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Complete List of Authors:	Wu, Dongmei; University of Electronic Science and Technology of China, The Clinical Hospital of Chengdu Brain Science Institute, MOE Key Lab for Neuroinformation; The Fourth People's Hospital of Chengdu & Chengdu Mental Health Center, Psychiatric Research Laboratory Yang, Rumei; University of Utah College of Nursing Li, Changwei; Tulane University School of Public Health and Tropical Medicine, Department of Epidemiology Ge, Song; Johns Hopkins University School of Nursing WANG, YAN YAN; West China Hospital, Sichuan University, National Clinical Research Center for Geriatrics Du, Yan; Tulane University Liu, Tingting; Department of Epidemiology
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Validating the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A longitudinal study

Dongmei Wu, Rumei Yang, Changwei Li, Song Ge, Yanyan Wang, Yan Du, Tingting Liu

Correspondence should be made to:

Tingting Liu, PhD, RN

Postal address: 1440 Canal St, Suite 2000, New Orleans, LA 70112

Email: tliu10@tulane.edu

Tel: 504-988-3738

Fax: 504-988-6809

The full names, institutions, city, and country of all other co-authors:

Dongmei Wu, PhD, RN

The Fourth People's Hospital of Chengdu, Chengdu, Sichuan Province, China

Rumei Yang, MS, RN

University of Utah College of Nursing, Salt Lake City, UT, USA

Changwei Li, PhD, MD, MPH

Department of Epidemiology and Biostatistics,

University of Georgia College of Public Health, Athens, GA, USA

Song Ge, BSN, RN

Johns Hopkins University School of Nursing, Baltimore, MD, USA

Yanyan Wang, PhD, RN

West China Hospital, Chengdu, China

Yan Du, PhD, RN

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

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Abstract

Introduction: Currently, China has the largest number of people with diabetes in the world, and the disease has reached epidemic proportions in the adult population. Individuals with diabetes perform about 95% of their own care. Diabetes self-management is an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their diabetes. Several studies have consistently shown that diabetes self-management practice is suboptimal among Chinese adults with type 2 diabetes. The reason for poor adherence to diabetes self-management among Chinese adults is not well known and no conceptual model has been used to guide diabetes self-management interventions in this population. Although the information-motivation-behavioral skills model has been tested among Chinese adults with type 2 diabetes, some key components of the original model were not tested. In the proposed study, we will refine and test longitudinally a culturally tailored model of diabetes self-management among 250 Chinese adults residing in China.

Methods and Analysis: This is a prospective, longitudinal study at a tertiary hospital in Chengdu, China. A total of 250 adults with type 2 diabetes will be enrolled into current study, and will be followed up for 3 months. Multiple domains will be collected, including demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Main analyses comprise linear regression models after controlling for covariates and structural equation model.

Ethics and Dissemination: Ethical approval has been obtained through the Fourth People's Hospital of Chengdu Research Ethics Committee (study number 2017017). We aim to disseminate the findings through international conferences, international peer-reviewed journals and social media.

Study registration number: ChiCTR-ROC-17013592.

Introduction

Diabetes is a major public health problem worldwide and it is increasing by epidemic proportions. Globally, the total number of people living with diabetes is projected to rise from 425 million cases in 2017 to 649 million cases by 2045, with over 75% of cases living in low- and middle-income countries [1]. In China alone, the most comprehensive nationwide survey showed that about 114 million (11.6%) adults had diabetes in 2010, a two-fold increase over the past decade [2]. Type 2 diabetes (T2D) accounts for approximately 90% to 95% of all diagnosed cases of diabetes [3]. In China, it is estimated that 102.5 to 108.2 million individuals have T2D. Individuals with T2D perform about 95% of their own care [4]. Diabetes self-management (DSM) is therefore an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their T2D such as self-monitoring blood glucose (SMBG), dietary and physical activity [5]. DSM is complex, requires major lifestyle changes and behavioral tasks that are incorporated into an individual's daily routine and high levels of adherence for effective management and halting disease progression [6].

Mounting evidence has consistently shown that better DSM was associated with better health outcomes, including improved glycemic control [7], improved quality of life [8], and reduced incidence of diabetes-related complications [9]. DSM has transformed diabetes to a controllable and treatable chronic condition, and individuals with diabetes have been shown to make a great impact on the progression and development of their disease by participating in their own care. However, adherence to some of these activities has been found to be low, especially when looking at long-term changes [10]. This suggests a critical need for a comprehensive and well-tested conceptual model to guide future DSM interventions.

Although the information-motivation-behavioral skills (IMB) model has been tested among Chinese adults with T2D [11], some key components of the original IMB model were not tested. For example, it is well known that personal motivation may influence DSM among Chinese adults [12]. Additionally, important moderators known to influence DSM in Chinese adults such as depressive symptoms, female gender and educational level were not included in the model [11], and this may add important insights into DSM specific to this population. Therefore, a revised conceptual model based on

the IMB model is needed to take account the effects of interactive relationships among the related factors. The proposed IMB-DSM model will help fill this void by examining the potential moderators of DSM in this population, so that intervention studies based on this model can not only show whether the intervention works, but also why the intervention works and under what conditions the intervention works.

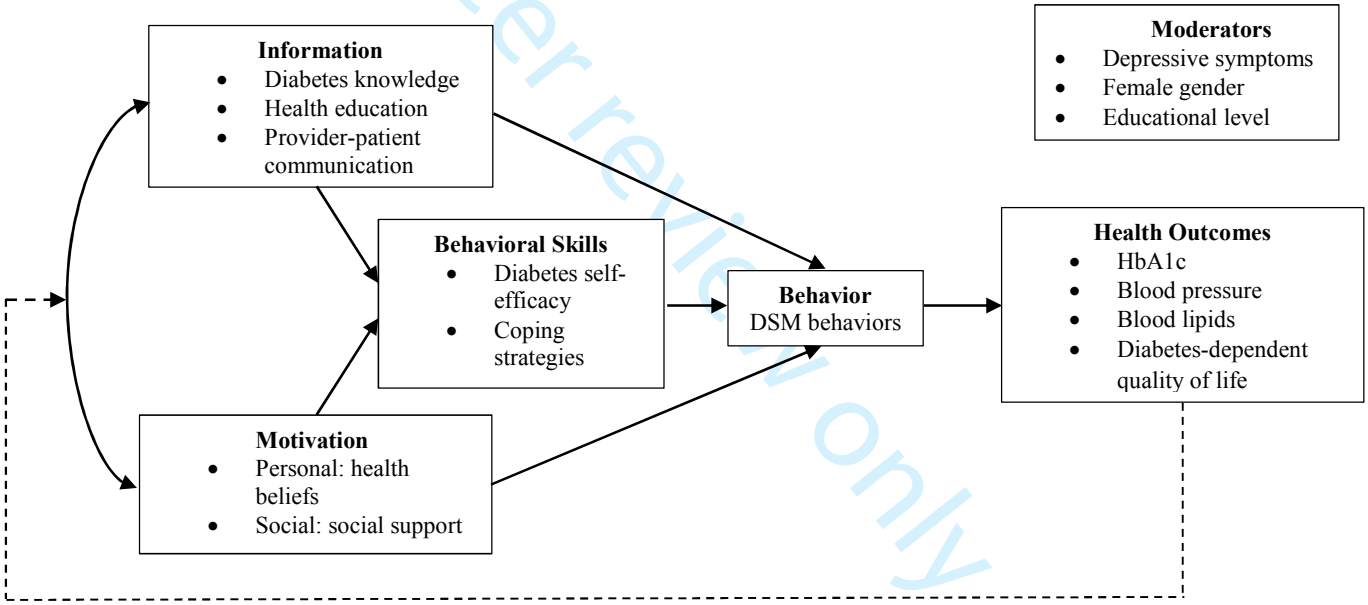
Validating the IMB-DSM model has important scientific and clinical implications, particularly in the light of the high morbidity and mortality associated with diabetes and subsequent diabetes-related complications. This study will have particular relevance for clinical practice and the broader field of public health. First, although the IMB model has been well-supported across populations and health-related behaviors [13], its use in DSM is limited [11 14 15]. This study will contribute to the growing body of literature on the use of the IMB model in DSM in Chinese population, and will provide preliminary evidence on the model's utility in designing and evaluating interventions aimed at improving DSM in this patient population. Secondly, the findings of this study will be used to develop a culturally-tailored, theory-based DSM intervention for patients with T2D, which will ultimately help reduce the occurrence of complications, and aid patients in dealing with diabetes-related psychosocial issues. Finally, the findings may contribute to policy development on the importance of promoting national DSM educational programs to support and to assist diabetes educators in providing evidence-based diabetes education and DSM.

Conceptual Framework

Overview of the IMB model. The IMB provided the theoretical basis for this study. The IMB model is used to frame these variables because: (a) the constructs from the model can be easily translated into intervention components, and (b) it adequately captures essential constructs that are well supported in the literature to improve DSM behaviors, including information (e.g., diabetes knowledge), motivation (e.g., social support), and behavioral skills (e.g., diabetes self-efficacy). The model postulates that individuals are more likely to take health-related action, such as DSM, if they are well informed, highly motivated (personally and socially), and have adequate and appropriate behaviors, and thus, experience

positive health outcomes [13]. The model is based on three constructs: information, motivation, and behavioral skills. Behavioral skills to perform the behavior are proposed to mediate the effects of information and motivation on behavior under study and the behavior is directly linked to health outcomes, which, in turn, are conceptualized as influencing one's future maintenance of the behavior via a feedback loop that affects one's future levels of information, motivation, and behavioral skills overtime [16 17]. The IMB model further postulates that favorable health outcomes may strengthen an individual's information, motivation, and behavioral skills to perform the behavior in the future. In contrast, unfavorable health outcomes may cause an individual to lose confidence in his or her knowledge, motivation, and behavioral skills to perform the behavior overtime [17].

Figure 1 The IMB-DSM Model



The IMB-DSM model. Figure 1 portrays the overarching conceptual framework of this study. The IMB-DSM model provides a comprehensive insight to explore the relationships that influence DSM and its related health outcomes, based on a systematic review of literature in this area. The framework consists of the following six key interrelated components: DSM-related information, motivation, behavioral skills, DSM, health outcomes, and moderators. Consistent with the original IMB assumptions, the IMB-DSM model asserts that DSM-related information, motivation, and behavioral skills are

fundamental determinants of DSM behaviors. DSM-related information and motivation are proposed to work primarily through behavioral skills to affect initiation and maintenance of DSM behaviors. DSM behaviors lead to health outcomes, which, in turn, can influence one's future maintenance of the behavior via a feedback loop that affects one's future levels of DSM-related information, motivation, and behavioral skills overtime. The proposed moderators can influence the relationship among variables in the IMB-DSM model.

DSM-Related information. DSM-related information is a necessary but insufficient prerequisite for DSM behaviors. The link between DSM-related information and DSM behaviors has been well established in the literature. DSM-related information primarily includes diabetes knowledge, health education and provider-patient communication. A positive relationship was found between diabetes knowledge and overall DSM performance [18-20], exercise, foot care [21], diet control, or SMBG [22] in some studies, but not others [23 24]. Additionally, diabetes knowledge was also found to be negatively related to smoking cessation in one study [22]. A significantly positive relationship between health education and overall DSM performance was reported in three studies [25-27]. Positive relationships were also reported between health education and some specific DSM behaviors, such as diet modification, foot care, regulating highs and lows in blood glucose, SMBG, engaging in exercise, taking medications, smoking cessation [25 28 29]. Three studies reported the relationship between provider-patient communication and DSM behaviors, and both studies found that better provider-patient communication was an independent, direct predictor of better overall DSM performance [11 24 30].

DSM-Related motivation. Another fundamental determinant of DSM behaviors is an individual's motivation to perform DSM. Consistent with the IMB model, the IMB-DSM model posits that an individual's motivation includes personal and social motivation. Personal motivation to perform DSM refers to one's beliefs about the DSM behaviors and evaluations of the outcomes. Social motivation to perform DSM rests on the one's perception of social support for DSM and one's motivation to comply with referent others [14 31].

In the IMB-DSM model, health beliefs are used to conceptualize personal motivation. Perceived susceptibility, perceived barriers, perceived benefits, or cues to action has each been positively associated with overall DSM performance and all aspects of DSM behaviors except smoking cessation [12 32]. There was inconsistent evidence of the relationship between perceived severity and DSM behaviors. Yu (2009) reported a negative association, whereas Sun and coworkers (2012a) reported a positive association. One possible explanation for the inconsistency between perceived severity and DSM behaviors involves the fact that both studies are cross-sectional. Thus, a person who is currently engaging in DSM behaviors may both perceive him- or herself as not being at risk and may report few feelings of severity. Alternatively, a person who is presently engaging in less DSM behaviors may report more feelings of severity and few risk-reduction efforts. The inconsistency warrants more investigations from longitudinal studies. Research evidence is consistent with a positive relationship between perceived social support from significant others and overall DSM performance, diet control, taking medications, engaging in physical activity, SMBG, foot care and regulating highs and lows in blood glucose [11 21 24 33-35].

DSM-Related behavioral skills. Behavioral skills involve objective and perceived skills for performing DSM behaviors and a sense of self-efficacy for doing so [14]. In the IMB-DSM model, behavioral skills include diabetes self-efficacy and positive coping strategy. A great deal of studies has linked levels of self-efficacy and DSM behaviors [11 19 21 24 34 36-39]. There was a consistent strong association between increased self-efficacy level and better DSM behaviors, including diet modification, taking medications, foot care, physical activity, SMBG, and regulating highs and lows in blood glucose.

Available evidence also supports a relationship between objective abilities and DSM behaviors. Coping strategies have been well studied in this population. Individuals with positive coping strategies such as confrontation tend to be more willing to learn how to manage their disease. In contrast, individuals with negative coping strategies such as avoidance or acceptance-resignation may not be willing to follow management recommendations. Research evidence is consistent with a positive relationship between confrontation and overall DSM performance [40], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 32 36].

Alternatively, acceptance-resignation was negatively associated with overall DSM performance [40], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 32 36]. Avoidance had negative effects on taking medications [12 32] and regulating highs and lows in blood glucose [32], but had favorable effects on overall DSM performance [12 36] and other aspects of DSM behaviors except smoking cessation [12 32 36].

One cross-sectional study provided evidence for the role of DSM-related behavioral skills as a mediator between DSM-related information, motivation, and DSM behaviors. Information on demographics, provider-patient communication, social support, and self-efficacy, and diabetes self-care was collected among 222 participants with T2D in Shanghai. There were significant, positive, direct paths from self-efficacy (β=.41, p<.001), social support (β=.19, p=.007), and provider-patient communication (β=.12, p=.037) to DSM behaviors. Paths from provider-patient communication to self-efficacy (β=.23, p<.001) and from social support to self-efficacy (β=.19, p<.05) were significant and positive. Structural equations modeling showed that self-efficacy mediated the effects of social support (indirect effect β=.08, p=.008) and provider-patient communication (indirect effect β=.09, p=.002) [11]. Overall, the study provided support for the specific direct and mediating relationships between DSM-related information, motivation, behavioral skills, and DSM behaviors. However, one limitation of this study is that the adapted IMB model does not include all relevant constructs. For example, information on personal motivation was not collected. Therefore, the study only partially validated the IMB model.

Health outcomes. The IMB-DSM model asserts that DSM behaviors are directly linked to health outcomes, which has been well supported in the literature. Since adults with T2D are two to four times more likely to have cardiovascular disease (CVD) than adults without T2D, and CVD is the leading cause of mortality for patients with T2D [41], monitoring of cardiometabolic markers is essential in the clinical management of patients with T2D. In the proposed study, blood pressure and blood lipids are measured to identify subsequent CVD risks among adults with T2D. The health outcomes include hemoglobin A1c (HbA1c), blood pressure, blood lipids, and diabetes-dependent quality of life. DSM had a direct effect on glycemic control (β=-.02, p=.007) [30], total cholesterol (TC)/high-density lipoprotein cholesterol (HDL-C)

(β=-.31, p<.001), and low-density lipoprotein cholesterol (LDL-C)/HDL-C (β=-.30, p<.001) [11]. A previous study has shown that the participants' blood pressure decreased and remained within optimal range 3 months after diabetes educational program among Chinese immigrants in the United States [42], indicating that blood pressure may be a highly relevant outcome to explore as part of DSM [43]. However, it is not clear whether DSM is directly related to blood pressure in Chinese adults with T2D, and this will be examined in this study. Compared to the general population, people affected by T2D consistently reported diminished health-related quality of life [44]. A meta-analysis of 20 intervention studies found that people with diabetes experience improved health-related quality of life from participation in DSM training programs [8]. However, the relationship between DSM and health-related quality of life has not been systematically studied among Chinese adults with T2D, and this study will fill the knowledge gaps.

DSM behaviors, health outcomes, and future DSM behaviors. The model assumes that favorable or unfavorable health outcomes that result from DSM behaviors, are linked via a feedback loop to the strengthening or weakening of subsequent DSM behaviors. Diet modification, physical activity, taking medications, SMBG, foot care, regulating highs and lows in blood glucose, and overall DSM performance was each positively associated with lower systolic blood pressure [45]. Hyperlipidemia was negatively associated with taking medications [45]. In addition to blood pressure, higher levels of HbA1c was related to better overall DSM performance [12]. However, all evidence supporting health outcomes as a predictor for future DSM behaviors comes from cross-sectional studies, in which temporal precedence of health outcomes and DSM behaviors cannot be established. These lines of evidence speak most clearly to the association between health outcomes and DSM observed at a single point in time. This study will be conducted to investigate the longitudinal effects of health outcomes on changes in DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors.

Moderators. A moderator is defined as a variable that alters the direction or strength of the relationship between a predictor and an outcome [46].The IMB-DSM model postulates that certain personal characteristics may act as moderators that influence the associations of the model constructs with DSM behaviors, and that the degree of moderation depends on the level or intensity of the moderator. High

levels of moderators are assumed to directly influence DSM behaviors, whereas lower levels of moderators are assumed to work through the IMB-DSM model constructs to influence DSM behaviors and not obscure the relationships between these constructs and DSM behaviors. These moderators include depressive symptom, female gender, and educational level.

Depressive symptoms have been consistently found to negatively affect DSM behaviors, such as SMBG, foot care, diet modification, regulating highs and lows in blood glucose, and overall DSM performance in these studies [47-49]. Generally, female patients had better overall DSM performance than their male counterparts [12 50]. People with a higher educational level tended to manage their diabetes better, compared to people with lower educational level [26 34 45].

Because existing studies investigating factors associated with DSM are primarily univariate in nature, they generally address only one aspect of the IMB-DSM model, that is, they establish support for a direct relationship between DSM behaviors and DSM-related information, motivation, or behavioral skills. So far, no studies have been conducted to systematically evaluate how potential moderators may influence the relationship among variables in the IMB-DSM model, and this study is expected to fill those knowledge gaps.

Objectives

In the proposed study, we will refine and test longitudinally a culturally tailored IMB model of DSM (IMB-DSM) among 250 Chinese adults residing in China. The proposed study has one primary aim, one secondary aim, and one exploratory aim.

Primary Aim: In Chinese adults with T2D, determine which baseline variables are most predictive of DSM and better health outcomes (hemoglobin A1c [HbA1c], blood pressure, blood lipids, and diabetes-dependent quality of life) at 3-month follow-up period?

H1: Compared to baseline DSM-related information and motivation, are baseline behavioral skills most predictive of DSM at 3-month follow-up period?

H2: Compared to baseline DSM-related information, motivation, and behavioral skills, is DSM most predictive of better health outcomes at 3-month follow-up period?

Secondary Aim: Investigate the effects of baseline health outcomes on changes in DSM-related information, motivation, behavioral skills and subsequent DSM at 3-month follow-up period.

RQ1: What are the effects of baseline HbA1c on changes in DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors?

RQ2: What are the effects of baseline blood pressure on changes in DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors?

RQ3: What are the effects of baseline blood lipids on changes in DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors?

RQ4: What are the effects of baseline diabetes-dependent quality of life of on changes in DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors?

Exploratory Aim: In Chinese adults with T2D, examine mediating and moderating factors associated with DSM at baseline and the 3 month follow-up period.

RQ1: Are diabetes self-efficacy and coping strategies mediators of DSM at baseline and 3-month follow-up period?

RQ2: Are depressive symptoms, female gender, and educational level as moderators of DSM at baseline and 3-month follow-up period?

Methods and Analysis

Design

A descriptive, repeated-measures design will be used to examine the relationships among variables in the IMB-DSM model, the role of variables in predicting DSM, the potential moderators and mediators, and investigate the longitudinal effects of health outcomes on changes in DSM-related information, motivation, behavioral skills and subsequent DSM. Data will be collected at two time points, 3 months apart to allow predictive modeling of the IMB-DSM model's independent (i.e., DSM-related information, motivation, and behavioral skills collected at baseline) and dependent (i.e., DSM behaviors collected at 3-month follow-up visit) variables.

Sample and Setting

This study will be conducted in Chengdu metropolitan area, which is the provincial capital of Sichuan province in Southwest China. One community health center will be selected from each of six urban districts in Chengdu metropolitan area: the Yulin community health center in Wuhou District, the Supo community health center in Qingyang District, the Longzhoulu community health center in Jinjiang District, the Caojiaxiang community health center in Jinniu District, the Shuanglin community health center in Chenghua District, and the Guixi community health center in Gaoxin District. The inclusion criteria for participation in the research are: (a) diagnosed with T2D; (b) able to read, write, and speak Chinese; (c)≥18 years of age; (d) a score of the Chinese version of Mini-Mental State Examination (C-MMSE) > 24 (see **Screening** below); (e) no other chronic physical or mental disorders; and (f) mentally competent to give informed consent. Patients will be excluded if they are pregnant, have been diagnosed with cancer or organ failure, refuse to participate in the proposed study, self-identified bilateral hearing loss, or cognitive impairment (inability to comprehend the informed consent).

Sample Size

The Power Analysis and Sample Size Software was used for sample size calculation. Sample size was calculated based on the weakest correlation among all the tested variable pairs, that is, diabetes knowledge and social support (r=.197). Assuming 80% power, type I error rate of .05, and attrition rate of 20%, a total of 250 participants will be needed to detect the correlation coefficient of .197. This sample size will have a higher power to detect correlations with larger coefficient.

Participant Recruitment

The research team will actively recruit participants from six selected community health centers. The principal investigator and her undergraduate mentors have relationships with these community health centers and will be able to facilitate recruitment from these sites. An electronic medical database of the residents kept each community health center will also be used to identify patients with T2D in these communities. The research team will also have access to the database from which participants can be recruited.

Once the approval from the Ethics Committees for Clinical Trials and Biomedical Research in the Fourth People's Hospital of Chengdu is obtained, patients who come to the local clinics for evaluations and care will be approached after agreeing to hear about the study by a research staff member, who will explain the study, provide a consent form for review, answer questions and seek their participation. Subjects who agree to participate will be screened on study criteria. Screening (see Screening below) will take about 10 minutes. Those who meet study criteria will be entered into the study. In addition, advertisements about the study will be placed on buses and subways. Those interested in the study will be invited to the study site and asked to participate after reviewing study procedures and consent forms. Weekly and monthly recruitment goals will be set to ensure adequate progress on participant enrollment. If recruitment is slow, recruitment procedures will be reviewed, problems identified, and adjustments will be made so that participant accrual is conducted at a satisfactory rate.

Screening

A questionnaire will assess eligibility via questions on age, length of diabetes, period of time when starting diabetes treatment, provider referral, and willingness to participate. Since this population is at risk for cognitive impairment that may, in some cases, limit capacity to provide consent [51], the C-MMSE will be administered to evaluate global cognitive functioning of all eligible participants. The original MMSE is the most commonly used screening tool for cognitive impairment and dementia worldwide [52], and a high sensitivity (90.8%) and specificity (93%) of the C-MMSE were reported from a cross-sectional, population-based study among Chinese general population [53]. The C-MMSE has been used among Chinese adults with T2D [54]. Those who obtain a score <=23 will be excluded because subjects with such low scores were considered to have possible dementia [55]. Potential participants with serious cognitive problems will be referred immediately to a mental health professional used by the respective community health centers.

Reducing Attrition

There will be a potential problem with attrition of the proposed study because the 3 month follow-up for the longitudinal study design opens up to the problem of attrition. Steps that will be taken to

reduce attrition include: informing subjects of the importance of continued participation in all aspects of the study; giving a subject incentive of ¥155 (about $25) Walmart gift card per completed data collection session; making telephone calls and sending a reminder card prior to scheduled data collections. A participant locator form will be completed for each subject entered in the study and at all data collection sessions to ensure proper contact information for follow-up visit is maintained.

Data Collection and Procedures

After consenting to participate, each subject will be requested to come to the study site for baseline data collection in a private office at the research site. Baseline data collection will include administration of the following questionnaires: Demographic Data Form, the Diabetes Knowledge Questionnaire, the Health Education Form, the Provider-Patient Communication Scale, the Health Belief Scale, the Social Support Rating Scale, the Diabetes Self-Efficacy Scale, the Medical Coping Modes Questionnaire, the Diabetes Self-Care Scale, the Self-rating Depression Scale, and the Audit of Diabetes-Dependent Quality-of-Life. At the 3 month follow-up data collections, all the measures will be administered again except the Demographic Data Form. Data collection from each participant should take about 60 minutes. The instruments will be administered by a trained research assistant as an interview to reduce respondent burden and to standardize the approach due to the differing response formats. If the participant becomes fatigued, the battery of questionnaires may be completed in two sessions.

Training of Data Collectors

In an effort to improve inter-rater reliability, project data collectors will be trained to collect data for baseline and follow-up data collections. Data collectors will attend intensive training sessions at the beginning of the project, and periodic refresher sessions will be offered every 2 to 3 weeks to reinforce the basic training. Data collectors will practice conducting data collections and blood pressure measurement and these sessions will be monitored and each data collector will be certified. To control for measurement error, a data collection protocol manual will be developed that will include data collection protocol related specifically to each questionnaire and blood pressure measurement. The specific

measures, including instruments and physical biomarkers, that will be used within this study are described below.

Instruments

Demographics. This questionnaire is designed to collect background data from participants on their demographic characteristics, including age, gender, income, education, marital status, length of diabetes, health insurance, current treatment plan for diabetes, and relevant health history indicators. The information will be used to fully describe the sample.

The diabetes knowledge questionnaire. Diabetes knowledge is defined as patient understanding of information about diabetes and its management, and will be measured with the Chinese version of the Diabetes Knowledge Scale adapted from the Diabetes Knowledge Scales [56]. The Diabetes Knowledge Scale was first designed to measure patients' knowledge in basic physiology of diabetes, food choices, general diabetes care, and sick day management. The original scale in U.S. samples was reasonably internally consistent (Cronbach's alpha ranged from .72 to .79) and differentiated known groups [56]. The Chinese version of the Diabetes Knowledge Scale consists of 14 items. Participants receive a score of 1 for a correct answer or 0 for an incorrect or unknown answer. The total score ranges from 0 to 14, with a higher score indicating a higher level of diabetes knowledge. The Cronbach's alpha for the Chinese version of the knowledge measure was .62. The diabetes knowledge score in the Chinese sample was significantly higher in the group with more education ($t[28]=2.83$, $p< .01$), indicating that the Chinese version had satisfactory construct validity [57].

The health education form. Information on health education is based on self-reports. All participants will be asked if they have had received any form of diabetes education. If the answer is YES, the patient should answer the source of diabetes education. The source of diabetes education could be health care professionals, community consulting service, journals/books, TV/radio, internet and others.

The provider-patient communication scale. Provider-patient communication is defined as individual's understanding of and ability to interact with a range of health organizations and health professionals, and will be measured by the Provider-Patient Communication Scale. The scale consists of 5

items with a scoring range from 0 to 6, where 0 indicates "strongly disagree" and 6 indicates "strongly agree". High scores characterize a person who is confident in their ability to communicate with healthcare professionals and has good understanding of ways to access healthcare in order to get their needs met. The Cronbach's alpha coefficient is reported at .929, indicating excellent internal consistency [11].

The health belief scale. Health beliefs refer to one's perceptions about T2D and how it can be treated. The Health Belief Scale was developed based on the Health Belief Model by Yamei Chen in China [58]. The 20-item scale comprises 5 subscales (perceived susceptibility, perceived benefits, perceived severity, perceived barriers, and cues to action) and uses a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score represents stronger health beliefs. The content validity is .81, the test-retest reliability ranges from .78 to .82, and the Cronbach's alpha is .79 [58].

The social support rating scale. Social support is defined as the perception of support from family members, and will be assessed by the Social Support Rating Scale. The scale was developed by Shuiyuan Xiao in China [59]. The 10-item instrument measures aspects of objective social support (3 items), subjective social support (4 items) and usage of social support (3 items). The item scores range from 14 (worst possible social support) to 66 (best possible social support) [60]. The test-retest reliability coefficient and the internal consistency of the scale are .92 and .88-.94, respectively [34].

The diabetes self-efficacy scale. Self-efficacy is a key tenet in the Social Cognitive Theory [61]. Diabetes self-efficacy has been defined as the judgment of one's own capability to monitor, plan, and perform diabetes activities [62], and will be measured with the Chinese version of a measure adapted from the Self-Efficacy Scale for patients with T2D developed by van der Bijl, van Poelgeest-Eeltink, and Shortridge-Baggett (1999). The scale measures the degree of confidence an individual with T2D has in performing DSM [63]. The Cronbach's alpha of the original scale was .81, and the items loaded on four factors that explained 55% of the variance [63]. The 7-item Chinese version of the Diabetes Self-Efficacy Scale evaluates participants how capable they are when performing DSM activities. The items are scored on a 5-point Likert-type scale, with higher scores indicating higher self-efficacy in performing DSM behaviors. The Chinese version of the Diabetes Self-Efficacy Scale has a Cronbach's alpha of .87. Factor

analysis showed that seven items loaded on five factors, which explains 97.9% of the variance, and the five factors are consistent with confidence in performing the five aspects of DSM behaviors [57].

The medical coping modes questionnaire. Coping strategies refer to cognitive and behavioral efforts made by the individual to deal with stress [64], and will be measured by the Medical Coping Modes Questionnaire. The 19-item questionnaire was designed to assess 3 forms of coping strategies with chronic diseases: confrontation, avoidance, and acceptance-resignation [65]. Items are answered on a four-point Likert scale ranging from 1 (never) to 4 (very often). Scores from the three subscales are compared, and the highest score indicates the corresponding dominant pattern of coping utilized by the participant [65]. The 20-item Chinese version of the Medical Coping Modes Questionnaire was adapted from the original instrument, with one more item adding to the acceptance-resignation subscale [66]. The Cronbach's alpha for the confrontation, avoidance, and acceptance-resignation subscales is reported at .69, .60, .76, respectively [66].

The diabetes self-care scale. The 26-item Diabetes Self-Care Scale is comprised of 6 subscales: diet modification, taking medications, SMBG, foot care, physical activity, and regulating highs and lows in blood glucose. Responses for each item range from 1 (never) to 5 (very often). Total score can range from 26 to 130 by adding up scores of 6 subscales, with higher scores indicating better overall DSM performance. The construct validity is .68, and the Cronbach's alpha is .87 [67].

The self-rating depression scale. Depressive symptoms refer to thoughts, feelings, and behaviors demonstrating sadness, loss of interest in life, and negative perception of self or the future [68 69]. Depressive symptoms will be assessed using the Self-Rating Depression Scale, a 20-item self-administered questionnaire developed by Zung [70]. The scale precisely and quickly measures the symptoms and severity of depression. Each item is rated on a four-point Likert scale, ranging from 1 (where depression symptoms are very seldom) to 4 (where depression symptoms are most of the time) and computed as an original score, then multiplied by 1.25 to get the standard score. A score of 53 or higher has been used as the cut-off point for presence of depressive symptoms in Chinese version of the Self-Rating Depression Scale. A score ranges from 53 to 62 indicates mild depressive symptoms, a score

ranges from 63 to 72 indicates moderate depressive symptoms, and a score higher than 72 indicates severe depressive symptoms [71].

The audit of diabetes-dependent quality of life. Health-related quality of life is defined as the patient's perception of the overall impact of their illness on physical, psychological and social status [72], and will be measured with a diabetes specific instrument. The Audit of Diabetes-Dependent Quality of Life was originally designed to measure individuals' perceptions of the impact of diabetes on various domains of their life [73]. The questionnaire has been found to be sensitive to complications of diabetes and to improvement following treatment, especially DSM education program [74-76]. The Chinese version of Audit of Diabetes-Dependent Quality of Life measures both generic and diabetes-specific quality of life. The first two overview items assess generic quality of life on a seven-point Likert scale (-3 [extremely bad] to 3 [excellent]) and quality of life without diabetes. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how their quality of life would be if they did not have diabetes. The subsequent 19 items evaluates diabetes-specific quality of life, measuring physical functioning, symptoms, psychological well-being, social well-being, role activities and personal constructs. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how particular aspects of their life would be if they did not have diabetes. The importance of each aspect on their life is rated on a four-point scale (0 to 3). The two ratings are multiplied and summed for a final impact score that ranges from -9 to 3, where more negative scores indicate worse quality of life and more negative impact of diabetes on quality of life. A score of 0 is assigned to "unimportant" domains, regardless of the magnitude of its impact. Similarly, a core of 0 is assigned to items with no impact of diabetes, regardless of their importance to quality of life. The questionnaire is an individualized instrument, which allows respondents to only assess the impact of diabetes on the domains they are concerned and value the importance of these domains to their life [77]. The average weighted rating score is obtained by dividing the sum of weighted ratings for applicable domains by the number of the applicable domains. Strong reliability (Cronbach's alpha=.941) has been reported [77]. Factor analysis showed that all items had high performance in the structural validity evaluation, with most factor loading values being larger than .40 (varied from .44 to .88) [77].

Physical Markers

Physical markers include HbA1c, blood pressure, and blood lipids, which will be measured at baseline and 3-month follow-up visit. All blood samples will be processed at the Clinical Laboratory of the Fourth People's Hospital of Chengdu, which has regular external quality assessment organized by the Chinese Ministry of Health and conducts assay quality control samples on a daily basis. The Clinical Laboratory has been accredited by the Sichuan Health Bureau and offers approximately 200 different clinical assays in immunology, chemistry, hematology, virology, and molecular biology. This laboratory has excellent performance during annual evaluation by External Quality Assurance Program organized by the National Center for Clinical Laboratories, China Ministry of Health. After collection, the fresh venous blood samples will be immediately transported at 4°C temperature to the Clinical Laboratory of the Fourth People's Hospital of Chengdu by trained research nurses within 2 hours. The samples will then be placed in a deep freezer and stored at -80°C until assays start.

HbA1c. HbA1c is a form of hemoglobin that is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. HbA1c will be used as a marker of T2D and glycemic control and will be analyzed from whole blood samples (4 ml). HbA1c is the gold standard for monitoring glycemic control and reflects a person's glucose control for the preceding 8 to 10 weeks. The American Diabetes Association recommends a goal of <7.0% for patients with diabetes [78]. Analysis will be conducted using high performance liquid chromatography, with standardization through commercial available assays (coefficient of variation<2%).

Blood pressure. Blood pressure is the pressure exerted by circulating arterial blood upon the walls of blood vessels, and it is one of the principal vital signs. In adults, the ideal blood pressure at rest is within the range of 90 mmHg to 119 mmHg systolic and 60 mmHg to 79 mmHg diastolic. Prehypertension refers to blood pressure higher than normal but not high enough to be diagnosed as hypertension. Readings greater than or equal to 130/80 mmHg are considered hypertension [79].

Blood pressure will be obtained by a trained nurse using a standard sphygmomanometer for a minimum of 2 consecutive readings at intervals of at least 1 minute, based on the American Heart

Association guidelines [80]. According to the American Heart Association [80], the patient should be seated comfortably with the back supported and the upper arm bared, without constrictive clothing. The legs should not be crossed. The arm should be supported at the heart level, with the bladder of the cuff encircling at least 80% of the arm circumference. The mercury column should be deflated at 2 to 3 mm/s, and the first and last audible sounds should be taken as systolic and diastolic pressure. The column should be read to the nearest 2 mmHg. Neither the patient nor the observer should talk during the measurement procedure. The average of those readings will be used to represent the patient's blood pressure [80].

Blood lipids. Blood lipids include TC, HDL-C, LDL-C, and triglycerides (TG). Analysis of blood lipids will be conducted using enzymatic colorimetric test, with standardization through commercial available assays (coefficient of variation<2%). Fasting serum samples will be collected in the morning after 8 hours fasting. The American Diabetes Association has set guidelines for TC, TG, LDL-C, and HDL-C levels: TC<200 mg/dl (5.17 mmol/l), TG levels<150 mg/dl (1.7 mmol/l), LDL-C<100 mg/dl (2.6 mmol/l), and HDL-C>40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable [78].

Data Analyses

Data analyses for Primary Aim 1: Linear regression models will be applied to assess the associations between DSM at 3 months follow-up visit and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age and gender at baseline. Linear regression models will also be applied to assess the associations between health outcomes at 3 months follow-up visit and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age and gender at baseline.

Data analyses for Secondary Aim: Changes in DSM-related information, motivation, behavioral skills, and DSM will be calculated for participants with measures at both baseline and follow-up visit. The associations between changes in these variables and baseline health outcome variables will be evaluated using linear regression models, controlling for age and gender at baseline.

Data analyses for Exploratory Aim: Both baseline and 3-month follow-up measures will be used for exploratory aim. Structural equation modeling will be used to explore the fit of the data to the IMB-DSM model. Data will be first assessed whether they meet the assumptions of maximum likelihood estimation of structural equation modeling. Then, hypotheses regarding structural relations among the IMB-DSM model constructs will be evaluated with an inspection of the direction and magnitude of the path coefficients (direct effects) and indirect effects, which indicate mediation. Significant indirect effects occur when the relationship between a predictor and an outcome is due to the predictor being associated with a third variable (i.e., all or part of the direct effect of A on C is due to a relationship between A and B). Criteria used to test the structural model will be the comparative fit index (≥.95 indicates good fit), the root mean square error of approximation (≤.06 with confidence interval .00-.08 indicates good fit), and the standardized root mean square residual (<.08 indicates acceptable fit, and 0 indicates perfect fit) [81]. Agreement between multiple indices provides the best support a model has good data fit [81]. Moderators will be tested by doing multi-group testing in AMOS 21, a structural equation modeling program. To examine whether depressive symptoms, female gender, and educational level moderate the relationships in the model, multi-group analysis will be used comparing a constrained model (i.e., a model in which the coefficients are set equal across the groups) with an unconstrained model (i.e., a model in which these coefficients are allowed to vary freely). A significant difference between these two models implies that there are significant differences among the groups. A series of nested models will be tested to see where the differences are.

Ethics and Dissemination

The study poses little to no risk to participants and their families. Signed informed consent will be obtained from all participating families. Participation in the study does not interfere with the usual care patients receive in the primary care settings. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals.

Strengths and limitations of this study

- This study will recruit and follow-up Chinese adults with diabetes for 3 months, and validate the information-motivation-behavioral skills model of diabetes self-management longitudinally for the first time.
- It will collect data in demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Therefore, this study will provide preliminary evidence on the model's utility in designing and evaluating interventions aimed at improving diabetes self-management in this patient population.
- As with previous studies, the representative nature of our sample is limited due to the likelihood that not all adults with type 2 diabetes present for medical treatment to selected community health centers.

Contributor ship statement

All authors contribute to the conception and design of this study. TL, CL, and DW drafted the manuscript. RY, YW, SG, and YD revised the manuscript. All authors approved the final version to be submitted to the journal.

Competing interests statement:

None declared.

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Data sharing statement:

We have not yet collected data. Once data collection is finished, the individual de-identified participant data (including data dictionaries) will be shared. The shared data will include demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. The data will become available as soon as we collect all data and for one year.

References

1. International Diabetes Federation. IDF diabetes atlet, 8th edition 2017 [Available from: http://www.diabetesatlas.org/across-the-globe.html accessed Nov 28, 2017.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *Journal of the American Medical Association* 2013;310:948-59. doi: 10.1001/jama.2013.168118 [published Online First: 2013/09/05]

3. Centers for Disease Control and Prevention. Awareness of prediabetes--United States, 2005-2010. *Morbidity and Mortality Weekly Report* 2013;62(11):209-12. [published Online First: 2013/03/22]

4. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943-49. [published Online First: 1995/07/01]

5. Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-92. [published Online First: 1999/12/10]

6. Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. *Journal of diabetes and metabolic disorders* 2013;12:14. doi: 10.1186/2251-6581-12-14 [published Online First: 2013/03/19]

7. 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(7):1159-71. [published Online First: 2002/06/28]

8. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educator* 2008;34:815-23. doi: 10.1177/0145721708323640 [published Online First: 2008/10/04]

9. American Diabetes Association. Standards of medical care in diabetes - 2013. *Diabetes Care* 2013;36:S11-S66. doi: 10.2337/dc13-S011

10. Sun X, Huang X, Yuan C, et al. Influence of health belief and coping style on self-management behavior in patients with type 2 diabetes mellitus [Chinese]. *Journal of Nursing (China)* 2012;19(1A):8-11.

11. Gao J, Wang J, Zhu Y, et al. Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC public health* 2013;13:100. doi: 10.1186/1471-2458-13-100 [published Online First: 2013/02/06]

12. Yu P. The relationship between coping strategy, health beliefs and self-management among people with type 2 diabetes in Changsha [Master thesis]. Central South University, 2009.

13. Fisher WA, Fisher JD, Harman J. The information-motication-behavioral slills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social psychological foundations of health and illness. Malden, MA: Wiley-Blackwell 2003:82-106.

14. Osborn CY, Egede LE. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient education and counseling* 2010;79:49-54. doi: 10.1016/j.pec.2009.07.016 [published Online First: 2009/08/25]

15. Osborn CY, Rivet Amico K, Fisher WA, et al. An information-motivation-behavioral skills analysis of diet and exercise behavior in Puerto Ricans with diabetes. *Journal of health psychology* 2010;15:1201-13. doi: 10.1177/1359105310364173 [published Online First: 2010/05/11]

16. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychological bulletin* 1992;111(3):455-74. [published Online First: 1992/05/01]

17. Fisher JD, Fisher WA, Amico KR, et al. An information-motivation-behavioral skills model of adherence to antiretroviral therapy. *Health Psychology* 2006;25:462-73. doi: 10.1037/0278-6133.25.4.462 [published Online First: 2006/07/19]

18. Huang J, Liu Y, Zhang Y, et al. Correlation between self-management and knowledge of and attitude to diabetes in type 2 diabetic patients in Changsha [Chinese]. *Journal of Central South University (Medical Sciences)* 2013;38:176-81. doi: 10.3969/j.issn.1672-7347.2013.02.011 [published Online First: 2013/03/05]

19. Kong L, Ye Y, Ding F, et al. The relationship between diabetes knowledge, self-efficaicy, and self-management practice among individuals with type 2 diabetes in community [Chinese]. *Journal of Hubei University of Science and Technology* 2013;27(4):334-38.

20. Wang X, Lv W, Ding Y, et al. Study on correlation between self-management behaviors of elderly type 2 diabetic patients and diabetes knowledge level [Chinese]. *Chinese Nursing Research* 2013;27(9):2973-74.

21. Quan J. The research about the current status and influencing factors of self-management behavior in middle-aged and over patients who with type 2 diabetes mellitus [Master thesis]. Yanbian University, 2013.

22. Wang X, Lan W, Liu J, et al. Evaluation analysis of influencing factors of type II diabetes patients self-management in Shanxi Province [Chinese]. *Journal of Qiqihar Medical College* 2012;33(8):1065-69.

23. Hu J, Gruber KJ, Liu H, et al. Diabetes knowledge among older adults with diabetes in Beijing, China. *Journal of clinical nursing* 2013;22:51-60. doi: 10.1111/j.1365-2702.2012.04273.x [published Online First: 2012/12/12]

24. Xu Y, Toobert D, Savage C, et al. Factors influencing diabetes self-management in Chinese people with type 2 diabetes. *Research in nursing & health* 2008;31:613-25. doi: 10.1002/nur.20293 [published Online First: 2008/07/10]

25. Jia Y, Wang J, Liu W. Study on self-care level of patients with type 2 diabetes mellitus and analysis of related factors [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2005;22(7):21-23.

26. Meng F. Research on health education and self-managing level of community non-insulin dependent diabetic patients [Master thesis]. Sun Yat-Sen University, 2010.

27. Wang L, Zhang J. Self-management of elderly patients with type 2 diabetes and its influencing factors [Chinese]. *Journal of Nursing (China)* 2012;19(4A):39-42.

28. Guo XH, Yuan L, Lou QQ, et al. A nationwide survey of diabetes education, self-management and glycemic control in patients with type 2 diabetes in China. *Chinese medical journal* 2012;125(23):4175-80. [published Online First: 2012/12/12]

29. Wang J, Zhang X. Survey of self-care behavior among 2 type diabetes patients [Chinese]. *Journal of Nurses Training* 2002;17(9):663-65.

30. Gao J, Wang J, Zheng P, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. *BMC family practice* 2013;14:66. doi: 10.1186/1471-2296-14-66 [published Online First: 2013/05/28]

31. Ajzen I, Fishbein M. Understanding attitudes and predicting social behavior. Englewood Cliffs, NJ: Prentice-Hall 1980.

32. Sun X, Huang X, Yuan C, et al. The relationship between coping strategy and self-management behavior among patients with type 2 diabetes [Chinese]. *Journal of Nurses Training* 2012;27(12):1084-86.

33. Du L, Lin T, Liu X. Study on correlation between social support and self-care behavior of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2012;388(26):697-99.

34. Huang M, Zhao R, Li S, et al. Self-management behavior in patients with type 2 diabetes: A cross-sectional survey in western urban China. *PloS one* 2014;9(4):e95138. doi: 10.1371/journal.pone.0095138 [published Online First: 2014/04/20]

35. Wan Q, Shang S, Liu Y, et al. A study of factors of the self-care behaviors of the elderly with type 2 diabetes [Chinese]. *Chinese General Practice* 2003;6(8):659-62.

36. Fang S, Yu Z, Tao Y. The relationship between coping strategy, self-efficacy, and diabetes self-management among people living in rural areas [Chinese]. *World Health Digest Medical Periodical* 2013;10(23):79-80.

37. Gao H. The relationship between diabetes self-efficacy and self-care behavior in patients with type 2 diabetes [Chinese]. *Jilin Medical Journal* 2012;33(35):7646-47.

38. Jia Y, Gong T, Sang M. Investigating on self-management and self-efficacy of patients with type 2 diabetes mellitus [Chinese]. *Modern Nursing* 2005;11(19):1586-88.

39. Wang JQ, Tak-Ying Shiu A. Diabetes self-efficacy and self-care behaviour of Chinese patients living in Shanghai. *Journal of clinical nursing* 2004;13:771-72. doi: 10.1111/j.1365-2702.2004.00918.x [published Online First: 2004/08/20]

40. Wan Q, Wang Q, Shang S. Correlation of self-management behavior and coping patterns of patients with type 2 diabetes [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2008;25(1B):18-21, 23.

41. American Heart Association. Cardiovascular disease & diabetes 2012 [Available from: http://www.heart.org/HEARTORG/Conditions/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp accessed February 6, 2014.

42. Wang CY, Chan SM. Culturally tailored diabetes education program for Chinese Americans: A pilot study. *Nursing research* 2005;54(5):347-53. [published Online First: 2005/10/15]

43. Zeng B, Sun W, Gary RA, et al. Towards a conceptual model of diabetes self-management among Chinese immigrants in the United States. *International journal of environmental research and public health* 2014;11:6727-42. doi: 10.3390/ijerph110706727 [published Online First: 2014/07/01]

44. Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in type 2 diabetes patients. *Quality of life research* 2007;16:165-77. doi: 10.1007/s11136-006-9105-0 [published Online First: 2006/10/13]

45. Xia Z, Yang T. Diabetes self-management behaviors and related factors among patients with type 2 diabetes in Xiuying District, Haikou [Chinese]. *Seek Medical and Ask the Medicine* 2011;9(11):526-27.

46. Baron RM, Kenny DA. The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of personality and social psychology* 1986;51(6):1173-82.

47. Jia Y, Wang J, Teng X. Study on the correlation between psychological health level and self-management in patients with type 2 diabetes mellitus [Chinese]. *Shanghai Nursing* 2004;4(4):1-3.

48. Lin T, Lin X, Wan L. A study on correlation between self-care behavior and psychological concordance and depression of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2009;23(1A):22-24.

49. Wang Q, Wan Q, Shang S. Correlation of self-management behavior and depression in patients with type 2 diabetes [Chinese]. *Journal of Nursing Science* 2009;24(7):14-15.

50. Lin T, Wang J, Qin X. Study on self-care behaviors and its related factors in patients with type 2 diabetes [Chinese]. *Chinese Journal of Modern Nursing* 2008;14(11):1254-56.

51. Cheng G, Huang C, Deng H, et al. Diabetes as a risk factor for dementia and mild cognitive impairment: A meta-analysis of longitudinal studies. *Internal medicine journal* 2012;42:484-91. doi: 10.1111/j.1445-5994.2012.02758.x [published Online First: 2012/03/01]

52. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *Journal of psychiatric research* 1975;12(3):189-98. [published Online First: 1975/11/01]

53. Zhang ZX, Zahner GE, Roman GC, et al. Dementia subtypes in China: prevalence in Beijing, Xian, Shanghai, and Chengdu. *Archives of neurology* 2005;62:447-53. doi: 10.1001/archneur.62.3.447 [published Online First: 2005/03/16]

54. Chen Y, Liu Z, Zhang J, et al. Altered brain activation patterns under different working memory loads in patients with type 2 diabetes. *Diabetes Care* 2014;37:3157-63. doi: 10.2337/dc14-1683 [published Online First: 2014/11/19]

55. Zhang M. Users' guide for psychiatric scales. Changsha, China: Human Sciences & Technology Publishing House 2003.

56. Beeney LJ, Dunn SM, Welch G. Measurement of diabetes knowledge: The development of the DKN scales. In: Bradley C, ed. Handbook of psychology and diabetes. New York, NY: Psychology Press 2003:159-89.

57. Xu Y, Savage C, Toobert D, et al. Adaptation and testing of instruments to measure diabetes self-management in people with type 2 diabetes in mainland China. *Journal of Transcultural Nursing* 2008;19:234-42. doi: 10.1177/1043659608319239 [published Online First: 2008/06/27]

58. Chen Y. Study on compliance and influence factors of the re-hospitalized patients with diabetes mellitus. [Master thesis]. Central South Universtiy, 2007.

59. Xiao S. Theoretical foundation and research application about the social support rating scale. *Journal of Clincial Psychiatry* 1994;4:98-100.

60. Yao S, Wu D. Psychological health rating scale. In: Yao S, ed. Psychological Assessment Beijing, China: People's Medical Publishing House 2008:89-126.

61. Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. *Psychological review* 1977;84(2):191-215. [published Online First: 1977/03/01]

62. Hurley AC, Shea CA. Self-efficacy: strategy for enhancing diabetes self-care. *Diabetes Educator* 1992;18(2):146-50. [published Online First: 1992/03/01]

63. Bijl JV, Poelgeest-Eeltink AV, Shortridge-Baggett L. The psychometric properties of the diabetes management self-efficacy scale for patients with type 2 diabetes mellitus. *Journal of advanced nursing* 1999;30(2):352-59. [published Online First: 1999/08/24]

64. Folkman S. Personal control and stress and coping processes: A theoretical analysis. *Journal of personality and social psychology* 1984;46(4):839-52. [published Online First: 1984/04/01]

65. Feifel H, Strack S, Nagy VT. Coping strategies and associated features of medically ill patients. *Psychosom Medicine* 1987;49(6):616-25. [published Online First: 1987/11/01]

66. Shen X, Jiang Q. Report on application of Chinese version of MCMQ in 701 patients [Chinese]. *Chinese Journal of Behavioral Medican Science* 2000;9(1):18-20.

67. Wang JS, Wang RH, Lin CC. Self-care behavior and related factors in outpatients newly diagnosed with non-insulin-dependent diabetes mellitus [Chinese]. *Journal of Nursing (Taiwan)* 1998;45(2):60-74. [published Online First: 1999/01/15]

68. Beck AT, Steer RA, Ball R, et al. Comparison of Beck Depression Inventories -IA and -II in psychiatric outpatients. *Journal of Personality Assessment* 1996;67:588-97. doi: 10.1207/s15327752jpa6703_13 [published Online First: 1996/12/01]

69. Steer RA, Ball R, Ranieri WF, et al. Dimensions of the Beck Depression Inventory-II in clinically depressed outpatients. *Journal of Clinical Psychology* 1999;55(1):117-28. [published Online First: 1999/04/01]

70. Zung WW. A self-rating depression scale. *Archives of general psychiatry* 1965;12:63-70. [published Online First: 1965/01/01]

71. Tang P. Medical Psychology. Beijing, China: People's Medical Publishing House 2009.

72. Shively M, Wilson IB. Health-related quality of life outcomes in heart failure: A conceptual model. In: Moser DK, Riegel B, eds. Improving outcomes in heart failure: An interdisciplinary approach. Gaithersburg, MD: Jones & Bartlett Learning 2001:18-30.

73. Bradley C, Todd C, Gorton T, et al. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: The ADDQoL. *Quality of Life Research* 1999;8(1-2):79-91. [published Online First: 1999/08/24]

74. Bradley C, Speight J. Patient perceptions of diabetes and diabetes therapy: Assessing quality of life. *Diabetes/metabolism research and reviews* 2002;18 Suppl 3:S64-S69. doi: 10.1002/dmrr.279 [published Online First: 2002/09/27]

75. Speight J, Bradley C. ADDQoL indicates negative impact of diabetes on quality of life despite high levels of satisfaction with treatment. *Diabetologia* 2000;43 Suppl 1:A225.

76. Holmanová E, Ziaková K. Audit diabetes-dependent quality of life questionnaire: Usefulness in diabetes self-management education in the Slovak population. *Journal of clinical nursing* 2009;18:1276-86. doi: 10.1111/j.1365-2702.2008.02602.x [published Online First: 2008/12/17]

77. Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. *Diabetes research and clinical practice* 2011;94:45-52. doi: 10.1016/j.diabres.2011.05.026 [published Online First: 2011/06/21]

78. American Diabetes Association. 3. Comprehensive medical evaluation and assessment of comorbidities. *Diabetes care* 2017;40 Suppl. 1:S25-S32. doi: 10.2337/dc17-S006 [published Online First: 2016/12/17]

79. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension (Dallas, Tex : 1979)* 2017 doi: 10.1161/hyp.0000000000000066 [published Online First: 2017/11/15]

80. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: Blood pressure measurement in humans: A statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation* 2005;111:697-716. doi: 10.1161/01.cir.0000154900.76284.f6 [published Online First: 2005/02/09]

81. Kline RB. Principles and practices of structural equation modeling. 3 ed. New York, NY: The Guilford Press 2010.

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A longitudinal study

Dongmei Wu, Changwei Li, Rumei Yang, Song Ge, Yanyan Wang, Yan Du, Tingting Liu

Correspondence should be made to:

Tingting Liu, PhD, RN

Department of Epidemiology,

Postal address: 1440 Canal St, Suite 2000, New Orleans, LA 70112

Email: tliu10@tulane.edu

Tel: 504-988-3738

Fax: 504-988-6809

The full names, institutions, city, and country of all other co-authors:

Dongmei Wu, PhD, RN

Psychiatric Research Laboratory

The Fourth People's Hospital of Chengdu, Chengdu, Sichuan Province, China

Changwei Li, PhD, MD, MPH

Department of Epidemiology and Biostatistics,

University of Georgia College of Public Health, Athens, GA, USA

Rumei Yang, MS, RN

University of Utah College of Nursing, Salt Lake City, UT, USA

Song Ge, BSN, RN

Johns Hopkins University School of Nursing, Baltimore, MD, USA

Yanyan Wang, PhD, RN

National Clinical Research Center for Geriatrics

West China Hospital, Chengdu, China

Yan Du, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

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Abstract

Introduction: Currently, China has the largest number of people with diabetes in the world, and the disease has reached epidemic proportions in the adult population. Individuals with diabetes perform about 95% of their own care. Diabetes self-management is an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their diabetes. Several studies have consistently shown that diabetes self-management practice is suboptimal among Chinese adults with type 2 diabetes. The reason for poor adherence to diabetes self-management among Chinese adults is not well known and no conceptual model has been used to guide diabetes self-management interventions in this population. Although the information-motivation-behavioral skills model has been tested among Chinese adults with type 2 diabetes, some key components of the original model were not tested. In the proposed study, we will refine and test longitudinally a culturally tailored model of diabetes self-management among 250 Chinese adults residing in China.

Methods and Analysis: This is a descriptive, repeated-measure study at a tertiary hospital in Chengdu, China. A total of 250 adults with type 2 diabetes will be enrolled into current study, and will be followed up for 3 months. Multiple domains will be collected, including demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Main analyses comprise linear regression models after controlling for covariates and structural equation model.

Ethics and Dissemination: Ethical approval has been obtained through the Fourth People's Hospital of Chengdu Research Ethics Committee (study number 2017017). We aim to disseminate the findings through international conferences, international peer-reviewed journals and social media.

Study registration number: ChiCTR-ROC-17013592.

Strengths and limitations of this study

- This study will recruit and follow-up Chinese adults with diabetes for 3 months, and test the information-motivation-behavioral skills model of diabetes self-management longitudinally for the first time.
- This study relies primarily on self-reported measures, and objective, observable levels of diabetes self-care behaviors should be used in future studies.
- The study sample will be conducted in Chengdu, a typical city in southwestern China, and therefore the findings of the study may not be generalized to other parts of China, and the chosen centers are not from areas that are representative of the general Chinese population in regards to socioeconomic status.

Introduction

Diabetes is a major public health problem worldwide and it is increasing by epidemic proportions. Globally, the total number of people living with diabetes is projected to rise from 425 million cases in 2017 to 649 million cases by 2045, with over 75% of cases living in low- and middle-income countries [1]. In China alone, the most comprehensive nationwide survey showed that about 114 million (11.6%) adults had diabetes in 2010, a two-fold increase over the past decade [2]. Type 2 diabetes (T2D) accounts for approximately 90% to 95% of all diagnosed cases of diabetes [3], and therefore it is estimated that 102.5 to 108.2 million individuals have T2D. Individuals with T2D perform about 95% of their own care [4]. Diabetes self-management (DSM) is therefore an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their T2D such as self-monitoring blood glucose (SMBG), dietary changes, and physical activity [5]. DSM is complex, requires major lifestyle changes and behavioral tasks that are incorporated into an individual's daily routine and high levels of adherence for effective management and halting disease progression [6].

Mounting evidence has consistently shown that better DSM was associated with better health outcomes, including improved glycemic control [7], improved quality of life [8], and reduced incidence of diabetes-related complications [9]. Individuals with diabetes have been shown to make a great impact on the progression and development of their disease by participating in their own care. However, adherence to some of these activities has been found to be low, especially when looking at long-term changes [10]. This suggests a critical need for a comprehensive and well-tested conceptual model to guide future DSM interventions.

Although the information-motivation-behavioral skills (IMB) model has been tested among Chinese adults with T2D [11], some key components of the original IMB model were not tested. For example, it is well known that personal motivation, such as health beliefs, may influence DSM among Chinese adults [12]. Additionally, important moderators known to influence DSM in Chinese adults such as depressive symptoms, female gender, and educational level were not included in the model [11], and this may add important insights into DSM specific to this population. Therefore, a revised conceptual model

based on the IMB model is needed to take account the effects of interactive relationships among the related factors. The proposed IMB-DSM model will help fill this void by examining the potential moderators of DSM in this population, so that intervention studies based on this model can not only show whether the intervention works, but also why the intervention works and under what conditions the intervention works.

Conceptual Framework

Overview of the IMB model. The IMB provided the theoretical basis for this study. The IMB model is used to frame these variables because: (a) the constructs from the model can be easily translated into intervention components, and (b) it adequately captures essential constructs that are well supported in the literature to improve DSM behaviors, including information (e.g., diabetes knowledge), motivation (e.g., social support), and behavioral skills (e.g., diabetes self-efficacy). The model postulates that individuals are more likely to take health-related actions, such as DSM behaviors, if they are well informed, highly motivated (personally and socially), and have adequate and appropriate behaviors, and thus, experience positive health outcomes [13]. The model is based on three constructs: information, motivation, and behavioral skills. For complex behaviors, information and motivation are believed to work largely through behavioral skills to initiate and maintain the behavior at focus, and the behavior is directly linked to health outcomes, which, in turn, are conceptualized as influencing one's future maintenance of the behavior via a feedback loop that affects one's future levels of information, motivation, and behavioral skills overtime [14 15]. The IMB model further postulates that favorable health outcomes may strengthen an individual's information, motivation, and behavioral skills to perform the behavior in the future. In contrast, unfavorable health outcomes may cause an individual to lose confidence in his or her knowledge, motivation, and behavioral skills to perform the behavior overtime [15].

Overview of the IMB-DSM model. Figure 1 portrays the overarching conceptual framework of this study. The IMB-DSM model provides a comprehensive insight to explore the relationships that influence DSM and its related health outcomes, based on a systematic review of literature in this area. The framework consists of the following six key interrelated components: DSM-related information,

DSM-related motivation, DSM-related behavioral skills, DSM behaviors, health outcomes, and moderators. Consistent with the original IMB assumptions, the IMB-DSM model asserts that DSM-related information, motivation, and behavioral skills are fundamental determinants of DSM behaviors. DSM-related information and motivation are proposed to work primarily through behavioral skills to affect initiation and maintenance of DSM behaviors. DSM behaviors lead to health outcomes, which, in turn, can influence one's future maintenance of the behavior via a feedback loop that affects one's future levels of DSM-related information, motivation, and behavioral skills overtime. The proposed moderators can influence the relationship among variables in the IMB-DSM model. Each part of the IMB-DSM is presented in detail below.

DSM-related information. DSM-related information is a necessary but insufficient prerequisite for DSM behaviors. The link between DSM-related information and DSM behaviors has been well established in the literature. DSM related information includes diabetes knowledge, health education, and provider-patient communication. A positive relationship was found between diabetes knowledge and overall DSM performance [16-18], exercise, foot care [19], diet control, or SMBG [20] in some studies, but not others [21 22]. A significantly positive relationship was reported between health education, overall DSM performance [23-25], and some specific DSM behaviors, such as diet modification, foot care, regulating highs and lows in blood glucose, SMBG, engaging in exercise, taking medications, smoking cessation [23 26 27]. Three studies reported the relationship between provider-patient communication and DSM behaviors, and both studies found that better provider-patient communication was an independent, direct predictor of better overall DSM performance [11 22 28].

DSM-related motivation. Another fundamental determinant of DSM behaviors is an individual's motivation to perform DSM. Consistent with the IMB model, the IMB-DSM model posits that an individual's motivation includes personal and social motivation. Personal motivation to perform DSM refers to one's beliefs about the DSM behaviors and evaluations of the outcomes. Social motivation to perform DSM rests on the one's perception of social support for DSM and one's motivation to comply with referent others [29].

In the IMB-DSM model, health beliefs are used to conceptualize personal motivation. Perceived susceptibility, perceived barriers, perceived benefits, or cues to action has each been positively associated with overall DSM performance and all aspects of DSM behaviors except smoking cessation [12 30]. There was inconsistent evidence of the relationship between perceived severity and DSM behaviors. Yu [12] reported a negative association, whereas Sun and coworkers [10] reported a positive association. One possible explanation for the inconsistency between perceived severity and DSM behaviors involves the fact that both studies are cross-sectional. Thus, a person who is currently engaging in DSM behaviors may both perceive him- or herself as not being at risk and may report few feelings of severity. Alternatively, a person who is presently engaging in less DSM behaviors may report more feelings of severity and few risk-reduction efforts. The inconsistency warrants further investigations from longitudinal studies. Research evidence is consistent with a positive relationship between perceived social support from significant others and overall DSM performance, diet control, taking medications, engaging in physical activity, SMBG, foot care and regulating highs and lows in blood glucose [11 19 22 31-33].

DSM-related behavioral skills. Behavioral skills involve objective and perceived skills for performing DSM behaviors and a sense of self-efficacy for doing so [29]. In the IMB-DSM model, behavioral skills include diabetes self-efficacy and positive coping strategy. A great deal of studies has reported a consistent strong association between levels of self-efficacy and DSM behaviors, including diet modification, taking medications, foot care, physical activity, SMBG, and regulating highs and lows in blood glucose [11 17 19 22 32 34-37]. Coping strategies have been well studied in this population. Research evidence is consistent with a positive relationship between confrontation and overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Alternatively, acceptance-resignation was negatively associated with overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Avoidance had negative effects on taking medications [12 30] and regulating highs and lows in blood glucose [30].

One cross-sectional study provided evidence for the role of DSM-related behavioral skills as a mediator between DSM-related information, motivation, and DSM behaviors. Information on demographics, provider-patient communication, social support, and self-efficacy, and diabetes self-care was collected among 222 participants with T2D in Shanghai. There were significant, positive, direct paths from self-efficacy (β=.41, p<.001), social support (β=.19, p=.007), and provider-patient communication (β=.12, p=.037) to DSM behaviors. Paths from provider-patient communication to self-efficacy (β=.23, p<.001) and from social support to self-efficacy (β=.19, p<.05) were significant and positive. Structural equations modeling showed that self-efficacy mediated the effects of social support (indirect effect β=.08, p=.008) and provider-patient communication (indirect effect β=.09, p=.002) on DSM behaviors [11]. Overall, the study provided support for the specific direct and mediating relationships between DSM-related information, motivation, behavioral skills, and DSM behaviors. However, one limitation of this study is that the adapted IMB model does not include all relevant constructs. For example, information on personal motivation was not collected. Therefore, the study only partially tested the IMB model.

DSM behaviors. DSM behaviors primarily include dietary changes, weight loss, and increased physical activity, SMBG, foot care, and taking prescribed medications. Based on the guidelines of the American Diabetes Association [9], individuals with T2D are encouraged to increase intake of whole grains, fiber, vegetables, and fruits, and reduce intake of total and saturated fat, sugar-flavored beverages, and high calorie snacks. They are also encouraged to engage in 150 min or more of moderate-to-vigorous intensity physical activity per week, and lose about 5%-7% of initial body weight if these individuals are overweight/obese.

Health outcomes. The IMB-DSM model asserts that DSM behaviors are directly linked to health outcomes, which has been well supported in the literature. Since adults with T2D are two to four times more likely to have cardiovascular disease (CVD) than adults without T2D [9], monitoring cardiometabolic markers is essential in the clinical management of patients with T2D. In the proposed study, blood pressure and blood lipids are measured to identify subsequent CVD risks among adults with T2D. The health outcomes include hemoglobin A1c (HbA1c), blood pressure, blood lipids, and diabetes-dependent

quality of life. DSM behaviors had a direct effect on glycemic control (β=-.02, p=.007) [28], total cholesterol (TC)/high-density lipoprotein cholesterol (HDL-C) (β=-.31, p<.001), and low-density lipoprotein cholesterol (LDL-C)/HDL-C (β=-.30, p<.001) [11]. It is not clear whether DSM behaviors are directly related to blood pressure in Chinese adults with T2D, and this will be examined in this study. Compared to the general population, people affected by T2D consistently reported diminished health-related quality of life [39]. However, the relationship between DSM behaviors and health-related quality of life has not been systematically studied among Chinese adults with T2D, and this study will fill the knowledge gaps.

Moderators. The IMB-DSM model postulates that certain personal characteristics may act as moderators that influence the associations of the model constructs with DSM behaviors, and that the degree of moderation depends on the level or intensity of the moderator. High levels of moderators are assumed to directly influence DSM behaviors, whereas lower levels of moderators are assumed to work through the IMB-DSM model constructs to influence DSM behaviors and not obscure the relationships between these constructs and DSM behaviors. These moderators include depressive symptom, female gender, and educational level.

Depressive symptoms have been consistently found to negatively affect DSM behaviors, such as SMBG, foot care, diet modification, regulating highs and lows in blood glucose, and overall DSM performance in these studies [40-42]. Generally, female patients had better overall DSM performance than their male counterparts [12 43]. People with a higher educational level tended to manage their diabetes better, compared to people with lower educational level [24 32 44]. Because existing studies investigating factors associated with DSM are primarily univariate in nature, they generally address only one aspect of the IMB-DSM model, that is, they establish support for a direct relationship between DSM behaviors and DSM-related information, motivation, or behavioral skills. So far, no studies have been conducted to systematically evaluate how potential moderators may influence the relationship among variables in the IMB-DSM model, and this study is expected to fill those knowledge gaps.

Objectives

In the proposed study, we will refine and test longitudinally a culturally tailored IMB-DSM among 250 Chinese adults residing in Chengdu, China.

Aim 1: In Chinese adults with T2D, to determine which baseline variables are most predictive of baseline DSM behaviors, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education.

RQ: Among baseline DSM-related information, motivation, and behavioral skills, which is most predictive of baseline DSM behaviors?

Aim 2: To examine the feedback loop as described in the original IMB model by investigating the relationships between baseline health outcomes (HbA1c, blood pressure, blood lipids, and diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up period, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education at baseline.

RQ1: What is the relationship between baseline HbA1c levels and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ2: What is the relationship between baseline blood pressure and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ3: What is the relationship between baseline blood lipids and DSM-related information, motivation, and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ4: What is the relationship between baseline diabetes-dependent quality of life and DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

Aim 3: In Chinese adults with T2D, to examine mediating and moderating factors associated with DSM behaviors at baseline and the 3 month follow-up period.

Research Question 1: Are behavioral skills (diabetes self-efficacy and coping strategies) mediators of DSM behaviors at baseline and 3-month follow-up period?

Research Question 2: Are depressive symptoms, female gender, and educational level as moderators of DSM behaviors at baseline and 3-month follow-up period?

Methods and Analysis

Design

A descriptive, repeated-measure design will be used to examine the relationships among variables in the IMB-DSM model, the role of variables in predicting baseline DSM behaviors, the potential moderators and mediators, and investigate the relationship between baseline health outcomes and DSM-related information, motivation, behavioral skills and subsequent DSM behaviors at three-month follow-up. Data will be collected at two time points, 3 months apart. Since HbA1c is considered the gold standard for monitoring glycemic control and reflects a person's glucose control for the preceding 8 to 10 weeks [9], three-month of observation is deemed long enough to see a change in HbA1c and other physical markers, since HbA1c, dyslipidemia, and hypertension are closely related [45].

Sample and Setting

This study will be conducted in Chengdu metropolitan area, which is the provincial capital of Sichuan province in Southwest China. One community health center will be selected from each of six urban districts in Chengdu metropolitan area: the Yulin community health center in Wuhou District, the Supo community health center in Qingyang District, the Longzhoulu community health center in Jinjiang District, the Caojiaxiang community health center in Jinniu District, the Shuanglin community health center in Chenghua District, and the Guixi community health center in Gaoxin District. The inclusion criteria for participation in the research are: (a) diagnosed with T2D; (b) able to read, write, and speak Chinese; (c)$\geqslant$18 years of age; (d) a score of the Chinese version of Mini-Mental State Examination (C-MMSE) > 24 (see **Screening** below); (e) no other chronic physical or mental disorders; and (f) mentally competent to give informed consent. Patients will be excluded if they are pregnant, have been diagnosed with cancer or organ failure, refuse to participate in the proposed study, self-identified bilateral hearing loss, or cognitive impairment (inability to comprehend the informed consent).

Sample Size

The Power Analysis and Sample Size Software was used for sample size calculation. Sample size was calculated based on the weakest correlation among all the tested variable pairs, that is, diabetes knowledge and social support (r=.197). Assuming 80% power, type I error rate of .05, and attrition rate of 20%, a total of 250 participants will be needed to detect the correlation coefficient of .197. This sample size will have a higher power to detect correlations with larger coefficient.

Participant Recruitment

The research team will actively recruit participants from six selected community health centers. The principal investigator and her undergraduate mentors have established relationships with these community health centers and will be able to facilitate recruitment from these sites. An electronic medical database of the residents kept each community health center will also be used to identify patients with T2D in these communities. The research team will also have access to the database from which participants can be recruited.

Once the approval from the Ethics Committees for Clinical Trials and Biomedical Research in the Fourth People's Hospital of Chengdu is obtained, patients who come to the local clinics for evaluations and care will be approached after agreeing to hear about the study by a research staff member, who will explain the study, provide a consent form for review, answer questions and seek their participation. Subjects who agree to participate will be screened on inclusion criteria. Screening (see Screening below) will take about 10 minutes. Those who meet study criteria will be entered into the study. In addition, advertisements about the study will be placed on buses and subways. Those interested in the study will be invited to the study site and asked to participate after reviewing study procedures and consent forms. Weekly and monthly recruitment goals will be set to ensure adequate progress on participant enrollment. If recruitment is slow, recruitment procedures will be reviewed, problems identified, and adjustments will be made so that participant accrual is conducted at a satisfactory rate.

Screening

A questionnaire will assess participants' eligibility via questions on age, length of diabetes, period of time when starting diabetes treatment, provider referral, and willingness to participate. Since

this population is at risk for cognitive impairment that may, in some cases, limit their capacity to provide consent [46], the C-MMSE will be administered to evaluate global cognitive functioning of all eligible participants. The C-MMSE has been used among Chinese adults with T2D [47]. Those who obtain a score <=23 will be excluded because subjects with such low scores were considered to have possible dementia [48]. Potential participants with serious cognitive problems will be referred immediately to a mental health professional used by the respective community health centers.

Reducing Attrition

There will be a potential problem with attrition of the proposed study because the 3 month follow-up for this longitudinal study design opens up to the problem of attrition. Steps that will be taken to reduce attrition include: informing subjects of the importance of continued participation in all aspects of the study; giving a subject incentive of ¥155 (about $25) Walmart gift card per completed data collection session; making telephone calls and sending a reminder card prior to scheduled data collections. A participant locator form will be completed for each subject entered in the study and at all data collection sessions to ensure proper contact information for follow-up visit is maintained.

Data Collection and Procedures

After consenting to participate, each subject will be requested to come to the study site for baseline data collection in a private office at the research site. Baseline data collection will include administration of the following questionnaires: Demographic Data Form, the Diabetes Knowledge Questionnaire, the Health Education Form, the Provider-Patient Communication Scale, the Health Belief Scale, the Social Support Rating Scale, the Diabetes Self-Efficacy Scale, the Medical Coping Modes Questionnaire, the Diabetes Self-Care Scale, the Self-rating Depression Scale, and the Audit of Diabetes-Dependent Quality-of-Life. At the 3 month follow-up data collections, all the measures will be administered again except the Demographic Data Form. Data collection from each participant should take about 60 minutes. The instruments will be administered by a trained research assistant as an interview to reduce respondent burden and to standardize the approach due to the differing response formats. If the participant becomes fatigued, the battery of questionnaires may be completed in two sessions.

Training of Data Collectors

In an effort to improve inter-rater reliability, data collectors will be trained to collect data for baseline and follow-up data collections. They will attend intensive training sessions at the beginning of the project, and periodic refresher sessions will be offered every 2 to 3 weeks to reinforce the basic training. Data collectors will practice conducting data collections and blood pressure measurement and these sessions will be monitored and each data collector will be certified. To control for measurement error, a data collection protocol manual will be developed that will include data collection protocol related specifically to each questionnaire and blood pressure measurement. The specific measures, including instruments and physical biomarkers, that will be used in this study are described below.

Instruments

Demographics. This questionnaire is designed to collect background data from participants on their demographic characteristics, including age, gender, income, education, marital status, length of diabetes, health insurance, current treatment plan for diabetes, and relevant health history indicators.

The diabetes knowledge questionnaire. Diabetes knowledge in Figure 1 will be measured with the Chinese version of the Diabetes Knowledge Scale adapted from the Diabetes Knowledge Scales [49]. The Chinese version of the Diabetes Knowledge Scale consists of 14 items. Participants receive a score of 1 for a correct answer or 0 for an incorrect or unknown answer. The total score ranges from 0 to 14, with a higher score indicating a higher level of diabetes knowledge. The Cronbach's alpha for the Chinese version of the knowledge measure was .62. The diabetes knowledge score in the Chinese sample was significantly higher in the group with more education ($t[28]=2.83$, $p< .01$), indicating that the Chinese version had satisfactory construct validity [50].

The health education form. Information on health education in Figure 1 is based on self-reports. All participants will be asked if they have had received any form of diabetes education. If the answer is YES, the patient should answer the source of diabetes education. The source of diabetes education could be health care professionals, community consulting service, journals/books, TV/radio, internet and others.

The provider-patient communication scale. Provider-patient communication in Figure 1 will be measured by the Provider-Patient Communication Scale. The scale consists of 5 items with a scoring range from 0 to 6, where 0 indicates "strongly disagree" and 6 indicates "strongly agree". High scores characterize a person who is confident in their ability to communicate with healthcare professionals and has good understanding of ways to access healthcare in order to get their needs met. The Cronbach's alpha coefficient is reported at .929, indicating excellent internal consistency [11].

The health belief scale. Health beliefs (i.e., personal motivation in Figure 1) refer to one's perceptions about T2D and how it can be treated [51]. The Health Belief Scale was developed based on the Health Belief Model by Yamei Chen [51]. The 20-item scale comprises 5 subscales (perceived susceptibility, perceived benefits, perceived severity, perceived barriers, and cues to action) and uses a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score represents stronger health beliefs. The content validity index is .81, the test-retest reliability ranges from .78 to .82, and the Cronbach's alpha is .79 [51].

The social support rating scale. Social support (i.e., social motivation in Figure 1) will be assessed by the Social Support Rating Scale [52]. The 10-item instrument measures aspects of objective social support (3 items), subjective social support (4 items) and usage of social support (3 items). The item scores range from 14 (worst possible social support) to 66 (best possible social support) [52]. The test-retest reliability coefficient and the internal consistency of the scale are .92 and .88-.94, respectively [32].

The diabetes self-efficacy scale. Diabetes self-efficacy in Figure 1 will be measured with the 7-item Chinese version of the Diabetes Self-Efficacy Scale, which evaluates participants how capable they are when performing DSM activities. The items are scored on a 5-point Likert-type scale, with higher scores indicating higher self-efficacy in performing DSM behaviors. The Chinese version of the Diabetes Self-Efficacy Scale has a Cronbach's alpha of .87. Factor analysis showed that seven items loaded on five factors, which explains 97.9% of the variance, and the five factors are consistent with confidence in performing the five aspects of DSM behaviors [50].

The medical coping modes questionnaire. Coping strategies in Figure 1 will be measured by the 20-item Chinese version of the Medical Coping Modes Questionnaire. It assess 3 forms of coping strategies associated with chronic illness: confrontation, avoidance, and acceptance-resignation [53]. Items are answered on a four-point Likert scale ranging from 1 (never) to 4 (very often). Scores from the three subscales are compared, and the highest score indicates the corresponding dominant pattern of coping utilized by the participant. The Cronbach's alpha for the confrontation, avoidance, and acceptance-resignation subscales is reported at .69, .60, .76, respectively [53].

The diabetes self-care scale. DSM in Figure 1 will be measured by the 26-item Diabetes Self-Care Scale, which is comprised of 6 subscales: diet modification, taking medications, SMBG, foot care, physical activity, and regulating highs and lows in blood glucose. Responses for each item range from 1 (never) to 5 (very often). Total score can range from 26 to 130 by adding up scores of 6 subscales, with higher scores indicating better overall DSM performance. The construct validity is .68, and the Cronbach's alpha is .87 [54].

The self-rating depression scale. Depressive symptoms in Figure 1 will be assessed using the Self-Rating Depression Scale, a 20-item self-administered questionnaire [55]. Each item is rated on a four-point Likert scale, ranging from 1 (very seldom) to 4 (most of the time) and computed as an original score, then multiplied by 1.25 to get the standard score. A score ranges from 53 to 62 indicates mild depressive symptoms, a score ranges from 63 to 72 indicates moderate depressive symptoms, and a score higher than 72 indicates severe depressive symptoms [56].

The audit of diabetes-dependent quality of life. Diabetes-related quality of life in Figure 1 will be measured by the Chinese version of Audit of Diabetes-Dependent Quality of Life, which measures both generic and diabetes-specific quality of life. The first two overview items assess generic quality of life on a seven-point Likert scale (-3 [extremely bad] to 3 [excellent]) and quality of life without diabetes. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how their quality of life would be if they did not have diabetes. The subsequent 19 items evaluates diabetes-specific quality of life. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how particular aspects of

their life would be if they did not have diabetes. The importance of each aspect on their life is rated on a four-point scale (0 to 3). The two ratings are multiplied and summed for a final impact score that ranges from -9 to 3, where more negative scores indicate worse quality of life. A score of 0 is assigned to "unimportant" domains, regardless of the magnitude of its impact. Similarly, a score of 0 is assigned to items with no impact of diabetes, regardless of their importance to quality of life. The average weighted rating score is obtained by dividing the sum of weighted ratings for applicable domains by the number of the applicable domains. Strong reliability (Cronbach's alpha=.941) has been reported [57]. Factor analysis showed that all items had high performance in the structural validity evaluation, with most factor loading values being larger than .40 (varied from .44 to .88) [57].

Physical Markers

Physical markers include HbA1c, blood pressure, and blood lipids. All blood samples will be processed at the Clinical Laboratory of the Fourth People's Hospital of Chengdu. After collection, the fresh venous blood samples will be immediately transported at 4°C temperature to the Clinical Laboratory within 2 hours. The samples will then be placed in a deep freezer and stored at -80°C until assays start.

HbA1c. HbA1c will be used as a marker of T2D and glycemic control and will be analyzed from whole blood samples (4 ml). Analysis will be conducted using high performance liquid chromatography, with standardization through commercial available assays (coefficient of variation<2%).

Blood pressure. Blood pressure will be obtained by a trained nurse using a standard sphygmomanometer for a minimum of 2 consecutive readings at intervals of at least 1 minute. The patient should be seated comfortably with the back supported and the upper arm bared, without constrictive clothing. The legs should not be crossed. The arm should be supported at the heart level, with the bladder of the cuff encircling at least 80% of the arm circumference. The mercury column should be deflated at 2 to 3 mm/s, and the first and last audible sounds should be taken as systolic and diastolic pressure. The column should be read to the nearest 2 mmHg. Neither the patient nor the observer should talk during the measurement procedure. The average of those readings will be used to represent the patient's blood pressure.

Blood lipids. Blood lipids include TC, HDL-C, LDL-C, and triglycerides (TG). Analysis of blood lipids will be conducted using enzymatic colorimetric test, with standardization through commercial available assays (coefficient of variation<2%). Fasting serum samples will be collected in the morning after 8 hours fasting.

Data Analyses

Data analyses for Aim 1: Linear regression models will be applied to assess the associations between baseline DSM behaviors and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 2: Linear regression models will be applied to assess the associations between baseline health outcomes (i.e., HbA1c, blood pressure, blood lipids, diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and DSM behaviors at 3 months follow-up, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 3: Both baseline and 3-month follow-up measures will be used for Aim 3. Structural equation modeling will be used to explore the fit of the data to the IMB-DSM model. Data will be first assessed whether they meet the assumptions of maximum likelihood estimation of structural equation modeling. Then, hypotheses regarding structural relations among the IMB-DSM model constructs will be evaluated with an inspection of the direction and magnitude of the path coefficients (direct effects) and indirect effects, which indicate mediation. Significant indirect effects occur when the relationship between a predictor and an outcome is due to the predictor being associated with a third variable (i.e., all or part of the direct effect of A on C is due to a relationship between A and B). Criteria used to test the structural model will be the comparative fit index (≥.95 indicates good fit), the root mean square error of approximation (≤.06 with confidence interval .00-.08 indicates good fit), and the standardized root mean square residual (<.08 indicates acceptable fit, and 0 indicates perfect fit) [58]. Agreement between multiple indices provides the best support a model has good data fit [58]. Moderators

will be tested by doing multi-group testing in AMOS 21, a structural equation modeling program. To examine whether depressive symptoms, female gender, and educational level moderate the relationships in the model, multi-group analysis will be used comparing a constrained model (i.e., a model in which the coefficients are set equal across the groups) with an unconstrained model (i.e., a model in which these coefficients are allowed to vary freely). A significant difference between these two models implies that there are significant differences among the groups. A series of nested models will be tested to see where the differences are.

Ethics and Dissemination

The study poses little to no risk to participants and their families. Signed informed consent will be obtained from all participating families. Participation in the study does not interfere with the usual care patients receive in the primary care settings. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals.

Figure Legend

Figure 1. The DSM-IMB Model

Contributorship statement

All authors contribute to the conception and design of this study. TL, CL, and DW drafted the manuscript. RY, YW, SG, and YD revised the manuscript. All authors approved the final version to be submitted to the journal.

Competing interests statement:

None declared.

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Data sharing statement:

We have not yet collected data. Once data collection is finished, the individual de-identified participant data (including data dictionaries) will be shared. The shared data will include demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. The data will become available as soon as we collect all data and for one year.

References

1. International Diabetes Federation. IDF diabetes atlet, 8th edition 2017 [Available from: http://www.diabetesatlas.org/across-the-globe.html accessed Nov 28, 2017.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *JAMA : the journal of American Medical Association* 2013;310:948-59. doi: 10.1001/jama.2013.168118 [published Online First: 2013/09/05]

3. Centers for Disease Control and Prevention. Awareness of prediabetes--United States, 2005-2010. *Morbidity and mortality weekly report* 2013;62(11):209-12. [published Online First: 2013/03/22]

4. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943-49. [published Online First: 1995/07/01]

5. Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-92. [published Online First: 1999/12/10]

6. Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. *Journal of diabetes and metabolic disorders* 2013;12:14. doi: 10.1186/2251-6581-12-14 [published Online First: 2013/03/19]

7. 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(7):1159-71. [published Online First: 2002/06/28]

8. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educator* 2008;34:815-23. doi: 10.1177/0145721708323640 [published Online First: 2008/10/04]

9. American Diabetes Association. 4. Lifestyle management: Standards of medical care in Diabetes-2018. *Diabetes care* 2018;41:S38-S50. doi: 10.2337/dc18-S004 [published Online First: 2017/12/10]

10. Sun X, Huang X, Yuan C, et al. The influence of health belief and coping style on self-management behavior in patients with type 2 diabetes mellitus [Chinese]. *Journal of Nursing (China)* 2012;19(1A):8-11.

11. Gao J, Wang J, Zhu Y, et al. Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC public health* 2013;13:100. doi: 10.1186/1471-2458-13-100 [published Online First: 2013/02/06]

12. Yu P. The relationship between coping strategy, health beliefs and self-management among people with type 2 diabetes in Changsha [Master thesis]. Central South University, 2009.

13. Fisher WA, Fisher JD, Harman J. The information-motication-behavioral slills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social psychological foundations of health and illness. Malden, MA: Wiley-Blackwell 2003:82-106.

14. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychological bulletin* 1992;111(3):455-74. [published Online First: 1992/05/01]

15. Fisher JD, Fisher WA, Amico KR, et al. An information-motivation-behavioral skills model of adherence to antiretroviral therapy. *Health Psychology* 2006;25:462-73. doi: 10.1037/0278-6133.25.4.462 [published Online First: 2006/07/19]

16. Huang J, Liu Y, Zhang Y, et al. Correlation between self-management and knowledge of and attitude to diabetes in type 2 diabetic patients in Changsha [Chinese]. *Journal of Central South University (Medical Sciences)* 2013;38:176-81. doi: 10.3969/j.issn.1672-7347.2013.02.011 [published Online First: 2013/03/05]

17. Kong L, Ye Y, Ding F, et al. The relationship between diabetes knowledge, self-efficaicy, and self-management practice among individuals with type 2 diabetes in community [Chinese]. *Journal of Hubei University of Science and Technology* 2013;27(4):334-38.

18. Wang X, Lv W, Ding Y, et al. Study on correlation between self-management behaviors of elderly type 2 diabetic patients and diabetes knowledge level [Chinese]. *Chinese Nursing Research* 2013;27(9):2973-74.

19. Quan J. The research about the current status and influencing factors of self-management behavior in middle-aged and over patients who with type 2 diabetes mellitus [Master thesis]. Yanbian University, 2013.

20. Wang X, Lan W, Liu J, et al. Evaluation analysis of influencing factors of type II diabetes patients self-management in Shanxi Province [Chinese]. *Journal of Qiqihar Medical College* 2012;33(8):1065-69.

21. Hu J, Gruber KJ, Liu H, et al. Diabetes knowledge among older adults with diabetes in Beijing, China. *Journal of clinical nursing* 2013;22:51-60. doi: 10.1111/j.1365-2702.2012.04273.x [published Online First: 2012/12/12]

22. Xu Y, Toobert D, Savage C, et al. Factors influencing diabetes self-management in Chinese people with type 2 diabetes. *Research in nursing & health* 2008;31:613-25. doi: 10.1002/nur.20293 [published Online First: 2008/07/10]

23. Jia Y, Wang J, Liu W. Study on self-care level of patients with type 2 diabetes mellitus and analysis of related factors [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2005;22(7):21-23.

24. Meng F. Research on health education and self-managing level of community non-insulin dependent diabetic patients [Master thesis]. Sun Yat-Sen University, 2010.

25. Wang L, Zhang J. Self-management of elderly patients with type 2 diabetes and its influencing factors [Chinese]. *Journal of Nursing (China)* 2012;19(4A):39-42.

26. Guo XH, Yuan L, Lou QQ, et al. A nationwide survey of diabetes education, self-management and glycemic control in patients with type 2 diabetes in China. *Chinese medical journal* 2012;125(23):4175-80. [published Online First: 2012/12/12]

27. Wang J, Zhang X. Survey of self-care behavior among 2 type diabetes patients [Chinese]. *Journal of Nurses Training* 2002;17(9):663-65.

28. Gao J, Wang J, Zheng P, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. *BMC family practice* 2013;14:66. doi: 10.1186/1471-2296-14-66 [published Online First: 2013/05/28]

29. Osborn CY, Egede LE. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient education and counseling* 2010;79:49-54. doi: 10.1016/j.pec.2009.07.016 [published Online First: 2009/08/25]

30. Sun X, Huang X, Yuan C, et al. The relationship between coping strategy and self-management behavior among patients with type 2 diabetes [Chinese]. *Journal of Nurses Training* 2012;27(12):1084-86.

31. Du L, Lin T, Liu X. Study on correlation between social support and self-care behavior of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2012;388(26):697-99.

32. Huang M, Zhao R, Li S, et al. Self-management behavior in patients with type 2 diabetes: A cross-sectional survey in western urban China. *PloS one* 2014;9(4):e95138. doi: 10.1371/journal.pone.0095138 [published Online First: 2014/04/20]

33. Wan Q, Shang S, Liu Y, et al. A study of factors of the self-care behaviors of the elderly with type 2 diabetes [Chinese]. *Chinese General Practice* 2003;6(8):659-62.

34. Fang S, Yu Z, Tao Y. The relationship between coping strategy, self-efficacy, and diabetes self-management among people living in rural areas [Chinese]. *World Health Digest Medical Periodical* 2013;10(23):79-80.

35. Gao H. The relationship between diabetes self-efficacy and self-care behavior in patients with type 2 diabetes [Chinese]. *Jilin Medical Journal* 2012;33(35):7646-47.

36. Jia Y, Gong T, Sang M. Investigating on self-management and self-efficacy of patients with type 2 diabetes mellitus [Chinese]. *Modern Nursing* 2005;11(19):1586-88.

37. Wang JQ, Tak-Ying Shiu A. Diabetes self-efficacy and self-care behaviour of Chinese patients living in Shanghai. *Journal of clinical nursing* 2004;13:771-72. doi: 10.1111/j.1365-2702.2004.00918.x [published Online First: 2004/08/20]

38. Wan Q, Wang Q, Shang S. Correlation of self-management behavior and coping patterns of patients with type 2 diabetes [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2008;25(1B):18-21, 23.

39. Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in type 2 diabetes patients. *Quality of life research* 2007;16:165-77. doi: 10.1007/s11136-006-9105-0 [published Online First: 2006/10/13]

40. Jia Y, Wang J, Teng X. Study on the correlation between psychological health level and self-management in patients with type 2 diabetes mellitus [Chinese]. *Shanghai Nursing* 2004;4(4):1-3.

41. Lin T, Lin X, Wan L. A study on correlation between self-care behavior and psychological concordance and depression of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2009;23(1A):22-24.

42. Wang Q, Wan Q, Shang S. Correlation of self-management behavior and depression in patients with type 2 diabetes [Chinese]. *Journal of Nursing Science* 2009;24(7):14-15.

43. Lin T, Wang J, Qin X. Study on self-care behaviors and its related factors in patients with type 2 diabetes [Chinese]. *Chinese Journal of Modern Nursing* 2008;14(11):1254-56.

44. Xia Z, Yang T. Diabetes self-management behaviors and related factors among patients with type 2 diabetes in Xiuying District, Haikou [Chinese]. *Seek Medical and Ask the Medicine* 2011;9(11):526-27.

45. Hu H, Hori A, Nishiura C, et al. Hba1c, blood Pressure, and lipid control in people with diabetes: Japan Epidemiology Collaboration on Occupational Health Study. *PloS one* 2016;11:e0159071. doi: 10.1371/journal.pone.0159071 [published Online First: 2016/07/22]

46. Cheng G, Huang C, Deng H, et al. Diabetes as a risk factor for dementia and mild cognitive impairment: A meta-analysis of longitudinal studies. *Internal medicine journal* 2012;42:484-91. doi: 10.1111/j.1445-5994.2012.02758.x [published Online First: 2012/03/01]

47. Chen Y, Liu Z, Zhang J, et al. Altered brain activation patterns under different working memory loads in patients with type 2 diabetes. *Diabetes Care* 2014;37:3157-63. doi: 10.2337/dc14-1683 [published Online First: 2014/11/19]

48. Zhang M. Users' guide for psychiatric scales. Changsha, China: Human Sciences & Technology Publishing House 2003.

49. Beeney LJ, Dunn SM, Welch G. Measurement of diabetes knowledge: The development of the DKN scales. In: Bradley C, ed. Handbook of psychology and diabetes. New York, NY: Psychology Press 2003:159-89.

50. Xu Y, Savage C, Toobert D, et al. Adaptation and testing of instruments to measure diabetes self-management in people with type 2 diabetes in mainland China. *Journal of transcultural nursing : official journal of the Transcultural Nursing Society / Transcultural Nursing Society* 2008;19:234-42. doi: 10.1177/1043659608319239 [published Online First: 2008/06/27]

51. Chen Y. Study on compliance and influence factors of the re-hospitalized patients with diabetes mellitus. [Master thesis]. Central South Universtiy, 2007.

52. Yao S, Wu D. Psychological health rating scale. In: Yao S, ed. Psychological Assessment Beijing, China: People's Medical Publishing House 2008:89-126.

53. Shen X, Jiang Q. Report on application of Chinese version of MCMQ in 701 patients [Chinese]. *Chinese Journal of Behavioral Medican Science* 2000;9(1):18-20.

54. Wang JS, Wang RH, Lin CC. Self-care behavior and related factors in outpatients newly diagnosed with non-insulin-dependent diabetes mellitus [Chinese]. *Journal of Nursing (Taiwan)* 1998;45(2):60-74. [published Online First: 1999/01/15]

55. Zung WW. A self-rating depression scale. *Archives of general psychiatry* 1965;12:63-70. [published Online First: 1965/01/01]

56. Tang P. Medical Psychology. Beijing, China: People's Medical Publishing House 2009.

57. Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. *Diabetes research and clinical practice* 2011;94:45-52. doi: 10.1016/j.diabres.2011.05.026 [published Online First: 2011/06/21]

58. Kline RB. Principles and practices of structural equation modeling. 3 ed. New York, NY: The Guilford Press 2010.

Figure 1. The DSM-IMB Model

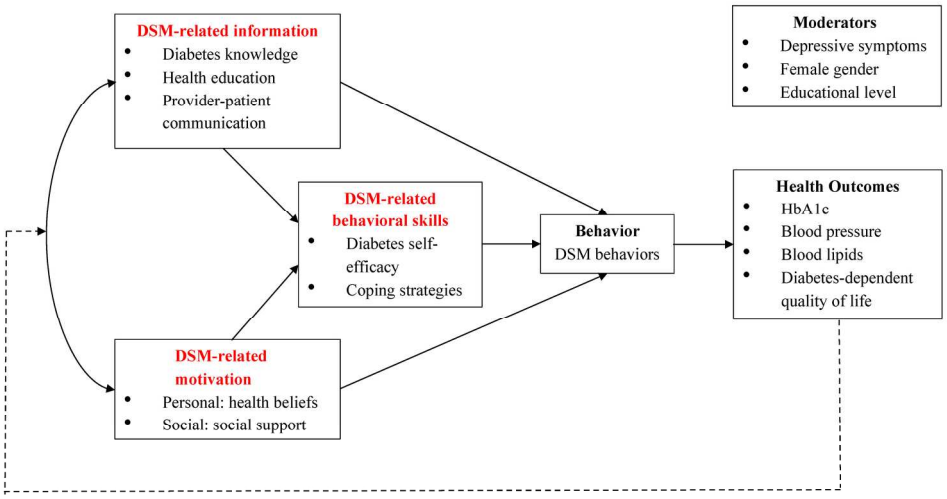

Figure 1. The DSM-IMB Model

190x142mm (300 x 300 DPI)

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A three-month follow-up study

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A three-month follow-up study

Dongmei Wu, Tingting Liu, Changwei Li, Rumei Yang, Song Ge, Yanyan Wang, Yan Du

Correspondence should be made to:

Tingting Liu, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

Postal address: 1440 Canal St, Suite 2000, New Orleans, LA 70112

Email: tliu10@tulane.edu

Tel: 504-988-3738

Fax: 504-988-6809

The full names, institutions, city, and country of all other co-authors:

Tingting Liu*, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine

Dongmei Wu*, PhD, RN

Psychiatric Research Laboratory

The Fourth People's Hospital of Chengdu, Chengdu, Sichuan Province, China

Jing Wang, PhD, MPH, RN, FAAN

University of Texas Health Science Center at Houston Cizik School of Nursing

Changwei Li, PhD, MD, MPH

Department of Epidemiology and Biostatistics,

University of Georgia College of Public Health, Athens, GA, USA

Rumei Yang, MS, RN

University of Utah College of Nursing, Salt Lake City, UT, USA

Song Ge, BSN, RN

Johns Hopkins University School of Nursing, Baltimore, MD, USA

Yanyan Wang, PhD, RN

National Clinical Research Center for Geriatrics

West China Hospital, Chengdu, China

Yan Du, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

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Drs. Dongmei Wu and Tingting Liu contributed equally to this manuscript.

Abstract

Introduction: Currently, China has the largest number of people with diabetes in the world, and the disease has reached epidemic proportions in the adult population. Individuals with diabetes perform about 95% of their own care. Diabetes self-management is an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their diabetes. Several studies have consistently shown that diabetes self-management practice is suboptimal among Chinese adults with type 2 diabetes. The reason for poor adherence to diabetes self-management among Chinese adults is not well known and no conceptual model has been used to guide diabetes self-management interventions in this population. Although the information-motivation-behavioral skills model has been tested among Chinese adults with type 2 diabetes, some key components of the original model were not tested. In the proposed study, we will refine and test longitudinally a culturally tailored model of diabetes self-management among 250 Chinese adults residing in China. This paper is to report the study protocol for the proposed study.

Methods and Analysis: This is a descriptive, repeated-measure study to be conducted at a tertiary hospital in Chengdu, China. A total of 250 adults with type 2 diabetes will be enrolled into the study, and will be followed for 3 months. Multiple domains will be collected, including demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Main analyses comprise linear regression modeling controlling for covariates and structural equation modeling.

Ethics and Dissemination: Ethical approval has been obtained through the Fourth People's Hospital of Chengdu Research Ethics Committee (study approval number 2017017). We aim to disseminate the findings through international conferences, international peer-reviewed journals and social media.

Study registration number: ChiCTR-ROC-17013592.

Strengths and limitations of this study

- This study will recruit and follow-up Chinese adults with diabetes for 3 months, and test the information-motivation-behavioral skills model of diabetes self-management longitudinally for the first time.
- This study relies primarily on self-reported measures, and objective, observable levels of diabetes self-care behaviors should be used in future studies.
- The study sample will be conducted in Chengdu, a typical city in southwestern China, and therefore the findings of the study may not be generalized to other parts of China, and the chosen centers are not from areas that are representative of the general Chinese population in regards to socioeconomic status.

Introduction

Diabetes is a major public health problem worldwide and it is increasing by epidemic proportions. Globally, the total number of people living with diabetes is projected to rise from 425 million cases in 2017 to 649 million cases by 2045, with over 75% of cases living in low- and middle-income countries [1]. In China alone, the most comprehensive nationwide survey showed that about 114 million (11.6%) adults had diabetes in 2010, a two-fold increase over the past decade [2]. Type 2 diabetes (T2D) accounts for approximately 90% to 95% of all diagnosed cases of diabetes [3], and therefore it is estimated that 102.5 to 108.2 million individuals have T2D. Individuals with T2D perform about 95% of their own care [4]. Diabetes self-management (DSM) is therefore an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their T2D such as self-monitoring blood glucose (SMBG), dietary changes, and physical activity [5]. DSM is complex, requires major lifestyle changes and behavioral tasks that are incorporated into an individual's daily routine and high levels of adherence for effective management and halting disease progression [6].

Mounting evidence has consistently shown that better DSM was associated with better health outcomes, including improved glycemic control [7], improved quality of life [8], and reduced incidence of diabetes-related complications [9]. Individuals with diabetes have been shown to make a great impact on the progression and development of their disease by participating in their own care. However, adherence to some of these activities has been found to be low, especially when looking at long-term changes [10]. This suggests a critical need for a comprehensive and well-tested conceptual model to guide future DSM interventions.

Although the information-motivation-behavioral skills (IMB) model has been tested among Chinese adults with T2D [11], some key components of the original IMB model were not tested. For example, it is well known that personal motivation, such as health beliefs, may influence DSM among Chinese adults [12]. Additionally, important moderators known to influence DSM in Chinese adults such as depressive symptoms, female gender, and educational level were not included in the model [11], and this may add important insights into DSM specific to this population. Therefore, a revised conceptual model

based on the IMB model is needed to take account the effects of interactive relationships among the related factors. The proposed IMB-DSM model will help fill this gap by examining the potential moderators of DSM in this population, so that intervention studies based on this model can not only show whether the intervention works, but also why the intervention works and under what conditions the intervention works.

Conceptual Framework

Overview of the IMB model. The IMB provided the theoretical basis for this study. The IMB model is used to frame these variables because: (a) the constructs from the model can be easily translated into intervention components, and (b) it adequately captures essential constructs that are well supported in the literature to improve DSM behaviors, including information (e.g., diabetes knowledge), motivation (e.g., social support), and behavioral skills (e.g., diabetes self-efficacy). The model postulates that individuals are more likely to take health-related actions, such as DSM behaviors, if they are well informed, highly motivated (personally and socially), and have adequate and appropriate behaviors, and thus, experience positive health outcomes [13]. The model is based on three constructs: information, motivation, and behavioral skills. For complex behaviors, information and motivation are believed to work largely through behavioral skills to initiate and maintain the behavior at focus, and the behavior is directly linked to health outcomes, which, in turn, are conceptualized as influencing one's future maintenance of the behavior via a feedback loop that affects one's future levels of information, motivation, and behavioral skills overtime [14 15]. The IMB model further postulates that favorable health outcomes may strengthen an individual's information, motivation, and behavioral skills to perform the behavior in the future. In contrast, unfavorable health outcomes may cause an individual to lose confidence in his or her knowledge, motivation, and behavioral skills to perform the behavior overtime [15].

Overview of the IMB-DSM model. Figure 1 portrays the overarching conceptual framework of this study. The IMB-DSM model provides a comprehensive insight to explore the relationships that influence DSM and its related health outcomes, based on a systematic review of literature in this area. The framework consists of the following six key interrelated components: DSM-related information,

DSM-related motivation, DSM-related behavioral skills, DSM behaviors, health outcomes, and moderators. Consistent with the original IMB assumptions, the IMB-DSM model asserts that DSM-related information, motivation, and behavioral skills are fundamental determinants of DSM behaviors. DSM-related information and motivation are proposed to work primarily through behavioral skills to affect initiation and maintenance of DSM behaviors. DSM behaviors lead to health outcomes, which, in turn, can influence one's future maintenance of the behavior via a feedback loop that affects one's future levels of DSM-related information, motivation, and behavioral skills overtime. The proposed moderators can influence the relationship among variables in the IMB-DSM model. Each part of the IMB-DSM is presented in detail below.

DSM-related information. DSM-related information is a necessary but insufficient prerequisite for DSM behaviors. The link between DSM-related information and DSM behaviors has been well established in the literature. DSM related information includes diabetes knowledge, health education, and provider-patient communication. A positive relationship was found between diabetes knowledge and overall DSM performance [16-18], exercise, foot care [19], diet control, or SMBG [20] in some studies, but not others [21 22]. A significantly positive relationship was reported between health education, overall DSM performance [23-25], and some specific DSM behaviors, such as diet modification, foot care, regulating highs and lows in blood glucose, SMBG, engaging in exercise, taking medications, smoking cessation [23 26 27]. Three studies reported the relationship between provider-patient communication and DSM behaviors, and both studies found that better provider-patient communication was an independent, direct predictor of better overall DSM performance [11 22 28].

DSM-related motivation. Another fundamental determinant of DSM behaviors is an individual's motivation to perform DSM. Consistent with the IMB model, the IMB-DSM model posits that an individual's motivation includes personal and social motivation. Personal motivation to perform DSM refers to one's beliefs about the DSM behaviors and evaluations of the outcomes. Social motivation to perform DSM rests on the one's perception of social support for DSM and one's motivation to comply with referent others [29].

In the IMB-DSM model, health beliefs are used to conceptualize personal motivation. Perceived susceptibility, perceived barriers, perceived benefits, or cues to action has each been positively associated with overall DSM performance and all aspects of DSM behaviors except smoking cessation [12 30]. There was inconsistent evidence of the relationship between perceived severity and DSM behaviors. Yu [12] reported a negative association, whereas Sun and coworkers [10] reported a positive association. One possible explanation for the inconsistency between perceived severity and DSM behaviors involves the fact that both studies are cross-sectional. Thus, a person who is currently engaging in DSM behaviors may both perceive him- or herself as not being at risk and may report few feelings of severity. Alternatively, a person who is presently engaging in less DSM behaviors may report more feelings of severity and few risk-reduction efforts. The inconsistency warrants further investigations from longitudinal studies. Research evidence is consistent with a positive relationship between perceived social support from significant others and overall DSM performance, diet control, taking medications, engaging in physical activity, SMBG, foot care and regulating highs and lows in blood glucose [11 19 22 31-33].

DSM-related behavioral skills. Behavioral skills involve objective and perceived skills for performing DSM behaviors and a sense of self-efficacy for doing so [29]. In the IMB-DSM model, behavioral skills include diabetes self-efficacy and positive coping strategy. A great deal of studies has reported a consistent strong association between levels of self-efficacy and DSM behaviors, including diet modification, taking medications, foot care, physical activity, SMBG, and regulating highs and lows in blood glucose [11 17 19 22 32 34-37]. Coping strategies have been well studied in this population. Research evidence is consistent with a positive relationship between confrontation and overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Alternatively, acceptance-resignation was negatively associated with overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Avoidance had negative effects on taking medications [12 30] and regulating highs and lows in blood glucose [30].

One cross-sectional study provided evidence for the role of DSM-related behavioral skills as a mediator between DSM-related information, motivation, and DSM behaviors. Information on demographics, provider-patient communication, social support, and self-efficacy, and diabetes self-care was collected among 222 participants with T2D in Shanghai. There were significant, positive, direct paths from self-efficacy (β=.41, p<.001), social support (β=.19, p=.007), and provider-patient communication (β=.12, p=.037) to DSM behaviors. Paths from provider-patient communication to self-efficacy (β=.23, p<.001) and from social support to self-efficacy (β=.19, p<.05) were significant and positive. Structural equations modeling showed that self-efficacy mediated the effects of social support (indirect effect β=.08, p=.008) and provider-patient communication (indirect effect β=.09, p=.002) on DSM behaviors [11]. Overall, the study provided support for the specific direct and mediating relationships between DSM-related information, motivation, behavioral skills, and DSM behaviors. However, one limitation of this study is that the adapted IMB model does not include all relevant constructs. For example, information on personal motivation was not collected. Therefore, the study only partially tested the IMB model.

DSM behaviors. DSM behaviors primarily include dietary changes, weight loss, and increased physical activity, SMBG, foot care, and taking prescribed medications. Based on the guidelines of the American Diabetes Association [9], individuals with T2D are encouraged to increase intake of whole grains, fiber, vegetables, and fruits, and reduce intake of total and saturated fat, sugar-flavored beverages, and high calorie snacks. They are also encouraged to engage in 150 min or more of moderate-to-vigorous intensity physical activity per week, and lose about 5%-7% of initial body weight if these individuals are overweight/obese.

Health outcomes. The IMB-DSM model asserts that DSM behaviors are directly linked to health outcomes, which has been well supported in the literature. Since adults with T2D are two to four times more likely to have cardiovascular disease (CVD) than adults without T2D [9], monitoring cardiometabolic markers is essential in the clinical management of patients with T2D. In the proposed study, blood pressure and blood lipids are measured to identify subsequent CVD risks among adults with T2D. The health outcomes include hemoglobin A1c (HbA1c), blood pressure, blood lipids, and diabetes-dependent

quality of life. DSM behaviors had a direct effect on glycemic control (β=-.02, p=.007) [28], total cholesterol (TC)/high-density lipoprotein cholesterol (HDL-C) (β=-.31, p<.001), and low-density lipoprotein cholesterol (LDL-C)/HDL-C (β=-.30, p<.001) [11]. It is not clear whether DSM behaviors are directly related to blood pressure in Chinese adults with T2D, and this will be examined in this study. Compared to the general population, people affected by T2D consistently reported diminished health-related quality of life [39]. However, the relationship between DSM behaviors and health-related quality of life has not been systematically studied among Chinese adults with T2D, and this study will fill the knowledge gaps.

Moderators. The IMB-DSM model postulates that certain personal characteristics may act as moderators that influence the associations of the model constructs with DSM behaviors, and that the degree of moderation depends on the level or intensity of the moderator. High levels of moderators are assumed to directly influence DSM behaviors, whereas lower levels of moderators are assumed to work through the IMB-DSM model constructs to influence DSM behaviors and not obscure the relationships between these constructs and DSM behaviors. These moderators include depressive symptom, female gender, and educational level.

Depressive symptoms have been consistently found to negatively affect DSM behaviors, such as SMBG, foot care, diet modification, regulating highs and lows in blood glucose, and overall DSM performance in these studies [40-42]. Generally, female patients had better overall DSM performance than their male counterparts [12 43]. People with a higher educational level tended to manage their diabetes better, compared to people with lower educational level [24 32 44]. Because existing studies investigating factors associated with DSM are primarily univariate in nature, they generally address only one aspect of the IMB-DSM model, that is, they establish support for a direct relationship between DSM behaviors and DSM-related information, motivation, or behavioral skills. So far, no studies have been conducted to systematically evaluate how potential moderators may influence the relationship among variables in the IMB-DSM model, and this study is expected to fill those knowledge gaps.

Objectives

In the proposed study, we will refine and test longitudinally a culturally tailored IMB-DSM among 250 Chinese adults residing in Chengdu, China.

Aim 1: In Chinese adults with T2D, to determine which baseline variables are most strongly related to baseline DSM behaviors, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education.

Research question (RQ): Among baseline DSM-related information, motivation, and behavioral skills, which is most strongly related to baseline DSM behaviors?

Aim 2: To examine the feedback loop as described in the original IMB model by investigating the relationships between baseline health outcomes (HbA1c, blood pressure, blood lipids, and diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up period, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education at baseline.

RQ1: What is the relationship between baseline HbA1c levels and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ2: What is the relationship between baseline blood pressure and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ3: What is the relationship between baseline blood lipids and DSM-related information, motivation, and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ4: What is the relationship between baseline diabetes-dependent quality of life and DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

Aim 3: In Chinese adults with T2D, to examine mediating and moderating factors associated with DSM behaviors at baseline and the 3 month follow-up period.

Research Question 1: Are behavioral skills (diabetes self-efficacy and coping strategies) mediators of DSM behaviors at baseline and 3-month follow-up period?

Research Question 2: Are depressive symptoms, female gender, and educational level as moderators of DSM behaviors at baseline and 3-month follow-up period?

Methods and Analysis

Design

A descriptive, repeated-measure design is used to examine the relationships among variables in the IMB-DSM model, the role of variables in predicting baseline DSM behaviors, the potential moderators and mediators, and investigate the relationship between baseline health outcomes and DSM-related information, motivation, behavioral skills and subsequent DSM behaviors at three-month follow-up. Data will be collected at two time points, 3 months apart. Since HbA1c is considered the gold standard for monitoring glycemic control and reflects a person's glucose control for the preceding 8 to 10 weeks [9], three-month of observation is deemed long enough to reflect the glucose control.

Sample and Setting

This study will be conducted in Chengdu metropolitan area, which is the provincial capital of Sichuan province in Southwest China. One community health center will be selected from each of six urban districts in Chengdu metropolitan area: the Yulin community health center in Wuhou District, the Supo community health center in Qingyang District, the Longzhoulu community health center in Jinjiang District, the Caojiaxiang community health center in Jinniu District, the Shuanglin community health center in Chenghua District, and the Guixi community health center in Gaoxin District. The inclusion criteria for participation in the research are: (a) diagnosed with T2D; (b) able to read, write, and speak Chinese; (c)$\geqslant$18 years of age; (d) a score of the Chinese version of Mini-Mental State Examination (C-MMSE) > 24 (see **Screening** below); (e) no other chronic physical or mental disorders; and (f) mentally competent to give informed consent. Patients will be excluded if they are pregnant, have been diagnosed with cancer or organ failure, refuse to participate in the proposed study, self-identified bilateral hearing loss, or cognitive impairment (inability to comprehend the informed consent).

Sample Size

The Power Analysis and Sample Size Software was used for sample size calculation. Sample size was calculated based on the weakest correlation among all the tested variable pairs, that is, diabetes

knowledge and social support (r=.197). Assuming 80% power, type I error rate of .05, and attrition rate of 20%, a total of 250 participants will be needed to detect the correlation coefficient of .197. This sample size will have a higher power to detect correlations with larger coefficient.

Participant Recruitment

The research team will actively recruit participants from six selected community health centers. The principal investigator and her undergraduate mentors have established relationships with these community health centers and will be able to facilitate recruitment from these sites. An electronic medical database of the residents kept each community health center will also be used to identify patients with T2D in these communities. The research team will also have access to the database from which participants can be recruited.

Once the approval from the Ethics Committees for Clinical Trials and Biomedical Research in the Fourth People's Hospital of Chengdu is obtained, patients who come to the local clinics for evaluations and care will be approached after agreeing to hear about the study by a research staff member, who will explain the study, provide a consent form for review, answer questions and seek their participation. Subjects who agree to participate will be screened on inclusion criteria. Screening (see Screening below) will take about 10 minutes. Those who meet study criteria will be entered into the study. In addition, advertisements about the study will be placed on buses and subways. Those interested in the study will be invited to the study site and asked to participate after reviewing study procedures and consent forms. Weekly and monthly recruitment goals will be set to ensure adequate progress on participant enrollment. If recruitment is slow, recruitment procedures will be reviewed, problems identified, and adjustments will be made so that participant accrual is conducted at a satisfactory rate.

Screening

A questionnaire will be used to assess participants' eligibility with questions on age, length of diabetes, period of time when starting diabetes treatment, provider referral, and willingness to participate. Since this population is at risk for cognitive impairment that may, in some cases, limit their capacity to provide consent [45], the C-MMSE will be administered to evaluate global cognitive functioning of all

eligible participants. The C-MMSE has been used among Chinese adults with T2D [46]. Those who obtain a score <=23 will be excluded because subjects with such low scores were considered to have possible dementia [47]. Potential participants with serious cognitive problems will be referred immediately to a mental health professional used by the respective community health centers.

Reducing Attrition

There will be a potential problem with attrition of the proposed study because the 3 month follow-up for this longitudinal study design opens up to the problem of attrition. Steps that will be taken to reduce attrition include: informing subjects of the importance of continued participation in all aspects of the study; giving a subject incentive of ¥155 (about $25) Walmart gift card per completed data collection session; making telephone calls and sending a reminder card prior to scheduled data collections. A participant locator form will be completed for each subject entered in the study and at all data collection sessions to ensure proper contact information for follow-up visit is maintained.

Data Collection and Procedures

After consenting to participate, each subject will be requested to come to the study site for baseline data collection in a private office at the research site. Baseline data collection will include administration of the following questionnaires: Demographic Data Form, the Diabetes Knowledge Questionnaire, the Health Education Form, the Provider-Patient Communication Scale, the Health Belief Scale, the Social Support Rating Scale, the Diabetes Self-Efficacy Scale, the Medical Coping Modes Questionnaire, the Diabetes Self-Care Scale, the Self-rating Depression Scale, and the Audit of Diabetes-Dependent Quality-of-Life. At the 3 month follow-up data collections, all the measures will be administered again except the Demographic Data Form. Data collection from each participant should take about 60 minutes. The instruments will be administered by a trained research assistant as an interview to reduce respondent burden and to standardize the approach due to the differing response formats. If the participant becomes fatigued, the battery of questionnaires may be completed in two sessions.

Training of Data Collectors

In an effort to improve inter-rater reliability, data collectors will be trained to collect data for baseline and follow-up data collections. They will attend intensive training sessions at the beginning of the project, and periodic refresher sessions will be offered every 2 to 3 weeks to reinforce the basic training. Data collectors will practice conducting data collections and blood pressure measurement and these sessions will be monitored and each data collector will be certified. To control for measurement error, a data collection protocol manual will be developed that will include data collection protocol related specifically to each questionnaire and blood pressure measurement. The specific measures, including instruments and physical biomarkers, that will be used in this study are described below.

Instruments

Demographics. This questionnaire is designed to collect background data from participants on their demographic characteristics, including age, gender, income, education, marital status, length of diabetes, health insurance, current treatment plan for diabetes, and relevant health history indicators.

The diabetes knowledge questionnaire. Diabetes knowledge in Figure 1 will be measured with the Chinese version of the Diabetes Knowledge Scale adapted from the Diabetes Knowledge Scales [48]. The Chinese version of the Diabetes Knowledge Scale consists of 14 items. Participants receive a score of 1 for a correct answer or 0 for an incorrect or unknown answer. The total score ranges from 0 to 14, with a higher score indicating a higher level of diabetes knowledge. The Cronbach's alpha for the Chinese version of the knowledge measure was .62. The diabetes knowledge score in the Chinese sample was significantly higher in the group with more education ($t[28]=2.83$, $p< .01$), indicating that the Chinese version had satisfactory construct validity [49].

The health education form. Information on health education in Figure 1 is based on self-reports. All participants will be asked if they have had received any form of diabetes education. If the answer is YES, the patient should answer the source of diabetes education. The source of diabetes education could be health care professionals, community consulting service, journals/books, TV/radio, internet and others.

The provider-patient communication scale. Provider-patient communication in Figure 1 will be measured by the Provider-Patient Communication Scale. The scale consists of 5 items with a scoring

range from 0 to 6, where 0 indicates "strongly disagree" and 6 indicates "strongly agree". High scores characterize a person who is confident in their ability to communicate with healthcare professionals and has good understanding of ways to access healthcare in order to get their needs met. The Cronbach's alpha coefficient is reported at .929, indicating excellent internal consistency [11].

The health belief scale. Health beliefs (i.e., personal motivation in Figure 1) refer to one's perceptions about T2D and how it can be treated [50]. The Health Belief Scale was developed based on the Health Belief Model by Yamei Chen [50]. The 20-item scale comprises 5 subscales (perceived susceptibility, perceived benefits, perceived severity, perceived barriers, and cues to action) and uses a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score represents stronger health beliefs. The content validity index is .81, the test-retest reliability ranges from .78 to .82, and the Cronbach's alpha is .79 [50].

The social support rating scale. Social support (i.e., social motivation in Figure 1) will be assessed by the Social Support Rating Scale [51]. The 10-item instrument measures aspects of objective social support (3 items), subjective social support (4 items) and usage of social support (3 items). The item scores range from 14 (worst possible social support) to 66 (best possible social support) [51]. The test-retest reliability coefficient and the internal consistency of the scale are .92 and .88-.94, respectively [32].

The diabetes self-efficacy scale. Diabetes self-efficacy in Figure 1 will be measured with the 7-item Chinese version of the Diabetes Self-Efficacy Scale, which evaluates participants how capable they are when performing DSM activities. The items are scored on a 5-point Likert-type scale, with higher scores indicating higher self-efficacy in performing DSM behaviors. The Chinese version of the Diabetes Self-Efficacy Scale has a Cronbach's alpha of .87. Factor analysis showed that seven items loaded on five factors, which explains 97.9% of the variance, and the five factors are consistent with confidence in performing the five aspects of DSM behaviors [49].

The medical coping modes questionnaire. Coping strategies in Figure 1 will be measured by the 20-item Chinese version of the Medical Coping Modes Questionnaire. It assess 3 forms of coping strategies associated with chronic illness: confrontation, avoidance, and acceptance-resignation [52]. Items

are answered on a four-point Likert scale ranging from 1 (never) to 4 (very often). Scores from the three subscales are compared, and the highest score indicates the corresponding dominant pattern of coping utilized by the participant. The Cronbach's alpha for the confrontation, avoidance, and acceptance-resignation subscales is reported at .69, .60, .76, respectively [52].

The diabetes self-care scale. DSM in Figure 1 will be measured by the 26-item Diabetes Self-Care Scale, which is comprised of 6 subscales: diet modification, taking medications, SMBG, foot care, physical activity, and regulating highs and lows in blood glucose. Responses for each item range from 1 (never) to 5 (very often). Total score can range from 26 to 130 by adding up scores of 6 subscales, with higher scores indicating better overall DSM performance. The construct validity is .68, and the Cronbach's alpha is .87 [53].

The self-rating depression scale. Depressive symptoms in Figure 1 will be assessed using the Self-Rating Depression Scale, a 20-item self-administered questionnaire [54]. Each item is rated on a four-point Likert scale, ranging from 1 (very seldom) to 4 (most of the time) and computed as an original score, then multiplied by 1.25 to get the standard score. A score ranges from 53 to 62 indicates mild depressive symptoms, a score ranges from 63 to 72 indicates moderate depressive symptoms, and a score higher than 72 indicates severe depressive symptoms [55].

The audit of diabetes-dependent quality of life. Diabetes-related quality of life in Figure 1 will be measured by the Chinese version of Audit of Diabetes-Dependent Quality of Life, which measures both generic and diabetes-specific quality of life. The first two overview items assess generic quality of life on a seven-point Likert scale (-3 [extremely bad] to 3 [excellent]) and quality of life without diabetes. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how their quality of life would be if they did not have diabetes. The subsequent 19 items evaluates diabetes-specific quality of life. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how particular aspects of their life would be if they did not have diabetes. The importance of each aspect on their life is rated on a four-point scale (0 to 3). The two ratings are multiplied and summed for a final impact score that ranges from -9 to 3, where more negative scores indicate worse quality of life. A score of 0 is assigned to

"unimportant" domains, regardless of the magnitude of its impact. Similarly, a score of 0 is assigned to items with no impact of diabetes, regardless of their importance to quality of life. The average weighted rating score is obtained by dividing the sum of weighted ratings for applicable domains by the number of the applicable domains. Strong reliability (Cronbach's alpha=.941) has been reported [56]. Factor analysis showed that all items had high performance in the structural validity evaluation, with most factor loading values being larger than .40 (varied from .44 to .88) [56].

Physical Markers

Physical markers include HbA1c, blood pressure, and blood lipids. All blood samples will be processed at the Clinical Laboratory of the Fourth People's Hospital of Chengdu. After collection, the fresh venous blood samples will be immediately transported at 4°C temperature to the Clinical Laboratory within 2 hours. The samples will then be placed in a deep freezer and stored at -80°C until assays start.

HbA1c. HbA1c will be used as a marker of T2D and glycemic control and will be analyzed from whole blood samples (4 ml). Analysis will be conducted using high performance liquid chromatography, with standardization through commercial available assays (coefficient of variation<2%).

Blood pressure. Blood pressure will be obtained by a trained nurse using a standard sphygmomanometer for a minimum of 2 consecutive readings at intervals of at least 1 minute. The patient should be seated comfortably with the back supported and the upper arm bared, without constrictive clothing. The legs should not be crossed. The arm should be supported at the heart level, with the bladder of the cuff encircling at least 80% of the arm circumference. The mercury column should be deflated at 2 to 3 mm/s, and the first and last audible sounds should be taken as systolic and diastolic pressure. The column should be read to the nearest 2 mmHg. Neither the patient nor the observer should talk during the measurement procedure. The average of those readings will be used to represent the patient's blood pressure.

Blood lipids. Blood lipids include TC, HDL-C, LDL-C, and triglycerides (TG). Analysis of blood lipids will be conducted using enzymatic colorimetric test, with standardization through

commercial available assays (coefficient of variation<2%). Fasting serum samples will be collected in the morning after 8 hours fasting.

Data Analyses

Data analyses for Aim 1: Linear regression models will be applied to assess the associations between baseline DSM behaviors and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 2: Linear regression models will be applied to assess the associations between baseline health outcomes (i.e., HbA1c, blood pressure, blood lipids, diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and DSM behaviors at 3 months follow-up, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 3: Both baseline and 3-month follow-up measures will be used for Aim 3. Structural equation modeling will be used to explore the fit of the data to the IMB-DSM model. Data will be first assessed whether they meet the assumptions of maximum likelihood estimation of structural equation modeling. Then, hypotheses regarding structural relations among the IMB-DSM model constructs will be evaluated with an inspection of the direction and magnitude of the path coefficients (direct effects) and indirect effects, which indicate mediation. Significant indirect effects occur when the relationship between a predictor and an outcome is due to the predictor being associated with a third variable (i.e., all or part of the direct effect of A on C is due to a relationship between A and B). Criteria used to test the structural model will be the comparative fit index (≥.95 indicates good fit), the root mean square error of approximation (≤.06 with confidence interval .00-.08 indicates good fit), and the standardized root mean square residual (<.08 indicates acceptable fit, and 0 indicates perfect fit) [57]. Agreement between multiple indices provides the best support a model has good data fit [57]. Moderators will be tested by doing multi-group testing in AMOS 21, a structural equation modeling program. To examine whether depressive symptoms, female gender, and educational level moderate the relationships

in the model, multi-group analysis will be used comparing a constrained model (i.e., a model in which the coefficients are set equal across the groups) with an unconstrained model (i.e., a model in which these coefficients are allowed to vary freely). A significant difference between these two models implies that there are significant differences among the groups. A series of nested models will be tested to see where the differences are.

Ethics and Dissemination

The study poses little to no risk to participants and their families. Signed informed consent will be obtained from all participating families. Participation in the study does not interfere with the usual care patients receive in the primary care settings. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals.

Patient and Public Involvement

The development of the research question and outcome measures were informed by previously published research studies that engaged patients' experience. We did not involve patients in the study design, recruitment, and conduct of the study. Both the baseline and three-month outcomes on blood pressure, HbA1c, and blood lipids will be mailed to each participant. After we finish the data analysis, we will present the study findings in lay terms to study participants who were enrolled in our study.

Figure Legend

Figure 1. The DSM-IMB Model

Contributorship statement

All authors contribute to the conception and design of this study. TL, CL, and DW drafted the manuscript. JW, RY, YW, SG, and YD revised the manuscript. All authors approved the final version to be submitted to the journal.

Competing interests statement:

None declared.

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Data sharing statement:

We have not yet collected data. Once data collection is finished, the individual de-identified participant data (including data dictionaries) will be shared. The shared data will include demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. The data will become available as soon as we collect all data and for one year.

References

1. International Diabetes Federation. IDF diabetes atlet, 8th edition 2017 [Available from: http://www.diabetesatlas.org/across-the-globe.html accessed Nov 28, 2017.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *JAMA : the journal of American Medical Association* 2013;310:948-59. doi: 10.1001/jama.2013.168118 [published Online First: 2013/09/05]

3. Centers for Disease Control and Prevention. Awareness of prediabetes--United States, 2005-2010. *Morbidity and mortality weekly report* 2013;62(11):209-12. [published Online First: 2013/03/22]

4. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943-49. [published Online First: 1995/07/01]

5. Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-92. [published Online First: 1999/12/10]

6. Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. *Journal of diabetes and metabolic disorders* 2013;12:14. doi: 10.1186/2251-6581-12-14 [published Online First: 2013/03/19]

7. 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(7):1159-71. [published Online First: 2002/06/28]

8. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educator* 2008;34:815-23. doi: 10.1177/0145721708323640 [published Online First: 2008/10/04]

9. American Diabetes Association. 4. Lifestyle management: Standards of medical care in Diabetes-2018. *Diabetes care* 2018;41:S38-S50. doi: 10.2337/dc18-S004 [published Online First: 2017/12/10]

10. Sun X, Huang X, Yuan C, et al. The influence of health belief and coping style on self-management behavior in patients with type 2 diabetes mellitus [Chinese]. *Journal of Nursing (China)* 2012;19(1A):8-11.

11. Gao J, Wang J, Zhu Y, et al. Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC public health* 2013;13:100. doi: 10.1186/1471-2458-13-100 [published Online First: 2013/02/06]

12. Yu P. The relationship between coping strategy, health beliefs and self-management among people with type 2 diabetes in Changsha [Master thesis]. Central South University, 2009.

13. Fisher WA, Fisher JD, Harman J. The information-motication-behavioral slills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social psychological foundations of health and illness. Malden, MA: Wiley-Blackwell 2003:82-106.

14. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychological bulletin* 1992;111(3):455-74. [published Online First: 1992/05/01]

15. Fisher JD, Fisher WA, Amico KR, et al. An information-motivation-behavioral skills model of adherence to antiretroviral therapy. *Health Psychology* 2006;25:462-73. doi: 10.1037/0278-6133.25.4.462 [published Online First: 2006/07/19]

16. Huang J, Liu Y, Zhang Y, et al. Correlation between self-management and knowledge of and attitude to diabetes in type 2 diabetic patients in Changsha [Chinese]. *Journal of Central South University (Medical Sciences)* 2013;38:176-81. doi: 10.3969/j.issn.1672-7347.2013.02.011 [published Online First: 2013/03/05]

17. Kong L, Ye Y, Ding F, et al. The relationship between diabetes knowledge, self-efficaicy, and self-management practice among individuals with type 2 diabetes in community [Chinese]. *Journal of Hubei University of Science and Technology* 2013;27(4):334-38.

18. Wang X, Lv W, Ding Y, et al. Study on correlation between self-management behaviors of elderly type 2 diabetic patients and diabetes knowledge level [Chinese]. *Chinese Nursing Research* 2013;27(9):2973-74.

19. Quan J. The research about the current status and influencing factors of self-management behavior in middle-aged and over patients who with type 2 diabetes mellitus [Master thesis]. Yanbian University, 2013.

20. Wang X, Lan W, Liu J, et al. Evaluation analysis of influencing factors of type II diabetes patients self-management in Shanxi Province [Chinese]. *Journal of Qiqihar Medical College* 2012;33(8):1065-69.

21. Hu J, Gruber KJ, Liu H, et al. Diabetes knowledge among older adults with diabetes in Beijing, China. *Journal of clinical nursing* 2013;22:51-60. doi: 10.1111/j.1365-2702.2012.04273.x [published Online First: 2012/12/12]

22. Xu Y, Toobert D, Savage C, et al. Factors influencing diabetes self-management in Chinese people with type 2 diabetes. *Research in nursing & health* 2008;31:613-25. doi: 10.1002/nur.20293 [published Online First: 2008/07/10]

23. Jia Y, Wang J, Liu W. Study on self-care level of patients with type 2 diabetes mellitus and analysis of related factors [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2005;22(7):21-23.

24. Meng F. Research on health education and self-managing level of community non-insulin dependent diabetic patients [Master thesis]. Sun Yat-Sen University, 2010.

25. Wang L, Zhang J. Self-management of elderly patients with type 2 diabetes and its influencing factors [Chinese]. *Journal of Nursing (China)* 2012;19(4A):39-42.

26. Guo XH, Yuan L, Lou QQ, et al. A nationwide survey of diabetes education, self-management and glycemic control in patients with type 2 diabetes in China. *Chinese medical journal* 2012;125(23):4175-80. [published Online First: 2012/12/12]

27. Wang J, Zhang X. Survey of self-care behavior among 2 type diabetes patients [Chinese]. *Journal of Nurses Training* 2002;17(9):663-65.

28. Gao J, Wang J, Zheng P, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. *BMC family practice* 2013;14:66. doi: 10.1186/1471-2296-14-66 [published Online First: 2013/05/28]

29. Osborn CY, Egede LE. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient education and counseling* 2010;79:49-54. doi: 10.1016/j.pec.2009.07.016 [published Online First: 2009/08/25]

30. Sun X, Huang X, Yuan C, et al. The relationship between coping strategy and self-management behavior among patients with type 2 diabetes [Chinese]. *Journal of Nurses Training* 2012;27(12):1084-86.

31. Du L, Lin T, Liu X. Study on correlation between social support and self-care behavior of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2012;388(26):697-99.

32. Huang M, Zhao R, Li S, et al. Self-management behavior in patients with type 2 diabetes: A cross-sectional survey in western urban China. *PloS one* 2014;9(4):e95138. doi: 10.1371/journal.pone.0095138 [published Online First: 2014/04/20]

33. Wan Q, Shang S, Liu Y, et al. A study of factors of the self-care behaviors of the elderly with type 2 diabetes [Chinese]. *Chinese General Practice* 2003;6(8):659-62.

34. Fang S, Yu Z, Tao Y. The relationship between coping strategy, self-efficacy, and diabetes self-management among people living in rural areas [Chinese]. *World Health Digest Medical Periodical* 2013;10(23):79-80.

35. Gao H. The relationship between diabetes self-efficacy and self-care behavior in patients with type 2 diabetes [Chinese]. *Jilin Medical Journal* 2012;33(35):7646-47.

36. Jia Y, Gong T, Sang M. Investigating on self-management and self-efficacy of patients with type 2 diabetes mellitus [Chinese]. *Modern Nursing* 2005;11(19):1586-88.

37. Wang JQ, Tak-Ying Shiu A. Diabetes self-efficacy and self-care behaviour of Chinese patients living in Shanghai. *Journal of clinical nursing* 2004;13:771-72. doi: 10.1111/j.1365-2702.2004.00918.x [published Online First: 2004/08/20]

38. Wan Q, Wang Q, Shang S. Correlation of self-management behavior and coping patterns of patients with type 2 diabetes [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2008;25(1B):18-21, 23.

39. Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in type 2 diabetes patients. *Quality of life research* 2007;16:165-77. doi: 10.1007/s11136-006-9105-0 [published Online First: 2006/10/13]

40. Jia Y, Wang J, Teng X. Study on the correlation between psychological health level and self-management in patients with type 2 diabetes mellitus [Chinese]. *Shanghai Nursing* 2004;4(4):1-3.

41. Lin T, Lin X, Wan L. A study on correlation between self-care behavior and psychological concordance and depression of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2009;23(1A):22-24.

42. Wang Q, Wan Q, Shang S. Correlation of self-management behavior and depression in patients with type 2 diabetes [Chinese]. *Journal of Nursing Science* 2009;24(7):14-15.

43. Lin T, Wang J, Qin X. Study on self-care behaviors and its related factors in patients with type 2 diabetes [Chinese]. *Chinese Journal of Modern Nursing* 2008;14(11):1254-56.

44. Xia Z, Yang T. Diabetes self-management behaviors and related factors among patients with type 2 diabetes in Xiuying District, Haikou [Chinese]. *Seek Medical and Ask the Medicine* 2011;9(11):526-27.

45. Cheng G, Huang C, Deng H, et al. Diabetes as a risk factor for dementia and mild cognitive impairment: A meta-analysis of longitudinal studies. *Internal medicine journal* 2012;42:484-91. doi: 10.1111/j.1445-5994.2012.02758.x [published Online First: 2012/03/01]

46. Chen Y, Liu Z, Zhang J, et al. Altered brain activation patterns under different working memory loads in patients with type 2 diabetes. *Diabetes Care* 2014;37:3157-63. doi: 10.2337/dc14-1683 [published Online First: 2014/11/19]

47. Zhang M. Users' guide for psychiatric scales. Changsha, China: Human Sciences & Technology Publishing House 2003.

48. Beeney LJ, Dunn SM, Welch G. Measurement of diabetes knowledge: The development of the DKN scales. In: Bradley C, ed. Handbook of psychology and diabetes. New York, NY: Psychology Press 2003:159-89.

49. Xu Y, Savage C, Toobert D, et al. Adaptation and testing of instruments to measure diabetes self-management in people with type 2 diabetes in mainland China. *Journal of transcultural nursing : official journal of the Transcultural Nursing Society / Transcultural Nursing Society* 2008;19:234-42. doi: 10.1177/1043659608319239 [published Online First: 2008/06/27]

50. Chen Y. Study on compliance and influence factors of the re-hospitalized patients with diabetes mellitus. [Master thesis]. Central South Universtiy, 2007.

51. Yao S, Wu D. Psychological health rating scale. In: Yao S, ed. Psychological Assessment Beijing, China: People's Medical Publishing House 2008:89-126.

52. Shen X, Jiang Q. Report on application of Chinese version of MCMQ in 701 patients [Chinese]. *Chinese Journal of Behavioral Medican Science* 2000;9(1):18-20.

53. Wang JS, Wang RH, Lin CC. Self-care behavior and related factors in outpatients newly diagnosed with non-insulin-dependent diabetes mellitus [Chinese]. *Journal of Nursing (Taiwan)* 1998;45(2):60-74. [published Online First: 1999/01/15]

54. Zung WW. A self-rating depression scale. *Archives of general psychiatry* 1965;12:63-70. [published Online First: 1965/01/01]

55. Tang P. Medical Psychology. Beijing, China: People's Medical Publishing House 2009.

56. Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. *Diabetes research and clinical practice* 2011;94:45-52. doi: 10.1016/j.diabres.2011.05.026 [published Online First: 2011/06/21]

57. Kline RB. Principles and practices of structural equation modeling. 3 ed. New York, NY: The Guilford Press 2010.

Figure 1. The DSM-IMB Model

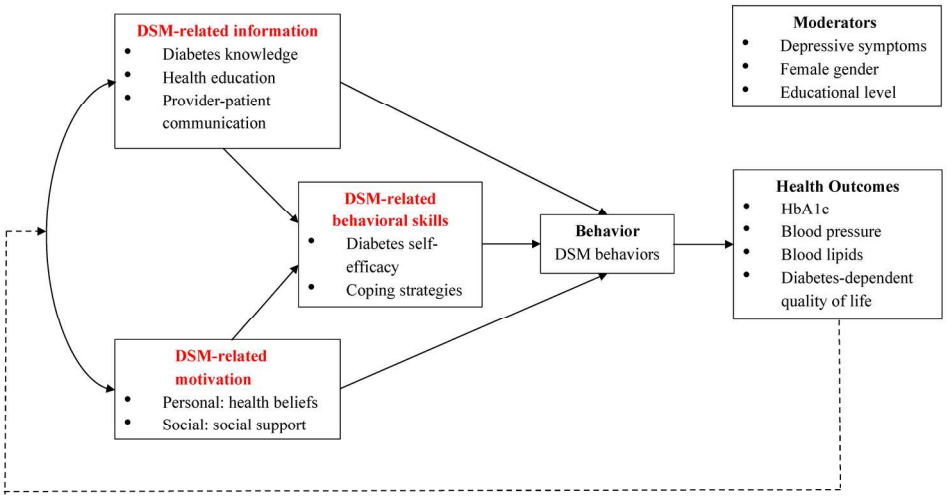

Figure 1. The DSM-IMB Model

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A proposal of a three-month follow-up study

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A proposal of a three-month follow-up study

Tingting Liu, Dongmei Wu, Jing Wang, Changwei Li, Rumei Yang, Song Ge

Correspondence should be made to:

Tingting Liu, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

Postal address: 1440 Canal St, Suite 2000, New Orleans, LA 70112

Email: tliu10@tulane.edu

Tel: 504-988-3738

Fax: 504-988-6809

The full names, institutions, city, and country of all other co-authors:

Tingting Liu*, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

Dongmei Wu*, PhD, RN

Psychiatric Research Laboratory

The Fourth People's Hospital of Chengdu, Chengdu, Sichuan Province, China

Jing Wang, PhD, MPH, RN, FAAN

University of Texas Health Science Center at Houston Cizik School of Nursing, Houston, TX, USA

Changwei Li, PhD, MD, MPH

Department of Epidemiology and Biostatistics,

University of Georgia College of Public Health, Athens, GA, USA

Rumei Yang, MS, RN

University of Utah College of Nursing, Salt Lake City, UT, USA

Song Ge, BSN, RN

Johns Hopkins University School of Nursing, Baltimore, MD, USA

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Drs. Tingting Liu and Dongmei Wu contributed equally to this manuscript.

Abstract

Introduction: Currently, China has the largest number of people with diabetes in the world, and the disease has reached epidemic proportions in the adult population. Individuals with diabetes perform about 95% of their own care. Diabetes self-management is an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their diabetes. Several studies have consistently shown that diabetes self-management practice is suboptimal among Chinese adults with type 2 diabetes. The reason for poor adherence to diabetes self-management among Chinese adults is not well known and no conceptual model has been used to guide diabetes self-management interventions in this population. Although the information-motivation-behavioral skills model has been tested among Chinese adults with type 2 diabetes, some key components of the original model were not tested. In the proposed study, we will refine and test longitudinally a culturally tailored model of diabetes self-management among 250 Chinese adults residing in China. This paper is to report the study protocol for the proposed study.

Methods and Analysis: This is a descriptive, repeated-measure study to be conducted at a tertiary hospital in Chengdu, China. A total of 250 adults with type 2 diabetes will be enrolled into the study, and will be followed for 3 months. Multiple domains will be collected, including demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Main analyses comprise linear regression modeling controlling for covariates and structural equation modeling.

Ethics and Dissemination: Ethical approval has been obtained through the Fourth People's Hospital of Chengdu Research Ethics Committee (study approval number 2017017). We aim to disseminate the findings through international conferences, international peer-reviewed journals and social media.

Study registration number: ChiCTR-ROC-17013592.

Strengths and limitations of this study

- This study will recruit and follow-up Chinese adults with diabetes for 3 months, and test the information-motivation-behavioral skills model of diabetes self-management longitudinally for the first time.
- This study relies primarily on self-reported measures, and objective, observable levels of diabetes self-care behaviors should be used in future studies.
- The study sample will be conducted in Chengdu, a typical city in southwestern China, and therefore the findings of the study may not be generalized to other parts of China, and the chosen centers are not from areas that are representative of the general Chinese population in regards to socioeconomic status.
- This is a descriptive, repeated-measure study. A randomized controlled trial with a group of patients receiving no DSM interventions would have been desirable to test the model.

Introduction

Diabetes is a major public health problem worldwide and it is increasing by epidemic proportions. Globally, the total number of people living with diabetes is projected to rise from 425 million cases in 2017 to 649 million cases by 2045, with over 75% of cases living in low- and middle-income countries [1]. In China alone, the most comprehensive nationwide survey showed that about 114 million (11.6%) adults had diabetes in 2010, a two-fold increase over the past decade [2]. Type 2 diabetes (T2D) accounts for approximately 90% to 95% of all diagnosed cases of diabetes [3], and therefore it is estimated that 102.5 to 108.2 million individuals have T2D. Individuals with T2D perform about 95% of their own care [4]. Diabetes self-management (DSM) is therefore an essential element of diabetes care, and refers to daily behaviors that individuals perform to manage their T2D such as self-monitoring blood glucose (SMBG), dietary changes, and physical activity [5]. DSM is complex, requires major lifestyle changes and behavioral tasks that are incorporated into an individual's daily routine and high levels of adherence for effective management and halting disease progression [6].

Mounting evidence has consistently shown that better DSM was associated with better health outcomes, including improved glycemic control [7], improved quality of life [8], and reduced incidence of diabetes-related complications [9]. Individuals with diabetes have been shown to make a great impact on the progression and development of their disease by participating in their own care. However, adherence to some of these activities has been found to be low, especially when looking at long-term changes [10]. This suggests a critical need for a comprehensive and well-tested conceptual model to guide future DSM interventions.

Although the information-motivation-behavioral skills (IMB) model has been tested among Chinese adults with T2D [11], some key components of the original IMB model were not tested. For example, it is well known that personal motivation, such as health beliefs, may influence DSM among Chinese adults [12]. Additionally, important moderators known to influence DSM in Chinese adults such as depressive symptoms, female gender, and educational level were not included in the model [11], and this may add important insights into DSM specific to this population. Therefore, a revised conceptual model

based on the IMB model is needed to take account the effects of interactive relationships among the related factors. The proposed IMB-DSM model will help fill this gap by examining the potential moderators of DSM in this population, so that intervention studies based on this model can not only show whether the intervention works, but also why the intervention works and under what conditions the intervention works.

Conceptual Framework

Overview of the IMB model. The IMB provided the theoretical basis for this study. The IMB model is used to frame these variables because: (a) the constructs from the model can be easily translated into intervention components, and (b) it adequately captures essential constructs that are well supported in the literature to improve DSM behaviors, including information (e.g., diabetes knowledge), motivation (e.g., social support), and behavioral skills (e.g., diabetes self-efficacy). The model postulates that individuals are more likely to take health-related actions, such as DSM behaviors, if they are well informed, highly motivated (personally and socially), and have adequate and appropriate behaviors, and thus, experience positive health outcomes [13]. The model is based on three constructs: information, motivation, and behavioral skills. For complex behaviors, information and motivation are believed to work largely through behavioral skills to initiate and maintain the behavior at focus, and the behavior is directly linked to health outcomes, which, in turn, are conceptualized as influencing one's future maintenance of the behavior via a feedback loop that affects one's future levels of information, motivation, and behavioral skills overtime [14 15]. The IMB model further postulates that favorable health outcomes may strengthen an individual's information, motivation, and behavioral skills to perform the behavior in the future. In contrast, unfavorable health outcomes may cause an individual to lose confidence in his or her knowledge, motivation, and behavioral skills to perform the behavior overtime [15].

Overview of the IMB-DSM model. Figure 1 portrays the overarching conceptual framework of this study. The IMB-DSM model provides a comprehensive insight to explore the relationships that influence DSM and its related health outcomes, based on a systematic review of literature in this area. The framework consists of the following six key interrelated components: DSM-related information,

DSM-related motivation, DSM-related behavioral skills, DSM behaviors, health outcomes, and moderators. Consistent with the original IMB assumptions, the IMB-DSM model asserts that DSM-related information, motivation, and behavioral skills are fundamental determinants of DSM behaviors. DSM-related information and motivation are proposed to work primarily through behavioral skills to affect initiation and maintenance of DSM behaviors. DSM behaviors lead to health outcomes, which, in turn, can influence one's future maintenance of the behavior via a feedback loop that affects one's future levels of DSM-related information, motivation, and behavioral skills overtime. The proposed moderators can influence the relationship among variables in the IMB-DSM model. Each part of the IMB-DSM is presented in detail below.

DSM-related information. DSM-related information is a necessary but insufficient prerequisite for DSM behaviors. The link between DSM-related information and DSM behaviors has been well established in the literature. DSM related information includes diabetes knowledge, health education, and provider-patient communication. A positive relationship was found between diabetes knowledge and overall DSM performance [16-18], exercise, foot care [19], diet control, or SMBG [20] in some studies, but not others [21 22]. A significantly positive relationship was reported between health education, overall DSM performance [23-25], and some specific DSM behaviors, such as diet modification, foot care, regulating highs and lows in blood glucose, SMBG, engaging in exercise, taking medications, smoking cessation [23 26 27]. Three studies reported the relationship between provider-patient communication and DSM behaviors, and both studies found that better provider-patient communication was an independent, direct predictor of better overall DSM performance [11 22 28].

DSM-related motivation. Another fundamental determinant of DSM behaviors is an individual's motivation to perform DSM. Consistent with the IMB model, the IMB-DSM model posits that an individual's motivation includes personal and social motivation. Personal motivation to perform DSM refers to one's beliefs about the DSM behaviors and evaluations of the outcomes. Social motivation to perform DSM rests on the one's perception of social support for DSM and one's motivation to comply with referent others [29].

In the IMB-DSM model, health beliefs are used to conceptualize personal motivation. Perceived susceptibility, perceived barriers, perceived benefits, or cues to action has each been positively associated with overall DSM performance and all aspects of DSM behaviors except smoking cessation [12 30]. There was inconsistent evidence of the relationship between perceived severity and DSM behaviors. Yu [12] reported a negative association, whereas Sun and coworkers [10] reported a positive association. One possible explanation for the inconsistency between perceived severity and DSM behaviors involves the fact that both studies are cross-sectional. Thus, a person who is currently engaging in DSM behaviors may both perceive him- or herself as not being at risk and may report few feelings of severity. Alternatively, a person who is presently engaging in less DSM behaviors may report more feelings of severity and few risk-reduction efforts. The inconsistency warrants further investigations from longitudinal studies. Research evidence is consistent with a positive relationship between perceived social support from significant others and overall DSM performance, diet control, taking medications, engaging in physical activity, SMBG, foot care and regulating highs and lows in blood glucose [11 19 22 31-33].

DSM-related behavioral skills. Behavioral skills involve objective and perceived skills for performing DSM behaviors and a sense of self-efficacy for doing so [29]. In the IMB-DSM model, behavioral skills include diabetes self-efficacy and positive coping strategy. A great deal of studies has reported a consistent strong association between levels of self-efficacy and DSM behaviors, including diet modification, taking medications, foot care, physical activity, SMBG, and regulating highs and lows in blood glucose [11 17 19 22 32 34-37]. Coping strategies have been well studied in this population. Research evidence is consistent with a positive relationship between confrontation and overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Alternatively, acceptance-resignation was negatively associated with overall DSM performance [38], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [12 30 34]. Avoidance had negative effects on taking medications [12 30] and regulating highs and lows in blood glucose [30].

One cross-sectional study provided evidence for the role of DSM-related behavioral skills as a mediator between DSM-related information, motivation, and DSM behaviors. Information on demographics, provider-patient communication, social support, and self-efficacy, and diabetes self-care was collected among 222 participants with T2D in Shanghai. There were significant, positive, direct paths from self-efficacy (β=.41, p<.001), social support (β=.19, p=.007), and provider-patient communication (β=.12, p=.037) to DSM behaviors. Paths from provider-patient communication to self-efficacy (β=.23, p<.001) and from social support to self-efficacy (β=.19, p<.05) were significant and positive. Structural equations modeling showed that self-efficacy mediated the effects of social support (indirect effect β=.08, p=.008) and provider-patient communication (indirect effect β=.09, p=.002) on DSM behaviors [11]. Overall, the study provided support for the specific direct and mediating relationships between DSM-related information, motivation, behavioral skills, and DSM behaviors. However, one limitation of this study is that the adapted IMB model does not include all relevant constructs. For example, information on personal motivation was not collected. Therefore, the study only partially tested the IMB model.

DSM behaviors. DSM behaviors primarily include dietary changes, weight loss, and increased physical activity, SMBG, foot care, and taking prescribed medications. Based on the guidelines of the American Diabetes Association [9], individuals with T2D are encouraged to increase intake of whole grains, fiber, vegetables, and fruits, and reduce intake of total and saturated fat, sugar-flavored beverages, and high calorie snacks. They are also encouraged to engage in 150 min or more of moderate-to-vigorous intensity physical activity per week, and lose about 5%-7% of initial body weight if these individuals are overweight/obese.

Health outcomes. The IMB-DSM model asserts that DSM behaviors are directly linked to health outcomes, which has been well supported in the literature. Since adults with T2D are two to four times more likely to have cardiovascular disease (CVD) than adults without T2D [9], monitoring cardiometabolic markers is essential in the clinical management of patients with T2D. In the proposed study, blood pressure and blood lipids are measured to identify subsequent CVD risks among adults with T2D. The health outcomes include hemoglobin A1c (HbA1c), blood pressure, blood lipids, and diabetes-dependent

quality of life. DSM behaviors had a direct effect on glycemic control (β=-.02, p=.007) [28], total cholesterol (TC)/high-density lipoprotein cholesterol (HDL-C) (β=-.31, p<.001), and low-density lipoprotein cholesterol (LDL-C)/HDL-C (β=-.30, p<.001) [11]. It is not clear whether DSM behaviors are directly related to blood pressure in Chinese adults with T2D, and this will be examined in this study. Compared to the general population, people affected by T2D consistently reported diminished health-related quality of life [39]. However, the relationship between DSM behaviors and health-related quality of life has not been systematically studied among Chinese adults with T2D, and this study will fill the knowledge gaps.

Moderators. The IMB-DSM model postulates that certain personal characteristics may act as moderators that influence the associations of the model constructs with DSM behaviors, and that the degree of moderation depends on the level or intensity of the moderator. High levels of moderators are assumed to directly influence DSM behaviors, whereas lower levels of moderators are assumed to work through the IMB-DSM model constructs to influence DSM behaviors and not obscure the relationships between these constructs and DSM behaviors. These moderators include depressive symptom, female gender, and educational level.

Depressive symptoms have been consistently found to negatively affect DSM behaviors, such as SMBG, foot care, diet modification, regulating highs and lows in blood glucose, and overall DSM performance in these studies [40-42]. Generally, female patients had better overall DSM performance than their male counterparts [12 43]. People with a higher educational level tended to manage their diabetes better, compared to people with lower educational level [24 32 44]. Because existing studies investigating factors associated with DSM are primarily univariate in nature, they generally address only one aspect of the IMB-DSM model, that is, they establish support for a direct relationship between DSM behaviors and DSM-related information, motivation, or behavioral skills. So far, no studies have been conducted to systematically evaluate how potential moderators may influence the relationship among variables in the IMB-DSM model, and this study is expected to fill those knowledge gaps.

Objectives

In the proposed study, we will refine and test longitudinally a culturally tailored IMB-DSM among 250 Chinese adults residing in Chengdu, China.

Aim 1: In Chinese adults with T2D, to determine which baseline variables are most strongly related to baseline DSM behaviors, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education.

Research question (RQ): Among baseline DSM-related information, motivation, and behavioral skills, which is most strongly related to baseline DSM behaviors?

Aim 2: To examine the feedback loop as described in the original IMB model by investigating the relationships between baseline health outcomes (HbA1c, blood pressure, blood lipids, and diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up period, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education at baseline.

RQ1: What is the relationship between baseline HbA1c levels and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ2: What is the relationship between baseline blood pressure and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ3: What is the relationship between baseline blood lipids and DSM-related information, motivation, and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ4: What is the relationship between baseline diabetes-dependent quality of life and DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

Aim 3: In Chinese adults with T2D, to examine mediating and moderating factors associated with DSM behaviors at baseline and the 3 month follow-up period.

Research Question 1: Are behavioral skills (diabetes self-efficacy and coping strategies) mediators of DSM behaviors at baseline and 3-month follow-up period?

Research Question 2: Are depressive symptoms, female gender, and educational level as moderators of DSM behaviors at baseline and 3-month follow-up period?

Methods and Analysis

Design

A descriptive, repeated-measure design is used to examine the relationships among variables in the IMB-DSM model, the role of variables in predicting baseline DSM behaviors, the potential moderators and mediators, and investigate the relationship between baseline health outcomes and DSM-related information, motivation, behavioral skills and subsequent DSM behaviors at three-month follow-up. Data will be collected at two time points, 3 months apart. Since HbA1c is considered the gold standard for monitoring glycemic control and reflects a person's glucose control for the preceding 8 to 10 weeks [9], three-month of observation is deemed long enough to reflect the glucose control.

Sample and Setting

This study will be conducted in Chengdu metropolitan area, which is the provincial capital of Sichuan province in Southwest China. One community health center will be selected from each of six urban districts in Chengdu metropolitan area: the Yulin community health center in Wuhou District, the Supo community health center in Qingyang District, the Longzhoulu community health center in Jinjiang District, the Caojiaxiang community health center in Jinniu District, the Shuanglin community health center in Chenghua District, and the Guixi community health center in Gaoxin District. The inclusion criteria for participation in the research are: (a) diagnosed with T2D; (b) able to read, write, and speak Chinese; (c)$\geqslant$18 years of age; (d) a score of the Chinese version of Mini-Mental State Examination (C-MMSE) > 24 (see **Screening** below); (e) no other chronic physical or mental disorders; and (f) mentally competent to give informed consent. Patients will be excluded if they are pregnant, have been diagnosed with cancer or organ failure, refuse to participate in the proposed study, self-identified bilateral hearing loss, or cognitive impairment (inability to comprehend the informed consent).

Sample Size

The Power Analysis and Sample Size Software was used for sample size calculation. Sample size was calculated based on the weakest correlation among all the tested variable pairs, that is, diabetes

knowledge and social support (r=.197). Assuming 80% power, type I error rate of .05, and attrition rate of 20%, a total of 250 participants will be needed to detect the correlation coefficient of .197. This sample size will have a higher power to detect correlations with larger coefficient.

Participant Recruitment

The research team will actively recruit participants from six selected community health centers. The principal investigator and her undergraduate mentors have established relationships with these community health centers and will be able to facilitate recruitment from these sites. An electronic medical database of the residents kept each community health center will also be used to identify patients with T2D in these communities. The research team will also have access to the database from which participants can be recruited.

Once the approval from the Ethics Committees for Clinical Trials and Biomedical Research in the Fourth People's Hospital of Chengdu is obtained, patients who come to the local clinics for evaluations and care will be approached after agreeing to hear about the study by a research staff member, who will explain the study, provide a consent form for review, answer questions and seek their participation. Subjects who agree to participate will be screened on inclusion criteria. Screening (see Screening below) will take about 10 minutes. Those who meet study criteria will be entered into the study. In addition, advertisements about the study will be placed on buses and subways. Those interested in the study will be invited to the study site and asked to participate after reviewing study procedures and consent forms. Weekly and monthly recruitment goals will be set to ensure adequate progress on participant enrollment. If recruitment is slow, recruitment procedures will be reviewed, problems identified, and adjustments will be made so that participant accrual is conducted at a satisfactory rate.

Screening

A questionnaire will be used to assess participants' eligibility with questions on age, length of diabetes, period of time when starting diabetes treatment, provider referral, and willingness to participate. Since this population is at risk for cognitive impairment that may, in some cases, limit their capacity to provide consent [45], the C-MMSE will be administered to evaluate global cognitive functioning of all

eligible participants. The C-MMSE has been used among Chinese adults with T2D [46]. Those who obtain a score <=23 will be excluded because subjects with such low scores were considered to have possible dementia [47]. Potential participants with serious cognitive problems will be referred immediately to a mental health professional used by the respective community health centers.

Reducing Attrition

There will be a potential problem with attrition of the proposed study because the 3 month follow-up for this longitudinal study design opens up to the problem of attrition. Steps that will be taken to reduce attrition include: informing subjects of the importance of continued participation in all aspects of the study; giving a subject incentive of ¥155 (about $25) Walmart gift card per completed data collection session; making telephone calls and sending a reminder card prior to scheduled data collections. A participant locator form will be completed for each subject entered in the study and at all data collection sessions to ensure proper contact information for follow-up visit is maintained.

Data Collection and Procedures

After consenting to participate, each subject will be requested to come to the study site for baseline data collection in a private office at the research site. Baseline data collection will include administration of the following questionnaires: Demographic Data Form, the Diabetes Knowledge Questionnaire, the Health Education Form, the Provider-Patient Communication Scale, the Health Belief Scale, the Social Support Rating Scale, the Diabetes Self-Efficacy Scale, the Medical Coping Modes Questionnaire, the Diabetes Self-Care Scale, the Self-rating Depression Scale, and the Audit of Diabetes-Dependent Quality-of-Life. At the 3 month follow-up data collections, all the measures will be administered again except the Demographic Data Form. Data collection from each participant should take about 60 minutes. The instruments will be administered by a trained research assistant as an interview to reduce respondent burden and to standardize the approach due to the differing response formats. If the participant becomes fatigued, the battery of questionnaires may be completed in two sessions.

Training of Data Collectors

In an effort to improve inter-rater reliability, data collectors will be trained to collect data for baseline and follow-up data collections. They will attend intensive training sessions at the beginning of the project, and periodic refresher sessions will be offered every 2 to 3 weeks to reinforce the basic training. Data collectors will practice conducting data collections and blood pressure measurement and these sessions will be monitored and each data collector will be certified. To control for measurement error, a data collection protocol manual will be developed that will include data collection protocol related specifically to each questionnaire and blood pressure measurement. The specific measures, including instruments and physical biomarkers, that will be used in this study are described below.

Instruments

Demographics. This questionnaire is designed to collect background data from participants on their demographic characteristics, including age, gender, income, education, marital status, length of diabetes, health insurance, current treatment plan for diabetes, and relevant health history indicators.

The diabetes knowledge questionnaire. Diabetes knowledge in Figure 1 will be measured with the Chinese version of the Diabetes Knowledge Scale adapted from the Diabetes Knowledge Scales [48]. The Chinese version of the Diabetes Knowledge Scale consists of 14 items. Participants receive a score of 1 for a correct answer or 0 for an incorrect or unknown answer. The total score ranges from 0 to 14, with a higher score indicating a higher level of diabetes knowledge. The Cronbach's alpha for the Chinese version of the knowledge measure was .62. The diabetes knowledge score in the Chinese sample was significantly higher in the group with more education ($t[28]=2.83$, $p< .01$), indicating that the Chinese version had satisfactory construct validity [49].

The health education form. Information on health education in Figure 1 is based on self-reports. All participants will be asked if they have had received any form of diabetes education. If the answer is YES, the patient should answer the source of diabetes education. The source of diabetes education could be health care professionals, community consulting service, journals/books, TV/radio, internet and others.

The provider-patient communication scale. Provider-patient communication in Figure 1 will be measured by the Provider-Patient Communication Scale. The scale consists of 5 items with a scoring

range from 0 to 6, where 0 indicates "strongly disagree" and 6 indicates "strongly agree". High scores characterize a person who is confident in their ability to communicate with healthcare professionals and has good understanding of ways to access healthcare in order to get their needs met. The Cronbach's alpha coefficient is reported at .929, indicating excellent internal consistency [11].

The health belief scale. Health beliefs (i.e., personal motivation in Figure 1) refer to one's perceptions about T2D and how it can be treated [50]. The Health Belief Scale was developed based on the Health Belief Model by Yamei Chen [50]. The 20-item scale comprises 5 subscales (perceived susceptibility, perceived benefits, perceived severity, perceived barriers, and cues to action) and uses a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score represents stronger health beliefs. The content validity index is .81, the test-retest reliability ranges from .78 to .82, and the Cronbach's alpha is .79 [50].

The social support rating scale. Social support (i.e., social motivation in Figure 1) will be assessed by the Social Support Rating Scale [51]. The 10-item instrument measures aspects of objective social support (3 items), subjective social support (4 items) and usage of social support (3 items). The item scores range from 14 (worst possible social support) to 66 (best possible social support) [51]. The test-retest reliability coefficient and the internal consistency of the scale are .92 and .88-.94, respectively [32].

The diabetes self-efficacy scale. Diabetes self-efficacy in Figure 1 will be measured with the 7-item Chinese version of the Diabetes Self-Efficacy Scale, which evaluates participants how capable they are when performing DSM activities. The items are scored on a 5-point Likert-type scale, with higher scores indicating higher self-efficacy in performing DSM behaviors. The Chinese version of the Diabetes Self-Efficacy Scale has a Cronbach's alpha of .87. Factor analysis showed that seven items loaded on five factors, which explains 97.9% of the variance, and the five factors are consistent with confidence in performing the five aspects of DSM behaviors [49].

The medical coping modes questionnaire. Coping strategies in Figure 1 will be measured by the 20-item Chinese version of the Medical Coping Modes Questionnaire. It assess 3 forms of coping strategies associated with chronic illness: confrontation, avoidance, and acceptance-resignation [52]. Items

are answered on a four-point Likert scale ranging from 1 (never) to 4 (very often). Scores from the three subscales are compared, and the highest score indicates the corresponding dominant pattern of coping utilized by the participant. The Cronbach's alpha for the confrontation, avoidance, and acceptance-resignation subscales is reported at .69, .60, .76, respectively [52].

The diabetes self-care scale. DSM in Figure 1 will be measured by the 26-item Diabetes Self-Care Scale, which is comprised of 6 subscales: diet modification, taking medications, SMBG, foot care, physical activity, and regulating highs and lows in blood glucose. Responses for each item range from 1 (never) to 5 (very often). Total score can range from 26 to 130 by adding up scores of 6 subscales, with higher scores indicating better overall DSM performance. The construct validity is .68, and the Cronbach's alpha is .87 [53].

The self-rating depression scale. Depressive symptoms in Figure 1 will be assessed using the Self-Rating Depression Scale, a 20-item self-administered questionnaire [54]. Each item is rated on a four-point Likert scale, ranging from 1 (very seldom) to 4 (most of the time) and computed as an original score, then multiplied by 1.25 to get the standard score. A score ranges from 53 to 62 indicates mild depressive symptoms, a score ranges from 63 to 72 indicates moderate depressive symptoms, and a score higher than 72 indicates severe depressive symptoms [55].

The audit of diabetes-dependent quality of life. Diabetes-related quality of life in Figure 1 will be measured by the Chinese version of Audit of Diabetes-Dependent Quality of Life, which measures both generic and diabetes-specific quality of life. The first two overview items assess generic quality of life on a seven-point Likert scale (-3 [extremely bad] to 3 [excellent]) and quality of life without diabetes. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how their quality of life would be if they did not have diabetes. The subsequent 19 items evaluates diabetes-specific quality of life. A five-point scale (-3 to +1) measures the impact of diabetes by asking patients how particular aspects of their life would be if they did not have diabetes. The importance of each aspect on their life is rated on a four-point scale (0 to 3). The two ratings are multiplied and summed for a final impact score that ranges from -9 to 3, where more negative scores indicate worse quality of life. A score of 0 is assigned to

"unimportant" domains, regardless of the magnitude of its impact. Similarly, a score of 0 is assigned to items with no impact of diabetes, regardless of their importance to quality of life. The average weighted rating score is obtained by dividing the sum of weighted ratings for applicable domains by the number of the applicable domains. Strong reliability (Cronbach's alpha=.941) has been reported [56]. Factor analysis showed that all items had high performance in the structural validity evaluation, with most factor loading values being larger than .40 (varied from .44 to .88) [56].

Physical Markers

Physical markers include HbA1c, blood pressure, and blood lipids. All blood samples will be processed at the Clinical Laboratory of the Fourth People's Hospital of Chengdu. After collection, the fresh venous blood samples will be immediately transported at 4°C temperature to the Clinical Laboratory within 2 hours. The samples will then be placed in a deep freezer and stored at -80°C until assays start.

HbA1c. HbA1c will be used as a marker of T2D and glycemic control and will be analyzed from whole blood samples (4 ml). Analysis will be conducted using high performance liquid chromatography, with standardization through commercial available assays (coefficient of variation<2%).

Blood pressure. Blood pressure will be obtained by a trained nurse using a standard sphygmomanometer for a minimum of 2 consecutive readings at intervals of at least 1 minute. The patient should be seated comfortably with the back supported and the upper arm bared, without constrictive clothing. The legs should not be crossed. The arm should be supported at the heart level, with the bladder of the cuff encircling at least 80% of the arm circumference. The mercury column should be deflated at 2 to 3 mm/s, and the first and last audible sounds should be taken as systolic and diastolic pressure. The column should be read to the nearest 2 mmHg. Neither the patient nor the observer should talk during the measurement procedure. The average of those readings will be used to represent the patient's blood pressure.

Blood lipids. Blood lipids include TC, HDL-C, LDL-C, and triglycerides (TG). Analysis of blood lipids will be conducted using enzymatic colorimetric test, with standardization through

commercial available assays (coefficient of variation<2%). Fasting serum samples will be collected in the morning after 8 hours fasting.

Data Analyses

Data analyses for Aim 1: Linear regression models will be applied to assess the associations between baseline DSM behaviors and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 2: Linear regression models will be applied to assess the associations between baseline health outcomes (i.e., HbA1c, blood pressure, blood lipids, diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and DSM behaviors at 3 months follow-up, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 3: Both baseline and 3-month follow-up measures will be used for Aim 3. Structural equation modeling will be used to explore the fit of the data to the IMB-DSM model. Data will be first assessed whether they meet the assumptions of maximum likelihood estimation of structural equation modeling. Then, hypotheses regarding structural relations among the IMB-DSM model constructs will be evaluated with an inspection of the direction and magnitude of the path coefficients (direct effects) and indirect effects, which indicate mediation. Significant indirect effects occur when the relationship between a predictor and an outcome is due to the predictor being associated with a third variable (i.e., all or part of the direct effect of A on C is due to a relationship between A and B). Criteria used to test the structural model will be the comparative fit index (≥.95 indicates good fit), the root mean square error of approximation (≤.06 with confidence interval .00-.08 indicates good fit), and the standardized root mean square residual (<.08 indicates acceptable fit, and 0 indicates perfect fit) [57]. Agreement between multiple indices provides the best support a model has good data fit [57]. Moderators will be tested by doing multi-group testing in AMOS 23, a structural equation modeling program. To examine whether depressive symptoms, female gender, and educational level moderate the relationships

in the model, multi-group analysis will be used comparing a constrained model (i.e., a model in which the coefficients are set equal across the groups) with an unconstrained model (i.e., a model in which these coefficients are allowed to vary freely). A significant difference between these two models implies that there are significant differences among the groups. A series of nested models will be tested to see where the differences are.

Ethics and Dissemination

The study poses little to no risk to participants and their families. Signed informed consent will be obtained from all participating families. Participation in the study does not interfere with the usual care patients receive in the primary care settings. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals.

Patient and Public Involvement

The development of the research question and outcome measures were informed by previously published research studies that engaged patients' experience. We did not involve patients in the study design, recruitment, and conduct of the study. Both the baseline and three-month outcomes on blood pressure, HbA1c, and blood lipids will be mailed to each participant. After we finish the data analysis, we will present the study findings in lay terms to study participants who were enrolled in our study.

Figure Legend

Figure 1. The DSM-IMB Model

Contributorship statement

All authors contribute to the conception and design of this study. TL, CL, and DW drafted the manuscript. JW, RY, and SG revised the manuscript. All authors approved the final version to be submitted to the journal.

Competing interests statement:

None declared.

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Data sharing statement:

We have not yet collected data. Once data collection is finished, the individual de-identified participant data (including data dictionaries) will be shared. The shared data will include demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. The data will become available as soon as we collect all data and for one year.

References

1. International Diabetes Federation. IDF diabetes atlet, 8th edition 2017 [Available from: http://www.diabetesatlas.org/across-the-globe.html accessed Nov 28, 2017.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *JAMA : the journal of American Medical Association* 2013;310:948-59. doi: 10.1001/jama.2013.168118 [published Online First: 2013/09/05]

3. Centers for Disease Control and Prevention. Awareness of prediabetes--United States, 2005-2010. *Morbidity and mortality weekly report* 2013;62(11):209-12. [published Online First: 2013/03/22]

4. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943-49. [published Online First: 1995/07/01]

5. Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-92. [published Online First: 1999/12/10]

6. Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. *Journal of diabetes and metabolic disorders* 2013;12:14. doi: 10.1186/2251-6581-12-14 [published Online First: 2013/03/19]

7. 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(7):1159-71. [published Online First: 2002/06/28]

8. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educator* 2008;34:815-23. doi: 10.1177/0145721708323640 [published Online First: 2008/10/04]

9. American Diabetes Association. 4. Lifestyle management: Standards of medical care in Diabetes-2018. *Diabetes care* 2018;41:S38-S50. doi: 10.2337/dc18-S004 [published Online First: 2017/12/10]

10. Sun X, Huang X, Yuan C, et al. The influence of health belief and coping style on self-management behavior in patients with type 2 diabetes mellitus [Chinese]. *Journal of Nursing (China)* 2012;19(1A):8-11.

11. Gao J, Wang J, Zhu Y, et al. Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC public health* 2013;13:100. doi: 10.1186/1471-2458-13-100 [published Online First: 2013/02/06]

12. Yu P. The relationship between coping strategy, health beliefs and self-management among people with type 2 diabetes in Changsha [Master thesis]. Central South University, 2009.

13. Fisher WA, Fisher JD, Harman J. The information-motication-behavioral slills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social psychological foundations of health and illness. Malden, MA: Wiley-Blackwell 2003:82-106.

14. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychological bulletin* 1992;111(3):455-74. [published Online First: 1992/05/01]

15. Fisher JD, Fisher WA, Amico KR, et al. An information-motivation-behavioral skills model of adherence to antiretroviral therapy. *Health Psychology* 2006;25:462-73. doi: 10.1037/0278-6133.25.4.462 [published Online First: 2006/07/19]

16. Huang J, Liu Y, Zhang Y, et al. Correlation between self-management and knowledge of and attitude to diabetes in type 2 diabetic patients in Changsha [Chinese]. *Journal of Central South University (Medical Sciences)* 2013;38:176-81. doi: 10.3969/j.issn.1672-7347.2013.02.011 [published Online First: 2013/03/05]

17. Kong L, Ye Y, Ding F, et al. The relationship between diabetes knowledge, self-efficaicy, and self-management practice among individuals with type 2 diabetes in community [Chinese]. *Journal of Hubei University of Science and Technology* 2013;27(4):334-38.

18. Wang X, Lv W, Ding Y, et al. Study on correlation between self-management behaviors of elderly type 2 diabetic patients and diabetes knowledge level [Chinese]. *Chinese Nursing Research* 2013;27(9):2973-74.

19. Quan J. The research about the current status and influencing factors of self-management behavior in middle-aged and over patients who with type 2 diabetes mellitus [Master thesis]. Yanbian University, 2013.

20. Wang X, Lan W, Liu J, et al. Evaluation analysis of influencing factors of type II diabetes patients self-management in Shanxi Province [Chinese]. *Journal of Qiqihar Medical College* 2012;33(8):1065-69.

21. Hu J, Gruber KJ, Liu H, et al. Diabetes knowledge among older adults with diabetes in Beijing, China. *Journal of clinical nursing* 2013;22:51-60. doi: 10.1111/j.1365-2702.2012.04273.x [published Online First: 2012/12/12]

22. Xu Y, Toobert D, Savage C, et al. Factors influencing diabetes self-management in Chinese people with type 2 diabetes. *Research in nursing & health* 2008;31:613-25. doi: 10.1002/nur.20293 [published Online First: 2008/07/10]

23. Jia Y, Wang J, Liu W. Study on self-care level of patients with type 2 diabetes mellitus and analysis of related factors [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2005;22(7):21-23.

24. Meng F. Research on health education and self-managing level of community non-insulin dependent diabetic patients [Master thesis]. Sun Yat-Sen University, 2010.

25. Wang L, Zhang J. Self-management of elderly patients with type 2 diabetes and its influencing factors [Chinese]. *Journal of Nursing (China)* 2012;19(4A):39-42.

26. Guo XH, Yuan L, Lou QQ, et al. A nationwide survey of diabetes education, self-management and glycemic control in patients with type 2 diabetes in China. *Chinese medical journal* 2012;125(23):4175-80. [published Online First: 2012/12/12]

27. Wang J, Zhang X. Survey of self-care behavior among 2 type diabetes patients [Chinese]. *Journal of Nurses Training* 2002;17(9):663-65.

28. Gao J, Wang J, Zheng P, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. *BMC family practice* 2013;14:66. doi: 10.1186/1471-2296-14-66 [published Online First: 2013/05/28]

29. Osborn CY, Egede LE. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient education and counseling* 2010;79:49-54. doi: 10.1016/j.pec.2009.07.016 [published Online First: 2009/08/25]

30. Sun X, Huang X, Yuan C, et al. The relationship between coping strategy and self-management behavior among patients with type 2 diabetes [Chinese]. *Journal of Nurses Training* 2012;27(12):1084-86.

31. Du L, Lin T, Liu X. Study on correlation between social support and self-care behavior of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2012;388(26):697-99.

32. Huang M, Zhao R, Li S, et al. Self-management behavior in patients with type 2 diabetes: A cross-sectional survey in western urban China. *PloS one* 2014;9(4):e95138. doi: 10.1371/journal.pone.0095138 [published Online First: 2014/04/20]

33. Wan Q, Shang S, Liu Y, et al. A study of factors of the self-care behaviors of the elderly with type 2 diabetes [Chinese]. *Chinese General Practice* 2003;6(8):659-62.

34. Fang S, Yu Z, Tao Y. The relationship between coping strategy, self-efficacy, and diabetes self-management among people living in rural areas [Chinese]. *World Health Digest Medical Periodical* 2013;10(23):79-80.

35. Gao H. The relationship between diabetes self-efficacy and self-care behavior in patients with type 2 diabetes [Chinese]. *Jilin Medical Journal* 2012;33(35):7646-47.

36. Jia Y, Gong T, Sang M. Investigating on self-management and self-efficacy of patients with type 2 diabetes mellitus [Chinese]. *Modern Nursing* 2005;11(19):1586-88.

37. Wang JQ, Tak-Ying Shiu A. Diabetes self-efficacy and self-care behaviour of Chinese patients living in Shanghai. *Journal of clinical nursing* 2004;13:771-72. doi: 10.1111/j.1365-2702.2004.00918.x [published Online First: 2004/08/20]

38. Wan Q, Wang Q, Shang S. Correlation of self-management behavior and coping patterns of patients with type 2 diabetes [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2008;25(1B):18-21, 23.

39. Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in type 2 diabetes patients. *Quality of life research* 2007;16:165-77. doi: 10.1007/s11136-006-9105-0 [published Online First: 2006/10/13]

40. Jia Y, Wang J, Teng X. Study on the correlation between psychological health level and self-management in patients with type 2 diabetes mellitus [Chinese]. *Shanghai Nursing* 2004;4(4):1-3.

41. Lin T, Lin X, Wan L. A study on correlation between self-care behavior and psychological concordance and depression of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2009;23(1A):22-24.

42. Wang Q, Wan Q, Shang S. Correlation of self-management behavior and depression in patients with type 2 diabetes [Chinese]. *Journal of Nursing Science* 2009;24(7):14-15.

43. Lin T, Wang J, Qin X. Study on self-care behaviors and its related factors in patients with type 2 diabetes [Chinese]. *Chinese Journal of Modern Nursing* 2008;14(11):1254-56.

44. Xia Z, Yang T. Diabetes self-management behaviors and related factors among patients with type 2 diabetes in Xiuying District, Haikou [Chinese]. *Seek Medical and Ask the Medicine* 2011;9(11):526-27.

45. Cheng G, Huang C, Deng H, et al. Diabetes as a risk factor for dementia and mild cognitive impairment: A meta-analysis of longitudinal studies. *Internal medicine journal* 2012;42:484-91. doi: 10.1111/j.1445-5994.2012.02758.x [published Online First: 2012/03/01]

46. Chen Y, Liu Z, Zhang J, et al. Altered brain activation patterns under different working memory loads in patients with type 2 diabetes. *Diabetes Care* 2014;37:3157-63. doi: 10.2337/dc14-1683 [published Online First: 2014/11/19]

47. Zhang M. Users' guide for psychiatric scales. Changsha, China: Human Sciences & Technology Publishing House 2003.

48. Beeney LJ, Dunn SM, Welch G. Measurement of diabetes knowledge: The development of the DKN scales. In: Bradley C, ed. Handbook of psychology and diabetes. New York, NY: Psychology Press 2003:159-89.

49. Xu Y, Savage C, Toobert D, et al. Adaptation and testing of instruments to measure diabetes self-management in people with type 2 diabetes in mainland China. *Journal of transcultural nursing : official journal of the Transcultural Nursing Society / Transcultural Nursing Society* 2008;19:234-42. doi: 10.1177/1043659608319239 [published Online First: 2008/06/27]

50. Chen Y. Study on compliance and influence factors of the re-hospitalized patients with diabetes mellitus. [Master thesis]. Central South Universtiy, 2007.

51. Yao S, Wu D. Psychological health rating scale. In: Yao S, ed. Psychological Assessment Beijing, China: People's Medical Publishing House 2008:89-126.

52. Shen X, Jiang Q. Report on application of Chinese version of MCMQ in 701 patients [Chinese]. *Chinese Journal of Behavioral Medican Science* 2000;9(1):18-20.

53. Wang JS, Wang RH, Lin CC. Self-care behavior and related factors in outpatients newly diagnosed with non-insulin-dependent diabetes mellitus [Chinese]. *Journal of Nursing (Taiwan)* 1998;45(2):60-74. [published Online First: 1999/01/15]

54. Zung WW. A self-rating depression scale. *Archives of general psychiatry* 1965;12:63-70. [published Online First: 1965/01/01]

55. Tang P. Medical Psychology. Beijing, China: People's Medical Publishing House 2009.

56. Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. *Diabetes research and clinical practice* 2011;94:45-52. doi: 10.1016/j.diabres.2011.05.026 [published Online First: 2011/06/21]

57. Kline RB. Principles and practices of structural equation modeling. 3 ed. New York, NY: The Guilford Press 2010.

Figure 1. The DSM-IMB Model

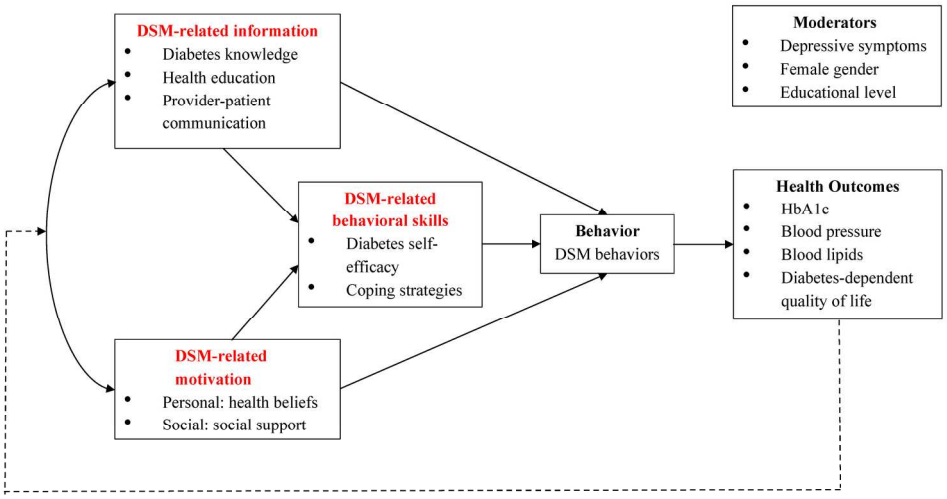

Figure 1. The DSM-IMB Model

190x142mm (300 x 300 DPI)

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A protocol of a three-month follow-up study

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Testing the information-motivation-behavioral skills model of diabetes self-management among Chinese adults with type 2 diabetes: A protocol of a three-month follow-up study

Tingting Liu, Dongmei Wu, Jing Wang, Changwei Li, Rumei Yang, Song Ge, Yan Du, Yanyan Wang

Correspondence should be made to:

Tingting Liu, PhD, RN

Department of Epidemiology

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

Postal address: 1440 Canal St, Suite 2000, New Orleans, LA, 70112

Email: tliu10@tulane.edu

Tel: 479-575-4885

Fax: 479-575-3119

The full names, institutions, city, and country of all other co-authors:

Tingting Liu*, PhD, RN

University of Arkansas Eleanor Mann School of Nursing, Fayetteville, AR, USA

Dongmei Wu*, PhD, RN

Psychiatric Research Laboratory

The Fourth People's Hospital of Chengdu, Chengdu, Sichuan Province, China

Jing Wang, PhD, MPH, RN, FAAN

UT Health San Antonio School of Nursing, San Antonio, TX, USA

Changwei Li, PhD, MD, MPH

Department of Epidemiology and Biostatistics,

University of Georgia College of Public Health, Athens, GA, USA

Rumei Yang, MS, RN

University of Utah College of Nursing, Salt Lake City, UT, USA

Song Ge, BSN, RN

Johns Hopkins University School of Nursing, Baltimore, MD, USA

Yan Du, PhD, RN

Department of Biostatistics

Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA

Yanyan Wang, PhD, RN

National Clinical Research Center for Geriatrics

West China Hospital, Chengdu, China

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Drs. Tingting Liu and Dongmei Wu contributed equally to this manuscript.

Abstract

Introduction: Currently, China leads the world in the number of people with diabetes, making it home to one third of the global diabetic population. Persons with diabetes have to carry out 95% of their self-care. As an important component of diabetes care, diabetes self-management is defined as everyday behaviors that persons carry out to control diabetes. Consistent findings have been reported that level of compliance to suggested diabetes self-management behaviors is not considered optimal among Chinese adults with type 2 diabetes. The underlying reasons for suboptimal diabetes self-management behaviors among Chinese adults are not well known and no conceptual model has been developed to guide diabetes self-management interventions in this population. Although the information-motivation-behavioral skills model has been tested among Chinese adults with type 2 diabetes, some key components of the original model were not tested. In this proposed study protocol, we will refine and test a culturally tailored model of diabetes self-management longitudinally among 250 Chinese adults residing in China.

Methods and Analysis: This is a descriptive, repeated-measure study to be conducted at a tertiary hospital in Chengdu, China. A total of 250 adults with type 2 diabetes will be enrolled and followed for 3 months in this study. Information of multiple domains will be collected, including demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. Main analyses comprise linear regression modeling controlling for covariates and structural equation modeling.

Ethics and Dissemination: Ethical approval has been obtained through the Fourth People's Hospital of Chengdu Research Ethics Committee (study approval number 2017017). We aim to disseminate the findings through international conferences, international peer-reviewed journals and social media.

Study registration number: ChiCTR-ROC-17013592.

Strengths and limitations of this study

- This study will recruit and follow-up Chinese adults with diabetes for 3 months, and test the information-motivation-behavioral skills model of diabetes self-management longitudinally for the first time.
- This study relies primarily on self-reported measures, and objective, observable levels of diabetes self-care behaviors should be used in future studies.
- The study will be conducted in Chengdu, a city in southwestern China, and therefore the findings of the study may not be generalized to other parts of China, and the chosen centers are not from areas that are representative of the general Chinese population in regards to socioeconomic status.
- This is a descriptive, repeated-measure study. A randomized controlled trial with a group of patients receiving no DSM interventions would have been desirable to test the model.

Introduction

Diabetes is a global public health challenge because of its high prevalence and associated mortality and morbidity. The estimated number of individuals with diabetes is estimated to increase from 425 million in 2017 to 649 million in 2045 worldwide, with over 75% of diabetics residing in low- and middle-income countries [1]. The most comprehensive nationwide survey showed that approximately 114 million (11.6%) Chinese adults in total had diabetes in 2010, and this was a two-fold rise over the past decade [2]. About 90% to 95% of people with diabetes have type 2 diabetes (T2D) [3]. Individuals with T2D carry out 95% of their diabetes care [4]. Diabetes self-management (DSM) is therefore an important part of diabetes care, and is defined as daily behaviors that persons carry out to control T2D, including self-monitoring blood glucose (SMBG), dietary changes, engaging in regular physical activity, diabetes foot care, managing high or low blood glucose, taking prescribed medications, and smoking cessation [5 6]. DSM is complex, and involves major lifestyle changes which need to become part of a person's daily routine and require high levels of adherence to these lifestyle changes are also expected [7].

Mounting evidence has consistently demonstrated that better DSM was associated with improved health outcomes, including lower hemoglobin A1c (HbA1c) levels [8], better quality of life [9], and decreased incidence of diabetes-related complications [10]. It has been reported that persons with diabetes can make a great impact on the progression of diabetes by performing their own care. However, adherence to some of DSM behaviours has been found to be low, especially when looking at behavioural long-term changes [11]. This suggests a critical need for a comprehensive and well-tested conceptual model to guide future DSM interventions.

Although the information-motivation-behavioral skills (IMB) model has been tested among Chinese adults with T2D [12], some key components of the original IMB model were not tested. For example, it is well known that personal motivation, such as health beliefs, may influence DSM among Chinese adults [13]. Additionally, important moderators known to influence DSM in Chinese adults such as depressive symptoms, female gender, and educational level were not included in the model [12], and this may add important insights into DSM specific to this population. Therefore, a revised conceptual model

based on the IMB model is needed to take account the effects of the interactive relationships among these related factors. The proposed IMB-DSM model will help fill this gap by examining the potential moderators of DSM in this population, so that intervention studies based on this model will not only show whether the intervention works, but also why the it works and under what conditions the it works.

Conceptual Framework

Overview of the IMB model. The IMB provided the theoretical basis for this study. The IMB model is used to frame these variables because: (a) the concepts from the IMB model can easily be translated into intervention components [14], and (b) the IMB model adequately captures essential concepts which have been well supported in the literature to improve DSM behaviors, including information (e.g., diabetes knowledge), motivation (e.g., social support), and behavioral skills (e.g., diabetes self-efficacy). The model postulates that individuals are more likely to take health-related actions, such as DSM behaviors, if they are well informed, highly motivated (personally and socially), and have adequate and appropriate behaviors, and thus, experience positive health outcomes [15]. The model is based on three constructs: information, motivation, and behavioral skills. For behaviors that are complex such as DSM, information and motivation are thought to work largely through behavioral skills to initiate and maintain the behavior at focus, and the behavior is directly linked to health outcomes, which, in turn, are believed to affect one's maintenance of the behavior through a feedback loop that influence one's future levels of information, motivation, and behavioral skills overtime [16 17]. The IMB model further postulates that favorable health outcomes may strengthen an individual's information, motivation, and behavioral skills to perform the behavior in the future. In contrast, unfavorable health outcomes may cause an individual to lose confidence in his or her knowledge, motivation, and behavioral skills to perform the behavior overtime [17].

Overview of the IMB-DSM model. Figure 1 portrays the overarching conceptual framework of this study. The IMB-DSM model provides a comprehensive insight to examine the relationships that affect DSM and its related health outcomes, based on a systematic review of literature in this area. The framework consists of the following six key interrelated components: DSM-related information, DSM-

related motivation, DSM-related behavioral skills, DSM behaviors, health outcomes, and moderators. Consistent with the original IMB assumptions, the IMB-DSM model asserts that DSM-related information, motivation, and behavioral skills are fundamental determinants of DSM behaviors. DSM-related information and motivation are proposed to work primarily through behavioral skills to affect the initiation and maintenance of DSM behaviors. DSM behaviors lead to health outcomes, which, in turn, can influence one's future maintenance of the behavior through a feedback loop that affects one's levels of DSM-related information, motivation, and behavioral skills overtime. The proposed moderators can influence the relationship among the variables in the IMB-DSM model. Each part of the IMB-DSM is presented in detail below.

DSM-related information. DSM-related information is a necessary but insufficient prerequisite for DSM behaviors. The link between DSM-related information and DSM behaviors has been well established in the literature. DSM related information includes diabetes knowledge, health education, and provider-patient communication. A positive relationship was found between diabetes knowledge and overall DSM performance [18-20], exercise, foot care [21], diet control, or SMBG [22] in some studies, but not others [23 24]. A significantly positive relationship was reported between health education, overall DSM performance [25-27], and some specific DSM behaviors, such as diet modification, foot care, managing high or low blood glucose, SMBG, taking exercise, taking prescribed medications, smoking cessation [25 28 29]. Three studies examined the relationship between provider-patient communication and DSM behaviors, and found that better provider-patient communication was an independent, direct predictor of better overall DSM performance [12 24 30].

DSM-related motivation. Another fundamental determinant of DSM behaviors is an individual's motivation to perform DSM. Consistent with the IMB model, the IMB-DSM model posits that an individual's motivation includes personal and social motivation. Personal motivation to perform DSM refers to one's beliefs about the DSM behaviors and evaluations of the outcomes. Social motivation to perform DSM refers to one's perception about social support for DSM and one's motivation to adhere to important others [31].

In the IMB-DSM model, health beliefs are used to conceptualize personal motivation. Perceived susceptibility, perceived barriers, perceived benefits, or cues to action has each been related to overall DSM performance and all DSM behaviors except smoking cessation positively [13 32]. There was inconsistent evidence on the relationship between perceived severity and DSM behaviors. Yu [13] reported a negative association, whereas Sun and coworkers [11] reported a positive association. One possible explanation for the inconsistency between perceived severity and DSM behaviors involves the fact that both studies are cross-sectional. Thus, a person who is currently engaging in DSM behaviors may both perceive him- or herself as not being at risk and may report few feelings of severity. Alternatively, a person who is presently engaging in less DSM behaviors may report more feelings of severity and few risk-reduction efforts. The inconsistency warrants further investigations from longitudinal studies. Consistent findings have been reported between higher perceived social support and better overall DSM performance, diet control, taking medications, taking regular exercise, SMBG, diabetes foot care, and managing high or low blood glucose [12 21 24 33-35].

DSM-related behavioral skills. Behavioral skills involve objective and perceived skills for performing DSM behaviors and a feeling of confidence for doing so [31]. In the IMB-DSM model, behavioral skills include diabetes self-efficacy and positive coping strategy. A large number of studies has reported a consistent strong association between levels of self-efficacy and DSM behaviors, including diet modification, taking medications, foot care, taking regular exercise, SMBG, and managing high or low blood glucose [12 19 21 24 34 36-39]. Coping strategies have been well studied in this population. Research evidence is consistent with a positive relationship between confrontation and overall DSM performance [40], dietary modification, taking medications, foot care, physical activity, SMBG, or managing high or low blood glucose [13 32 36]. Alternatively, acceptance-resignation was negatively associated with overall DSM performance [40], dietary modification, taking medications, foot care, physical activity, SMBG, or regulating highs and lows in blood glucose [13 32 36]. Avoidance had negative effects on taking medications [13 32] and regulating highs and lows in blood glucose [32].

One cross-sectional study supported the role of DSM-related behavioral skills as a mediator between DSM-related information, motivation, and DSM behaviors. Data on demographics, provider-patient communication, social support, and self-efficacy, and diabetes self-care were collected among 222 participants with T2D in Shanghai. There were significant, positive, and direct paths from self-efficacy (β=.41, p<.001), social support (β=.19, p=.007), and provider-patient communication (β=.12, p=.037) to DSM behaviors. Paths from provider-patient communication to self-efficacy (β=.23, p<.001) and from social support to self-efficacy (β=.19, p<.05) were significant and positive. Structural equations modeling showed that self-efficacy mediated the effects of social support (indirect effect β=.08, p=.008) and provider-patient communication (indirect effect β=.09, p=.002) on DSM behaviors [12]. Overall, the study provided support for the specific direct and mediating relationships between DSM-related information, motivation, behavioral skills, and DSM behaviors. However, one limitation of this study is that the adapted IMB model does not include all relevant constructs. For example, information on personal motivation was not collected. Therefore, the study only partially tested the IMB model.

DSM behaviors. DSM behaviors primarily include dietary changes, weight loss, and increased physical activity, SMBG, foot care, and taking prescribed medications. Based on the guidelines of the American Diabetes Association [10], individuals with T2D are encouraged to increase intake of whole grains, fiber, vegetables, and fruits, and to reduce intake of total and saturated fat, sugar-flavored beverages, and high calorie snacks. They are also encouraged to engage in 150 min or more of moderate-to-vigorous intensity physical activity per week, and to lose about 5%-7% of initial body weight if these individuals are overweight/obese.

Health outcomes. The IMB-DSM model asserts that DSM behaviors are directly linked to health outcomes, which has been well supported in the literature. Since adults with T2D are two to four times more likely to have cardiovascular disease (CVD) than adults without T2D [10], monitoring cardiometabolic markers is essential in the clinical management of patients with T2D. In the proposed study, blood pressure and blood lipids are measured to identify subsequent CVD risks among adults with T2D. The health outcomes include HbA1c, blood pressure, blood lipids, and diabetes-dependent quality of life.

DSM behaviors was directly related to glycemic control (β=-.02, p=.007) [30], total cholesterol (TC)/high-density lipoprotein cholesterol (HDL-C) (β=-.31, p<.001), and low-density lipoprotein cholesterol (LDL-C)/HDL-C (β=-.30, p<.001) [12]. It is not clear whether DSM behaviors are directly related to blood pressure in Chinese adults with T2D, and this will be examined in this proposed study. Compared to the general population, people affected by T2D consistently reported diminished health-related quality of life [41]. However, the association of DSM behaviors with health-related quality of life has not been systematically examined among Chinese adults with T2D, and this study will fill the knowledge gaps.

Moderators. The IMB-DSM model postulates that certain personal characteristics may work as moderators which affect associations of the model concepts with DSM behaviors, and that the extent of moderation is based on levels of the moderator. High levels of moderators are assumed to directly influence DSM behaviors, whereas lower levels of moderators are assumed to act through the IMB-DSM model constructs to influence DSM behaviors and will not obscure the relationships between these constructs and DSM behaviors. These moderators include depressive symptom, female gender, and educational level.

Depressive symptoms have been consistently found to negatively affect DSM behaviors, including SMBG, diabetes foot care, diet modification, managing high or low blood glucose, and overall DSM performance in these studies [6 42-44]. Generally, female patients had better overall DSM performance than their male counterparts [13 45]. People with a higher educational level tended to manage their diabetes better, compared to people with lower educational level [26 34 46]. As extant studies investigating factors associated with DSM are predominately univariate in nature, these studies generally examine a direct relationship between specific DSM behaviors and DSM-related information, motivation, or behavioral skills. So far, no studies have been conducted to systematically evaluate how potential moderators may influence the relationship among the variables in the IMB-DSM model, and this study is expected to fill those knowledge gaps.

Objectives

In the proposed study, we will refine and test longitudinally a culturally tailored IMB-DSM among 250 Chinese adults residing in Chengdu, China.

Aim 1: In Chinese adults with T2D, to determine which baseline variables are most strongly related to baseline DSM behaviors, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education.

Research question (RQ): Among baseline DSM-related information, motivation, and behavioral skills, which is most strongly related to baseline DSM behaviors?

Aim 2: To examine the feedback loop as described in the original IMB model by investigating the relationships between baseline health outcomes (HbA1c, blood pressure, blood lipids, and diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up period, controlling for age, gender, duration of diabetes diagnosis, differences in diabetes treatment, and prior diabetes DSM education at baseline.

RQ1: What is the relationship between baseline HbA1c levels and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ2: What is the relationship between baseline blood pressure and DSM-related information, motivation, behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ3: What is the relationship between baseline blood lipids and DSM-related information, motivation, and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

RQ4: What is the relationship between baseline diabetes-dependent quality of life and DSM-related information, motivation and behavioral skills, and subsequent DSM behaviors at 3-month follow-up?

Aim 3: In Chinese adults with T2D, to examine mediating and moderating factors associated with DSM behaviors at baseline and the 3 month follow-up period.

Research Question 1: Are behavioral skills (diabetes self-efficacy and coping strategies) mediators of DSM behaviors at baseline and 3-month follow-up period?

Research Question 2: Are depressive symptoms, female gender, and educational level as moderators of DSM behaviors at baseline and 3-month follow-up period?

Methods and Analysis

Design

A descriptive, repeated-measure design is used to examine the relationships among variables in the IMB-DSM model, the role of variables in predicting baseline DSM behaviors, the potential moderators and mediators, and investigate the relationship between baseline health outcomes and DSM-related information, motivation, behavioral skills and subsequent DSM behaviors at three-month follow-up. Data will be collected at two time points, 3 months apart. Since HbA1c is considered the gold standard for monitoring glycemic control and reflects a person's glucose control for the preceding 8 to 10 weeks [10], three-month of observation is deemed long enough to reflect the glucose control.

Sample and Setting

This study will be conducted in Chengdu metropolitan area, which is the provincial capital of Sichuan province in Southwest China. One community health center will be selected from each of six urban districts in Chengdu metropolitan area: the Yulin community health center in Wuhou District, the Supo community health center in Qingyang District, the Longzhoulu community health center in Jinjiang District, the Caojiaxiang community health center in Jinniu District, the Shuanglin community health center in Chenghua District, and the Guixi community health center in Gaoxin District. The inclusion criteria for participation in the research are: (a) diagnosed with T2D; (b) able to read, write, and speak Chinese; (c)$\geqslant$18 years of age; (d) a score of the Chinese version of Mini-Mental State Examination (C-MMSE) > 24 (see **Screening** below); (e) no other chronic physical or mental disorders; and (f) mentally competent to give informed consent. Patients will be excluded if they are pregnant, have been diagnosed with cancer or organ failure, refuse to participate in the proposed study, self-identified bilateral hearing loss, or cognitive impairment (inability to comprehend the informed consent).

Sample Size

The Power Analysis and Sample Size Software was used for sample size calculation. Sample size was calculated based on the weakest correlation among all the tested variable pairs, that is, diabetes

knowledge and social support (r=.197). Assuming 80% power, type I error rate of .05, and attrition rate of 20%, a total of 250 participants will be needed to detect the correlation coefficient of .197. This sample size will have a higher power to detect correlations with larger coefficient.

Participant Recruitment

The research team will actively recruit participants from six selected community health centers. The principal investigator and her undergraduate mentors have established relationships with these community health centers and will be able to facilitate recruitment from these sites. An electronic medical database of the residents kept each community health center will also be used to identify patients with T2D in these communities. The research team will also have access to the database from which participants can be recruited.

Once the approval from the Ethics Committees for Clinical Trials and Biomedical Research in the Fourth People's Hospital of Chengdu is obtained, patients who come to the local clinics for evaluations and care will be approached after agreeing to hear about the study by a research staff member, who will explain the study, provide a consent form for review, answer questions and seek their participation. Subjects who agree to participate will be screened on inclusion criteria. Screening (see Screening below) will take about 10 minutes. Those who meet study criteria will be entered into the study. In addition, advertisements about the study will be placed on buses and subways. Those interested in the study will be invited to the study site and asked to participate after reviewing study procedures and consent forms. Weekly and monthly recruitment goals will be set to ensure adequate progress on participant enrollment. If recruitment is slow, recruitment procedures will be reviewed, problems identified, and adjustments will be made so that participant accrual is conducted at a satisfactory rate.

Screening

A questionnaire will be used to assess participants' eligibility with questions on age, length of diabetes, period of time when starting diabetes treatment, provider referral, and willingness to participate. Since this population is at risk for cognitive impairment that may, in some cases, limit their capacity to provide consent [47], the C-MMSE will be administered to evaluate global cognitive functioning of all

eligible participants. The C-MMSE has been used among Chinese adults with T2D [48]. Those who obtain a score <=23 will be excluded because subjects with such low scores were considered to have possible dementia [49]. Potential participants with serious cognitive problems will be referred immediately to a mental health professional used by the respective community health centers.

Reducing Attrition

There will be a potential problem with attrition of the proposed study because the 3 month follow-up for this longitudinal study design opens up to the problem of attrition. Steps that will be taken to reduce attrition include: informing subjects of the importance of continued participation in all aspects of the study; giving a subject incentive of ¥155 (about $25) Walmart gift card per completed data collection session; making telephone calls and sending a reminder card prior to scheduled data collections. A participant locator form will be completed for each subject entered in the study and at all data collection sessions to ensure proper contact information for follow-up visit is maintained.

Data Collection and Procedures

After consenting to participate, each subject will be requested to come to the study site for baseline data collection in a private office at the research site. Baseline data collection will include administration of the following questionnaires: Demographic Data Form, the Diabetes Knowledge Questionnaire, the Health Education Form, the Provider-Patient Communication Scale, the Health Belief Scale, the Social Support Rating Scale, the Diabetes Self-Efficacy Scale, the Medical Coping Modes Questionnaire, the Diabetes Self-Care Scale, the Self-rating Depression Scale, and the Audit of Diabetes-Dependent Quality-of-Life. At the 3 month follow-up data collections, all the measures will be administered again except the Demographic Data Form. Data collection from each participant should take about 60 minutes. The instruments will be administered by a trained research assistant as an interview to reduce respondent burden and to standardize the approach due to the differing response formats. If the participant becomes fatigued, the battery of questionnaires may be completed in two sessions.

Training of Data Collectors

In an effort to improve inter-rater reliability, data collectors will be trained to collect data for baseline and follow-up data collections. They will attend intensive training sessions at the beginning of the project, and periodic refresher sessions will be offered every 2 to 3 weeks to reinforce the basic training. Data collectors will practice conducting data collections and blood pressure measurement and these sessions will be monitored and each data collector will be certified. To control for measurement error, a data collection protocol manual will be developed that will include data collection protocol related specifically to each questionnaire and blood pressure measurement. The specific measures, including instruments and physical biomarkers, that will be used in this study are described below.

Instruments

Demographics. This questionnaire is designed to collect background data from participants on their demographic characteristics, including age, gender, income, education, marital status, length of diabetes, health insurance, current treatment plan for diabetes, and relevant health history indicators.

The diabetes knowledge questionnaire. Diabetes knowledge will be measured by the Chinese version of the Diabetes Knowledge Scale, which consists of 14 items. Participants will be scored on correct answers they provide in the Scale. The total score ranges from 0 to 14, with a higher score corresponding to a higher level of diabetes knowledge. The Cronbach's alpha for the Scale was .62. The score was significantly higher in a group with more education ($t[28]=2.83$, $p< .01$), suggesting that the Chinese version had satisfactory construct validity [50].

The health education form. Information on health education in Figure 1 is based on self-reports. All participants will be asked if they have had received any form of diabetes education. If the answer is YES, the patient should answer the source of diabetes education. The source of diabetes education could be health care professionals, community consulting service, journals/books, TV/radio, internet and others.

The provider-patient communication scale. Provider-patient communication in Figure 1 will be measured by the Provider-Patient Communication Scale. The 5-item scale is scored on a Likert scale ranging from 0 to 6, where 0 indicates "strongly disagree" and 6 indicates "strongly agree". High scores indicate a person who is confident in their capability to communicate with healthcare professionals and

knows means to get access to healthcare service in order to meet their needs. The Cronbach's alpha coefficient is reported at .929, indicating excellent internal consistency [12].

The health belief scale. Health beliefs (i.e., personal motivation in Figure 1) refer to one's perceptions about T2D and how it can be treated [51]. The Health Belief Scale was developed based on the Health Belief Model by Yamei Chen [51]. The 20-item scale comprises 5 subscales (perceived susceptibility, perceived benefits, perceived severity, perceived barriers, and cues to action) and uses a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score represents stronger health beliefs. The content validity index is .81, the test-retest reliability ranges from .78 to .82, and the Cronbach's alpha is .79 [51].

The social support rating scale. Social support (i.e., social motivation in Figure 1) will be measured by the Social Support Rating Scale [52]. The 10-item instrument measures aspects of objective social support (3 items), subjective social support (4 items) and usage of social support (3 items). The item scores range from 14 (worst possible social support) to 66 (best possible social support) [52]. The test-retest reliability coefficient and the internal consistency of the scale are .92 and .88-.94, respectively [34].

The diabetes self-efficacy scale. Diabetes self-efficacy will be measured with the 7-item Chinese version of the Diabetes Self-Efficacy Scale, which evaluates how confident participants are while performing DSM behaviors. The items are scored on a 5-point Likert-type scale, with a higher score corresponding to a higher self-efficacy in performing DSM behaviors. The Chinese version of the Diabetes Self-Efficacy Scale has a Cronbach's alpha of .87. Factor analysis showed that seven items were loaded on five factors, which explains 97.9% of the variance, and the five factors indicated confidence in performing five DSM behaviors [50].

The medical coping modes questionnaire. Coping strategies in Figure 1 will be measured by the 20-item Chinese version of the Medical Coping Modes Questionnaire. It assess 3 forms of coping strategies associated with chronic illness: confrontation, avoidance, and acceptance-resignation [53]. Items are answered on a four-point Likert scale ranging from 1 (never) to 4 (very often). Scores from the three subscales are compared, and the highest score indicates the corresponding dominant pattern of coping

utilized by the participant. The Cronbach's alpha for the confrontation, avoidance, and acceptance-resignation subscales is reported at .69, .60, .76, respectively [53].

The diabetes self-care scale. DSM in Figure 1 will be measured by the 26-item Diabetes Self-Care Scale, which is comprised of 6 subscales: diet modification, taking medications, SMBG, foot care, physical activity, and regulating highs and lows in blood glucose. Responses for each item range from 1 (never) to 5 (very often). Total score can range from 26 to 130 by adding up scores of 6 subscales, with higher scores indicating better overall DSM performance. The construct validity is .68, and the Cronbach's alpha is .87 [54].

The self-rating depression scale. Depressive symptoms in Figure 1 will be assessed using the Self-Rating Depression Scale, a 20-item self-administered questionnaire [55]. Each item is rated on a four-point Likert scale, ranging from 1 (very seldom) to 4 (most of the time) and computed as an original score, then multiplied by 1.25 to get the standard score. A score ranges from 53 to 62 indicates mild depressive symptoms, a score ranges from 63 to 72 indicates moderate depressive symptoms, and a score higher than 72 indicates severe depressive symptoms [56].

The audit of diabetes-dependent quality of life. Diabetes-related quality of life in Figure 1 will be measured by the Chinese version of Audit of Diabetes-Dependent Quality of Life, which measures both generic and diabetes-specific quality of life. The first two overview items assess generic quality of life on a seven-point Likert scale (-3 [extremely bad] to 3 [excellent]) and quality of life without diabetes. A five-point scale (-3 to +1) evaluates the influence of diabetes by asking participants how they would like to rate their quality of life if they did not live with diabetes. The subsequent 19 items evaluates diabetes-specific quality of life. A five-point scale (-3 to +1) evaluates the influence of diabetes by asking participants what specific aspects of their life would be if they did not live with diabetes. The importance of each aspect on their life is scored on a four-point scale (0 to 3). The two ratings are then multiplied and summed for a final impact score which ranges from -9 to 3, with more negative scores suggesting worse quality of life. A score of 0 is assigned to "unimportant" domains, regardless of the magnitude of its impact. Similarly, a score of 0 is assigned to items with no impact of diabetes, regardless of their

importance to quality of life. The average weighted rating score is obtained by dividing the sum of weighted ratings for applicable domains by the number of the applicable domains. Strong reliability (Cronbach's alpha=.941) has been reported [57]. Factor analysis showed that all items had high performance in the structural validity evaluation, with most factor loading values being larger than .40 (varied from .44 to .88) [57].

Physical Markers

Physical markers include HbA1c, blood pressure, and blood lipids. All blood samples will be processed at the Clinical Laboratory of the Fourth People's Hospital of Chengdu. After collection, the fresh venous blood samples will be immediately transported at 4°C temperature to the Clinical Laboratory within 2 hours. The samples will then be placed in a deep freezer and stored at -80°C until assays start.

HbA1c. HbA1c will be used as a marker of T2D and glycemic control and will be analyzed from whole blood samples (4 ml). Analysis will be conducted using high performance liquid chromatography, with standardization through commercial available assays (coefficient of variation<2%).

Blood pressure. Blood pressure will be obtained by a trained nurse using a standard sphygmomanometer for a minimum of 2 consecutive readings at intervals of at least 1 minute, based on the American Heart Association guidelines [58]. The seated participant should have his/her back supported and the upper arm bared, with legs uncrossed and feet on the ground. The arm should be placed in the cuff at the heart level. The mercury column should be deflated at 2 to 3 mm/s, and the first and last audible sounds should be taken as systolic and diastolic pressure. Both the participant and the nurse must remain still and silent during the procedure for the most accurate reading. The average of those readings will be used to represent the patient's blood pressure.

Blood lipids. Blood lipids include TC, HDL-C, LDL-C, and triglycerides (TG). Analysis of blood lipids will be conducted using enzymatic colorimetric test, with standardization through commercial available assays (coefficient of variation<2%). Fasting serum samples will be collected in the morning after 8 hours fasting.

Patient and Public Involvement

The development of the research question and outcome measures were informed by previously published research studies that engaged patients' experience. We did not involve patients in the study design, recruitment, and conduct of the study. Both the baseline and three-month outcomes on blood pressure, HbA1c, and blood lipids will be mailed to each participant. After we finish the data analysis, we will present the study findings in lay terms to study participants who were enrolled in our study.

Data Analyses

Data analyses for Aim 1: Linear regression models will be applied to assess the associations between baseline DSM behaviors and baseline DSM-related information variables, motivation variables, and behavioral skills variables, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 2: Linear regression models will be applied to assess the associations between baseline health outcomes (i.e., HbA1c, blood pressure, blood lipids, diabetes-dependent quality of life) and DSM-related information, motivation, behavioral skills, and DSM behaviors at 3 months follow-up, respectively, controlling for age, gender, differences in diabetes treatment, duration of diabetes diagnosis, and prior diabetes DSM education at baseline.

Data analyses for Aim 3: Both baseline and 3-month follow-up measures will be used for Aim 3. Structural equation modeling will be used to explore the fit of the data to the IMB-DSM model. Data will be first assessed whether they meet the assumptions of maximum likelihood estimation of structural equation modeling. Then, hypotheses on structural relations among the IMB-DSM model concepts will be assessed with an analysis of the magnitude and direction of direct effects as well as indirect effects, which indicate mediation. Significant indirect effects occur when the association of a predictor with an outcome results from the predictor being linked to a third variable. The model will be evaluated using goodness-of-fit statistic (χ^2), the comparative fit index (CFI), the root mean square error of approximation (RMSEA), and the standardized root mean residual (SRMR). A statistically nonsignificant χ^2 ($p>.05$) indicates a good fit between the data and the hypothesized model. A high CFI value ($\geq.95$), a low SRMR value ($\leq.08$), and a low RMSEA value close to 0 ($<.05$) are desirable [59].

Moderators will be tested by doing multi-group testing in AMOS 23. Consistent with a prior similar study [14], to examine whether depressive symptoms, female gender, and educational level moderate the relationships in the model, multi-group analysis will be used to compare if there is a significant difference between a constrained model (i.e., a model in which the coefficients are set equal across the groups) and an unconstrained model (i.e., a model in which these coefficients are allowed to vary freely). A significant difference between these two models indicates significant differences among the groups. A number of nested models will be tested to see where the differences are.

Ethics and Dissemination

The study poses little to no risk to participants and their families. Signed informed consent will be obtained from all participating families. Participation in the study does not interfere with the usual care patients receive in the primary care settings. Results from this study will be disseminated at regional and international conferences and in peer-reviewed journals.

Figure Legend

Figure 1. The DSM-IMB Model

Contributorship statement

All authors contribute to the conception and design of this study. TL, CL, and DW drafted the manuscript. JW, RY, SG, YD, and YW revised the manuscript. All authors approved the final version to be submitted to the journal.

Competing interests statement:

None declared.

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Data sharing statement:

We have not yet collected data. Once data collection is finished, the individual de-identified participant data (including data dictionaries) will be shared. The shared data will include demographics, diabetes knowledge, health education form, provider-patient communication, health beliefs, social support, diabetes self-efficacy, the medical coping modes, the diabetes self-care, depression, diabetes-dependent quality of life, hemoglobin A1c, blood pressure, and blood lipids at baseline and 3-month follow-up. The data will become available as soon as we collect all data and for one year.

References

1. International Diabetes Federation. IDF diabetes atlet, 8th edition 2017 [Available from: http://www.diabetesatlas.org/across-the-globe.html accessed Nov 28, 2017.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. *JAMA : the journal of American Medical Association* 2013;310:948-59. doi: 10.1001/jama.2013.168118 [published Online First: 2013/09/05]

3. Centers for Disease Control and Prevention. Awareness of prediabetes--United States, 2005-2010. *Morbidity and mortality weekly report* 2013;62(11):209-12. [published Online First: 2013/03/22]

4. Anderson RM, Funnell MM, Butler PM, et al. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995;18(7):943-49. [published Online First: 1995/07/01]

5. Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. *Diabetes Care* 1999;22(12):2090-92. [published Online First: 1999/12/10]

6. Luo X, Liu T, Yuan X, et al. Factors Influencing Self-Management in Chinese Adults with Type 2 Diabetes: A Systematic Review and Meta-Analysis. *International journal of environmental research and public health* 2015;12(9):11304-27. doi: 10.3390/ijerph120911304 [published Online First: 2015/09/18]

7. Shrivastava SR, Shrivastava PS, Ramasamy J. Role of self-care in management of diabetes mellitus. *Journal of diabetes and metabolic disorders* 2013;12:14. doi: 10.1186/2251-6581-12-14 [published Online First: 2013/03/19]

8. 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(7):1159-71. [published Online First: 2002/06/28]

9. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educator* 2008;34:815-23. doi: 10.1177/0145721708323640 [published Online First: 2008/10/04]

10. American Diabetes Association. 4. Lifestyle management: Standards of medical care in Diabetes-2018. *Diabetes care* 2018;41:S38-S50. doi: 10.2337/dc18-S004 [published Online First: 2017/12/10]

11. Sun X, Huang X, Yuan C, et al. The influence of health belief and coping style on self-management behavior in patients with type 2 diabetes mellitus [Chinese]. *Journal of Nursing (China)* 2012;19(1A):8-11.

12. Gao J, Wang J, Zhu Y, et al. Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC public health* 2013;13:100. doi: 10.1186/1471-2458-13-100 [published Online First: 2013/02/06]

13. Yu P. The relationship between coping strategy, health beliefs and self-management among people with type 2 diabetes in Changsha [Master thesis]. Central South University, 2009.

14. Kelly S, Melnyk BM, Belyea M. Predicting physical activity and fruit and vegetable intake in adolescents: A test of the information, motivation, behavioral skills model. *Research in nursing & health* 2012;35(2):146-63. doi: 10.1002/nur.21462 [published Online First: 2012/01/21]

15. Fisher WA, Fisher JD, Harman J. The information-motication-behavioral slills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social psychological foundations of health and illness. Malden, MA: Wiley-Blackwell 2003:82-106.

16. Fisher JD, Fisher WA. Changing AIDS-risk behavior. *Psychological bulletin* 1992;111(3):455-74. [published Online First: 1992/05/01]

17. Fisher JD, Fisher WA, Amico KR, et al. An information-motivation-behavioral skills model of adherence to antiretroviral therapy. *Health Psychology* 2006;25:462-73. doi: 10.1037/0278-6133.25.4.462 [published Online First: 2006/07/19]

18. Huang J, Liu Y, Zhang Y, et al. Correlation between self-management and knowledge of and attitude to diabetes in type 2 diabetic patients in Changsha [Chinese]. *Journal of Central South University*

(Medical Sciences) 2013;38:176-81. doi: 10.3969/j.issn.1672-7347.2013.02.011 [published Online First: 2013/03/05]

19. Kong L, Ye Y, Ding F, et al. The relationship between diabetes knowledge, self-efficaicy, and self-management practice among individuals with type 2 diabetes in community [Chinese]. *Journal of Hubei University of Science and Technology* 2013;27(4):334-38.
20. Wang X, Lv W, Ding Y, et al. Study on correlation between self-management behaviors of elderly type 2 diabetic patients and diabetes knowledge level [Chinese]. *Chinese Nursing Research* 2013;27(9):2973-74.
21. Quan J. The research about the current status and influencing factors of self-management behavior in middle-aged and over patients who with type 2 diabetes mellitus [Master thesis]. Yanbian University, 2013.
22. Wang X, Lan W, Liu J, et al. Evaluation analysis of influencing factors of type II diabetes patients self-management in Shanxi Province [Chinese]. *Journal of Qiqihar Medical College* 2012;33(8):1065-69.
23. Hu J, Gruber KJ, Liu H, et al. Diabetes knowledge among older adults with diabetes in Beijing, China. *Journal of clinical nursing* 2013;22:51-60. doi: 10.1111/j.1365-2702.2012.04273.x [published Online First: 2012/12/12]
24. Xu Y, Toobert D, Savage C, et al. Factors influencing diabetes self-management in Chinese people with type 2 diabetes. *Research in nursing & health* 2008;31:613-25. doi: 10.1002/nur.20293 [published Online First: 2008/07/10]
25. Jia Y, Wang J, Liu W. Study on self-care level of patients with type 2 diabetes mellitus and analysis of related factors [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2005;22(7):21-23.
26. Meng F. Research on health education and self-managing level of community non-insulin dependent diabetic patients [Master thesis]. Sun Yat-Sen University, 2010.

27. Wang L, Zhang J. Self-management of elderly patients with type 2 diabetes and its influencing factors [Chinese]. *Journal of Nursing (China)* 2012;19(4A):39-42.

28. Guo XH, Yuan L, Lou QQ, et al. A nationwide survey of diabetes education, self-management and glycemic control in patients with type 2 diabetes in China. *Chinese medical journal* 2012;125(23):4175-80. [published Online First: 2012/12/12]

29. Wang J, Zhang X. Survey of self-care behavior among 2 type diabetes patients [Chinese]. *Journal of Nurses Training* 2002;17(9):663-65.

30. Gao J, Wang J, Zheng P, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. *BMC family practice* 2013;14:66. doi: 10.1186/1471-2296-14-66 [published Online First: 2013/05/28]

31. Osborn CY, Egede LE. Validation of an Information-Motivation-Behavioral Skills model of diabetes self-care (IMB-DSC). *Patient education and counseling* 2010;79:49-54. doi: 10.1016/j.pec.2009.07.016 [published Online First: 2009/08/25]

32. Sun X, Huang X, Yuan C, et al. The relationship between coping strategy and self-management behavior among patients with type 2 diabetes [Chinese]. *Journal of Nurses Training* 2012;27(12):1084-86.

33. Du L, Lin T, Liu X. Study on correlation between social support and self-care behavior of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2012;388(26):697-99.

34. Huang M, Zhao R, Li S, et al. Self-management behavior in patients with type 2 diabetes: A cross-sectional survey in western urban China. *PloS one* 2014;9(4):e95138. doi: 10.1371/journal.pone.0095138 [published Online First: 2014/04/20]

35. Wan Q, Shang S, Liu Y, et al. A study of factors of the self-care behaviors of the elderly with type 2 diabetes [Chinese]. *Chinese General Practice* 2003;6(8):659-62.

36. Fang S, Yu Z, Tao Y. The relationship between coping strategy, self-efficacy, and diabetes self-management among people living in rural areas [Chinese]. *World Health Digest Medical Periodical* 2013;10(23):79-80.

37. Gao H. The relationship between diabetes self-efficacy and self-care behavior in patients with type 2 diabetes [Chinese]. *Jilin Medical Journal* 2012;33(35):7646-47.

38. Jia Y, Gong T, Sang M. Investigating on self-management and self-efficacy of patients with type 2 diabetes mellitus [Chinese]. *Modern Nursing* 2005;11(19):1586-88.

39. Wang JQ, Tak-Ying Shiu A. Diabetes self-efficacy and self-care behaviour of Chinese patients living in Shanghai. *Journal of clinical nursing* 2004;13:771-72. doi: 10.1111/j.1365-2702.2004.00918.x [published Online First: 2004/08/20]

40. Wan Q, Wang Q, Shang S. Correlation of self-management behavior and coping patterns of patients with type 2 diabetes [Chinese]. *Nursing Journal of Chinese People's Liberation Army* 2008;25(1B):18-21, 23.

41. Sundaram M, Kavookjian J, Patrick JH, et al. Quality of life, health status and clinical outcomes in type 2 diabetes patients. *Quality of life research* 2007;16:165-77. doi: 10.1007/s11136-006-9105-0 [published Online First: 2006/10/13]

42. Jia Y, Wang J, Teng X. Study on the correlation between psychological health level and self-management in patients with type 2 diabetes mellitus [Chinese]. *Shanghai Nursing* 2004;4(4):1-3.

43. Lin T, Lin X, Wan L. A study on correlation between self-care behavior and psychological concordance and depression of type 2 diabetes mellitus patients [Chinese]. *Chinese Nursing Research* 2009;23(1A):22-24.

44. Wang Q, Wan Q, Shang S. Correlation of self-management behavior and depression in patients with type 2 diabetes [Chinese]. *Journal of Nursing Science* 2009;24(7):14-15.

45. Lin T, Wang J, Qin X. Study on self-care behaviors and its related factors in patients with type 2 diabetes [Chinese]. *Chinese Journal of Modern Nursing* 2008;14(11):1254-56.

46. Xia Z, Yang T. Diabetes self-management behaviors and related factors among patients with type 2 diabetes in Xiuying District, Haikou [Chinese]. *Seek Medical and Ask the Medicine* 2011;9(11):526-27.

47. Cheng G, Huang C, Deng H, et al. Diabetes as a risk factor for dementia and mild cognitive impairment: A meta-analysis of longitudinal studies. *Internal medicine journal* 2012;42:484-91. doi: 10.1111/j.1445-5994.2012.02758.x [published Online First: 2012/03/01]

48. Chen Y, Liu Z, Zhang J, et al. Altered brain activation patterns under different working memory loads in patients with type 2 diabetes. *Diabetes Care* 2014;37:3157-63. doi: 10.2337/dc14-1683 [published Online First: 2014/11/19]

49. Zhang M. Users' guide for psychiatric scales. Changsha, China: Human Sciences & Technology Publishing House 2003.

50. Xu Y, Savage C, Toobert D, et al. Adaptation and testing of instruments to measure diabetes self-management in people with type 2 diabetes in mainland China. *Journal of transcultural nursing : official journal of the Transcultural Nursing Society / Transcultural Nursing Society* 2008;19:234-42. doi: 10.1177/1043659608319239 [published Online First: 2008/06/27]

51. Chen Y. Study on compliance and influence factors of the re-hospitalized patients with diabetes mellitus. [Master thesis]. Central South Universtiy, 2007.

52. Yao S, Wu D. Psychological health rating scale. In: Yao S, ed. Psychological Assessment Beijing, China: People's Medical Publishing House 2008:89-126.

53. Shen X, Jiang Q. Report on application of Chinese version of MCMQ in 701 patients [Chinese]. *Chinese Journal of Behavioral Medican Science* 2000;9(1):18-20.

54. Wang JS, Wang RH, Lin CC. Self-care behavior and related factors in outpatients newly diagnosed with non-insulin-dependent diabetes mellitus [Chinese]. *Journal of Nursing (Taiwan)* 1998;45(2):60-74. [published Online First: 1999/01/15]

55. Zung WW. A self-rating depression scale. *Archives of general psychiatry* 1965;12:63-70. [published Online First: 1965/01/01]

56. Tang P. Medical Psychology. Beijing, China: People's Medical Publishing House 2009.

57. Kong D, Ding Y, Zuo X, et al. Adaptation of the Audit of Diabetes-Dependent Quality of Life questionnaire to people with diabetes in China. *Diabetes research and clinical practice* 2011;94:45-52. doi: 10.1016/j.diabres.2011.05.026 [published Online First: 2011/06/21]

58. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: Blood pressure measurement in humans: A statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation* 2005;111:697-716. doi: 10.1161/01.cir.0000154900.76284.f6 [published Online First: 2005/02/09]

59. Kline RB. Principles and practices of structural equation modeling. 3 ed. New York, NY: The Guilford Press 2010.

Figure 1. The DSM-IMB Model

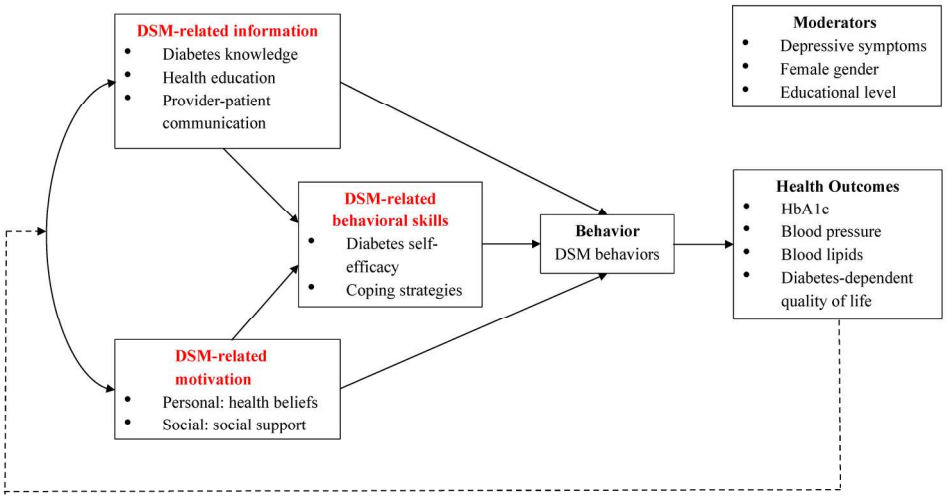

Figure 1. The DSM-IMB Model

190x142mm (300 x 300 DPI)