetes risk: results from the Diabetes Prevention Program Outcomes Study. *Lancet (London, England)* 2012;379:2243-51
3. de Vegt F, Dekker JM, Jager A, et al. Relation of impaired fasting and postload glucose with incident type 2 diabetes in a Dutch population: The Hoorn Study. *Jama* 2001;285:2109-13
4. Forouhi NG, Luan J, Hennings S, et al. Incidence of Type 2 diabetes in England and its association with baseline impaired fasting glucose: the Ely study 1990-2000. *Diabetic medicine : a journal of the British Diabetic Association* 2007;24:200-7
5. Nathan DM, Davidson MB, DeFronzo RA, et al. Impaired fasting glucose and impaired glucose tolerance: implications for care. *Diabetes care* 2007;30:753-9
6. Wang HM, Beyer M, Gensichen J, et al. Health-related quality of life among general practice patients with differing chronic diseases in Germany: cross sectional survey. *BMC public health* 2008;8:246
7. Jayasinghe UW, Harris MF, Parker SM, et al. The impact of health literacy and life style risk factors on health-related quality of life of Australian patients. *Health and quality of life outcomes* 2016;14:68
8. Keles H, Ekici A, Ekici M, et al. Effect of chronic diseases and associated psychological distress on health-related quality of life. *Internal medicine journal* 2007;37:6-11
9. Alfonso-Rosa RM, Del Pozo-Cruz B, Del Pozo-Cruz J, et al. The relationship between nutritional status, functional capacity, and health-related quality of life in older adults with type 2 diabetes: a pilot explanatory study. *The journal of nutrition, health & aging* 2013;17:315-21
10. Tapp RJ, Dunstan DW, Phillips P, et al. Association between impaired glucose metabolism and quality of life: results from the Australian diabetes obesity and lifestyle study. *Diabetes research and clinical practice* 2006;74:154-61
11. Ghorbani A, Ziaee A, Esmailzadehha N, et al. Association between health-related quality of life and impaired glucose metabolism in Iran: the Qazvin Metabolic Diseases Study. *Diabetic medicine : a journal of the British Diabetic Association* 2014;31:754-8
12. Hunger M, Holle R, Meisinger C, et al. Longitudinal changes in health-related quality of life in normal glucose tolerance, prediabetes and type 2 diabetes: results from the KORA S4/F4 cohort study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2014;23:2515-20
13. Lam CL, Fong DY, Lauder IJ, et al. The effect of health-related quality of life (HRQOL) on health service utilisation of a Chinese population. *Social science & medicine (1982)* 2002;55:1635-46
14. Chen T, Li L. Influence of health-related quality of life on health service utilization in addition to socio-demographic and morbidity variables among primary care patients in China. *International journal of public health* 2009;54:325-32
15. Alonso J, Ferrer M, Gandek B, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2004;13:283-98

16. Berkman ND, Davis TC, McCormack L. Health literacy: what is it? *Journal of health communication* 2010;15 Suppl 2:9-19
17. Gazmararian JA, Williams MV, Peel J, et al. Health literacy and knowledge of chronic disease. *Patient education and counseling* 2003;51:267-75
18. Bennett IM, Chen J, Soroui JS, et al. The contribution of health literacy to disparities in self-rated health status and preventive health behaviors in older adults. *Ann Fam Med* 2009;7:204-11
19. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. *BMJ* 2012;344:e1602
20. Sarkar U, Karter AJ, Liu JY, et al. Hypoglycemia is more common among type 2 diabetes patients with limited health literacy: the Diabetes Study of Northern California (DISTANCE). *Journal of general internal medicine* 2010;25:962-8
21. Niknami M, Mirbalouchzahi A, Zareban I, et al. Association of health literacy with type 2 diabetes mellitus self-management and clinical outcomes within the primary care setting of Iran. *Australian journal of primary health* 2018;24:162-70
22. Institute of Medicine Committee on Health L. In: Nielsen-Bohlman L, Panzer AM, Kindig DA, eds. Health Literacy: A Prescription to End Confusion. Washington (DC): National Academies Press (US)
23. Copyright 2004 by the National Academy of Sciences. All rights reserved., 2004.
24. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes care* 2002;25:1159-71
25. Yamashita T, Kart CS. Is diabetes-specific health literacy associated with diabetes-related outcomes in older adults? *J Diabetes* 2011;3:138-46
26. Chen GD, Huang CN, Yang YS, et al. Patient perception of understanding health education and instructions has moderating effect on glycemic control. *BMC public health* 2014;14:683
27. Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes care* 2006;29:823-9
28. Al Sayah F, Majumdar SR, Johnson JA. Association of Inadequate Health Literacy with Health Outcomes in Patients with Type 2 Diabetes and Depression: Secondary Analysis of a Controlled Trial. *Canadian journal of diabetes* 2015;39:259-65
29. Naimi AJ, Naderiravesh N, Bayat ZS, et al. Correlation between health literacy and health-related quality of life in patients with hypertension, in Tehran, Iran, 2015-2016. *Electronic physician* 2017;9:5712-20
30. Gonzalez-Chica DA, Mnisi Z, Avery J, et al. Effect of Health Literacy on Quality of Life amongst Patients with Ischaemic Heart Disease in Australian General Practice. *PloS one* 2016;11:e0151079
31. Zheng M, Jin H, Shi N, et al. The relationship between health literacy and quality of life: a systematic review and meta-analysis. *Health and quality of life outcomes* 2018;16:201
32. Ran M, Peng L, Liu Q, et al. The association between quality of life(QOL) and health literacy among junior middle school students: a cross-sectional study. *BMC public health* 2018;18:1183
33. Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. *Diabetic medicine : a journal of the British Diabetic Association* 1998;15:539-53

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
33. Xu H, Tang L, Hu Z, et al. Association between physical activity and health-related quality of life in elderly individuals with pre-diabetes in rural Hunan Province, China: a cross-sectional study. *BMJ Open* 2018;8:e019836
 34. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *Jama* 1995;273:402-7
 35. Qin L, Xu H. A cross-sectional study of the effect of health literacy on diabetes prevention and control among elderly individuals with prediabetes in rural China. *BMJ Open* 2016;6:e011077
 36. Wu Y. Overweight and obesity in China. *Bmj* 2006;333:362-3
 37. Collaboration OI. Is central obesity a better discriminator of the risk of hypertension than body mass index in ethnically diverse populations? *Journal of hypertension* 2008;26:169-77
 38. Li L, Li Y, Nie X, et al. An analysis of health literacy about diabetes prevention and control and its influencing factors among the residents in six provinces in China. *Zhonghua yu fang yi xue za zhi [Chinese journal of preventive medicine]* 2014;48:561-5
 39. Zhou B, Chen K, Wang JF, et al. Reliability and validity of a Short-Form Health Survey Scale (SF-36), Chinese version used in an elderly population of Zhejiang province in China. *Zhonghua liu xing bing xue za zhi = Zhonghua liuxingbingxue zazhi* 2008;29:1193-8
 40. Ware J, Kosinski M, Keller S. SF-36 physical and mental health summary scales: a user's manual. 5th edn. Boston, MA: Health Assessment Lab. New England Medical Center, . 1994
 41. Cohen J. A power primer. *Psychological bulletin* 1992;112:155-9
 42. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *Jama* 2013;310:948-59
 43. Lee EH, Lee YW, Lee KW, et al. A new comprehensive diabetes health literacy scale: Development and psychometric evaluation. *International journal of nursing studies* 2018;88:1-8
 44. Yeh JZ, Wei CJ, Weng SF, et al. Disease-specific health literacy, disease knowledge, and adherence behavior among patients with type 2 diabetes in Taiwan. *BMC public health* 2018;18:1062
 45. Lutfiyya MN, Lipsky MS, Bales RW, et al. Disparities in knowledge of heart attack and stroke symptoms among adult men: an analysis of behavioral risk factor surveillance survey data. *Journal of the National Medical Association* 2008;100:1116-24
 46. Aihara Y, Minai J. Barriers and catalysts of nutrition literacy among elderly Japanese people. *Health promotion international* 2011;26:421-31
 47. Miller DB, Cage JL, Nowacki AS, et al. Health Literacy (HL) & Health-Related Quality of Life (HRQL) Among Minority Men. *Journal of the National Medical Association* 2018;110:124-29
 48. Montbleau KE, King D, Henault L, et al. Health literacy, health-related quality of life, and atrial fibrillation. *Cogent medicine* 2017;4:1412121
 49. Divaris K, Lee JY, Baker AD, et al. The relationship of oral health literacy with oral health-related quality of life in a multi-racial sample of low-income female caregivers. *Health and quality of life outcomes* 2011;9:108
 50. Song L, Mishel M, Bensen JT, et al. How does health literacy affect quality of life among men with newly diagnosed clinically localized prostate cancer? Findings from the North Carolina-Louisiana Prostate Cancer Project (PCaP). *Cancer* 2012;118:3842-51

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
51. Sayah FA, Qiu W, Johnson JA. Health literacy and health-related quality of life in adults with type 2 diabetes: a longitudinal study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2016;25:1487-94
 52. Macabasco-O'Connell A, DeWalt DA, Broucksou KA, et al. Relationship between literacy, knowledge, self-care behaviors, and heart failure-related quality of life among patients with heart failure. *Journal of general internal medicine* 2011;26:979-86
 53. Halverson JL, Martinez-Donate AP, Palta M, et al. Health Literacy and Health-Related Quality of Life Among a Population-Based Sample of Cancer Patients. *Journal of health communication* 2015;20:1320-9
 54. Lincoln A, Paasche-Orlow MK, Cheng DM, et al. Impact of health literacy on depressive symptoms and mental health-related: quality of life among adults with addiction. *Journal of general internal medicine* 2006;21:818-22
 55. Couture EM, Chouinard MC, Fortin M, et al. The relationship between health literacy and quality of life among frequent users of health care services: a cross-sectional study. *Health and quality of life outcomes* 2017;15:137
 56. Panagiotti M, Skevington SM, Hann M, et al. Effect of health literacy on the quality of life of older patients with long-term conditions: a large cohort study in UK general practice. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2018;27:1257-68
 57. Lee SJ, Song M, Im EO. Effect of a Health Literacy-Considered Diabetes Self-Management Program for Older Adults in South Korea. *Research in gerontological nursing* 2017;10:215-25
 58. Taylor LM, Spence JC, Raine K, et al. Physical activity and health-related quality of life in individuals with prediabetes. *Diabetes research and clinical practice* 2010;90:15-21
 59. Ibrahim N, Moy FM, Awalludin IA, et al. The health-related quality of life among pre-diabetics and its association with body mass index and physical activity in a semi-urban community in Malaysia--a cross sectional study. *BMC public health* 2014;14:298
 60. Cigolle CT, Langa KM, Kabeto MU, et al. Geriatric conditions and disability: the Health and Retirement Study. *Annals of internal medicine* 2007;147:156-64

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

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
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	NA
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	6

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA
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	6,7
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	NA
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	6
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	8,9,10
		(b) Report category boundaries when continuous variables were categorized	8,9,10
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
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	12,13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	14

*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.

BMJ Open

Association between diabetes-specific health literacy and health-related quality of life among elderly individuals with prediabetes in rural Hunan Province, China: A cross-sectional study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028648.R1
Article Type:	Research
Date Submitted by the Author:	09-Jul-2019
Complete List of Authors:	Zhao, Hu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management lulu, Qin; School of Medicine, Hunan Normal University, Department of Social Medicine and Health Management Huilan, Xu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Epidemiology, Diabetes and endocrinology
Keywords:	quality of life, health literacy, elderly, prediabetes

SCHOLARONE™
Manuscripts

1
2
3 Association between diabetes-specific health literacy and health-related quality of life
4 among elderly individuals with prediabetes in rural Hunan Province, China: A
5 cross-sectional study
6
7

8 Zhao Hu¹, Lulu Qin², Huilan Xu^{1,*}

9
10 1 Department of Social Medicine and Health Management, Xiangya School of Public
11 Health, Central South University, Changsha, 410078, China(15200807487@163.com)

12 2 Department of Social Medicine and Health Management, School of Medicine, Hunan
13 Normal University, Changsha, 410013, China(qinlulu_1989@sina.com)

14 *Correspondence: Huilan Xu, E-mail: xhl6363@sina.com; Tel./Fax: +86-731-8480-5459
15
16

17 ABSTRACT

18
19 **Objectives** To examine the association between diabetes-specific health literacy (DSHL)
20 and health-related quality of life (HRQoL) among elderly individuals with prediabetes in rural
21 China.
22

23 **Design, setting and participants** A cross-sectional study included 434 elderly individuals
24 with prediabetes from 42 villages in rural China.
25

26 **Main outcome measures** HRQoL was assessed using the Medical Outcomes Study
27 36-Item Short Form Health Survey (SF-36). DSHL was measured by a validated questionnaire
28 in China. Differences in HRQoL between groups with and without adequate DSHL were tested
29 by multivariate analysis of covariance (MANCOVA).
30

31 **Results** The prevalence of prediabetes was 21.5%. The average age of participants (n=434)
32 was 69.4±6.4 years, and 58.5% were female. Bivariate analysis showed that those with high
33 DSHL had increases of 2.9 points in the physical health component score (PCS) and 4.4 points
34 in the mental health component score (MCS) compared to those without. After adjustment for
35 potential confounders, a significant MANCOVA model (Wilks'λ=0.974, F=5.63, P=0.004)
36 indicated that individuals with prediabetes who had high DSHL reported higher MCS
37 (M_{diff}=3.5, 95%CI: 1.8, 6.3, effect size=0.38). This remained significant across subscales:
38 general health (P=0.028), vitality (P=0.014), social functioning (P=0.017) and mental health
39 (P=0.005).
40
41

42 **Conclusions** Low DSHL was associated with worsening HRQoL among elderly individuals
43 with prediabetes in rural China, particularly in the mental health components.
44

45 **Keywords** quality of life; health literacy; elderly; prediabetes

46 **Trial registration number** ChiCTR-IOR-15007033
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Article summary

Strengths and limitations of this study

- This is the first study to examine the association between health-related quality of life (HRQoL) and diabetes-specific health literacy among elderly individuals with pre-diabetes in rural China.
- The study provides valuable information on HRQoL among elderly with prediabetes in rural areas in China.
- The association between HRQoL and DSHL is analysed from eight domains, as well as from the physical health component and the mental health component, making the results more comprehensive.
- The cross-sectional study design makes causal relationships undeterminable.

For peer review only

Introduction

Prediabetes describes individuals who have impaired fasting glucose (IFG) or/and impaired glucose tolerance (IGT)¹. Several studies have identified that individuals with prediabetes have a high risk of developing diabetes, and the occurrence increases with age²⁻⁴. Approximately 5%–10% of people with prediabetes become diabetic annually, although the progression rate varies by population and the definition of prediabetes^{5 6}. In China, the estimated prevalence of prediabetes was 35.7% in adults and 45.8% in the elderly population in 2013⁷. Therefore, people with prediabetes especially for elderly are an important target group for interventions intended to prevent diabetes.

Health-related quality of life (HRQoL) is a comprehensive and multidimensional condition that refers to an individual's perceived physical and mental health under the influence of illness, injury and treatment over time^{8 9}. Several studies have demonstrated that many risk factors, such as smoking, chronic diseases, poor diet, insufficient physical activity, and overweight, lead to lower HRQoL¹⁰⁻¹². Because biomedical measures sometimes may not sensitively indicate the deterioration or improvement in symptoms and health status, HRQoL has been increasingly incorporated as a complementary and essential outcome measure in medical interventions and population health surveys to assess changes in physical, mental, social and well-being of these individuals. Studies have found that the HRQoL is usually impaired in individuals with prediabetes compared to healthy population; additionally, individuals with prediabetes progressing to diabetes suffer from a great loss in HRQoL¹³⁻¹⁵. Moreover, HRQoL affects both the entry and subsequent utilization of health services and the cost of health care in China^{16 17}. Thus, assessing HRQoL in the intermediate period between normal plasma glucose and type 2 diabetes is important, because the concept has a broader definition that enables us to fully understand both the somatic and emotional health status of individuals with prediabetes and consequently create interventions to improve it, especially by relieving pain, malaise and consequences of diseases¹⁸.

Health literacy (HL) is the degree to which individuals have the capacity to obtain, process and understand the basic health information and service need to make informed health decision¹⁹. Over the past decades, a growing body of research suggests that inadequate HL is associated with adverse health outcomes, such as poor self-rated health, misunderstandings about medical conditions and increased mortality risk²⁰⁻²². However, HL is arguably a broad multidimensional concept that serves as a bridge between literacy skills and abilities and the illness context in which individuals find themselves²³. Clearly, some dimensions of literacy skills and abilities are generalizable across all health populations. However, in the presence of a specific illness context, some disease-specific HL would seem necessary for successful self-management of that disease. For example, diabetes-specific HL (DSHL) is particularly salient in the assessment of self-care for type 2 diabetes in adults²⁴. Nevertheless, there is no clear definition of DSHL in the current literature. In general, DSHL represents the ability to obtain and understand diabetes-related information and to make informed diabetes care decisions. A study demonstrated that DSHL was positively associated with self-graded assessment of diabetes care²⁵. Some studies have indicated that DSHL is associated with diabetes-related knowledge, diabetes-care behaviors and glycemic control^{26 27}.

Several studies have evaluated the impact of HL on HRQoL in patients with type 2 diabetes²⁸, hypertension²⁹ and ischemic heart disease³⁰. However, these studies focus on

HL related to obtaining and comprehending general medical information rather than disease or condition-specific HL. Furthermore, some HRQoL measures have also been widely used in cost-utility analyses to determine the cost-effectiveness of treatments and interventions in several populations including those with chronic conditions^{31 32}. Therefore, an exploration of the impact of DSHL on HRQoL would also be of great importance for determining whether it is necessary to incorporate it as a potential confounding factor in cost-utility analyses of type 2 diabetes interventions. At present, there is a few studies have investigated the relationship between specific HL and HRQoL, and almost no studies in the literature have explored the effect of diabetes-specific HL on HRQoL among individuals with prediabetes.

Therefore, to address these issues and to help bridge the gap between HL and outcome research in individuals with prediabetes, the current study aimed to explore the impact of DSHL on HRQoL among the elderly with prediabetes in rural areas in China. We hypothesized that elderly individuals with prediabetes with high DSHL would report better HRQoL. We hope that this study will contribute to the formulation of effective interventions to improve HRQoL and promote diabetes prevention.

Research design and methods

Study design

This cross-sectional study was conducted in the rural areas of Yiyang City of Hunan Province in China between April and July 2015. The study was registered at the Chinese Clinical Trial Registry (trial registration number: ChiCTR-IOR-15007033). The study was approved by the Medical Ethics Committee of Central South University (Changsha, China; Identification Code: CTXY-150002-7; 27 February 2015). All participants signed the respective consent forms.

Sample size

Sample size was calculated using the formula for cross-sectional studies, as follows:

$$N = \frac{Z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

where $Z_{1-\alpha/2}^2=1.96$ when $\alpha=0.05$, p is the prevalence of prediabetes (which was 20% in this study according to our presurvey), and d is an admissible error (which was 4%). According to the formula, the theoretical sample size was 423, which included an extra 10% to allow for subjects lost during the study.

Participants

Participants in this study were aged 60 years and older and were from the rural areas of Yiyang City of Hunan Province. To select a representative sample of the elderly population with prediabetes, a screening program was carried out among the elderly population in Yiyang City. A multistage cluster randomized sampling method was used to select a representative sample. In the first stage, two out of six counties were selected according to geographical characteristics. In the second stage, 2 (Yangluozhou and Yinfengqiao) out of 11 townships and 2 (Qingshuzui and Maocaojie) out of 9 townships were randomly selected. In the third stage, 25% of the rural villages were randomly selected from each chosen township (each township contains 30–50 villages). In the final stage, all households in each selected village with elderly individuals who had lived in the area for 3 years or longer were eligible to participate in the screening program ($n=3,197$). Among them, 603 moved away, 336 had severe physical or mental illness, and 114 refused to participate. Finally, a total of 2,144 individuals participated

1
2
3 in the screening program.

4 An oral glucose tolerance test (OGTT) was used to distinguish between prediabetes and
5 normal plasma glucose. The diagnostic standards for prediabetes as stated in the 1999 WHO
6 criteria³³ were (1) an IFG group with fasting plasma glucose of 6.1–7.0 mmol/L and a 2-hour
7 postglucose load of <7.8 mmol/L; (2) an IGT group with a 2-hour postglucose load of 7.8–11.1
8 mmol/L and fasting plasma glucose of ≤6.1 mmol/L; and (3) an IFG+IGT group.

9
10 More details of the study population and screening procedure have been published
11 elsewhere³⁴. In brief, 2,144 elderly individuals took part in the screening program, and 461
12 elderly individuals had prediabetes. For various reasons, 21 of those with prediabetes
13 provided no response, and the response rate was 95.4%. Six individuals had incomplete data
14 also excluded in this study. Finally, a total of 434 individuals with prediabetes from 42 villages
15 were included in this study.

16 **Data collection**

17 Sociodemographic information was collected by trained staff using a set of structured
18 questionnaires, which included age, gender, education, marital status, presence of other
19 chronic diseases, history of hyperglycemia, family history of diabetes, physical activity,
20 smoking and alcohol drinking. Marital status was classified as married and nonmarried.
21 Nonmarried status included divorced, never married and lost a partner. Chronic diseases
22 included hypertension, coronary heart disease, dyslipidemia and others. History of
23 hyperglycemia was defined as a situation of fasting glucose >6.1 mmol/L or 2-hour
24 glucose >7.8 mmol/L without a diagnosis of diabetes. Physical activity was assessed using the
25 International Physical Activity Questionnaire-long version (IPAQ), and individuals who
26 achieved ≥600 metabolic equivalent(MET)-min/week were categorized as active³⁵. Smoking
27 was defined as averaging one or more cigarettes per day in the last year. Alcohol drinking was
28 defined as drinking more than one glass of wine (approximately 250 mL beer or 100 mL sake or
29 20 mL liquor) per month in the last year. Anthropometric measurements, including height,
30 weight, blood pressure, waist circumference and hip circumference, were assessed using a
31 standard tool. The measurement procedure was published in a previous study³⁶. Body mass
32 index (BMI) was calculated using the formula of weight in kilograms divided by height in m²
33 (kg/m²). The current Chinese standard classification states that the cut-off values for normal
34 weight, overweight and obesity BMI are 18.5 kg/m², 24.0 kg/m² and 28.0 kg/m² ³⁷,
35 respectively. Hypertension was defined as systolic blood pressure ≥140 mm Hg and/or
36 diastolic blood pressure ≥90 mm Hg. The waist to hip ratio (WHR) was calculated by dividing
37 the waist circumference by the hip circumference. A WHR >0.9 in men or >0.8 in women was
38 defined as abnormal WHR³⁸.

39 DSHL was assessed using the Questionnaire of Health Literacy of Diabetes Mellitus of the
40 Public in China, which was designed by the Chinese Center for Health Education to assess
41 health literacy about diabetes prevention and control in the general population ³⁹. This
42 questionnaire was widely used in epidemiological studies in China, and has high reliability
43 and validity, with a Cronbach's α of 0.866³⁹. DSHL can provide a comprehensive evaluation of
44 an individual's diabetes prevention and control knowledge, risk awareness, and ability to
45 manage risk factors. The questionnaire is organized into three main domains: diabetes-related
46 knowledge, diabetes-related behavior, and acquisition and utilization of diabetes information.
47 The diabetes-related knowledge section assessed attitudes toward diabetes, typical symptoms
48
49
50
51
52
53
54
55
56
57
58
59
60

of diabetes, complications of diabetes, factors conferring a high risk of developing diabetes and methods to prevent diabetes. The diabetes-related behaviors included sitting time duration, physical exercise, dietary pattern, physical examination, and smoking and alcohol drinking habits. In the part about the acquisition and utilization of diabetes information, the participants were asked about the method or way to find diabetes-related information, the degree of their acquisition of diabetes-related information and their ability to identify the correctness of diabetes-related information. An alternative classification was used where the scores 19.5 points and above were classified as high DSHL and remaining classified as low .

HRQoL was assessed using the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36)⁴⁰. The SF-36 health survey questionnaire has been translated and validated in Chinese, and the Chinese version has been proven to be reliable and valid in an elderly population⁴¹. This 36-item measure is organized into eight domains that constitute two main components: the physical health component and the mental health component. The physical health component includes four parts: physical functioning (PF), role physical (RP), bodily pain (BP) and general health (GH). Vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH) are included in the mental health component. The eight domains were scored from 0 to 100, indicating the worst to best possible health. Each domain score was further summarized and standardized into the physical component score (PCS) and the mental component score (MCS) according to American norms to allow for international comparisons⁴².

Data analysis

Data were presented as n (%) for categorical variables and mean±SD or median (P₂₅-P₇₅) for numerical variables. Nonparametric tests were used because the distribution of the DSHL scores was non-Gaussian. The Mann-Whitney U test or Kruskal-Wallis test was used to identify the differences in total DSHL scores according to different variables. The *t*-test or one-way variance (ANOVA) was used to compare the differences in the scores for different domains of HRQoL. General linear models of multivariate analysis of covariance (MANCOVA) were used to test differences in HRQoL between the adequate DSHL group and the inadequate group. Sociodemographic and anthropometric variables were treated as possible covariates. A significant MANCOVA was followed by univariate *F*-tests using the Wilks' λ statistic. Linear independent pairwise comparisons were analyzed to examine the magnitude of the difference in the mean scores of the dependent variables. Effect sizes (*d*) were computed by dividing the difference in means between groups by the pooled SD and were interpreted as small ($d \leq 0.20$), medium ($0.2 < d \leq 0.50$) or large ($0.5 < d \leq 0.80$)⁴³. The data were analyzed using SPSS Version.20.0 (SPSS/IBM, Armonk, New York, USA).

Patient and public involvement

Neither patients nor public were directly involved in the development, design or recruitment of the study. Anthropometric and glucose test results were provided to the participants at the point of testing. The participants, as part of the consent process, were fully informed about the time burden of participation and the nature of the questions. The participants answered the survey only after they provided their written informed consent to participate in the study.

Results

A total of 461 elderly individuals had prediabetes, and the prevalence of prediabetes was 21.5%

(461/2,144) in rural areas of Yiyang City. In total, 434 elderly individuals with prediabetes were included in this study. The average age of all participants was 69.4±6.4 years. The average fasting plasma glucose was 5.9±0.5 mmol/L, and the average 2-hour plasma glucose load was 7.2±1.9 mmol/L. A majority of the subjects were female, had completed less than 6 years of education, smoked, drank no alcohol and had no hypertension. The characteristics of the study subjects are shown in Table 1.

The overall median DSHL score was 10.0 (IQR 7.0-13.0). A total of 53 (12.2%) subjects with prediabetes reported high DSHL. Men had lower HL scores than women. Furthermore, married elderly individuals had higher DSHL scores than nonmarried individuals. Individuals with a history of hyperglycemia had a higher DSHL score than people with no history. Similarly, individuals with prediabetes who had completed 6 years or more of education had a higher score than those who had completed less than 6 years. The DSHL score according to different characteristics is presented in Table 1.

Table 1 The DSHL score according to different characteristics

Characteristics	n (%)	DSHL score [†]	P-value [‡]
Age			
60-69 years	239 (55.1)	10.0 (8.0-15.0)	0.461
70 years and older	195 (44.9)	10.0 (7.5-11.0)	
Gender			
Male	180 (41.5)	9.0 (7.0-12.0)	<0.001
Female	254 (58.5)	11.0 (8.0-13.0)	
Marital status			
Married	312 (71.9)	10.0 (7.0-13.0)	0.044
Nonmarried	122 (28.1)	9.0 (7.0-11.0)	
Education			
Less than 6 years	353 (81.3)	9.0 (6.5-12.0)	<0.001
6 years and more	81 (18.7)	12.0 (9.0-16.0)	
History of hyperglycemia			
Yes	28 (6.5)	12.5 (9.3-20.5)	0.001
No	406 (93.5)	9.0 (7.0-12.0)	
Family history of diabetes			
Yes	36 (8.3)	12.0 (7.0-13.8)	0.165
No	398 (91.7)	10.0 (7.0-12.0)	
Have other chronic disease			
Yes	176 (40.6)	10.0 (7.0-13.0)	0.544
No	258 (59.4)	10.0 (7.0-13.0)	
Physical activity			
Active	182 (41.9)	10.5 (8.0-13.5)	0.227
Inactive	252 (58.1)	9.5 (8.0-13.0)	
Smoking			
Yes	99(22.8)	10.0 (8.0-12.0)	0.525
No	335(77.2)	10.0 (8.0-13.0)	
Alcohol drinking			

Yes	98 (22.6)	10.0 (8.0-12.0)	0.308
No	336 (77.4)	10.0 (7.5-13.0)	
BMI			
Lean	17 (3.9)	9.0 (5.5-13.5)	0.547
Normal	233 (53.7)	9.0 (7.0-13.0)	
Overweight	129 (29.7)	10.0 (7.0-12.0)	
Obese	55 (12.7)	10.0 (7.0-13.0)	
Hypertension			
Yes	173 (39.9)	10.5 (8.5-13.0)	0.256
No	261 (60.1)	9.5 (8.0-12.0)	
WHR			
Normal	77 (17.7)	9.0 (7.0-12.0)	0.074
Abnormal	357 (82.3)	10.0 (7.0-13.0)	

DSHL, diabetes-specific health literacy

†Data are presented as the median (P₂₅-P₇₅)

*P value was determined by Kruskal-Wallis test or Mann-Whitney U test.

BMI, body mass index; WHR, waist to hip ratio

Health-related quality of life score

Individuals with prediabetes reported a PCS of 42.1 points (95%CI: 41.2, 43.1) and an MCS of 46.4 points (95%CI: 45.5, 47.1). The scores for the four domains of the PCS were 76.1±23.4, 71.4±42.4, 75.7±15.9 and 57.8±21.5, and the scores for the four domains of the MCS were 72.2±18.1, 79.7±17.1, 85.1±33.3 and 74.8±17.5. The means and their SDs for eight subscales of HRQoL scores according to different characteristics are shown in Table 2. Neither domain score showed a significant difference for the variables of gender, family history of diabetes or alcohol drinking (All $P > 0.05$). The BP and GH scores were lower among people aged 70 years and older. The MH score was lower among people who were not married. Individuals with prediabetes who had completed 6 years of education or more had higher SF and RE scores than people educated 1-6 years. Individuals who achieved active physical activity seemed to have higher scores in the PF, BP and GH domains. The RP, GH and RE scores were similarly higher among elderly people with normal BMI. Moreover, individuals with normal WHR had higher BP, SF and RE scores.

Table 2 HRQoL scores of eight domains measured by SF-36

Characteristics	Physical Health Components				Mental Health Components			
	PF	RP	BP	GH	VT	SF	RE	MH
Overall	76.1±23.4	71.4±42.4	75.7±15.9	57.8±21.5	72.2±18.1	79.7±17.1	85.1±33.3	74.8±17.5
Age								
60-69 years	76.9±23.5	74.1±41.6	77.4±16.6*	60.0±21.5*	72.9±17.7	80.5±16.6	87.2±31.1	75.7±17.4
70 years and older	74.9±23.1	67.2±43.4	73.1±14.4*	54.8±21.1*	71.1±18.8	78.5±17.8	82.0±36.3	73.4±17.7
Gender								
Male	75.8±23.4	73.3±41.4	74.9±16.5	58.5±20.7	72.5±18.3	80.7±16.3	86.0±32.3	74.2±18.5
Female	76.3±23.4	70.1±43.2	76.3±15.5	57.2±22.1	72.0±18.0	79.0±17.6	84.5±34.0	75.2±16.9
Marital status								
Married	75.6±23.9	73.2±42.2	75.3±16.3	58.8±21.6	73.0±18.1	79.7±16.9	85.4±33.2	76.0±16.9*

Nonmarried	77.5±21.8	66.6±42.9	76.7±14.9	54.9±20.8	69.9±18.1	79.8±17.7	84.4±33.6	71.4±18.8 [*]
Education								
Less than 6 years	75.9±23.6	71.0±42.7	75.7±15.7	57.4±21.5	71.5±18.5	78.8±16.9 [*]	83.1±34.9 [*]	74.4±17.6
6 years and more	76.9±22.8	73.3±41.4	75.7±16.7	59.1±21.4	75.0±16.3	83.2±17.5 [*]	93.1±24.5 [*]	76.3±17.2
History of hyperglycemia								
Yes	75.9±23.5	67.9±43.3	73.2±12.9	51.2±30.1 [*]	64.0±20.9 [*]	76.0±17.3	80.9±36.6	69.2±19.9
No	77.2±22.5	71.9±42.3	76.0±16.2	58.5±20.3 [*]	73.2±17.5 [*]	80.2±17.0	85.7±32.9	75.5±17.1
Family history of diabetes								
Yes	75.7±23.9	72.9±42.3	75.2±16.2	58.4±21.9	72.7±18.2	79.5±16.8	84.5±34.0	75.6±17.2
No	77.2±22.1	67.5±42.5	77.1±15.0	55.9±20.3	70.8±17.8	80.3±17.9	86.8±31.4	72.6±18.4
Other chronic disease								
Yes	72.9±24.1 [*]	72.0±42.6	71.7±16.2 [*]	56.7±20.5	71.9±18.0	78.7±17.1	84.8±33.5	74.0±18.3
No	78.1±22.7 [*]	71.1±42.4	78.1±15.2 [*]	58.4±22.1	72.4±18.2	80.3±17.1	85.3±33.2	75.3±17.0
Physical activity								
Active	80.4±24.5 [*]	72.9±42.8	78.5±17.2 [*]	61.6±21.8 [*]	73.8±16.4	80.9±18.3	90.1±28.0	76.3±16.4
Inactive	74.5±23.7 [*]	70.9±42.3	74.6±15.3 [*]	56.3±21.2 [*]	71.6±18.7	79.2±16.6	83.3±34.9	74.2±17.9
Smoking								
Yes	76.2±24.2	70.1±43.2	75.3±16.3	57.2±21.4	71.9±18.1	78.1±17.8 [*]	85.0±33.8	73.8±17.4
No	75.9±22.4	73.0±41.5	76.1±15.5	58.5±21.5	72.6±18.2	81.7±16.1 [*]	85.4±32.8	75.9±17.7
Alcohol drinking								
Yes	76.3±23.1	71.1±42.7	75.3±15.7	57.7±21.4	72.7±18.0	79.6±16.9	84.0±34.5	74.8±17.4
No	75.4±24.5	72.4±41.5	76.8±16.7	57.9±21.7	70.4±18.6	80.1±17.9	89.1±28.6	74.5±18.0
BMI								
Lean	79.1±25.4	60.9±45.7 [*]	73.9±13.4	53.7±23.5 [*]	65.6±17.7	78.7±16.0	78.3±39.7 [*]	69.2±20.7
Normal	76.7±22.8	77.0±39.6 [*]	76.1±16.0	59.9±20.3 [*]	73.7±18.0	81.2±17.1	89.2±28.5 [*]	75.7±17.3
Overweight	75.1±24.5	76.6±39.2 [*]	76.2±15.3	57.7±21.5 [*]	70.7±18.8	78.7±17.5	82.6±36.2 [*]	73.9±16.9
Obese	74.1±23.2	47.0±47.2 [*]	73.9±17.4	51.6±23.9 [*]	71.1±17.3	76.0±16.3	76.1±40.5 [*]	74.4±18.0
Hypertension								
Yes	78.0±22.9 [*]	66.9±44.4	75.3±17.1	55.5±23.8	71.0±18.7	77.8±17.5	78.5±38.0 [*]	74.7±17.7
No	73.1±23.8 [*]	74.3±40.9	75.9±15.1	59.2±19.8	73.0±17.9	80.9±16.7	89.4±29.2 [*]	74.8±17.5
WHR								
Normal	77.3±23.5	72.8±41.6	78.4±17.1 [*]	59.2±21.6	72.8±18.3	81.6±15.8 [*]	88.1±29.8 [*]	76.0±17.6
Abnormal	74.4±23.2	69.4±43.6	71.8±13.1 [*]	55.8±21.2	71.4±17.8	76.9±18.4 [*]	80.9±37.5 [*]	73.1±17.4

Data are presented as the mean±SD, and analysis was performed using analysis of variance (ANOVA) or t-test. * $P<0.05$; PF, physical functioning; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health

Association between DSHL and HRQoL

Crude analysis indicated that when the eight subscales of HRQoL were placed as the dependent variables and DSHL (as a binary variable) was entered as the independent variable, the overall MANCOVA showed significant differences in the general health, vitality, social functioning and mental health scores between the two groups (Wilk' $\lambda=0.955$, $F=2.44$, $P=0.014$). After adjusting for other covariants, individuals with high DSHL reported higher scores on GH ($M_{diff}=6.8$, $P=0.028$), VT ($M_{diff}=6.6$, $P=0.014$), SF ($M_{diff}=6.0$, $P=0.017$) and MH

($M_{\text{diff}}=7.4$, $P=0.005$) than did those with low DSHL. The associations between DSHL and different domains of HRQoL are shown in Table 3.

Crude analysis showed that with two components of HRQoL entered as dependent variables, the overall MANCOVA was significant (Wilks' $\lambda=0.965$, $F=7.87$, $P<0.001$). Individuals with high DSHL had higher PCS score($M_{\text{diff}}=2.9$, $ES=0.30$) and MCS score($M_{\text{diff}}=4.4$, $ES=0.47$) than those with low DSHL. After adjusting for age, gender, education, marital status, other chronic diseases, family history of diabetes, history of hyperglycemia, physical activity, hypertension, smoking, drinking, BMI and WHR, a linear independent pairwise comparison indicated that individuals with prediabetes who had higher DSHL reported higher MCS ($M_{\text{diff}}=3.5$, 95%CI: 1.8, 6.3) with a medium effect size ($ES=0.38$). The association between DSHL and HRQoL among elderly individuals with prediabetes is shown in Table 4.

Table 3 Association between DSHL and different subscales of HRQoL among elderly individuals with prediabetes

SF-36 domains	High DSHL		Low DSHL		Difference		
	Mean	SE	Mean	SE	M_{diff} (95%CI)	$ES(d)$	P -value
Crude analysis (Wilk' $\lambda=0.955$, $F=2.44$, $P=0.014$)							
PF	80.0	3.2	75.5	1.2	4.6 (-2.3,11.2)	0.20	0.193
RP	74.5	5.8	70.9	2.3	3.5 (-5.7,15.4)	0.08	0.224
BP	78.9	2.2	75.2	0.8	3.7 (-1.8, 8.3)	0.23	0.110
GH	64.5	2.9	56.8	1.1	7.6 (1.6,13.7)	0.38	0.013
VT	78.9	2.5	71.3	0.9	7.5 (2.4,12.8)	0.42	0.004
SF	86.0	2.3	78.8	0.9	7.2 (2.4,12.1)	0.43	0.001
RE	91.2	4.6	84.3	1.7	6.9 (-2.7,16.5)	0.21	0.158
MH	81.8	2.4	73.8	0.9	8.0 (3.0,13.0)	0.46	0.002
Adjusted analysis (Wilk' $\lambda=0.958$, $F=2.31$, $P=0.019$) [†]							
PF	79.6	3.2	75.6	1.2	4.0 (-2.8,10.8)	0.17	0.252
RP	73.1	5.9	71.2	2.1	1.9 (-6.7,14.2)	0.07	0.186
BP	78.4	2.1	75.3	0.8	3.1 (-1.2,7.5)	0.19	0.161
GH	63.7	2.9	56.9	1.1	6.8 (1.7,12.9)	0.33	0.028
VT	78.0	2.5	71.4	0.9	6.6 (1.3,11.8)	0.37	0.014
SF	84.9	2.3	79.0	0.9	6.0 (1.1,10.9)	0.36	0.017
RE	88.0	4.6	84.7	1.7	3.4 (-6.2,12.9)	0.10	0.492
MH	81.2	2.4	73.9	0.9	7.4 (2.3,12.5)	0.43	0.005

DSHL, diabetes-specific health literacy; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

[†] Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

M_{diff} , mean difference; $ES(d)$, mean difference/pooled SD.

Table 4 Association between DSHL and HRQoL among elderly individuals with prediabetes

Variables	High DSHL		Low DSHL		Difference		
	Mean	SE	Mean	SE	M_{diff} (95%CI)	$ES(d)$	P -value

Crude analysis (Wilks' λ =0.965, F =7.87, P <0.001)							
PCS	44.6	1.3	41.7	0.5	2.9 (1.4,5.7)	0.30	0.046
MCS	50.2	1.3	45.8	0.5	4.4 (1.7,7.1)	0.47	0.001
Adjusted analysis (Wilks' λ =0.974, F =5.63, P =0.004) [†]							
PCS	44.4	1.3	41.8	0.6	2.6 (-1.2,5.4)	0.27	0.067
MCS	49.4	1.3	45.9	0.7	3.5 (1.8, 6.3)	0.38	0.012

DSHL, diabetes-specific health literacy; M_{diff} , mean difference; ES (d), mean difference/pooled SD; PCS, physical health component score; MCS, mental health component score.

[†]Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

Discussion

This cross-sectional study showed a high prevalence (21.5%) of prediabetes among the elderly population in rural areas in China, which is similar to the findings of the earlier study⁴⁴. The results, together with the large elderly population living in rural areas, suggest that this serious public health problem in China requires better prevention.

Many studies have used general HL measurement instruments, such as REALM or TOFHLA, which are not disease or condition-specific. However, our study used a DSHL questionnaire with high reliability and validity that was designed by the Chinese Center for Health Education, and is suitable for a nondiabetic population³⁹. The questionnaire was able to effectively and accurately examine the level of HL about diabetes knowledge, diabetes prevention behaviors and the acquisition and utilization of diabetes information among individuals with prediabetes. There is a direct association between DSHL and patient assessments of their self-care ability, which indicates that HL measures should include indicators of knowledge and understanding²⁵. Thus, in terms of prevention, knowing the HL of individuals with prediabetes regarding diabetes prevention and control contribute to the development of more effective interventions and health education methods. Based on the results of the univariate analysis, the DSHL score showed significant differences in the variables of gender, education and history of hyperglycemia, which are consistent with the findings of other studies^{45 46}.

Although the effect of HL on HRQoL has been widely discussed among some populations in previous studies⁴⁷⁻⁴⁹, few studies have explored the association between HL and HRQoL among individuals with prediabetes. There is also a lack of research probing the effect of disease- or condition-specific HL on HRQoL. To the best of our knowledge, this is the first study to examine the relationship between DSHL and HRQoL among elderly individuals with prediabetes. Our study found that DSHL was positively associated with some health domains of HRQoL according to bivariate and multivariate analyses. Compared with individuals with prediabetes with lower HL levels, subjects with higher HL reported higher score on GH, VT, SF and MH subscales. That is, the prediabetic older adults with lower HL were more likely to have limited social activities, poor health perceptions, tiredness and psychological distress. When the eight domain scores standardized and summarized as the PCS and MCS, the relationship between HL levels and HRQoL was significant in the mental-well being (SF-36 MCS), while physical health (SF36 PCS) was significant only in the bivariate model and became nonsignificant after controlling for sociodemographic and somatometric covariates.

1
2
3 On the one hand, more subscales of the MCS component than the PCS were significant
4 associated with DSHL. On the other hand, some information loss may occur in the process of
5 standardizing and summarizing the scores of the eight domain into two components. However,
6 these results are in concordance with those of previous studies that targeted the relationship
7 between general HL and HRQoL^{10 50-53}. For instance, Jayasinghe and her colleagues found
8 that HL accounted for 45% and 70% of the total between-patient variance explained in PCS-12
9 and MCS-12, respectively¹⁰. Furthermore, a study conducted in 605 patients with
10 symptomatic heart failure (HF) showed that those with higher literacy had better HRQoL
11 scores (mean difference=7.2, $P<0.01$) than did those with lower literacy⁵². A cross-sectional
12 survey of 1841 cancer patients in Wisconsin also indicated that higher HL was positively
13 associated with the physical, functional, emotional, and social well-being subscales of
14 HRQoL⁵³. However, our results also contradict the findings of previous studies that examined
15 the association^{28-30 54-56}. Data from a clinical trial that included 154 predominantly white
16 patients with type 2 diabetes who screened positive for depression showed that the
17 between-HL group difference in change over 1 year was only nonsignificant at 0.76 points for
18 PCS and 0.56 points for MCS²⁸. In another study conducted among frequent users of health
19 care services, no association was found between HL and HRQoL on both PCS and MCS⁵⁵.
20 Two other studies^{30 54} demonstrated that HL was not significantly associated with only the
21 mental component of HRQoL. A prospective cohort study of 4278 older adults in the UK
22 showed that low HL significantly predicted declines in the physical, psychological and
23 environmental domains of HRQoL but not in the social relationship HRQoL⁵⁶. There are
24 three reasons for this variance. First, most studies pay attention to the impact of general HL
25 rather than specific HL on HRQoL. However, general HL includes the ability to obtain,
26 process and understand all basic health information, not just a specific disease. Second, the
27 various studies used different tools to measure HL and HRQoL. Last, the contradictory results
28 were also likely due to differences in social and culture factors, and in the study populations
29 and sample sizes.

30
31
32 These results suggest that individuals with newly diagnosed prediabetes who have higher
33 levels of DSHL may have higher HRQoL, especially for the mental health component. A
34 potential explanation for the relationship between DSHL and the physical and mental
35 components of HRQoL may be that low DSHL limits individuals' understanding of complex
36 information about diabetes knowledge and prevention, and thus becomes a barrier to
37 individuals' participation in diabetes education and intervention. Moreover, people with lower
38 HL tend to have difficulty communicating, which prevents them from asking questions,
39 clearly expressing their concerns, emotions, and needs to providers and seeking additional
40 services, such as support for mental health^{50 53}. Furthermore, as a previous study found that
41 subjects with low literacy were 3 times more likely to have depression⁵⁴. Considering that
42 individuals with lower HL were more likely to have limited social activities, tiredness and
43 psychological distress, lower DSHL may further limit the individual's ability to talk with their
44 families and health education and care providers about difficult emotional issues or abstract
45 psychosocial implications of diabetes. Individuals with lower levels of DSHL may not have
46 knowledge of signs or symptoms of concern and may experience a psychological panic,
47 reducing the MCS of HRQoL. The findings about the impact of DSHL on HRQoL in the
48 prediabetic population could help us to identify focus groups and provide multifaceted and
49
50
51
52
53
54
55
56
57
58
59
60

collaborative interventions to delay the development of type 2 diabetes. They also provide information that could contribute to assessments of the effects and cost-effectiveness of diabetes education and intervention. Healthcare staff should be aware of health literacy problems among elderly adults, and should simplify health-related information to increase the responsiveness of subjects with low health literacy during consultations and interventions. Furthermore, the finding that DSHL is associated with changes in HRQoL outcomes raises the need for testing the hypothesis of whether HL is a modifiable factor and, if so, considering whether interventions aimed at improving HL also lead to improvements in HRQoL and health conditions in this population.

Our study also revealed that individuals with prediabetes showed lower PCS than MCS, and the mean scores of the four domains of the mental health components were likewise higher than those of four subscales of the physical health components, which was consistent with the findings of other studies⁵⁷⁻⁵⁸. One explanation is that some elderly have difficulties in physical activities due to illness. A study has also shown that chronic diseases have a stronger effect on reducing physical function than psychological function⁵⁹. Similar to the results of our study, elderly individuals with chronic disease, overweight or obesity and physical inactivity have lower scores on the subscales of physical function, bodily pain and general health; however, these domains are components of the physical health aspect of HRQoL.

Our study also has several limitations. Firstly, its cross-sectional design did not permit causal inferences. Furthermore, both cohort studies and randomized controlled trial designs garner a deeper understanding of the relationship between DSHL and HRQoL. Secondly, HL was measured using the public questionnaire of HL of diabetes mellitus. This may influence the way in which our study may be compared to previous studies, the majority of which measured multidimensional competences rather than a single competence of functional HL. Thirdly, self-administered questionnaires were used to assess some variables maybe induce recall bias. However, this limitation was minimized because instruments used in this study are valid and reliable. Finally, our study sample was taken from rural areas in one city of one province of China. Therefore, the generalization of the results to other populations should be carefully considered.

Conclusions

In summary, lower DSHL was associated with poorer HRQoL among elderly individuals with prediabetes in rural areas in China, particularly in terms of mental health components. These findings suggest that assessing and improving both DSHL and HRQoL may be important for individuals with prediabetes.

Acknowledgements

We thank all the participants very much for their collaboration.

Author contributions

ZH and LQ completed the statistical analyses and drafted the manuscript. HLX checked and revised the manuscript. All the authors read and approved the final manuscript.

Funding

This study was funded by the Teachers Research Fund of Central South University (2013JSJJ034) and the Central South University Graduate Student Independent Exploration Innovation Project (NO.2013zzts286).

Competing interests

1
2
3 None declared.

4 **Patient consent**

5
6 Obtained.

7 **Ethical approval**

8 The study was approved by the Medical Ethics Committee of Central South University
9 (Changsha, China; Identification Code: CTXY-150002-7; 27 February 2015).

10
11 **Data sharing statement**

12 No additional data are available.
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

References

1. Punthakee Z, Goldenberg R, Katz P. Definition, Classification and Diagnosis of Diabetes, Prediabetes and Metabolic Syndrome. *Canadian journal of diabetes* 2018;42 Suppl 1:S10-s15.
2. Perreault L, Pan Q, Mather KJ, et al. Effect of regression from prediabetes to normal glucose regulation on long-term reduction in diabetes risk: results from the Diabetes Prevention Program Outcomes Study. *Lancet (London, England)* 2012;379:2243-51.
3. de Vegt F, Dekker JM, Jager A, et al. Relation of impaired fasting and postload glucose with incident type 2 diabetes in a Dutch population: The Hoorn Study. *Jama* 2001;285:2109-13.
4. Ang YG, Wu CX, Toh MP, et al. Progression rate of newly diagnosed impaired fasting glycemia to type 2 diabetes mellitus: a study using the National Healthcare Group Diabetes Registry in Singapore. *J Diabetes* 2012;4:159-63.
5. Forouhi NG, Luan J, Hennings S, et al. Incidence of Type 2 diabetes in England and its association with baseline impaired fasting glucose: the Ely study 1990-2000. *Diabetic medicine : a journal of the British Diabetic Association* 2007;24:200-7.
6. Nathan DM, Davidson MB, DeFronzo RA, et al. Impaired fasting glucose and impaired glucose tolerance: implications for care. *Diabetes care* 2007;30:753-9.
7. Wang L, Gao P, Zhang M, et al. Prevalence and Ethnic Pattern of Diabetes and Prediabetes in China in 2013. *Jama* 2017;317:2515-23.
8. Group W. The World Health Organization Quality of Life Assessment (WHOQOL): development and general psychometric properties. *Social science & medicine (1982)* 1998;46:1569-85.
9. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Annals of internal medicine* 1993;118:622-9.
10. Jayasinghe UW, Harris MF, Parker SM, et al. The impact of health literacy and life style risk factors on health-related quality of life of Australian patients. *Health and quality of life outcomes* 2016;14:68.
11. Keles H, Ekici A, Ekici M, et al. Effect of chronic diseases and associated psychological distress on health-related quality of life. *Internal medicine journal* 2007;37:6-11.
12. Alfonso-Rosa RM, Del Pozo-Cruz B, Del Pozo-Cruz J, et al. The relationship between nutritional status, functional capacity, and health-related quality of life in older adults with type 2 diabetes: a pilot explanatory study. *The journal of nutrition, health & aging* 2013;17:315-21.
13. Tapp RJ, Dunstan DW, Phillips P, et al. Association between impaired glucose metabolism and quality of life: results from the Australian diabetes obesity and lifestyle study. *Diabetes research and clinical practice* 2006;74:154-61.
14. Ghorbani A, Ziaee A, Esmailzadehha N, et al. Association between health-related quality of life and impaired glucose metabolism in Iran: the Qazvin Metabolic Diseases Study. *Diabetic medicine : a journal of the British Diabetic Association* 2014;31:754-8.
15. Hunger M, Holle R, Meisinger C, et al. Longitudinal changes in health-related quality of life in normal glucose tolerance, prediabetes and type 2 diabetes: results from the KORA S4/F4 cohort study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2014;23:2515-20.
16. Lam CL, Fong DY, Lauder IJ, et al. The effect of health-related quality of life (HRQOL) on health service utilisation of a Chinese population. *Social science & medicine (1982)* 2002;55:1635-46.
17. Chen T, Li L. Influence of health-related quality of life on health service utilization in addition to

- socio-demographic and morbidity variables among primary care patients in China. *International journal of public health* 2009;54:325-32.
18. Alonso J, Ferrer M, Gandek B, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2004;13:283-98.
 19. Berkman ND, Davis TC, McCormack L. Health literacy: what is it? *Journal of health communication* 2010;15 Suppl 2:9-19.
 20. Gazmararian JA, Williams MV, Peel J, et al. Health literacy and knowledge of chronic disease. *Patient education and counseling* 2003;51:267-75.
 21. Bennett IM, Chen J, Soroui JS, et al. The contribution of health literacy to disparities in self-rated health status and preventive health behaviors in older adults. *Ann Fam Med* 2009;7:204-11.
 22. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older adults: longitudinal cohort study. *BMJ* 2012;344:e1602.
 23. Institute of Medicine Committee on Health L. In: Nielsen-Bohlman L, Panzer AM, Kindig DA, eds. *Health Literacy: A Prescription to End Confusion*. Washington (DC): National Academies Press (US)
Copyright 2004 by the National Academy of Sciences. All rights reserved., 2004.
 24. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes care* 2002;25:1159-71.
 25. Yamashita T, Kart CS. Is diabetes-specific health literacy associated with diabetes-related outcomes in older adults? *J Diabetes* 2011;3:138-46.
 26. Chen GD, Huang CN, Yang YS, et al. Patient perception of understanding health education and instructions has moderating effect on glycemic control. *BMC public health* 2014;14:683.
 27. Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes care* 2006;29:823-9.
 28. Al Sayah F, Majumdar SR, Johnson JA. Association of Inadequate Health Literacy with Health Outcomes in Patients with Type 2 Diabetes and Depression: Secondary Analysis of a Controlled Trial. *Canadian journal of diabetes* 2015;39:259-65.
 29. Naimi AJ, Naderiravesh N, Bayat ZS, et al. Correlation between health literacy and health-related quality of life in patients with hypertension, in Tehran, Iran, 2015-2016. *Electronic physician* 2017;9:5712-20.
 30. Gonzalez-Chica DA, Mnisi Z, Avery J, et al. Effect of Health Literacy on Quality of Life amongst Patients with Ischaemic Heart Disease in Australian General Practice. *PloS one* 2016;11:e0151079.
 31. Robinson R. Cost-utility analysis. *Bmj* 1993;307:859-62.
 32. Zhang XH, Li SC, Fong KY, et al. The impact of health literacy on health-related quality of life (HRQoL) and utility assessment among patients with rheumatic diseases. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2009;12 Suppl 3:S106-9.
 33. Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. *Diabetic medicine : a journal of the British Diabetic Association* 1998;15:539-53.

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
34. Xu H, Tang L, Hu Z, et al. Association between physical activity and health-related quality of life in elderly individuals with pre-diabetes in rural Hunan Province, China: a cross-sectional study. *BMJ Open* 2018;8:e019836.
35. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine. *Jama* 1995;273:402-7.
36. Qin L, Xu H. A cross-sectional study of the effect of health literacy on diabetes prevention and control among elderly individuals with prediabetes in rural China. *BMJ Open* 2016;6:e011077.
37. Wu Y. Overweight and obesity in China. *Bmj* 2006;333:362-3.
38. Collaboration OiA. Is central obesity a better discriminator of the risk of hypertension than body mass index in ethnically diverse populations? *Journal of hypertension* 2008;26:169-77.
39. Li L, Li Y, Nie X, et al. An analysis of health literacy about diabetes prevention and control and its influencing factors among the residents in six provinces in China. *Chinese journal of preventive medicine* 2014;48:561-5.
40. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical care* 1992;30:473-83.
41. Zhou B, Chen K, Wang JF, et al. Reliability and validity of a Short-Form Health Survey Scale (SF-36), Chinese version used in an elderly population of Zhejiang province in China. *Chin J Epidemiol* 2008;29:1193-8.
42. Ware J, Kosinski M, Keller S. SF-36 physical and mental health summary scales: a user's manual. 5th edn. Boston, MA: Health Assessment Lab. New England Medical Center, . 1994
43. Cohen J. A power primer. *Psychological bulletin* 1992;112:155-9.
44. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *Jama* 2013;310:948-59.
45. Lutfiyya MN, Lipsky MS, Bales RW, et al. Disparities in knowledge of heart attack and stroke symptoms among adult men: an analysis of behavioral risk factor surveillance survey data. *Journal of the National Medical Association* 2008;100:1116-24.
46. Aihara Y, Minai J. Barriers and catalysts of nutrition literacy among elderly Japanese people. *Health promotion international* 2011;26:421-31.
47. Miller DB, Cage JL, Nowacki AS, et al. Health Literacy (HL) & Health-Related Quality of Life (HRQL) Among Minority Men. *Journal of the National Medical Association* 2018;110:124-29.
48. Montbleau KE, King D, Henault L, et al. Health literacy, health-related quality of life, and atrial fibrillation. *Cogent medicine* 2017;4:1412121.
49. Divaris K, Lee JY, Baker AD, et al. The relationship of oral health literacy with oral health-related quality of life in a multi-racial sample of low-income female caregivers. *Health and quality of life outcomes* 2011;9:108.
50. Song L, Mishel M, Bensen JT, et al. How does health literacy affect quality of life among men with newly diagnosed clinically localized prostate cancer? Findings from the North Carolina-Louisiana Prostate Cancer Project (PCaP). *Cancer* 2012;118:3842-51.
51. Sayah FA, Qiu W, Johnson JA. Health literacy and health-related quality of life in adults with type 2 diabetes: a longitudinal study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2016;25:1487-94.

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
52. Macabasco-O'Connell A, DeWalt DA, Broucksou KA, et al. Relationship between literacy, knowledge, self-care behaviors, and heart failure-related quality of life among patients with heart failure. *Journal of general internal medicine* 2011;26:979-86.
53. Halverson JL, Martinez-Donate AP, Palta M, et al. Health Literacy and Health-Related Quality of Life Among a Population-Based Sample of Cancer Patients. *Journal of health communication* 2015;20:1320-9.
54. Lincoln A, Paasche-Orlow MK, Cheng DM, et al. Impact of health literacy on depressive symptoms and mental health-related: quality of life among adults with addiction. *Journal of general internal medicine* 2006;21:818-22.
55. Couture EM, Chouinard MC, Fortin M, et al. The relationship between health literacy and quality of life among frequent users of health care services: a cross-sectional study. *Health and quality of life outcomes* 2017;15:137.
56. Panagioti M, Skevington SM, Hann M, et al. Effect of health literacy on the quality of life of older patients with long-term conditions: a large cohort study in UK general practice. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2018;27:1257-68.
57. Taylor LM, Spence JC, Raine K, et al. Physical activity and health-related quality of life in individuals with prediabetes. *Diabetes research and clinical practice* 2010;90:15-21.
58. Ibrahim N, Moy FM, Awalludin IA, et al. The health-related quality of life among pre-diabetics and its association with body mass index and physical activity in a semi-urban community in Malaysia--a cross sectional study. *BMC public health* 2014;14:298.
59. Cigolle CT, Langa KM, Kabeto MU, et al. Geriatric conditions and disability: the Health and Retirement Study. *Annals of internal medicine* 2007;147:156-64.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

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
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5,6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	NA
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	6

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA
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	7
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	NA
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	7
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	8,9,10
		(b) Report category boundaries when continuous variables were categorized	8,9,10
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
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	12,13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12,13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	13

*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.

BMJ Open

Association between diabetes-specific health literacy and health-related quality of life among elderly individuals with prediabetes in rural Hunan Province, China: A cross-sectional study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028648.R2
Article Type:	Research
Date Submitted by the Author:	02-Aug-2019
Complete List of Authors:	Zhao, Hu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management lulu, Qin; School of Medicine, Hunan Normal University, Department of Social Medicine and Health Management Huilan, Xu; Central South University Xiangya School of Public Health, Department of Social Medicine and Health Management
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Epidemiology, Diabetes and endocrinology
Keywords:	quality of life, health literacy, elderly, prediabetes

SCHOLARONE™
Manuscripts

1
2
3 Association between diabetes-specific health literacy and health-related quality of life
4 among elderly individuals with prediabetes in rural Hunan Province, China: A
5 cross-sectional study
6
7

8 Zhao Hu¹, Lulu Qin², Huilan Xu^{1,*}
9

10 1 Department of Social Medicine and Health Management, Xiangya School of Public
11 Health, Central South University, Changsha, 410078, China(15200807487@163.com)

12 2 Department of Social Medicine and Health Management, School of Medicine, Hunan
13 Normal University, Changsha, 410013, China(qinlulu_1989@sina.com)

14 *Correspondence: Huilan Xu, E-mail: xhl6363@sina.com; Tel./Fax: +86-731-8480-5459
15
16

17 ABSTRACT

18
19 **Objectives** To examine the association between diabetes-specific health literacy (DSHL)
20 and health-related quality of life (HRQoL) among elderly individuals with prediabetes in rural
21 China.
22

23 **Design, setting and participants** This cross-sectional study included 434 elderly
24 individuals with prediabetes from 42 villages in rural China.
25

26 **Main outcome measures** HRQoL was assessed using the Medical Outcomes Study
27 36-Item Short Form Health Survey (SF-36). DSHL was measured by a validated questionnaire
28 in China. Differences in HRQoL between groups with and without adequate DSHL were tested
29 by multivariate analysis of covariance (MANCOVA).
30

31 **Results** The prevalence of prediabetes was 21.5%. The average age of participants (n=434)
32 was 69.4±6.4 years, and 58.5% were female. Bivariate analysis showed that those with high
33 DSHL had increases of 2.9 points in the physical health component score (PCS) and 4.4 points
34 in the mental health component score (MCS) compared to those without. After adjustment for
35 potential confounders, a significant MANCOVA model (Wilks'λ=0.974, F=5.63, P=0.004)
36 indicated that individuals with prediabetes who had high DSHL reported higher MCS
37 (M_{diff}=3.5, 95%CI: 1.8, 6.3, effect size=0.38). This remained significant across subscales:
38 general health (P=0.028), vitality (P=0.014), social functioning (P=0.017) and mental health
39 (P=0.005).
40
41

42 **Conclusions** Low DSHL was associated with worsening HRQoL among elderly individuals
43 with prediabetes in rural China, particularly in the mental health components.
44

45 **Keywords** quality of life; health literacy; elderly; prediabetes

46 **Trial registration number** ChiCTR-IOR-15007033
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Article summary

Strengths and limitations of this study

- This is the first study to examine the association between health-related quality of life (HRQoL) and diabetes-specific health literacy among elderly individuals with pre-diabetes in rural China.
- The study provides valuable information on HRQoL among elderly individuals with prediabetes in rural areas in China.
- The association between HRQoL and DSHL was analyzed in eight domains , as well as in the physical health component and the mental health component, making the results more comprehensive.
- The cross-sectional study design makes causal relationships undeterminable.

For peer review only

Introduction

Prediabetes describes individuals who have impaired fasting glucose (IFG) or/and impaired glucose tolerance (IGT)¹. Prediabetes is a less common but important condition that constitutes an intermediate state between type 2 diabetes and a healthy status. Several studies have identified that individuals with prediabetes have a high risk of developing diabetes, and the occurrence increases with age²⁻⁴. Approximately 5%–10% of people with prediabetes become diabetic annually, although the progression rate varies by population and the definition of prediabetes^{5 6}. In China, the estimated prevalence of prediabetes was 35.7% in adults and 45.8% in the elderly population in 2013⁷. Therefore, people with prediabetes especially for elderly are an important target group for interventions intended to prevent diabetes.

Health-related quality of life (HRQoL) is a comprehensive and multidimensional condition that refers to an individual's perceived physical and mental health under the influence of illness, injury and treatment over time^{8 9}. Several studies have demonstrated that many risk factors, such as smoking, chronic diseases, poor diet, insufficient physical activity, and overweight, lead to lower HRQoL¹⁰⁻¹². Because biomedical measures sometimes may not sensitively indicate the deterioration or improvement in symptoms and health status, HRQoL has been increasingly incorporated as a complementary and essential outcome measure in medical interventions and population health surveys to assess changes in the physical, mental, and social well-being of these individuals. Studies have found that the HRQoL is usually impaired in individuals with prediabetes compared to the healthy population; additionally, individuals with prediabetes progressing to diabetes suffer from a great loss in HRQoL¹³⁻¹⁵. Moreover, HRQoL affects both the entry and subsequent utilization of health services and the cost of health care in China^{16 17}. Thus, assessing HRQoL in the intermediate period between normal plasma glucose and type 2 diabetes is important; because the concept has a broader definition that enables us to fully understand both the somatic and emotional health statuses of individuals with prediabetes and consequently create interventions to improve it, especially by relieving pain, malaise and consequences of diseases¹⁸.

Health literacy (HL) is the degree to which individuals have the capacity to obtain, process and understand the basic health information and service need to make informed health decision¹⁹. Over the past decades, a growing body of research suggests that inadequate HL is associated with adverse health outcomes, such as poor self-rated health, misunderstandings about medical conditions and increased mortality risk²⁰⁻²². However, HL is arguably a broad multidimensional concept that serves as a bridge between literacy skills and abilities and the illness context in which individuals find themselves²³. Clearly, some dimensions of literacy skills and abilities are generalizable across all health populations. However, in the presence of a specific illness context, some disease-specific HL would seem necessary for successful self-management of that disease. For example, diabetes-specific HL (DSHL) is particularly salient in the assessment of self-care for type 2 diabetes in adults²⁴. Nevertheless, there is no clear definition of DSHL in the current literature. In general, DSHL represents the ability to obtain and understand diabetes-related information and to make informed diabetes care decisions. A study demonstrated that DSHL was positively associated with self-graded assessment of diabetes care²⁵. Some studies have indicated that DSHL is associated with diabetes-related knowledge, diabetes-care behaviors and glycemic control^{26 27}.

Thus, prediabetes patients with lower levels of DSHL may not have knowledge of the signs or symptoms of concern and may have a higher risk of developing poor health outcomes than those who have higher DSHL.

Several studies have evaluated the impact of HL on HRQoL in patients with type 2 diabetes²⁸, hypertension²⁹ and ischemic heart disease³⁰. However, these studies focus on HL related to obtaining and comprehending general medical information rather than disease or condition-specific HL. Furthermore, some HRQoL measures have also been widely used in cost-utility analyses to determine the cost-effectiveness of treatments and interventions in several populations including those with chronic conditions^{31 32}. Therefore, an exploration of the impact of DSHL on HRQoL would also be of great importance for determining whether it is necessary to incorporate it as a potential confounding factor in cost-utility analyses of type 2 diabetes interventions. Moreover, examining the association between DSHL and HRQoL could help us to identify new targets and create more precise and multifaceted prevention and intervention strategies to delay the development of type 2 diabetes. At present, there are a few studies that have investigated the relationship between specific HL and HRQoL, and almost no studies in the literature have explored the effect of diabetes-specific HL on HRQoL among individuals with prediabetes.

Therefore, to address these issues and to help bridge the gap between HL and outcome research in individuals with prediabetes, the current study aimed to explore the impact of DSHL on HRQoL among elderly individuals with prediabetes in rural areas in China. We hypothesized that elderly individuals with prediabetes with high DSHL would report better HRQoL. We hope that this study will contribute to the formulation of effective interventions to improve HRQoL and promote diabetes prevention.

Research design and methods

Study design

This cross-sectional study was conducted in the rural areas of Yiyang City of Hunan Province in China between April and July 2015. The study was registered at the Chinese Clinical Trial Registry (trial registration number: ChiCTR-IOR-15007033). The study was approved by the Medical Ethics Committee of Central South University (Changsha, China; Identification Code: CTXY-150002-7; 27 February 2015). All participants signed the respective consent forms.

Sample size

Sample size was calculated using the formula for cross-sectional studies, as follows:

$$N = \frac{Z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

where $Z_{1-\alpha/2}^2 = 1.96$ when $\alpha = 0.05$, p is the prevalence of prediabetes (which was 20% in this study according to our presurvey), and d is an admissible error (which was 4%). According to the formula, the theoretical sample size was 423, which included an extra 10% to allow for subjects lost during the study.

Participants

Participants in this study were aged 60 years and older and were from the rural areas of Yiyang City of Hunan Province. To select a representative sample of the elderly population with prediabetes, a screening program was carried out among the elderly population in Yiyang City. A multistage cluster randomized sampling method was used to select a representative

1
2
3 sample. In the first stage, two (Nanxian and Yuanjiang) out of six counties were selected
4 according to geographical characteristics (north and south of Yiyang city). In the second stage,
5 2 (Yangluozhou and Yinfengqiao) out of 11 townships from Yuanjiang county and 2
6 (Qingshuzui and Maocaojie) out of 9 townships from Nanxian county were randomly selected
7 by drawn lots. In the third stage, as each township contains 30-50 villages, a proportionate
8 sampling method was used to select 25% of the villages from each selected township. Thus 12
9 villages from Yangluozhou township, 9 villages from Yinfengqiao township, 11 villages from
10 Qingshuzui township, and 10 villages from Maocaojie township were randomly selected. In
11 the final stage, all households in each selected village with elderly individuals who had lived in
12 the area for 3 years or longer were eligible to participate in the screening program(n=3,197).
13 Among them, 603 moved away, 336 had severe physical or mental illness, and 114 refused to
14 participate. Finally, a total of 2,144 individuals participated in the screening program.

15
16 An oral glucose tolerance test (OGTT) was used to distinguish between prediabetes and
17 normal plasma glucose. The diagnostic standards for prediabetes as stated in the 1999 WHO
18 criteria³³ were (1) an IFG group with fasting plasma glucose of 6.1–7.0 mmol/L and a 2-hour
19 postglucose load of <7.8 mmol/L; (2) an IGT group with a 2-hour postglucose load of 7.8–11.1
20 mmol/L and fasting plasma glucose of ≤6.1 mmol/L; and (3) an IFG+IGT group.

21
22 More details of the study population and screening procedure have been published
23 elsewhere³⁴. In brief, 2,144 elderly individuals took part in the screening program, and 461
24 elderly individuals had prediabetes. For various reasons, 21 of those with prediabetes
25 provided no response, and the response rate was 95.4%. Six individuals who had incomplete
26 data were also excluded from this study. Finally, a total of 434 individuals with prediabetes
27 from 42 villages were included in this study.

28 **Data collection**

29 Sociodemographic information was collected by trained staff using a set of structured
30 questionnaires, which included age, gender, education, marital status, presence of other
31 chronic diseases, history of hyperglycemia, family history of diabetes, physical activity,
32 smoking and alcohol drinking. Marital status was classified as married and nonmarried.
33 Nonmarried status included divorced, never married and lost a partner. Chronic diseases
34 included hypertension, coronary heart disease, dyslipidemia and others. History of
35 hyperglycemia was defined as a situation of fasting glucose >6.1 mmol/L or 2-hour
36 glucose >7.8 mmol/L without a diagnosis of diabetes. Physical activity was assessed using the
37 International Physical Activity Questionnaire-long version (IPAQ), and individuals who
38 achieved ≥600 metabolic equivalent(MET)-min/week were categorized as active³⁵. Smoking
39 was defined as averaging one or more cigarettes per day in the last year. Alcohol drinking
40 was defined as drinking more than one glass of wine (approximately 250 mL beer or 100 mL sake
41 or 20 mL liquor) per month in the last year.

42 Anthropometric measurements, including height, weight, blood pressure, waist
43 circumference and hip circumference, were assessed using a standard tool. The measurement
44 procedure was published in a previous study³⁶. Body mass index (BMI) was calculated using
45 the formula of weight in kilograms divided by height in m² (kg/m²). The current Chinese
46 standard classification states that the cut-off values for normal weight, overweight and obesity
47 BMI are 18.5 kg/m², 24.0 kg/m² and 28.0 kg/m²³⁷, respectively. Hypertension was defined as
48 systolic blood pressure ≥140 mm Hg and/or diastolic blood pressure ≥90 mm Hg. The waist
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 to hip ratio (WHR) was calculated by dividing the waist circumference by the hip
4 circumference. A WHR >0.9 in men or >0.8 in women was defined as abnormal WHR³⁸.

5
6 DSHL was assessed using the Questionnaire of Health Literacy of Diabetes Mellitus of the
7 Public in China, which was designed by the Chinese Center for Health Education to assess
8 health literacy about diabetes prevention and control in the general population³⁹. This
9 questionnaire has been widely used in epidemiological studies in China, and has high
10 reliability and validity, with a Cronbach's α of 0.866³⁹. DSHL can provide a comprehensive
11 evaluation of an individual's diabetes prevention and control knowledge, risk awareness, and
12 ability to manage risk factors. The questionnaire is organized into three main domains:
13 diabetes-related knowledge, diabetes-related behavior, and acquisition and utilization of
14 diabetes information. The diabetes-related knowledge section assessed attitudes toward
15 diabetes, typical symptoms of diabetes, complications of diabetes, factors conferring a high
16 risk of developing diabetes and methods to prevent diabetes. The diabetes-related behaviors
17 included sitting time duration, physical exercise, dietary pattern, physical examination, and
18 smoking and alcohol drinking habits. In the part about the acquisition and utilization of
19 diabetes information, the participants were asked about the method or way to find
20 diabetes-related information, the degree of their acquisition of diabetes-related information
21 and their ability to identify the correctness of diabetes-related information. An alternative
22 classification was used where the scores 19.5 points and above were classified as high DSHL
23 and the remaining were classified as low. Although the prediabetic population may not
24 experience certain symptoms of diabetes, people with a high health literacy status can identify
25 the risk factors related to the development of type 2 diabetes and thus engage in diabetes care
26 behavior. The purpose and structure of this questionnaire allows it to effectively and
27 accurately measure the participants' ability to obtain, process and understand diabetes-related
28 information and make informed diabetes care decisions.

29
30 HRQoL was assessed using the Medical Outcomes Study 36-Item Short Form Health
31 Survey (SF-36)⁴⁰. The SF-36 health survey questionnaire has been translated and validated in
32 Chinese, and the Chinese version has been proven to be reliable and valid in an elderly
33 population⁴¹. This 36-item measure is organized into eight domains that constitute two main
34 components: the physical health component and the mental health component. The physical
35 health component includes four parts: physical functioning (PF), role physical (RP), bodily
36 pain (BP) and general health (GH). Vitality (VT), social functioning (SF), role-emotional (RE)
37 and mental health (MH) are included in the mental health component. The eight domains
38 were scored from 0 to 100, indicating the worst to best possible health. Each domain score
39 was further summarized and standardized into the physical component score (PCS) and the
40 mental component score (MCS) according to American norms to allow for international
41 comparisons⁴².

42 **Data analysis**

43 Data were presented as n (%) for categorical variables and mean \pm SD or median (P₂₅-P₇₅)
44 for numerical variables. Nonparametric tests were used because the distribution of the DSHL
45 scores was non-Gaussian. The Mann-Whitney U test or Kruskal-Wallis test was used to
46 identify the differences in total DSHL scores according to different variables. The *t*-test or
47 one-way variance (ANOVA) was used to compare the differences in the scores for different
48 domains of HRQoL. General linear models of multivariate analysis of covariance (MANCOVA)
49
50
51
52
53
54
55
56
57
58
59
60

were used to test differences in HRQoL between the adequate DSHL group and the inadequate group. Sociodemographic and anthropometric variables were treated as possible covariates. A significant MANCOVA was followed by univariate *F*-tests using the Wilks' λ statistic. Linear independent pairwise comparisons were analyzed to examine the magnitude of the difference in the mean scores of the dependent variables. Effect sizes (*d*) were computed by dividing the difference in means between groups by the pooled SD and were interpreted as small ($d \leq 0.20$), medium ($0.2 < d \leq 0.50$) or large ($0.5 < d \leq 0.80$)⁴³. The data were analyzed using SPSS Version.20.0 (SPSS/IBM, Armonk, New York, USA).

Patient and public involvement

Neither patients nor public were directly involved in the development, design or recruitment of the study. Anthropometric and glucose test results were provided to the participants at the point of testing.

Results

A total of 461 elderly individuals had prediabetes, and the prevalence of prediabetes was 21.5% (461/2,144) in rural areas of Yiyang City. In total, 434 elderly individuals with prediabetes were included in this study. The average age of all participants was 69.4±6.4 years. The average fasting plasma glucose was 5.9±0.5 mmol/L, and the average 2-hour plasma glucose load was 7.2±1.9 mmol/L. A majority of the subjects were female, had completed less than 6 years of education, smoked, drank no alcohol and had no hypertension. The characteristics of the study subjects are shown in Table 1.

The overall median DSHL score was 10.0 (IQR 7.0-13.0). Men had lower HL scores than women. Furthermore, married elderly individuals had higher DSHL scores than nonmarried individuals. Individuals with a history of hyperglycemia had a higher DSHL score than people with no history. Similarly, individuals with prediabetes who had completed 6 years or more of education had a higher score than those who had completed less than 6 years. The DSHL score according to different characteristics is presented in Table 1.

Table 1 The DSHL score according to different characteristics

Characteristics	n (%)	DSHL score [†]	<i>P</i> -value [‡]
Age			
60-69 years	239 (55.1)	10.0 (8.0-15.0)	0.461
70 years and older	195 (44.9)	10.0 (7.5-11.0)	
Gender			
Male	180 (41.5)	9.0 (7.0-12.0)	<0.001
Female	254 (58.5)	11.0 (8.0-13.0)	
Marital status			
Married	312 (71.9)	10.0 (7.0-13.0)	0.044
Nonmarried	122 (28.1)	9.0 (7.0-11.0)	
Education			
Less than 6 years	353 (81.3)	9.0 (6.5-12.0)	<0.001
6 years and more	81 (18.7)	12.0 (9.0-16.0)	
History of hyperglycemia			
Yes	28 (6.5)	12.5 (9.3-20.5)	0.001
No	406 (93.5)	9.0 (7.0-12.0)	

Family history of diabetes			
Yes	36 (8.3)	12.0 (7.0-13.8)	0.165
No	398 (91.7)	10.0 (7.0-12.0)	
Have other chronic disease			
Yes	176 (40.6)	10.0 (7.0-13.0)	0.544
No	258 (59.4)	10.0 (7.0-13.0)	
Physical activity			
Active	182 (41.9)	10.5 (8.0-13.5)	0.227
Inactive	252 (58.1)	9.5 (8.0-13.0)	
Smoking			
Yes	99(22.8)	10.0 (8.0-12.0)	0.525
No	335(77.2)	10.0 (8.0-13.0)	
Alcohol drinking			
Yes	98 (22.6)	10.0 (8.0-12.0)	0.308
No	336 (77.4)	10.0 (7.5-13.0)	
BMI			
Lean	17 (3.9)	9.0 (5.5-13.5)	0.547
Normal	233 (53.7)	9.0 (7.0-13.0)	
Overweight	129 (29.7)	10.0 (7.0-12.0)	
Obese	55 (12.7)	10.0 (7.0-13.0)	
Hypertension			
Yes	173 (39.9)	10.5 (8.5-13.0)	0.256
No	261 (60.1)	9.5 (8.0-12.0)	
WHR			
Normal	77 (17.7)	9.0 (7.0-12.0)	0.074
Abnormal	357 (82.3)	10.0 (7.0-13.0)	

DSHL, diabetes-specific health literacy

†Data are presented as the median (P₂₅-P₇₅)

‡P value was determined by Kruskal-Wallis test or Mann-Whitney U test.

BMI, body mass index; WHR, waist to hip ratio

Health-related quality of life score

Individuals with prediabetes reported a PCS of 42.1 points (95%CI: 41.2, 43.1) and an MCS of 46.4 points (95%CI: 45.5, 47.1). The scores for the four domains of the PCS were 76.1±23.4, 71.4±42.4, 75.7±15.9 and 57.8±21.5, and the scores for the four domains of the MCS were 72.2±18.1, 79.7±17.1, 85.1±33.3 and 74.8±17.5. The means and their SDs for eight subscales of HRQoL scores according to different characteristics are shown in Table 2. Neither domain score showed a significant difference for the variables of gender, family history of diabetes or alcohol drinking (All $P > 0.05$). The BP and GH scores were lower among people aged 70 years and older. The MH score was lower among people who were not married. Individuals with prediabetes who had completed 6 years of education or more had higher SF and RE scores than people educated 1-6 years. Individuals who achieved active physical activity seemed to have higher scores in the PF, BP and GH domains. The RP, GH and RE scores were similarly higher among elderly people with normal BMI. Moreover, individuals with normal WHR had higher BP, SF and RE scores.

Table 2 HRQoL scores of eight domains measured by SF-36

Characteristics	Physical Health Components				Mental Health Components			
	PF	RP	BP	GH	VT	SF	RE	MH
Overall	76.1±23.4	71.4±42.4	75.7±15.9	57.8±21.5	72.2±18.1	79.7±17.1	85.1±33.3	74.8±17.5
Age								
60-69 years	76.9±23.5	74.1±41.6	77.4±16.6*	60.0±21.5*	72.9±17.7	80.5±16.6	87.2±31.1	75.7±17.4
70 years and older	74.9±23.1	67.2±43.4	73.1±14.4*	54.8±21.1*	71.1±18.8	78.5±17.8	82.0±36.3	73.4±17.7
Gender								
Male	75.8±23.4	73.3±41.4	74.9±16.5	58.5±20.7	72.5±18.3	80.7±16.3	86.0±32.3	74.2±18.5
Female	76.3±23.4	70.1±43.2	76.3±15.5	57.2±22.1	72.0±18.0	79.0±17.6	84.5±34.0	75.2±16.9
Marital status								
Married	75.6±23.9	73.2±42.2	75.3±16.3	58.8±21.6	73.0±18.1	79.7±16.9	85.4±33.2	76.0±16.9*
Nonmarried	77.5±21.8	66.6±42.9	76.7±14.9	54.9±20.8	69.9±18.1	79.8±17.7	84.4±33.6	71.4±18.8*
Education								
Less than 6 years	75.9±23.6	71.0±42.7	75.7±15.7	57.4±21.5	71.5±18.5	78.8±16.9*	83.1±34.9*	74.4±17.6
6 years and more	76.9±22.8	73.3±41.4	75.7±16.7	59.1±21.4	75.0±16.3	83.2±17.5*	93.1±24.5*	76.3±17.2
History of hyperglycemia								
Yes	75.9±23.5	67.9±43.3	73.2±12.9	51.2±30.1*	64.0±20.9*	76.0±17.3	80.9±36.6	69.2±19.9
No	77.2±22.5	71.9±42.3	76.0±16.2	58.5±20.3*	73.2±17.5*	80.2±17.0	85.7±32.9	75.5±17.1
Family history of diabetes								
Yes	75.7±23.9	72.9±42.3	75.2±16.2	58.4±21.9	72.7±18.2	79.5±16.8	84.5±34.0	75.6±17.2
No	77.2±22.1	67.5±42.5	77.1±15.0	55.9±20.3	70.8±17.8	80.3±17.9	86.8±31.4	72.6±18.4
Other chronic disease								
Yes	72.9±24.1*	72.0±42.6	71.7±16.2*	56.7±20.5	71.9±18.0	78.7±17.1	84.8±33.5	74.0±18.3
No	78.1±22.7*	71.1±42.4	78.1±15.2*	58.4±22.1	72.4±18.2	80.3±17.1	85.3±33.2	75.3±17.0
Physical activity								
Active	80.4±24.5*	72.9±42.8	78.5±17.2*	61.6±21.8*	73.8±16.4	80.9±18.3	90.1±28.0	76.3±16.4
Inactive	74.5±23.7*	70.9±42.3	74.6±15.3*	56.3±21.2*	71.6±18.7	79.2±16.6	83.3±34.9	74.2±17.9
Smoking								
Yes	76.2±24.2	70.1±43.2	75.3±16.3	57.2±21.4	71.9±18.1	78.1±17.8*	85.0±33.8	73.8±17.4
No	75.9±22.4	73.0±41.5	76.1±15.5	58.5±21.5	72.6±18.2	81.7±16.1*	85.4±32.8	75.9±17.7
Alcohol drinking								
Yes	76.3±23.1	71.1±42.7	75.3±15.7	57.7±21.4	72.7±18.0	79.6±16.9	84.0±34.5	74.8±17.4
No	75.4±24.5	72.4±41.5	76.8±16.7	57.9±21.7	70.4±18.6	80.1±17.9	89.1±28.6	74.5±18.0
BMI								
Lean	79.1±25.4	60.9±45.7*	73.9±13.4	53.7±23.5*	65.6±17.7	78.7±16.0	78.3±39.7*	69.2±20.7
Normal	76.7±22.8	77.0±39.6*	76.1±16.0	59.9±20.3*	73.7±18.0	81.2±17.1	89.2±28.5*	75.7±17.3
Overweight	75.1±24.5	76.6±39.2*	76.2±15.3	57.7±21.5*	70.7±18.8	78.7±17.5	82.6±36.2*	73.9±16.9
Obese	74.1±23.2	47.0±47.2*	73.9±17.4	51.6±23.9*	71.1±17.3	76.0±16.3	76.1±40.5*	74.4±18.0
Hypertension								
Yes	78.0±22.9*	66.9±44.4	75.3±17.1	55.5±23.8	71.0±18.7	77.8±17.5	78.5±38.0*	74.7±17.7
No	73.1±23.8*	74.3±40.9	75.9±15.1	59.2±19.8	73.0±17.9	80.9±16.7	89.4±29.2*	74.8±17.5
WHR								

Normal	77.3±23.5	72.8±41.6	78.4±17.1*	59.2±21.6	72.8±18.3	81.6±15.8*	88.1±29.8*	76.0±17.6
Abnormal	74.4±23.2	69.4±43.6	71.8±13.1*	55.8±21.2	71.4±17.8	76.9±18.4*	80.9±37.5*	73.1±17.4

Data are presented as the mean±SD, and analysis was performed using analysis of variance (ANOVA) or t-test. * $P<0.05$; PF, physical functioning; RP, role physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health

Association between DSHL and HRQoL

Crude analysis indicated that when the eight subscales of HRQoL were placed as the dependent variables and DSHL (as a binary variable) was entered as the independent variable, the overall MANCOVA showed significant differences in the general health, vitality, social functioning and mental health scores between the two groups (Wilk' $\lambda=0.955$, $F=2.44$, $P=0.014$). After adjusting for other covariants, individuals with high DSHL reported higher scores on GH ($M_{diff}=6.8$, $P=0.028$), VT ($M_{diff}=6.6$, $P=0.014$), SF ($M_{diff}=6.0$, $P=0.017$) and MH ($M_{diff}=7.4$, $P=0.005$) than did those with low DSHL. The associations between DSHL and different domains of HRQoL are shown in Table 3.

Crude analysis showed that with two components of HRQoL entered as dependent variables, the overall MANCOVA was significant (Wilks' $\lambda=0.965$, $F=7.87$, $P<0.001$). Individuals with high DSHL had higher PCS score ($M_{diff}=2.9$, $ES=0.30$) and MCS score ($M_{diff}=4.4$, $ES=0.47$) than those with low DSHL. After adjusting for age, gender, education, marital status, other chronic diseases, family history of diabetes, history of hyperglycemia, physical activity, hypertension, smoking, drinking, BMI and WHR, a linear independent pairwise comparison indicated that individuals with prediabetes who had higher DSHL reported higher MCS ($M_{diff}=3.5$, 95%CI: 1.8, 6.3) with a medium effect size ($ES=0.38$). The association between DSHL and HRQoL among elderly individuals with prediabetes is shown in Table 4.

Table 3 Association between DSHL and different subscales of HRQoL among elderly individuals with prediabetes

SF-36 domains	High DSHL		Low DSHL		Difference		
	Mean	SE	Mean	SE	M_{diff} (95%CI)	ES(<i>d</i>)	<i>P</i> -value
Crude analysis (Wilk' $\lambda=0.955$, $F=2.44$, $P=0.014$)							
PF	80.0	3.2	75.5	1.2	4.6 (-2.3,11.2)	0.20	0.193
RP	74.5	5.8	70.9	2.3	3.5 (-5.7,15.4)	0.08	0.224
BP	78.9	2.2	75.2	0.8	3.7 (-1.8, 8.3)	0.23	0.110
GH	64.5	2.9	56.8	1.1	7.6 (1.6,13.7)	0.38	0.013
VT	78.9	2.5	71.3	0.9	7.5 (2.4,12.8)	0.42	0.004
SF	86.0	2.3	78.8	0.9	7.2 (2.4,12.1)	0.43	0.001
RE	91.2	4.6	84.3	1.7	6.9 (-2.7,16.5)	0.21	0.158
MH	81.8	2.4	73.8	0.9	8.0 (3.0,13.0)	0.46	0.002
Adjusted analysis (Wilk' $\lambda=0.958$, $F=2.31$, $P=0.019$) [†]							
PF	79.6	3.2	75.6	1.2	4.0 (-2.8,10.8)	0.17	0.252
RP	73.1	5.9	71.2	2.1	1.9 (-6.7,14.2)	0.07	0.186
BP	78.4	2.1	75.3	0.8	3.1 (-1.2,7.5)	0.19	0.161
GH	63.7	2.9	56.9	1.1	6.8 (1.7,12.9)	0.33	0.028

VT	78.0	2.5	71.4	0.9	6.6 (1.3,11.8)	0.37	0.014
SF	84.9	2.3	79.0	0.9	6.0 (1.1,10.9)	0.36	0.017
RE	88.0	4.6	84.7	1.7	3.4 (-6.2,12.9)	0.10	0.492
MH	81.2	2.4	73.9	0.9	7.4 (2.3,12.5)	0.43	0.005

DSHL, diabetes-specific health literacy; PF, physical functioning; RP, role-physical; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role-emotional; MH, mental health.

† Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

M_{diff}, mean difference; ES(*d*), mean difference/pooled SD.

Table 4 Association between DSHL and HRQoL among elderly individuals with prediabetes

Variables	High DSHL		Low DSHL		Difference		
	Mean	SE	Mean	SE	M _{diff} (95%CI)	ES (d)	P-value
Crude analysis (Wilks'λ=0.965, F=7.87, P<0.001)							
PCS	44.6	1.3	41.7	0.5	2.9 (1.4,5.7)	0.30	0.046
MCS	50.2	1.3	45.8	0.5	4.4 (1.7,7.1)	0.47	0.001
Adjusted analysis (Wilks'λ=0.974, F=5.63, P=0.004)†							
PCS	44.4	1.3	41.8	0.6	2.6 (-1.2,5.4)	0.27	0.067
MCS	49.4	1.3	45.9	0.7	3.5 (1.8, 6.3)	0.38	0.012

DSHL, diabetes-specific health literacy; M_{diff}, mean difference; ES (d), mean difference/pooled SD; PCS, physical health component score; MCS, mental health component score.

†Adjusted for age, gender, education, marital status, other chronic disease, physical activity, family history of diabetes, history of hyperglycemia, smoking, drinking, hypertension, BMI and WHR.

Discussion

This cross-sectional study showed a high prevalence (21.5%) of prediabetes among the elderly population in rural areas in China, which is similar to the findings of the earlier study⁴⁴. The results, together with the large elderly population living in rural areas, suggest that this serious public health problem in China requires better prevention.

Many studies have used general HL measurement instruments, such as REALM or TOFHLA, which are not disease or condition-specific. However, our study used a DSHL questionnaire with high reliability and validity that was designed by the Chinese Center for Health Education, and is suitable for a nondiabetic population³⁹. The questionnaire was able to effectively and accurately examine the level of HL about diabetes knowledge, diabetes prevention behaviors and the acquisition and utilization of diabetes information among individuals with prediabetes. There is a direct association between DSHL and patient assessments of their self-care ability, which indicates that HL measures should include indicators of knowledge and understanding²⁵. Thus, in terms of prevention, knowing the HL of individuals with prediabetes regarding diabetes prevention and control contribute to the development of more effective interventions and health education methods. Based on the results of the univariate analysis, the DSHL score showed significant differences in the variables of gender, education and history of hyperglycemia, which are consistent with the findings of other studies^{45 46}.

Although the effect of HL on HRQoL has been widely discussed among some populations

1
2
3 in previous studies⁴⁷⁻⁴⁹, few studies have explored the association between HL and HRQoL
4 among individuals with prediabetes. There is also a lack of research probing the effect of
5 disease- or condition-specific HL on HRQoL. To the best of our knowledge, this is the first
6 study to examine the relationship between DSHL and HRQoL among elderly individuals with
7 prediabetes. Our study found that DSHL was positively associated with some health domains
8 of HRQoL according to bivariate and multivariate analyses. Compared with individuals with
9 prediabetes with lower HL levels, subjects with higher HL reported higher scores on the
10 GH,VT,SF and MH subscales of HRQoL. That is, the prediabetic older adults with lower HL
11 were more likely to have limited social activities(SF), poor general health perceptions(GH),
12 tiredness(VT) and psychological distress(MH).When the eight domain scores were
13 standardized and summarized as the PCS and MCS, the relationship between DSHL levels and
14 HRQoL was significant in the mental-well being(SF-36 MCS), while it was significant in the
15 physical health domain(SF36 PCS) only in the bivariate model and became nonsignificant
16 after controlling for sociodemographic and somatometric covariates. On the one hand, more
17 subscales of the MCS component than of the PCS were significantly associated with DSHL;
18 this finding could be helpful in further studies exploring the influence of HL on certain
19 subscales of HRQoL. On the other hand, some information loss may occur in the process of
20 standardizing and summarizing the scores of the eight domains into two components because
21 of the different weights of the eight domains. However, the PCS and MCS scales are scored
22 using the linear T-score transformation method so that a one-point difference is one-tenth of
23 a standard deviation, and higher scores indicate a better health status⁴². Therefore, a 2- to
24 3-point difference in the PCS and MCS score in our study is significant and meaningful. These
25 results are in concordance with those of previous studies that targeted the relationship
26 between general HL and HRQoL^{10 50-53}. For instance, Jayasinghe and her colleagues found
27 that HL accounted for 45% and 70% of the total between-patient variance explained in PCS-12
28 and MCS-12, respectively¹⁰. Furthermore, a study conducted in 605 patients with
29 symptomatic heart failure (HF) showed that those with higher literacy had better HRQoL
30 scores (mean difference=7.2, $P<0.01$) than did those with lower literacy⁵². A cross-sectional
31 survey of 1841 cancer patients in Wisconsin also indicated that higher HL was positively
32 associated with the physical, functional, emotional, and social well-being subscales of
33 HRQoL⁵³. However, our results also contradict the findings of previous studies that examined
34 the association^{28-30 54-56}. Data from a clinical trial that included 154 predominantly white
35 patients with type 2 diabetes who screened positive for depression showed that the
36 between-HL group difference in change over 1 year was only nonsignificant at 0.76 points for
37 PCS and 0.56 points for MCS²⁸. In another study conducted among frequent users of health
38 care services, no association was found between HL and HRQoL on both PCS and MCS⁵⁵.
39 Two other studies^{30 54} demonstrated that HL was not significantly associated with only the
40 mental component of HRQoL. A prospective cohort study of 4278 older adults in the UK
41 showed that low HL significantly predicted declines in the physical, psychological and
42 environmental domains of HRQoL but not in the social relationship HRQoL⁵⁶. There are
43 three reasons for this variance. First, most studies pay attention to the impact of general HL
44 rather than specific HL on HRQoL. However, general HL includes the ability to obtain,
45 process and understand all basic health information, not just a specific disease. Second, the
46 various studies used different tools to measure HL and HRQoL. Last, the contradictory results
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 were also likely due to differences in social and culture factors, and in the study populations
4 and sample sizes.

5
6 These results suggest that individuals with newly diagnosed prediabetes who have higher
7 levels of DSHL may have higher HRQoL, especially for the mental health component. A
8 potential explanation for the relationship between DSHL and the physical and mental
9 components of HRQoL may be that low DSHL limits individuals' understanding of complex
10 information about diabetes knowledge and prevention, and thus becomes a barrier to
11 individuals' participation in diabetes education and intervention. Moreover, people with lower
12 HL tend to have difficulty communicating, which prevents them from asking questions,
13 clearly expressing their concerns, emotions, and needs to providers and seeking additional
14 services, such as support for mental health^{50 53}. Furthermore, as a previous study found that
15 subjects with low health literacy were 3 times more likely to have depression⁵⁴. Considering
16 that individuals with lower HL were more likely to have limited social activities, tiredness and
17 psychological distress, lower DSHL may further limit individuals' ability to talk with their
18 families and health education and care providers about difficult emotional issues or abstract
19 psychosocial implications of diabetes. Thus, different DSHL groups may show differences in
20 understanding and acceptance when faced with the same diabetes education information and
21 intervention programs. This process may be also associated with responsiveness during
22 consultations and interventions. Individuals with lower levels of DSHL may not have
23 knowledge of signs or symptoms of concern and may experience a psychological panic,
24 reducing the MCS of HRQoL. The findings about the impact of DSHL on HRQoL in the
25 prediabetic population could help us to identify new target groups and provide multifaceted
26 and collaborative interventions to delay the development of type 2 diabetes. They also provide
27 information that could contribute to assessments of the effects and cost-effectiveness of
28 diabetes education and intervention. Healthcare staff should be aware of health literacy
29 problems among elderly adults, and should simplify health-related information to increase
30 the responsiveness of subjects with low health literacy during consultations and interventions.
31 Although our findings were based on the results of a cross-sectional study, HRQoL could be
32 viewed as an essential supplementary outcome in health surveys or intervention process; thus,
33 it is important to carry out HRQoL monitoring to fully understand the health status of
34 different HL groups. Furthermore, the finding that DSHL is associated with changes in
35 HRQoL outcomes raises the need for testing the hypothesis of whether DSHL is a modifiable
36 factor and, if so, considering whether interventions aimed at improving DSHL may also lead
37 to improvements in HRQoL and health conditions in this population. Therefore, there are
38 important public health implications of examining the association between DSHL and
39 HRQoL.

40
41 Our study also revealed that individuals with prediabetes showed lower PCS than MCS,
42 and the mean scores of the four domains of the mental health components were likewise
43 higher than those of four subscales of the physical health components, which was consistent
44 with the findings of other studies^{57 58}. One explanation is that some elderly have difficulties in
45 physical activities due to illness. A study has also shown that chronic diseases have a stronger
46 effect on reducing physical function than psychological function⁵⁹. Similar to the results of our
47 study, elderly individuals with chronic disease, overweight or obesity and physical inactivity
48 have lower scores on the subscales of physical function, bodily pain and general health;
49

1
2
3 however, these domains are components of the physical health aspect of HRQoL.

4 Our study also has several limitations. First, its cross-sectional design did not permit
5 causal inferences. Furthermore, both cohort studies and randomized controlled trial designs
6 garner a deeper understanding of the relationship between DSHL and HRQoL. Second, HL
7 was measured using the public questionnaire of HL of diabetes mellitus. This may influence
8 the way in which our study may be compared to previous studies, the majority of which
9 measured multidimensional competences rather than a single competence of functional HL.
10 Third, self-administered questionnaires were used to assess some variables, which might have
11 introduced recall bias. However, this limitation was minimized because instruments used in
12 this study are valid and reliable. Finally, our study sample was taken from rural areas in one
13 city of one province of China. Therefore, the generalization of the results to other populations
14 should be carefully considered.

15 16 17 18 19 **Conclusions**

20 In summary, lower DSHL was associated with poorer HRQoL among elderly individuals
21 with prediabetes in rural areas in China, particularly in terms of the mental health component.
22 These findings suggest that assessing and improving both DSHL and HRQoL may be
23 important for individuals with prediabetes.

24 25 26 **Acknowledgements**

27 We thank all the participants very much for their collaboration.

28 29 **Author contributions**

30 ZH and LQ completed the statistical analyses and drafted the manuscript. HLX checked
31 and revised the manuscript. All the authors read and approved the final manuscript.

32 33 **Funding**

34 This study was funded by the Teachers Research Fund of Central South University
35 (2013JSJJ034) and the Central South University Graduate Student Independent
36 Exploration Innovation Project (NO.2013zzts286).

37 38 **Competing interests**

39 None declared.

40 41 **Patient consent**

42 Obtained.

43 44 **Ethical approval**

45 The study was approved by the Medical Ethics Committee of Central South University
(Changsha, China; Identification Code: CTXY-150002-7; 27 February 2015).

46 47 **Data sharing statement**

48 No additional data are available.

49 50 **References**

- 51 1. Punthakee Z, Goldenberg R, Katz P. Definition, Classification and Diagnosis of Diabetes,
52 Prediabetes and Metabolic Syndrome. *Canadian journal of diabetes* 2018;42 Suppl 1:S10-s15.
- 53 2. Perreault L, Pan Q, Mather KJ, et al. Effect of regression from prediabetes to normal glucose
54 regulation on long-term reduction in diabetes risk: results from the Diabetes Prevention
55 Program Outcomes Study. *Lancet (London, England)* 2012;379:2243-51.
- 56 3. de Vegt F, Dekker JM, Jager A, et al. Relation of impaired fasting and postload glucose with
57 incident type 2 diabetes in a Dutch population: The Hoorn Study. *Jama* 2001;285:2109-13.
- 58 4. Ang YG, Wu CX, Toh MP, et al. Progression rate of newly diagnosed impaired fasting glycemia to
59
60

- 1
2
3 type 2 diabetes mellitus: a study using the National Healthcare Group Diabetes Registry in
4 Singapore. *J Diabetes* 2012;4:159-63.
- 5
6 5. Forouhi NG, Luan J, Hennings S, et al. Incidence of Type 2 diabetes in England and its association
7 with baseline impaired fasting glucose: the Ely study 1990-2000. *Diabetic medicine : a*
8 *journal of the British Diabetic Association* 2007;24:200-7.
- 9
10 6. Nathan DM, Davidson MB, DeFronzo RA, et al. Impaired fasting glucose and impaired glucose
11 tolerance: implications for care. *Diabetes care* 2007;30:753-9.
- 12
13 7. Wang L, Gao P, Zhang M, et al. Prevalence and Ethnic Pattern of Diabetes and Prediabetes in China
14 in 2013. *Jama* 2017;317:2515-23.
- 15
16 8. The WHOQOL Group. The World Health Organization Quality of Life Assessment (WHOQOL):
17 development and general psychometric properties. *Social science & medicine (1982)*
18 1998;46:1569-85.
- 19
20 9. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. *Annals of internal*
21 *medicine* 1993;118:622-9.
- 22
23 10. Jayasinghe UW, Harris MF, Parker SM, et al. The impact of health literacy and life style risk
24 factors on health-related quality of life of Australian patients. *Health and quality of life*
25 *outcomes* 2016;14:68.
- 26
27 11. Keles H, Ekici A, Ekici M, et al. Effect of chronic diseases and associated psychological distress on
28 health-related quality of life. *Internal medicine journal* 2007;37:6-11.
- 29
30 12. Alfonso-Rosa RM, Del Pozo-Cruz B, Del Pozo-Cruz J, et al. The relationship between nutritional
31 status, functional capacity, and health-related quality of life in older adults with type 2
32 diabetes: a pilot explanatory study. *The journal of nutrition, health & aging* 2013;17:315-21.
- 33
34 13. Tapp RJ, Dunstan DW, Phillips P, et al. Association between impaired glucose metabolism and
35 quality of life: results from the Australian diabetes obesity and lifestyle study. *Diabetes*
36 *research and clinical practice* 2006;74:154-61.
- 37
38 14. Ghorbani A, Ziaee A, Esmailzadehha N, et al. Association between health-related quality of life
39 and impaired glucose metabolism in Iran: the Qazvin Metabolic Diseases Study. *Diabetic*
40 *medicine : a journal of the British Diabetic Association* 2014;31:754-8.
- 41
42 15. Hunger M, Holle R, Meisinger C, et al. Longitudinal changes in health-related quality of life in
43 normal glucose tolerance, prediabetes and type 2 diabetes: results from the KORA S4/F4
44 cohort study. *Quality of life research : an international journal of quality of life aspects of*
45 *treatment, care and rehabilitation* 2014;23:2515-20.
- 46
47 16. Lam CL, Fong DY, Lauder IJ, et al. The effect of health-related quality of life (HRQOL) on health
48 service utilisation of a Chinese population. *Social science & medicine (1982)*
49 2002;55:1635-46.
- 50
51 17. Chen T, Li L. Influence of health-related quality of life on health service utilization in addition to
52 socio-demographic and morbidity variables among primary care patients in China.
53 *International journal of public health* 2009;54:325-32.
- 54
55 18. Alonso J, Ferrer M, Gandek B, et al. Health-related quality of life associated with chronic
56 conditions in eight countries: results from the International Quality of Life Assessment
57 (IQOLA) Project. *Quality of life research : an international journal of quality of life aspects*
58 *of treatment, care and rehabilitation* 2004;13:283-98.
- 59
60 19. Berkman ND, Davis TC, McCormack L. Health literacy: what is it? *Journal of health*
communication 2010;15 Suppl 2:9-19.

- 1
- 2
- 3
- 4 20. Gazmararian JA, Williams MV, Peel J, et al. Health literacy and knowledge of chronic disease. *Patient education and counseling* 2003;51:267-75.
- 5
- 6 21. Bennett IM, Chen J, Soroui JS, et al. The contribution of health literacy to disparities in self-rated
- 7 health status and preventive health behaviors in older adults. *Ann Fam Med* 2009;7:204-11.
- 8
- 9 22. Bostock S, Steptoe A. Association between low functional health literacy and mortality in older
- 10 adults: longitudinal cohort study. *BMJ* 2012;344:e1602.
- 11
- 12 23. Institute of Medicine Committee on Health Literacy. In: Nielsen-Bohlman L, Panzer AM, Kindig
- 13 DA, eds. *Health Literacy: A Prescription to End Confusion*. Washington (DC): National
- 14 Academies Press (US) Copyright 2004 by the National Academy of Sciences. All rights
- 15 reserved., 2004.
- 16
- 17 24. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a
- 18 meta-analysis of the effect on glycemic control. *Diabetes care* 2002;25:1159-71.
- 19
- 20 25. Yamashita T, Kart CS. Is diabetes-specific health literacy associated with diabetes-related
- 21 outcomes in older adults? *J Diabetes* 2011;3:138-46.
- 22
- 23 26. Chen GD, Huang CN, Yang YS, et al. Patient perception of understanding health education and
- 24 instructions has moderating effect on glycemic control. *BMC public health* 2014;14:683.
- 25
- 26 27. Sarkar U, Fisher L, Schillinger D. Is self-efficacy associated with diabetes self-management across
- 27 race/ethnicity and health literacy? *Diabetes care* 2006;29:823-9.
- 28
- 29 28. Al Sayah F, Majumdar SR, Johnson JA. Association of Inadequate Health Literacy with Health
- 30 Outcomes in Patients with Type 2 Diabetes and Depression: Secondary Analysis of a
- 31 Controlled Trial. *Canadian journal of diabetes* 2015;39:259-65.
- 32
- 33 29. Naimi AJ, Naderiravesh N, Bayat ZS, et al. Correlation between health literacy and health-related
- 34 quality of life in patients with hypertension, in Tehran, Iran, 2015-2016. *Electronic physician*
- 35 2017;9:5712-20.
- 36
- 37 30. Gonzalez-Chica DA, Mnisi Z, Avery J, et al. Effect of Health Literacy on Quality of Life amongst
- 38 Patients with Ischaemic Heart Disease in Australian General Practice. *PloS one*
- 39 2016;11:e0151079.
- 40
- 41 31. Robinson R. Cost-utility analysis. *Bmj* 1993;307:859-62.
- 42
- 43 32. Zhang XH, Li SC, Fong KY, et al. The impact of health literacy on health-related quality of life
- 44 (HRQoL) and utility assessment among patients with rheumatic diseases. *Value in health : the*
- 45 *journal of the International Society for Pharmacoeconomics and Outcomes Research* 2009;12
- 46 Suppl 3:S106-9.
- 47
- 48 33. Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its
- 49 complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a
- 50 WHO consultation. *Diabetic medicine : a journal of the British Diabetic Association*
- 51 1998;15:539-53.
- 52
- 53 34. Xu H, Tang L, Hu Z, et al. Association between physical activity and health-related quality of life
- 54 in elderly individuals with pre-diabetes in rural Hunan Province, China: a cross-sectional
- 55 study. *BMJ Open* 2018;8:e019836.
- 56
- 57 35. Pate RR, Pratt M, Blair SN, et al. Physical activity and public health. A recommendation from the
- 58 Centers for Disease Control and Prevention and the American College of Sports Medicine.
- 59 *Jama* 1995;273:402-7.
- 60
36. Qin L, Xu H. A cross-sectional study of the effect of health literacy on diabetes prevention and
- control among elderly individuals with prediabetes in rural China. *BMJ Open*

- 2016;6:e011077.
37. Wu Y. Overweight and obesity in China. *Bmj* 2006;333:362-3.
38. Obesity in Asia Collaboration. Is central obesity a better discriminator of the risk of hypertension than body mass index in ethnically diverse populations? *Journal of hypertension* 2008;26:169-77.
39. Li L, Li Y, Nie X, et al. An analysis of health literacy about diabetes prevention and control and its influencing factors among the residents in six provinces in China. *Chinese journal of preventive medicine* 2014;48:561-5.
40. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical care* 1992;30:473-83.
41. Zhou B, Chen K, Wang JF, et al. Reliability and validity of a Short-Form Health Survey Scale (SF-36), Chinese version used in an elderly population of Zhejiang province in China. *Chin J Epidemiol* 2008;29:1193-8.
42. Ware J, Kosinski M, Keller S. SF-36 physical and mental health summary scales: a user's manual. 5th edn. Boston, MA: Health Assessment Lab. New England Medical Center, . 1994
43. Cohen J. A power primer. *Psychological bulletin* 1992;112:155-9.
44. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *Jama* 2013;310:948-59.
45. Lutfiyya MN, Lipsky MS, Bales RW, et al. Disparities in knowledge of heart attack and stroke symptoms among adult men: an analysis of behavioral risk factor surveillance survey data. *Journal of the National Medical Association* 2008;100:1116-24.
46. Aihara Y, Minai J. Barriers and catalysts of nutrition literacy among elderly Japanese people. *Health promotion international* 2011;26:421-31.
47. Miller DB, Cage JL, Nowacki AS, et al. Health Literacy (HL) & Health-Related Quality of Life (HRQL) Among Minority Men. *Journal of the National Medical Association* 2018;110:124-29.
48. Montbleau KE, King D, Henault L, et al. Health literacy, health-related quality of life, and atrial fibrillation. *Cogent medicine* 2017;4:1412121.
49. Divaris K, Lee JY, Baker AD, et al. The relationship of oral health literacy with oral health-related quality of life in a multi-racial sample of low-income female caregivers. *Health and quality of life outcomes* 2011;9:108.
50. Song L, Mishel M, Bensen JT, et al. How does health literacy affect quality of life among men with newly diagnosed clinically localized prostate cancer? Findings from the North Carolina-Louisiana Prostate Cancer Project (PCaP). *Cancer* 2012;118:3842-51.
51. Sayah FA, Qiu W, Johnson JA. Health literacy and health-related quality of life in adults with type 2 diabetes: a longitudinal study. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2016;25:1487-94.
52. Macabasco-O'Connell A, DeWalt DA, Broucksou KA, et al. Relationship between literacy, knowledge, self-care behaviors, and heart failure-related quality of life among patients with heart failure. *Journal of general internal medicine* 2011;26:979-86.
53. Halverson JL, Martinez-Donate AP, Palta M, et al. Health Literacy and Health-Related Quality of Life Among a Population-Based Sample of Cancer Patients. *Journal of health communication* 2015;20:1320-9.
54. Lincoln A, Paasche-Orlow MK, Cheng DM, et al. Impact of health literacy on depressive

- 1
2
3 symptoms and mental health-related: quality of life among adults with addiction. *Journal of*
4 *general internal medicine* 2006;21:818-22.
5
6 55. Couture EM, Chouinard MC, Fortin M, et al. The relationship between health literacy and quality
7 of life among frequent users of health care services: a cross-sectional study. *Health and*
8 *quality of life outcomes* 2017;15:137.
9
10 56. Panagioti M, Skevington SM, Hann M, et al. Effect of health literacy on the quality of life of older
11 patients with long-term conditions: a large cohort study in UK general practice. *Quality of life*
12 *research : an international journal of quality of life aspects of treatment, care and*
13 *rehabilitation* 2018;27:1257-68.
14
15 57. Taylor LM, Spence JC, Raine K, et al. Physical activity and health-related quality of life in
16 individuals with prediabetes. *Diabetes research and clinical practice* 2010;90:15-21.
17
18 58. Ibrahim N, Moy FM, Awalludin IA, et al. The health-related quality of life among pre-diabetics and
19 its association with body mass index and physical activity in a semi-urban community in
20 Malaysia--a cross sectional study. *BMC public health* 2014;14:298.
21
22 59. Cigolle CT, Langa KM, Kabeto MU, et al. Geriatric conditions and disability: the Health and
23 Retirement Study. *Annals of internal medicine* 2007;147:156-64.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

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
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any pre-specified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5,6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5,6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	NA
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	6

		<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA
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	7
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	NA
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	NA
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	7
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	8,9,10
		(b) Report category boundaries when continuous variables were categorized	8,9,10
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
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	12,13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12,13
Generalisability	21	Discuss the generalisability (external validity) of the study results	13
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	13

*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.