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Diabetes distress as mediators of loneliness and health promotion behavior: a cross-sectional study

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Diabetes distress as mediators of loneliness and health promotion behavior: a cross-sectional study

Feiyang Zhou^{1,2}, Lu Deng^{1,*}, Chunbo Guo^{1,*}, Keyu Long², Linlin Xie², Tingting Yang², Qian Lv^{1,2}

*Lu Deng, the Second Xiangya Hospital, Central South University, No. 139, Renmin Middle Road, Changsha 410011, China. Email: csdenglu1026@csu.edu.cn

* Chunbo Guo, the Second Xiangya Hospital, Central South University, No. 139, Renmin Middle Road, Changsha 410011, China. E-mail: 154780593@qq.com

1 The Second Xiangya Hospital, Central South University, Changsha, Hunan, China

2 Central South University, Changsha, Hunan, China

Abstract

Objectives: To explore the mediating effect of diabetes distress on loneliness to health promotion.

Design: Cross-sectional survey design.

Setting: Changsha, China

Participants: 140 elderly diabetic patients

Methods: We employed path models to analyze data on diabetes distress, loneliness, and health promotion behaviors. We used convenience sampling to sample 140 elderly diabetic patients from three tertiary A hospitals in Hunan Province. We collected demographic and disease characteristics, diabetes distress, loneliness, and health promotion behavior from January 2022 to October 2022. Mediation analysis was performed by SPSS 26.0's PROCESS macro.

Result: According to bootstrapping results, the total effect of loneliness on health promotion behavior was significantly negative ($\beta=-0.312$, $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress ($\beta=-0.043$, $p < 0.001$), while diabetes distress significantly and negatively correlated with health promotion behaviors ($\beta=-2.724$, $p = 0.008$). Both the indirect effect and the direct effect of loneliness on health promotion behavior were significant.

Conclusion: Diabetes distress plays a mediating role in the relationship between loneliness and health promotion behavior. It is suggested that healthcare providers assessing and

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3 addressing diabetes distress need to increase attention to psychological distress, including
4 loneliness, and then intervene to improve health promotion behaviors and disease
5 management gains for older patients with type 2 diabetes.
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8 **KEYWORDS**

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10 diabetes distress; loneliness; health promotion behaviors; mediation effect; diabetes
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13 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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- 15 ● The study used to collect information face to face, rather than online consulting, to avoid
16 caused by online survey bias
- 17 ● This study indicated attention to psychological factors such as diabetes distress.
- 18 ● The study relies on self-reported outcomes which may introduce measurement bias.
- 19 ● This was not a multicenter study not representative of a pan-global population.
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25 **1. Background**

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27 As the population increases, lifespan is extended, the population of older adults grows and
28 diseases in older adults have brought great attention worldwide ¹. Diabetes is one of the fastest-
29 growing diseases worldwide, projected to affect 693 million adults by 2045 ². The past 50 years
30 have seen a growing aging population with an increasing prevalence of diabetes mellitus (DM);
31 now, nearly half of all individuals with diabetes mellitus are older adults (aged ≥ 65 years) ³.
32 Older adults with diabetes face a higher risk of premature death, functional disability and
33 coexisting conditions than older adults without diabetes⁴. Diabetes increases the vulnerability
34 of older adults to several common geriatric syndromes, such as polypharmacy, cognitive
35 impairment, depression, urinary incontinence, injurious falls, persistent pain, and frailty⁵.
36 Moreover, the complexity of disease management in older adults is compounded by the
37 presence of comorbidities, the higher susceptibility to hypoglycemic events, and the
38 individualized care needs ⁶.
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45 Health promotion behavior is a beneficial strategy to effectively delay the development of
46 diabetic complications, which can effectively break its vicious circle and promote the body,
47 biochemical and other indicators to return to normal levels ⁷. Health promotion behaviors for
48 people with diabetes include blood glucose monitoring, use of insulin and medications, use of
49 diabetes technology, physical activity and nutritional changes ⁸. Health promotion behavior is
50 vital for diabetes in older adults. Psychological factors are proven to influence the behavior of
51 patients with DM ⁹.
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55 Loneliness is the feeling of isolation regardless of objective social network size ¹⁰. In
56 industrialized countries around a third of people are affected by this condition, with one person
57 in 12 affected severely, and these proportions are increasing ¹¹. A longitudinal cohort study
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3 showed loneliness had negative effects on health promotion behaviors¹². Higher loneliness was,
4 however, associated consistently with worse health outcomes among older adults¹³.

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6 Another negative psychological characteristic reported in patients with DM is diabetes
7 distress¹⁴. Diabetes distress refers to the worries, concerns, fears, and threats that are associated
8 with struggling with a demanding chronic disease like diabetes over time, including its
9 management, threats of complications, potential loss of functioning, and concerns about access
10 to care¹⁵. Many studies have found that diabetes distress is associated with health promotion
11 behavior in older patients with DM^{16 17}. In summary, loneliness and diabetes distress are
12 negative characteristics that seem to be associated with health promotion behavior in older
13 patients with DM.
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18 Considering all this evidence, it seems that loneliness and diabetes distress were considered
19 as individual factors associated with health promotion behavior in older patients with DM.
20 However, such studies remain narrow in focus dealing only with unidirectional relationship.
21 Up to now, no previous study has investigated the mediating role of diabetes distress on
22 loneliness to health promotion behavior in older patients with DM.
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26 The theoretical framework of this study is the Health Belief Model (HBM)¹⁸. The HBM
27 interprets an individual's health promoting behavior as the result of perceptions of being
28 exposure to a certain health threat. Loneliness is seen as an exposure risk, diabetes distress is
29 seen as a health threat, and lonely individuals form beliefs about health promoting behaviors
30 through their perceptions of diabetes distress. If individuals believe that distress increases
31 health risk, they may be more inclined to adopt positive health behaviors. Based on the
32 theoretical framework, we propose the hypothesis: loneliness directly affects health promotion
33 behavior, and it also has an indirect effect on health promotion behavior through diabetes
34 distress as a mediator.
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40 Hence, this study was designed to investigate the mediating association of diabetes distress
41 on loneliness to health promotion behavior and to clarify the direct/indirect relationships in
42 older patients with DM.
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44 **2. Methods**

45 **2.1 Aims**

46 This study aimed to examine the mediating role of diabetes distress on the relationship
47 between loneliness and health promotion behaviors. The hypotheses were diabetes distress
48 plays a mediation role in the relationship between loneliness and health promotion behaviors
49 in diabetes in older adults.
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53 **2.2 Design**

54 This study employed a cross-sectional design.

55 **2.3 Participants**

56 Participants were recruited from three third-class hospitals in Hunan by convenience
57 sampling. The inclusion criteria for recruitment included participants aged above 65 years
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having been diagnosed with T2DM. Eligible participants were excluded if having mental or visual problems in completing self-reported questionnaires. G power 3.1.9.6 software was used to calculate the adequate sample size. Based on an α level of 0.05, a power of 0.80, and an effect size of 0.2 for the correlation coefficient, 84 samples were required. Finally, 140 patients finished this study, and the sample size was adequate to test the hypotheses of this study.

2.4 Data collection

The questionnaire is distributed by uniformly trained graduate students and filled in independently by the respondents. For those with blurred vision or a low knowledge level, investigators read out the content and options of the article without implication and complete it on their behalf. After the questionnaire is completed, the investigator will take it back on the spot and check the completeness of the questionnaire to ensure its completeness and validity.

2.4.1 Demographic and disease characteristics

Age, gender, medical payment method, comorbidities (no/yes), course of disease, and use of insulin(no/yes) were collected.

2.4.2 Diabetes distress

We measured the diabetes distress levels in participants using the Chinese version of the Diabetes Distress Scale¹⁹. This scale has 17 items and uses a Likert 6-point scoring method, ranging from 1(Not a problem) to 6(Serious problem). The scale evaluates the results based on the average score of the item. A higher score indicated a higher level of diabetes distress. An average score of ≥ 3 on the scales suggests more than moderate distress and requires clinical attention.

2.4.3 Loneliness

We measured loneliness using the Chinese version of the UCLA Loneliness Scale²⁰. This scale has 20 items and uses a 4-point Likert scoring method, ranging from 1(Never) to 4(Always). The total scores on this scale vary from 20 (least lonely) to 80 (most lonely). A higher score indicated a higher level of loneliness.

2.4.4 Health promotion behavior

We used a 20-item Chinese version of the Elderly Health Promotion Scale to measure health promotion behavior²¹. This scale has a subscale that assesses health habits, community participation, health responsibilities, health diet, regular movement, and oral health care.

2.5 Data analysis

The statistical analyses were performed using SPSS 26.0 and PROCESS macro for SPSS Version 3.3²². Besides descriptive statistics, the student t-test, ANOVA, Spearman's correlation tests, and multiple linear regression analysis were used to examine the association among variables. PROCESS macro with Model 4 for SPSS using 5000 bootstrap samples was conducted to examine the mediating role of diabetes distress on the relationship between loneliness and health promotion behaviors.

2.6 Validity and reliability

We collected data using the Chinese versions of the scales because all participants were Chinese. We examined the internal consistency of each scale by Cronbach's α based on the data

from all participants. The Cronbach's α values were 0.95, 0.84, and 0.89 for the scales of diabetes distress, loneliness, and health promotion behavior, respectively. These values indicated the validity and reliability of the measurements.

3. RESULTS

We distributed 150 questionnaires and collected 140 valid questionnaires finally. Table 1 shows the demographic and disease features of participants and their association with health promotion behaviors. Participants were equally male (50.0%) and female (50.0%), with a mean age of 72.57 years. All demographic and disease characteristics besides the use of insulin did not significantly associate with health promotion behaviors. Thus, we did not consider these characteristics in the mediating tests.

Table 2 shows the distribution of the subscale and total scale of health promotion behaviors, loneliness, and diabetes distress. We used Spearman's correction to test the correlations among the variables. As shown in Table 2, Diabetes distress and loneliness were both significantly and negatively related to health promotion behaviors. Loneliness and diabetes stress also had a significantly positive relationship.

Table 3 reports the results of the regression analysis of health promotion behaviors, loneliness, and diabetes distress. We performed a multiple linear regression analysis with health promotion behaviors of diabetic patients as the dependent variable and loneliness and diabetes distress scores as independent variables. The results indicated that both loneliness and diabetes distress entered the regression equation. Loneliness and diabetes distress negatively predicted the health promotion behavior scores of patients.

Figure 1 and Table 4 show the mediating effect of diabetes distress on the relationship between loneliness and health promotion behaviors. The total effect of loneliness on health promotion behavior was significantly negative (c path, $\beta=-0.312$, $se=0.055$, 95% CI [-0.204, -0.436], $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress (a path, $\beta=-0.043$, $se=0.005$, 95% CI [0.035, 0.052], $p < 0.001$), whilst diabetes distress significantly and negatively correlated with health promotion behaviors (b path, $\beta=-2.724$, $se=1.019$, 95% CI [-4.739, -0.710], $p = 0.008$). According to the results of bootstrapping, the indirect effect of loneliness on health promotion behavior was significant ($\beta = -0.118$, $se = 0.046$, 95% CI [-0.211, -0.027]). The direct effect of loneliness on health promotion behavior was significant (c' path, $\beta=-0.194$, $se=0.07$, 95% CI [-0.331, -0.056], $p = 0.006$). This result suggested that diabetes distress partially mediated the association of loneliness with health promotion behaviors.

TABLE 1 Distributions of demographic and disease characteristics and the association with health promotion behaviors in participants (N = 140)

Variables	n (%) / Mean \pm SD	r/t/F values	P values
Age	72.57 \pm 4.60	r=-0.034	0.688
Gender		t=0.532	0.595
Female	70(50)		
Male	70(50)		

Medical payment method		F=1.780	0.154
New Rural Cooperative	44(31.4)		
Provincial medical insurance	43(30.7)		
Municipal medical insurance	13(9.3)		
Employee medical insurance	40(28.6)		
Comorbidities		t=-0.916	0.361
No	29		
Yes	111		
Course of disease	15.19±4.94	F=1.538	0.208
Less than 5 years			
5-9years	2(1.4)		
10-20years	14(10.0)		
more than 20 years	98(70.0)		
	26(18.6)		
Use of insulin		t=2.156	0.033
No	82(58.6)		
Yes	58(14.4)		

TABLE 2 Distribution and Correlation amongst health promotion behaviors, loneliness, and diabetes distress (N = 140)

Variable	Mean±SD	Loneliness	Diabetes distress
Health promotion		-0.436 **	-0.432 **
Health habits	52.02±3.33		
Community participation	17.14±1.62		
Health responsibilities	4.38±1.28		
Health diet	4.38±1.28		
Regular movement	5.34±1.77		
Oral health care	8.81±1.04		
	6.06±1.05		
	6.71±1.11		
Loneliness	38.02±4.64	1	
Diabetes distress	2.77±0.32	0.636 **	1

Note: *p < .05; **p < .01; ***p < .001.

TABLE 3 The multiple linear regression analysis results of health promotion behaviors, loneliness, and diabetes distress (N=140)

Variable	Unstandardized coefficient	SE	Standardization coefficient	t values	P values
Constant	66.931	2.351	-	28.470	<0.001
Loneliness	-0.194	0.070	-0.271	-2.785	0.006
Diabetes distress	-2.724	1.019	-0.260	-2.674	0.008

TABLE 4 Effect of loneliness on health promotion behavior (N=140)

Loneliness		Effect	SE	t values	P values	95% CI
Health promotion behavior	Total effect	-0.312	0.055	-5.686	<0.001	-0.204, -0.436
	Direct effect	-0.194	0.07	-2.785	0.006	-0.331, -0.562
	Indirect effect	-0.118	0.046			-0.211, -0.027

Note : 95%CI, 95% Confidence Interval

4. DISCUSSION

To the best of our knowledge, this is the first study to explore the mediating role of diabetes distress in the relationship between loneliness and health promotion behaviors among older patients with DM. The result indicated that diabetes distress had a distinct mediating effect on the relationship between loneliness and health promotion behaviors. In this study, the mean age of diagnosis with diabetes was 72.57 ± 4.60 , which is older than 57.9 ± 5.60 and 66.9 ± 5.80 in previous large sample studies^{23 24}. This result may be explained by the fact that advanced age is one of the risk factors for admission in diabetic patients, and our study included hospitalized patients. Comparing a previous study that used the same scale but did not limit to older patients with DM, the health promotion behaviors were at the middle level²⁵. Another important finding is that older adults with DM performed poorly in community participation and health responsibilities. Further studies are needed to verify this phenomenon.

Diabetes distress also has positive and significant association with health promotion behaviors. This finding was also reported by Schmitt et al.²⁶, indicating that diabetes distress is important in diabetes management in older adults. Evidence supports that the level of diabetes distress can significantly affect glucose control in older patients with DM²⁷. Many patients with DM experience a psychosocial burden and mental health problems related to the disease. Diabetes distress has distinct effects on behaviors and disease control²⁸. These findings imply that the assessment and intervention of psychological dimensions in diabetes management are essential.

In this study, Diabetes distress plays a mediating role in relationship between loneliness and health promotion behaviors among older patients with DM. Previous studies have explored the mediating link between negative psychology and behavior in diabetes distress²⁹. This study explores the mediating relationship between diabetes distress and loneliness and health promotion behaviors. This study and previous studies indicated that diabetes distress can be used as a window for the intervention of psychological state and behavior change in patients with diabetes. Future research and clinical work need to evaluate and intervene in disease-related suffering in diabetic patients.

The major contribution of this study was to use the Health Belief Model as a theoretical

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3 basis to propose the mediating role of diabetes distress in the relationship between loneliness
4 and health promotion behaviors. The findings show that the relationship between loneliness
5 and health promotion behaviors has two effects: a direct effect arising and an indirect effect
6 through diabetes distress.
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9 Some limitations might have influenced the results obtained. First, we selected the study
10 population from three tertiary care hospitals in Changsha, which might limit generalizability.
11 Further studies may need to recruit more elderly diabetic patients different levels of hospitals
12 and the community to validate the findings. Second, cross-sectional designs cannot examine
13 trends in health promotion behaviors over time. Third, the factors included in this study did not
14 fully explain the network relationship between loneliness, diabetes distress, and health
15 promotion behaviors. Further work is required to establish the effects of other negative
16 psychological traits on the health promotion behavior of diabetes mellitus in the elderly.
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19 20 21 **5. CONCLUSION**

22 The present research aimed to examine the mediating role of diabetes distress in the
23 relationship between loneliness and health promotion behavior. When the loneliness of the
24 elderly cannot be changed in a short period, improving diabetes distress can be used as a way
25 to change their health promotion behaviors for disease management. Another broad
26 recommendation is to pay more attention to the negative psychological states in the elderly.
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29 30 31 **Author Contributions.**

32 All authors meet the authorship requirement of the International Committee of Medical
33 Journal of Editors. LD and CBG are joint correspond authors. FYZ designed the study and
34 collected the data. FYZ, KYL, LLX, and CBG involved in the data analysis. FYZ, KYL, LD,
35 CBG, LLX, TTY, and QL prepared the first version of the paper and revised the paper. LD and
36 CBG provided technical guidance throughout the process. All authors read and approved the
37 final manuscript.
38
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45 19]. This funding source had no role in the design of this study and will not have any role.
46

47 48 49 **Competing interests**

None declared.

50 51 52 **Data sharing statement**

53 The data supporting the findings of this study are available from the corresponding author
54 upon reasonable request.
55

56 57 58 **Ethics approval**

59 The study was approved by the Ethics Committee of Xiangya School of Nursing, Central
60 South University(E202283). All participants were informed of the purpose and process of this

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3 study before the study began. Our study obtained informed consent from each participant in
4 writing prior to completing the questionnaire. For participants who were not literate enough to
5 comprehend the informed consent form, explanations of each entry were provided on an
6 individual basis. And their legally authorized representatives were also given informed consent.
7
8 Participation in this study was voluntary. Participants may withdraw from this study at any
9 time. All the participants were informed that they would bear no penalty for refusal to
10 participate in the study and would be allowed to withdraw at any time without affecting their
11 treatments. All information collected here is strictly confidential. Confidentiality and
12 anonymity were maintained by not asking for names and by numbering the questionnaires (each
13 participant received a number on the debriefing form). Any student wishing to withdraw data
14 before data analysis can use this number to contact the researcher. All data were kept in a locked
15 cabinet and on a password-protected computer to ensure privacy. All methods follow the
16 relevant guidelines and regulations.
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23 24 **Patient and public involvement**

25 No patient involved.
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28 **Consent for publication**

29 Informed consent was obtained from all subjects involved in the study.
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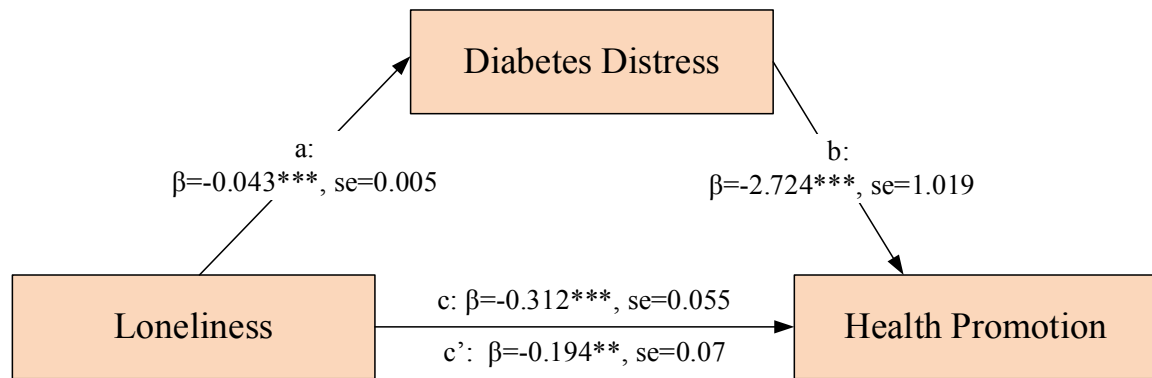


FIGURE 1 The mediated model represents the total direct effect (path c), direct effect (path c'), and indirect effect (path a and b) from loneliness to health promotion behaviors.

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

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 3
Methods			
Study design	4	Present key elements of study design early in the paper	Page 3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Page 3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	None
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4
Bias	9	Describe any efforts to address potential sources of bias	Page 4
Study size	10	Explain how the study size was arrived at	None
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	None
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 4
		(b) Describe any methods used to examine subgroups and interactions	Page 4
		(c) Explain how missing data were addressed	None
		(d) If applicable, describe analytical methods taking account of sampling strategy	None
		(e) Describe any sensitivity analyses	None
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5
		(b) Give reasons for non-participation at each stage	None
		(c) Consider use of a flow diagram	None
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 1
		(b) Indicate number of participants with missing data for each variable of interest	None
Outcome data	15*	Report numbers of outcome events or summary measures	Page 5
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	None

		(b) Report category boundaries when continuous variables were categorized	Page 5
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	None
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 6
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 8

*Give information separately for exposed and unexposed groups.

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

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Diabetes distress as mediators of loneliness and health promotion behavior: a cross-sectional study

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Diabetes distress as mediators of loneliness and health promotion behavior: a cross-sectional study

Feiyang Zhou^{1,2}, Lu Deng¹, Chunbo Guo¹, Keyu Long², Linlin Xie², Tingting Yang², Qian Lv^{1,2}

Correspondence to: Lu Deng; csdenglu1026@csu.edu.cn

Chunbo Guo; 154780593@qq.com

¹ The Second Xiangya Hospital, Central South University, Changsha, Hunan, China

² Central South University, Changsha, Hunan, China

Abstract

Objectives: The purpose of this study was to explore the mediating effect of diabetes distress on loneliness to health promotion in older adults with diabetes.

Design: A cross-sectional study.

Setting: The study was conducted at three tertiary hospitals in Changsha, Hunan Province, China.

Participants: The sample included 140 diabetic patients (65 years and older, mean age 72.6 years, SD=4.6).

Methods: We employed path models to analyze data on diabetes distress, loneliness, and health promotion behaviors. We collected diabetes distress, loneliness, and health promotion behavior with self-reported questionnaires including the Diabetes Distress Scale, the UCLA Loneliness Scale and the Elderly Health Promotion Scale from January 2022 to October 2022. Mediation analysis was performed by SPSS 26.0's PROCESS macro.

Result: The findings of this study indicated diabetes distress acted as a mediator between loneliness and health promotion behavior. According to bootstrapping results, the total effect of loneliness on health promotion behavior was significantly negative ($\beta=-0.312$, $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress ($\beta=-0.043$, $p < 0.001$), while diabetes distress significantly and negatively correlated with health promotion behaviors ($\beta=-2.724$, $p = 0.008$). Both the indirect effect and the direct effect of loneliness on health promotion behavior were significant.

Conclusion: Our study illustrated that loneliness was negatively associated with health promotion behaviors, and diabetes distress acted as a mediator in this relationship. It is suggested that healthcare providers assessing and addressing diabetes distress need to increase

1
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3 attention to psychological distress, including loneliness, and then intervene to improve health
4 promotion behaviors and disease management gains for older patients with diabetes.
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7 **KEYWORDS**

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9 diabetes distress; loneliness; health promotion behaviors; mediation effect; diabetes
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12 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 13
- 14 ● The study employed face-to-face data collection methods instead of online consultations
15 to mitigate potential biases associated with online surveying.
- 16
- 17 ● This study indicated attention to psychological factors such as diabetes distress.
- 18
- 19 ● The study relies on self-reported outcomes which may introduce measurement bias.
- 20
- 21 ● This was not a multicenter study not representative of a pan-global population.
22

23 **1. Background**

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26 Diabetes mellitus (DM) is one of the fastest-growing diseases worldwide, projected to
27 affect 693 million adults by 2045.(1) The past 50 years have seen a growing aging population
28 with an increasing prevalence of DM. Now, nearly half of all individuals with DM are older
29 adults (aged ≥ 65 years).(2) Older adults with DM face a higher risk of premature death,
30 functional disability and coexisting conditions than older adults without DM.(3) DM increases
31 the vulnerability of older adults to several common geriatric syndromes, such as polypharmacy,
32 cognitive impairment, depression, urinary incontinence, injurious falls, persistent pain, and
33 frailty.(4) Moreover, the complexity of disease management in older adults is compounded by
34 the presence of comorbidities, the higher susceptibility to hypoglycemic events, and the
35 individualized care needs.(5) Improving the health promotion behaviors of older adults with
36 DM is an important goal in disease management.
37

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40 Health promotion behavior can effectively delay the development of diabetic complications
41 and cause the body, biochemical, and other indicators to return to normal levels.(6) Health
42 promotion behaviors for people with DM include blood glucose monitoring, use of insulin and
43 medications, use of diabetes technology, physical activity and nutritional changes.(7) Health
44 promotion behavior is vital for older adults with DM. However, psychological factors are
45 proven to influence the behavior of patients with DM.(8)
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49 One such psychological factor is loneliness. Loneliness is the feeling of isolation
50 regardless of objective social network size.(9) In industrialized countries around one-third of
51 people are affected by this condition, with one person in 12 affected severely, and these
52 proportions are increasing.(10) A longitudinal cohort study showed loneliness had negative
53 effects on health promotion behaviors.(11) The result of a phenomenological study showed that
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4 loneliness in people with DM is related to diabetes distress.(12) Higher loneliness was also
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6 associated consistently with worse health outcomes among older adults.(13)

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8 Another negative psychological characteristic reported in patients with DM is diabetes
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10 distress.(14) Diabetes distress refers to the worries, concerns, fears, and threats that are
11
12 associated with struggling with a demanding chronic disease like diabetes over time, including
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14 its management, threats of complications, potential loss of functioning, and concerns about
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16 access to care.(15) Many studies have found that diabetes distress is negatively associated with
17
18 health promotion behavior in older patients with DM.(16 17) In summary, loneliness and
19
20 diabetes distress are independently negative characteristics that seem to be associated with
21
22 health promotion behavior in older patients with DM.

23
24 Considering all this evidence, the relationship among these three important factors has not
25
26 been fully explored. Up to now, previous studies remain narrow in focus dealing only with
27
28 unidirectional relationship. No previous study has investigated the mediating role of diabetes
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30 distress on loneliness to health promotion behavior in older patients with DM.

31
32 The theoretical framework of this study is the Health Belief Model (HBM).(18) The HBM
33
34 interprets an individual's health promoting behavior as the result of perceptions of being
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36 exposure to a certain health threat. Loneliness is seen as an exposure risk, diabetes distress is
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38 seen as a health threat, and lonely individuals form beliefs about health promoting behaviors
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40 through their perceptions of diabetes distress. If individuals believe that distress increases
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42 health risk, they may be more inclined to adopt positive health behaviors. Based on the
43
44 theoretical framework, we propose the hypothesis: loneliness directly affects health promotion
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46 behavior, and it also has an indirect effect on health promotion behavior through diabetes
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48 distress as a mediator.

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50 Hence, this study was designed to investigate the mediating association of diabetes distress
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52 on loneliness to health promotion behavior and to clarify the direct/indirect relationships in
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54 older patients with DM.

55 **2. Methods**

56 2.1 Aims

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58 This study aimed to examine the mediating role of diabetes distress on the relationship
59
60 between loneliness and health promotion behaviors. The hypothesis was diabetes distress plays
a mediation role in the relationship between loneliness and health promotion behaviors in older
adults with DM.

2.2 Design

This study employed a cross-sectional design.

2.3 Participants

Participants were recruited from three third-class hospitals in Hunan by convenience
sampling. The inclusion criteria for recruitment included participants aged above 65 years

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having been diagnosed with DM. Exclusion criteria included patients with psychiatric problems and blindness. G power 3.1.9.6 software was used to calculate the adequate sample size. Based on an α level of 0.05, a power of 0.80, and an effect size of 0.2 for the correlation coefficient, 84 samples were required. Finally, 140 patients finished this study, and the sample size was adequate to test the hypotheses of this study.

2.4 Data collection

Participants complete the questionnaire independently. For those with blurred vision or a low knowledge level, investigators read out the content and options of the article without implication and complete it on their behalf. After the questionnaire is completed, the investigator will take it back on the spot and check the completeness of the questionnaire to ensure its completeness and validity.

2.4.1 Demographic and disease characteristics

Age, gender, medical payment method, comorbidities (no/yes), course of disease, and use of insulin(no/yes) were collected.

2.4.2 Diabetes distress

We measured the diabetes distress levels in participants using the Chinese version of the Diabetes Distress Scale.(19) This scale has 17 items and uses a Likert 6-point scoring method, ranging from 1(Not a problem) to 6(Serious problem). The scale evaluates the results based on the average score of the item. A higher score indicated a higher level of diabetes distress. An average score of ≥ 3 on the scales suggests more than moderate distress and requires clinical attention. The Cronbach's α values of this scale was 0.92.

2.4.3 Loneliness

We measured loneliness using the Chinese version of the UCLA Loneliness Scale.(20) This scale has 20 items and uses a 4-point Likert scoring method, ranging from 1(Never) to 4(Always). The total scores on this scale vary from 20 (least lonely) to 80 (most lonely). A higher score indicated a higher level of loneliness. A score of ≥ 34 on the scales represents a patient with more than moderate loneliness. The Cronbach's α values of this scale was 0.86.

2.4.4 Health promotion behavior

We used a 20-item Chinese version of the Elderly Health Promotion Scale to measure health promotion behavior.(21) This scale has a subscale that assesses health habits, community participation, health responsibilities, health diet, regular movement, and oral health care. A higher score indicated a higher level of health promotion behavior. The Cronbach's α values of this scale was 0.90.

2.5 Data analysis

The statistical analyses were performed using SPSS 26.0 and PROCESS macro for SPSS Version 3.3.(22) The independent t-test and ANOVA test were used to assess the difference of the means of normally distributed variables. A multiple linear regression and Spearman correlation analyses were performed to examine the correlations among variables. PROCESS macro with Model 4 for SPSS using 5000 bootstrap samples was conducted to examine the

mediating role of diabetes distress on the relationship between loneliness and health promotion behaviors.

2.7 Patient and public involvement

No patient involved.

3. RESULTS

We distributed 150 questionnaires and collected 140 valid questionnaires finally. Table 1 shows the demographic and disease features of participants and their association with health promotion behaviors. Participants were equally male (50.0%) and female (50.0%), with a mean age of 72.57 years. All demographic and disease characteristics except the use of insulin did not significantly associate with health promotion behaviors. Thus, we did not consider these characteristics in the mediating tests.

Table 2 shows the distribution of the subscale and total scale of health promotion behaviors, loneliness, and diabetes distress. We used Spearman's correction to test the correlations among the variables. As shown in Table 2, Diabetes distress and loneliness were both significantly and negatively related to health promotion behaviors. Loneliness and diabetes distress also had a significantly positive relationship.

Table 3 reports the results of the regression analysis of health promotion behaviors, loneliness, and diabetes distress. We performed a multiple linear regression analysis with health promotion behaviors of diabetic patients as the dependent variable and loneliness and diabetes distress scores as independent variables. The results indicated that both loneliness and diabetes distress entered the regression equation. Loneliness and diabetes distress negatively predicted the health promotion behavior scores of patients.

Figure 1 and Table 4 show the mediating relationship of diabetes distress on the relationship between loneliness and health promotion behaviors. The total effect of loneliness on health promotion behavior was significantly negative (c path, $\beta=-0.312$, $se=0.055$, 95% CI [-0.204, -0.436], $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress (a path, $\beta=-0.043$, $se=0.005$, 95% CI [0.035, 0.052], $p<0.001$), whilst diabetes distress significantly and negatively correlated with health promotion behaviors (b path, $\beta=-2.724$, $se=1.019$, 95% CI [-4.739, -0.710], $p=0.008$). According to the results of bootstrapping, the indirect effect of loneliness on health promotion behavior was significant ($\beta=-0.118$, $se=0.046$, 95% CI [-0.211, -0.027]). The direct effect of loneliness on health promotion behavior was significant (c' path, $\beta=-0.194$, $se=0.07$, 95% CI [-0.331, -0.056], $p=0.006$). This result suggested that diabetes distress partially mediated the association of loneliness with health promotion behaviors.

TABLE 1 Distributions of demographic and disease characteristics and the association with health promotion behaviors in participants (N = 140)

Variables	n (%) / Mean \pm SD	r/t/F values	P values
Age	72.57 \pm 4.60	r = -0.034	0.688
Gender		t = 0.532	0.595
Female	70 (50)		
Male	70 (50)		
Medical payment method		F = 1.780	0.154
New Rural Cooperative	44 (31.4)		

Provincial medical insurance	43(30.7)		
Municipal medical insurance	13(9.3)		
Employee medical insurance	40(28.6)		
Comorbidities		t=-0.916	0.361
No	29		
Yes	111		
Course of disease	15.19±4.94	F=1.538	0.208
Less than 5 years	2(1.4)		
5-9years	14(10.0)		
10-20years	98(70.0)		
more than 20 years	26(18.6)		
Use of insulin		t=2.156	0.033
No	82(58.6)		
Yes	58(14.4)		

TABLE 2 Distribution and Correlation amongst health promotion behaviors, loneliness, and diabetes distress (N = 140)

Variable	Mean±SD	Loneliness	Diabetes distress
Health promotion	52.02±3.33	-0.436 **	-0.432 **
Health habits	17.14±1.62		
Community participation	4.38±1.28		
Health responsibilities	5.34±1.77		
Health diet	8.81±1.04		
Regular movement	6.06±1.05		
Oral health care	6.71±1.11		
Loneliness	38.02±4.64	1	
Diabetes distress	2.77±0.32	0.636 **	1

Note: *p < .05; **p < .01; ***p < .001.

TABLE 3 The multiple linear regression analysis results of health promotion behaviors, loneliness, and diabetes distress (N=140)

Variable	Unstandardized coefficient	SE	Standardization coefficient	t values	P values
Constant	66.931	2.351	-	28.470	<0.001
Loneliness	-0.194	0.070	-0.271	-2.785	0.006
Diabetes distress	-2.724	1.019	-0.260	-2.674	0.008

TABLE 4 Effect of loneliness on health promotion behavior (N=140)

Loneliness	Effect	SE	t values	P values	95% CI	
Health promotion behavior	Total effect	-0.312	0.055	-5.686	<0.001	-0.204, -0.436
	Direct effect	-0.194	0.07	-2.785	0.006	-0.331, -0.562
	Indirect effect	-0.118	0.046			-0.211, -0.027

Note : 95%CI, 95% Confidence Interval

4. DISCUSSION

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3 To the best of our knowledge, this is the first study to explore the mediating role of diabetes
4 distress in the relationship between loneliness and health promotion behaviors among older
5 patients with DM. The result indicated that diabetes distress had a distinct mediating effect on
6 the relationship between loneliness and health promotion behaviors.
7

8 In this study, the mean age of diagnosis with DM was 72.57 ± 4.60 , which is older than
9 57.9 ± 5.60 and 66.9 ± 5.80 in previous large sample studies.(23 24) This result may be explained
10 by the fact that advanced age is one of the risk factors for admission in diabetic patients, and
11 our study included hospitalized patients. Comparing a previous study that used the same scale
12 but did not limit to older patients with DM, the health promotion behaviors were at the middle
13 level.(25) Another important finding is that older adults with DM performed poorly in
14 community participation and health responsibilities. Health responsibilities are relevant to
15 health policy development.(26) Community participation is associated with gaining health-
16 related information, reducing physical and mental stress, and maintaining motor function.(27)
17 Further studies are needed to investigate the effects of these two factors on older adults with
18 DM.
19

20 Loneliness has a negative and significant association with health promotion. This may be
21 because individuals who experience heightened levels of loneliness tend to also experience
22 elevated levels of stress. And stress maladaptation can trigger poor health promotion
23 behaviors.(28) Loneliness correlates with heightened sedentary behavior and decreased levels
24 of physical activity.(29) The correlation between loneliness and activity levels could therefore
25 play a crucial role in the inverse connection between loneliness and health promotion behaviors.
26

27 Diabetes distress also has a negative and significant association with health promotion
28 behaviors. This finding was also reported by previous study.(30) One potential explanation is
29 that diabetes distress, a negative psychological factor experienced by individuals with DM,
30 influences their ability to self-manage their condition, subsequently leading to poorer health
31 promotion behaviors.(31) Evidence supports that the level of diabetes distress can significantly
32 affect glucose control in older patients with DM.(32) Many patients with DM experience a
33 psychosocial burden and mental health problems related to the disease. Diabetes distress has
34 distinct effects on behaviors and disease control.(33) These findings imply that the assessment
35 and intervention of psychological dimensions in diabetes management are essential.
36

37 In this study, diabetes distress plays a mediating role in the relationship between loneliness
38 and health promotion behaviors among older patients with DM. Previous studies have explored
39 the mediating link between negative psychology and behavior in diabetes distress.(34) Older
40 patients with DM experiencing high levels of diabetes distress exhibit more pronounced
41 negative psychological factors associated with their disease compared to those with
42 significantly lower levels of diabetes distress. These individuals tend to employ ineffective
43 coping strategies in response to feelings of loneliness and engage in suboptimal health
44 promotion behaviors. This study explores the mediating relationship between diabetes distress
45 and loneliness and health promotion behaviors. This suggests that loneliness not only directly
46 affects health promotion behaviors in people with DM, but also indirectly affects health
47 promotion behaviors through the level of diabetes distress. HBM theory provides a framework
48 for understanding the networks that are responsible for health promotion behaviors. When older
49 adults with DM experience loneliness, they are at risk for worsening health promotion
50 behaviors that can lead to a worsening of their disease condition. This study validates the key
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3 role of diabetes distress in this process of change. The detection rate of diabetic distress in
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5 China is 50%,⁽³⁵⁾ which surpasses that of Perrin et al. (39%).⁽³⁶⁾ This implies that there is a
6
7 greater need for increased consideration of diabetes distress in China.

8
9 Traditionally, the focus has often been on improving health promotion behaviors by
10 increasing disease knowledge among people with DM, while neglecting psychological factors.
11 Findings from our research are intriguing because diabetes distress is important as an
12 intervenable mediator in influencing health promotion behaviors during periods of loneliness
13 caused by irresistible factors (e.g., the COVID-19 pandemic). This study and previous studies
14 indicated that diabetes distress can be used as a window for the intervention of psychological
15 state and behavior change in patients with DM. Future research and clinical work need to
16 evaluate and intervene in disease distress in patients with DM.

17
18 Some limitations need to be considered in this study. First, self-report questionnaires
19 which may result in recall and reporting bias. Second, this study did not control confounding
20 factors. Third, the factors included in this study did not fully explain the network relationship
21 between loneliness, diabetes distress, and health promotion behaviors. Additional research is
22 needed to determine how other negative psychological traits impact the health promotion
23 behavior of elderly patients with DM.
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27

28 5. CONCLUSION

29 The present research aimed to examine the mediating role of diabetes distress in the
30 relationship between loneliness and health promotion behavior. When the loneliness of the
31 elderly cannot be changed in a short period, improving diabetes distress can be used as a way
32 to change their health promotion behaviors for disease management. Another broad
33 recommendation is to pay more attention to the negative psychological states in the elderly.
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38 **Author Contributions.**

39 All authors meet the authorship requirement of the International Committee of Medical
40 Journal of Editors. LD and CBG are joint correspond authors. FYZ designed the study and
41 collected the data. FYZ, KYL, LLX, and CBG involved in the data analysis. FYZ, KYL, LD,
42 CBG, LLX, TTY, and QL prepared the first version of the paper and revised the paper. LD and
43 CBG provided technical guidance throughout the process. All authors read and approved the
44 final manuscript.
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51 Program[kzd22018] and the Second Xiangya Hospital Nursing Research Fund[2022-HLKY-
52 19]. This funding source had no role in the design of this study and will not have any role.
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54

55 **Competing interests**

56 None declared.
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59 **Data sharing statement**

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3 The data supporting the findings of this study are available from the corresponding author
4 upon reasonable request.
5
6

7 **Ethics approval**

8 The study was approved by the Ethics Committee of Xiangya School of Nursing, Central
9 South University(E202283). All participants were informed of the purpose and process of this
10 study before the study began. Our study obtained informed consent from each participant in
11 writing prior to completing the questionnaire. For participants who were not literate enough to
12 comprehend the informed consent form, explanations of each entry were provided on an
13 individual basis. And their legally authorized representatives were also given informed consent.
14 Participation in this study was voluntary. Participants may withdraw from this study at any
15 time. All the participants were informed that they would bear no penalty for refusal to
16 participate in the study and would be allowed to withdraw at any time without affecting their
17 treatments. All information collected here is strictly confidential. Confidentiality and
18 anonymity were maintained by not asking for names and by numbering the questionnaires (each
19 participant received a number on the debriefing form). Any student wishing to withdraw data
20 before data analysis can use this number to contact the researcher. All data were kept in a locked
21 cabinet and on a password-protected computer to ensure privacy. All methods follow the
22 relevant guidelines and regulations.
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31 **Consent for publication**

32 Informed consent was obtained from all subjects involved in the study.
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35 **REFERENCE**

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36 **Figure legend**

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38 **FIGURE 1** The mediated model represents the total direct effect (path c), direct effect (path
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40 c'), and indirect effect (path a and b) from loneliness to health promotion behaviors.
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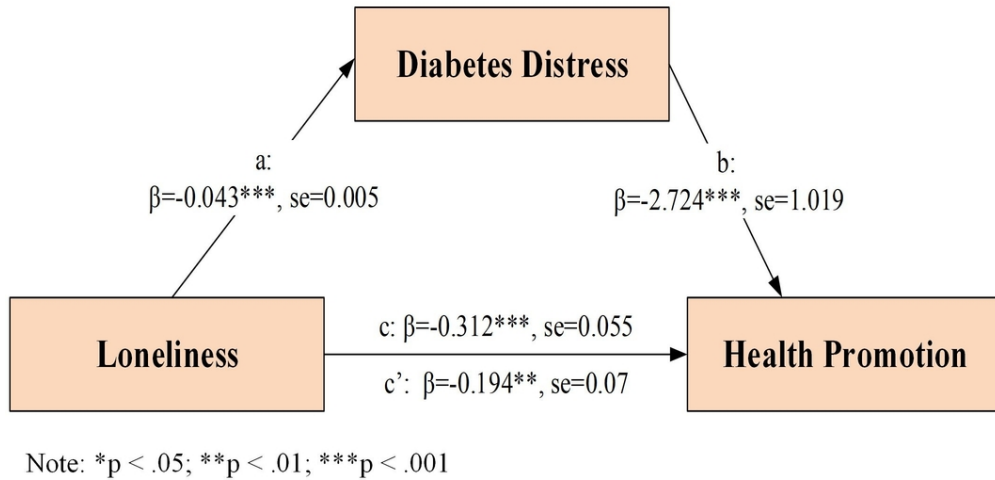


Figure 1 The mediated model represents the total direct effect (path c), direct effect (path c'), and indirect effect (path a and b) from loneliness to health promotion behaviors.

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

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 3
Methods			
Study design	4	Present key elements of study design early in the paper	Page 3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Page 3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	None
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4
Bias	9	Describe any efforts to address potential sources of bias	Page 4
Study size	10	Explain how the study size was arrived at	None
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	None
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 4
		(b) Describe any methods used to examine subgroups and interactions	Page 4
		(c) Explain how missing data were addressed	None
		(d) If applicable, describe analytical methods taking account of sampling strategy	None
		(e) Describe any sensitivity analyses	None
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5
		(b) Give reasons for non-participation at each stage	None
		(c) Consider use of a flow diagram	None
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 1
		(b) Indicate number of participants with missing data for each variable of interest	None
Outcome data	15*	Report numbers of outcome events or summary measures	Page 5
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	None

		(b) Report category boundaries when continuous variables were categorized	Page 5
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	None
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 6
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 8

*Give information separately for exposed and unexposed groups.

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

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Diabetes distress as mediators of loneliness and health promotion behavior: a cross-sectional study

Feiyang Zhou^{1,2}, Lu Deng¹, Chunbo Guo¹, Keyu Long², Linlin Xie², Tingting Yang², Qian Lv^{1,2}

Correspondence to: Lu Deng; csdenglu1026@csu.edu.cn

Chunbo Guo; 154780593@qq.com

¹ The Second Xiangya Hospital, Central South University, Changsha, Hunan, China

² Central South University, Changsha, Hunan, China

Abstract

Objectives: The purpose of this study was to explore whether diabetes distress mediated the relationship between loneliness and health promotion in older adults with diabetes.

Design: A cross-sectional study.

Setting: The study was conducted at three tertiary hospitals in Changsha, Hunan Province, China.

Participants: The sample included 140 diabetic patients (65 years and older, mean age 72.6 years, SD=4.6).

Methods: We employed path models to analyze data on diabetes distress, loneliness, and health promotion behaviors. We collected diabetes distress, loneliness, and health promotion behavior with self-reported questionnaires including the Diabetes Distress Scale, the UCLA Loneliness Scale and the Elderly Health Promotion Scale from January 2022 to October 2022. Mediation analysis was performed by SPSS 26.0's PROCESS macro.

Result: The findings of this study indicated diabetes distress acted as a mediator between loneliness and health promotion behavior. According to bootstrapping results, the total effect of loneliness on health promotion behavior was significantly negative ($\beta=-0.312$, $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress ($\beta=-0.043$, $p < 0.001$), while diabetes distress significantly and negatively correlated with health promotion behaviors ($\beta=-2.724$, $p = 0.008$). Both the indirect effect and the direct effect of loneliness on health promotion behavior were significant.

Conclusion: Our study illustrated that loneliness was negatively associated with health promotion behaviors, and diabetes distress acted as a mediator in this relationship. It is suggested that healthcare providers should prioritize the identification and management of

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3 diabetes distress in older patients with diabetes who experience loneliness to improve health
4 promotion behaviors and optimize disease management outcomes.
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7 **KEYWORDS**

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9 diabetes distress; loneliness; health promotion behaviors; mediation effect; diabetes
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12 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 13
- 14 ● The study employed face-to-face data collection methods instead of online consultations
15 to mitigate potential biases associated with online surveying.
- 16
- 17 ● This study indicated attention to diabetes distress among older adults with diabetes.
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- 19 ● The study relies on self-reported outcomes which may introduce measurement bias.
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- 21 ● This was not a multicenter study not representative of a pan-global population.
- 22

23 **1. Background**

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26 Diabetes mellitus (DM) is one of the fastest-growing diseases worldwide, projected to
27 affect 693 million adults by 2045.(1) The past 50 years have seen a growing aging population
28 with an increasing prevalence of DM. Now, nearly half of all individuals with DM are older
29 adults (aged ≥ 65 years).(2) Older adults with DM face a higher risk of premature death,
30 functional disability and coexisting conditions than older adults without DM.(3) DM increases
31 the vulnerability of older adults to several common geriatric syndromes, such as polypharmacy,
32 cognitive impairment, depression, urinary incontinence, injurious falls, persistent pain, and
33 frailty.(4) Moreover, the complexity of disease management in older adults is compounded by
34 the presence of comorbidities, the higher susceptibility to hypoglycemic events, and the
35 individualized care needs.(5) Improving the health promotion behaviors of older adults with
36 DM is an important goal in disease management.
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40 Health promotion behavior can effectively delay the development of diabetic complications
41 and cause the body, biochemical, and other indicators to return to normal levels.(6) Health
42 promotion behaviors for people with DM include blood glucose monitoring, use of insulin and
43 medications, use of diabetes technology, physical activity and nutritional changes.(7) Health
44 promotion behavior is vital for older adults with DM. However, psychological factors are
45 proven to influence the behavior of patients with DM.(8)
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49 One such psychological factor is loneliness. Loneliness is the feeling of isolation
50 regardless of objective social network size.(9) In industrialized countries around one-third of
51 people are affected by this condition, with one person in 12 affected severely, and these
52 proportions are increasing.(10) A longitudinal cohort study showed loneliness had a negative
53 impact on health promotion behaviors.(11) The result of a phenomenological study showed that
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4 loneliness in people with DM is related to diabetes distress.(12) Higher loneliness was also
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6 associated consistently with worse health outcomes among older adults.(13)

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8 Another negative psychological characteristic reported in patients with DM is diabetes
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10 distress.(14) Diabetes distress refers to the worries, concerns, fears, and threats that are
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12 associated with struggling with a demanding chronic disease like diabetes over time, including
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14 its management, threats of complications, potential loss of functioning, and concerns about
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16 access to care.(15) Many studies have found that diabetes distress is negatively associated with
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18 health promotion behavior in older patients with DM.(16 17) In summary, loneliness and
19
20 diabetes distress are independently negative characteristics that seem to be associated with
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22 health promotion behavior in older patients with DM.

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24 Considering all this evidence, the relationship among these three important factors has not
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26 been fully explored. Up to now, previous studies remain narrow in focus dealing only with
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28 unidirectional relationship. No previous study has investigated the mediating role of diabetes
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30 distress on loneliness to health promotion behavior in older patients with DM.

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32 The theoretical framework of this study is the Health Belief Model (HBM).(18) The HBM
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34 interprets an individual's health promoting behavior as the result of perceptions of being
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36 exposure to a certain health threat. Loneliness is seen as an exposure risk, diabetes distress is
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38 seen as a health threat, and lonely individuals form beliefs about health promoting behaviors
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40 through their perceptions of diabetes distress. If individuals believe that distress increases
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42 health risk, they may be more inclined to adopt positive health behaviors. Based on the
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44 theoretical framework, we propose the hypothesis: loneliness directly affects health promotion
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46 behavior and indirectly influences health promotion behavior through diabetes distress as a
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48 mediator.

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50 Hence, this study was designed to investigate the mediating association of diabetes distress
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52 on loneliness to health promotion behavior and to clarify the direct/indirect relationships in
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54 older patients with DM.

55 **2. Methods**

56 2.1 Aims

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58 This study aimed to examine the mediating role of diabetes distress on the relationship
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60 between loneliness and health promotion behaviors. The hypothesis was diabetes distress plays
a mediation role in the relationship between loneliness and health promotion behaviors in older
adults with DM.

2.2 Design

This study employed a cross-sectional design.

2.3 Participants

Participants were recruited from three third-class hospitals in Hunan by convenience
sampling. The inclusion criteria for recruitment included participants aged above 65 years

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having been diagnosed with DM. Exclusion criteria included patients with psychiatric problems and blindness. G power 3.1.9.6 software was used to calculate the adequate sample size. Based on an α level of 0.05, a power of 0.80, and an effect size of 0.2 for the correlation coefficient, 84 samples were required. Finally, 140 patients finished this study, and the sample size was adequate to test the hypotheses of this study.

2.4 Data collection

Participants complete the questionnaire independently. For those with blurred vision or a low knowledge level, investigators read out the content and options of the article without implication and complete it on their behalf. After the questionnaire is completed, the investigator will take it back on the spot and check the completeness of the questionnaire to ensure its completeness and validity.

2.4.1 Demographic and disease characteristics

Age, gender, medical payment method, comorbidities (no/yes), course of disease, and use of insulin(no/yes) were collected.

2.4.2 Diabetes distress

We measured the diabetes distress levels in participants using the Chinese version of the Diabetes Distress Scale.(19) This scale has 17 items and uses a Likert 6-point scoring method, ranging from 1(Not a problem) to 6(Serious problem). The scale evaluates the results based on the average score of the item. A higher score indicated a higher level of diabetes distress. An average score of ≥ 3 on the scales suggests more than moderate distress and requires clinical attention. The Cronbach's α values of this scale was 0.92.

2.4.3 Loneliness

We measured loneliness using the Chinese version of the UCLA Loneliness Scale.(20) This scale has 20 items and uses a 4-point Likert scoring method, ranging from 1(Never) to 4(Always). The total scores on this scale vary from 20 (least lonely) to 80 (most lonely). A higher score indicated a higher level of loneliness. A score of ≥ 34 on the scales represents a patient with more than moderate loneliness. The Cronbach's α values of this scale was 0.86.

2.4.4 Health promotion behavior

We used a 20-item Chinese version of the Elderly Health Promotion Scale to measure health promotion behavior.(21) This scale has a subscale that assesses health habits, community participation, health responsibilities, health diet, regular movement, and oral health care. A higher score indicated a higher level of health promotion behavior. The Cronbach's α values of this scale was 0.90.

2.5 Data analysis

The statistical analyses were performed using SPSS 26.0 and PROCESS macro for SPSS Version 3.3.(22) The independent t-test and ANOVA test were used to assess the difference of the means of normally distributed variables. A multiple linear regression and Spearman correlation analyses were performed to examine the correlations among variables. PROCESS macro with Model 4 for SPSS using 5000 bootstrap samples was conducted to examine the

mediating role of diabetes distress on the relationship between loneliness and health promotion behaviors.

2.7 Patient and public involvement

No patient involved.

3. RESULTS

We distributed 150 questionnaires and collected 140 valid questionnaires finally. Table 1 shows the demographic and disease features of participants and their association with health promotion behaviors. Participants were equally male (50.0%) and female (50.0%), with a mean age of 72.57 years. All demographic and disease characteristics except the use of insulin did not significantly associate with health promotion behaviors. Thus, we did not consider these characteristics in the mediating tests.

Table 2 shows the distribution of the subscale and total scale of health promotion behaviors, loneliness, and diabetes distress. We used Spearman's correction to test the correlations among the variables. As shown in Table 2, Diabetes distress and loneliness were both significantly and negatively related to health promotion behaviors. Loneliness and diabetes distress also had a significantly positive relationship.

Table 3 reports the results of the regression analysis of health promotion behaviors, loneliness, and diabetes distress. We performed a multiple linear regression analysis with health promotion behaviors of diabetic patients as the dependent variable and loneliness and diabetes distress scores as independent variables. The results indicated that both loneliness and diabetes distress entered the regression equation. Loneliness and diabetes distress negatively predicted the health promotion behavior scores of patients.

Figure 1 and Table 4 show the mediating role of diabetes distress on the relationship between loneliness and health promotion behaviors. The total effect of loneliness on health promotion behavior was significantly negative (c path, $\beta=-0.312$, $se=0.055$, 95% CI [-0.204, -0.436], $p=0.006$). Loneliness significantly and negatively correlated with diabetes distress (a path, $\beta=-0.043$, $se=0.005$, 95% CI [0.035, 0.052], $p<0.001$), whilst diabetes distress significantly and negatively correlated with health promotion behaviors (b path, $\beta=-2.724$, $se=1.019$, 95% CI [-4.739, -0.710], $p=0.008$). According to the results of bootstrapping, the indirect effect of loneliness on health promotion behavior was significant ($\beta=-0.118$, $se=0.046$, 95% CI [-0.211, -0.027]). The direct effect of loneliness on health promotion behavior was significant (c' path, $\beta=-0.194$, $se=0.07$, 95% CI [-0.331, -0.056], $p=0.006$). This result suggested that diabetes distress partially mediated the association of loneliness with health promotion behaviors.

TABLE 1 Distributions of demographic and disease characteristics and the association with health promotion behaviors in participants (N = 140)

Variables	n (%) / Mean \pm SD	r/t/F values	P values
Age	72.57 \pm 4.60	r = -0.034	0.688
Gender		t = 0.532	0.595
Female	70 (50)		
Male	70 (50)		
Medical payment method		F = 1.780	0.154
New Rural Cooperative	44 (31.4)		

Provincial medical insurance	43(30.7)		
Municipal medical insurance	13(9.3)		
Employee medical insurance	40(28.6)		
Comorbidities		t=-0.916	0.361
No	29		
Yes	111		
Course of disease	15.19±4.94	F=1.538	0.208
Less than 5 years	2(1.4)		
5-9years	14(10.0)		
10-20years	98(70.0)		
more than 20 years	26(18.6)		
Use of insulin		t=2.156	0.033
No	82(58.6)		
Yes	58(14.4)		

TABLE 2 Distribution and Correlation amongst health promotion behaviors, loneliness, and diabetes distress (N = 140)

Variable	Mean±SD	Loneliness	Diabetes distress
Health promotion	52.02±3.33	-0.436 **	-0.432 **
Health habits	17.14±1.62		
Community participation	4.38±1.28		
Health responsibilities	5.34±1.77		
Health diet	8.81±1.04		
Regular movement	6.06±1.05		
Oral health care	6.71±1.11		
Loneliness	38.02±4.64	1	
Diabetes distress	2.77±0.32	0.636 **	1

Note: *p < .05; **p < .01; ***p < .001.

TABLE 3 The multiple linear regression analysis results of health promotion behaviors, loneliness, and diabetes distress (N=140)

Variable	Unstandardized coefficient	SE	Standardization coefficient	t values	P values
Constant	66.931	2.351	-	28.470	<0.001
Loneliness	-0.194	0.070	-0.271	-2.785	0.006
Diabetes distress	-2.724	1.019	-0.260	-2.674	0.008

TABLE 4 Total, direct, and indirect effect of loneliness on health promotion behavior (N=140)

Loneliness	Effect	SE	t values	P values	95% CI	
Health promotion behavior	Total effect	-0.312	0.055	-5.686	<0.001	-0.204, -0.436
	Direct effect	-0.194	0.07	-2.785	0.006	-0.331, -0.562
	Indirect effect	-0.118	0.046			-0.211, -0.027

Note : 95%CI, 95% Confidence Interval

4. DISCUSSION

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3 To the best of our knowledge, this is the first study to explore the mediating role of diabetes
4 distress in the relationship between loneliness and health promotion behaviors among older
5 patients with DM. The result indicated that diabetes distress partially mediates the association
6 between loneliness and health promotion behaviors.
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9 In this study, the mean age of participants was 72.57 ± 4.60 , which is older than 57.9 ± 5.60
10 and 66.9 ± 5.80 in previous large sample studies.(23 24) This result may be explained by the fact
11 that advanced age is one of the risk factors for admission in diabetic patients, and our study
12 included hospitalized patients. Comparing a previous study that used the same scale but did not
13 limit to older patients with DM, the health promotion behaviors were at the middle level.(25)
14 Another important finding is that older adults with DM performed poorly in community
15 participation and health responsibilities. Health responsibilities are relevant to health policy
16 development.(26) Community participation is associated with gaining health-related
17 information, reducing physical and mental stress, and maintaining motor function.(27) Further
18 studies are needed to investigate the effects of these two factors on older adults with DM.
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21 Loneliness has a negative and significant association with health promotion. This may be
22 because individuals who experience heightened levels of loneliness tend to also experience
23 elevated levels of stress. And stress maladaptation is significantly associated with poor health
24 promotion behaviors.(28) Loneliness correlates with heightened sedentary behavior and
25 decreased levels of physical activity.(29) The correlation between loneliness and activity levels
26 could therefore play a crucial role in the inverse connection between loneliness and health
27 promotion behaviors.
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30 Diabetes distress also has a negative and significant association with health promotion
31 behaviors. This finding was also reported by previous study.(30) One potential explanation is
32 that diabetes distress, as a negative psychological factor, compromises their ability to self-
33 manage their condition. Narrower self-management abilities are associated with poorer health-
34 promoting behaviors.(31) Evidence supports that the level of diabetes distress can significantly
35 affect glucose control in older patients with DM.(32) Many patients with DM experience a
36 psychosocial burden and mental health problems related to the disease. Diabetes distress has
37 distinct effects on behaviors and disease control.(33) These findings imply that the assessment
38 and intervention of psychological dimensions in diabetes management are essential.
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41 In this study, diabetes distress partially mediates the relationship between loneliness and
42 health promotion behaviors among older patients with DM. Previous studies have explored the
43 mediating relationship between negative psychology and behavior in diabetes distress.(34)
44 Older patients with DM experiencing high levels of diabetes distress exhibit more pronounced
45 negative psychological factors associated with their disease compared to those with
46 significantly lower levels of diabetes distress. These individuals tend to employ ineffective
47 coping strategies in response to feelings of loneliness and engage in suboptimal health
48 promotion behaviors. This study explores the mediating relationship between diabetes distress
49 and loneliness and health promotion behaviors. This suggests that loneliness not only directly
50 affects health promotion behaviors in people with DM, but also indirectly affects health
51 promotion behaviors through the level of diabetes distress. HBM theory provides a framework
52 for understanding the networks that are responsible for health promotion behaviors. When older
53 adults with DM experience loneliness, they are at risk for worsening health promotion
54 behaviors that may lead to a worsening of their disease condition. This study validates the key
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3 role of diabetes distress in this process of change. The detection rate of diabetic distress in
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5 China is 50%,(35) which surpasses that of Perrin et al. (39%).(36) This implies that there is a
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7 greater need for increased consideration of diabetes distress in China.

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9 Traditionally, the focus has often been on improving health promotion behaviors by
10 increasing disease knowledge among people with DM, while neglecting psychological factors.
11 Findings from our research are intriguing because diabetes distress is important as an
12 intervenable mediator in influencing health promotion behaviors during periods of loneliness
13 caused by irresistible factors (e.g., the COVID-19 pandemic). This study and previous studies
14 indicated that diabetes distress can be used as a window for the intervention of psychological
15 state and behavior change in patients with DM. Future research and clinical work need to
16 evaluate and intervene in disease distress in patients with DM.

17
18 Some limitations need to be considered in this study. First, self-report questionnaires
19 which may result in recall and reporting bias. Second, this study did not control confounding
20 factors. Third, the factors included in this study did not fully explain the network relationship
21 between loneliness, diabetes distress, and health promotion behaviors. Additional research is
22 needed to determine how other negative psychological traits impact the health promotion
23 behavior of elderly patients with DM.
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28 **5. CONCLUSION**

29 The present research aimed to examine the mediating role of diabetes distress in the
30 relationship between loneliness and health promotion behavior. When the loneliness of the
31 elderly cannot be changed in a short period, improving diabetes distress can be used as a way
32 to change their health promotion behaviors for disease management. Another broad
33 recommendation is to pay more attention to the negative psychological states in the elderly.
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38 **Author Contributions.**

39 All authors meet the authorship requirement of the International Committee of Medical
40 Journal of Editors. LD and CBG are joint correspond authors. FYZ designed the study and
41 collected the data. FYZ, KYL, LLX, and CBG involved in the data analysis. FYZ, KYL, LD,
42 CBG, LLX, TTY, and QL prepared the first version of the paper and revised the paper. LD and
43 CBG provided technical guidance throughout the process. All authors read and approved the
44 final manuscript.
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48

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51 Program[kzd22018] and the Second Xiangya Hospital Nursing Research Fund[2022-HLKY-
52 19]. This funding source had no role in the design of this study and will not have any role.
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55 **Competing interests**

56 None declared.
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59 **Data sharing statement**

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3 The data supporting the findings of this study are available from the corresponding author
4 upon reasonable request.
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7 **Ethics approval**

8 The study was approved by the Ethics Committee of Xiangya School of Nursing, Central
9 South University(E202283). All participants were informed of the purpose and process of this
10 study before the study began. Our study obtained informed consent from each participant in
11 writing prior to completing the questionnaire. For participants who were not literate enough to
12 comprehend the informed consent form, explanations of each entry were provided on an
13 individual basis. And their legally authorized representatives were also given informed consent.
14 Participation in this study was voluntary. Participants may withdraw from this study at any
15 time. All the participants were informed that they would bear no penalty for refusal to
16 participate in the study and would be allowed to withdraw at any time without affecting their
17 treatments. All information collected here is strictly confidential. Confidentiality and
18 anonymity were maintained by not asking for names and by numbering the questionnaires (each
19 participant received a number on the debriefing form). Any student wishing to withdraw data
20 before data analysis can use this number to contact the researcher. All data were kept in a locked
21 cabinet and on a password-protected computer to ensure privacy. All methods follow the
22 relevant guidelines and regulations.
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32 **Consent for publication**

33 Informed consent was obtained from all subjects involved in the study.
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36 **Figure legend**

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38 **FIGURE 1** The mediated model represents the total direct effect (path c), direct effect (path
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40 c'), and indirect effect (path a and b) from loneliness to health promotion behaviors.
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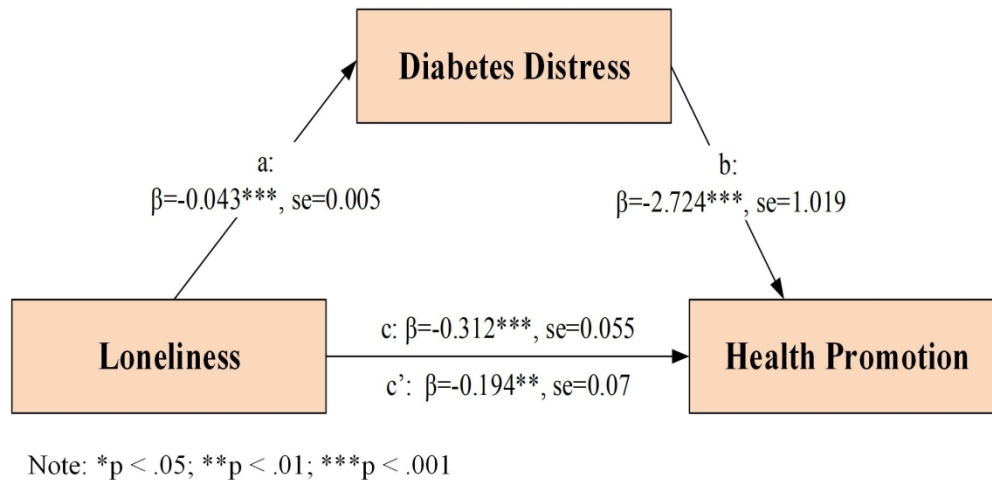


Figure 1 The mediated model represents the total direct effect (path c), direct effect (path c'), and indirect effect (path a and b) from loneliness to health promotion behaviors.

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

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 2
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 3
Methods			
Study design	4	Present key elements of study design early in the paper	Page 3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Page 3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	None
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 4
Bias	9	Describe any efforts to address potential sources of bias	Page 4
Study size	10	Explain how the study size was arrived at	None
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	None
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 4
		(b) Describe any methods used to examine subgroups and interactions	Page 4
		(c) Explain how missing data were addressed	None
		(d) If applicable, describe analytical methods taking account of sampling strategy	None
		(e) Describe any sensitivity analyses	None
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 5
		(b) Give reasons for non-participation at each stage	None
		(c) Consider use of a flow diagram	None
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 1
		(b) Indicate number of participants with missing data for each variable of interest	None
Outcome data	15*	Report numbers of outcome events or summary measures	Page 5
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	None

		(b) Report category boundaries when continuous variables were categorized	Page 5
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	None
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 6
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 7
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 8

*Give information separately for exposed and unexposed groups.

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.