DIABETES SELF-MANAGEMENT AND HEALTH OUTCOMES AMONG CHINESE PATIENTS WITH TYPE 2 DIABETES

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There is limited evidence on theory-based research conducted in China and little is known about the relationships of personal, behavioral, and environmental factors, self-management behaviors, glycemic control, and metabolic syndrome among Chinese patients with type 2 diabetes (T2DM), especially among those who live in suburban areas. Using Social Cognitive Theory this cross-sectional study was conducted among patients with T2DM recruited from an outpatient clinic in a suburban area of Beijing, China. The aims of the study were to describe patient characteristics in selected personal, behavioral and environmental factors, self-management behaviors, and health outcomes; examine the association and impact of modifiable study variables on self-management behaviors and health outcomes (HbA1c and existence of metabolic syndrome); and explore the mediation role of self-management behaviors among study variables and glycemic control. A convenience sample of 207 patients provided informed consent; self-reported questionnaires were completed during a patient's clinic appointment. A clinic nurse retrieved clinical information from the medical record. The results showed that 40.1% had optimal glycemic control, 16.4% had an adequate level in performing self-management behaviors, and 89.4% were identified to have metabolic syndrome. Compared to men, women in this sample demonstrated poorer health literacy and problem-solving, received less social support and had more depressive symptoms ($p<0.05$). Multiple regression analysis showed that self-efficacy was a significant correlate of all self-management behaviors ($p<0.05$). Social support was related to overall self-management, diabetes knowledge was related to diet,

and depressive symptoms was related to self-monitoring (p<0.05). Problem-solving, self-management behaviors related to medication and diet were significant correlates for glycemic control (p<0.05). Health literacy (OR =0.77) and self-management behaviors related to physical activity (OR=0.84) were protective factors for metabolic syndrome (p<0.05). There was no mediation of self-management behaviors between the study variables and glycemic control. Patients' overall glycemic control and self-management behaviors were suboptimal and a large proportion were at risk for developing cardiovascular disease. Gender differences should be considered when targeting strategies to improve health outcomes. Findings suggest that future research needs to consider designing and testing an intervention using a multifactorial approach to improve health outcomes among Chinese patients with T2DM.

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PREFACE

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1.0 INTRODUCTION

Diabetes is the most prevalent and fastest growing chronic disease globally; the prevalence of diabetes has reached 422 (8.5%) million worldwide among individuals aged 18 years and older with most people with diabetes living in low and middle income countries (World Health Organization, 2016). This number is predicted to rise to 642 million by 2040 (International Diabetes Federation, 2015), in which 143 million people with diabetes are projected to live in China in 2035 (Guariguata et al., 2014). Diabetes is a significant public health issue in China. A recent large scale survey (n=170,287) has revealed that the estimated standardized prevalence of diabetes in China is 10.9%, a slight decrease from 11.6% (n=98,658) from the previous survey among adults residing in 31 provinces or regions in mainland China (L. Wang et al., 2017; Yu Xu et al., 2013); with more than 90% of those with diabetes being diagnosed with type 2 diabetes ([T2DM] Chinese Diabetes Society, 2014; Weng et al., 2016).

T2DM, formerly called non-insulin dependent diabetes, is characterized as insulin impairment or insulin resistance which is caused by the body's lack of ability to use insulin (World Health Organization, 2016). If diabetes is not managed properly, serious complications such as heart disease, renal problems, blindness, etc. can ensue and reduce life expectancy, and cause significant morbidity and diminished quality of life (International Diabetes Federation, 2015). Effective self-management of the disease is key in achieving optimal glycemic control and preventing complications associated with diabetes (Shrivastava, Shrivastava, & Ramasamy,

2013). The American Association of Diabetes Educators ([AADE], 2008) has identified seven key factors in diabetes self-management namely AADE7 which includes healthy eating, being active, self-monitoring, taking medication, problem-solving, healthy coping, and reducing risks. AADE7 has been incorporated as the general framework and outcome standards for diabetes self-management education programs (Funnell et al., 2012). The national guidelines for diabetes management in China also incorporate similar strategies into diabetes daily management (Chinese Diabetes Society, 2014a). The metaphor "five carriages" expresses the importance of diet, physical exercise, medication, self-monitoring of blood glucose, and diabetes education in diabetes management in China and has been emphasized among researchers (Shen & Guo, 2010; C. Tang, 2017), which is comparable to the concept of AADE7 in the US (AADE, 2008). However, despite the positive effect on glycemic control through self-management education and interventions reported among many studies globally (Heinrich, Schaper, & Vries, 2010; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012; Zhao, Suhonen, Koskinen, & Leino-kilpi, 2017), the level of self-management behaviors and glycemic control among Chinese patients with T2DM is suboptimal (J. Ji et al., 2014; L. Ji et al., 2016; K. Lin et al., 2017; X. Sun, Huang, Yuan, & Cui, 2012a; Wenjia Yang, Cai, Han, & Ji, 2016; Yue, Chen, Wang, Su, & Wu, 2013). In addition, according to the standard from the National Cholesterol Education Program ([NCEP], 2001), 46%-48% of patients with T2DM have been identified as having metabolic syndrome (MetS), which is defined as the co-existence of several conditions including insulin resistance, abdominal obesity, dyslipidemia and hypertension (Huang, 2009; Music et al., 2015; Yadav et al., 2013). The combination of MetS and T2DM greatly increases the risk of complications especially cardiovascular disease (Ginsberg & MacCallum, 2009; Yao et al., 2016). Therefore, the parameters related to MetS, such as blood pressure (BP), body mass index

(BMI) or waist circumference, high-density lipoprotein (HDL), low-density lipoprotein (LDL) and triglyceride, should not be overlooked among patients with T2DM.

According to Bandura (1986), Social Cognitive Theory (SCT) suggests that there are reciprocal relationships among personal, behavioral and environmental factors impacting health behavior leading to better health outcomes. Previous research has demonstrated that behavioral and environmental factors such as self-efficacy, depressive symptoms, problem-solving, social support, and neighborhood factors along with personal factors are important elements influencing one's ability to perform self-management behaviors and therefore gain glycemic control (Adam & Folds, 2014; Fitzpatrick, Schumann, & Hill-Briggs, 2013; Gao et al., 2013; Luo et al., 2015; Shin et al., 2017; Y. Zhang, Ting, Yang, et al., 2015). However, a search of the literature focusing on Chinese patients with T2DM revealed limited evidence examining the relationships among these factors using a theoretical model; in addition, no studies have been done to examine problem-solving in this population. Since problem-solving is inherent in strategies used to resolve issues related to diabetes self-management activities, understanding problem-solving and other factors (such as self-efficacy, depressive symptoms, health literacy etc.) in this population and their impact on self-management behaviors and health outcomes (HbA1c, existence of MetS) is essential.

1.1 PURPOSE OF THE STUDY

Based on SCT (Bandura, 1986), the purpose of this study was to examine the association of personal (sociodemographic, disease related factors, diabetes knowledge, health literacy), behavioral (self-efficacy, depressive symptoms, problem-solving) and environmental (social

support, neighborhood) factors and their impact on health behaviors (self-management behaviors) and health outcomes (HbA1c, existence of MetS based on parameters of BP, waist circumferences or BMI, HDL, LDL and Triglyceride) in adult Chinese patients with T2DM.

1.2 SPECIFIC AIMS

The specific aims were to:

1. Characterize the sample of Chinese patients with T2DM recruited from a suburban area in Beijing;
2. Examine the associations between personal (sociodemographic, disease related factors, diabetes knowledge, health literacy), behavioral (self-efficacy, depressive symptoms, problem-solving), environmental (social support, neighborhood) factors, health behaviors (self-management behaviors), and health outcomes (HbA1c, MetS determined by BP, BMI/waist circumference, HDL, LDL and Triglyceride);
3. Examine the impact of modifiable variables on self-management behaviors and health outcomes (HbA1c, existence of MetS determined by BP, Waist/BMI, HDL, LDL and Triglyceride).
4. Examine the mediation role of self-management behaviors among personal, behavioral, and environmental factors and HbA1c in this sample.

2.0 LITERATURE REVIEW AND THEORETICAL FRAMEWORK

2.1 BACKGROUND AND SIGNIFICANCE

The prevalence of diabetes in China has increased significantly over the past four decades. The overall estimated prevalence was 0.67% in 1980 and increased to 10.9% in 2013 in China (National Diabetes Research Group, 1981; L. Wang et al., 2017); more than 90% of this population has T2DM (Chinese Diabetes Society, 2014a; Weng et al., 2016). Diabetes and its complications have increased health cost substantially in China. A recent study based on the number of people with diabetes worldwide has shown that the cost estimate is $825 billion globally with about $170 billion being contributed from China alone (NCD Risk Factor Collaboration, 2016). Fast economic growth over the past few decades may have contributed to this significant increase in prevalence of diabetes in China. Studies done in China reveal that the prevalence of diabetes is significantly higher among those who live in more developed areas with high incomes, such as those who live in urban areas, than those who live in rural areas (Weng et al., 2016; Wenying Yang et al., 2010). However, the all-cause mortality among patients with diabetes in China is higher among those who live in rural areas (Bragg et al., 2017). In China, those who live in the suburban areas of a large city, such as Tongzhou District in Beijing, are underrepresented among studies targeting patients with T2DM. Such suburban areas of a large

city are often associated with fast development both economically and environmentally that may potentially influence how patients with diabetes adapt to and manage their health condition.

Although self-management has been identified as critically important among patients with T2DM, self-management and glycemic control among Chinese patients with T2DM are suboptimal (J. Ji et al., 2014; L. Ji et al., 2016; K. Lin et al., 2017; X. Sun, Huang, Yuan, & Cui, 2012b; Wenjia Yang et al., 2016). In examining the factors related to self-management behaviors among Chinese patients with T2DM, diabetes knowledge, health literacy, self-efficacy, depressive symptoms, social support were often examined among researches done in China (Luo et al., 2015; M. Wang, Yan, Yang, Huang, & Ma, 2016; Y. Zhang, Ting, Yang, et al., 2015; Zheng, Han, Guo, & Lin, 2015). However, although problem-solving is an essential element in self-management behaviors as identified by AADE7 (AADE, 2008), it has not been evaluated among Chinese patients with T2DM. In addition, a lack of a theoretical model in guiding the research was common among studies done in China which may limit the ability to comprehensively evaluate the influencing factors in diabetes management and patient health outcomes. Social Cognitive Theory (Bandura, 1986) which suggests that personal, behavioral and environmental factors interactively impact health behaviors, provides a theoretical framework to understand how these factors influence self-management behaviors and health outcomes among patients with T2DM. A theory-based descriptive study is essential to provide the basis for future research and help researchers gain insight into diabetes management among Chinese patients with T2DM who live in a suburban area. It will also provide evidence for future self-management interventions to improve health outcomes among these patients.

2.2 LITERATURE REVIEW

2.2.1 Factors influencing diabetes self-management

The concept of self-management was first introduced in the 1960s and has been extensively examined (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Creer, Renne, & Christian, 1976; Lorig, 1993; Lorig & Holman, 2003; W. R. Miller, Lasiter, Ellis, & Buelow, 2015). Although the definition of self-management varies among researchers, it can be summarized as a process which involves patients' active engagement in participation of events or tasks to gain control of the disease. Diabetes self-management plays an important role in diabetes management, and effective self-management of the disease is key in preventing complications associated with diabetes (AADE, 2008; American Diabetes Association, 2013; Heinrich et al., 2010; International Diabetes Federation Guideline Development Group, 2014; Shrivastava et al., 2013). AADE7 has identified seven tasks related to diabetes self-management behaviors that are necessary for gaining control of diabetes including healthy eating, being active, self-monitoring, taking medication, problem-solving, healthy coping, and reducing risks (AADE, 2008). As research has indicated, about 95% of the care activities can be performed by patients with T2DM on their own; necessary changes such as lifestyle and behavioral changes should be made to acquire competent self-management skills in order to achieve optimal glycemic control (International Diabetes Federation, 2009; Weng et al., 2016). According to Bandura (1986), there are multiple factors influencing self-management behaviors among patients with chronic conditions, including personal factors, behavioral factors and environmental factors, that will have an impact on control of diabetes collectively among patients with T2DM.

2.2.1.1 Personal factors

As defined in SCT, personal factors refer to the cognitive, affective and biological events that are presented by an individual (Bandura, 1986, 2001, 2004). In reviewing the literature, personal factors such as sociodemographic information including age, gender, and educational levels, as well as disease related factors such as duration of the disease, medication regimen, presence of comorbidity and treatment options, as well as diabetes knowledge and health literacy, are commonly reported as influential factors in diabetes self-management in patients with T2DM (Kueh, Morris, Borkoles, & Shee, 2015; Luo et al., 2015; Zeng, Sun, Gary, Li, & Liu, 2014).

Sociodemographic. Inconsistent findings have been reported for the relationship between age and diabetes self-management behaviors. For example, in a review study among Chinese patients with T2DM, some researchers reported that better self-management behaviors were associated with older age while others reported that people with younger age had better self-management behaviors (Luo et al., 2015). In addition, a positive relationship between age and diabetes self-management behaviors was reported among Chinese immigrants in the United States (Zeng et al., 2014). In other studies conducted in the United States, individuals with poorly controlled T2DM (HbA1c >8.0%) were identified significantly among younger people; older age was significantly associated with poor diet and less exercise (Crowley et al., 2014; Hessler, Fisher, Mullan, Glasgow, & Masharani, 2011), and was associated with better glycemic control (Walker, Smalls, & Egede, 2015). Educational level has been reported as being positively related to diabetes self-management among Chinese patients with T2DM (Luo et al., 2015); and a lower level of education (defined as not being able to read and write, or only having received education up to eighth grade) has been linked to poor self-management behaviors (Kassahun, Eshetie, & Gesesew, 2016; Kassahun, Gesesew, Mwanri, & Eshetie, 2016; Yin et al., 2015).

Gender has been identified as an influential factor in diabetes management but with inconsistent findings (Gonzalez-zacarias, Mavarez-martinez, Arias-morales, Stoicea, & Rogers, 2016). While females have been reported to be more likely to have better glycemic control, as well as less incidence of comorbidities than males among patients with T2DM in the USA (Roy et al., 2016; Walker et al., 2015), being female along with a low level of education have been identified as being associated with poor glycemic control among Chinese patients with T2DM (Yin et al., 2015).

Disease related factors. Mixed results have been found between the duration of diabetes and diabetes self-management behaviors. Some studies have reported that the duration of diabetes affects diabetes self-management directly and indirectly through self-efficacy with a positive relationship (Yin Xu, Toobert, Savage, Pan, & Whitmer, 2008). Researchers have identified that longer duration of the disease is associated with better self-management among Chinese patients with T2DM (Luo et al., 2015; Yin Xu, Toobert, et al., 2008). Other researchers have demonstrated a negative relationship between the duration of disease and self-management (Kueh et al., 2015); and identified a longer duration of disease as being associated with poorer glycemic control (Walker et al., 2015; Yin et al., 2015). In addition, among Chinese patients with T2DM treated with insulin, longer duration was identified to be associated with fewer patients reaching the target goal of less than 7% on HbA1c (Ji et al., 2016). Both the natural disease progression and self-management behaviors may have contributed to the somewhat contradictory findings in the literature since diabetes management requires a life-long commitment in lifestyle modification.

Comorbidity is also an important factor affecting disease management of patients with chronic conditions (France et al., 2012). The number of comorbidities has been frequently

examined by researchers among patients with diabetes, and the complexity of diabetes management increases with the number of comorbidities. Some studies have not shown a significant relationship between presence or number of comorbidities and glycemic control among patients with diabetes (Bayliss, Blatchford, Newcomer, Steiner, & Fairclough, 2011; Luijks, Biermans, Bor, Weel, & Lagro-janssen, 2015), while other research has demonstrated that a greater number of comorbidities was related to worsening of diabetes self-management activities and glycemic control (Kerr et al., 2007; Walker et al., 2015).

The medication regimen for patients with diabetes also affects how well patients with T2DM control their condition. Patients with a combination of oral and injectable insulin treatments were more likely to have poor medication management and glycemic control (Kassahun, Eshetie, et al., 2016). In addition, as the number of comorbidities increases, the number of medications prescribed for patients with diabetes also increases, which could complicate diabetes management. In order to prevent complications from diabetes, patients with T2DM often are prescribed medications to control their blood glucose and blood pressure, dyslipidemia, and other conditions (American Diabetes Association, 2013). Studies have shown a high level of medication adherence despite the complexity of medication regimen prescribed for patients with T2DM (Grant, Devita, Singer, & Meigs, 2003; Waheed, Jamal, & Amin, 2017). However, a multi-drug regimen is more difficult to follow and has increased risk for adverse drug effects especially for older adults (Valencia & Florez, 2014). Meanwhile, medications prescribed for controlling blood pressure may not always be protective in preventing cardiovascular events and beneficial for glucose metabolism. Researchers have demonstrated that different antihypertensive drug classes have different effects on glucose metabolism; angiotensin converting enzyme inhibitors and angiotensin receptor blockers are shown to be

beneficial for glucose metabolism, beta blockers and diuretics are shown to be detrimental for glucose metabolism (Rizos & Elisaf, 2014). A study conducted in Japan has demonstrated that, among patients with diabetes, the cumulative event rate for cardiovascular events as well as the incidence of severe hypoglycemia were significantly higher among those on a beta-blocker than those who were not (Tsujimoto, Sugiyama, Shapiro, Noda, & Kajio, 2017). Yet, among patients with T2DM and also diagnosed with coronary heart disease, the all-cause mortality was significantly lower in those receiving beta-blockers than those who were not (Tsujimoto, Sugiyama, & Kajio, 2017). In addition, traditional Chinese medicine has often been prescribed as adjunct therapy for treatment of diabetes among patients with T2DM in China (E. Wang & Wylie-rosett, 2008; Xie, Zhao, & Zhang, 2011). This adds another challenge to the already complex medication regimen among this population, and could potentially induce adverse drug effects and contraindications. Therefore, it is essential to understand the complete medication regimen and number of medications that the patients have been prescribed by health care providers when evaluating self-management behaviors among Chinese patients with T2DM.

Diabetes knowledge. Diabetes knowledge is defined as the level of understanding related to the physiological aspects of the disease and the principles related to diabetes management (Beeney, Dunn, & Welch, 2003). Reports have indicated that diabetes knowledge is a significant predictor for diabetes self-management with a positive relationship in terms of self-monitoring of glucose among patients with T2DM (Kueh et al., 2015). Poor knowledge is associated with poor self-management behaviors and adherence to medication (Islam, Niessen, Seissler, Ferrari, & Biswas, 2015; Kassahun, Gesesew, et al., 2016), and a higher level of diabetes knowledge is associated with better medication adherence and glycemic control (Al-Qazaz et al., 2011). Among Chinese patients with T2DM, studies have shown that diabetes knowledge is positively

associated with overall diabetes self-management as well as behaviors specific to medication taking, self-monitoring, foot care, and smoking cessation (Jie Hu, Gruber, Liu, Zhao, & Garcia, 2012; Luo et al., 2015).

Health literacy. Health literacy is defined as the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Nielsen-Bohlman & Institute of Medicine (U.S.), 2004). Researchers have demonstrated the importance of adequate health literacy in chronic disease management (Heijmans, Waverijn, Rademakers, & Vaart, 2015; N. J. Zhang, Terry, & Mchorney, 2014). Because management of diabetes is a complicated process, being health literate is important for patients to navigate the health care system and utilize information and resources in achieving optimal care. Individuals with inadequate health literacy are more likely to experience difficulties in understanding and following self-care instructions and educational materials related to diabetes management. As research has shown, health literacy has been consistently and positively related to self-care activities among patients with T2DM (Reisi et al., 2016; Y. H. Tang, Pang, Chan, Yeung, & Yeung, 2008; M. Wang et al., 2016). Health literacy was negatively related to glycemic control among patients with T2DM (Tang et al., 2008; Wang et al., 2016). Health literacy was identified as a significant predictor in reducing HbA1c. However, a recent review study has shown that some studies did not detect any significant associations between health literacy and glycemic control (Bailey et al., 2015), in which the authors argued that this might be due to small sample size or over-adjustment of potential confounders such as educational levels. This finding warrants that future studies should take a multifactorial approach in examining the relationships of health literacy and self-management behaviors and glycemic outcomes.

2.2.1.2 Behavioral factors

Self-efficacy. Self-efficacy is essential in behavior change. It is defined as "people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives" (Bandura, 1977). Self-efficacy plays a central role in regulating self-management behaviors and contributes to good glycemic control among patients with T2DM, in which patients with greater levels of self-efficacy are more likely to actively participate in their self-care and therefore have better glycemic control (Bandura, 1977, 2004). Researchers have reported consistent positive relationships between self-efficacy and self-management behaviors across studies and often with an indirect effect on glycemic control through self-management behaviors (Beckerle & Lavin, 2013; Dehghan et al., 2017; Saad et al., 2018). Among Chinese patients with T2DM, studies have also demonstrated a consistent positive relationship between self-efficacy and self-management behaviors (S. Chen & Lin, 2014; Gao et al., 2013; Luo et al., 2015; Yin Xu, Toobert, et al., 2008).

Depressive symptoms. Depression is often prevalent among patients with T2DM; it is almost two times as great compared to those without the disease (17.6% Vs 9.8%), and it is more prevalent in women than men (Ali, Stone, Peters, Davies, & Khunti, 2006). Comorbid depression or significant depressive symptoms along with diabetes creates significant challenges in disease management among patients with T2DM (Holt, Groot, & Golden, 2014; Kim, Park, Storr, Tran, & Juon, 2015). Depressive symptoms are a set of psychological and physical symptoms identified by the *Diagnostic and Statistical Manual of Mental Disorders-V*, which includes symptoms such as depressed mood, decreased interest, change in sleep or activities, fatigue, feeling guilt or worthlessness, diminished ability in thinking and thoughts of suicide (American Psychiatric Association, 2013). Depression or significant depressive symptoms negatively affects

adherence to diabetes self-care with a worsening of clinical outcomes among patients with diabetes (Penckofer, Doyle, Byrn, & Lustman, 2014). Depression has been identified as the direct consequence of neurochemical changes with diabetes and adversely affects health outcomes (Gemeay et al., 2015). Research has shown that, with increased depressive symptoms, patients with T2DM have reported less performance of appropriate diet and exercise, demonstrated more diabetes symptoms, and showed poorer physical functioning (Adam & Folds, 2014; Ciechanowski, Katon, Russo, & Hirsch, 2003). With a history of major depression and with a worsening of the depressive symptoms, patients with T2DM were more likely to report high HbA1c and BMI, and reduced self-monitoring of blood glucose (Whitworth et al., 2016). The incidence of depression and diabetes distress has been reported as 24 % and 64% among Chinese patients with T2DM (n=200), and poorer treatment adherence was associated with a higher level of diabetes distress (Zhang et al., 2013); depression was associated with higher HbA1c (Zhang et al., 2015).

Problem-solving. Problem-solving, one of the seven self-management tasks by AADE7, is an important element in diabetes self-management (AADE, 2008). The concept of problem-solving is defined as "the self-directed cognitive-behavioral process by which an individual, couple, or group attempts to identify or discover effective solutions for specific problems encountered in everyday life" (Chang, D'Zurilla, & Sanna, 2004). Hill-Briggs (2003) proposed a problem-solving model of diabetes self-management in which problem-solving was identified as the core concept in diabetes self-management. The model suggested that effective problem-solving, such as adequate problem-solving skills and disease specific knowledge, positive problem-solving orientation, and ability to transfer past experience, will produce effective self-management behaviors and therefore have an impact on glycemic control (Hill-briggs, 2003).

Problem-solving has been reported as an effective approach in improving diabetes self-management among patients with T2DM (Glasgow, Fisher, Skaff, Mullan, & Toobert, 2007; King et al., 2010), especially for diet, physical activity and medication adherence (King et al., 2010); in addition, some studies have found the same relationship among men but not with women (Hunt et al., 2012). However, in a search of the literature, there were limited studies examining the relationships between problem-solving and diabetes self-management among Chinese patients with T2DM.

2.2.1.3 Environmental factors

Social support. According to SCT (Bandura, 1977, 2001), self-management occurs in a social-environmental context in which the social network, such as family members and friends, health care providers, etc. as well as the physical environment interact with other factors in achieving desirable behaviors. The importance of social support in diabetes management has been emphasized by many researchers (King et al., 2010; Schiøtz, Bøgelund, Almdal, Jensen, & Willaing, 2012; Wilkinson, Whitehead, & Ritchie, 2014). Social support, as defined in a pyramid model related to diabetes management developed by Glasgow et al. (Glasgow, Strycker, Toobert, & Eakin, 2000), refers to the informal interpersonal support from family and friends, neighborhood and community, as well as formal institutional support from the health care team, workplace, as well as media and related policy. The International Diabetes Federation has clearly identified that poor social support is associated with poor adherence related to prescribed therapy in diabetes management (International Diabetes Federation Guideline Development Group, 2014). A greater level of structural and functional social support has been reported as being associated with more health-promoting self-management behaviors and well-being among patient with T2DM (Schiøtz et al., 2012). A significant positive relationship has been reported

between support from family or friends and treatment adherence among patients with diabetes (Miller & DiMatteo, 2013). Research has also demonstrated that lack of family support is the major barrier in performing self-management behaviors among patients with chronic disease (Gallant, Spitze, & Prohaska, 2007), which suggests that assessing and incorporating strategies related to family support in chronic disease management, such as diabetes, is essential in promoting better health outcomes. Among Chinese patients with diabetes, those who perceived greater social support demonstrated better practice of self-management behaviors and better glycemic control (Shao, Liang, Shi, Wan, & Yu, 2017). Both direct and indirect social support had significant positive relationships with general self-management behaviors such as diet, physical exercise, self-monitoring of blood glucose, foot care, and smoking reduction especially indirect support, which has been claimed as a potential predictor in self-management behaviors (Zhang et al., 2017).

Social support from family members plays an important role in diabetes management among Chinese patients. As research has shown, family members of Chinese patients often take on reciprocal role responsibilities in addressing family issues; decision making on disease management is rarely independent from concerns of the whole family (Chesla, Chun, & Kwan, 2009). Family members of Chinese patients with T2DM are integrally involved with constructing diabetes management for the patient, however, the disruptions in diet preferences and valued family rituals due to prescribed treatment regimen for diabetes has placed a great burden on the whole family which makes it challenging for patients to achieve optimal health outcomes (Chesla et al., 2009).

Neighborhood factors. Neighborhood factors including safety issues, availability of healthy food and space to exercise, and residential stability have been reported as important

factors impacting self-management behaviors and health outcomes in patients with T2DM (Echeverria, Diez-roux, & Link, 2004; Gonzalez-zacarias et al., 2016). Researchers have found direct effects from neighborhood factors to glycemic control, and suggested that individuals living in a safe, aesthetic environment, having resources or support available for healthy food and exercise were more likely to perform activities to improve glycemic control (Smalls, Gregory, Zoller, & Egede, 2015a, 2015b); an unsafe neighborhood was associated with non-adherence to treatment among patients with T2DM (Billimek & Sorkin, 2011). In addition, research has suggested that high residential stability is associated with adherence to diabetes treatment among patients with diabetes (de Vries McClintock et al., 2015).

2.2.2 Diabetes self-management among Chinese patients with T2DM

Although self-management has been identified as critically important among patients with T2DM, self-management behaviors and glycemic control among Chinese patients with T2DM are less than optimal. Poor adherence to self-management behaviors and glycemic control have been identified among studies done in China.

In a multicenter study (n=2,819 from 24 hospitals in urban areas from 10 provinces, China) among patients with T2DM treated with insulin, the mean HbA1c was reported as 8.48% (SD=1.94%) with only 24.2% of the participants achieving the goal of HbA1c below 7%; and more than half (54.6%) of the participants reporting HbA1c as above 8% (L. Ji et al., 2016). The study also reported that only 15.6% of the participants fully adhered to the physicians' advice on blood glucose self-monitoring. Lack of time, the cost of test strips, procedure being complicated, and lack of knowledge on how to adjust insulin based on readings were identified among those

patients who did not adhere to the self-monitoring behavior (Ji et al., 2016). Sun et al. reported that 90.9% of patients in their study were identified as less than optimal (actual score / total score ≤ 80%) in performing self-management behaviors evaluated with the Diabetes Self-Care Scale among patients (n=252) with T2DM at an in-patient setting in China (Sun, Huang, Yuan, & Cui, 2012a, 2012b). Among self-management behaviors performed by these patients, medication adherence was reported as the most adherent behavior with 75.4% of patients being identified as optimal in following medication treatment, followed by physical exercise (48.8%), foot care (25.4%), actions in preventing hypo or hyper glycemic events (21.4%), self-monitoring of blood glucose (9.9%), and diet (7.6%) (Sun, Huang, Yuan, & Cui, 2012a, 2012b). In a study done by Ji et al. (2014) among Chinese patients with T2DM (n=435), self-management behaviors, evaluated with the Chinese version of the Scale of the Diabetes Self-Care Activities, had a mean score of 39.55 (SD=1.59) with only 9.2% achieving the optimal level (actual score / total score ≥80%) in which medication adherence received the highest score followed by general diet, physical exercise, specific diet, foot care, and self-monitoring of blood glucose. In addition, the mean HbA1c was reported as 9% (SD=2.38) with only 22.76% achieving the recommended level of less than 7% (Ji et al., 2014). In examining the associations between self-management behaviors and HbA1c, the findings of the study demonstrated that better self-management behaviors were associated with low value on HbA1c ($r=-0.358$, $p<0.001$). Similar findings were also identified by other researchers (Guo et al., 2012; S. Sun, Zhao, Dong, & Li, 2011; Yue et al., 2013).

A national survey addressing self-management and glycemic control among patients with T2DM in China (n=5,961) reported that the mean HbA1c was 8.27% among all participants with only 32.1 % of participants reaching the recommended goal of HbA1c (<7%) (Guo et al., 2012).

Among those who perceived themselves as having had diabetes education in the past, a mean HbA1c of 8.15% was reported (Guo et al., 2012). In terms of self-management behaviors, the frequency for blood glucose monitoring was self-reported as less than 3 days per week whereas adherence to medication regimen was reported as 6 days per week (Guo et al., 2012).

Disparities among these self-management behaviors was largely due to the fact that these patients had perceived that following medication treatment was the most efficient method in controlling blood glucose level; they lacked knowledge of other important elements of the self-management regimen. It has been pointed out that lifestyle and behavior change have been largely ignored by many Chinese patients (Zhang, 2017). Ignoring these changes was common among patients from other ethnic backgrounds, in which self-management behaviors were also identified as suboptimal with the best behavior being recognized as related to medication treatment and the lowest for physical exercise, self-monitoring of blood glucose, and foot care (Gonzalez-zacarias et al., 2016; Nicolucci et al., 2013).

Despite a low proportion of participants achieving the recommended level among studies as shown previously (22.8%-32.1%), a recent nationwide survey conducted every three years in China identified that 49.2% of participants with diabetes (type 1 and type 2 diabetes not distinguished) had reported adequate glycemic control (less than 7%) with an overall mean of HbA1c as 5.38% (SD=0.83) in 2013 (L. Wang et al., 2017). The proportion of participants who had adequate glycemic control increased from 39.7% from the previous survey in 2010 to 49.2% in the current survey in 2013 (L. Wang et al., 2017; Yu Xu et al., 2013); this is similar to the proportion (52.5%) of the US adult patients with diabetes who have achieved the target level for glycemic control (Stark Casagrande, Fradkin, Saydah, Rust, & Cowie, 2013). Limin Wang and colleagues (2017) have argued that the testing method for HbA1c may have contributed to this

higher proportion of participants achieving adequate glycemic control and the low prevalence of diabetes.

2.2.3 Health and clinical outcomes in diabetes self-management

Glycated Hemoglobin (HbA1c) provides the most reliable and objective measure about glucose control within the past 8-12 weeks among patients with T2DM (World Health Organization, 2011). It has been viewed as the gold standard in evaluating glycemic control among patients with diabetes, as well as in evaluating the effect of self-management interventions on diabetes management (Chrvala, Sherr, & Lipman, 2016; Crowley et al., 2014; Kassahun, Eshetie, et al., 2016).

In reviewing the literature, a large proportion (46%-48%) of patients with T2DM has been identified as having MetS, which is defined as the co-existence of several conditions including insulin resistance, abdominal obesity, dyslipidemia and hypertension (Huang, 2009; Music et al., 2015; Yadav et al., 2013). The combination of MetS and T2DM greatly increases patients' risk for developing complications related to cardiovascular disease (Ginsberg & MacCallum, 2009; Wilson, D'Agostino, Parise, Sullivan, & Meigs, 2005; Yao et al., 2016). Individuals with both MetS and T2DM often present with abnormalities in serum lipid levels including a low level of HDL and high triglyceride (Ginsberg & MacCallum, 2009). Studies focusing on health outcomes have included parameters related to MetS as part of the clinical outcomes in evaluating disease management among patients with diabetes, such as BMI, blood pressure and lipid levels (Luijks et al., 2015; Stark Casagrande et al., 2013). Since the presentation of MetS along with T2DM creates a substantial risk for developing cardiovascular disease (International Diabetes Federation, 2006), evaluation of clinical outcomes related to

MetS is essential among patients with T2DM. Therefore, the parameters such as blood pressure (BP), waist circumference or BMI, high-density lipoprotein (HDL), low-density lipoprotein (LDL) and triglyceride, should not be overlooked in this patient population.

2.3 SUMMARY

In this review of the literature, there were various factors influencing self-management behaviors and health outcomes among patients with T2DM, including personal, behavioral and environmental factors that were claimed as essential elements in behavior change as identified by SCT (Bandura, 1986). Current evidence shows that, self-management behaviors and glycemic control among Chinese patients with T2DM are suboptimal. Although there are notable changes in the proportion of patients achieving the target goal for glycemic control (< 7%) over the years, the number of people with diabetes overall is still increasing in China which remains as the highest globally (NCD Risk Factor Collaboration, 2016). The importance of "five carriages", a metaphor in expressing the importance of diet, physical exercise, medication, self-monitoring of blood glucose, and diabetes education in diabetes management, has been emphasized in the management of diabetes in China (Shen & Guo, 2010; C. Tang, 2017). However, tasks related to problem-solving, coping, and risk reduction have been largely omitted from daily practice, although they have been included in diabetes education to some extent. Problem-solving has been identified as an important factor and element in diabetes management (AADE, 2008; Hill-briggs, 2003; Hill-Briggs et al., 2006), few studies in China have considered the appraisal of problem-solving among Chinese patients with T2DM, and studies assessing behaviors related to problem-solving were limited among this patient population. These could be possible reasons

contributing to the suboptimal self-management behaviors and glycemic control among Chinese patients with diabetes.

Diabetes self-management interventions such as self-management educational programs provide the knowledge, skills and the ability necessary for patients with diabetes to perform self-care activities (Funnell et al., 2012; Haas et al., 2014). Developing such self-management interventions requires comprehensive understanding of factors that relate to self-management behaviors in order to provide tailored care. A theory-based descriptive study examining the relationships between personal, behavioral, environmental factors and health behaviors as well as health outcomes can provide a more comprehensive understanding of how these factors relate to each other and how they impact health behaviors and health outcomes overall. The results may provide necessary information for developing self-management interventions that would have the potential to optimize their effects in improving diabetes management among Chinese patients with T2DM in the future.

2.4 CONCEPTUAL MODEL

Based on the literature review, the current study was proposed based on SCT (Bandura, 1986) to address the relationships among personal, behavioral, and environmental factors associated with health behaviors and health outcomes among adult Chinese patients with T2DM. According to the theory, the conceptual model depicted in Figure 1 illustrates that personal factors, behavioral factors and environmental factors influence health behaviors (self-management behaviors) collectively and also have an impact on health outcomes such as HbA1c and existence of MetS

either directly or indirectly. This model provided the overall framework for conducting this proposed study.

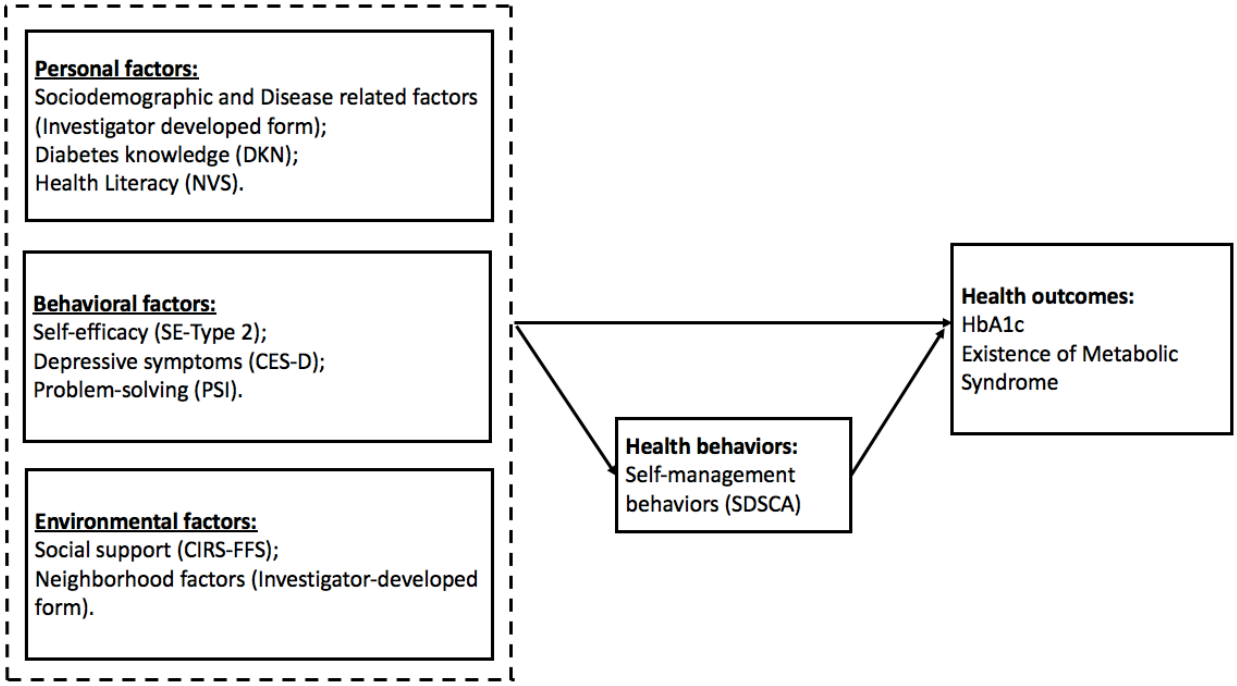

Figure 1. Conceptual Model

3.0 METHODOLOGY

3.1 RESEARCH DESIGN

This proposed study used a cross-sectional design to examine the associations of personal factors, behavioral factors, environmental factors, self-management health behaviors, and clinical health outcomes related to glycemic control and MetS among Chinese patients with T2DM using SCT (Bandura, 1986) as the framework.

3.2 SETTING

The proposed study was conducted at the outpatient clinic in the Endocrinology Center, Luhe Hospital located in a suburban area, named Tongzhou District, in Beijing, China. Luhe Hospital is a tier three tertiary hospital affiliated with Capital Medical University, Beijing, China. The Endocrinology Center is a clinical, educational, and research center for endocrine diseases ("Beijing Luhe Hospital Capital Medical University", 2017). It is one of the leading research centers in diabetes management and prevention in China. Both inpatient and outpatient clinics are available in this center. The center has an average of 120,000 patient visits (both initial and repeated visits) annually; about 50% are patients with diabetes (over 90% are diagnosed with T2DM).

Tongzhou District is identified as a "New Urban Development District" which has a total population of over 1.37 million as of 2015 with a density estimated at 1,521 per square kilometers (Beijing Municipal Bureau of Statistics, 2016). This number is expected to expand to 1.6 million in 2020 in response to the decentralization and dispersion of the capital, Beijing. It is a region where a combination of agriculture, industry, and governmental centers, etc. are located. In recent years, the population in this area has increased dramatically mainly due to the increase of nonresidents in this area in responding to the policy change which encourages people from the inner city to move to more suburban areas. This region has undergone fast expansion both in population growth, as well as economic growth which makes this region unique in its composition and living environment.

3.3 SAMPLE AND SAMPLING PROCEDURES

A convenience sample of 237 (n=213 completed the study) adult Chinese patients with T2DM was recruited by research investigators from the Endocrinology Center, Luhe Hospital, Tongzhou District, Beijing, China. Information about the study was posted at the center and flyers were distributed by nurses at the registration desk to patients who visited the center. A training session on recruitment procedures and study purposes was implemented by the primary investigator for clinic personnel assisting with this study. Informed consent was provided by participating patients before data collection was initiated. The study investigator or a research assistant was available during recruitment to answer any questions and explained the procedures of the study to those who were interested.

3.3.1 Sample selection

Inclusion Criteria. In order to be eligible for the study, patients (both male and female) needed to have a clear diagnosis of T2DM from a health care provider of no less than 6 months duration, and be at least 18 years of age or older. Eligible participants had to be Chinese patients and able to read, write and speak Mandarin.

Exclusion Criteria. Patients who had problems with hearing and/or vision, and documented renal disease or severe physical and/or mental illness were excluded from the study because of their limited ability to complete the questionnaires or the possibility of influence on the clinical laboratory values from the associated disease. Patients who were currently participating in a diabetes self-management intervention research study were also excluded since their experience could potentially introduce bias into the current study. In addition, women who were pregnant were also excluded from the current study since their management regimen was different from the general treatment regimen for patients with T2DM.

3.3.2 Sample size justification

Using G-Power, setting *a priori* α=0.05, two-tailed with 0.8 power, and using a small effect size at 0.2 for a correlational study (Aim 2), the estimated sample size was 193 subjects; setting *a priori* α=0.05, two-tailed with 0.8 power using effect size f^2 equals 0.1 for linear multiple regression with 13 possible predictors, the estimated sample size was 190 subjects (Aim 3); using an odds ratio of 1.5, two-tailed with 0.8 power and α=0.05, the sample size was estimated at 208 for the logistic regression (Aim 3). With the highest number of subjects being 208 from the sample size estimation, and considering an attrition rate of 10% among subjects who might

not be able to complete the study, the estimated sample size for the proposed study was set at 229. A total sample of 237 subjects were actually recruited for the study, and 213 completed the study (attrition rate at 10.1%). This number was expected to provide sufficient power to detect significant associations among study variables and their effects on health outcomes. Due to the unavailability of data on the number of unique patients with T2DM who visited the clinic each year, the representativeness of the sample (n=237) was unclear in terms of the total visits from patients with T2DM at the clinic.

3.3.3 Sampling procedures

Procedures for recruitment are displayed in Figure 2. Initial screening according to the inclusion and exclusion criteria took place at the registration desk by a clinical nurse when patients approached the registration desk during their clinic visit. Patients who met the criteria and agreed to learn more about the study were referred to the research investigators; after providing informed consent, patients were asked to complete a set of questionnaires including: an investigator-developed Sociodemographic and Health History Form, the Diabetes Knowledge Scale-DKN (Beeney et al., 2003), the Newest Vital Sign (Weiss et al., 2005), the modified Self-Efficacy Scale for People Living with Type 2 Diabetes-SE-T2DM (Van der Bijl, van Poelgeest-Eeltink, & Shortridge-Baggett, 1999), the Center for Epidemiological Studies Depression Scale-CES-D (Radloff, 1977), the Problem Solving Inventory-PSI (Heppner & Petersen, 1982), the Family and Friends Support Subscale of the Chronic Illness Resources Survey-CIRS (Glasgow et al., 2000), the Neighborhood Factors Form (investigator developed), and the modified Summary of Diabetes Self Care Activities-SDSCA (Toobert, Hampson, & Glasgow, 2000). All measures of study variables were available in Chinese and have demonstrated acceptable reliability and

validity in responding populations (see the instruments section for more details). Questionnaires were available for patients to take home and return to the center at a later date (such as the next visit); however, returning the document on the same day was preferred. The study investigator or research assistant was available at all times to answer any questions. Height, weight, waist circumference, and blood pressure were measured using standard equipment available at the center at the time of data collection. The most recent HbA1C, HDL, LDL and Triglyceride laboratory values were retrieved from the medical record.

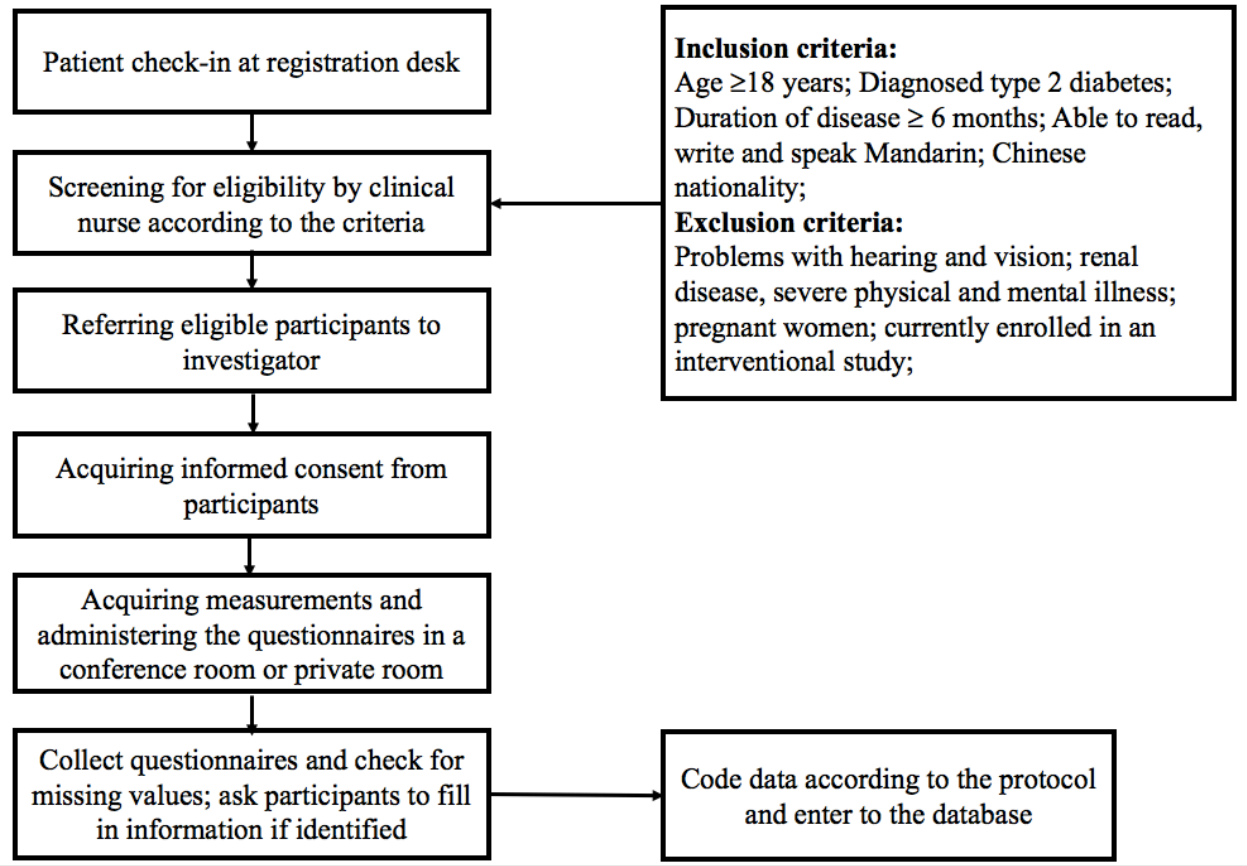

Figure 2. Flow Chart of the Recruitment Procedure.

3.3.4 Quality assurance

An instrument reference manual and protocol book were developed to assist the study investigator in collecting data. Personnel who were involved in the current study were trained by the principle investigator on procedures of recruitment, protocols to maintain privacy and confidentiality, and procedures to be used for coding and scoring of the measures. All personnel were asked to follow the instructions in the reference manual and protocol book when collecting data. A weekly meeting was held to make sure that all research personnel were following the same procedures and any arising issues were addressed.

3.4 INSTRUMENTS

3.4.1 Instruments

Sociodemographic and health history form. This form was an investigator developed questionnaire to collect participants' demographic information on age, gender, education level, marital status, family income, living conditions and health insurance information, as well as health related factors such as duration of T2DM, prescribed medications, smoking history and alcohol consumption, comorbidities. Measurements of height, weight, and waist circumference were obtained at the time of assessment using standard equipment available at the clinical center according to study protocol.

Diabetes knowledge. Knowledge about diabetes among participants was assessed using the Diabetes Knowledge Scale (DKN) Chinese version which consists of 14 multiple-choice questions and was modified from the original scale to meet the cultural differences among Chinese patients with diabetes in a previous study (Beeney et al., 2003; Yin Xu, Savage,

Toobert, Pan, & Whitmer, 2008). Only one answer was correct for each question; the possible total score for this scale ranged from 0 to 14. The higher the total score the greater the diabetes knowledge of participants. If participants answered the items correctly, the items were recorded as "1", otherwise as "0" (including "I don't know"). The DKN scale has been reported as reliable among the US patients with T2DM with Cronbach's alpha ranging from 0.72 to 0.79 and with satisfactory construct validity in the original study (Beeney et al., 2003). The Chinese version of the modified DKN among Chinese patients with T2DM (n=30) in mainland China has been reported as having a Cronbach's alpha of 0.62 for internal consistency (Xu, Savage, et al., 2008). In the modified DKN, modifications have been applied to reflect cultural differences, such as to substitute "butter" with "rice" since butter is not commonly consumed by Chinese people (Xu, Savage, et al., 2008).

Health literacy. Participants' health literacy was evaluated using the Chinese version of the Newest Vital Sign ([NVS], Weiss et al., 2005; Lin, 2010). The NVS is a widely-used instrument in assessing people's prose literacy, numeracy and document literacy, such as reading, math, abstract reasoning, etc. (Weiss et al., 2005). It includes 6 questions in the English version which are based on an ice cream nutritional fact label, and was initially tested among primary care patients yielding a Cronbach's alpha of 0.76, and reported concurrent validity with a correlation coefficient of 0.59 with the Test of Functional Health Literacy in Adults scale (Weiss et al., 2005). The Chinese version of the NVS was tested among early childhood teachers (n=199) in Taiwan and reported as valid and with a Cronbach's alpha of 0.65 (C. Lin, 2010). Each question was scored as "1" if participants answered correctly with a possible total score (number of correct answers) ranging from 0 to 6. A total score less than 1 indicates limited health

literacy, and a score of 2 to 3 indicates the possibility of limited literacy while a score higher than 4 indicates adequate literacy.

Self-efficacy. The modified Chinese version of the Self-Efficacy Scale for People with Type 2 Diabetes (SE-T2DM) was used to collect information on the level of confidence in managing diabetes among participants (Van der Bijl et al., 1999; Yin Xu, Savage, et al., 2008). The final version in the original study is a self-reported 20-item measure on an 11-point Likert scale and has demonstrated a Cronbach's alpha for the total score of 0.81; and 0.79 for test-retest reliability over 5 weeks (n=94) among patients with T2DM (Van der Bijl et al., 1999). Construct validity using principal component analysis showed that the instrument was valid in assessing self-efficacy among patients with T2DM. The modified Chinese version has 7 items with 5-point Likert scale ranging from 1 "no, definitely not" to 5 "yes, definitely" with the higher the score the greater the self-efficacy. Items were rephrased and irrelevant items were removed from the original scale to adapt to the cultural differences among a Chinese population (Yin Xu, Savage, et al., 2008). The Cronbach's alpha was reported as 0.87, and it showed construct validity with factor loading on similar factors identified in the original scale and acceptable content validity among Chinese patients (n=30) with T2DM (Yin Xu, Savage, et al., 2008).

Depressive symptoms. The Chinese version of the Center for Epidemiological Studies Depression Scale (CES-D) was used to assess the presence and severity of depressive symptoms among participants (Z. Chen, Yang, & Li, 2009; Radloff, 1977). The CES-D is a self-reported 20-item instrument evaluating experienced symptoms related to depression in the past seven days. The original scale is rated on a 4-point Likert scale ranging from 0 "rarely or none of the time" to 3 "most or almost all the time". The possible total score for the CES-D ranges from 0 to 60; a cut-off point at 16 or greater is considered as high risk for clinical depression (Lewinsohn,

Seeley, Roberts, & Allen, 1997). The CES-D was reported valid and reliable in the original study with a Cronbach's alpha of 0.85 for the total score and a test-retest reliability of 0.54 in the general population. The Chinese version of the CES-D is also a 20-item, 4-point Likert scale ranging from 0 as "less than 1 day", 1 as "1-2 days", 2 as "3-4 days", 3 as "5-7 days" to indicate the presence of symptoms during the last 7 days. It has been tested for psychometric properties among adolescents and suicide attempters in China (Z. Chen et al., 2009; L. Yang, Jia, & Qin, 2015). The Cronbach's alpha was reported as 0.88 among middle school students (n=10,210) and 0.94 among suicide attempters (n=409).

Problem-solving. The Problem Solving Inventory (PSI) Chinese version was used to assess the level of problem-solving appraisal among participants (Heppner & Petersen, 1982; Tian, Heppner, & Hou, 2014). The PSI is a 32-item (with additional 3 items as filler items that are not included in the scoring) self-reported instrument with three subscales in measuring one's problem-solving appraisal rather than applied problem-solving in everyday life (Heppner & Petersen, 1982). The three subscales include: Problem Solving Confidence, Approach-Avoidance Style and Personal Control. The PSI is rated on a 6-point Likert scale ranging from "strongly agree" to "strongly disagree" ("1" - "6"). Three subscale scores and a total score combining the three dimension scores are reflective of one's problem-solving appraisal with the total score ranging from 32 to 192; lower scores are indicative of successful or positive appraisal toward effective problem-solving (Heppner & Petersen, 1982). The PSI was initially tested among white college students (n=150) and reported as valid with moderate correlations with a simple self-rating problem-solving scale (r ranges from -.29 to -0.46 for the subscales and total score respectively), and reliable (α= 0.72 to 0.85 for the three subscales and 0.90 for the total scale). The PSI has been widely used in many studies (Heppner & Petersen, 1982; Heppner, Witty, &

Dixon, 2004). The Chinese version of the PSI was tested among Chinese college students (n=736); the result revealed a similar but somewhat different structure from the original scale in which 18 items with three factors (Problem Solving Confidence, Reflective Thinking, and Emotional Control) were identified by authors in this population (Tian et al., 2014). The 18-item scale was reported reliable with a Cronbach's alpha of 0.80 for the total score and 0.67 to 0.80 for the subscales (split half sample A, n=368); the validity was assessed through testing of both convergent (with locus of control) and construct validity in confirmatory and exploratory factor analyses. The translated Chinese version of the PSI with 32 items was obtained from the author and was used in this study to evaluate the appraisal of problem-solving among participants.

Social support. The Family and Friends Support subscale of the Chronic Illness Resources Survey (CIRS-FFS) was used to assess support and resources from their family among participants (Glasgow et al., 2000). The original CIRS-FFS is an 8-item, 5-point Likert scale. The items range from 1 as "not at all" to 5 as "a great deal" in responding to the level of family support over the past 3 months. The scale has been reported valid with good construct validity and acceptable concurrent and prospective criterion validity; it has demonstrated reliability with a Cronbach's alpha of 0.75 among patients with chronic diseases (n=123) in the original study (Glasgow et al., 2000). The Chinese version of the CIRS-FFS is a 6-item, 5-point Likert scale modified from the original scale; it is reported as valid with acceptable construct validity and reliable with a Cronbach's alpha of 0.86 among Chinese patients with T2DM (Yin Xu, Savage, et al., 2008). In the CIRS-FFS Chinese version, items related to "friends" were removed to reflect a focus on support received from family (Yin Xu, Savage, et al., 2008). A higher score is indicative of greater support from family as perceived by participants.

Neighborhood factors. A set of investigator developed questions (4 items) related to environmental safety, availability of healthy food and space to exercise, and residential stability was used to evaluate the neighborhood factors as suggested by researchers (Echeverria et al., 2004; Gonzalez-zacarias et al., 2016). Other than the question on residential stability, all questions received yes (coded as "1") or no (coded as "0") according to participants' actual response. According to the literature, residential stability is determined as living in one's current household equal to or more than 5 years (de Vries McClintock et al., 2015). Therefore, the question on residential stability was coded as "1" if participants responded as living at the current address for more than or equal to 5 years, otherwise the response was coded as "0". A cumulative score (0 to 4) of the four items was assigned to this variable.

Self-management behaviors. The modified Summary of Diabetes Self Care Activities-SDSCA was used to assess self-management behaviors related to diabetes management among participants (Toobert et al., 2000). The SDSCA is a widely used self-reported questionnaire with 25 items assessing self-management behaviors related to diet, physical exercise, medication taking, blood glucose testing, foot care during the last 7 days (rating from "1" to "7") as well as smoking. The SDSCA was shown to be valid using criterion validity testing. The inter-item correlations of the instrument among populations with T2DM in seven studies (n=1,988) in the original research were demonstrated to be reliable and reported as 0.57 to 0.71 for diet, 0.47 to 0.80 for exercise, and 0.69 to 0.75 for blood glucose monitoring across studies (Toobert et al., 2000). Three-month test-retest reliability was reported as 0.55 to 0.67 for general diet, 0.42 to 0.61 for specific diet, 0.42 to 0.55 for exercise, and 0.3 to 0.78 for blood glucose testing across studies. The modified SDSCA Chinese version consists of 10 items in which items related to specific diet were excluded due to cultural differences in the validation study; in addition, items

related to smoking were also excluded (Yin Xu, Savage, et al., 2008). The Chinese version of the SDSCA assesses the self-care activities related to regular diet, physical exercise, medication taking, self-monitoring of blood glucose, and foot care performed by participants over the past 7 days (rated from "0" to "7"). A higher score is indicative of better self-management behaviors. It has been reported with good construct validity and proved to be reliable with a Cronbach's alpha of 0.68 and inter-item correlation at 0.69 among Chinese patients with T2DM (n=30).

Glycemic control. HbA1c was used to assess glycemic control among participants. It is the percentage of the glycated hemoglobin in relation to the total hemoglobin; it reflects the average blood glucose level within the last 2 to 3 months (Freeman, 2014). It is the gold standard for assessing the long-term glycemic control among people with diabetes. The recommended target value of HbA1c for adult patients (excluding women with gestational diabetes) with T2DM in China is 7%, although an individualized target should be followed for each patient considering age, duration, life expectancy as well as comorbidities and severity of complications (Weng et al., 2016). The most recent value of HbA1c was retrieved from the medical record (within 3 months of the current visit).

Existence of MetS. Clinical indicators related to MetS were assessed among participants. The most recent information (within 6 months of current visit) on identified indicators of MetS including blood pressure, waist circumferences, high density lipoprotein (HDL), low density lipoprotein (LDL), as well as triglyceride were obtained. Values on related clinical indicators were retrieved from the medical record except for blood pressure, which was measured at the time of enrollment as a single causal measurement using automated device by a clinic nurse at the registration desk. A measurement of the waist circumference was also obtained at the time of assessment (using a standard measuring tape and measured at the level of the umbilicus on bare

skin). The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) for Asian population criteria was used to identify the parameters for MetS. Presentation of three or more of the following conditions was confirmed for MetS: insulin resistance or being diabetic; waist circumference ≥ 90cm in men or ≥ 80cm in women; systolic blood pressure ≥130 and/or diastolic blood pressure ≥ 85 mm Hg, or currently on treatment for hypertension; HDL < 1.03 mmol/L in men or < 1.30 mmol/L in women; and Triglyceride ≥1.7mmol/L or currently on treatment for dyslipidemia (Grundy et al., 2005). Since all patients had T2DM, those who met two or more of the other criteria were confirmed to have MetS.

3.5 PROCEDURES FOR DATA ANALYSIS

3.5.1 Data management

All data were coded and scored according to the instrument reference manual before entering it into the database. After appropriate coding, data were entered using the EpiData software by two people (one was the primary investigator, another one was the clinic nurse who helped to recruit patients for the study) to allow double entry and data verification. All data analysis was performed using the IBM Statistical Package for the Social Sciences for Mac (Version 24, SPSS, Inc., Chicago, Illinois, 2015) in this study. Statistics with p-value of less than or equal to 0.05, two-tailed, were determined to be statistically significant. All instruments used in this study were checked for their reliability using Cronbach's alpha.

3.5.2 Preliminary data analysis

Data screening. Data accuracy (meaningfulness of the data) and completeness were checked at the time of data collection and data entry to ensure quality of the data. Data coding and data entry were rechecked to determine if any discrepancies existed. Pattern of missingness among 213 participants was checked, which indicated missing completely at random (Little's MCAR test: X^2=95.82, df=99, p=0.572). A total of 15 cases (7.0%) had missing values on self-reported variables and related clinical values. Data on nine cases with missing values on self-reported variables (SE-T2DM and PSI) were imputed using mean imputation (participants' total score was divided by the number of items answered by each patient, and multiply the number of total items for the scale). Both univariate and multivariate outliers were checked using z scores and Mahalanobis distance. Five cases were identified as multivariate outliers due to extreme values on clinical indicators. However, they were included in the final analysis since the extreme values were clinically meaningful.

Checking assumptions. After the data were screened for accuracy and completeness, appropriate assumptions of study variables were checked for all statistical tests used in the current study. Assumptions of normality for each variable were assessed through observation of test statistics including skewness and kurtosis, as well as graphics such as histograms, scatter plots and normal Q-Q plots. The assumption of normality was met for all variables except for self-management behaviors related to medication adherence (negatively skewed). Log transformation of the data on self-management behaviors related to medication adherence was attempted; the results on related statistical methods did not differ when the original data was used. Residual plots and bivariate scatter plots between study variables were examined for linearity. In order to check homoscedasticity, the Levene's test and scatter plots were assessed to

determine if all data points of the study variables were clustered around the horizontal line. In testing multicollinearity for regression models, the tolerance and variance inflation factors (VIF) were examined among variables. A VIF value near 10 or greater than 10 and a small tolerance value were considered as an issue for multicollinearity. As a result, no multicollinearity and heteroscedasticity were observed among study variables.

3.5.3 Data analysis

The aims of the study were addressed through the following analytic approaches.

Aim 1: To characterize the sample of adult Chinese patients with T2DM.

Continuous variables were described using mean, standard deviation, range and median for sociodemographic and disease related factors, personal, behavioral and environmental factors, as well as self-management behaviors and health outcomes. Categorical variables (such as gender, etc.) were described using frequency counts and percentages. Results on study variables and health outcomes were compared with findings from previous research and interpreted using clinical criteria or guidelines from the literature.

Aim 2: To examine the associations between personal, behavioral, environmental factors, health behaviors, and health outcomes;

After assumptions were checked and appropriate transformations were applied to satisfy statistical assumptions, the Pearson product-moment correlation was used to examine the relationships between study variables. A correlation matrix (Appendix D, Table 8) was generated among study variables (diabetes knowledge, health literacy, self-efficacy, depressive symptoms, problem-solving, social support, and neighborhood factors) and outcome variables (self-management behaviors and HbA1c) to examine their relationships. Scores and relationships of

personal, behavioral and environmental factors, self-management behaviors and health outcomes were analyzed in terms of the direction and strength of the correlation between variables.

Aim 3: To examine the impact of modifiable factors on various self-management behaviors and their impact on health outcomes (glycemic control and existence of MetS).

Simple linear regression was conducted to assess the independent contribution of the study variables on health outcomes related to self-management behaviors and HbA1c. Multiple linear regression analysis was used to determine the impact of study variables as a group on self-management behaviors controlling for covariates (age, gender, years of education, duration of disease, number of comorbidities, and number of medications). Unstandardized coefficient (β), the coefficient of determination r-squared (r^2), as well as the F change where appropriate were used to explain the impact of study variables on self-management behaviors and HbA1c. Logistic regression was used to examine the impact of study variables on the existence of MetS. The odds ratio, 95% confidence interval and p values were used to describe the results. The impact of individual self-management behaviors was also assessed using simple and multiple linear regression or logistic regression to determine their effect in predicting HbA1c and the existence of MetS.

Aim 4: To examine the mediation role of the overall self-management behaviors between personal, behavioral, environmental factors, and HbA1c in this sample.

The correlation matrix (Table 8) was used to examine the relationships among study variables, self-management behaviors, and HbA1c. Observing the correlation matrix showed that there were no significant correlations between HbA1c and other study variables except for problem-solving and self-management behaviors. However, the relationship between problem-solving and self-management behaviors was not significant in this sample; therefore, the mediation effect

was not able to be tested. If there were significant relationships detected among these variables, multiple linear regression analysis using a hierarchical approach controlling for personal factors would have been applied to determine the mediation role of self-management behaviors between personal, behavioral, environmental factors and health outcome (HbA1c). Simple linear regression would have first been performed to determine if there were significant linear relationships among each of the study variables, self-management behaviors and HbA1c controlling for covariates. Using the hierarchical regression approach, covariates would have been entered first in the model; each of the modifiable variables would have been entered separately in the model to determine if these study variables had significant linear relationships with both self-management behaviors and HbA1c. For the final step, self-management behaviors would have been entered next to determine if the model was still significant in explaining the outcome variables (HbA1c) with all covariates already in the model. Statistics such as unstandardized coefficient (β) and the coefficient of determination r-squared (r^2) would have been used to explain the strength of variables in predicting self-management behaviors and HbA1c when variables were added to the model.

3.6 RESEARCH PARTICIPANT RISK AND PROTECTION

The likelihood of risk to participants in this study was minimal. Participants might have experienced fatigue due to the time (25 to 55 minutes) to complete the questionnaires; they were advised to take breaks during data collection when needed. Participants were offered a private room to complete the questionnaires (a small private room was available to accommodate 3 to 5

people). They did not benefit directly from the study; however, findings of the study may better inform health care providers about diabetes self-management. In addition, if any participants were identified as having severe depressive symptoms based on the CES-D (≥16), they were referred to a psychiatrist for further assessment. Study approvals from the Human Research Protections Office of the University of Pittsburgh and Luhe Hospital were obtained before implementation of the study. Informed consent from eligible participants was obtained before data collection was initiated. The primary investigator and trained research assistant were the individuals collecting the self-reported materials and assured that information was complete and that confidentiality was maintained at all times during the study. All participants were assigned a unique coded identifier for materials obtained; study materials were kept in a locked file cabinet without relating to participants' identity. Documents such as a list of study participants, consent forms, and questionnaires were kept in locked file cabinet or locked drawers separately from each other. Only research personnel in the study had access to the documents. A data and safety monitoring plan (continuous evaluation of patients' risks in participating the study, weekly meetings to discuss issues emerged) was implemented by the principal investigator to ensure that there were no changes in the risk or benefit ratio during the course of the study and that confidentiality of research data was maintained. The principal investigator (PI) worked closely with the dissertation advisor to ensure the study was carried out as planned. Each member of the study team met with the PI and reviewed confidentiality issues prior to having contact with participants. Investigators and study personnel met weekly or biweekly to discuss recruitment procedures, address any issues or concerns, and assure that the study was carried out appropriately. Minutes were kept of these meetings and were maintained in a study binder. If there had been any instances of adverse events, they would have been reported immediately to

the University of Pittsburgh IRB using standard forms and/or procedures that have been established by the IRB. The IRB renewal (if needed) for this study will include a summary report of the Data and Safety Monitoring Plan findings from the prior renewal period.

4.0 MANUSCRIPT #1 (TO BE SUBMITTED): CHARACTERIZING A SAMPLE OF CHINESE PATIENTS WITH TYPE 2 DIABETES AND SELECTED HEALTH OUTCOMES

This chapter reports the study findings related to the first aim of the dissertation project:

Aim 1: Characterize the sample of Chinese patients with T2DM recruited from a suburban area in Beijing, China.

Characterizing a Sample of Chinese Patients with Type 2 Diabetes and Selected Health Outcomes

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Declaration of interest: None.

4.1 ABSTRACT

Objective: To describe the characteristics and selected health outcomes of a sample of Chinese patients with type 2 diabetes and examine gender differences based on Social Cognitive Theory. **Methods:** Data were collected from 207 patients from an outpatient clinic at a tertiary hospital in a suburban area of Beijing, China. Participants completed a survey and HbA1c and other clinical values were retrieved from the patient's medical record. **Results:** Overall, 40.1% of patients had optimal glycemic control (<7%); only 16.4% had recommended levels in performing self-management behaviors. Compared to men, women demonstrated poorer health literacy and problem-solving, received less social support and presented with more depressive symptoms (t= 2.66, -3.67, 2.86, -2.94 respectively, $p<0.01$). Of the participants, 89.4% had metabolic syndrome and 72% were overweight or obese. **Conclusion**: Glycemic control and self-management behaviors were suboptimal in this sample and a large proportion of the sample were at risk for developing cardiovascular disease. Gender differences exist regarding health literacy, depressive symptoms, problem-solving and social support. Social Cognitive Theory may provide a lens for addressing factors that are important in improving health outcomes and providing tailored care to Chinese patients with type 2 diabetes.

Keywords: Chinese patients with type 2 diabetes; diabetes self-management; health outcomes; gender differences.

4.2 INTRODUCTION

Diabetes is the most prevalent and fastest growing chronic disease globally; of the 422 million adults with diabetes worldwide, nearly 129.3 million people with diabetes live in China and account for about 30% of all patients with diabetes globally (World Health Organization, 2016). Diabetes is a significant public health issue in China affecting 10.9 % of the population (L. Wang et al., 2017), with more than 90% of those with diabetes being diagnosed with type 2 diabetes ([T2DM]; Weng et al., 2016).

Fast economic growth and improvement in quality of life over the past few decades has probably contributed to this significant increase in the prevalence of diabetes in China (L. Wang et al., 2017). Studies in China reveal that the prevalence of diabetes is significantly higher among those who have high incomes and live in more developed areas (Weng et al., 2016). In China, those who live in the suburbs of a large city, such as Beijing, are underrepresented among studies targeting patients with T2DM. Few studies have focused on the self-management of patients with T2DM in suburban areas (He et al., 2016). Suburban areas of a large city in China are often associated with fast economic development which may potentially influence how patients with diabetes adapt to and manage their condition due to a change of lifestyle following urbanization.

Although self-management has been identified as critically important among patients with T2DM, self-management and glycemic control among Chinese patients with T2DM are suboptimal. Researchers have reported the mean HbA1c being 8.5% to 9.2% among Chinese patients with T2DM, with only 24.2% to 35.8% achieving the target goal for HbA1c as <7% (L. Ji et al., 2016; K. Lin et al., 2017; Wenjia Yang et al., 2016). Using a proportion standard (actual score/total score ≥80%) for evaluating optimal self-management behaviors, only 9.1 to 9.2 % of patients have achieved an adequate goal of performing overall self-management behaviors, according to the studies that were done in China (J. Ji et al., 2014; X. Sun et al., 2012b).

Bandura's Social Cognitive Theory (SCT), considers personal, behavioral, and environmental factors to be essential elements in behavior change among patients with chronic disease (Bandura, 1986). As suggested by SCT, triadic reciprocal relationships exist among these factors and interactively influence human functioning such as health related behaviors, and therefore impact health outcomes. An understanding of the relationship of these factors to self-management and glycemic control of patients with T2DM is necessary before developing and testing tailored interventions. A paucity of research exists that comprehensively examines the personal, behavioral, and environmental factors on Chinese patients with T2DM who reside in the suburbs of a large city.

We chose SCT to examine the underlying factors contributing to diabetes management among Chinese patients with T2DM. Personal factors, including sociodemographic (age, gender, years of education) and disease related factors (duration of diabetes, number of medications, number of comorbidities), play an important role in self-management of chronic disease and are significant in diabetes management (Luo et al., 2015; Walker et al., 2015). Patients' level of diabetes knowledge and health literacy are also important in diabetes management and in predicting glycemic control (Kueh et al., 2015; Luo et al., 2015). Behavioral factors including self-efficacy, depressive symptoms, and problem-solving are essential for diabetes management (Adam & Folds, 2014; Luo et al., 2015; Shin et al., 2017; Y. Zhang, Ting, Lam, et al., 2015). The importance of social support, and neighborhood factors such as safety, availability of healthy food and space for exercise have been reported as necessary for diabetes management (de Vries McClintock et al., 2015; Smalls et al., 2015b). Meanwhile, gender, as identified under the personal factors within SCT, differences between males and females have been recognized to exist among patients with T2DM in regard to diabetes self-management and associated factors.

Compared to men, women have exhibited poorer diabetes outcomes, more depressive symptoms, less social support and limited problem-solving (Góis et al., 2018; Mansyur, Rustveld, Nash, & Jibaja-Weiss, 2016; Shin et al., 2017).

In addition, metabolic syndrome (MetS), commonly seen among patients with diabetes, increases the risk for diabetes complications such as cardiovascular disease (Ginsberg & MacCallum, 2009; Yao et al., 2016). As many as 72.5% of Chinese patients with T2DM have been shown to have MetS (Jing et al., 2018; Yao et al., 2016). Therefore, parameters of MetS, including blood pressure, waist circumference or body mass index (BMI), high-density lipoprotein (HDL), low-density lipoprotein (LDL) and triglyceride, also need to be addressed when evaluating the level of diabetes management among patients with T2DM.

Currently, there is limited evidence in theory-driven research conducted among patients with T2DM in China. According to SCT, the personal, behavioral, and environmental factors influencing health behavior have not been explicitly examined among Chinese patients with T2DM, especially those living in the suburbs of a large city (Bandura, 1986). Therefore, the aims of the current study were to 1) describe the characteristics and selected health outcomes of Chinese patients with T2DM in a suburban area of a large city and 2) compare gender differences on selected personal, behavioral, and environmental factors, as well as health outcomes.

4.3 MATERIALS AND METHODS

4.3.1 Design

This study was a cross-sectional study conducted at the outpatient clinic in the Endocrinology Center of a tertiary hospital in a suburban area of Beijing, China. The Endocrinology Center is one of the leading research centers in diabetes management and prevention in China. The outpatient clinic receives an average of 120,000 patient visits each year (both initial and repeat visits), and accepts patients with conditions such as diabetes, thyroid deficiency, cardiovascular disease, and obesity.

4.3.2 Recruitment procedure

Data collection was conducted between November 2017 and January 2018. Ethical approval for the study was received from the Ethical Committee of the study hospital in Beijing and from the Human Research Protections Office at the University of Pittsburgh in the US prior to the start of the study. Inclusion criteria were: Chinese patients with T2DM diagnosed for a minimum of 6 months; both male and female; at least 18 years old; and able to read, write, and speak Mandarin. In addition, laboratory tests on HbA1c (within the prior 3 months) and other clinical values related to metabolic syndrome (within the prior 6 months) needed to be available at the time of data collection or during the current clinic visit. Individuals who had problems with hearing and/or vision, documented renal disease, severe physical and mental illness, or were pregnant were excluded from the study. Potential patients were screened at the registration desk by nurses who worked at the clinic. Patients who met the criteria and agreed to participate in the study

were referred to the research investigator. Eligible patients provided informed consent. Then patients' height, weight, and waist circumference were assessed by a clinic nurse. A routine single measurement of blood pressure using an automatic blood pressure device was taken by a clinic nurse at the registration desk. Participants were asked to complete a set of questionnaires which took 25 to 55 minutes to complete. Clinical values for HbA1c, triglyceride, HDL, LDL were retrieved from the medical record by the clinic nurse after questionnaires were returned. A total of 207 patients completed the study. The detailed recruitment procedure is displayed in Figure 3.

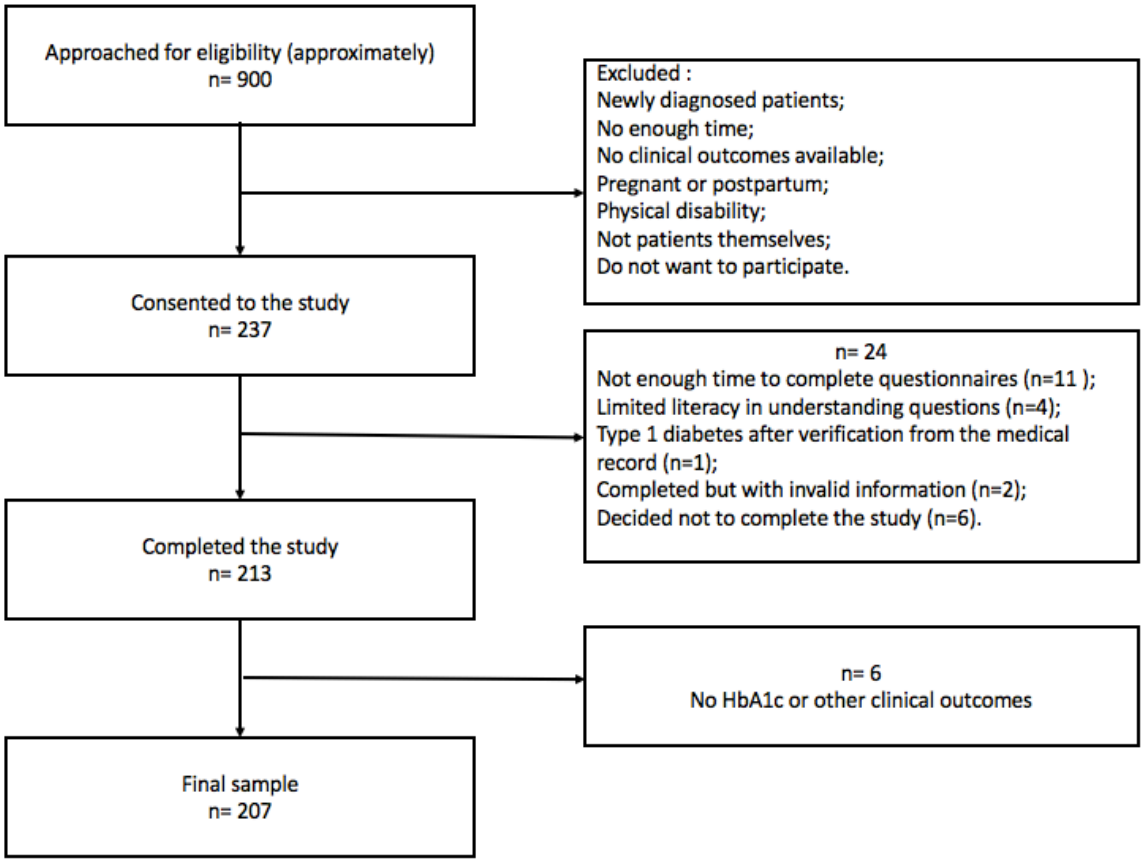

Figure 3. Participant Recruitment Flow Chart

4.3.3 Measures

A total of 9 questionnaires were used to collect information on selected personal, behavioral and environmental factors, as well as health outcomes. The sociodemographic, health related information, and neighborhood factors were collected using investigator-developed forms. The other study variables were evaluated using validated instruments that were originally developed in English and tested for reliability and validity in a Chinese population in previous studies. Diabetes knowledge was evaluated using the Chinese version of the Diabetes Knowledge Scale ([DKN]; Beeney, Dunn, & Welch, 2003; Xu, Savage, Toobert, Pan, & Whitmer, 2008). Health literacy was assessed using the Chinese version of the Newest Vital Sign ([NVS]; C. Lin, 2010; Weiss et al., 2005). The Chinese version of the Self-Efficacy Scale for People with Type 2 Diabetes (SE-T2DM) was used to evaluate patients' level of self-efficacy(Van der Bijl et al., 1999; Yin Xu, Savage, et al., 2008). Depressive symptoms was assessed using the Chinese version of the Center for Epidemiological Studies Depression Scale ([CES-D]; Chen, Yang, & Li, 2009; Radloff, 1977). The Chinese version of the Problem Solving Inventory (PSI) was used to assess perceived effectiveness in problem-solving among participants (Heppner & Petersen, 1982; Tian et al., 2014). Level of family social support was examined using the Chinese version of the Family and Friends Support subscale of the Chronic Illness Resources Survey (CIRS-FFS) over the past 3 months (Glasgow et al., 2000; Yin Xu, Savage, et al., 2008). To evaluate self-management behaviors among participants, the Chinese version of the Summary of Diabetes Self Care Activities (SDSCA) which was modified and underwent psychometric testing among Chinese patients with T2DM in a previous study was used (Toobert et al., 2000; Yin Xu, Savage, et al., 2008); the SDSCA Chinese version included five subscales in measuring behaviors in regard to medication treatment, diet, physical activity, self-monitoring of blood glucose and foot

care for the past seven days. See Table 1 for detailed information about the instruments. All but two instruments (DKN and SDSCA) demonstrated acceptable reliability (Tavakol & Dennick, 2011); Cronbach's alphas ranged from 0.64 to 0.90 in the current study.

Table 1. Instruments Used in the Current Study

Variables	Measures	#of items: Score Range	Cronbach's Alpha		
			1	2	3
Diabetes Knowledge	Diabetes Knowledge Scale (DKN)	14: 0-14	0.72-0.79	0.62[a]	0.67
Health Literacy	Newest Vital Sign (NVS)	6: 0-6	0.59	0.65	0.86
Self-Efficacy	Self-efficacy Scale for Patients with Type 2 Diabetes Mellitus (SE-T2DM)	7: 7-35	0.81	0.87[a]	0.70
Depressive Symptoms	Center for Center for Epidemiological Studies Depression Scale (CES-D)	20: 0-60	0.85	0.88-0.94	0.90
Problem-Solving	Problem Solving Inventory (PSI)	32: 32-192	0.90	0.80	0.85
Social Support	The Family and Friends Support subscale of the Chronic Illness Resources Survey (CIRS-FFS)	6: 6-30	0.75	0.86[a]	0.83
Neighborhood Factors	Investigator-developed (NF)	4: 0-4	-	-	-
Self-management behaviors	Summary of Diabetes Self-Care Activities (SDSCA)	9: 0-63	0.47-0.80[b]	0.68[a]	0.64

Note: [1]Original study; [2]Chinese population; [3]Current study; [a] Study was done among Chinese patients with type 2 diabetes; [b] Reported as inter-item correlation.

The most recent HbA1c (within the prior 3 months) was obtained from the medical record to assess glycemic control among participants. Blood pressure was measured on participants' arm at the time of enrollment by a clinic nurse using an automated device with the patient in a sitting position after at least 5 minutes of resting time. Laboratory values on HbA1c, HDL, LDL, and triglyceride were retrieved from the medical record by a clinic nurse after questionnaires were returned to the investigator. All data were deidentified and kept in locked drawers in a locked office with consent forms stored separately from the data. Only personnel on the study team had access to the data.

4.3.4 Data analysis

The IBM SPSS for Mac, Version 24 was used to analyze the data. Of the 207 participants who completed the study, 9 cases had missing data with the missing pattern identified as completely at random (Little's MCAR test: X^2=35.468, df=44, p=0.817). They were imputed using case-based mean imputation. Therefore, the total sample (n= 207) was included for final analysis. Continuous variables such as age, patients' adherence on diabetes management including self-management behaviors, HbA1c, etc. were described using the mean and standard deviation. Categorical variables were described using frequencies and percentages. Independent Sample T-test and Chi-square test were used to compare the differences on related personal, behavioral and environmental factors as well as health outcomes between male and female. Statistical significance was set *a priori* as 0.05, two-tailed. As for the SDSCA total score, communication with the author of the original study was carried out to clarify the scoring of the two items related to medication treatment. Since some participants were taking both insulin and oral medications, the two items were combined to reflect adherence to medication treatment, in which the lowest score was used if the patients were prescribed both oral medication and insulin. A a result, the SDSCA total score was ranged from 0 to 63 with 9 items.

4.4 RESULTS

Participants (n=207) were on average 56.1 (SD=11.4) years old with 11.3 (SD=3.4) years of education (less than high school graduation); they had been diagnosed with T2DM on average 8.9 (SD=6.9) years. A majority of the participants (72%) were identified as overweight or obese

with a mean BMI of 25.7 (SD=2.9); 89.4% were identified as having coexisting MetS. There were 16.4% of participants who had had adequate self-management behaviors (SDSCA: actual score/ total score ≥ 80%), and about 40.1% had the optimal goal for glycemic control (HbA1c<7%).

Compared to male participants, female participants were significantly different in demographic characteristics and health related factors such as age, level of education, BMI. Statistically significant lower scores were identified for health literacy ($t= 2.66$, $p<0.01$) and social support ($t= 2.86$, $p<0.01$), and higher scores were identified for problem-solving ($t= -3.67$, $p<0.01$) and depressive symptoms ($t= -2.94$, $p<0.01$) among females. A detailed description of the socio-demographic characteristics, health related factors, associated personal, behavioral and environmental factors for the total sample, as well as for each gender are displayed in Table 2 and Table 3.

Table 2. Characteristics and Gender Differences on Demographics and Health Related Factors (n = 207)

Measure	Mean ± SD/n (%)			Statistic
	Total (n=207)	Male (n=103)	Female (n=104)	t/x^2
Age	56.1±11.4	53.3±11.8	58.9±10.3	-3.65**
Marital Status				8.69*
Single	1 (0.5)	0 (0)	1 (1.0)	
Married	183(88.4)	96 (93.2)	87 (83.7)	
Divorced/Separated	9 (4.3)	5 (4.9)	4 (3.8)	
Widowed	14 (6.8)	2 (1.9)	12 (11.5)	
Years of Education	11.3 ± 3.4	12.1±3.7	10.5±2.9	3.45**
Employment Status				41.97*
Full-time	58 (28)	49 (47.6)	9 (8.7)	
Part-time	3 (1.4)	2 (1.9)	1 (1.0)	
Unemployed	5 (2.4)	3 (2.9)	2 (1.9)	
Retired	128(61.8)	43 (41.7)	85 (81.7)	
Other	13 (6.3)	6 (5.8)	7 (6.7)	
Family Income (Monthly)				7.81*
FI <$475	16 (7.7)	7 (6.8)	9 (8.7)	
$475 ≤ FI <$795	51 (24.6)	21 (20.4)	30 (28.8)	
$795 ≤ FI ≤ $1270	63 (30.4)	27 (26.2)	36 (34.6)	
FI≥ $1270	77 (37.2)	48 (46.6)	29 (27.9)	
Height (cm)	165.6±8.0	171.3±5.9	159.9±5.1	14.90**
Weight (kg)	70.9±11.7	77.6±10.5	64.2±8.5	10.16**
Waist (cm)	91.1 ± 8.7	95.1±8.2	87.2±7.5	7.21**
Body Mass Index (BMI)	25.7 ± 2.9	26.4±2.9	25.1±2.8	3.39**
BMI≥24	149 (72)	83 (80.6)	66 (63.5)	7.52**
Diabetes Duration (years)	8.9 ± 6.9	8.5±6.2	9.4±7.5	-0.98
# of Medications	4.7 ± 2.6	4.8±2.5	4.6±2.7	0.47
# of Comorbidities	1.5 ± 1.3	1.5±1.3	1.5±1.3	-0.45

*p<0.05; **p<0.01

Table 3. Descriptive Statistics and Gender Differences on Associated Factors and Health Outcomes (n = 207)

Variable	Mean ± SD/n (%)			Statistic
	Total (n=207)	Male (n=103)	Female (n=104)	t/x^2
Diabetes Knowledge	10.7± 2.4	10.6± 2.4	10.7± 2.4	-0.13
Health Literacy	2.0 ± 2.1	2.4 ± 2.1	1.6 ± 2.1	2.66**
Self-Efficacy	29.0 ± 4.4	29.3 ± 4.1	28.7 ± 4.6	0.85
Problem-Solving	93.3±16.0	89.3±14.8	97.3± 16.1	-3.67**
Depressive Symptoms	6.4 ± 8.5	4.7 ± 5.9	8.1 ± 10.2	-2.94**
CES-D ≥16	20 (9.7)	5 (4.9)	15 (14.4)	5.43*
Social Support	21.1± 5.4	22.2± 5.0	20.1± 5.5	2.86**
Neighborhood Factors	3.7 ± 0.6	3.7 ± 0.6	3.7 ± 0.6	-0.74
Self-management (Total Score)	40.1±11.6	39.6±11.6	40.5 ±11.6	-0.56
Adequate [a]	34 (16.4)	16 (15.5)	18 (17.3)	0.12
Medication treatment	6.4 ± 1.7	6.3 ± 1.8	6.5 ± 1.7	0.39
Diet	9.7 ± 4.1	10.1 ± 3.9	9.3 ± 4.3	0.14
Physical activity	10.4 ± 4.3	9.9 ± 4.6	10.9 ± 4.0	0.12
Self-monitoring	4.7 ± 4.5	4.9 ± 4.5	4.6 ± 4.6	0.54
Foot care	8.87 ± 5.0	8.4 ± 5.0	9.4 ± 4.9	0.15
HbA1c (%)	7.8 ± 1.8	7.8 ± 2.0	7.8 ± 1.6	0.28
HbA1c≥7(%)	124(59.9)	59 (57.3)	65 (62.5)	0.59
Blood Pressure				
Systolic	133 ±14.2	132.8±15.8	133.1±12.5	-0.16
Diastolic	82.8±12.0	83.3±11.9	82.3± 12.0	0.58
High-density Lipoprotein (mmol/L)	1.3±0.8	1.1 ± 0.3	1.5 ± 1.1	-3.50**
Low-density Lipoprotein (mmol/L)	2.9 ± 0.9	2.8 ± 0.8	3.0 ± 1.0	-1.54
Triglyceride (mmol/L)	2.4 ± 4.6	2.6 ± 5.6	2.2 ± 3.3	0.57
Metabolic Syndrome	185 (89.4)	91(88.3)	94 (90.4)	0.23

*p<0.05; **p<0.01; [a] Self-management total score>=50.4 or above 80% of the highest total score; CES-D: Center for Epidemiological Studies Depression Scale.

4.5 DISCUSSION

In previous research, most studies have focused on a limited number of constructs identified as significant in diabetes management. This study was one of the first studies to explicitly examine selected personal, behavioral, and environmental factors identified as essential for chronic disease management using Social Cognitive Theory (Bandura, 1986).

4.5.1 Characteristics of participating patients on study variables

Personal factors On average, participants indicated nearly adequate knowledge related to diabetes management. The level of diabetes knowledge among participants was comparable with findings (76.4% vs 77.0%) in a study conducted in the US (Fitzgerald et al., 2016), and much higher than that (76.4% vs 43.2%) in a study conducted among Chinese patients with T2DM in a rural area (Geng & Zhang, 2017). The level of health literacy among participants indicated limited health literacy (Weiss et al., 2005), possibly suggesting a limitation in understanding of diabetes self-management. Our results on health literacy are lower than the findings in previous research in which a majority of a sample of urban Chinese patients with T2DM were reported to have adequate health literacy (Dai, Liu, Li, & Li, 2017). In the current study, the scale for measuring health literacy (NVS) may not have fully reflected participants' level of health literacy due to cultural differences in diet preferences: an ice cream nutritional label might not be sensitive to the Chinese population since not many persons with diabetes consumed ice cream in their diet regularly. However, the NVS showed acceptable reliability in this sample. Meanwhile, participants in this sample had on average less than a high school education, and the level of education is significant for health literacy, suggesting that the educational level among

participants may have influenced the response to questions that were not fully understood in this sample. In addition, only a small proportion of participants (21.7%) responded correctly to all four items that are related to numeracy, suggesting limited ability in calculating daily values related to diet.

Behavioral factors In this study, participants' level of self-efficacy toward diabetes self-management were somewhat confident in performing activities related to diabetes management (Van der Bijl et al., 1999). Using the mean score divided by the total score, the results from the current study on self-efficacy was greater than that (82.9% vs 73.4%) reported in a study conducted in China among older adults in rural areas (Jianjiang Hu, Dong, Wei, & Huang, 2013), and also greater than that (82.9% vs 73.5%) among Chinese patients with T2DM in a suburban area (He et al., 2016). In both cases, self-efficacy among participants in this sample demonstrated a slightly better level of self-efficacy compared to others in previous studies. This discrepancy may be due to patients being older, and largely from rural areas in previous studies.

Using a cutoff of 16 for the CES-D, 9.7% of the participants demonstrated significant depressive symptoms and needed further evaluation (Radloff, 1977). The prevalence of participants with significant depressive symptoms in the current study was lower than that of patients with T2DM as demonstrated (17.6%) by other researchers (Ali et al., 2006), as well as lower than that in a previous study (31.0%) which was conducted among Chinese patients with T2DM in Hong Kong (Y. Zhang, Ting, Yang, et al., 2015).

Regarding problem-solving appraisal, participants in the current study perceived themselves as neither very positive nor very negative toward effective problem-solving (Heppner & Petersen, 1982). Using the mean score divided by the highest possible total score, the level of problem-solving was much higher than that among patients with T2DM in the US (51.4% vs

9.7%), in which, a different scale specific for health-related problem-solving was used (Shin et al., 2017). In addition, in previous study, a large proportion of participants (39.8%) were identified as having minor or major depressive disorders which may have contributed to the much lower level of effective problem-solving, in which depression was identified to be significantly associated with less effective problem-solving (Shin et al., 2017).

Environmental factors Over the past three months, participants in the current study perceived that they received social support sometimes but not very often from their family members (Glasgow et al., 2000). The level of social support was slightly better compared to that of Chinese patients with T2DM among older adults (70.3% vs 66.4%) but considered as receiving moderate social support in both studies (Song, Gao, & Liu, 2016). The response to neighborhood factors indicated that a majority of the participants perceived themselves as living in a relatively safe and stable environment, and had adequate resources or space available to exercise and purchase healthy foods. To our knowledge, these types of questions have not been included in prior studies with this patient population; future research should include these aspects.

4.5.2 Health and clinical outcomes

Using a standard score for adequate self-management as suggested by previous research (actual score /63 ≥ 80%), the SDSCA total score demonstrated that only 16.4% of participants was identified to have an adequate level of performing self-management activities. Although this score was higher than several other studies (9.1% and 9.2 %) that were conducted among patients with T2DM in China (J. Ji et al., 2014; X. Sun et al., 2012b), the performance of self-management activities was still suboptimal in the current study. The use of different scales for

measuring self-management (SDSCA vs Diabetes Self-Care Scale) or persons with a longer diabetes duration (Mean 8.9 vs 7.5 years) may have contributed to the somewhat better self-management behaviors in the current study (J. Ji et al., 2014; X. Sun et al., 2012b). In addition, the level of self-efficacy also can play a role in diabetes self-management, as with more confidence, people were more likely to better self-managing their disease. The current study demonstrated that the most frequently performed behavior was medication taking, followed by physical activity, diet, foot care and self-monitoring of blood glucose. Our findings are consistent with the findings in a previous study which was done among patients with T2DM in a suburban area in China and showed the same trend (He et al., 2016).

The mean HbA1c (7.8% ±1.8) was lower than that of patients with T2DM described in previous studies (8.5% to 9.3%) conducted in China (J. Ji et al., 2014; L. Ji et al., 2016; Wenjia Yang et al., 2016). Despite a clinically meaningful 0.5% difference, the glycemic control among the majority of participants in the current study was still suboptimal. In the current study, 40.1% of the sample was identified to have optimal glycemic control, which was higher than that of previous studies among patients with T2DM conducted in China. This may be because previous studies were largely done with patients from the urban areas where higher prevalence of diabetes was identified (J. Ji et al., 2014; L. Ji et al., 2016), or were conducted with hospitalized patients with more male patients (49.8% vs 59.8% and 59.5%) being included in the previous study (X. Sun et al., 2012b; Wenjia Yang et al., 2016). In China, patients with diabetes were often acquired to be hospitalized to gain better control of their condition not necessarily when they were critically ill. Meanwhile, the current study was conducted at an endocrinology center which largely provided care to patients with diabetes and specialized in diabetes management. This level of care might have also contributed to the somewhat better self-management and glycemic

control among participants.

The proportion of participants with MetS (89.4%) in the current study was higher than that in previous studies using the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) criteria for Asian populations (Grundy et al., 2005). Since all patients had diabetes, MetS was confirmed when two or more of the following were present: waist circumference ≥ 90cm in male or ≥80cm in females; systolic blood pressure ≥ 130 mm Hg or diastolic blood pressure ≥85 mm Hg, or currently on treatment for hypertension; HDL < 1.03 mmol/L in males or < 1.30 mmol/L in females; TG ≥ 1.7mmol/L or currently on treatment for dyslipidemia. Using NCEP ATP III identified by the National Institute of Health in the US, researchers reported up to 84% among patients with T2DM to co-exist with MetS (Music et al., 2015). In the modified NCEP ATP III criteria for Asian populations, a smaller value for waist circumference (90cm vs 102 in men, and 80cm vs 88cm in women) as suggested by NCEP was used to identify the existence of MetS (Grundy et al., 2005); this measurement difference may have contributed to the higher proportion of MetS in this sample than that in previous studies. In addition, using the modified NCEP APT III criteria, the proportion of MetS was also higher than that (89.4% vs 57.4% and 72.5%) in studies conducted among patients with T2DM in China (Jing et al., 2018; Yao et al., 2016). The current study took into account those who had diagnoses of or were currently on treatment for hypertension or dyslipidemia when identifying patients with MetS (Grundy et al., 2005). This may have contributed to the much higher rate in the current study, since the previous studies conducted in China did not clarify the criteria for whether current treatments were included to identify MetS. Those studies also had much larger samples (n= 1,708 and 25,454) recruited from primary care hospitals in urban areas (Jing et al., 2018; Yao et al., 2016).

4.5.3 Gender differences on modifiable study variables

The current study showed significant gender differences in health literacy, problem-solving, social support and depressive symptoms among participants. Compared to females, males showed significantly higher levels of health literacy with better problem-solving, social support, and less depressive symptoms. These findings were consistent with findings from previous studies among people from different countries (Góis et al., 2018; Kourmousi, Xythali, Theologitou, & Koutras, 2016; Mansyur et al., 2016; Shin et al., 2017). No significant gender differences on self-management, glycemic control and incidence of metabolic syndrome were observed. A recent review identified a gap in knowledge about gender differences in health literacy among patients with T2DM (Caruso et al., 2018); therefore, findings from this study add to the evidence on health literacy. In addition, there were also differences on level of education between males and females which was significant for health literacy. A previous study demonstrated that men perceived better social support compared to women among patients with T2DM among Hispanics in the US (Mansyur et al., 2016). The results from the current study confirm findings from previous research. This is not surprising since Chinese women often assume important family roles in taking care of others and are largely the ones who provide social support for their family members. Problem-solving has been identified to be better among males than females both among educators in Europe and patients with T2DM in the US (Kourmousi et al., 2016; Shin et al., 2017); results from the current study corroborate findings of previous research. Evidence has shown that women demonstrate more depressive symptoms than men among patients with T2DM in the US and in Europe (Góis et al., 2018; Shin et al., 2017). In the current study, it may be possible that women were more willing to report on depressive symptoms, and therefore they look like they have symptoms but in fact they do not. Our results

are congruent with the findings of previous research that women have more depressive symptoms; and significantly more women had severe depressive symptoms needing further attention compared to men. The findings on gender differences suggest that women may need additional support in improving their health literacy, problem-solving and social support, as well as assistance in addressing their depressive symptoms.

The current study had some limitations. This was a cross-sectional study and used self-reported measures. Thus, the data might reflect bias in the participants' responses. In addition, this study was conducted in one outpatient clinic in one suburban area of Beijing; an endocrinology center where the study was conducted may be different from other community health settings. These factors may limit the generalizability of the findings to other clinic settings. Meanwhile, the original scales used in the current study were largely developed in English, and a few had not been tested using Chinese patients with T2DM, such as the Problem Solving Inventory and the Newest Vital Sign. Some of these Chinese measures were only implemented in younger populations, and our population was middle aged and older. With a few instruments that reported less than acceptable Cronbach's alpha values (< 0.7), further research is needed to include instruments that have higher internal consistency and test-retest reliability with additional psychometric testing. However, using currently available Chinese instruments that have demonstrated reliability and validity in other groups will help researchers understand the associated factors according to SCT. This might provide future clarification for researchers and assist clinicians to consider these factors in their practice. Furthermore, items related to smoking were omitted in the Chinese version of the measure for self-management behaviors, this may have limited the ability in assessing the overall behaviors related to diabetes managements in this sample. Similar studies need to be carried out in a larger sample or through a multi-center

approach to gain a broader view about diabetes management among Chinese patients with T2DM.

4.6 CONCLUSION

In conclusion, the current study describes the characteristics of a sample of Chinese patients with T2DM living in a suburban area of a large city using constructs within Social Cognitive Theory. Selected personal, behavioral and environmental factors were examined, along with health outcomes including self-management activities, glycemic control and parameters related to metabolic syndrome. The overall self-management and glycemic control of the participants in the current study were suboptimal. Gender differences existed related to health literacy, problem solving, social support and depressive symptoms among participants. This suggests researchers and clinicians need to pay additional attention regarding these aspects with a multifactorial approach when working with Chinese women with T2DM. In addition, there was a high prevalence of metabolic syndrome in this sample suggesting that lifestyle modification and concurrent treatment for hypertension and dyslipidemia are essential in order to prevent diabetes complications especially cardiovascular disease.

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5.0 MANUSCRIPT #2 (TO BE SUBMITTED): CORRELATES OF SELF-MANAGEMENT BEHAVIORS, GLYCEMIC CONTROL AND METABOLIC SYNDROME AMONG CHINESE PATIENTS WITH TYPE 2 DIABETES

This chapter addresses aim 2 and aim 3 of the study, and examined the associations and the impact of the modifiable factors on various self-management behaviors, and their impact on health outcomes.

Aim 2: Examine the associations between personal (sociodemographic, disease related factors, diabetes knowledge, health literacy), behavioral (self-efficacy, depressive symptoms, problem solving), environmental (social support, neighborhood) factors, health behaviors (self-management behaviors), and health outcomes (HbA1c, metabolic syndrome determined by BP, BMI/waist circumference, HDL, LDL and Triglyceride);

Aim 3: Examine the impact of modifiable study variables on self-management behaviors and health outcomes (HbA1c, incidence of metabolic syndrome determined by BP, Waist/BMI, HDL, LDL and Triglyceride).

Correlates of Self-Management Behaviors, Glycemic Control and Metabolic Syndrome among Chinese Patients with Type 2 Diabetes

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5.1 ABSTRACT

Aim: To examine the impact of personal, behavioral, and environmental factors on self-management behaviors, glycemic control, and metabolic syndrome among Chinese patients with Type 2 diabetes (T2DM). **Methods:** A cross-sectional study was conducted among 207 patients with T2DM living in a suburban area of Beijing, China. Regression models were applied to examine the impact of selected personal, behavioral, and environmental factors on self-management behaviors, glycemic control and metabolic syndrome. The relationship between individual self-management behaviors, glycemic control and metabolic syndrome was also examined. **Results:** Self-efficacy was significantly associated with all self-management behaviors. Social support was related to overall self-management, diabetes knowledge was related to diet, and depressive symptoms was related to self-monitoring ($p<0.05$). Problem-solving (B= 0.02, $p<0.05$), self-management behaviors related to medication adherence (B=-0.19, $p<0.05$) and diet (B= -0.07, $p<0.05$) were significant correlates of glycemic control. Health literacy (OR: 0.77, $p<0.05$) and self-management behaviors related to physical activity (OR: 0.84, $p<0.05$) were correlates of metabolic syndrome. **Conclusion:** Findings suggest that a multifactorial approach may be necessary when providing care for Chinese patients with T2DM. Additionally, these findings provide support for the development and testing of tailored interventions addressing problem-solving, health literacy, and self-efficacy related to self-management. Such interventions may help patients achieve optimal glycemic control thereby reducing their risk for metabolic syndrome and related complications.

Keywords: Chinese patients with type 2 diabetes; glycemic control; self-management behaviors; metabolic syndrome.

5.2 INTRODUCTION

China has the largest number of people with diabetes in the world. A national survey showed that 10.9% adults in China live with diabetes (L. Wang et al., 2017), which is higher than that (9.6%) reported by the International Diabetes Federation (IDF) in earlier research (Guariguata et al., 2014). More than 90% of those with diabetes have T2DM (Weng et al., 2016). Urbanization and associated life style changes may be contributors to this pandemic; projections are that there will be 13% of the population living with diabetes in China in 2035 (Guariguata et al., 2014). This upsurge in diabetes in China is creating challenges for patients and health care providers; and diabetes self-management and glycemic control among individuals with T2DM are suboptimal. Studies conducted in China have reported that less than 35.8% of patients have achieved the target goal of 7%; the mean HbA1c reported is between 8.5% and 9.3% (L. Ji et al., 2016; K. Lin et al., 2017; Wenjia Yang et al., 2016). Although self-management has been identified as the key element in T2DM management, only slightly more than 9% of Chinese patients with T2DM perform self-management behaviors adequately (J. Ji et al., 2014; X. Sun et al., 2012b); adhering to medication treatment is the most performed behavior followed by diet, physical activity, foot care, and self-monitoring of blood glucose.

In a review of the literature, several concepts have been identified as essential in diabetes self-management and related health outcomes. Diabetes knowledge which is defined as the knowledge level essential for diabetes management (Beeney et al., 2003), has been reported to have positive relationships with self-management behaviors and better glycemic control (Kueh et al., 2015; Luo et al., 2015). Health literacy, or the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Nielsen-Bohlman & Institute of Medicine [U.S.], 2004), has been

reported to be consistently and positively related to self-management behaviors and negatively related to HbA1c among patients with T2DM (Reisi et al., 2016; M. Wang et al., 2016).

Self-efficacy is essential for behavior change (Bandura, 1977, 1986). Self-efficacy and self-management behaviors have demonstrated consistent positive relationships among patients with T2DM (Gao et al., 2013; Luo et al., 2015; Saad et al., 2018). Significant relationships between a higher level of self-efficacy (both in general and in specific areas, such as diet and exercise) and lower HbA1c have been reported (Beckerle & Lavin, 2013; Gao et al., 2013; Saad et al., 2018). Also, research has shown that increased depressive symptoms are associated with decreased frequency in patients performing self-management behaviors such as following recommendations related to diet, exercise, etc.; these individuals are more likely to report higher HbA1c (Adam & Folds, 2014; Whitworth et al., 2016; Y. Zhang, Ting, Yang, et al., 2015). Problem-solving, another concept that is essential in diabetes management (American Association of Diabetes Educators, 2008), has been reported to be positively related to self-management behaviors and better control of HbA1c among patients with T2DM in the US (Hill-Briggs et al., 2006; Hunt et al., 2012). However, there are limited studies examining the relationships between problem-solving and diabetes self-management and glycemic control among Chinese patients with T2DM.

Social support may ensure that adequate diabetes self-management behaviors occur in a social environmental context. Higher social support is reported as being associated with more health-promoting self-management behaviors among patients with T2DM (Schiøtz et al., 2012; Shao et al., 2017), as well as a positive relationship to better glycemic control (Shao et al., 2017). Among Chinese patients with T2DM, social support has also been identified as a predictor for self-management behaviors and significantly and positively related to various self-management

behaviors, either directly or indirectly (X. Zhang et al., 2017). On the other hand, poor social support is associated with poor adherence related to treatments in diabetes management (IDF Guideline Development Group, 2014). In addition, researchers have found that individuals who live in a safe, aesthetic environment, and have resources or support available for healthy food and exercise are more likely to perform activities to improve glycemic control (Smalls et al., 2015b); an unsafe neighborhood has been associated with non-adherence to diabetes self-management among patients with T2DM (Billimek & Sorkin, 2011). Research also has suggested that high residential stability is associated with adherence to diabetes self-management among patients with diabetes (de Vries McClintock et al., 2015).

In addition, metabolic syndrome (MetS) has gained increased attention among researchers and health care providers focused on people with T2DM. Although the definition of MetS varies, it is usually viewed as the cluster of several conditions including insulin resistance or diabetes, abdominal obesity, high cholesterol, and hypertension (International Diabetes Federation, 2006). Patients with T2DM have significant risk for developing cardiovascular disease (Ginsberg & MacCallum, 2009, Yao et al., 2016). However, there is limited research examining the relationships among associated factors essential for diabetes self-management and the existences of MetS.

Bandura's (1986) Social Cognitive Theory (SCT) suggests that personal, behavioral, and environmental factors interact with each other and have a collective impact on health behavior change among persons with chronic disease. For patients with T2DM, diabetes knowledge and health literacy can be included under personal factors along with sociodemographic characteristics such as age, gender and level of education, and health related factors including duration of diabetes, number of prescribed medications and number of comorbidities that are

claimed to be essential for diabetes management. The concepts of self-efficacy, depressive symptoms and problem-solving are related to a person's behavioral and cognitive processing and can be best described to reflect the behavioral factors under SCT. Social support and neighborhood factors are essential external elements to reflect the environmental factors under SCT.

Based on the prior literature, there is limited research examining the collective influence of personal, behavioral, and environmental factors related to self-management behaviors and glycemic control among Chinese patients with T2DM, especially among those who live in suburban areas. While evaluating clinical outcomes related to MetS is essential, less attention has focused on the overall influence of related personal, behavioral, environmental factors as well as various self-management behaviors on MetS among Chinese patients with T2DM. There also is limited evidence that uses theory to guide such research in China. Therefore, using SCT, this study examined the impact of selected personal, behavioral, and environmental factors on self-management health behaviors, glycemic control, and the existence of MetS among Chinese patients with T2DM (Bandura, 1986). The conceptual model depicted in Figure 4 guided the current study and provided the underlying framework to understand how these factors influence self-management behaviors and health outcomes among patients with T2DM in China.

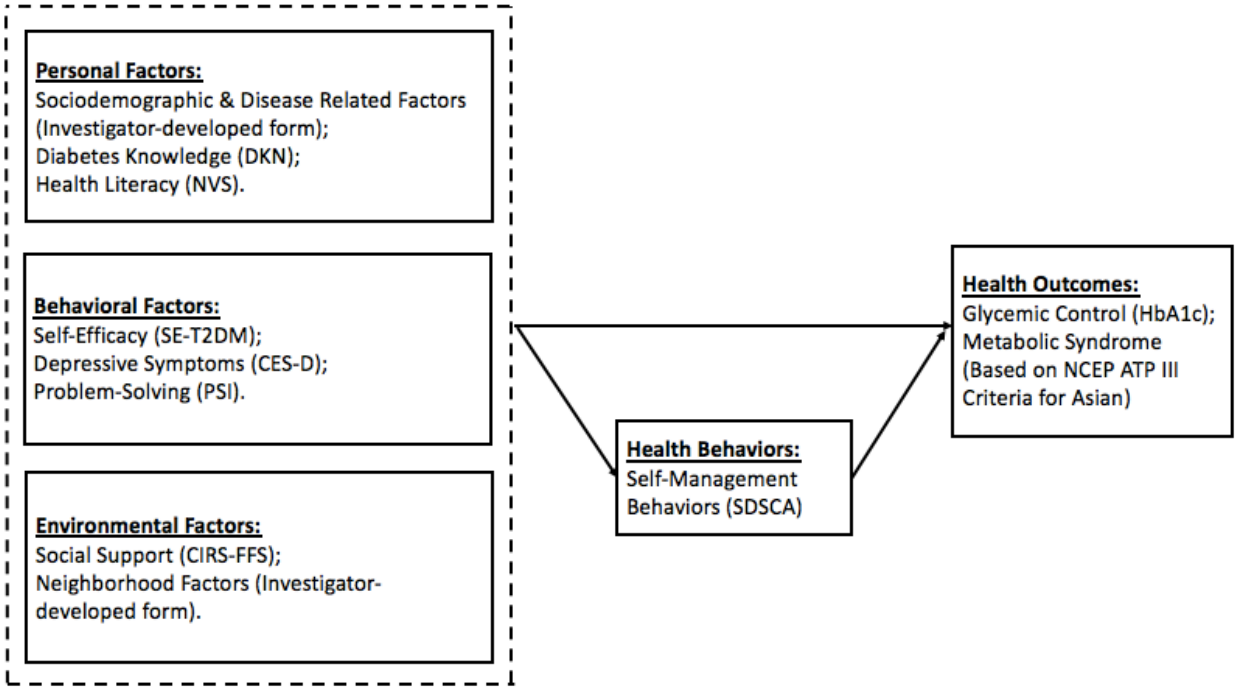

Figure 4. Conceptual Model Based on Social Cognitive Theory

5.3 MATERIAL AND METHODS

5.3.1 Sample and design

This study used a cross-sectional design. Institutional Review Board approval to conduct this study was obtained from the Ethical Committee of the study hospital and from the Human Research Protections Office of the University of Pittsburgh prior to study initiation. Using convenience sampling, 207 participants were recruited and enrolled from an outpatient clinic of a tertiary hospital in a suburban area of Beijing, China. The inclusion criteria were: Chinese male and female patients with T2DM for at least 6 months; age≥ 18 years old; Mandarin as the primary language. Patients' test results on HbA1c (within prior 3 months) and laboratory values

related to MetS (within prior 6 months) needed to be available at the time of enrollment or obtained during the current visit. Exclusion criteria were patients with hearing and/or vision impairment, renal disease, or severe physical and/or mental illness, or who were pregnant. After patients provided informed consent, their height, weight, and waist circumference were obtained by nurses at the clinic using standard equipment. Blood pressure was assessed as a single customary measurement using an automatic blood pressure monitor by a clinic nurse. Information related to personal, behavioral, and environmental factors, as well as self-management behaviors were self-reported through the administration of questionnaires. Other clinical outcomes including HbA1c (within the last 3 months) and lipid profile such as high density lipoprotein (HDL), low density lipoprotein (LDL), and triglyceride within the last 6 months were retrieved from the medical record by a clinic nurse.

5.3.2 Measures

Sociodemographic and health history. An investigator-developed personal and health information form was used to collect the patient's age, gender, years of education, duration of diabetes, number of medications and comorbidities along with other information. All physical measures such as height, weight, waist circumference were obtained by a clinic nurse using the standard clinic equipment at the time of data collection.

Diabetes knowledge Diabetes knowledge was assessed using the Diabetes Knowledge Scale (DKN) which was modified to adapt to the cultural background of the Chinese population in a previous study (Yin Xu, Savage, et al., 2008). The Cronbach's alpha (α) of the DKN ranged from 0.72 to 0.79 in the original study and was 0.62 among Chinese patients with T2DM (Beeney et al., 2003; Yin Xu, Savage, et al., 2008), and 0.67 in the current study (n=207).

Although the internal consistency of the DKN in the current study was less than acceptable (Tavakol & Dennick, 2011), which suggests the DKN might be a questionable measure in evaluating diabetes knowledge in this sample, it was comparable to findings from a previous study (Yin Xu, Savage, et al., 2008).

Health literacy The Chinese version of the Newest Vital Sign (NVS) was used to examine the level of health literacy among participants (C. Lin, 2010). The NVS has six questions assessing a person's reading, numeracy and comprehension based on an ice cream nutritional label. The α was reported as 0.59 in the original study and as 0.65 among Chinese teachers in Taiwan (C. Lin, 2010; Weiss et al., 2005). The α of the NVS was 0.86 in the current study (n=207).

Self-efficacy The Chinese version of the Self-Efficacy Scale for People with Type 2 Diabetes (SE-T2DM) was used to evaluate the level of confidence in performing self-management behaviors related to diabetes (Yin Xu, Savage, et al., 2008). The Chinese version of the SE-T2DM is a 7-item questionnaire on a 5-point Likert scale. The α was reported as 0.81 with a rest-retest reliability of 0.79 over 5 weeks in the original study (Van der Bijl et al., 1999), and as 0.87 among Chinese patients with T2DM (Yin Xu, Savage, et al., 2008). The α was 0.70 in the current study (n=203).

Depressive symptoms The Chinese version of the Center for Epidemiological Studies Depression Scale (CES-D) was used to assess the presence and severity of depressive symptoms (Z. Chen et al., 2009). A cut-off point at equal to or greater than 16 indicates that the individual has significant depressive symptoms and needs further attention. The α of the CES-D was 0.85 with a test-retest reliability of 0.54 in the original study, and was reported as 0.88 to 0.94 among adolescents and middle school students in the Chinese population (Z. Chen et al., 2009; Radloff,

1977). The α was 0.90 in the current study (n=207).

Problem-solving The Chinese version of the Problem Solving Inventory (PSI) was used to assess problem-solving appraisal among participants (Tian et al., 2014). The PSI is a 32-item self-report instrument assessing one's problem-solving appraisal rather than applied problem-solving in everyday life; lower scores indicate better problem-solving (Heppner & Petersen, 1982). The α was reported as 0.90 in the original study among college students in the US and as 0.80 among Chinese college students (Heppner & Petersen, 1982; Tian et al., 2014). The current study demonstrated α of 0.85 (n=202).

Social support The Family and Friends Support subscale of the Chronic Illness Resources Survey (CIRS-FFS) was used to assess support and resources available from patients' family over the past three months (Glasgow et al., 2000). The tool had α at 0.75 in the original study (Glasgow et al., 2000). The Chinese version of the CIRS-FFS is a modified 6-item instrument with a 5-point Likert scale; with higher scores indicative of greater family support. The α was reported as 0.86 among Chinese patients with T2DM (Yin Xu, Savage, et al., 2008), and was 0.83 in the current study (n=207).

Neighborhood factors An investigator-developed questionnaire was used to assess patients' perception regarding environmental safety, availability of healthy food and space to exercise, and residential stability. Other than the question related to residential stability, all questions received yes ("1") or no ("0") depending on the patient's actual response. For persons who had lived in their current residence for 5 years or more, the item related to residential stability was scored as "1", otherwise "0". A cumulative score (ranging from "0" to "4") was assigned as a total score to reflect patients' perception on whether the neighborhood was safe, stable, having healthy food available, and space to exercise.

Self-management behaviors The Summary of Diabetes Self Care Activities (SDSCA) was used to assess self-management behaviors related to diet, physical activity, medication, self-monitoring of glucose, smoking and foot care during the past 7 days (Toobert et al., 2000). The inter-item correlations for each of the domains of the SDSCA ranged from 0.47 to 0.80, with 3-month test-retest reliability as 0.30 to 0.78 in the original study (Toobert et al., 2000). The Chinese version of the SDSCA is a modified 10-item questionnaire; items related to specific diets and smoking were excluded from the original scale (Yin Xu, Savage, et al., 2008). The α was reported as 0.68 and inter-item correlation at 0.69 among Chinese patients with T2DM (Yin Xu, Savage, et al., 2008). The α of the SDSCA was 0.64 in the current study (n=207), which is less than acceptable (Tavakol & Dennick, 2011) but of borderline acceptability with items to total score correlations ranged from 0.37 to 0.66. The α was also comparable to findings from a previous study (Yin Xu, Savage, et al., 2008).

Glycemic control and existence of MetS The level of HbA1c was used to evaluate glycemic control among participants. Existence of MetS was determined using parameters related to waist circumference, blood pressure, HDL, and triglyceride following the criteria identified by the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) for Asian population (Grundy et al., 2005). All clinical values including HbA1c, HDL, etc. were retrieved from the medical record by a clinic nurse who worked at the study site. Blood pressure was obtained as a single routine measurement using an automated device with participants in a sitting position with at least 5 minutes resting time by a clinic nurse. Following the NCEP ATP III criteria (Grundy et al., 2005), participants were identified for existence of MetS using the following cut-off values: waist circumference$\geq$ 90cm with males or $\geq$ 80cm with females; blood pressure $\geq$ 130 mm Hg for systolic or $\geq$ 85 mm Hg for diastolic, or currently on

hypertension medication; HDL< 1.03 mmol/L for males or < 1.30 mmol/L for females; TG ≥ 1.7mmol/L or currently on medication treatment. Participants who met 2 or more of the conditions were confirmed for existence of MetS (coded as "1", otherwise "0").

5.3.3 Data analysis

Data entry and data verification were achieved using the EpiData software (Epidata Association, Odense, Denmark). All data analysis was performed using SPSS version 24 for Mac (IBM Corp, Chicago, USA). Among 207 participants who completed the study, a pattern of missing completely at random was identified (Little's MCAR test: X^2=35.468, df=44, p=0.817), which including 9 cases with missing data on 2 independent variables (SE-T2DM and PSI). Case-based mean imputation was used to impute the variables with missing values. Five cases were determined to be multivariate outliers using Mahalanobis distance but they were included in the final analysis as they appeared as not influential. Therefore, all participants (n=207) recruited for the study were included for final data analysis. Means and standard deviations, as well as range and median were used to describe continuous variables. Frequencies and percentages were illustrated for categorical variables. Simple and multiple linear regression were carried out to determine the correlates of the overall and individual self-management behaviors, and HbA1c. Univariate and multiple logistic regression were applied to determine the factors that were significantly correlated with MetS. A *p* value less than 0.05, two-tailed was set *a priori* to determine significant findings. Stepwise procedures with backward deletion were used to select variables to be retained in the final models for the outcome variables, which is a fast procedure and less prone for overfitting the data, but possibly including unnecessary variables or excluding necessary variables in the final model (Jeon, 2015). Study variables with a $p \leq 0.05$ were

identified as remaining in the model as *a priori*. Sample size estimation was performed before the study was conducted. Using G*Power 3.0 with a power of 0.8, two tailed, sample size was estimated separately for multiple linear regression (effect size: 0.1, 13 predictors) and multiple logistic regression (odds ratio: 1.5) that suggested a total sample of 208 participants to adequately test the statistics used in the study. A total of 207 subjects were included in the current study demonstrating that this sample was sufficient and could detect significant findings.

5.4 RESULTS

5.4.1 Demographic and clinical characteristics

The mean age of the sample (n= 207) in the current study was 56.1 (SD= 11.4) years old; and 49.8% (n= 103) of the participants were male. On average, participants had 11.3 (SD=3.4) years of education. The Body Mass Index was 25.7 (SD= 2.9) on average, and 72% (n= 149) of the sample identified as overweight or obese. 89.4% (n= 185) of the participants were identified as having MetS. Participants reported an average of 8.9 (SD= 6.9) years since their diagnosis of T2DM; their mean HbA1c was 7.8% (SD= 1.8). See Table 4 for more detail.

Table 4. Descriptive Statistics of Sample Characteristics, Study Variables and Health Outcomes (N=207)

Measure	Mean ± SD/n(%)	Range/Median
Age	56.1±11.4	25-80/57.0
Gender		-
Male	103 (49.8)	
Education (years)	11.3 ± 3.4	4-25/11.0
Diabetes Duration (years)	8.9 ± 6.9	0.5-33/8.0
#Medications	4.7 ± 2.6	1-14/4.0
#Comorbidities	1.5 ± 1.3	0-7/1.0
Body Mass Index (BMI)	25.7 ± 2.9	18-34.8/25.6
BMI≥ 24	149 (72)	-
Diabetes Knowledge	10.7± 2.4	1-14/11.0
Health Literacy	2.0 ± 2.1	0-6/1.0
Self-Efficacy	29.0 ± 4.4	12-35/30.0
Problem-Solving	93.3±16.0	42-140/92.0
Depressive Symptoms	6.4 ± 8.5	0-47/3.0
CES-D ≥16	20 (9.7)	-
Social Support	21.1± 5.4	6-30/22.0
Neighborhood Factors	3.7 ± 0.6	1-4/4.0
Self-Management (SDSCA Total)	40.1±11.6	5-63/42.0
Adequate SDSCA[a]	34 (16.4)	-
Medication treatment	6.4 ± 1.7	0-7/7.0
Diet	9.7 ± 4.1	0-14/10.0
Physical activity	10.4 ± 4.3	0-14/12.0
Self-monitoring	4.7 ± 4.5	0-14/4.0
Foot care	8.87 ± 5.0	0-14/9.0
HbA1c (%)	7.8 ± 1.8	5.2-15.5/7.2
HbA1c≥7(%)	124(59.9)	-
Metabolic Syndrome	185 (89.4)	-

Note: [a] SDSCA total score/63≥ 80%; CES-D: Center for Epidemiological Studies Depression Scale; SDSCA: Summary of Diabetes Self Care Activities.

5.4.2 Correlates of the health behaviors and health outcomes

Multiple regression models were established to determine the significant correlates of outcome variables including the overall and individual self-management behaviors, glycemic control (HbA1c) and existence of MetS. In all models, covariates including age, gender, years of education, duration of diabetes, number of prescribed medications and number of comorbidities were forced into the model regardless of their significance for outcome variables. Seven modifiable study variables (diabetes knowledge, health literacy, self-efficacy, depressive symptoms, problem-solving, social support and neighborhood factors) were included in the model as a group after controlling covariates in various models (models for self-management behaviors, Model 1 for glycemic control and MetS). Five individual self-management behaviors (medication treatment, diet, physical activity, self-monitoring of blood glucose and foot care) were included in the model as a group after controlling covariates in determining the significant correlates of glycemic control and MetS among different self-management behaviors (Model 2).

5.4.2.1 Association and impact of study variables on self-management behaviors

Following multiple linear regression, after controlling for covariates, the seven modifiable study variables were included in the model as a group of independent variables and the overall and individual self-management behaviors as the dependent variables. As a result, this analysis showed that only two of the seven independent variables, self-efficacy and social support, were identified as significant correlates of the SDSCA total score. The overall model explained 46.1% (adjusted R^2=0.439) of the total variance for the SDSCA total score. After controlling for covariates, self-efficacy was the only independent variable associated with behaviors related to medication adherence, physical activity, and foot care; diabetes knowledge and self-efficacy

were identified as significant correlates of self-management behaviors related to diet; self-efficacy and depressive symptoms were significant correlates of self-management behaviors related to self-monitoring of blood glucose. The variance explained by the models for individual self-management behaviors ranged from 10.4% to 40.9% (Adjusted R^2 ranged from 0.07 to 0.38). See Table 5 for more detail.

Table 5. Summary of the Multiple Regression Analysis of Study Variables Related to Self-management Behaviors after Controlling for Covariates (n = 207)

	SDSCA		Medication		Diet		Physical Activity		Self-Monitoring		Foot Care	
Variable	*B*	*p*	*B*	*p*	*B*	*p*	*B*	*p*	*B*	*p*	*B*	*p*
Age	0.33	<0.001	0.03	0.022	0.07	0.005	0.13	<0.001	-0.07	0.042	0.17	<0.001
Gender	-0.70	0.59	-0.16	0.527	0.81	0.096	-0.27	0.618	-0.15	0.822	-0.30	0.647
Education	0.12	0.533	0.05	0.148	0.07	0.344	-0.08	0.294	0.15	0.131	-0.02	0.808
Duration	-0.06	0.588	0.01	0.795	-.004	0.907	-0.02	0.688	-0.01	0.789	-0.03	0.569
#Meds	0.70	0.042	0.03	0.655	0.13	0.313	-0.13	0.369	0.41	0.017	0.39	0.025
#Comorb	-1.23	0.059	0.03	0.788	-0.26	0.284	0.07	0.79	-0.56	0.094	-0.89	0.007
DKN	-	-	-	-	**-0.27**	**0.012**	-	-	-	-	-	-
SE-T2DM	**1.19**	**<0.001**	**0.06**	**0.028**	**0.54**	**<0.001**	**0.40**	**<0.001**	**0.18**	**0.022**	**0.21**	**0.005**
CES-D	-	-	-	-	-	-	-	-	**0.09**	**0.029**	-	-
CIRS-FFS	**0.26**	**0.035**	-	-	-	-	-	-	-	-	-	-
R^2	0.461*		0.104*		0.409*		0.336*		0.106*		0.254*	

*p<0.01, indicates the significance of r^2 change from the base model (only covariates were in the model) to the full model; B: Unstandardized coefficient;

Note: #Comorb: Number of comorbidities; DKN: Diabetes Knowledge Scale; SE-T2DM: Self-Efficacy Scale for People with Type 2 Diabetes; CES-D: Center for Epidemiological Studies Depression Scale; CIRS-FFS: Family and

Friends Support subscale of the Chronic Illness Resources Survey; SDSCA: Summary of Diabetes Self Care Activities.

5.4.2.2 Association and impact of study variables and self-management behaviors on glycemic control and metabolic syndrome

In Model 1(See Table 6), multiple linear regression was performed to investigate whether the seven study variables were associated with the level of glycemic control after controlling for covariates. As shown in Model 1, only problem-solving remained in the model and was significantly related with HbA1c following a stepwise procedure. The overall model explained 12.1% (Adjusted R^2= 0.09) of the variance for HbA1c. In Model 2, following multiple linear regression, self-management behaviors related to medication adherence and diet were significant correlates of HbA1c in the full model and explained 17.4% (Adjusted R^2= 0.14) of the variance in HbA1c.

Table 6. Summary of Multiple Regression Analysis of Variables for HbA1c Controlling Covariates (n = 207)

	Model 1		Model 2	
Variable	*B*	*p*	*B*	*p*
Age	-0.04	0.002	-0.03	0.04
Gender	0.04	0.88	0.14	0.577
Years of Education	-0.06	0.111	-0.07	0.054
Diabetes Duration	0.08	<0.001	0.08	<0.001
#of Medications	-0.07	0.337	-0.03	0.626
#of Comorbidities	0.19	0.147	0.13	0.30
Problem-Solving	**0.02**	**0.048**	-	-
Medication	-	-	**-0.19**	**0.012**
Diet	-	-	**-0.07**	**0.043**
R^2	**0.121***		**0.174***	

*p<0.01, indicates the significance of r^2 change from the base model to the full model.

As shown in Table 7, multiple logistic regression was performed to examine whether the seven study variables (Model 1) and various self-management behaviors (Model 2) as groups correlated with MetS after controlling for covariates. This analysis showed that health literacy remained significant in the final model (OR: 0.77, 95% CI:0.61-0.97, *p*=0.029); accuracy improved significantly when health literacy was included in the model (Chi-square=14.59, df=7, p=0.042; Model 1). The Nagelkerke's R^2 indicated that the model roughly explained 13.8% of the variation in MetS. Among the various self-management behaviors, physical activity was a significant correlate for MetS (OR:0.84, 95%CI: 0.72-0.99, p=0.033); accuracy also improved significantly (Chi-square=15.40, df=7, p=0.031; Model 2) and explained 14.6% of the variation in MetS.

Table 7. Summary of Logistic Regression Analysis of Study Variables and Self-management Behaviors for Metabolic Syndrome Controlling Covariates (n = 207)

Variables	Model 1				Model 2			
	OR	*95%CI*		*p*	OR	*95% CI*		*p*
		Lower	*Upper*			*Lower*	*Upper*	
Age	0.98	0.93	1.03	0.466	1.01	0.96	1.07	0.622
Gender	0.76	0.28	2.04	0.581	0.70	0.26	1.87	0.473
Education	1.11	0.94	1.30	0.223	1.04	0.90	1.20	0.614
DM Duration	0.96	0.88	1.04	0.315	0.96	0.89	1.04	0.350
#Medications	1.13	0.83	1.53	0.450	1.12	0.82	1.54	0.469
#Comorbidity	1.65	0.89	3.08	0.114	1.60	0.85	3.04	0.148
Health Literacy	**0.77**	**0.61**	**0.97**	**0.029**	-	-	-	-
Physical Activity	-	-	-	-	**0.84**	**0.72**	**0.99**	**0.033**

5.5 DISCUSSION

In accord with SCT (Bandura, 1986), this study's findings demonstrated that self-management is a key in disease management among patients with T2DM; multiple factors impact health behavior change and therefore impact health outcomes. The findings demonstrated a significant impact of associated factors on self-management behaviors, glycemic control, and existence of MetS among patients with T2DM living in a suburban area of a large city in China in this study.

5.5.1 Correlates of self-management behaviors

According to our results, self-efficacy was a significant correlate for the overall and all individual self-management behaviors. Our findings are congruent with previous research demonstrating that a consistent and positive relationship exists between self-efficacy and self-management behaviors (Gao et al., 2013; Luo et al., 2015; Saad et al., 2018). Diabetes knowledge was positively related to the overall self-management behaviors but not with the specific individual behaviors in the univariate analysis in our study (data not shown, see supplement materials). This result corroborated previous findings that emphasized the importance of diabetes knowledge in diabetes management (Kueh et al., 2015; Luo et al., 2015). However, after we controlled for the covariates, diabetes knowledge was no longer related to the overall self-management behaviors, but was significantly and negatively related to diet in the multifactorial model. This finding contradicts previous findings, and is possibly due to participants' inaccurate interpretation and response to the items related to diet. Individuals may have perceived themselves as following the dietary regimen but in fact they were not; how they engaged in actual following their diet is unknown. In addition, on average, participants reported having less than high school education, as well as limited health literacy. Level of education and health literacy were positively related to diabetes knowledge (see correlation matrix in the supplement materials) suggesting that both of these factors may play a role in the function of diabetes knowledge in the model. Further investigation is needed to clarify these issues.

Depressive symptoms were found to be a significant factor for the overall self-management behaviors and specific behaviors related to diet and physical activity, in the univariate analysis (data not shown, see supplement materials). These findings are consistent with previous findings in that patients with more depressive symptoms perform self-management

behaviors less often (Adam & Folds, 2014; Y. Zhang, Ting, Yang, et al., 2015). However, in the multiple regression model using all seven study variables as a group after controlling for covariates, the level of depressive symptoms was significantly and positively related to only the self-monitoring of blood glucose in the final model, suggesting that people with a lower level of depressive symptoms were actually self-monitoring their blood glucose less often in this sample. This might be related to the unique clinical characteristics of depression among Chinese people due to ethnic and cultural differences. The level of depressive symptoms may be underestimated among participants in the current study. The Chinese people tend to conceal their negative emotions especially when they are potentially related to a mental health problem; they try to save "face" by following an ordinary lifestyle just like others because of the social stigma of mental illness (Li & Zhang, 2011). In addition, although the recommendation for self-monitoring of blood glucose is the same as patients in the United States, Chinese patients are not as compliant (Chinese Diabetes Society, 2014b). This may be due to the fact that testing is inconvenient or simply is viewed as a financial burden when testing blood glucose levels every day. Self-management behaviors related to self-monitoring of blood glucose was rated the lowest in the current study; meanwhile, one third of the participants in the current study did not identify the correct answer for the item addressing self-monitoring in the diabetes knowledge scale. Further research is needed to more fully understand the self-monitoring behaviors among Chinese patients with T2DM.

Social support was a significant correlate for the overall self-management behaviors suggesting that the level of social support is essential for promoting lifestyle changes and better self-management behaviors among Chinese patients with T2DM. These results confirmed findings from prior research in that higher social support was associated with better adherence to

the recommended self-management behaviors (Schiøtz et al., 2012; Shao et al., 2017; X. Zhang et al., 2017). Although patient's perception of neighborhood factors did not show significance in the multifactorial models, those who perceived themselves as having resources or space for healthy food and exercise, living in a safe and stable environment were more likely to perform self-management behaviors especially behaviors related to diet, physical activity, and foot care, as shown in the univariate analysis (data not shown, see supplement materials). These results support findings from previous research (Billimek & Sorkin, 2011; de Vries McClintock et al., 2015; Smalls et al., 2015b), and suggest that a safe and relatively stable living space and support or resources for healthy food and physical activity are essential to ensure the occurrence of adequate self-management behaviors. However, limited research exists in China examining these neighborhood factors when evaluating diabetes self-management among patients with T2DM. Future research needs to consider a multifactorial approach and include these aspects in their studies.

5.5.2 Correlates of glycemic control and metabolic syndrome

Evidence demonstrates that increased ability in everyday problem-solving is essential for diabetes management (American Association of Diabetes Educators, 2008; Hill-Briggs et al., 2006). Our results showed that the level of problem-solving appraisal among participants was significantly related to glycemic control (HbA1c) with one unit change in problem-solving appraisal corresponding to a 0.02% decrease in HbA1c. This finding supports earlier research and demonstrates that better problem-solving is associated with better glycemic control (Hill-Briggs et al., 2006). In our study, self-management behaviors related to medication adherence and diet were significantly and negatively related to HbA1c. These findings further confirm that

self-management is the key in diabetes management (American Association of Diabetes Educators, 2008), and are convergent with results from previous research in that better self-management behaviors are associated with better glycemic control (K. Lin et al., 2017; Saad et al., 2018; Shao et al., 2017).

Although health literacy did not have significant relationships with self-management behaviors and glycemic control, it was a significant correlate for MetS. In previous research, a negative relationship has been shown between health literacy and MetS among men (Yokokawa et al., 2016). Our results confirmed these findings and suggest that higher health literacy is a protective factor for the existence of MetS. In addition, self-management behaviors related to physical activity was found to be inversely related to MetS in our study. As an important element in diabetes self-management, lifestyle modification such as physical activity is essential to sustain adequate control of diabetes (American Association of Diabetes Educators, 2008). Evidence has shown that a low level of physical activity is associated with increased prevalence of MetS among patients with T2DM (Abdel, Hamid, Hosseini, & Djafarian, 2017). Our study supports this finding and suggests that adequate physical activity is not only important for diabetes management but also essential for prevention of MetS, therefore reducing the risk of developing diabetes complications related to cardiovascular disease.

Some weaknesses existed in this study. A cross-sectional study design cannot confirm causal relationships between study variables and health outcomes. Longitudinal studies are needed to further investigate these relationships. Also, the sample was recruited from a single clinic setting which is an endocrinology center and specialized in diabetes care, this may have contributed to different findings when compared with studies in community settings. These factors limit the generalizability of the study findings. Meanwhile, the instruments were self-

reported measures; a few instruments had not been tested previously among Chinese patients with T2DM, such as the Problem Solving Inventory and the Newest Vital Sign. They had been mainly tested among a young population compared to a middle aged or older group; in the current study they demonstrated an acceptable Cronbach's alpha. In addition, two instruments (Diabetes Knowledge Scale and the Summary of Diabetes Self-Care Activities) used in the current study demonstrated less than acceptable Cronbach's alpha levels (0.67 and 0.64 respectively), suggesting that these two instruments may not be the most appropriate measures to assess related aspects among Chinese patients with T2DM. Additional research is needed to include measures with high internal consistency to evaluate diabetes knowledge and self-management behaviors among Chinese patients with T2DM. Although these instruments had been translated to Chinese and underwent psychometric testing, participants may have misinterpreted some of the items. Furthermore, given that the location for participants to complete the measures did not afford complete privacy for all because of limited space at the clinic, subjects' responses may have been influenced by other people. However, measures such as talking softly, separating out participants with distance were applied to minimize this influence.

5.6 CONCLUSIONS

The current study added knowledge to the state of the science in diabetes management among Chinese patients with T2DM. The findings suggest that healthcare providers need to consider a multifactorial approach when providing care to Chinese patients with T2DM. Routine assessment of problem-solving, health literacy etc. need to be included in practice in order to

achieve optimal care. Likewise, these findings support the need to develop and test tailored interventions among this patient population. Including strategies related to problem-solving, health literacy, self-efficacy etc. in the intervention may help patients achieve optimal glycemic control, thereby reducing the risks for metabolic syndrome and related complications. Additional research needs to investigate the effect of these variables on diabetes related health outcomes through a prospective approach.

Funding

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Acknowledgement

Authors would like to thank the support received from the Endocrinology Center at Luhe Hospital where the data collection was conducted, especially the clinic nurses including Xiaojing Wang, Huan Dong, Wenying Zhao, Ping Wang and Qianqian Li. Meanwhile, Ran Sun, PhD Candidate, at the School of Nursing, University of Pittsburgh has helped us in translating and validating the Chinese documents that were used in the study. In addition, we would like to extend our thanks to Dr. Ying Wu, Dean and Professor, School of Nursing, Capital Medical University, Beijing, China for providing support during implementation of the study.

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6.0 SUMMARY AND CONCLUSIONS

6.1 SUMMARY

A growing number of people has been living with T2DM in China over the past few decades. Limited research in China has addressed the self-management and health outcomes in this population using a theoretical approach. This cross-sectional study using Social Cognitive Theory (Bandura, 1986) was designed to address this gap in the literature and described the characteristics of Chinese patients with T2DM and examined the associations of related factors and their impact on relevant health outcomes. A convenience sample of 207 patients were recruited from the outpatient clinic of the study hospital in a suburb of Beijing, China from November 2017 through January 2018. Institutional review board approval was obtained from the clinic and from the University of Pittsburgh. After obtaining informed consent, participants completed a set of self-report questionnaires; clinical outcome data was retrieved from the patient's medical record by the clinic nurse. The findings from this study are described in two manuscripts and are briefly described below. This study addressed study aims 1 through 3. The relationships among self-management behaviors, study variables, and glycemic control did not satisfy the condition for testing the mediation role of the self-management behaviors among study variables and glycemic control. Therefore, aim 4 was not able to be accomplished.

In addition, a manuscript, ***Psychometric properties of the Problem Solving Inventory in caregivers of individuals with memory loss***, was submitted and will be published in the ***Journal of Gerontological Nursing*** (See Appendix C). The PSI was included in the current study as a key factor in predicting health outcomes among Chinese patients with T2DM. Findings of the current study are presented in the following manuscripts:

Manuscript #1: Characterizing a sample of Chinese patients with Type 2 Diabetes and selected health outcomes;

Manuscript #2: Correlates of self-management behaviors, glycemic control and metabolic syndrome among Chinese patients with Type 2 Diabetes.

Manuscript #1 (manuscript to be submitted, see Chapter 4), ***characterizing a sample of Chinese patients with Type 2 Diabetes and selected health outcomes,*** describes the sociodemographic and clinical characteristics of Chinese patients with T2DM and compares gender differences on personal, behavioral and environmental factors, as well as health outcomes. The results show that glycemic control and diabetes self-management among Chinese patients with T2DM living in the suburban areas are suboptimal. Among participants, the most frequently performed self-management behaviors in terms of number of days per seven days were adherence to medication treatment, followed by physical activity, diet, foot care and self-monitoring of blood glucose. These findings support previous research that diabetes self-management and glycemic control are less than optimal and are still challenging issues among Chinese patients with T2DM. In addition, a large proportion of participants were identified to have co-existing MetS, putting them at greater risk for developing diabetes complications especially those related to cardiovascular disease. Through a multifactorial approach, participants were identified to have low health literacy, somewhat limited problem-solving and social support

in the current study. Compared to males, females demonstrated more depressive symptoms and a lower level of health literacy, problem-solving and social support. These findings corroborate previous studies and suggest that women may need additional support to improve their overall diabetes self-management.

Manuscript #2 (manuscript to be submitted, see Chapter 5), ***correlates of self-management behaviors, glycemic control and metabolic syndrome among Chinese patients with Type 2 Diabetes***, examined the impact of modifiable personal, behavioral, and environmental factors on self-management behaviors, glycemic control, and existence of MetS among Chinese patients with T2DM. Findings revealed that self-efficacy is significantly related to both overall and individual self-management behaviors among participants. Problem-solving, self-management behaviors related to medication adherence and diet are significant correlates of glycemic control after controlling for covariates. The level of health literacy and participants' level of physical activity are significantly related to the existence of MetS. These findings corroborate previous research and suggest that it is important to evaluate these factors when providing care for Chinese patients with T2DM in order to help them gain control of the disease and improve their health outcomes.

6.2 LIMITATIONS

The current study has several limitations. This was a cross-sectional study which limited the ability in addressing the casual relationships among study variables and health outcomes. Recruitment of patients from one outpatient patient clinic which was specialized in diabetes management limited the generalizability of the study findings to other settings. A larger sample

is preferred to demonstrate more power in detecting significance among statistical tests. Researchers have suggested to have a preferred sample size over 400 for logistic regression (Bewick, Cheek, & Ball, 2005; Hosmer & Lemeshow, 2000). In addition, all instruments used in the study were self-reported measures; this may introduce recall bias and social desirability. Some of these measures were only implemented in younger Chinese populations, and our population is middle aged and older. With a few instruments that reported less than acceptable on Cronbach's alpha ($\alpha < 0.7$), further research is needed to include instruments that have higher α and acceptable test-retest reliability with additional psychometric testing. Accuracy of the information from participants may also have been an issue since participants may have rushed through the questionnaires because they had to go to their clinic appointment. Similar studies need to be carried out in a general setting or through a multi-center approach to gain a broader view about diabetes self-management among Chinese patients with T2DM.

6.3 CONCLUSIONS AND IMPLICATIONS

This study provided an overview of the current state of the science regarding diabetes self-management and related health outcomes among Chinese patients with T2DM. Based on the findings of the current study, gender differences exist in diabetes self-management related to the level of health literacy, problem-solving, social support and depressive symptoms; self-efficacy is a key factor for diabetes self-management; and there is evidence of inadequate glycemic control and high rate of MetS. Addressing problem-solving, health literacy, and lifestyle modifications may help patients gain control of diabetes and prevent related diabetes complications. Findings of the study also suggest that reducing MetS risk and improving overall

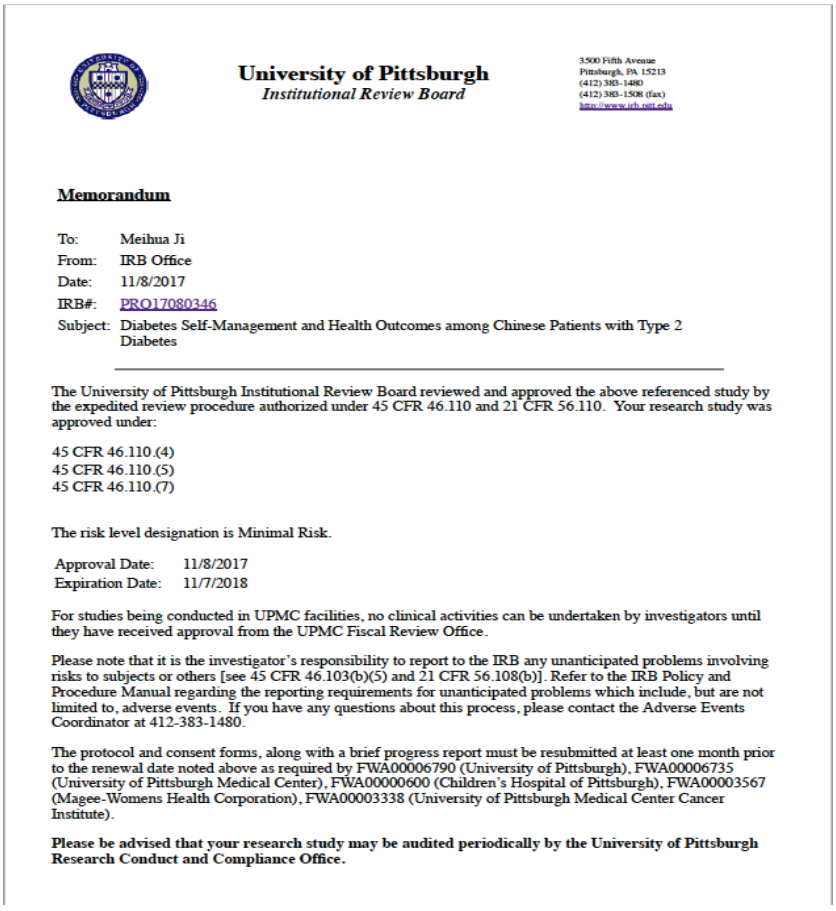
metabolic control are essential in diabetes self-management and promoting better health outcomes among patients with T2DM. Results of the current study suggest some areas for future research:

1) Qualitative studies to examine the lived experience of diabetes self-management among Chinese patients with T2DM;
2) Developing and testing theory-based interventions designed to promote self-management behaviors and glycemic control. Strategies to promote problem-solving, health literacy, self-efficacy etc. need to be considered;
3) Developing and testing interventions designed to prevent or delay diabetes complications in order to help Chinese patients with T2DM gain overall metabolic control.

APPENDIX A INSTITUTIONAL REVIEW BOARD APPROVAL DOCUMENTS

IRB APPROVAL LETTERS

A.1 APPROVAL LETTER FROM UNIVERSITY OF PITTSBURGH, PA, USA



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)
http://www.irb.pitt.edu

Memorandum

To: Meihua Ji
From: IRB Office
Date: 11/8/2017
IRB#: PRO17080346
Subject: Diabetes Self-Management and Health Outcomes among Chinese Patients with Type 2 Diabetes

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The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under:

45 CFR 46.110.(4)
45 CFR 46.110.(5)
45 CFR 46.110.(7)

The risk level designation is Minimal Risk.

Approval Date: 11/8/2017
Expiration Date: 11/7/2018

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office.

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

A.2 APPROVAL LETTERS (CHINESE AND ENGLISH TRANSLATION) FROM LUHE HOSPITAL, BEIJING, CHINA

伦理审查批件

批件号	2017LH-NZ-004		
项目名称	我国2型糖尿病患者自我管理及健康结局的相关因素研究		
项目来源	美国匹兹堡大学护理学院博士基金		
研究单位	首都医科大学附属北京潞河医院		
主要研究者	王晓静/季美华		
审查类别	临床科研项目	审查方式	快速审查
审查日期	2017.8.31	审查地点	医学伦理委员会办公室
审查委员	王辉、冯英梅		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007），SFDA《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循GCP原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权力。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

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年度/定期跟踪审查频率	12个月
有效期	2017.9-2018.8
联系人与联系电话	王晓静/18911187786
主任委员签字	
伦理委员会	（盖章）
日期	2017.8.31

Institutional Review Board Approval Form

批件号	2017LH-HZ-004		
Research Title	Diabetes Self-management and Health Outcomes among Chinese Patients with Type 2 Diabetes		
Funding resource	PhD Scholarship Fund School of Nursing, University of Pittsburgh, PA, US		
Research Site	Luhe Hospital, Capital Medical University, Beijing, China		
Principle investigators	Xiaojing Wang/ Meihua Ji		
Type of review	Clinical Research	Review Method	Expedited
Date of review	August, 31, 2017	location	Ethical and Human Research Protection Office
Review committee	Hui Wang, YingMei Feng		

Approval comments

According to the "Ethical Review Methods Relating to Human Biomedical Research" (Ministry of Health, China, 2007), "Declaration of Helsinki" (World Medical Association), International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS), "Good Clinical Practice of Pharmaceutical Products" and "Provision for Medical Device Classification", the **Ethical and Human Research Protection Office has approved the research protocol, consent form, and recruitment materials related to the study named above.**

Please register your study before conducting your research, adhere to the "Good Clinical Practice" and the approved research protocol from the review committee when conducting your study, and protect participants' health and privacy in all times.

If there is any change related to the principle investigators, research protocol, consent form or recruitment materials, the principle investigator need to submit a written application in making such changes.

If there are any adverse events, principal investigator needs to submit a report related to the event immediately.

Please follow the frequency required by the review committee in submitting annual/follow up review report which shall be submitted to the office one month in advance. A progress report is needed from involved centers which should be submitted to the review committee. A written report is needed when patients are predisposed to any increased riskes during the study, or any event that could affect the implementation of the study.

When patients who do not meet the stated inclusion and exclusion criteria are recruited to the study, or any risk exists among participants regarding patients right or their health, as well as any non-scientific results occur during the study which may induce results that against the principle of "Good Clinical Practice", the principle investigator should submit a violation report of the approved research protocol to the review committee.

In the event of temporary suspension or early termination of the study, please submit the termination/suspension report as soon as possible. When study is completed, please submit the completion report to the committee.

Follow up review frequency	12 months
Effective date	2017.09-2018.08
Contact information	Xiaojing Wang, Telephone：18911187786

首都医科大学附属北京潞河医院
潞河临床医学院
BEIJING LUHE HOSPITAL,CAPITAL MEDICAL UNIVERSITY

82 South Xinhua Road
Tongzhou District
Beijing, China, 101100
Tel: 010-69543901

May 1, 2017

To: University of Pittsburgh

From: Dong Zhao, Director, Endocrinology Center
Beijing Luhe Hospital-Capital Medical University
Re: < Diabetes self-management and health outcomes among Chinese patients with type 2 diabetes>

Letter of support

To whom it may concern,
On behalf of the Endocrinology Center, Luhe Hospital-Capital Medical University, Beijing, China, I am writing this letter to support the implementation of the research project titled as "Diabetes self-management and health outcomes among Chinese patients with type 2 diabetes" proposed by Meihua Ji (PhD student, School of Nursing, University of Pittsburgh). Luhe Hospital is a tier 3 tertiary hospital affiliated with Capital Medical University, Beijing, China. The Endocrinology Center at Luhe Hospital was established in 2003, and it is a clinical, educational, and research center for endocrine diseases. It is recognized as one of the leading research centers in diabetes management and prevention in China. We have both inpatient and outpatient clinics in our center and have an average of 120, 000 patient visits annually, in which about 50% are patients with diabetes.

Upon Meihua Ji's request, we happily provide permission for Meihua Ji to collect data (self-administrated questionnaires) among patients with type 2 diabetes who visit our center and agree to participate. She also has permission to access patients' medical records during the research period to retrieve relevant patient data. We are very happy to have Meihua Ji conduct her research project at our center. Our center will provide space and necessary support for Meihua Ji in completing her research project and data collection. This research will also promote evidence-based practice and encourage research translation in our site. Please feel free to let me know if you have further questions, I am very happy to assist.

Yours Sincerely,

Dong Zhao Dong Zhao
Director, Endocrinology Center, Luhe Hospital-Capital Medical University
Tele: 010-6954390-6908

APPENDIX B FUNDING SOURCE

MARGARET E. WILKES SCHOLARSHIP FUND AWARD FY18

University of Pittsburgh

School of Nursing
Center for Research and Evaluation

360 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
412-624-4854
Fax: 412-624-1201
www.nursing.pitt.edu/department/cre

June 29, 2017

Meihua Ji, MSN, RN
6004 Stanton Avenue, Apt. 21
Pittsburgh, PA 15206

RE: Margaret E. Wilkes Scholarship Fund Award FY18

Dear Ms. Ji:

Congratulations! I am pleased to inform you that your proposal, *Diabetes Self-Management and Health Outcomes among Chinese Patients with Type 2 Diabetes*, was selected for funding. The reviewers were impressed with your submitted proposal.

You will be formally recognized for your achievement at the Scholarship & Awards Luncheon on Monday, October 23, 2017 at the Wyndham here in Oakland. More information regarding the luncheon will be forwarded on a later date.

As an award recipient, you are asked to write a personal thank you note expressing what receiving the award means to you. Please address the letter to:

Mrs. Margaret Wilkes & Mr. James Wilkes
c/o Cynthia A. Henderson
University of Pittsburgh School of Nursing
3500 Victoria Street, Room 239
Pittsburgh, PA 15261

Information is enclosed regarding funding, the preparation of the final report and the citation of any publications or presentations produced as a result of this funding. The grant is awarded from July 1, 2017 to August 31, 2018, in the amount of $3,000. A compilation of the reviewer's comments will be forwarded within the next two weeks.

APPENDIX C MANUSCRIPT ON PROBLEM SOLVING INVENTORY

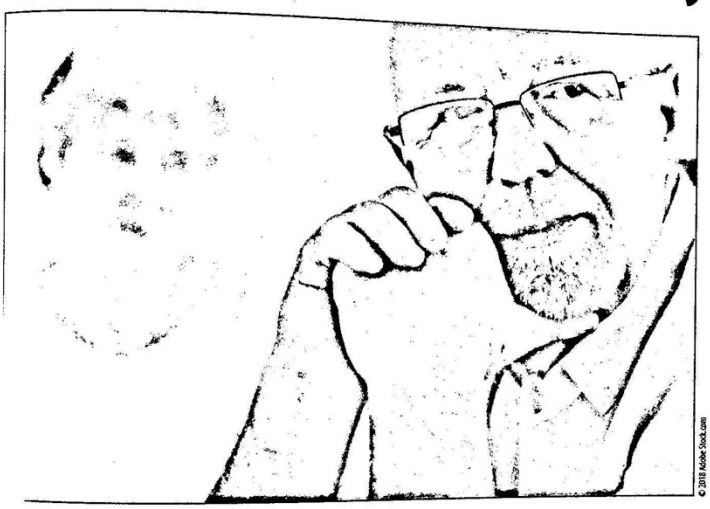
PSYCHOMETRIC PROPERTIES OF THE PROBLEM SOLVING INVENTORY IN CAREGIVERS OF INDIVIDUALS WITH MEMORY LOSS

Citation:

Ji, M., Sereika, S.M., Rohay, J.M., & Erlen, J.A. (2018). Psychometric properties of the Problem Solving Inventory in caregivers of individuals with memory loss. Journal of Gerontological Nursing, 44(6), 25-32. doi:10.3928/00989134-20180509-05

C.1 MANUSCRIPT

Psychometric Properties of the Problem Solving Inventory in Caregivers of Individuals With Memory Loss



ABSTRACT

Limited research exists assessing problem-solving capabilities among caregivers of individuals with memory loss using a validated instrument. To address this gap, the current study evaluated the psychometric properties of the Problem Solving Inventory (PSI) using data at baseline and 8 weeks from a randomized controlled trial among caregivers ($N = 78$) of community-dwelling individuals with memory loss. Participants were mainly White (85.9%), female (71.8%), and on average age 66.5. Cronbach's alphas ranged from 0.84 to 0.92 for the subscales and overall PSI. Test–retest reliability over 8 weeks ranged from 0.44 to 0.56. Five factors were retained through exploratory factor analysis. Spearman's correlations showed convergent validity and discriminant validity between scores on the PSI and Beck Depression Inventory®-II ($r = 0.32$, $p < 0.01$), the Self-Efficacy for Managing Chronic Disease Scale ($r = -0.44$, $p < 0.001$), and the Newest Vital Sign questionnaire ($r = -0.07$, $p > 0.05$). Findings show that the PSI is reliable and valid in assessing problem-solving capabilities among caregivers of individuals with memory loss. [*Journal of Gerontological Nursing, 44*(6), 25-32.]

Informal family caregivers often have primary responsibility for medication and disease management of older adults with memory loss living in community settings (Lingler et al., 2016; While, Duane, Beanland, & Koch, 2013). Medication management can be challenging for family caregivers, who are often older adults with multiple comorbidities themselves. In a qualitative study using a grounded theory approach, While et al. (2013) identified that assuming a caregiver role for individuals with memory loss is a major source of stress when concerns for medication safety increase. Strategies to decrease stress and burden related to patient care management need to be considered to promote effective medication adherence and positive care. As described in a recent review, the most commonly used methodologies among training programs for family caregivers of individuals with dementia are discussion, problem-solving, and skills and strategies training, such as coping and stress management skills (Sousa, Sequeira, Ferré-Grau, Neves, & Lleixà-Fortuño, 2016).

Problem solving, an important component in self-management of chronic disease (Lorig & Holman, 2003), is "the self-directed cognitive-behavioral process by which an individual, cou-

Meihua Ji, MSN, RN; Susan M. Sereika, PhD; Jeffrey M. Rohay, PhD, MSIS; and Judith A. Erlen, PhD, RN, FAAN

ple, or group attempts to identify or discover effective solutions for specific problems encountered in everyday life" (Chang, D'Zurilla, & Sanna, 2004, p. 12). Researchers have adapted problem-solving interventions for caregivers of individuals with memory loss, which have shown promising results (Chiu, Pauley, Wesson, Pushpakumar, & Sadavoy, 2015; Lingler et al., 2016). Adequate problem-solving skills are necessary for caregivers to adjust to the changing needs and behaviors of the care recipient as the individual's cognitive function declines. Thus, health care providers need to understand caregivers' problem-solving capabilities to provide individually tailored care, promote medication adherence for patients, and address challenging patient demands. However, limited research exists on assessing problem-solving capabilities among caregivers of individuals with memory loss using a validated instrument.

Health care providers need to understand caregivers' problem-solving capabilities to provide individually tailored care, promote medication adherence for patients, and address challenging patient demands.

Multiple instruments are available to assess problem solving. One widely used instrument is the Problem Solving Inventory (PSI; Heppner & Petersen, 1982). Researchers have used the PSI in various settings across different age groups and cultural backgrounds (Heppner & Petersen, 1982; Heppner, Witty, & Dixon, 2004). The PSI assesses perceived problem-solving abilities related to problem-solving behaviors and attitudes within three subdimensions: Problem-Solving Confidence, Personal Control, and Approach–Avoidance Style; lower scores indicate better problem solving (Heppner & Petersen, 1982). Most studies and psychometric testing of the PSI have been conducted with college students or in educational settings; the instrument has not been used or psychometrically tested among older adults or with caregivers of patients with memory loss.

In evaluating the validity of instruments related to problem solving, constructs such as depressive symptoms and self-efficacy have been applied to test the convergent validity of the instrument (Hawkins, Sofronoff, & Sheffield, 2009; Sahin, Sahin, & Heppner, 1993; Wang et al., 2013). Research findings suggest that depressive symptoms may impact problem solving. A negative relationship between depressive symptoms and problem solving either directly or indirectly has been identified among studies with various populations, including family caregivers (Elliott & Shewchuk, 2003; Prachakul, Grant, & Keltner, 2007; Yen, Rebok, Gallo, Jones, & Tennstedt, 2011). Depressive symptoms are reported to be high among caregivers of patients with dementia (Cuijpers, 2005; Givens, Mezzacappa, Heeren, Yaffe, & Fredman, 2014; Liang et al., 2016) and have a negative impact on caregivers' ability to solve everyday problems. Self-efficacy, a concept within Social Cognitive Theory, is associated with problem solving (Bandura, 1977). Research has demonstrated that individuals with higher self-efficacy have better problem-solving skills (Erözkan, 2014; Hunt et al., 2012). In an intervention study among patients with diabetes, researchers found a significant positive relationship between problem solving and self-efficacy in performing behaviors related to diet and physical exercise at baseline (Glasgow, Toobert, Barrera, & Strycker, 2004).

Intelligence tests or academic achievement have been suggested by researchers to test the discriminant validity of problem-solving instruments among college students (Hawkins et al., 2009; Heppner & Petersen, 1982). For older adults or patients with chronic disease, these concepts may be inappropriate. Health literacy, a concept often used to examine patients' capacity to obtain, process, and understand health information, has been found to assist patients with health decision making (Nielsen-Bohlman, Panzer, & Kindig, 2004). Research has shown that individuals with higher levels of health literacy are more likely to participate in problem solving and decision making (Goggins et al., 2014). However, the relationship between health literacy and everyday problem-solving skills remains unclear.

The current researchers' review of the literature showed that limited evidence exists evaluating problem-solving capabilities among caregivers of patients with memory loss using validated instruments. Thus, the purpose of the current study was to address this gap and examine the psychometric properties (i.e., reliability, validity, factorial construct) of the PSI among informal caregivers of community-dwelling individuals with memory loss. A valid and reliable tool will help health care providers assess caregivers' capabilities in problem solving and therefore assist in providing tailored interventions to address disease and medication management for patients with memory loss. Depressive symptoms and self-efficacy for managing chronic disease were investigated to examine the convergent validity of the PSI in the current study. Using the PSI, in which lower scores are indicative of

better problem solving, researchers hypothesized there would be a positive association between the scores on problem solving and depressive symptoms, and a negative association between the scores on problem solving and self-efficacy among caregivers in completing selected activities related to disease management for individuals with memory loss. In evaluating the discriminant validity of the PSI, the relationship between the score on problem solving and the score on the health literacy instrument was examined to determine whether a significant relationship existed among caregivers of patients with memory loss.

METHOD

Participants and Procedure

The current secondary data analysis used baseline and 8-week post-baseline assessments from a randomized controlled trial designed to improve informal caregivers' problem-solving skills related to medication management of community-dwelling individuals with memory loss. Participants were dyads (N = 91) of patients with memory loss and their caregivers who were recruited from a memory loss clinic and multiple community sites (Erlen et al., 2015). The parent study was approved by the University of Pittsburgh Institutional Review Board and funded by the National Institute of Nursing Research supported by a program grant. Dyads were randomized to either a tailored medication management intervention or usual care and followed following baseline data collection. Detailed inclusion and exclusion criteria, study procedure, intervention overview, and 8-week outcomes of the study have been reported elsewhere (Lingler et al., 2016). The current study is a descriptive study using baseline (N = 78 with complete data) and 8-week post-baseline data (control group only) to evaluate the psychometric properties of the PSI.

Measures

Sociodemographic. A questionnaire developed for the University of Pittsburgh School of Nursing Center for Research in Chronic Disorders was used to collect sociodemographic information for patients and caregivers in the parent study, including age, gender, race, education, and number of comorbidities, among other variables (Sereika & Engberg, 2006).

Problem Solving. Level of problem solving was measured using the PSI (Heppner & Petersen, 1982). The PSI is a self-reported 32-item, three-dimensional instrument structured to assess one's problem-solving capabilities in relation to one's perception or appraisal of problem solving. The three subscales include: Problem Solving Confidence, Approach–Avoidance Style, and Personal Control. Each item is rated from 1 (*strongly agree*) to 6 (*strongly disagree*). When combined, the three subscale scores create an overall score ranging from 32 to 192 that reflects one's problem-solving capability; lower scores indicate behaviors or attitudes associated with successful problem solving (Heppner & Petersen, 1982). The instrument was initially tested among college students with good internal consistency (α = 0.72 to 0.85 for the three subscales, α = 0.90 for the total scale) and has been reported as reliable and valid in other studies (Heppner et al., 2004).

Depressive Symptoms. The Beck Depression Inventory®-II (BDI®-II; Beck, Steer, & Brown, 1996) has been used to assess depressive symptoms among caregivers. The BDI-II is a widely used instrument across various populations. It is a self-reported instrument with 21 items assessing the severity and presence of depressive symptoms. The scale is reported to have a high Cronbach's alpha among outpatients (0.92) and college students (0.93). Items are rated using a 4-point Likert scale ranging from 0 to 3 for each item based on severity of the symptoms; the higher the score, the more severe the depressive symptoms; total scores range from 0 to 63.

Self-Efficacy. Self-efficacy of the caregiver's competence in performing selected activities related to disease and medication management, stress reduction, and symptom management was measured using the six-item self-reported Self-Efficacy for Managing Chronic Disease Scale (SEM; Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). Each item is rated from 1 (*not at all confident*) to 10 (*totally confident*), with higher scores indicating better self-efficacy; total scores range from 6 to 60. The internal consistency reliability of the scale was reported as 0.91 in the original study of patients with chronic disease (N = 498) (Lorig et al., 2001).

Health Literacy. Caregivers' health literacy was examined by the Newest Vital Sign (NVS), a six-item questionnaire using an ice cream nutritional label assessing caregivers' ability in reading, numeracy, and comprehension (Weiss et al., 2005). Each item is given 1 point for a correct answer and 0 points for an incorrect answer, with a total score ranging from 0 to 6. Higher scores indicate better health literacy. Cronbach's alpha was 0.76 in the original study, demonstrating acceptable internal consistency, and was identified as being valid in assessing patients' health literacy among patients with chronic disease (Kirk et al., 2012; Weiss et al., 2005).

Data Analysis

Analyses were performed using IBM SPSS version 24. Significance was set a priori at 0.05 for two-sided hypothesis testing. Means and standard deviations, range or frequency counts, and percentages were used to describe the sample. Normality of the continuous type variables was evaluated by the value on kurtosis and skewness and observation of scatter plots. Screening for outliers was performed through Mahalanobis distance techniques using a chi-square based critical value of 62.49 (p = 0.001, df = 32).

The Kaiser–Meyer–Olkin (KMO) statistic and Bartlett's test of sphericity

TABLE 1
DESCRIPTIVE STATISTICS FOR STUDY VARIABLES ($N = 78$)

PSI total	85.7 (20.8) (37 to 133)
PSC	25.0 (8.1) (11 to 43)
AAS	45.7 (10.9) (21 to 72)
PC	14.8 (5.5) (5 to 28)
BDI-II total	10.3 (8.2) (0 to 30)
SEM total	6.8 (2.3) (1 to 10)
NVS total	4.0 (1.9) (0 to 6)

Note. PSI = Problem Solving Inventory; PSC = Problem Solving Confidence; AAS = Approach–Avoidance Style; PC = Personal Control; BDI-II = Beck Depression Inventory®-II; SEM = Self-Efficacy for Managing Chronic Disease Scale; NVS = Newest Vital Sign.

TABLE 2
RELIABILITY AND VALIDITY ANALYSIS FOR THE PROBLEM SOLVING INVENTORY (PSI) ($N = 78$)

Reliability				
Cronbach's α	0.92	0.90	0.82	0.84
Test–retest ($n = 39$)[a]	0.56**	0.44*	0.59**	0.56**
Validity				
BDI-II total[b]	0.32*	—	—	—
SEM total[b]	−0.44**	—	—	—
NVS total[b]	−0.07	−0.03	−0.12	−0.21

Note. PSC = Problem Solving Confidence; AAS = Approach–Avoidance Style; PC = Personal Control; BDI-II = Beck Depression Inventory®-II; SEM = Self-Efficacy for Managing Chronic Disease Scale; NVS = Newest Vital Sign.
[a] Pearson correlation (for control group).
[b] Spearman's rank order correlation.
**p < 0.01; **p < 0.001.*

were performed to assess the appropriateness of the data for factor analysis. Principal component analysis (PCA) was applied to extract latent factors among these items and establish construct validity. To achieve simple structure, promax and varimax rotations were attempted to determine the appropriateness of factor loading. If the correlations among factors did not reach a value of 0.32 after promax rotation, an orthogonal rotation was warranted (Tabachnick & Fidell, 2007). Eigenvalues, screen plots, and the amount of variance explained from PCA were used to determine the number of components extracted within the 32 items of the PSI. To be considered important, a factor loading ≥0.4 was used to decide whether an item should be loaded on that factor (Hair, Anderson, Tatham, & Black, 1998).

Reliability of the scale and subscales was established using Cronbach's alpha. Pearson's correlation was used to assess test–retest reliability of the PSI at baseline and 8 weeks as an examination of the instrument's stability over time among the control group ($n = 39$). Redundancy of items was checked by examining the interitem correlations, and items with correlation coefficients >0.7 were considered redundant. Convergent validity was tested using Spearman's correlation among the total score of the PSI, BDI-II for depressive symptoms, and SEM at baseline. Discriminant validity was examined using Spearman's rank correlation between the total score on the NVS and PSI and scores on the three subscales.

RESULTS

Sample Characteristics

Of the 91 participants enrolled in the study, 13 (14.2%) participants had missing data, with a pattern of missingness identified as missing completely at random (Little's Missing Completely at Random test, $p = 1$); therefore, 78 caregivers with complete data were included for final analysis. Participants were mainly White (85.9%), female (71.8%), and on average age 66.5 ($SD = 12.3$ years) with 14.7 ($SD = 2.8$) years of education. Descriptive data on study variables are displayed in **Table 1**.

Reliability and Validity

Cronbach's alpha ranged from 0.82 to 0.90 for the three subscales, and was 0.92 for the total score. For caregivers in the control group ($n = 39$), test–retest reliability over 8 weeks demonstrated moderate correlations for the total score and scores of the three subscales (r range = 0.44 to 0.59) (**Table 2**). Spearman's correlations showed a moderate positive relationship between the PSI and BDI-II total score, and a moderate negative relationship between the PSI and SEM total scores. No significant relationships were identified between the NVS and PSI total score and the scores on the three subscales ($p > 0.05$).

TABLE 3

SUMMARY OF FACTOR LOADINGS FOR THE PROBLEM SOLVING INVENTORY AMONG INFORMAL CAREGIVERS OF INDIVIDUALS WITH MEMORY LOSS

Personal Control	Items 3, 11, 14, 15, 25, 26, 32, 34 Example: "Many problems I face are too complex for me to solve."	0.548 to 0.764
Problem Solving Confidence	Items 5, 10, 19, 21, 23, 24, 27, 31, 33 Example: "I am usually able to think up creative and effective alternatives to solve a problem."	0.522 to 0.705
Proactive Approach	Items 6, 7, 18 Example: "When I have a problem, I think up as many possible ways to handle it as I can until I can't come up with any more ideas."	0.554 to 0.743
Avoidance Style	Items 1, 2, 4, 30 Example: "When a solution to a problem was unsuccessful, I did not examine why it didn't work."	0.406 to 0.858
Decision Processing	Items 12, 16, 20, 28 Example: "When confronted with a problem, I stop and think about it before deciding on a next step."	0.426 to 0.659

Exploratory Factor Analysis

Although the PSI has a known factorial structure with three factors, the scale has not been tested among caregivers of patients with memory loss; therefore, exploratory factor analysis was performed to identify potential factors in the sample. The dataset was screened for univariate normality. Values of kurtosis and skewness showed floor and ceiling effects by item. No univariate outliers were identified. Using Mahalanobis distance, no multivariate outliers were identified among the 32 items. The value of the KMO statistic as 0.79 indicated that the dataset was suitable for factor analysis. Bartlett's test of sphericity was significant at 1,448.5 ($p < 0.001$), indicating that the interitem correlation matrix was significantly different than an identity matrix. The KMO statistic and Bartlett's test indicated that factor analysis was feasible. The communalities of 32 items of the PSI ranged from 0.55 to 0.83, which indicated a moderate to high value (Velicer & Fava, 1998) and suggested that items were moderately correlated in the current sample. The interitem correlations were examined to determine whether there were redundant items. The matrix showed no coefficient value >0.7 (Kline, 1979); therefore, no items were removed. However, there were coefficient values <0.2 among items, which suggested that these items might not be representative of the concept domain of problem solving demonstrated in the current sample. PCA using promax rotation was initially tested; however, correlation coefficients between factors after rotation were not all >0.32, indicating that factors were not well correlated and an oblique rotation for this dataset was not appropriate, as researchers had suggested (Tabachnick & Fidell, 2007). Therefore, PCA with varimax rotation was performed to examine the underlying constructs of the PSI. Using the criterion of a minimum eigenvalue of 1, the factor loading suggested seven factors within the current sample, explaining 67.7% of the total item variance. A coefficient of 0.4 was used as the cutoff point for actual loadings of each item (Stevens, 1992).

After examining the coefficient values on each factor loading and the items loaded on each factor, four items (Items 8, 13, 17, 35) were excluded from the scale, and a total of five factors with 28 items were retained. Item 35 did not load on any of the factors (<0.4). Factor 6 was excluded, as less than three items loaded on this factor. Factor 7 was also excluded, as it had less than two items. Items that cross-loaded on more than one factor (Items 4, 5, 11, 15, 16, 20, 27, 28, 30, 31) suggested that these items were measuring more than one factor. Therefore, content of the items was examined, reviewed by an expert (J.A.E.), and referred to the original PSI scale for clarification to determine whether they should be retained. The final factorial structure for the PSI in the current sample of informal caregivers for patients with memory loss was a five-factor scale with 28 items (**Table 3**). Factor 1, *Personal Control*, was loaded with eight items, with five items from the original subscale of Personal Control. Factor 2, *Problem Solving Confidence*, had nine items, with most items from the original Problem Solving Confidence subscale. Factor 3, *Proactive Approach* (three items), Factor 4, *Avoidance Style* (four items), and Factor 5, *Decision Processing* (four items) were loaded from the items that were mostly categorized in the original Approach–Avoidance Style subscale. Factor loadings for the PSI in the current study sample ranged from 0.406 to 0.858.

TABLE 4

ESTIMATED PEARSON CORRELATION MATRIX OF THE FIVE LATENT FACTORS FOR THE PROBLEM SOLVING INVENTORY

PC	—	—	—	—
PSC	0.620**	—	—	—
PA	0.336**	0.522**	—	—
AS	0.211	0.240*	0.379**	—
DP	0.400**	0.594**	0.591**	0.350**

Note. PC = Personal Control; PSC = Problem Solving Confidence; PA = Proactive Approach; AS = Avoidance Style; DP = Decision Processing.
*$p < 0.05$; **$p < 0.01$.

The estimated correlation matrix among these five factors is shown in **Table 4**. Four of the five latent subscales were found to be significantly related to each other. The correlation between Factor 1 (*Personal Control*) and Factor 4 (*Avoidance Style*) was small to moderate and approached significance ($r = 0.211$, $p = 0.064$), whereas correlations between Factor 4 and other factors also remained small to moderate.

DISCUSSION

The current study is the first to evaluate and report the psychometric properties of the PSI among informal caregivers of community-dwelling individuals with memory loss. Results of the study revealed that the PSI was internally consistent, showed temporal stability over 8 weeks, and indicated an acceptable level of internal consistency reliability in psychometric testing (Nunnally, 1978).

Extracted factors for the PSI within the current sample revealed a somewhat different structure when compared to the original scale, which was tested among undergraduate college students (Heppner & Petersen, 1982). The current study suggested a five-factor scale with 28 items. The more specific factors of *Proactive Approach, Avoidance Style,* and *Decision Processing,* in addition to Problem Solving Confidence and Personal Control in the original scale, are conceivably more helpful in assessing problem-solving behaviors among caregivers of individuals with memory loss. Identifying more specific factors related to problem-solving capabilities has the potential to enable health care providers to provide individualized care.

The relationship between the PSI total score and total scores of the BDI-II and SEM showed convergent validity. The significantly moderate positive relationship ($r = 0.32$, $p < 0.01$) observed between scores of the PSI and BDI-II supported findings from previous research and suggested that less severe depressive symptoms are associated with better problem solving (Elliott & Shewchuk, 2003; Prachakul et al., 2007; Yen et al., 2011). The relationship between the PSI total score and the score on the SEM showed a significantly moderate negative relationship ($r = -0.44$, $p < 0.001$), which was also similar to previous research suggesting that higher self-efficacy is associated with better problem solving (Erözkan, 2014; Glasgow et al., 2004; Hunt et al., 2012). Although some researchers have recommended that the correlation coefficient between two constructs should be between 0.5 and 0.7 or higher to achieve convergent validity (Carlson & Herdman, 2012), other researchers have argued for convergent validity with coefficients as low as 0.28 and 0.33 (Larraza-Kintana, Wiseman, Gomez-Mejia, & Welbourne, 2007; Sahin et al., 1993). The significant findings from the current study provide adequate evidence of convergent validity for the PSI, suggesting that better problem solving is associated with lower depressive symptoms and higher self-efficacy.

Due to the limited number of variables included in the parent study (Erlen et al., 2013), the relationship between health literacy and problem solving was examined to evaluate discriminant validity. The NVS was deemed appropriate to evaluate the discriminant validity of the PSI, as demonstrated by the nonsignificant findings between the NVS and PSI total scores ($r = -0.07$, $p > 0.05$), as well as the scores on the three subscales (r range = -0.03 to -0.21, $p > 0.05$). These correlation coefficients are close to 0 and confirm that health literacy and problem solving are not correlated (Trochim, 2001).

LIMITATIONS

There were several limitations in the current study. Although small sample size was a major limitation, statistics such as KMO and Bartlett's test of sphericity have suggested that the current dataset was suitable and criteria for factor analysis were met; however, to demonstrate a more reliable factor structure, a larger sample is needed. There is also limited generalizability of the results, as participants were mainly White and female. Another possible limitation is the test–retest reliability, which was performed over an 8-week period. A shorter time span is preferred. However, a relatively strong association, which showed temporal test–retest reliability between these two time points, adds evidence to support the stability of the PSI among informal caregivers. In addition, the relationship between the PSI and the selected observable variables was limited; additional variables need to be examined to add rigor to the assessment of validity. For

example, disease knowledge, which has been identified as a significant factor when examining problem solving, should be examined.

CONCLUSION AND CLINICAL IMPLICATIONS

The PSI is a reliable and valid tool for examining problem-solving capabilities among informal caregivers of individuals with memory loss. Disease and medication management become more problematic and complicated as patients' cognitive function declines over time. With a more specific structure identified in the current study, the PSI has the potential to help health care providers better evaluate problem-solving capabilities among caregivers and ultimately aid in identifying individualized interventions to improve clinical outcomes among individuals with memory loss. Understanding caregivers' problem-solving capabilities and use of a problem-solving approach by health care providers will help caregivers of patients with memory loss better adapt to the challenging patient demands, therefore promoting adherence.

Given the limitations of the small and homogeneous sample in the current study, future research needs to include a confirmatory factor analysis of the identified structure in a larger and more diverse sample with informal caregivers. The psychometric assessment of the instrument in caregivers of different patient populations, and an examination of concurrent validity using another problem-solving instrument, are additional future considerations.

Thus, the reliability and validity of the PSI were established among caregivers of individuals with memory loss in the current study; the PSI could assist nurses and health care providers in identifying barriers related to disease and medication management in everyday problem solving among caregivers; and the PSI may serve as a simple tool to evaluate caregivers' problem-solving capability and assist health care providers in developing individualized tailored interventions to promote treatment adherence.

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C.2 PERMISSION TO USE IN SCHOLARLY WORK

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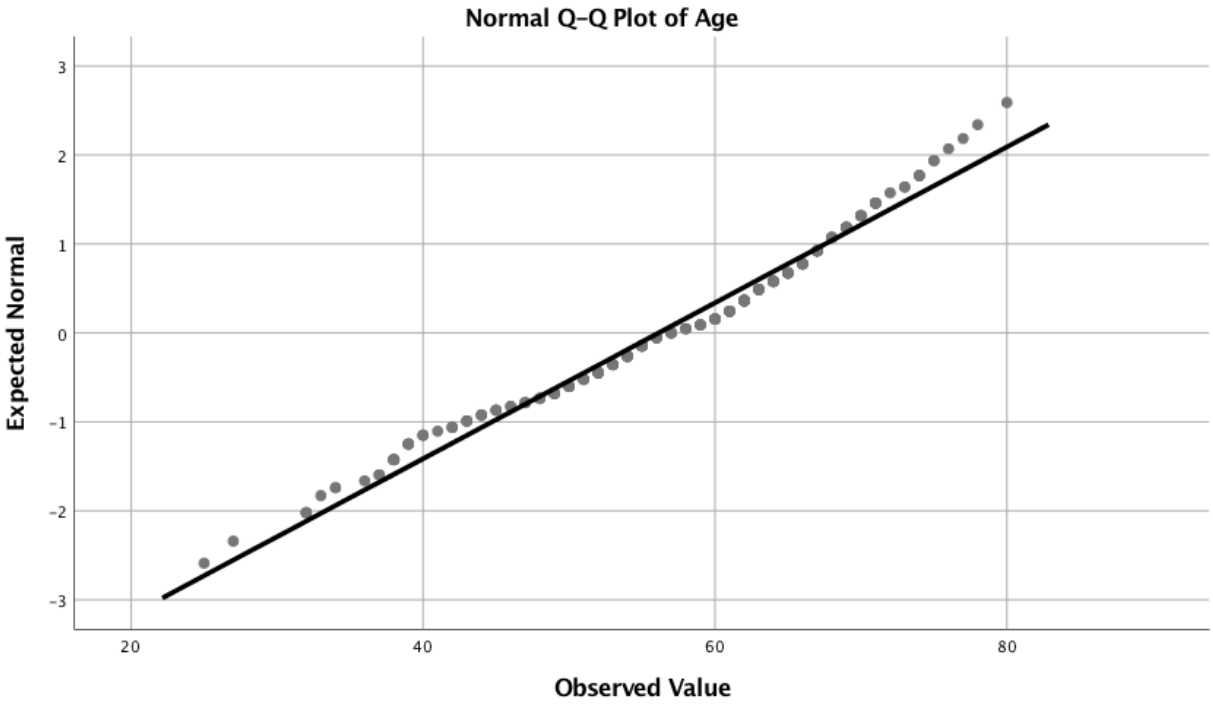
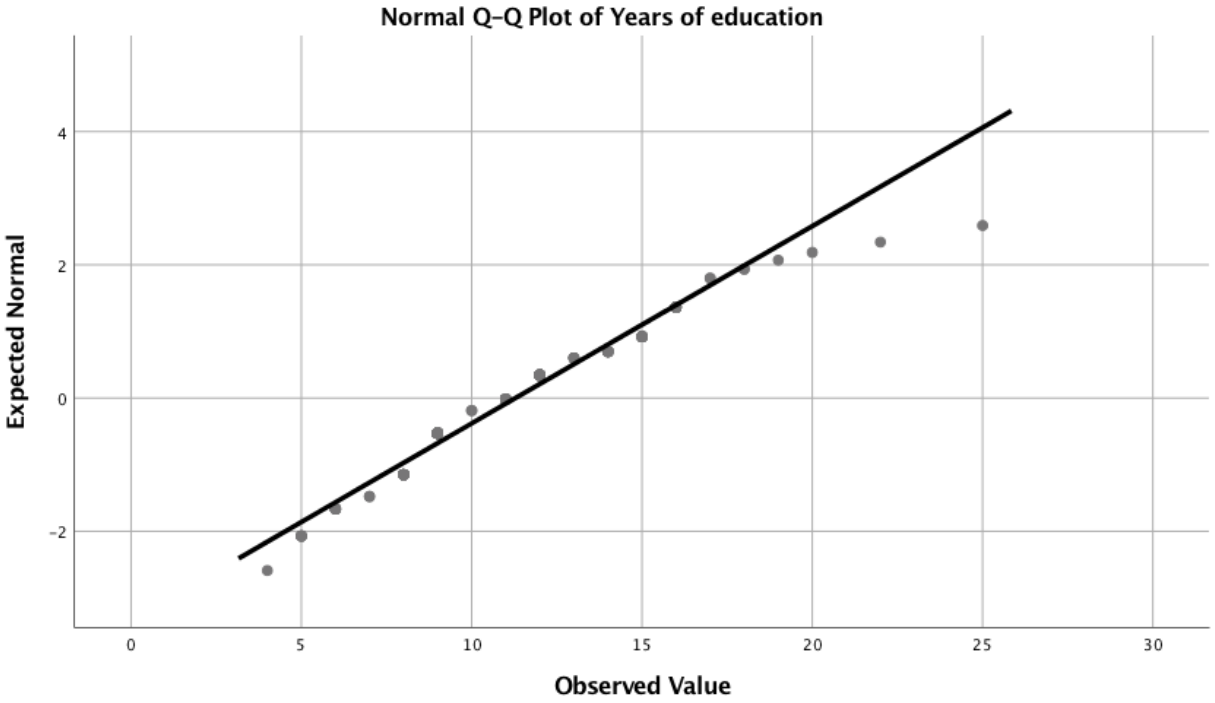
Please let me know if you have any additional questions.

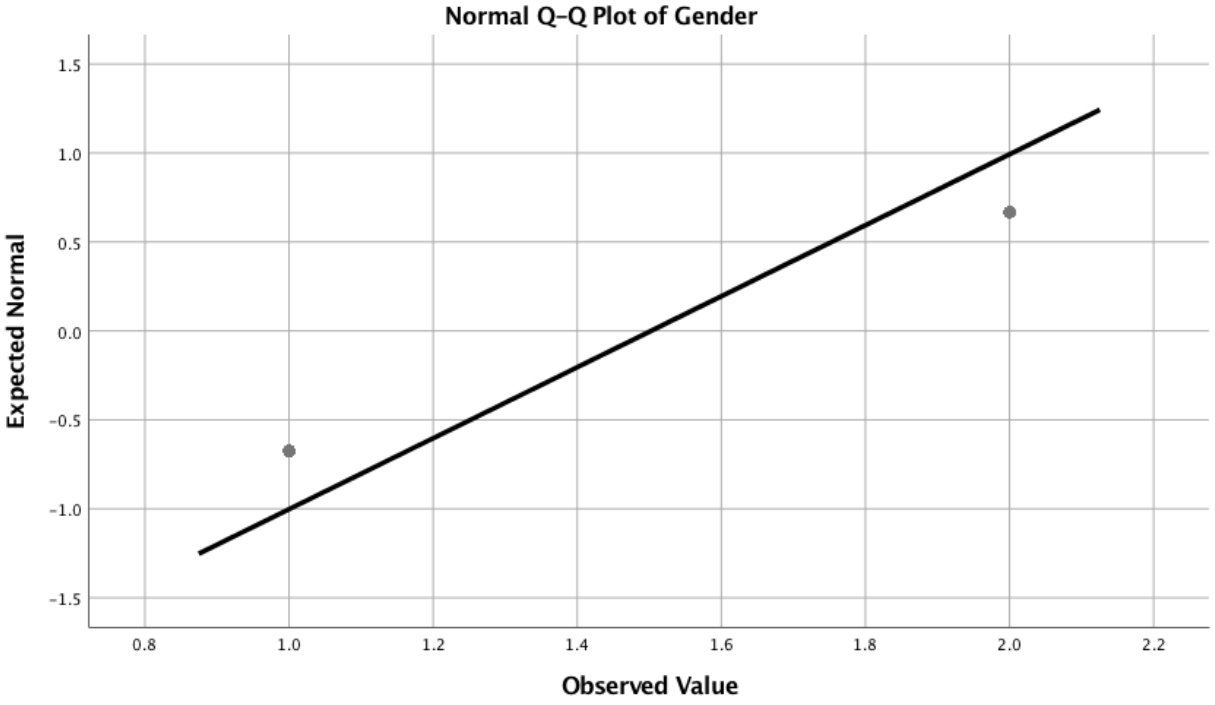
Best regards,
Aileen

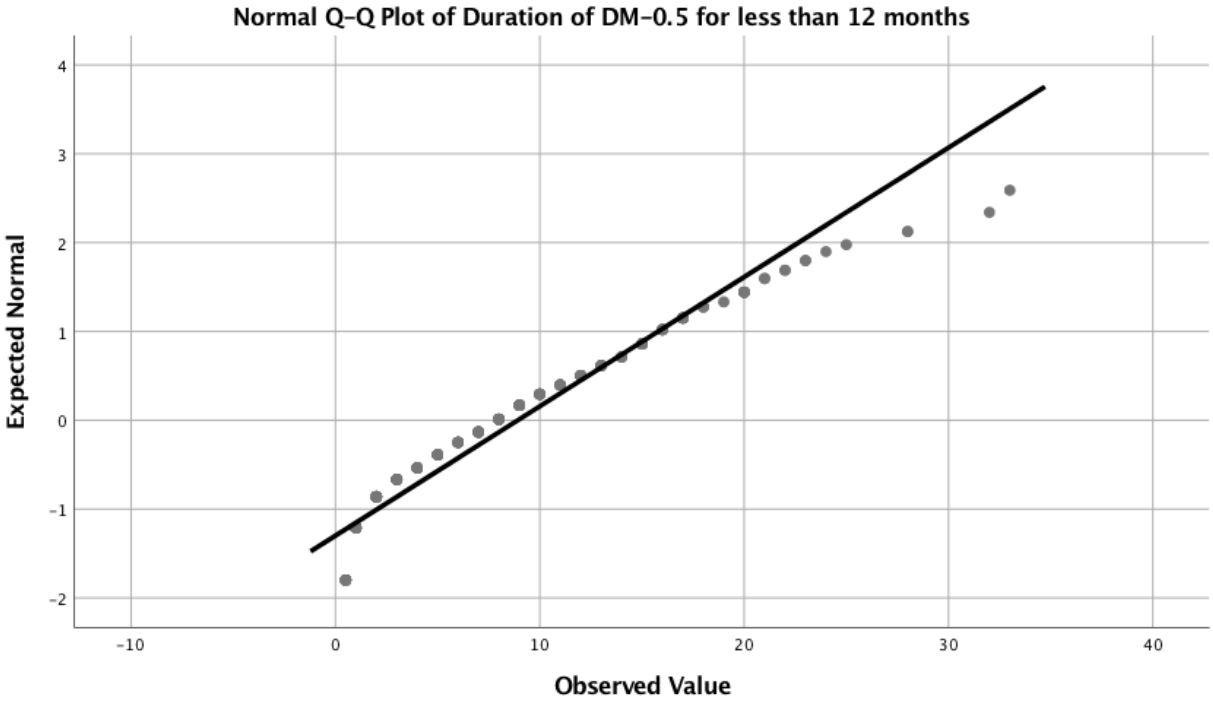
APPENDIX D Q-Q PLOTS AND ADDITIONAL RESULTS

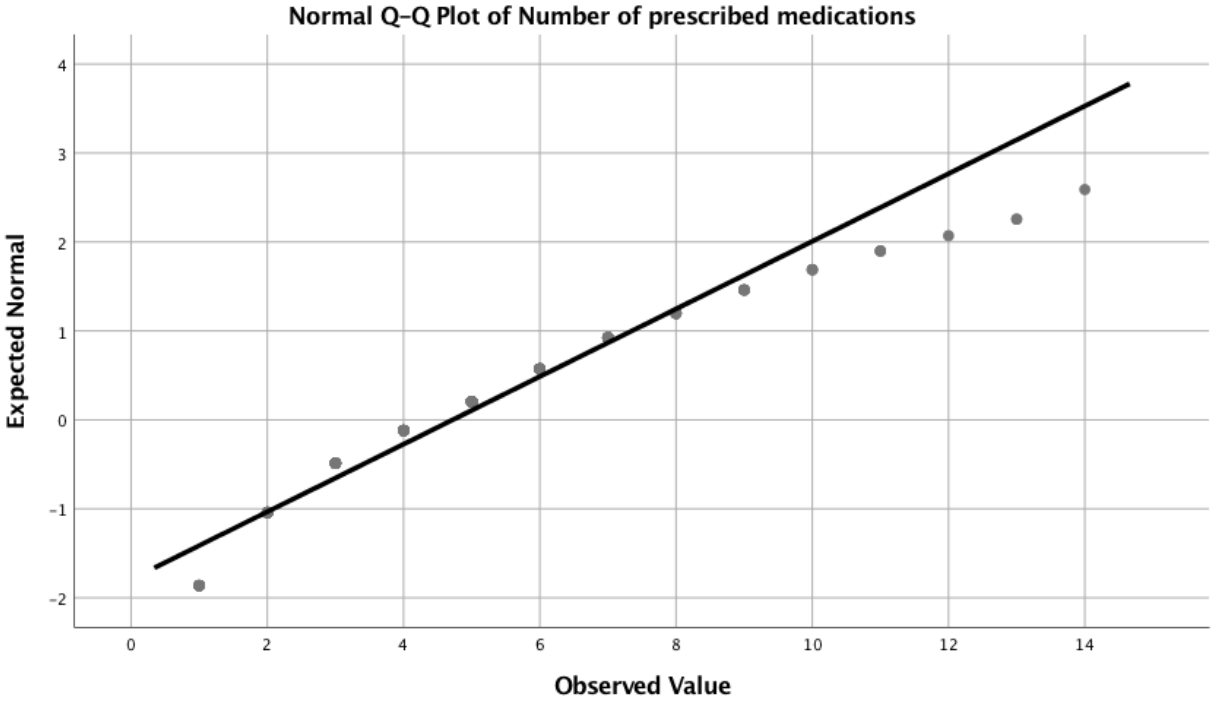
D.1 NORMAL Q-Q PLOTS OF STUDY VARIABLES AND HEALTH OUTCOMES

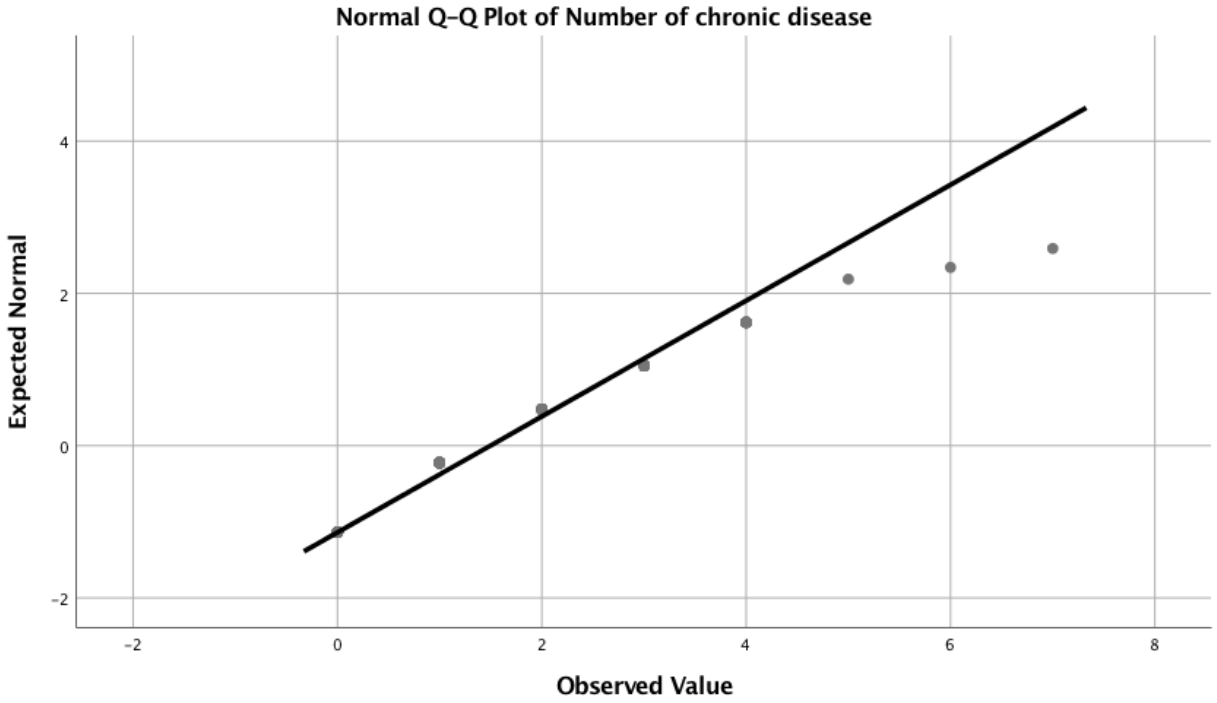


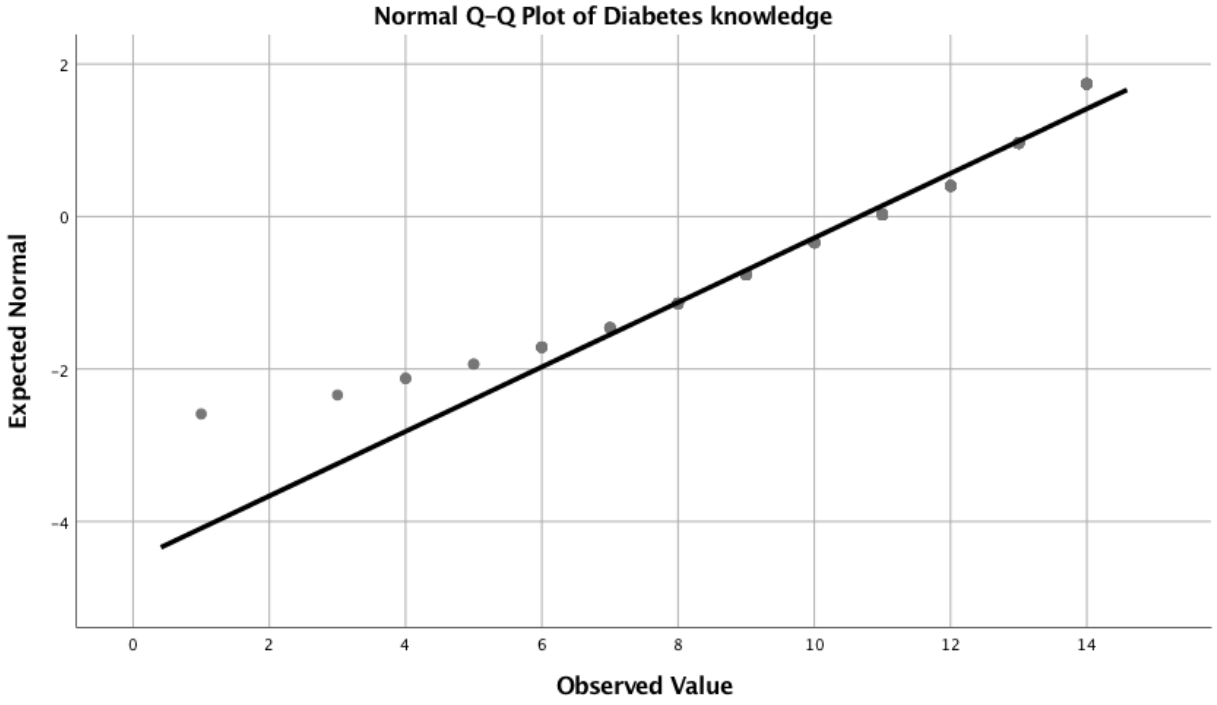

Normal Q–Q Plot of Years of education
Expected Normal
Observed Value
4
2
0
-2
0
5
10
15
20
25
30

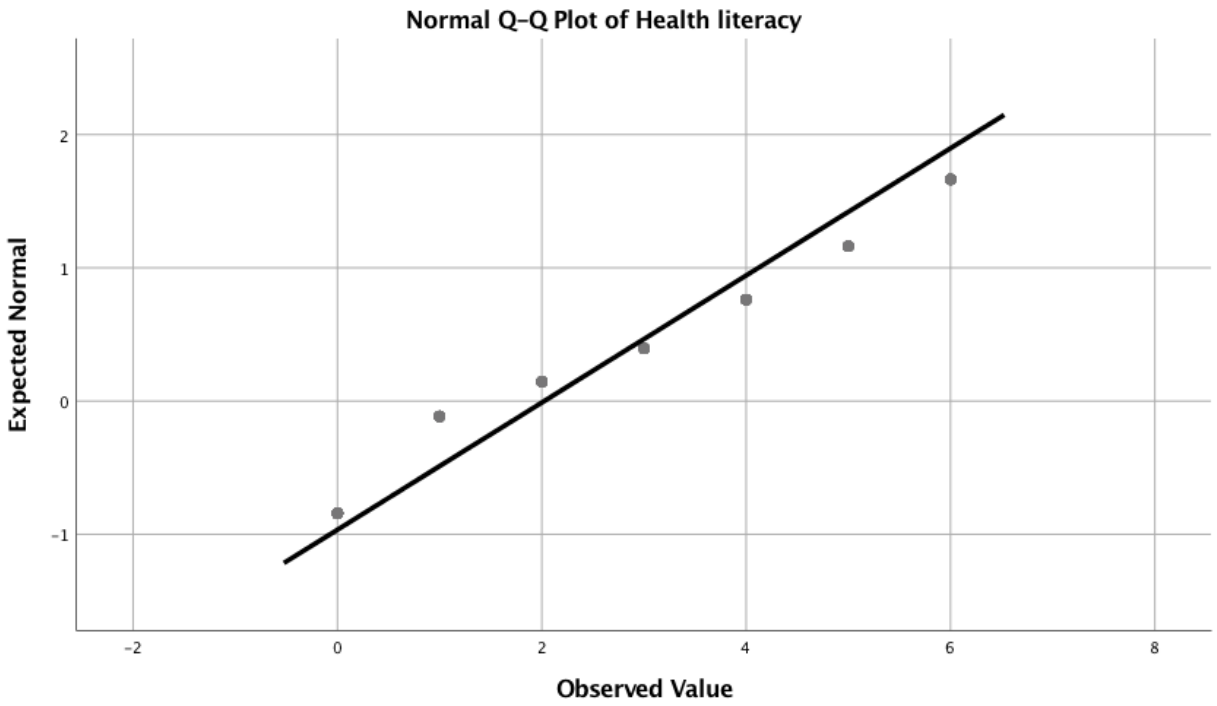

Normal Q–Q Plot of Gender
Expected Normal
Observed Value
1.5
1.0
0.5
0.0
-0.5
-1.0
-1.5
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2

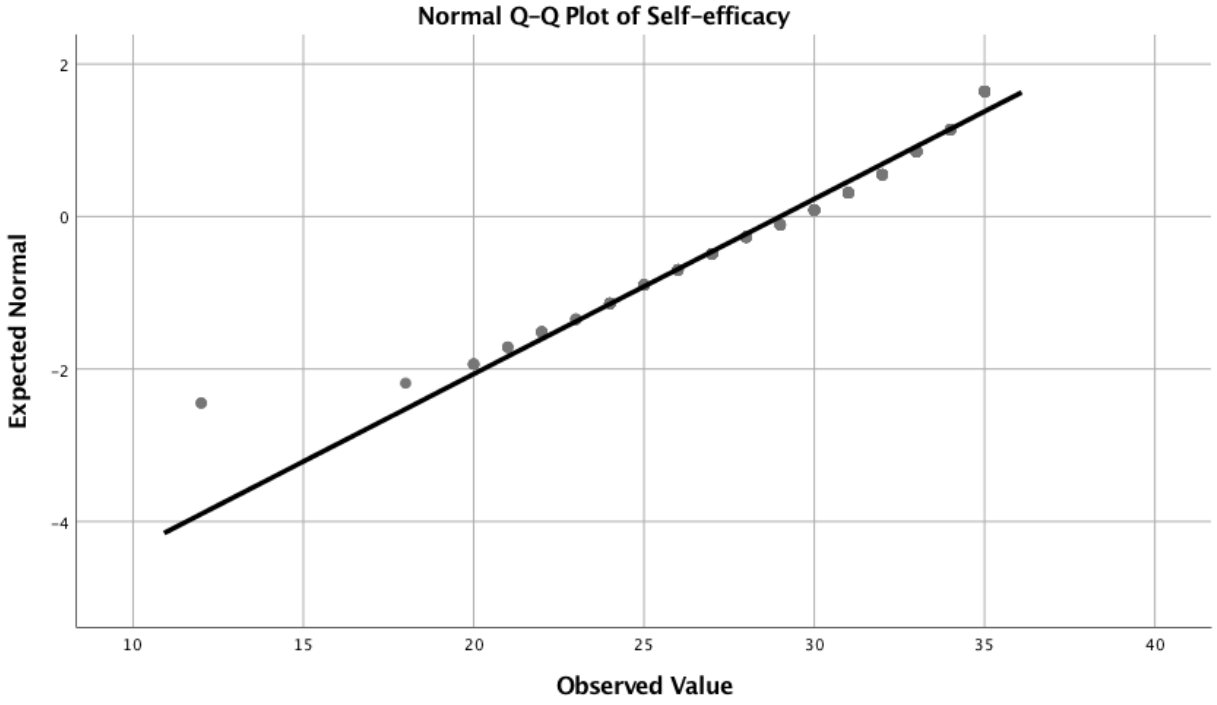

Normal Q-Q Plot of Duration of DM-0.5 for less than 12 months
Expected Normal
Observed Value
4
3
2
1
0
-1
-2
-10
0
10
20
30
40

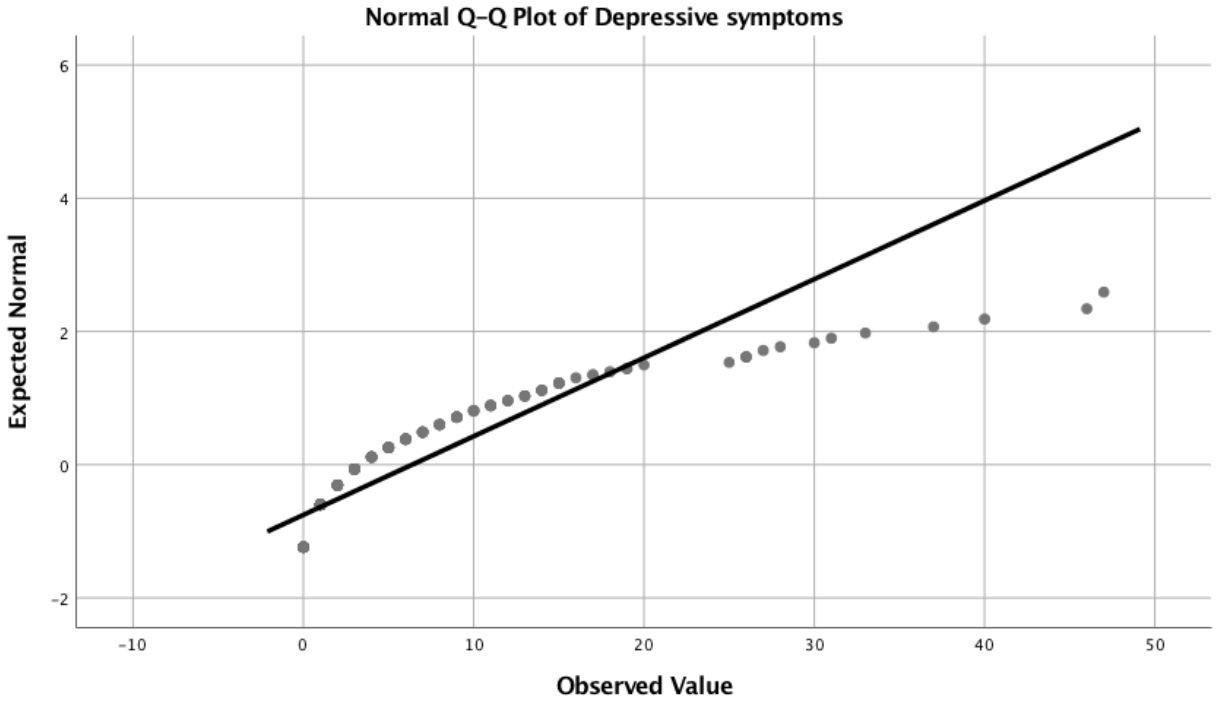

Normal Q-Q Plot of Number of prescribed medications
Expected Normal
Observed Value
4
3
2
1
0
-1
-2
0
2
4
6
8
10
12
14

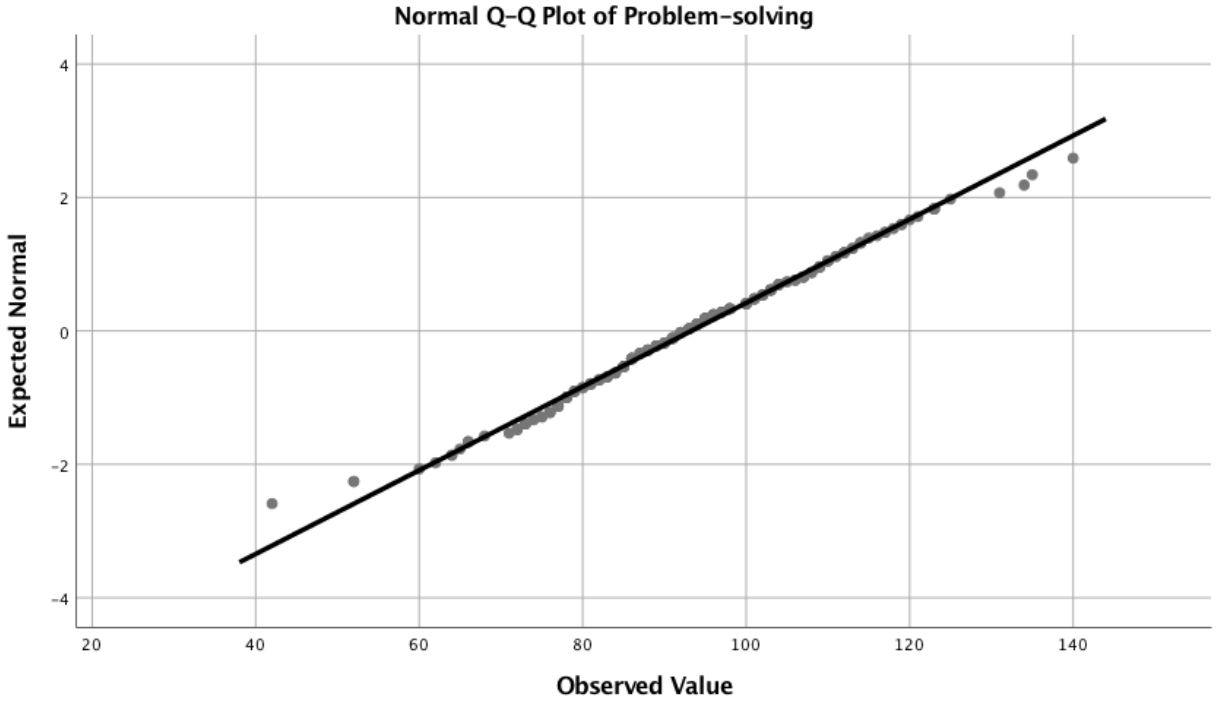

Normal Q-Q Plot of Number of chronic disease
Expected Normal
Observed Value
4
2
0
-2
-2
0
2
4
6
8

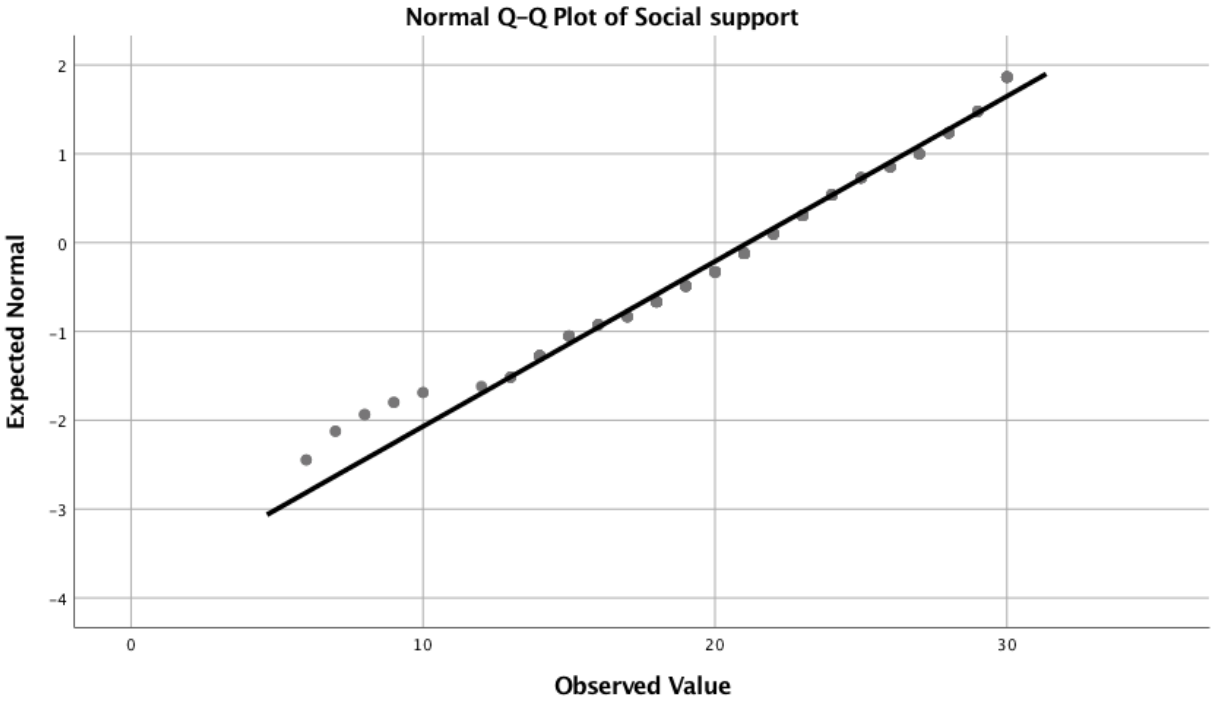

Normal Q-Q Plot of Diabetes knowledge
Expected Normal
Observed Value
2
0
-2
-4
0
2
4
6
8
10
12
14

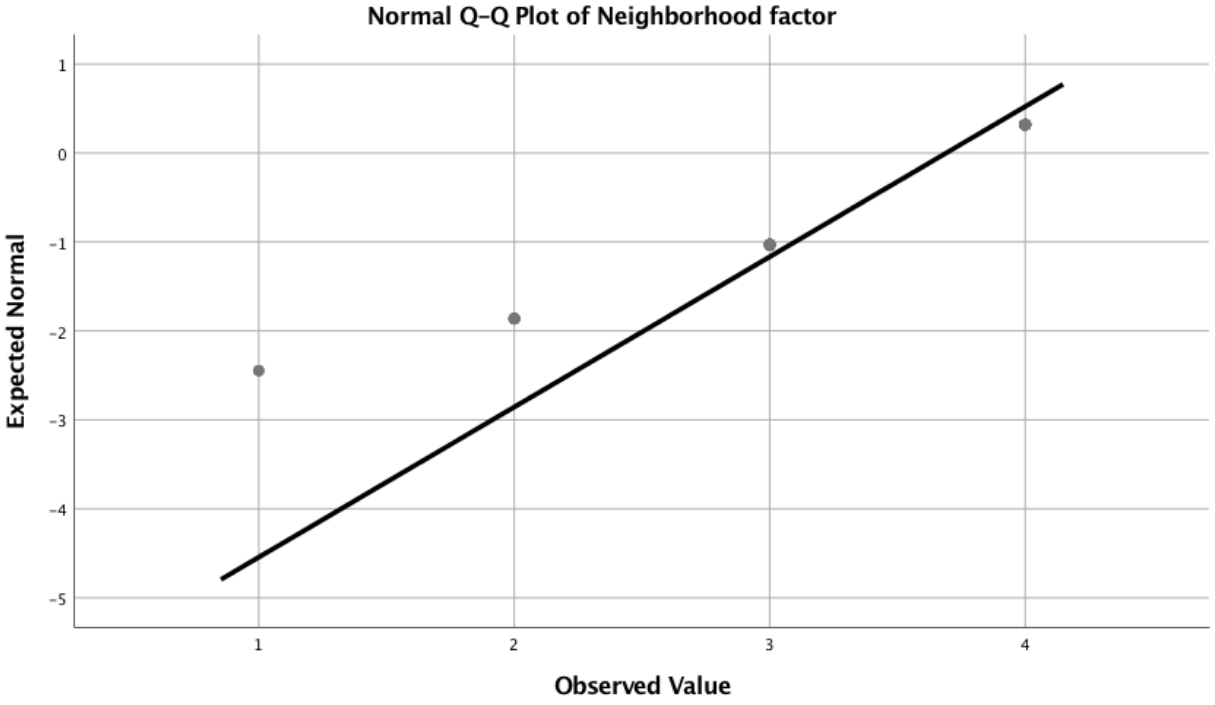

Normal Q-Q Plot of Health literacy
Expected Normal
Observed Value
2
1
0
-1
-2
0
2
4
6
8

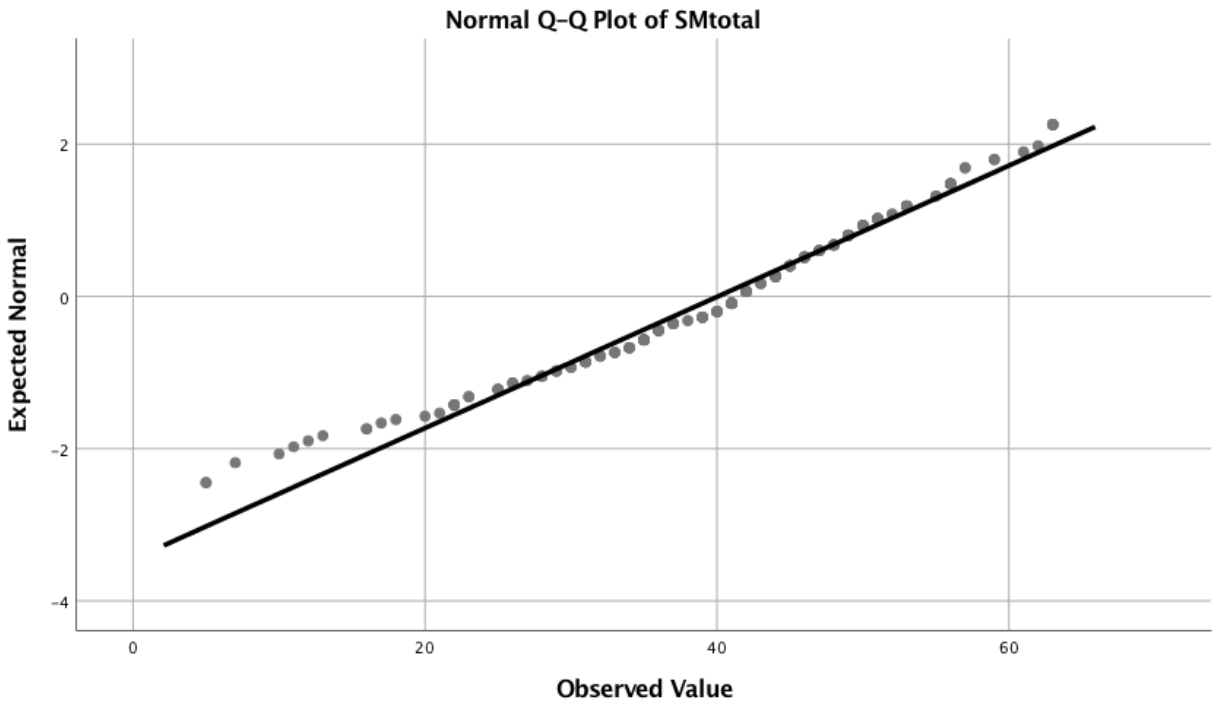

Normal Q-Q Plot of Self-efficacy
Expected Normal
Observed Value
2
0
-2
-4
10
15
20
25
30
35
40

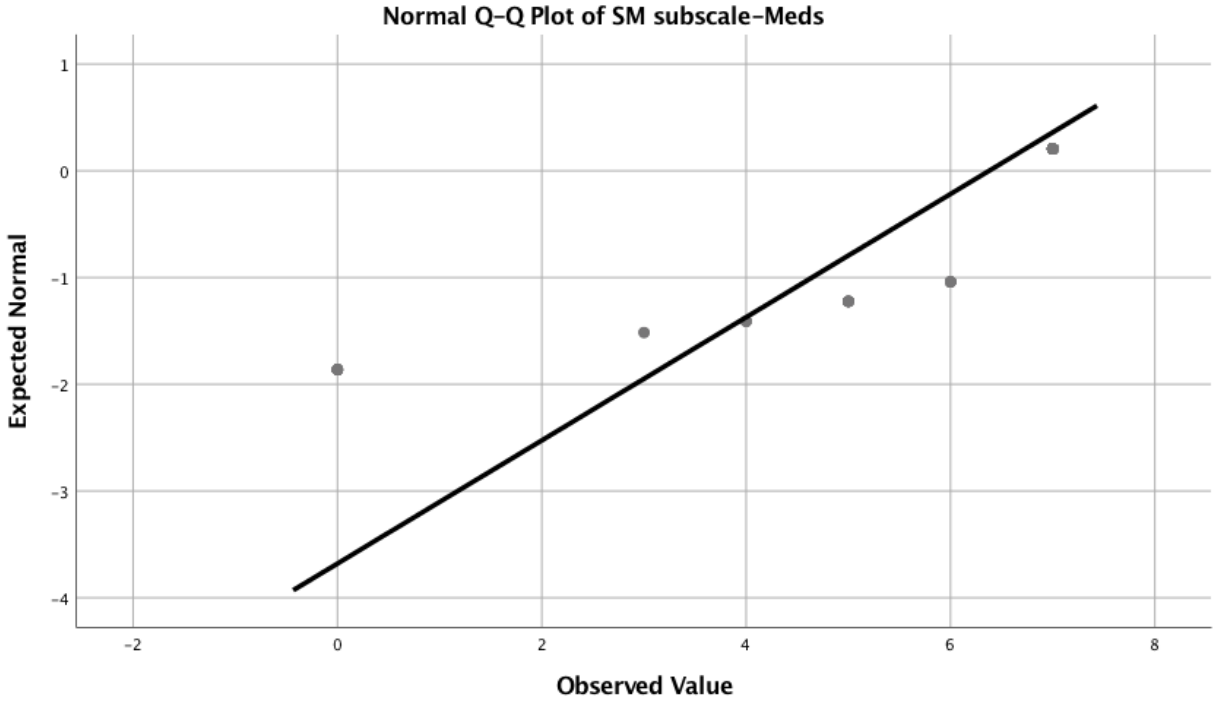

Normal Q-Q Plot of Depressive symptoms
Expected Normal
Observed Value
6
4
2
0
-2
-10
0
10
20
30
40
50

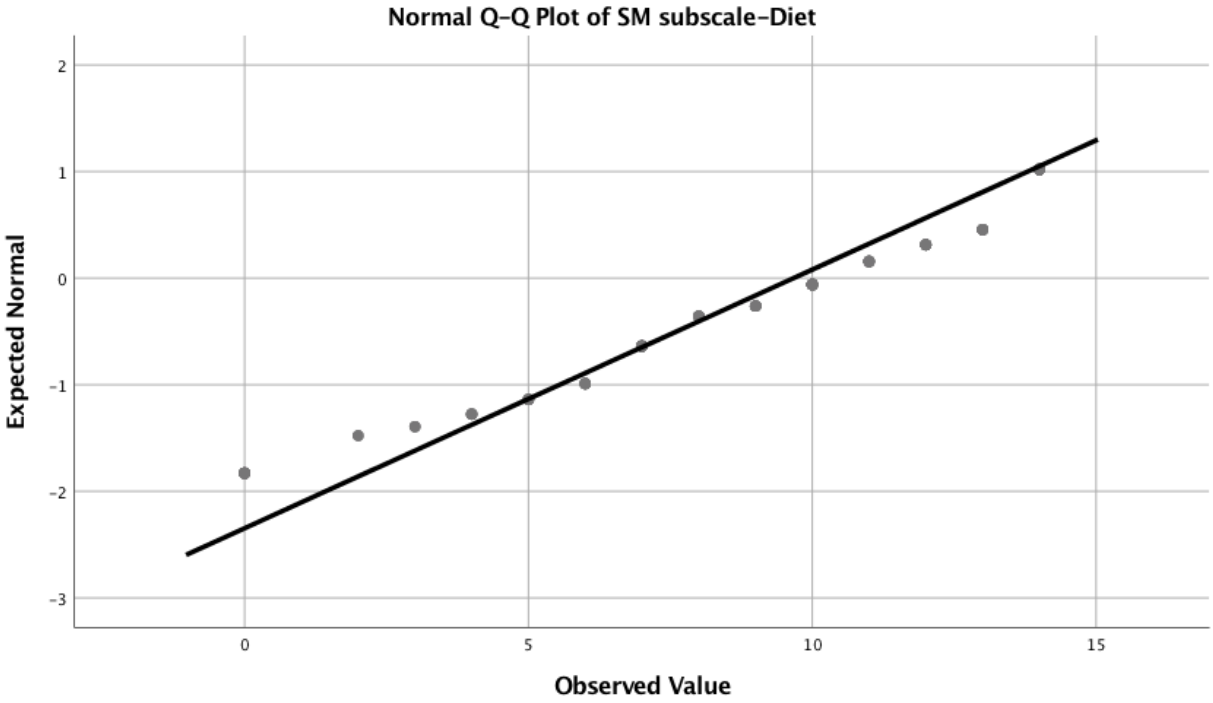

Normal Q-Q Plot of Problem-solving
Expected Normal
Observed Value
4
2
0
-2
-4
20
40
60
80
100
120
140

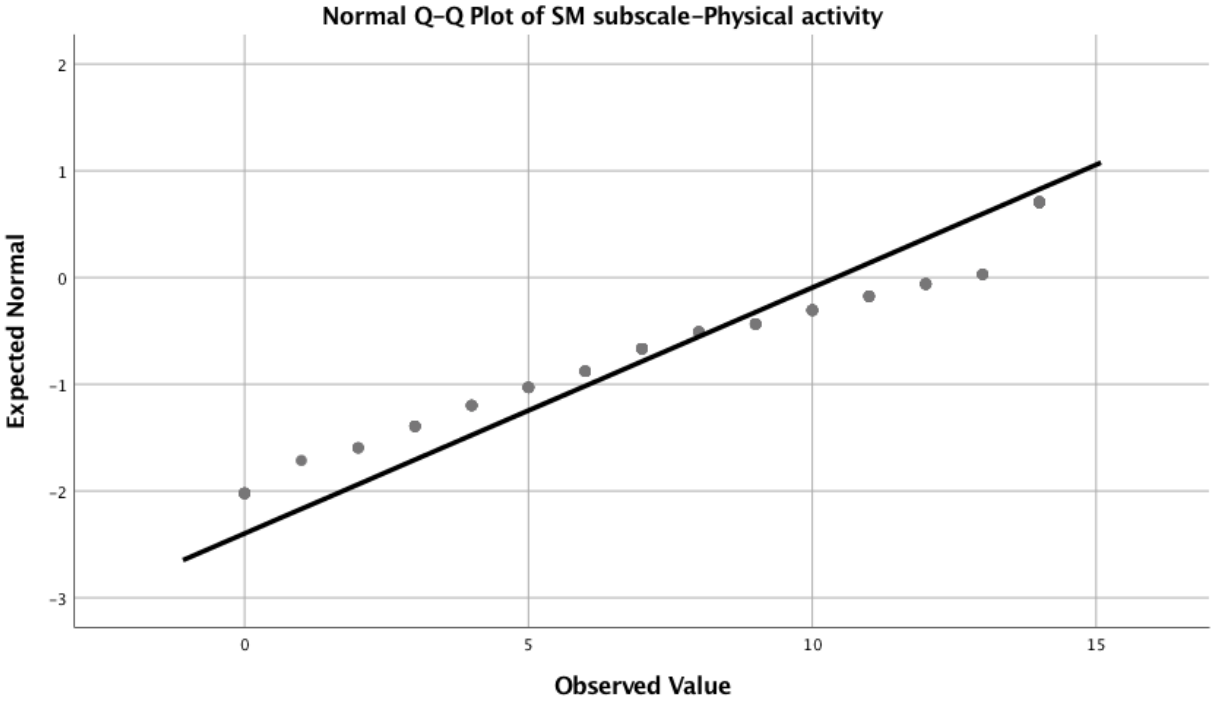

Normal Q-Q Plot of Social support
Expected Normal
Observed Value
2
1
0
-1
-2
-3
-4
0
10
20
30

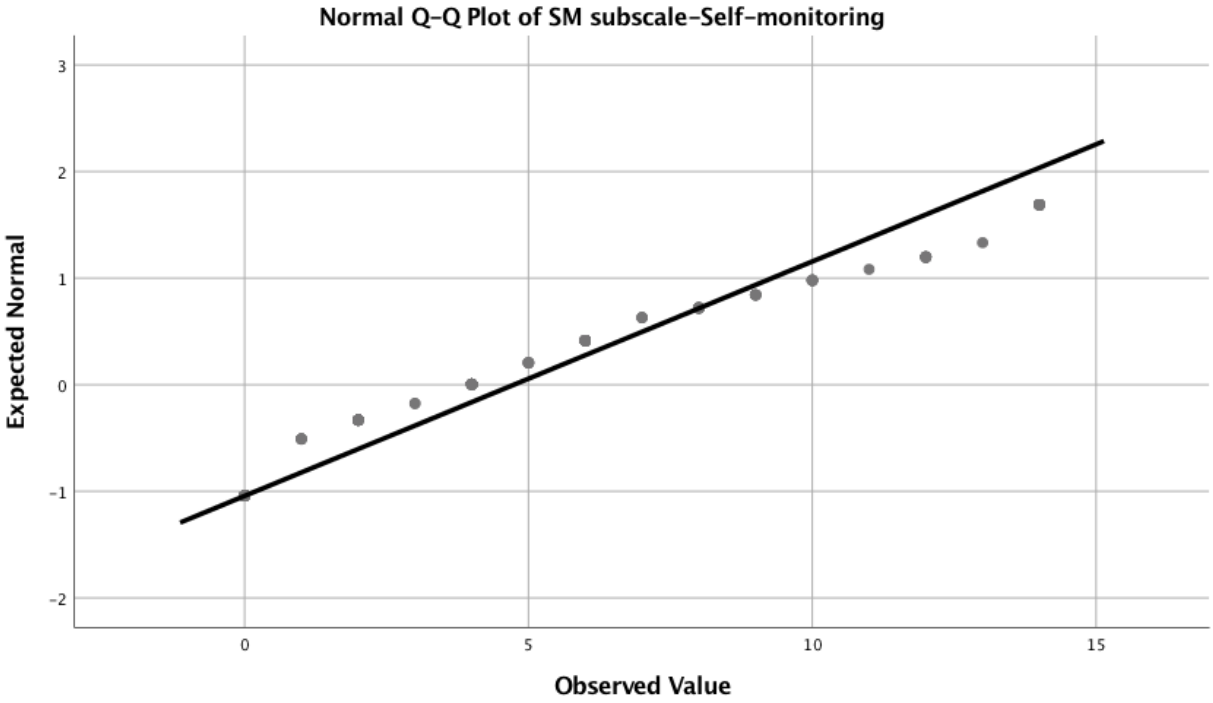

Normal Q-Q Plot of Neighborhood factor
Expected Normal
Observed Value
1
0
-1
-2
-3
-4
-5
1
2
3
4

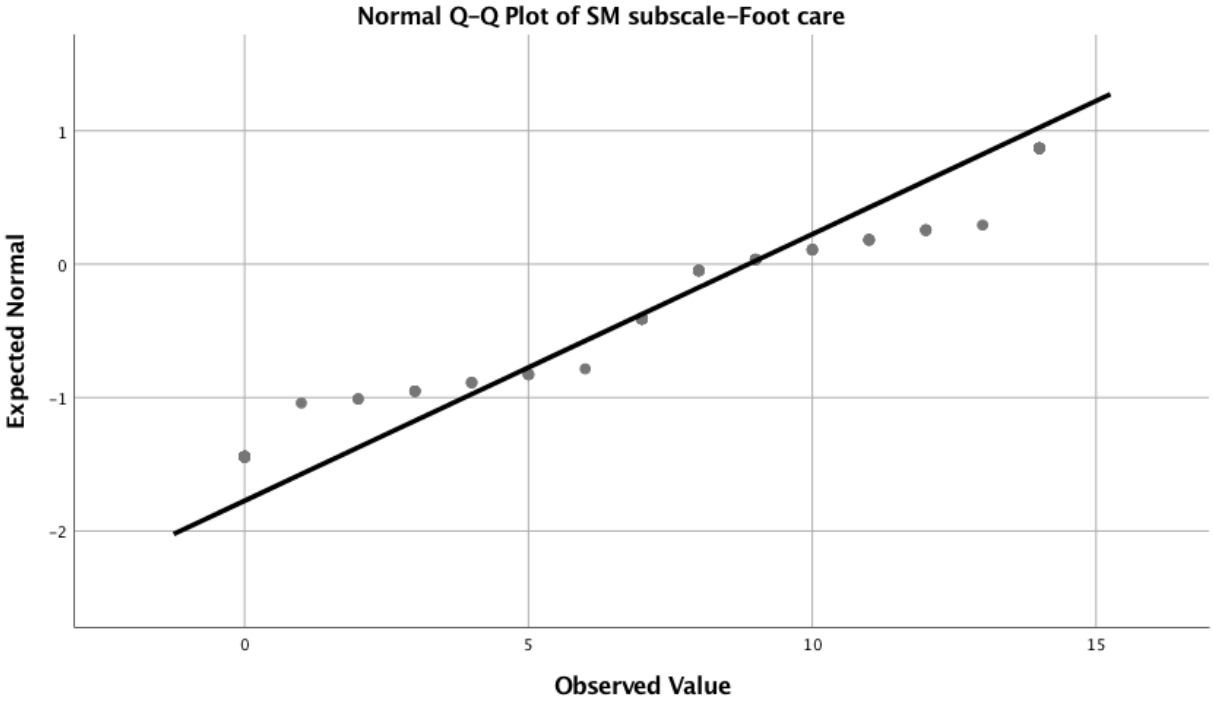

Normal Q-Q Plot of SMtotal
Expected Normal
Observed Value
2
0
-2
-4
0
20
40
60

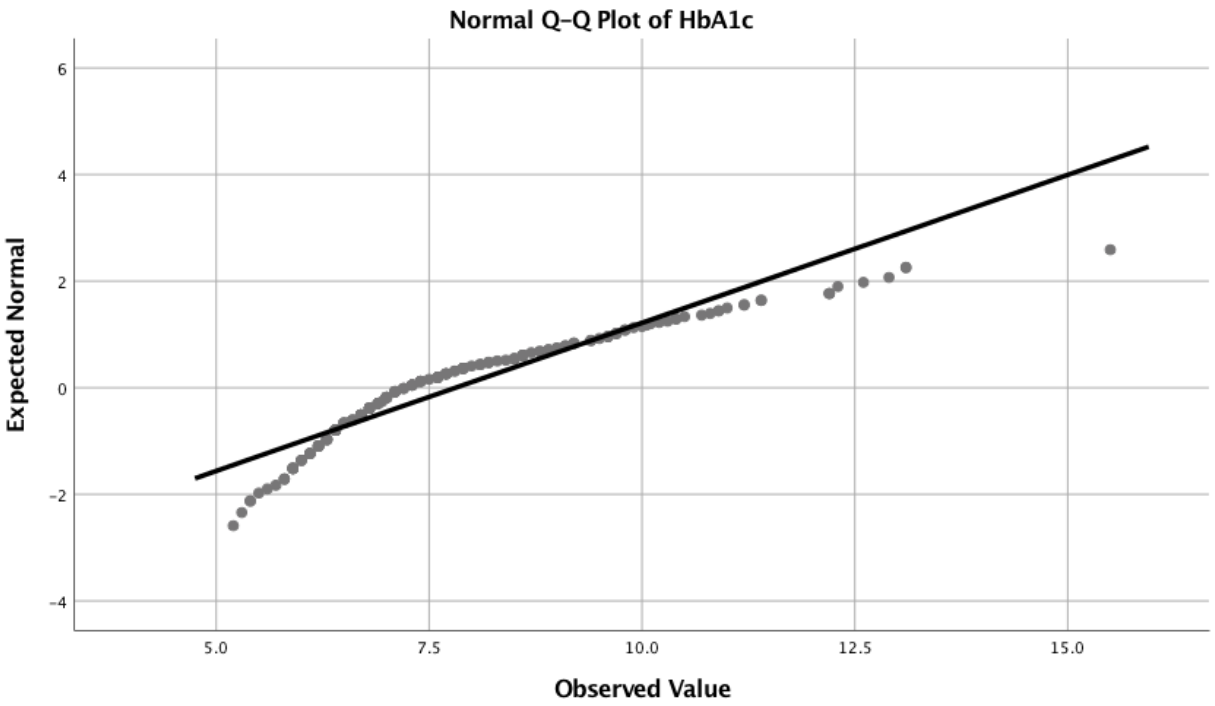

Normal Q-Q Plot of SM subscale-Meds
Expected Normal
Observed Value
1
0
-1
-2
-3
-4
-2
0
2
4
6
8

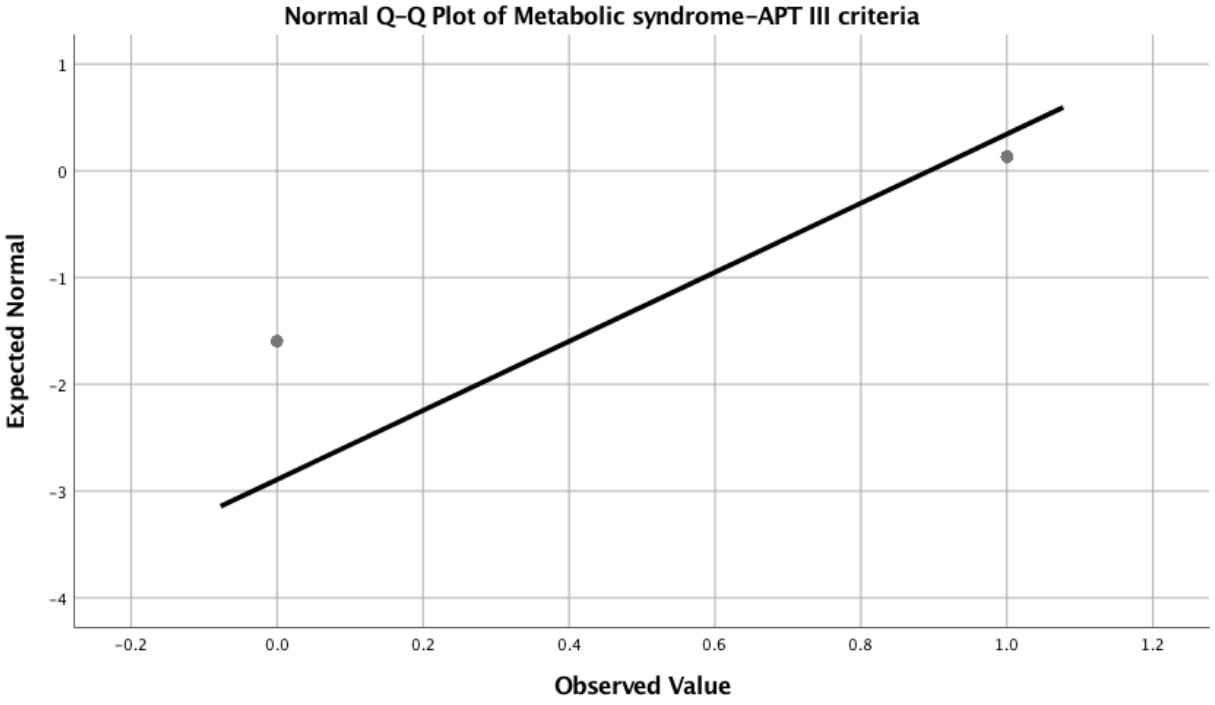

Normal Q-Q Plot of SM subscale-Diet
Expected Normal
Observed Value
2
1
0
-1
-2
-3
0
5
10
15


Normal Q-Q Plot of SM subscale-Physical activity
Expected Normal
Observed Value
2
1
0
-1
-2
-3
0
5
10
15


Normal Q-Q Plot of SM subscale-Self-monitoring
Expected Normal
Observed Value
3
2
1
0
-1
-2
0
5
10
15


Normal Q-Q Plot of SM subscale-Foot care
Expected Normal
Observed Value
1
0
-1
-2
0
5
10
15


Normal Q-Q Plot of HbA1c
Expected Normal
Observed Value
6
4
2
0
-2
-4
5.0
7.5
10.0
12.5
15.0


Normal Q-Q Plot of Metabolic syndrome-APT III criteria
Expected Normal
Observed Value
1
0
-1
-2
-3
-4
-0.2
0.0
0.2
0.4
0.6
0.8
1.0
1.2

D.2 CORRELATION MATRIX AMONG STUDY VARIABLES AND OUTCOME VARIABLES

This section was deleted from Manuscript 2 due to the number of tables and words limited by the Journal. However, the associations among study variables and outcome variables were also illustrated through regression analysis in Manuscript 2.

Through Pearson pairwise correlation analysis, the correlation matrix showed that all study variables were significantly related to the overall self-management behaviors with small to medium effect, except the level of problem solving and health literacy. Two variables were significantly correlated with HbA1c in this sample, with problem solving being positively related and the overall self-management behaviors being negatively related to glycemic control. Details of the correlations among study variables were displayed in Table 8.

Table 8. Correlation Matrix of Study Variables and Health Outcomes (N= 207)

Measures	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.	16.
1. Age	-															
2.Gender	**-0.25****	-														
3. Education	**-0.30****	**0.23****	-													
4. Duration	**0.45****	-0.07	-0.08	-												
5. #Meds	**0.36****	0.03	-0.12	**0.36****	-											
6. #Comorb	**0.30****	-0.03	-0.05	**0.24****	**0.69****	-										
7. DKN	-0.01	-0.01	**0.21****	0.10	0.12	-0.01	-									
8. NVS	**-0.20****	**0.18***	**0.28****	**-0.14***	-0.08	-0.05	**0.33****	-								
9. SE-Type2	**0.26****	0.06	0.04	**0.19****	**0.21****	0.07	**0.36****	**0.14***	-							
10. CES-D	**-0.16***	**-0.20****	0.04	-0.11	-0.03	0.14	-0.12	-0.06	**-0.35****	-						
11. PSI	0.11	**-0.25****	**-0.30****	0.11	0.09	0.12	**-0.29****	**-0.26****	**-0.27****	**0.19***	-					
12. CIRS-FFS	0.01	**0.20****	0.09	0.01	0.08	-0.06	**0.19****	0.06	**0.36****	**-0.19****	**-0.38****	-				
13. NF	**0.18****	-0.05	**-0.15***	0.08	**0.15***	-0.02	**0.27****	0.05	**0.33****	**-0.26****	-0.12	**0.26****	-			
14. SDSCA	**0.43****	-0.04	-0.05	**0.22****	**0.26****	0.08	**0.16****	-0.03	**0.59****	**-0.20****	-0.12	**0.30****	**0.29****	-		
15. HbA1c	-0.08	0.02	-0.11	**0.19****	0.03	0.06	-0.11	-0.10	-0.11	-0.05	**0.18***	-0.01	0.03	**-0.17***		
16. MetS	-0.01	-0.03	0.03	-0.02	0.13	**0.17***	-0.11	**-0.14***	-0.08	0.10	-0.02	-0.08	0.03	-0.13	0.12	-

$^{**}p<0.01$; $^{*}p<0.05$

Note: #Meds: Number of Medications; #Comorb: Number of Comorbidities; DKN: Diabetes Knowledge Scale; NVS: Newest Vital Sign; SE-Type 2: Self-Efficacy Scale for People with Type 2 Diabetes; PSI: Problem Solving

Inventory; CES-D: Center for Epidemiological Studies Depression Scale; NF: Neighborhood Factors; CIRS-FFS: Family and Friends Support subscale of the Chronic Illness Resources Survey; SDSCA: Summary of Diabetes Self Care Activities; MetS: Metabolic Syndrome.

D.3 UNIVARIATE ANALYSIS OF STUDY VARIABLES FOR HEALTH BEHAVIORS AND HEALTH OUTCOMES

Table 9. Summary of Univariate Analyses of Study Variables Related to Self-management Behaviors (n = 207)

Variable	SDSCA		Medication		Diet		Physical activity		Self-monitoring		Foot care	
	B	*p*	*B*	*p*	*B*	*p*	*B*	*p*	*B*	*p*	*B*	*p*
DKN	0.77	0.02	0.03	0.537	0.12	0.332	0.12	0.365	0.22	.097	0.28	0.058
NVS	-0.17	0.67	0.06	0.338	0.04	0.799	-0.03	0.831	-0.11	0.463	-0.11	0.494
SE-T2DM	**1.57**	**<0.001**	**0.09**	**0.001**	**0.56**	**<0.001**	**0.46**	**<0.001**	0.11	0.12	**0.35**	**<0.001**
CES-D	**-0.27**	**0.004**	-0.004	0.771	**-0.13**	**<0.001**	**-0.14**	**<0.001**	0.06	0.096	-0.06	0.12
PSI	-0.08	0.10	0.002	0.78	-0.04	0.049	-0.001	0.976	-0.02	0.251	-0.03	0.209
CIRS-FFS	**0.65**	**<0.001**	-0.02	0.49	**0.21**	**<0.001**	**0.14**	**0.011**	**0.14**	**0.015**	**0.17**	**0.008**
NF	**5.65**	**<0.001**	0.17	0.412	**1.48**	**0.002**	**1.68**	**0.001**	0.18	0.745	**2.15**	**<0.001**

Note: B: Unstandardized coefficient; DKN: Diabetes Knowledge Scale; NVS: Newest Vital Sign; SE-T2DM: Self-Efficacy Scale for People with Type 2 Diabetes; CES-D: Center for Epidemiological Studies Depression Scale ; PSI: Problem Solving Inventory; CIRS-FFS: Family and Friends Support subscale of the Chronic Illness Resources Survey; NF: Neighborhood Factors; SDSCA: Summary of Diabetes Self Care Activities; PA: Physical Activity.

Table 10. Univariate Regression of Study Variables for HbA1c and Metabolic Syndrome (n = 207)

	HbA1c		Metabolic Syndrome			
Variables	*B*	*p*	*OR*	*95% CI*		
				Lower	*Upper*	*p*
DKN	-0.09	0.109	0.84	0.67	1.05	0.118
NVS	-0.09	0.157	**0.82**	**0.67**	**1.00**	**0.051**
SE-T2DM	-0.05	0.114	0.93	0.83	1.05	0.232
CES-D	-0.01	0.454	1.06	0.98	1.15	0.155
PSI	**0.02**	**0.01**	1.00	0.97	1.02	0.799
CIRS-FFS	-0.004	0.875	0.95	0.87	1.04	0.258
NF	0.08	0.71	1.18	0.59	2.36	0.648
SDSCA	**-0.03**	**0.015**	**0.96**	**0.92**	**1.00**	**0.060**
Meds	-0.26	<0.001	1.07	0.85	1.34	0.578
Diet	**-0.10**	**0.001**	0.90	0.80	1.03	0.114
PA	-0.04	0.202	**0.86**	**0.75**	**0.99**	**0.041**
SMBG	0.01	0.846	0.98	0.89	1.07	0.632
Footcare	-0.19	0.453	0.95	0.87	1.05	0.328

Note: B: Unstandardized Coefficient; DKN: Diabetes Knowledge Scale; NVS: Newest Vital Sign; SE-T2DM: Self-Efficacy Scale for People with Type 2 Diabetes; CES-D: Center for Epidemiological Studies Depression Scale ; PSI: Problem Solving Inventory; CIRS-FFS: Family and Friends Support subscale of the Chronic Illness Resources Survey; NF: Neighborhood Factors; SDSCA: Summary of Diabetes Self Care Activities; PA: Physical Activity; SMBG: Self-Monitoring of Blood Glucose.

APPENDIX E SUPPLEMENT MATERIALS

This section includes all supporting materials necessary for the study.

E.1 CONSENT FORMS

E.1.1 Consent forms used in the study-English Version

University of Pittsburgh

School of Nursing

3500 Victoria Street
Pittsburgh, Pennsylvania 15261
Fax: 412-624-2401

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY
CROSS-SECTIONAL STUDY

TITLE: Diabetes Self-management and Health Outcomes among Chinese Patients with Type 2 Diabetes

PRINCIPAL INVESTIGATOR

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If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668. You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact Principal Investigator, Meihua Ji at 15210434269 or the Study coordinator Xiaojing Wang at 18911187786.

SOURCE OF SUPPORT:
This study is supported by the Margaret E. Wilkes Scholarship Fund from School of Nursing, University of Pittsburgh

CONFLICT OF INTEREST:
No conflict of interest needs to be disclosed among investigators.

Why is this research study being done?
The prevalence of diabetes in China is on the rise over the years, and diabetes has become a public health issue in China. Self-management and glycemic control of Chinese patients with type 2 diabetes are suboptimal. Based on the Social Cognitive Theory, this cross-section study is designed to assess the associated factors related to self-management and clinical health outcomes and their impact on related health behaviors and health outcomes.

Who is being asked to take part in this research study?
Patients who are diagnosed with type 2 diabetes and have hospital visits at the outpatient clinic at the Endocrinology center at Luhe Hospital in Beijing, China will be invited to participate in this study. Patients with type 2 diabetes accounts for more than 90% of those with diabetes, and it is a public issue in China. To be eligible for the study, participants must be: age ≥18 years; diagnosed with type 2 diabetes; duration of disease ≥ 6 months; able to read, write and speak Mandarin; have Chinese nationality. Those who have problems with hearing and vision; renal disease, severe physical and mental illness; pregnant women; currently enrolled in an interventional study will be excluded from the study.

What are the procedures that will be performed for research purposes?
If you are willing to participate in this research, you will be asked to complete:

- Measurement of **height, weight, waist circumference and blood pressure** using available equipment at the clinical center; identification of prescribed medications (self-reported or retrieved from medical record);
- 9 questionnaires in providing information related to your personal, behavioral and environmental factors as well as self-management behaviors will be administered during participant recruitment for the study (Investigator developed Sociodemographic and Disease Related Factors Form; Chinese Version of the Diabetes Knowledge Scale; Chinese Version of the Newest Vital Signs; Chinese Version of the Self-efficacy Scale for People Living with Type 2 Diabetes; Chinese version of Center for Epidemiological Studies Depression Scale; Chinese Version of the Problem Solving Inventory; Chinese Version of the Family and Friends Support Subscale of the Chronic Illness Resources Survey; Neighborhood Factors Form; Chinese Version of the Summary of Diabetes Self-Care Activities). The total number of page for the questionnaires is 17 pages (11 pages in Chinese) which may take up to 30 minutes to complete;
- Most recent values on **HbA1c, High & Low Density Lipoprotein, triglyceride and total cholesterol** will be obtained from your medical record.

What are the possible risks, side effects and discomforts of this research study?
This study has minimal risk to participants. A breach of confidentiality may be a concern. During the study, we will take actions to protect your personal information by not placing your identity on the questionnaires. All participants will be assigned a unique coded identifier for materials obtained, and a separate patient information document will include your name and patient ID in order to locate your health information from the medical record, this will be placed in a locked drawer in a locked office and only be available to the research team, and it will be stored separately from other documents, so it is unlikely that people other than those from our research team will link your information to your identity. People may feel tired in completing the questionnaires, we suggest participants to take breaks if they need.

What are the possible benefits from taking part in this study?
You will most likely receive no direct benefit from taking part in this study. Your participation will help us gain a better understanding of the personal, behavioral and environmental factors that could impact health behaviors and health outcomes among patients with type 2 diabetes, therefore inform future study to address these factors in designing interventions to improve health outcomes.

Who will know about my participation and have access to my identifiable information in this research study?
All obtained information from you will be kept as confidential as possible. A study ID will be assigned to you when answering the questionnaires, and study materials will be kept in a locked file cabinet without relating to your identity. Documents such as a list of study participants, consent forms, questionnaires will be kept in locked file cabinet or locked drawers separately from each other. Only research personnel in the study will have access to the documents. Documents that contain your name, such as your contact information and this consent form, will not be stored in the same cabinet as the questionnaires. Similarly, research data that are stored electronically will be coded with your study ID number in a password-protected database. Identifiable information will be stored in a separate password protected database. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies."

In unusual cases, your research records may be released in response to an order from a court of law. It is also possible that authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data for the purpose of monitoring the conduct of this study. The data may be shared with others but it will be shared without identifiers.

Will this research study involve the use or disclosure of my identifiable medical information?
Yes, this study will use your most recent values on blood pressure, HbA1c, High & Low Density Lipoprotein, triglyceride, total cholesterol and information on your medication and diagnosis retrieved from your medical record.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study. Your research records will be destroyed when such is approved by the sponsor of this study or, as per University policy, at 7 years following study completion, whichever should occur last.

Is my participation in this study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at the Endocrinology Center at Luhe Hospital, Beijing, China.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research for the use and disclosure of your identifiable information for the purposes described above. Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

After questionnaires has been collected, to formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. You also can simply not returning the questionnaires if you decided to withdraw from the current study when you have not returned the questionnaires.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at the Endocrinology Center at Luhe Hospital, Beijing, China.

Will I be paid if I take part in this research study?
You will receive $6 when you return the questionnaires to compensate your time spend for the study.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
You will not incur any expenses by participating in this cross-sectional study. The measurement for height, weight, waist circumference and blood pressure are taken at the center with no extra cost.

Note: By participation of this current study, we will potentially be contacting you for future studies that are related to diabetes management; it is up to you whether you will participate or not at that time in the future.

HIPPA AUTHORIZATION FORM

Who is requesting the PHI for research?
During our study, we are also requesting your authorization or permission to review your medical records.

Why is this information needed?
To determine whether you meet the conditions for participation in this study, and to use your earlier test result in evaluating your diabetes management.

What will be disclosed?
We will obtain the following information from your medical record: your diagnosis, current prescribed medications, blood pressure, HbA1c, High/Low Density Lipoprotein, triglyceride, and total cholesterol.

Will research data be placed in the medical record?
No.

How long will this information be made available to the researchers?

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Who (other than the investigators) will receive the PHI, and how will they use it?
Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the Food and Drug Administration, and the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study. Authorized representatives from Luhe Hospital or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside Luhe Hospital or the University.

How long will this authorization be valid?
This authorization is valid for an indefinite period of time. However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team. Subjects who do not sign this HIPPA authorization form cannot participate in the study

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date/Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date/Time

E.1.2 Consent forms used in the study-Chinese Version

University of Pittsburgh

School of Nursing

3500 Victoria Street
Pittsburgh, Pennsylvania 15261
Fax: 412-624-2401

课题参与知情同意书

题目：我国2型糖尿病患者自我管理及健康结局的相关因素研究

课题负责人：
季美华,博士在读, 美国注册护士，美国匹兹堡大学护理学院，地址：Victoria Building，匹兹堡, 宾州，美国；邮编：15261，电话: 15210434269 (中国)/1-412-265-8842(美国)；邮箱：mej61@pitt.edu

课题研究期间您如果有关于个人权利的相关问题可以随时拨打美国匹兹堡大学人类实验审查委员会电话1-866-212-2668。您也可以随时联系课题负责人季美华 （15210434269）或者王晓静（01069543901-6901）以澄清任何有关本课题研究的相关问题。

课题支持来源：
本课题经费由美国匹兹堡大学护理学院 Margaret E. Wilkes Scholarship 提供支持。

利益冲突:
主要课题负责人之间无任何利益冲突。

为什么做此项研究?
糖尿病的流行率在中国逐年增长，已成为公共卫生急需解决的健康问题，2型糖尿病患者的自我管理及血糖控制仍不乐观，需要进一步改善。基于社会认知理论，本研究旨在探索与健康行为及临床健康指标相关的各类因素，从而提高患者的自我管理及达到更好的临床结局。

谁可以参与本项研究?
所有就诊于北京市潞河医院内分泌科门诊并符合以下标准的2型糖尿病患者均被受邀参与此研究：年龄≥18周岁；诊断为2型糖尿病至少6个月以上；可以用中文听、说、读、写；并持有中国国籍。如果您有听力及视力受损、确诊的肾病、身体残障、精神疾病，孕妇或者目前正在参与其它自我管理干预性研究的患者将不能参与本研究。

有哪些与本课题相关的研究步骤?
如果您决定参与本项研究，您需要提供以下相关信息：

- 您的身高、体重、腰围及血压将由专业研究人员在门诊中心测量；您需要将目前正在服用的处方药罗列出来（或者由研究人员从医疗记录中获取）
- 您将回答9个相关的调查问卷以提供您的个人、行为及社会环境相关信息。问卷内容具体包括个人相关及健康历史、糖尿病知识、健康素养、自我效能、抑郁症状、家庭社会支持、居住环境、问题解决能力以及自我管理相关行为；问卷一共11页，可能需要大约30分钟时间完成。

University of Pittsburgh Institutional Review Board
Approval Date: November 8, 2017
Renewal Date: November 7, 2018
IRB #: PRO17080346

- 您的最近一次的糖化血红蛋白（HbA1c）、高密度和低密度血脂（HDL&LDL），甘油三脂以及总胆固醇的临床数据将从您的医疗记录里获取.

参与本研究可能具备的风险及负面影响？
参与本研究会有较小的风险。研究期间，您的个人信息可能会泄露，但几率很小。我们会尽一切可能保护您的个人隐私。所有参加本研究的每位患者将获得唯一的个人识别码，所有问卷将会匿名填写并标注唯一的识别码。我们会在单独的文件里记录您的姓名及相应的识别码以便查阅您的医疗记录。另外，所有材料将保存在上锁的办公室及上锁的材料柜里，并将保材料分开存放，只有参加本课题的研究人员可以查阅您的相关信息，其他无关人员将无权查阅。鉴于填写本问卷可能需要30分钟时间，我们建议您在填写期间适当休息。

参与本研究有什么既得利益？
通过参与本研究您可能不会直接受益，但您提供的信息可以帮助我们更好的了解2型糖尿病患者的个人、行为及社会环境因素对患者健康行为及健康结局的影响，从而在日后的临床干预中纳入相关内容以进一步改善患者的自我管理行为及各类健康指标。

研究期间，谁将有权限查阅患者的相关信息？
我们将尽最大可能保护好您的所有信息。在填写问卷时，每个患者将获得唯一的个人识别码。所有材料将保存在上锁的办公室及上锁的文件柜里，并分开存放，如您的知情同意书及患者名单。只有参与本课题的研究人员有权限查阅您的材料。与课题相关的数据也将存放在有密码保护的电脑及存储设备里。您的名字及个人识别信息将不被用于任何出版材料中，如有必要我们会向您获取相应的书面说明。在一些不常见的情况下，您的材料也可能会用于法律程序，以及接受来自美国匹兹堡大学研究行为办公室的工作人员的审阅以确保研究的合法性。您的资料在与其他人员分享时将不会提及您的个人身份信息。

如研究期间研究者发现有可能危及您或您至亲的身体健康，我们会按照法律的相关规定上报有关部门。

本课题是否需要患者提供相关的医疗信息？
是的，本课题需要通过查阅患者的医疗记录收集患者的相关临床数据，包括最近一次的糖化血红蛋白（HbA1c）、高密度和低密度血脂（HDL&LDL）、总胆固醇以及甘油三脂。另外，患者的身高、体重、腰围及血压将由专业研究人员在门诊中心测量。

涉及本研究的患者个人身份信息将被允许使用多久？
该课题研究人员可能在该课题结束后还将继续使用您的个人信息，根据匹兹堡大学的相关规定，所有与本课题相关的文字材料需要在该课题结束后保存5年，5年后将被销毁。

患者在本课题的参与是否自愿？
是的，您在本该课题的参与完全自愿（注：如果您没有提供允许研究人员使用您的个人相关信息的知情同意书，我们将无法将您纳入至本研究）。您是否提供知情同意书将不会影响您将来在北京市潞河医院内分泌中心的就诊，也不会影响将来与匹兹堡大学的关系。

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参与本研究的患者是否获得相应酬劳？
患者可以获得价值40元的购物卡或现金以感谢您对本研究的参与。

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患者将不会支付与本横断面研究所涉及的活动的任何费用（注：患者在内分泌中心就诊的相关费用仍由患者本人承担）。内分泌中心的专业人员将为您免费测量身高、体重、腰围及血压。

注：通过参与本课题，所有患者都有机会参与将来开展的与糖尿病管理相关的研究课题，到时我们会与您取得联系，届时是否参与研究将由您本人决定。

****

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研究期间，我们的研究团队成员将需要查阅您的医疗记录信息。

为什么需要您的相关信息？
明确您是否可以参与此次研究，并使用您的检查结果评估您的疾病管理情况。

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我们将从您的医疗记录中获取您的相关疾病诊断信息、用药、糖化血红蛋白、高/低密度脂肪、甘油三脂和总胆固醇。

研究数据是否保存到医疗记录中？
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我们将无限期使用您的医疗记录信息，但您可以在任何时间以书面形式通知研究者并要求终止使用您的医疗信息，一旦提交申请，您将自动退出本研究。在您正式提出退出之前的患者相关信息也可能还将继续用于本研究，您如果拒绝签署此授权书，也将不能参与本研究。

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有关本研究的所有相关信息已由研究负责人解释清楚，本人所有的与研究相关的问题也得以解答。我知道我也可以在试题进行期间随时提出与本研究相关的问题，研究人员需给予相应解答。

参与本研究期间，如有任何与个人权利相关的问题我将直接与美国匹兹堡大学人类研究伦理审查委员会联系（1-866-212-2668）。

通过在知情同意书上的签字署名，我同意参与本研究，本同意书一式两份，患者及试题负责人各持一份。

_____

患者签名　　年/月/日

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我声明已将所有有关本研究的研究属性及目的向该患者解释清楚，并讨论了有关的风险及利益。所有患者提出的问题已经得以解答，研究期间如有更多问题我也会随时解答。在此，我郑重声明任何与本研究相关的活动都没有在获取患者知情同意书之前进行。

_____

获取知情同意书人员姓名　　研究中的角色

_____

获取知情同意书人员签名　　年/月/日

E.2 INSTRUMENTS

E.2.1 Instruments used in the study-English Version

Note: Sociodemographic and health history and neighborhood factor forms was investigator-developed forms that were designed to meet the specific needs for the current study; all other questionnaires used in this study were originally available in English and have been translated to Chinese and tested for reliability and validity previously in a Chinese population (modifications were applied to adapt them to Chinese speaking population). Permission to use the instruments (PSI, SDSCA) has been acquired from authors (see attached), other instruments are identified in the public domain.

For Staff Use Only	
Participant ID#	**Administration Date**

Section A: Personal factors

I. Sociodemographic and health history form

Please enter or check the answer that best describes you:

a. Sociodemographic information:

1. Age: Birthdate:

   _____ years old _____

2. Sex:

   _____ Male

   _____Female

   _____Other (please specify) _____

3. What is your marital status?

   _____Never married

   _____Married/Partnered

   _____Separated/Divorced

   _____Widowed

4. How many years of education have you had? _____Years

5. What is your highest level of education?

   _____Primary school

   _____Middle school

   _____High school graduate

   _____Some college or technical school

   _____College graduate (bachelor's degree)

   _____Graduate degree

6. Employment status:

   _____Full time

_____Part time

_____Unemployed

_____Retired

_____Other (please indicate) _____

7. With whom do you live?

_____ Alone

_____ With parents

_____ With spouse and children

_____ With parents, spouse, and children

_____ With children

_____ Others (please indicate) _____

8. How many people currently live in your household?

_____

9. Where do you live?

Please enter your **Zip Code/District** _____

10. How long do you take to get to the clinic?

_____Hours _____Minutes

11. Which of the following categories best describes your family's monthly income from all sources?

_____ Less than 3,000 Yuan

_____3,001 Yuan to 4,999 Yuan

_____5,000 Yuan to 7,999 Yuan

_____8,000 Yuan or above

12. What is the source of your health insurance? (you can select one or more from the following)?

_____Health Plan supported by the government

_____Through an employer – the employer pays all or part of medical expenses

_____Private Medical Insurance

_____No insurance and needs to pay out of pocket

_____Other (Please indicate) _____

b. Health History (Could also be retrieved from the Medical Record such as medications):

1. Height _____

   Weight _____

   Waist circumference _____

2. When were you diagnosed with type 2 diabetes?

   Year _____ Month_____

3. Current prescribed medications (please list below):

   _____

   _____

   _____

   _____

4. Do you smoke?

   _____Yes If yes, how many packs/day? _____

   _____No

5. Do you drink alcohol?

   _____Yes, If yes, on average, how many glasses of wine/liquor per day? _____

   How many bottles of beer per day? _____

   _____No

6. What other condition do you have? (please list below)

   _____

   _____

   _____

   _____

II. Diabetes Knowledge:

Modified Diabetes Knowledge Scale – Multiple choice questions

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*. Ed. New York: Psychology Press; 2003:159-189.

There is only one correct answer for each question. If you know the answer, circle the letter in front of it. If you don't know the answer, circle the letter in front of **"I don't know".**

1. The usual cause of type 2 diabetes is:

    a) Eating too much sugar and other sweet foods
    b) Lack effective insulin in the body
    c) Failure of the kidneys to control sugar in the urine
    d) I don't know

2. In untreated diabetes the blood sugar is usually:

    a) Normal
    b) Increased
    c) Decreased
    d) I don't know

3. The NORMAL range for blood glucose is

    a) 2.8 mmol/l
    b) 6.1 mmol/l
    c) 7.0 mmol/l
    d) I don't know

4. Which of the following health problems is usually NOT complication of diabetes

    a) Kidney disease
    b) Eye problems
    c) Lung problems
    d) All the above
    e) I don't know

5. Which of the following is true?

a) It does not matter if my diabetes is not fully controlled, as long as I do not have a coma

b) It is best to show some sugar in the urine in order to avoid hypoglycemia

c) Poor control of diabetes could result in a greater chance of complications later

d) I don't know

6. The key to the control of diabetes is:

a) The balance between regular amounts of insulin/tablets, food and exercise

b) The maintenance of a low level of sugar in the urine in order to prevent hypoglycemia

c) A high-protein, high fiber diet

d) I don't know

7. People with diabetes should:

a) Have their food cooked separately from that of the family

b) Eat the same foods as the same time each day

c) Vary their diet by substituting different foods correctly from the diet exchange list

d) I don't know

8. In general, fit patients with diabetes should exercise for

a) 1 hour once a week

b) 20 to 30 minutes 3 to 5 times a week

c) 1 hour every day

d) I don't know

9. The general effect of exercise is to:

a) Lower the blood sugar level

b) Raise the blood sugar level

c) Increase sugar in the urine

d) I don't know

10. Rice is mainly:

a) Protein

b) Carbohydrate

c) Fat

d) I don't know

11. You can eat as much as you like of which of the following foods:

a) Apple

b) Celery

c) Meat

d) I don't know

12. Self-monitoring of blood glucose is:

a) The key to determining the right amount of medication

b) Important to see the effect of diabetes control such as diet and exercise

c) Both a and b

d) I don't know

13. People with diabetes should take good care of their feet because:

a) After a long period of time, injecting insulin into the legs may cause swelling of the feet

b) Flat feet are commonly associated with diabetes

c) Older people with diabetes may have poor circulation of the blood in this area

d) I don't know

14. The action of diabetes pills:

a) Lower blood sugar

b) Increase insulin secretion

c) Increase insulin sensitivity

d) All above

e) I don't know

III. Health Literacy:

The Newest Vital Signs- 6 items

Weiss, B. D., Mays, M. Z., Martz, W., Castro, K. M., DeWalt, D. A., Pgnone, M. P., & Hale, F. A. (2005). Quick assessment of literacy in primary care : The Newest Vital Sign. *Annals of Family Medicine*, *3*(6), 514–522. http://doi.org/10.1370/afm.405.

Read the following to participants: this information is on the back of a container of a pint of ice cream.

Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Items	Answer
1. If you eat the entire container, how many calories will you eat?	
2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?	

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?		
4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?		
READ TO SUBJECT: Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.		
5. Is it safe for you to eat this ice cream? (please check the corresponding box)	Yes	No
6. (Ask only if the patient responds "no" to question 5): Why not?		

For staff use: **Score on Health Literacy**						
Item	1	2	3	4	5	6
Correct						
Wrong						
Total Score						

Section B: Behavioral Factors

IV. Self-Efficacy:

Modified Self-Efficacy Scale for People Living with Type 2 Diabetes – 5-point Likert scale

Van der Bijl J, van Poelgeest-eeltink A, Shortridge-baggett L. The psychometric properties of the diabetes management self-efficacy scale for patients with type 2 diabetes mellitus. *J Adv Nurs*. 1999;30(2):352-359.

Please answer each question by checking the answer that best describes how you feel:

Items	**Definitely no**	**Probably no**	**Maybe Yes Maybe No**	**Probably yes**	**Definitely yes**
1. I think I am able to check my blood glucose.	1	2	3	4	5
2. I think I am able to follow my diabetic diet most of the time.	1	2	3	4	5
3. I think I am able to follow my diabetic diet when I dine out.	1	2	3	4	5
4. I think I am able to examine my feet for lesion.	1	2	3	4	5
5. I think I am able to get sufficient physical activities.	1	2	3	4	5
6. I think I am able to take extra exercise, when the doctor advises me to do so.	1	2	3	4	5
7. I think I am able to take medicine or inject the insulin as prescribed.	1	2	3	4	5

V. Depressive Symptoms:

Center for Epidemiological Studies Depression Scale - 4-point Likert scale

Radloff LS. The CES-D scale : A self-report depression scale for research in the general population. *Appl Psychol Meas*. 1977;1(3):3850401.

Instructions: Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt (less than 1 day; 1-2 days; 3-4days; 5-7days) this way during the past week.

Items	Less than 1 day	1-2 days	3-4 days	5-7 days
1. I was bothered by things that usually don't bother me.	0	1	2	3
2. I did not feel like eating; my appetite was poor.	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends.	0	1	2	3
4. I felt I was just as good as other people.	0	1	2	3
5. I had trouble keeping my mind on what I was doing.	0	1	2	3
6. I felt depressed.	0	1	2	3
7. I felt that everything I did was an effort.	0	1	2	3
8. I felt hopeful about the future.	0	1	2	3
9. I thought my life had been a failure.	0	1	2	3
10. I felt fearful.	0	1	2	3
11. My sleep was restless.	0	1	2	3
12. I was happy.	0	1	2	3
13. I talked less than usual.	0	1	2	3
14. I felt lonely.	0	1	2	3
15. People were unfriendly.	0	1	2	3
16. I enjoyed life.	0	1	2	3
17. I had crying spells.	0	1	2	3
18. I felt sad.	0	1	2	3
19. I felt that people disliked me.	0	1	2	3
20. I could not get "going."	0	1	2	3

VI. Problem Solving:
Problem Solving Inventory- 6-point Likert Scale

Heppner PP, Petersen CH. The development and implications of a personal problem-solving inventory. *J Couns Psychol*. 1982;29(1):66-75. doi:10.1037/0022-0167.29.1.66.

Read each statement and indicate the extent to which you agree or disagree with that statement, using the scale provided.

1	2	3	4	5	6
Strongly agree	**Moderately agree**	**Slightly Agree**	**Slightly disagree**	**Moderately disagree**	**Strongly disagree**

Mark your responses by check the number to the right of each statement.

Items	Scoring					
1. When a solution to a problem has failed, I do not examine why it didn't work	1	2	3	4	5	6
2. When I am confronted with a complex problem, I don't take the time to develop a strategy for collecting information that will help define the nature of the problem	1	2	3	4	5	6
3. When my first efforts to solve a problem fail, I become uneasy about my ability to handle the situation	1	2	3	4	5	6
4. After I solve a problem, I do not analyze what went right and what went wrong	1	2	3	4	5	6
5. I am usually able to think up creative and effective alternatives to solve a problem.	1	2	3	4	5	6
6. After I have tried to solve a problem with a certain course of action, I take time and compare the actual outcome to what I think should have happened.	1	2	3	4	5	6

Items	Scoring					
7. When I have a problem, I think up as many possible ways to handle it as I can until I can`t come up with any more ideas.	1	2	3	4	5	6
8. When confronted with a problem, I consistently examine my feelings to find out what is going on in a problem situation.	1	2	3	4	5	6
9. When I am confused with a problem, I do not try to define vague ideas or feelings into concrete or specific terms.	1	2	3	4	5	6
10. I have the ability to solve most problems even though initially no solution is immediately apparent.	1	2	3	4	5	6
11. Many problems I face are too complex for me to solve.	1	2	3	4	5	6
12. I make decisions and am happy with them later.	1	2	3	4	5	6
13. When confronted with a problem, I tend to do the first thing that I can think of to solve it.	1	2	3	4	5	6
14. Sometimes I do not stop and take time to deal with my problems, but just kind of muddle ahead.	1	2	3	4	5	6
15. When deciding on an idea or possible solution to a problem, I do not take time to consider the chances of each alternative being successful.	1	2	3	4	5	6
16. When confronted with a problem, I stop and think about it before deciding on a next step.	1	2	3	4	5	6
17. I generally go with the first good idea that comes into my mind.	1	2	3	4	5	6

Items	Scoring					
18. When making a decision, I weigh the consequences of each alternative and compare them against eachother.	1	2	3	4	5	6
19. When I make plans to solve a problem, I am almost certain that I can make them work.	1	2	3	4	5	6
20. I try to predict the overall result of carrying out a particular course of action.	1	2	3	4	5	6
21. When I try to think up possible solutions to a problem, I do not come up with very many alternatives.	1	2	3	4	5	6
22. In trying to solve a problem, one strategy I often use is to think of past problems that have been similar.	1	2	3	4	5	6
23. Given enough time and effort, I believe I can solve most problems that confront me.	1	2	3	4	5	6
24. When faced with a novel situation, I have confidence that I can handle problems that may arise.	1	2	3	4	5	6
25. Even though I work on a problem, sometimes I feel like I am groping or wandering and am not getting down to the real issue.	1	2	3	4	5	6
26. I make snap judgments and later regret them.	1	2	3	4	5	6
27. I trust my ability to solve new and difficult problems.	1	2	3	4	5	6
28. I have a systematic method for comparing alternatives and making decisions.	1	2	3	4	5	6

Items	Scoring					
29. When I try to think of ways of handling a problem, I do not try to combine different ideas together.	1	2	3	4	5	6
30. When confronted with a problem, I don`t usually examine what sort of external things in my environment may be contributing to my problem.	1	2	3	4	5	6
31. When I am confronted with a problem, one of the first things I do is survey the situation and consider all of the relevant pieces of information.	1	2	3	4	5	6
32. Sometimes I get so charged up emotionally that I am unable to consider many ways of dealing with my problem.	1	2	3	4	5	6
33. After making a decision, the outcome I expected usually matches the actual outcome.	1	2	3	4	5	6
34. When confronted with a problem, I am unsure of whether I can handle the situation.	1	2	3	4	5	6
35. When I become aware of a problem, one of the first things I do is to try to find out exactly what the problem is.	1	2	3	4	5	6

Section C: Environmental Factors

VII. Social Support:

Family and Friends Support Subscale of the Chronic Illness Resources Survey-5-point Likert scale

Glasgow RE, Strycker LA, Toobert DJ, Eakin E. A social – ecologic approach to assessing support for disease self-management : The chronic illness resources survey. *J Behav Med*. 2000;23(6):559-583.

Please answer each question by checking the answer that best indicates your experience over the past 3 months

Items	Never	Rarely	Sometimes	Often	Always
1. How often did your family listen carefully to what you have to say about your diabetes ?	1	2	3	4	5
2. How often did your family encourage you to participate in exercise?	1	2	3	4	5
3. How often did your family buy food or cook food for you that was especially recommended for your diabetes?	1	2	3	4	5
4. How often did your family select food choices required by diabetic diet when you ate with them?	1	2	3	4	5
5. How often did your family praise you for sticking to following diabetic diet, exercising, and self-monitoring blood/urine glucose?	1	2	3	4	5
6. How often did your family help you remember to take your oral medicine or inject insulin?	1	2	3	4	5

VIII. Neighborhood Factors

Do you perceive your neighborhood as a safe place to live? **Yes** _____ **No** _____

Are there any space /resources available for physical exercise? **Yes** _____**No** _____

If **yes**, please indicate (multiple answers):

_____ Parks

_____Gym

_____Walkways

_____others (Please indicate) _____

For staff use:
Total score:

_____

Are there any places you can go and buy healthy food? **Yes** _____**No** _____

How long have you been living in your current address? _____**Years** _____**Months**

Section D: Health Behaviors

IX. Self-management Behaviors

Modified Summary of Diabetes Self-Care Activities- 8-point Likert scale

Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care*. 2000;23(7):943-950

Please check the number on the right that best describes your situation:

Medications	Number of Days							
1. On average, over the past Seven days, how many DAYS have you taken your oral medication as prescribed	0	1	2	3	4	5	6	7
2. On how many of the last SEVEN DAYS have you taken your insulin as prescribed ?	0	1	2	3	4	5	6	7
Diet								
3. How many of the last SEVEN DAYS have you followed a healthful eating plan?	0	1	2	3	4	5	6	7
4. How many of the last SEVEN DAYS have you eat your meal at the same time (within 30minutes)?	0	1	2	3	4	5	6	7
Physical Activity								
5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity *(Total minutes of continuous activity, including walking).*	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
Blood Sugar Testing								
7. On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
8. On how many of the last SEVENDAYS did you test your blood sugar the number of times recommended								

by your health-care provider? 0 1 2 3 4 5 6 7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet? 0 1 2 3 4 5 6 7

10. On how many of the last SEVEN DAYS did you dry you toes after washing? 0 1 2 3 4 5 6 7

Section E: Health Outcomes

Lab values (Retrieved from the Medical Record)

Lab	**Values**
Blood Pressure (systolic/diastolic): Assessed at enrollment	
Body Mass Index (BMI)-Calculated from height weight	
HbA1c (%)	
HDL-High Density Lipoprotein (mmol/L)	
LDL-Low Density Lipoprotein (mmol/L)	
Triglyceride (mmol/L)	

This is a subsection (level-3 division) of appendix A.

E.2.2 Instruments used in the study-Chinese Version

感谢您参与该研究，请根据您的实际情况如实填写以下信息；本问卷共 11 页（9 个问卷），请您完整的回答该问卷的所有问题，谢谢！

我国 2 型糖尿病患者自我管理及健康结局的相关因素问卷调查	
参与研究者编号 # 2 0 1 7 - □□□	**问 卷 填 写 时 间 （ 年 / 月 / 日 ）** □□□□年□□月□□日

一、 个人信息及健康历史

请在相应空白处填写或勾选与您相关的信息：

A. 个人信息

1. **年龄** _____（岁）

2. **性别：** ⑴男 ⑵女

3. **婚姻状况**

❑ 未婚 ❑ 已婚 ❑ 离异 ❑ 丧偶

4. **您接受过多少年的正规教育？** _____（年）

5. **教育情况** （请填写您的最高学历）

❑ 小学 ❑ 初中 ❑ 高中

❑ 大学（含专科、本科） ❑ 研究生

6. **现工作状况**

❑ 全职 ❑ 兼职 ❑ 失业 ❑ 退休

❑ 其他 (请描述)_____

7. 您目前与谁一起居住?

❑ 独居 ❑ 父母、配偶及子女 ❑ 父母及配偶 ❑ 配偶及子女

❑ 配偶 ❑ 父母 ❑ 其他 (请详述)_____

8. 一共有几个家庭成员现在和您一起居住（请包括您自己）？_____（人）

9. 您现居住地址的邮政编码和所属市/县：

邮政编码_____ 所属市/县_____

10. 您到潞河医院就医一般需要多长时间？_____小时_____分钟

请指出您的居住地与潞河医院的大约路程：_____公里

请备注您到潞河医院就医的出行方式：

❑ 步行 ❑ 公交 ❑ 私家车/出租车 ❑其他 (请详述)_____

11. 您的家庭月收入情况（含全部收入）：

❑ 低于 3000 元 /月 ❑ 3000-4999 元/月

❑ 5000-7999 元/月 ❑ 8000 元及以上 /月

12. 请指出您的医疗保险信息（可多选）：

❑ 社会医疗保险 ❑ 公费医疗 ❑ 个人医疗保险 ❑ 无医疗保险（自费）

❑ 其他 (请详述)_____

B. 健康历史

1. **身高：**_____（厘米）；**体重：**_____（千克/公斤）
腰围：_____（厘米）

2. 您什么时候被诊断为糖尿病？

_____年 _____月

3. 请列出您目前使用的所有处方药：

_____

_____

4. 过去 30 天内您是否吸烟？

❑ 是　如您吸烟请指出您平均每天吸几支烟？_____（支）/天

❑ 否

5. 过去 30 天内您是否喝酒？

❑ 是　如您喝酒请指出您平均每天喝多少：

您平均每周喝几次？_____（次）/周

白酒/红酒：_____（两）或_____（杯）/天

啤酒：_____(瓶)/天

❑ 否

6. **请列出您所有的其他疾病：**

_____

_____

二、 糖尿病知识量表 （DKN）

请在您认为正确的选项前打“√”，每个问题只选一个正确答案．如果您不知道答案，请勾选“我不知道”选项．

1. 2 型糖尿病通常的病因是：

a) 身体不能很好地利用胰岛素
b) 身体根本不产生胰岛素
c) 身体排斥胰岛素
d) 我不知道

2. 没有经过治疗的糖尿病，血糖将会：

a) 正常
b) 升高
c) 降低
d) 我不知道

3. 正常的空腹血糖应低于：

a) 2.8 mmol/l
b) 6.1 mmol/l
c) 7.0 mmol/l
d) 我不知道

4. 糖尿病并发症包括：

a) 肾脏疾病
b) 眼部疾病
c) 足部疾病
d) 以上都是
e) 我不知道

5. 以下哪句话是正确的：

a) 只要没有糖尿病昏迷，糖尿病是否被完全控制并不重要
b) 最好是让尿中显示有糖，以避免低血糖发生
c) 若糖尿病不能很好地控制，糖尿病并发症会有较高的发生机会
d) 我不知道

6. 控制糖尿病的关键是：

a) 规律定量地用药、饮食、及体育锻炼之间达到平衡
b) 保持一个低的尿糖水平以避免低血糖
c) 高蛋白高纤维饮食
d) 我不知道

7. 糖尿病患者应该：

a) 将自己的食物与家里的食物分开烹饪
b) 每天在同一时间吃同样的食物
c) 根据食品交换表，正确地选择不同的替代食物以变化饮食
d) 我不知道

8. 通常来说，体形适当的糖尿病病人应该锻炼：
a) 每星期一个小时
b) 每星期 3 至 5 次，每次 20 至 30 分钟
c) 每天一个小时
d) 我不知道
9. 体育锻炼的效果通常是：
a) 降低血糖水平
b) 升高血糖水平
c) 升高尿糖水平
d) 我不知道
10. 米饭主要是：
a) 蛋白质
b) 碳水化合物
c) 脂肪
d) 我不知道
11. 以下食物中，您可以不限量吃的是：
a) 苹果
b) 芹菜
c) 肉类
d) 我不知道
12. 自己检查血糖的目的是：
a) 判断用药量是否正确的关键
b) 观测糖尿病控制的效果如何
c) 以上两条都对
d) 我不知道
13. 糖尿病患者应该照顾好自己的脚的原因是：
a) 长期地在腿上进行胰岛素注射会导致脚的肿胀
b) 糖尿病患者常会并发平足
c) 患糖尿病的中老年患者的脚部的血液循环可能会不好
d) 我不知道

14. 治疗糖尿病的口服药的作用是：

a) 降低血糖
b) 增加胰岛素的分泌
c) 增加胰岛素敏感性
d) 以上三个都可以
e) 我不知道

三、 自我效能量表 （SE-T2DM）

请根据您的实际情况在相应的空白处打“√”

问卷条目	肯定不行	可能不行	不确定	可能可以	肯定可以
1. 您觉得您能够自己检查血糖吗？	1	2	3	4	5
2. 您觉得您能够在大部分的时候按照糖尿病饮食要求吃饭吗？	1	2	3	4	5
3. 您觉得您能够在和家人或朋友聚餐的时候按照糖尿病饮食要求吃饭吗？	1	2	3	4	5
4. 您觉得您能够自己检查脚上是否有伤口吗？	1	2	3	4	5
5. 您觉得您能够进行充分的体育锻炼吗？比如每星期锻炼 4 到 5 次，每次约 30 分钟	1	2	3	4	5
6. 如果医生建议您进行额外的体育锻炼，您觉得您可以做到吗？	1	2	3	4	5
7. 您觉得您能够按照处方服用降糖药或注射胰岛素吗？	1	2	3	4	5

四、 问题解决能力量表 (PSI)

请按照如下指示回答下列问题：

1	2	3	4	5	6
非常同意	同意	稍微同意	稍微不同意	不同意	非常不同意

问卷条目						
1. 当解决一个问题的方法失败时，我不会检讨它为什么失败	1	2	3	4	5	6
2. 当碰到一个复杂的问题时，我不会花时间去发展一套搜集资料的方法来帮助我了解问题	1	2	3	4	5	6
3. 当我为解决一个问题所做的第一次努力失败时，我会对自己处理事情的能力感到不安	1	2	3	4	5	6
4. 当一个问题解决之后，我不会去检讨解决问题过程中，哪些地方做对了或哪些地方做错了	1	2	3	4	5	6
5. 我通常能设想出一些创新有效的方法来解决问题	1	2	3	4	5	6
6. 当采取行动解决一个问题后，我会去比较实际的结果与事前的预测有何不同	1	2	3	4	5	6
7. 当我有一个问题时，我会尽量想出所有可能解决问题的方法去处理它，直到我无法再想出其他的点子为止	1	2	3	4	5	6
8. 碰到一个问题时，我会持续的检视自己对这个问题的感受，以确定这个问题到底是怎么一回事	1	2	3	4	5	6
9. 当我被问题混淆时，我不会用具体的方法去思考以澄清自己含糊不清的想法与感受	1	2	3	4	5	6
10. 即使一开始未能立刻找到解决问题的方法，我仍相信我有能力去解决大部分的问题	1	2	3	4	5	6
11. 许多我所面对的问题，对我而言，往往太复杂而难以解决	1	2	3	4	5	6
12. 我在解决一个问题时所做的决定，之后会令我感到满意	1	2	3	4	5	6
13. 当面对一个问题时，我倾向用我第一个想到的方法来解决这个问题	1	2	3	4	5	6

问卷条目						
14. 有些时候，我没有停下来花时间去处理我的问题，而只是让自己马马虎虎或漫无计划的进行	1	2	3	4	5	6
15. 在考虑解决一个问题的方法时，我不会花时间去评估每一个方法成功的可能性	1	2	3	4	5	6
16. 当面对一个问题时，我会先停下来想想之后，才决定下一个步骤	1	2	3	4	5	6
17. 我通常用自己想到的第一个方法去解决问题	1	2	3	4	5	6
18. 当做一个决定时，我会比较每种方式并权衡轻重	1	2	3	4	5	6
19. 当我做计划解决一个问题时，我几乎有信心我可以使我的计划行得通	1	2	3	4	5	6
20. 我试着预测自己用以解决问题所采取的行动的效果	1	2	3	4	5	6
21. 当我试着思考可能解决问题的方法时，我不会一下子想出许多不同的解决办法	1	2	3	4	5	6
22. 当试着解决问题时，我常使用的方法是去回想过去类似的经验	1	2	3	4	5	6
23. 只要有充分的时间与努力，我相信我可以解决大多数我所面对的问题	1	2	3	4	5	6
24. 当面对一个新的情况时，我有信心自己有能力处理可能会发生的问题	1	2	3	4	5	6
25. 即使我已开始处理问题，有时我觉得自己只是在摸索与徘徊，并没有掌握到真正问题的所在	1	2	3	4	5	6
26. 当面对问题时，我急促地做判断而事后后悔.	1	2	3	4	5	6
27. 我相信自己具有解决新问题与困难问题的能力	1	2	3	4	5	6
28. 我使用一套有系统的方法去比较各种解决问题的方式，然后才做决定	1	2	3	4	5	6
29. 当想办法解决问题时，我很少结合各种解决问题的可能性去形成一个可行的方法	1	2	3	4	5	6
30. 当面对一个问题时，我很少评估有哪些外在因素可能造成这个问题	1	2	3	4	5	6
31. 当面对一个问题时，我通常先研究问题的情况来决定哪些是对解决问题有用的资讯（信息）	1	2	3	4	5	6
32. 有时我会因太情绪化，而无法想出其他解决某个问题的方法	1	2	3	4	5	6
33. 做决定后，真实的结果常常和我所预测的结果相似	1	2	3	4	5	6

问卷条目						
34. 当面对一个问题时，我不确定我是否可以处理好它	1	2	3	4	5	6
35. 当我察觉到一个问题时，其中一样我首先会做的事儿是去发现什么是真正的问题所在	1	2	3	4	5	6

五、 社会支持量表 (CIRS-FFS)

请按照如下指示回答下列问题：

请指出在过去的三个月中以下情况的发生频率，并勾选相应数字：					
条目	**没有**	**很少**	**有时**	**经常**	**总是**
1. 您的家人仔细听您讲述您的糖尿病病情吗？	1	2	3	4	5
2. 您的家人鼓励您参加体育锻炼吗？	1	2	3	4	5
3. 您的家人给您买或为您做些糖尿病特别推荐的食物吗？	1	2	3	4	5
4. 当您和家人吃饭的时候，您的家人挑选一些符合糖尿病饮食要求的食品吗？	1	2	3	4	5
5. 您的家人在您坚持糖尿病饮食或参加体育锻炼时表扬您吗？	1	2	3	4	5
6. 您的家人帮您记着吃药或注射胰岛素吗？	1	2	3	4	5

六、 健康素养量表 (NVS)

请仔细阅读以下信息，以下信息为某一品牌冰淇淋，总容量为 472 毫升，其容器包装上的营养标识如下，请根据此营养标识明细，依序回答以下六个问题。

总容量： 472 毫升	**营养标识明细**
每一份量： 118 毫升 **本包装含：4** 份	
每份含 **热量： 250** 大卡　　**脂肪热量 120 大卡**	
	每日所需营养标准百分比
脂肪总量： 13 克	**20%**
饱和脂肪 9 克	**40%**
胆固醇 28 毫克	**12%**
钠 55 毫克	**2%**
碳水化合物总量 30 克	**12%**
食物纤维 2 克	
糖 23 克	
蛋白质 4 克	**8%**

注：每日所需营养标准百分比（Percentage Daily Values, DV）是以 2000 卡路里（Calories）饮食为计算基准，您的每日所需营养量可依您的卡路里实际需求而增减。
成分：浓奶、脱脂牛奶、液糖、水、蛋黄、红糖、乳脂肪、花生油、糖、奶油、盐、洋菜、香草萃取物

请依据以上信息回答以下问题：

1. 假如您吃完一整个容器的冰淇淋，您一共吃下多少卡路里热量？_____
2. 假如您只被允许食用 60 克的碳水化合物，那您可以吃下多少毫升的冰淇淋？

   _____
3. 您的医生建议您降低饮食中饱和脂肪的含量，如果您每日经常吃 42 克的饱和脂肪，其中包含一份量的冰淇淋，假如您停止吃冰淇淋，那么您每日所食用的饱和脂肪变为几克？_____
4. 假如您经常每日吃下 2500 卡路里热量，假如您每日吃下一个份量的冰淇淋，那么冰淇淋占您每日所需营养的热量百分比为_____
5. 假如您对橡胶、花生、蜂螯、盘尼西林(青霉素)过敏，您吃下这种冰淇淋安全吗？

   _____
6. 请详述对第 5 题答案的理由_____

七、 流调中心抑郁量表 (CES-D)

请在最能描述您最近一周里您的感觉的数字上打“√”：

在过去的 7 天里	**少**	**1-2**	**3-4**	**5-7**
1、 我为平时不烦扰的事所烦扰	0	1	2	3
2、 我不想吃东西，我胃口不好	0	1	2	3
3、 我觉得即使有家人和朋友帮助，我也无法摆脱心中的苦闷	0	1	2	3
4、 我觉得我和别人一样好	0	1	2	3
5、 我很难集中精力做事	0	1	2	3
6、 我感到忧郁	0	1	2	3
7、 我感到做什么事情都很吃力	0	1	2	3
8、 我觉得前途是有希望的	0	1	2	3
9、 我觉得我的生活是失败的	0	1	2	3
10、 我感到害怕	0	1	2	3
11、 我的睡眠情况不好	0	1	2	3
12、 我感到高兴	0	1	2	3
13、 我比平时话要少了	0	1	2	3
14、 我感到孤单	0	1	2	3
15、 我觉得人们对我不太友好	0	1	2	3
16、 我觉得生活很有意思	0	1	2	3
17、 我曾哭泣	0	1	2	3
18、 我感到忧愁	0	1	2	3
19、 我觉得别人不喜欢我	0	1	2	3
20、 我得不到 “进取”	0	1	2	3

八、 居住环境

请根据你的实际情况回答以下问题：

1. 您觉得您居住的周围环境是否安全?

   ❑ **安全** ❑ **不安全**

2. 您居住的附近是否有地方可以锻炼身体？

   ❑ **有** ❑ **没有**

   如有，请指出有哪类可以健身的场所（可多选）:

   ❑ 公园/广场

   ❑ 健身房/公用健身器材

   ❑ 便道

   ❑ 其他 (请详述) _____

研究人员使用:

3. 您居住的附近是否有地方可以购买健康食品？

   ❑ **有** ❑ **没有**

4. 您已经在目前的家庭居住地居住了多少年？_____**年**_____**月**

九、 自我管理量表 (SDSCA)

请根据您的情况，指出在过去 7 天里您所完成的相关活动，并勾选对应的数字：

在过去的 7 天里,	0 天	1 天	2 天	3 天	4 天	5 天	6 天	7 天
1.有几天您按照处方服用口服降糖药?	0	1	2	3	4	5	6	7
2.有几天您按照处方使用胰岛素?	0	1	2	3	4	5	6	7
3.有几天您按照糖尿病饮食要求用餐?	0	1	2	3	4	5	6	7
4.有几天您每天大约同一时间用餐 (前后不超过半个小时)?	0	1	2	3	4	5	6	7
5.有几天您进行持续至少半个小时的体力活动?	0	1	2	3	4	5	6	7
6. 除了家务或工作以外，有几天您还参加某一特定体育锻炼，比如快步走、跑步、游泳、骑车、打太极拳?	0	1	2	3	4	5	6	7
7.有几天您自己检查血糖?	0	1	2	3	4	5	6	7
8.有几天您按照医生建议的血糖检测次数测量您的血糖?	0	1	2	3	4	5	6	7
9.有几天您检查您的脚是否有伤口或破损?	0	1	2	3	4	5	6	7
10.有几天您在洗脚后擦干脚趾缝?	0	1	2	3	4	5	6	7

问 卷 到 此 结 束 ， 以 下 为 研 究 人 员 使 用 ， 谢 谢 您 的 参 与 ！

****

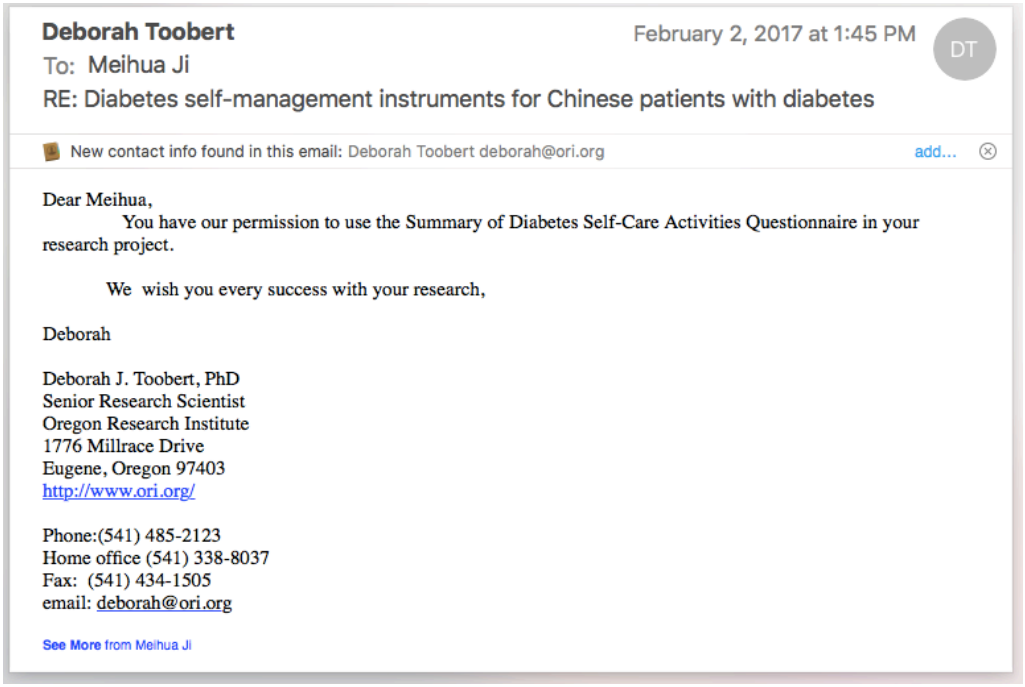
****

十、 实验室数据 (Lab values)

指标	数值
血压	
身体指数(BMI)	
糖化血红蛋白 HbA1c (%)	
高密度血脂- HDL (mmol/L)	
底密度血脂-LDL (mmol/L)	
甘油三脂 (mmol/L)	

E.3 SUPPORTING MATERIATLES

E.3.1 Permission for use and clarification on items of the SDSCA



Deborah Toobert February 2, 2017 at 1:45 PM

To: Meihua Ji

RE: Diabetes self-management instruments for Chinese patients with diabetes

New contact info found in this email: Deborah Toobert deborah@ori.org add...

Dear Meihua,

You have our permission to use the Summary of Diabetes Self-Care Activities Questionnaire in your research project.

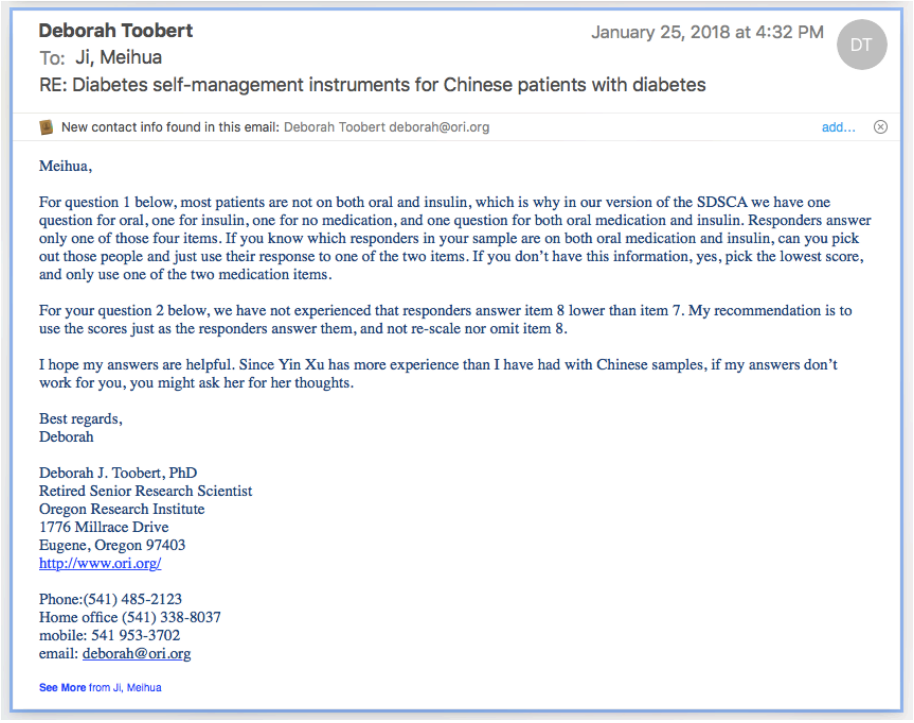
We wish you every success with your research,

Deborah

Deborah J. Toobert, PhD
Senior Research Scientist
Oregon Research Institute
1776 Millrace Drive
Eugene, Oregon 97403
http://www.ori.org/

Phone:(541) 485-2123
Home office (541) 338-8037
Fax: (541) 434-1505
email: deborah@ori.org

See More from Meihua Ji



Deborah Toobert January 25, 2018 at 4:32 PM

To: Ji, Meihua

RE: Diabetes self-management instruments for Chinese patients with diabetes

New contact info found in this email: Deborah Toobert deborah@ori.org add...

Meihua,

For question 1 below, most patients are not on both oral and insulin, which is why in our version of the SDSCA we have one question for oral, one for insulin, one for no medication, and one question for both oral medication and insulin. Responders answer only one of those four items. If you know which responders in your sample are on both oral medication and insulin, can you pick out those people and just use their response to one of the two items. If you don't have this information, yes, pick the lowest score, and only use one of the two medication items.

For your question 2 below, we have not experienced that responders answer item 8 lower than item 7. My recommendation is to use the scores just as the responders answer them, and not re-scale nor omit item 8.

I hope my answers are helpful. Since Yin Xu has more experience than I have had with Chinese samples, if my answers don't work for you, you might ask her for her thoughts.

Best regards,
Deborah

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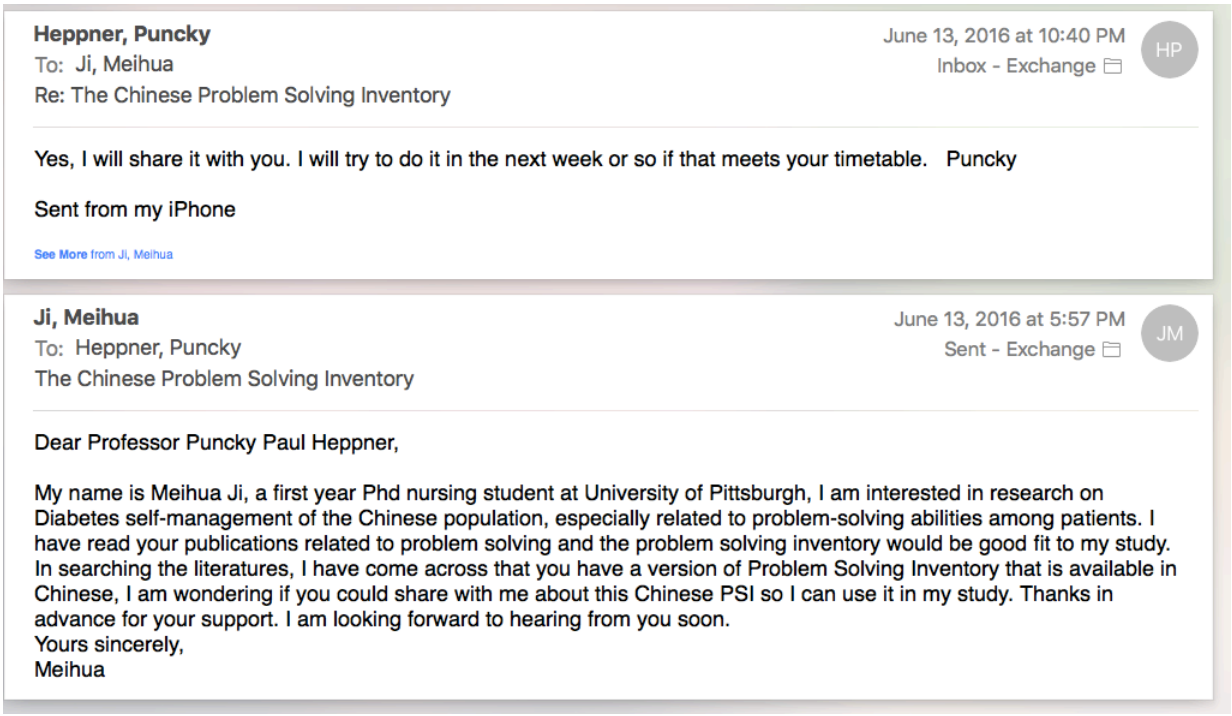
See More from Ji, Meihua

E.3.2 Permission for use of the PSI



Heppner, Puncky
To: Ji, Meihua
Re: The Chinese Problem Solving Inventory

June 13, 2016 at 10:40 PM
Inbox - Exchange

HP

Yes, I will share it with you. I will try to do it in the next week or so if that meets your timetable. Puncky

Sent from my iPhone

See More from Ji, Meihua

Ji, Meihua
To: Heppner, Puncky
The Chinese Problem Solving Inventory

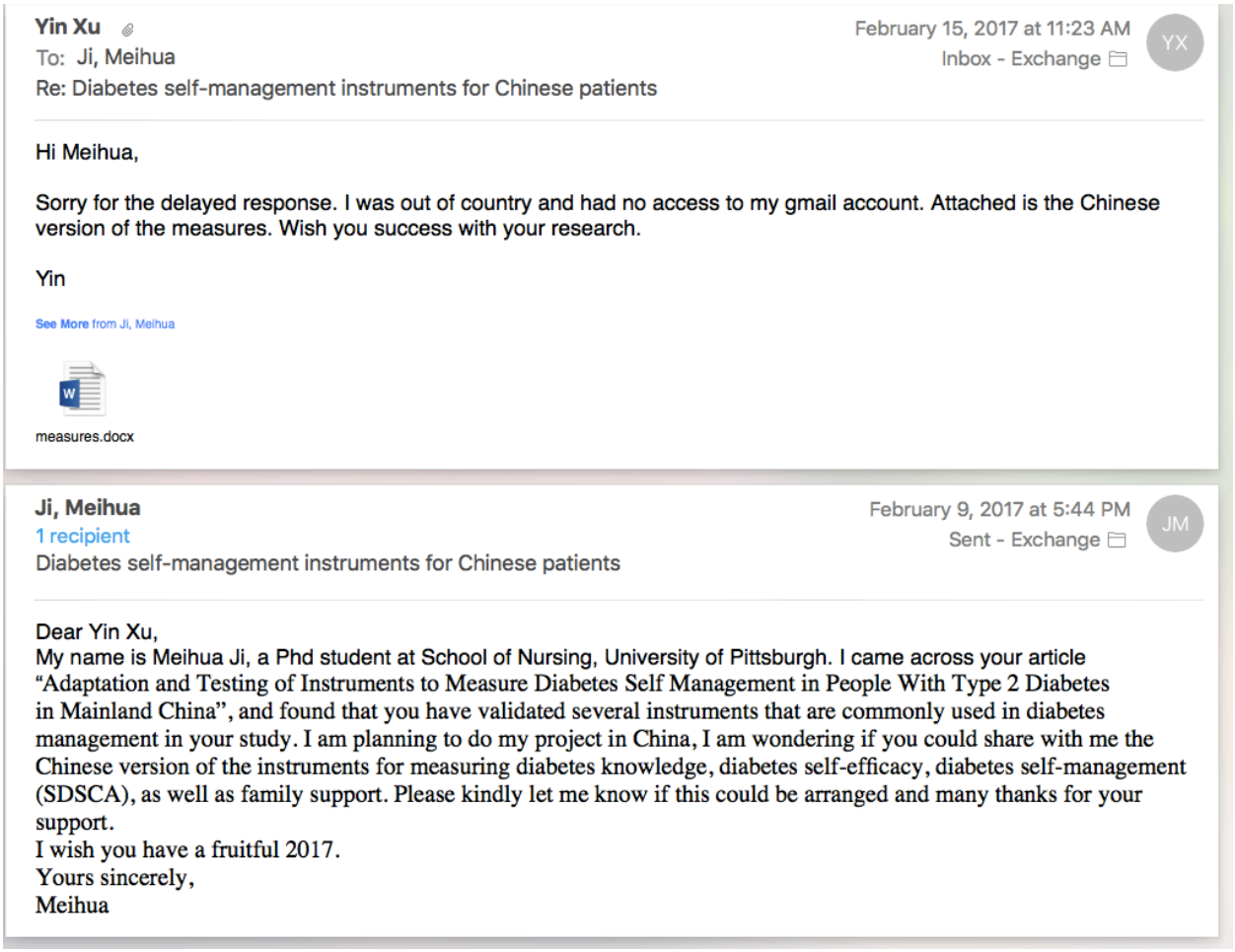
June 13, 2016 at 5:57 PM
Sent - Exchange

JM

Dear Professor Puncky Paul Heppner,

My name is Meihua Ji, a first year Phd nursing student at University of Pittsburgh, I am interested in research on Diabetes self-management of the Chinese population, especially related to problem-solving abilities among patients. I have read your publications related to problem solving and the problem solving inventory would be good fit to my study. In searching the literatures, I have come across that you have a version of Problem Solving Inventory that is available in Chinese, I am wondering if you could share with me about this Chinese PSI so I can use it in my study. Thanks in advance for your support. I am looking forward to hearing from you soon.
Yours sincerely,
Meihua

E.3.3 Permission for use of the Chinese version of the instruments



Yin Xu
To: Ji, Meihua
Re: Diabetes self-management instruments for Chinese patients

February 15, 2017 at 11:23 AM
Inbox - Exchange

YX

Hi Meihua,

Sorry for the delayed response. I was out of country and had no access to my gmail account. Attached is the Chinese version of the measures. Wish you success with your research.

Yin

See More from Ji, Meihua

measures.docx

Ji, Meihua
1 recipient
Diabetes self-management instruments for Chinese patients

February 9, 2017 at 5:44 PM
Sent - Exchange

JM

Dear Yin Xu,
My name is Meihua Ji, a Phd student at School of Nursing, University of Pittsburgh. I came across your article "Adaptation and Testing of Instruments to Measure Diabetes Self Management in People With Type 2 Diabetes in Mainland China", and found that you have validated several instruments that are commonly used in diabetes management in your study. I am planning to do my project in China, I am wondering if you could share with me the Chinese version of the instruments for measuring diabetes knowledge, diabetes self-efficacy, diabetes self-management (SDSCA), as well as family support. Please kindly let me know if this could be arranged and many thanks for your support.
I wish you have a fruitful 2017.
Yours sincerely,
Meihua

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