Alma Mater Studiorum – Università di Bologna

DOTTORATO DI RICERCA IN

Scienze Mediche Generali e Scienze dei Servizi

Ciclo XXXII

Settore Concorsuale: 06/M1

Settore Scientifico Disciplinare: MED/42

TITOLO TESI

Behind HbA1c: the role of self-efficacy in diabetes care

Presentata da: Dott.ssa Rossella Messina

Coordinatore Dottorato	**Supervisore**
Prof. Fabio Piscaglia	Prof.ssa Maria Pia Fantini

Esame finale anno 2020

CONTENTS

Abstract **5**
List of tables and figures **6**
List of supplementary materials **7**
Abbreviations **8**

1. Introduction **9**
2. Aims **14**
3. Methods **15**
3.1.1 Study I: Study design and population 15
3.1.2 Adaptation of the DMSES: face and content validity 16
3.1.3 Measures 17
3.1.4 Statistical analysis: Principal Component Analysis, Internal Consistency, Convergent/Discriminant validity 19
3.2.1 Study II: Study design and population 20
3.2.2 Statistical analysis: Network analysis 21
4. Results **23**
4.1 Study I: Sample characteristics 23
4.1.1 Psychometric validation of the IT-DMSES 23
4.1.2 IT-DMSES scoring instructions 24
4.2 Study II: Sample characteristics 25
4.2.1 Network analysis: Comparison between type 1 and type 2 diabetes 26
4.2.2 Network analysis: Gender differences in type 2 diabetes 27
4.2.3 Network analysis: Gender differences in type 1 diabetes 27
5. Discussion **28**
5.1 Study I 28
5.2 Study II 29
6. Conclusion **32**
6.1 Study I 32
6.2 Study II 32
References **33**
Tables and Figures **38**
Supplementary materials **48**

ABSTRACT

Purpose: This thesis aims to illustrate the Italian validation of a scale measuring self-efficacy in diabetes management (Diabetes Management Self-Efficacy Scale, DMSES) in adults with diabetes.

Methods: Two cross-sectional studies were conducted with patients attending the Diabetology Unit of San Marino and Bologna Hospitals. In study I, patients completed a socio-demographic and clinical data form, the Italian version of the DMSES (IT-DMSES) and 3 self-report questionnaires measuring diabetes distress (PAID-5), psychological well-being (WHO-5) and depression (PHQ-9). Psychometric testing included construct validity (Principal Component Analysis), internal consistency (Cronbach's α coefficient) and convergent/discriminant validity (Spearman's correlation coefficient). In study II, a network analysis of the IT-DMSES was conducted to investigate the differences in self-efficacy between type 1 and type 2 diabetes and between males and females.

Results: Overall, 105 patients with type 1 diabetes and 306 with type 2 diabetes were recruited at the two study sites. The IT-DMSES proved to consist of two factors, including disease management and lifestyle management. The second factor showed a good convergent validity with the well-being index. Results from network analysis showed that disease management and lifestyle management are two spatially distinct but related clusters of items, consistent across types of diabetes and genders. The pattern of correlations among items proved to be significantly different between type 1 and 2 diabetes.

Conclusions: IT-DMSES can be used in research and clinical practice in people living with diabetes to assess self-efficacy. In type 1 diabetes, educational interventions aimed at empowering patients in coping with their disease are likely to affect both disease management and lifestyle management. On the contrary, in type 2 diabetes, educational interventions targeted on disease management may have a limited effect on the adoption of healthy lifestyles and vice versa.

LIST OF TABLES AND FIGURES

Tables

Study I

Table 1. Comments to the items from pilot administration;

Table 2. Demographic, clinical characteristics and scales measuring self-efficacy, depression, diabetes distress and psychological well-being (N=165);

Table 3. Factor loadings of the two factors extracted using principal component analysis with promax rotation;

Table 4. Weights of the items.

Study II

Table 5. Socio-demographic and clinical characteristics of study participants (N=411);

Table 6. Gender differences in type 1 and type 2 diabetes (n=411 patients).

Figures

Study I

Figure 1. IT-DMSES items scores.

Study II

Figure 2. Network of self-efficacy IT-DMSES items for type 1 (on the left) and type 2 diabetes (on the right) and centrality indices (panel C: red line= type 1 diabetes; blue line= type 2 diabetes);

Figure 3. Network of self-efficacy IT-DMSES items for males (on the left) and females (on the right) in type 2 diabetes and centrality indices (blue line=females; red line=males);

Supplementary Figure 1. Network of self-efficacy IT-DMSES items for females (on the left) and males (on the right) in type 1 diabetes and centrality indices (blue line=females; red line=males).

LIST OF SUPPLEMENTARY MATERIALS

Supplementary material 1. The English version of the Diabetes Management Self-Efficacy Scale (DMSES-UK);

Supplementary material 2. The Italian version of the Diabetes Management Self-Efficacy Scale (IT-DMSES);

Supplementary material 3. The Problem Areas In Diabetes Scale (PAID-5);

Supplementary material 4. The Well-Being Index (WHO-5);

Supplementary material 5. The Patient Health Questionnaire (PHQ-9).

ABBREVIATIONS

AADE: The American Association of Diabetes Educators

ADA: The American Diabetes Association

CRT: Classification and Regression Trees statistical method

DMSES: Diabetes Management self-efficacy scale

DMSES UK: The Diabetes Management Self-Efficacy Scale of the United Kingdom

HbA1c: Glycated Haemoglobin

ISS: Institute for Social Security of San Marino

IT-DMSES: The Italian version of the Diabetes Management Self-Efficacy Scale

KMO: Kaiser-Meyer-Olkin measure

PAID-5: The Problem Areas In Diabetes-Short form

PCA: Principal Component Analysis

PHQ-9: The Patient Health Questionnaire

T2D: Type 2 diabetes

UK: United Kingdom

WHO-5: The World Health Organization-5 Well Being Index

CHAPTER 1

1. Introduction

Diabetes mellitus is a chronic condition with a high prevalence. In 2017 the International Diabetes Federation estimated that about 425 million of people (8,8% of adults 20-79 years) have diabetes (87-91% type 2 and 7-12% type 1) and that 4 million people die from diabetes or its complications (IDF, 2017).

In fact, diabetes is a major cause of blindness, kidney failure, heart attacks, stroke and lower-limb amputation (WHO, 2016).

In 2016, in Italy over 3.2 million people have been diagnosed with diabetes (about 90% have type 2 and 9-10% type 1 diabetes), representing 5.3% of the Italian population (16.5% among people 65 years old and over) (Istituto Nazionale di Statistica, 2017).

People with diabetes have to deal with multiple tasks in order to treat and regulate their disease, and especially to prevent chronic kidney disease, central nervous system complications, damage to the blood vessels of the eye. Blood sugar control, administration of insulin or taking oral hypoglycemic drugs and life styles concerning nutrition and physical exercise are examples of daily behaviors and activities that the patient needs to plan and carry out to manage their disease. Patients indicate that they consider managing self-care activities more difficult than the diagnosis of diabetes itself (Anderson, 1985).

In fact, once the diagnosis is established, patients with diabetes are expected to follow a complex set of self-care activities to manage their disease on a daily basis. The American Association of Diabetes Educators (AADE) specifies seven self-care behaviors to promote healthy outcomes, including healthy eating, physical activity, monitoring indicators of diabetes control (such as blood glucose and glycosylated haemoglobin),

taking medication, problem solving and healthy coping (Coyle, Francis, & Chapman, 2013). In order to support the person with diabetes in managing these self-care activities, the American Diabetes Association (ADA) and the AADE suggested to incorporate the diabetes self-management education and support in the healthcare models (Riddle et al., 2018). These interventions should facilitate the knowledge and ability necessary for diabetes self-care and support people with diabetes in implementing and sustaining the behaviors needed to manage their chronic condition (Beck et al., 2017).

On this regard, the ADA recommends to providers that they should consider the burden of treatment and patient levels of confidence/self-efficacy for management behaviors (Young-Hyman, 2016).

The concept of self-efficacy has been introduced in 1960 with Albert Bandura within the "social learning theory" and is defined as people's beliefs in their capability to organize and execute the course of action required to deal with prospective situations (Bandura 1997; 1998).

It is concerned not only with the skills one has but with judgements of what one can do with whatever skills one possesses (Bandura & National Inst of Ment Health, 1986). According to the self-efficacy theory (Bandura, 1994; Bandura & National Inst of Ment Health, 1986), the expectations of personal mastery (efficacy expectations or self-efficacy) and success (outcome expectations) determine whether an individual will engage in one particular behavior.

Self-efficacy, or the belief that one can self-manage one's own health, is an important goal of healthcare providers, particularly in chronic illness (Lenz, 2002).

Being highly self-efficacious is a key factor in successful chronic disease self-management (Devarajooh & Chinna, 2017).

For this reason, the ADA (Beck et al., 2017) recommends that self-efficacy should be measured to assess confidence in performing diabetes self-care activities. In fact, from a perspective of patient-centered psychosocial care in diabetes (Young-Hyman, 2016), targeting interventions according to patient's self-efficacy has a key role to improve diabetes self-management (Beckerle & Lavin, 2013; Iannotti et al., 2006; King et al., 2010; Nouwen, Urquhart Law, Hussain, McGovern, & Napier, 2009; Sarkar, Fisher, & Schillinger, 2006).

A systematic review (Hamzah, 2013) identified 14 studies that conducted research in the context of measuring self-efficacy in type 2 diabetes management. The review concluded that the Diabetes Management Self-Efficacy Scale (DMSES) is the most widely used scale and also some countries such as Australia, UK and China had accepted the use of the scale as a best practiced model. The DMSES in comparison to the Diabetes Empowerment Scale (Anderson, 2000), which assesses psychosocial self-efficacy perceptions, is focused on functional diabetes management behaviours. Moreover, it is based on self-care activities the patients have to carry out in order to manage their diabetes and to prevent complications. For this reason, the main advantage of using the DMSES is the possibility to assess attitudes regarding lifestyle, foot care, weight control, medication adherence, ability to measure blood glucose levels when necessary and also the differences between managing higher and lower blood glucose levels.

The original version of the instrument was developed in Dutch (Van der Bijl, 1999) and consisted of 20 items. Currently it has been validated in Greek, Korean, Chinese, Iranian, Turkish, Thai (Fappa et al., 2016; Lee et al., 2015; Vivienne et al., 2008; Noroozi et al., 2014; Kara et al., 2006; Sangruangake et al., 2017) and in an Australian (McDowell et al., 2005) population, demonstrating acceptable reliability and validity. Factor analysis in Greek, Korean and Chinese versions yielded four factors, five in the Iranian version and three in the Turkish version. A UK validation study reduced the DMSES to 15 items

(Sturt et al., 2010). The DMSES UK (Sturt et al., 2010) was found to be negatively correlated with diabetes distress and glycated haemoglobin levels and one factor solution was found.

Given the aims of study I, my interest moved than to analyse potential differences between type 1 and type 2 in the perceived confidence on diabetes self-management.

In fact, it is unknown whether the self-efficacy constructs measured by this scale and the correlations between items differ between type 1 and type 2 diabetes or between genders. Understanding whether specific aspects of self-efficacy are more prominent or more strongly interlinked in different patient subgroups is relevant for the design of targeted psychoeducational interventions to promote effective self-care.

In order to examine the empirical relationships among self-efficacy items in deeper detail, we used network analysis. Network modeling is a novel way of representing psychological constructs as complex systems of interacting variables. The inspection of networks allows understanding the extent to which items belonging to the same construct are connected to each other and the strength of their mutual relationships. Although in the majority of applications the analysis was typically limited to investigating a network structure in a single population, recently the focus has shifted from single population studies to studies comparing network structures from different subpopulations (van Borkulo et al., 2015) and specific tests have been developed (van Borkulo et al., 2016) to examine whether the network structure is identical across subpopulations, whether specific correlations differ in strength between subpopulations and whether the overall connectivity is equal across subgroups.

It is well known that type 1 and type 2 diabetes have a different pathogenesis, age of onset, and require different therapeutic strategies for the glycemic control. Regarding gender, differences have been reported on disease management compliance with treatment and complications (Ballotari, Venturelli, Greci, Giorgi Rossi, & Manicardi, 2017; Maiorino et al., 2018; McCollum, Hansen, Lu, & Sullivan, 2005).

Given clinical knowledge and previous evidence, we hypothesized that patients with type 1 and type 2 diabetes as well as males and females would feel differently capable of managing some aspects of their disease and applied network analysis to investigate the structure of the self-efficacy network in type 1 and type 2 diabetes, and in males and females stratified by type of diabetes.

CHAPTER 2

2. Aims

The aim of this thesis was to validate the Italian version of the DMSES and to explore whether specific aspects of self-efficacy are more strongly interlinked in different patient subgroups in order to design targeted psychoeducational interventions to promote effective self-care.

Study I (Messina, Rucci et al. 2018)

- To translate and adapt the English version of the scale to Italian and to evaluate the psychometric properties of the Italian version of DMSES (IT-DMSES) in type 2 diabetes.

Study II (Rucci, Messina et al. 2018)

- To investigate the structure of IT-DMSES self-efficacy network in type 1 and type 2 diabetes, and in males and females stratified by type of diabetes.

CHAPTER 3

3. Methods

3.1.1 *Study I: Study design and population*

A cross-sectional study was conducted, 165 patients with type 2 diabetes attending the Endocrine-Metabolic Disease Unit Care of the Internal Medicine Department of San Marino State Hospital were recruited between October 2016 and February 2017.

Inclusion criteria were: age >18-80 years; diagnosis of type 2 diabetes more than 6 months.

Exclusion criteria were: dementia; type 1 diabetes; gestational diabetes.

The Ethics Committee of the Institute for Social Security (ISS) of San Marino approved the study procedures (registration number: 28/2016/CERS). All eligible patients provided a written informed consent after receiving an explanation of study procedures and aims and after having an opportunity to ask questions.

3.1.2 *Adaptation of the DMSES: face and content validity*

The DMSES UK (Sturt et al., 2010) was chosen as the most appropriate version to translate to Italian because it had addressed the item redundancy in the original Dutch version of the instrument by reducing the number of items from 20 to 15.

The DMSES was translated to Italian and then backtranslated to English by a bilingual English native speaker (Carlson, 2000; Erkut et al., 1999; De Vellis, 2003; Ahmed et al., 2009). In order to improve the comprehensibility of the questionnaire for patients, items were reviewed by the research team, which included a public health professor, a statistician, a diabetologist and a psychologist.

After language review (reported in deeper in the Papers section, study I) the version agreed with the team was administered to a pilot sample of 5 people with type 2 diabetes of the diabetes center using a cognitive interviewing methodology to assess the perception, usefulness and interpretation of each question of the measure (Erkut et al., 1999; De Vellis, 2003).

During completion, the 5 participants were asked to provide comments on items and the terminology, and comments were recorded in field notes. Results of the supervised pilot administration of the instrument indicated that patients had difficulties rating items 2, 3, 4, 7, 11 and 12 (see table 1).

The pilot group reported that the questionnaire was interesting and introduced all the issues related to diabetes; they stated also that completing the questionnaire in the presence of a doctor may prevent people from answering the questions honestly. Following this stage, items were revised by adding some examples and the Italian final version of DMSES (IT-DMSES) was agreed (see the additional file 1).

The 15 items of the Italian version of DMSES measure the individual's efficacy expectations for engaging in diabetes self-management activities, for example, checking the blood sugar, following a healthy diet even when away from home. Items are scored on a 0–10 point numerical scale, with higher scores indicating higher self-efficacy levels (Fig. 1). The time of administration ranges from 10 to 20 minutes.

3.1.3 *Measures*

Patients completed a form including socio-demographic and information. Results from the scientific literature indicate that self-efficacy and diabetes self-management are associated with the psychological status of an individual (Sturt et al., 2015; Peyrot et al., 2005). Therefore the convergent/discriminant validity of the IT-DMSES, was investigated by administering 3 questionnaires evaluating: diabetes distress (the Problem Areas in Diabetes-short form, PAID-5), well-being (the World Health Organization-5 Well-Being Index, WHO-5) and depression (the Patient Health Questionnaire-9).

The Problem Areas In Diabetes- Short form (PAID-5)

This scale measures diabetes distress, patients' specific worries and negative emotions related to their diabetes (McGuire et al., 2010; Polonksy et al., 1995). The instrument has been used in more than a hundred studies and in the DAWN MIND (monitoring individual needs in people with diabetes) (Snoek et al., 2011; Nicolucci et al., 2013) program across ten countries. The PAID-5 short form has been validated in Italian in the BENCH-D study (Nicolucci et al., 2014).

It includes five items with responses on a five-point Likert scale, with a total score ranging from 0 to 100. A score ≥40 indicates elevated diabetes-related distress.

The World Health Organization-5 Well-Being Index (WHO-5)

This scale, developed by the World Health Organization, assesses psychological well-being, a core component of quality of life (Bech et al., 1996). The use of WHO-5 is recommended in international and some national treatment guidelines for diabetes after its worldwide use in the DAWN (Wroe, 2006).

It includes five items with responses on a six-point Likert scale, and the total score is rescaled to range from 0 to 100. A score ≤50 indicates poor psychological well-being, while a score ≤28 indicates likely depression.

The Patient Health Questionnaire-9

This questionnaire is used to screen patients for a possible diagnosis of major depression. Scores range from 0 to 27, with cut-points of 5, 10, 15 and 20 indicating mild, moderate, moderately severe and severe levels of depressive symptoms (Kroenke et al., 2010; Mazzotti et al., 2003).

3.1.4 *Statistical analysis: Principal Component Analysis, Internal Consistency, Convergent/Discriminant validity*

The sample size was set to a minimum of 150 in order to perform an exploratory principal component analysis, for which at least a ten-to-one ratio between patients and items is recommended (Nunnally, 1978).

After descriptive analysis, principal component analysis (PCA) was performed to investigate DMSES construct validity. For this analysis, the very few missing items were replaced with mean values (28 missing items overall in 22 patients, corresponding to 1%). The number of factors to be extracted was determined according to the scree-plot method (Cattell, 1983). Oblique rotation was performed using the promax method, to allow for the expected correlation between factors.

Kaiser–Meyer–Olkin measure of sampling adequacy (KMO) and Bartlett's test were calculated to evaluate the sample size adequacy. A KMO >0.8 indicates that the sampling is adequate. The p value of Bartlett's test of sphericity (which tests the null hypothesis that the original correlation matrix is an identity matrix) should be significant and lower than 0.05. Factor scores were calculated using the regression method.

Internal consistency was assessed using Cronbach's α coefficient with cut-offs of .8 and .9 denoting good and excellent reliability.

The convergent/discriminant validity of IT-DMSES vs. the PAID-5, the WHO-5 and the PHQ-9 was analysed by using Spearman's correlation coefficient, because of the asymmetrical frequency distribution of item responses. High levels of self-efficacy are expected to be associated with low diabetes distress, a good psychological well-being and no depressive symptoms (Sturt et al., 2010; Sturt et al., 2006; Thoolen et al., 2006).

Decision tree with CRT method was used to classify patients into homogeneous subgroups of self-efficacy based on demographic and clinical characteristics, including gender, age, years of education and duration of illness. All analyses were performed using IBM SPSS, version 20.

3.2.1 Study II: Study design and population

In study II, the sample derived from that of the previous study I plus another group of patients recruited at the Diabetology Unit of Sant'Orsola-Malpighi Hospital Bologna (between 1 May 2017 and 31 October 2017) during this second cross-sectional study.

Differently from study I, the sample included also people with type 1 diabetes.

So that, inclusion criteria were: age between 18-80 years, clinical diagnosis of type 1 or 2 diabetes for at least 6 months and willingness to sign informed consent¸ exclusion criteria were: clinical diagnosis of mild cognitive impairment/dementia and clinical diagnosis of gestational or iatrogenic diabetes.

The study protocol was approved by the Ethics Committee of Sant'Orsola Hospital (currently Independent Ethics Committee of Center Emilia Area) (registration number: 31/2017/U/Oss).

All participants provided a written informed consent to participate after receiving a thorough explanation of the study procedures and having an opportunity to ask questions.

Patients completed the validated version of the IT-DMSES.

3.2.2 *Statistical analysis: Network analysis*

The 15 IT-DMSES items were used for the network analyses. A network is a graphical representation of the correlations between items. In this representation items are depicted as nodes and correlations as edges. Thicker and more saturated edges denote stronger correlations. Positive correlations are represented as green edges and negative correlations as red edges. The network display is based on an algorithm (Fruchterman & Reingold, 1991) that places strongly associated nodes at the center of the network and weakly associated nodes at the periphery.

A network model including all possible correlations among items would require the estimation of a large number of parameters, including *n* threshold parameters for the nodes and *n*(n*-1)/2 parameters for the pairwise correlations between nodes. With 15 items, this would amount to estimating 120 parameters. To deal with the problem of a relatively small dataset compared to the number of parameters, we used the 'least absolute shrinkage and selection operator (LASSO)' technique (Tibshirani, 1996), that leads many edge estimates to shrink to exactly zero and to drop out of the model. The LASSO returns a sparse, i.e. conservative, network model in which only a relatively small number of edges are used to explain the relationships among items. Because of this sparsity, the estimated models become more interpretable. The LASSO utilizes a tuning parameter to control the degree to which the removal of small correlations is applied. We selected this tuning parameter by minimizing the Extended Bayesian Information Criterion (Chen & Chen, 2014). To take into account the skewed distribution of items, a nonparanormal transformation was applied to the data (Liu, Lafferty, & Wasserman, 2009).

Then, to quantify the importance of each node in the network, we used the betweenness, centrality and degree indices. The betweenness denotes the number of times a specific

node acts as a bridge along the shortest path between two nodes, the closeness measures the number of direct and indirect links between one node and the others and the degree is the strength of links with the other nodes. These indices are normalized (mean=0 and standard deviation=1), so that an index with a value >1 indicates that it is >1 SD from the mean.

The network analysis was conducted using the statistical software JASP version 0.8.6 (JASP Team University of Amsterdam, 2018).

The R-package NetworkComparisonTest was used to test (1) the invariant network structure, (2) the invariant edge strength, and (3) the invariant global strength between subgroups.

CHAPTER 4

4. Results

4.1 *Study I: Sample characteristics*

The study sample consists of 165 patients. Participants had a mean age of 65.2 (SD±9) years, 56.9% had been diagnosed for 1 to 15 years, 63% reported HbA1c levels >53mmol/mol, 66.7% were males, 79.7% were living with a spouse or partner and 71.5% were retired. Other clinical characteristics are reported in Table 2.

PHQ-9 scores indicated that 62.7 % of patients had no depressive symptoms, 25.2 % mild, 10.8% moderate and 1.3% moderate to severe depressive symptoms. PAID-5 scores showed that 51.2 % of patients had elevated diabetes distress. WHO-5 scores indicated that 74.2% of patients had good psychological well-being, 17.6% had poor psychological well-being and 8.2% likely depression.

4.1.1 *Psychometric validation of the IT-DMSES*

Patients who completed the IT-DMSES were included in all the analyses (N=159). The KMO index was 0.86, indicating that the sample was adequate for factor analysis and Bartlett's test of sphericity was significant, indicating strong correlation between variables. The PCA extracted three factors that accounted for 66.8% of the total variance. However, one of the factors included only two items and its eigenvalue was marginally higher than unity. Thus, a two-factor solution was selected that was more interpretable, and accounted for 56.6% of item variance. Factor 1 (including items: 1, 2, 3, 6, 14, 15) was labeled as "disease management" and factor 2 (including items: 4, 5, 7, 8, 9, 10, 11, 12, 13) was labeled as "lifestyles management". Table 3 shows the item loadings on the

two factors. Two items had a cross-loading (item n. 6, factor 1=.415 factor 2=.322; item n.7, factor 1=.359 factor 2= .444). Disease Management had a good reliability (α=.849) and Lifestyle Management had an excellent reliability (α=.900).

Patients who completed all scales were included in this analysis (N=151).

A negative and weak correlation was found between DMSES factor 2 (Lifestyle management), PAID-5 (r=-0.258, p=<0.01) and PHQ-9 (r=-0.274, p=<0.01) and a positive one with WHO-5 (r=0.325, p<0.01) supporting convergent validity. This suggests that patients with higher self-efficacy had a higher well-being, lower distress and fewer depressive symptoms.

DMSES factor 1 (Disease management) was uncorrelated with PAID-5 (r=-0.142, p=0.083), PHQ-9 (r=-0.145, p=0.076) and weekly correlated with WHO-5 (r=0.170, p=0.037) confirming discriminant validity.

4.1.2 *IT-DMSES Scoring Instructions*

Since IT-DMSES consists of two factors, two scores are necessary. Score 'Disease Management' is the weighted mean of items 1, 2, 3, 6, 14, 15. Score 'Lifestyle Management' is the weighted mean of items 4, 5, 7, 8, 9, 10, 11, 12, 13. Both of them range from 0-10: 0-3 denotes low levels of self-efficacy, 4-6 intermediate levels of self-efficacy, 7-10 high levels of self-efficacy. Weights are provided in Table 4.

4.2 *Study II: Sample characteristics*

Overall 411 patients were recruited, 246 in Bologna and 165 in San Marino.

The Bologna sample included 105 patients with type 1 diabetes and 141 patients with type 2 diabetes, while the San Marino sample included 165 patients with type 2 diabetes. Patient characteristics by type of diabetes and by gender are reported in Tables 5 and 6.

Patients with type 1 diabetes were younger, more frequently female, living with parents and employed than those with type 2 diabetes. They also had lower BMI, higher education and a longer history of disease. Hypertension, dyslipidemia, ischemic heart disease, kidney disease and eye damage were significantly more common in type 2 diabetes. The treatment regimen in type 2 diabetes was oral hypoglycemic mono or pluri-therapy in 42.2% of patients, combination of oral hypoglycemics and insulin in 43.8% and insulin alone in 10.5%. In type 1 diabetes, the large majority of patients were treated with insulin alone (93.3%) and 6.7% with insulin and oral hypoglycemics.

In type 2 diabetes, comparisons between genders revealed that males were more likely to have ischemic heart disease, dyslipidemia and kidney, neurological and peripheral circulatory complications. However, females had more frequently thyroid diseases as comorbidity. In type 1 diabetes, the only gender differences included a poorer glycemic control and a higher frequency of thyroid disease in females.

4.2.1 *Network analysis: Comparison between type 1 and type 2 diabetes*

This analysis was carried out in the overall sample, including 306 patients with type 2 diabetes and 105 with type 1 diabetes. The network structure in type 2 and type 1 diabetes indicated that the IT-DMSES domains disease management and lifestyle management, colored respectively in red and blue, comprised two distinct clusters. However, the network structure, i.e. the pattern of correlations among items, proved to be significantly different between type 1 and 2 diabetes (M=0.66, p<0.001) (Fig. 2).

The global strength test revealed a significantly stronger interconnection in type 2 compared with type 1 diabetes (S=0.77, p=0.019). Notably, this result is accounted by the strong association in type 2 diabetes between items DM14 *(take medications)* and DM15 *(adjust medications),* that are peripheral and almost disconnected from the rest of the network. Vice versa, in type 1 diabetes, self-efficacy in lifestyle management and disease management items are more densely but weakly interconnected with each other. As expected, tests of specific edge strengths confirmed a significant difference (p<0.001) between type 2 and type 1 diabetes for the item pair DM14 *(take medications)*-DM15 *(adjust medications)* (weight=0.790 in type 2, weight=0.280 in type 1) and identified additional differences for the pairs DM7 (*adjust the eating plan when ill*) -D10 *(adjust diet when exercising)* (weight=0.224 in type 1 and 0.023 in type 2), DM8 (*regular diet*) -DM11 (*eating diet when away from home*) (weight 0.360 in type 1, weight=0.027 in type 2), DM13 (*adjust diet when distressed*) -DM14 (*take meds*) (weight=0.149 in type 1, weight=0 in type 2).

Concerning the centrality of self-efficacy items, in type 2 diabetes 3 items played a key role: DM2 (*correct blood sugar when high*) has the highest betweenness (connected directly more items with each other), DM7 *(adjust diet when ill*) had the highest closeness (direct and indirect connections with other items) and item DM8 (*regular diet*)

has the highest degree (stronger links with other items). In type 1 diabetes, item DM7 (*adjust diet when ill*) has all the highest centrality indices.

4.2.2 *Network analysis: Gender differences in type 2 diabetes*

This analysis was carried out in the 192 males and 114 females with type 2 diabetes. The network structure was similar between genders (M=0.23, p=0.663) and the global strength was almost overlapping in males and females (S=0.02, p=0.953) (Fig. 3).

Still, a visual inspection of the network showed some unique edges in males and females. While DM10 (*adjust diet when exercising*) was connected with DM13 (*adjust diet when distressed*) only in males DM6 (*examine feet*) was connected with DM3 (*correct blood sugar when low*), DM12 (*healthy eating pattern when eating out*) with DM13 (*adjust diet when distressed*) and DM8 (*regular diet*) with DM13 (*adjust diet when distressed*) only in females.

4.2.3 *Network analysis: Gender differences in type 1 diabetes*

This analysis included 52 females and 53 males with type 1 diabetes. The network structure and the global strength of the correlations proved to be invariant between genders (M=0.41, p=0.577 and S=0.05, p=0.937). However, the network showed some unique edges. In males, DM7 (*adjust diet when ill*) was connected with DM8 (*regular diet*) and DM1 (*check blood sugar when necessary*) with DM4 (*choose correct foods*); in females DM8 (*regular diet*) was connected with DM9 (*take more exercise*) (Supplementary Figure 1).

CHAPTER 5

5. Discussion

5.1 Study I

The study indicates that IT-DMSES is not unidimensional, but consists of two main factors underlying the construct of self-efficacy: Disease Management and Lifestyle Management. Furthermore, the results showed that the DMSES factor 2 'Lifestyle Management' has a good convergent validity with the Well-Being index, suggesting that a higher perceived capability to manage diet and exercise is associated with higher subjective psychological well-being. This result is consistent with previous studies, in which higher self-efficacy was related to lower emotional distress (Sturt et al., 2010; Fisher et al., 2007). Factor 1 'Disease Management' was uncorrelated with PAID-5, PHQ-9 and WHO-5, confirming that this factor measures a conceptually different construct from distress, depression and well-being.

The identification of two dimensions of self-confidence in diabetes management has important implications on targeting personalised patient education interventions because it allows to know the activities in which patients are facing more difficulties.

In addition, we found that self-efficacy is related to illness duration, gender and age. Higher levels of self-efficacy in lifestyle management were found in patients diagnosed for at least 1 year up to 15 years and aged >65 years and the poorest self-efficacy was found in males < 65 years.

These results suggest that efforts to promote patient education to self-efficacy should be especially targeted to younger man, and to patients with a long-standing experience of disease.

The study has some limitations, one of which is the external validity, in fact the study sample attending the diabetes center included mostly elderly patients with comorbid diseases and complications. Therefore, our results cannot be generalized to all patients with type 2 diabetes.

Another possible limitation is the social desirability bias, that is the tendency to over-report good behaviors when answering questions. This may lead to an overestimation of patients' ability to manage their diabetes.

5.2 Study II

This study is, to our knowledge, the first attempt to apply network analysis to investigate the relationships between diabetes self-efficacy items and to investigate the network structure and the strength of item relationships between type 1 and type 2 diabetes and between genders.

The original result of the present study is the difference in the self-efficacy network structure between type 1 and type 2 diabetes. The high interconnections between items in type 1 diabetes indicated that, in general, patients' perceived ability to address specific tasks to manage their illness is associated with their ability to control their lifestyle. Thus, educational interventions aimed at empowering patients in coping with their disease are likely to affect both these aspects.

On the contrary, our findings indicate that in people with type 2 diabetes self-efficacy in taking and adjusting medications are two items strongly linked with each other but isolated and disconnected from the confidence in managing daily lifestyles. These findings suggest that an educational intervention targeted to support patients with type 2 diabetes in managing their disease may have a limited effect on the adoption of healthy lifestyles and vice versa. Thus this study points to the need to set up psychoeducational interventions for type 2 diabetes in which the adoption of healthy lifestyles should be

given at least the same attention as the glycemic control and the treatment management. Because educational programs vary in the method of delivery, content, illness and behavior change theory, their quality and outcomes should be monitored rigorously.

The IT-DMSES is a standardized validated tool that can be used to measure the psychosocial effects of educational programs in two ways. The first traditional way consists in analyzing changes in self-efficacy scores.

The second innovative way, based on a network approach, consists in analyzing the item correlations before and after the program. Stronger links among items at the end of the educational program indicate that self-efficacy is improved and that confidence in managing specific tasks is connected to confidence in managing other tasks. On the contrary, looser and weak links would suggest that self-efficacy worsened. We argue that this alternative approach would offer a deeper insight into the self-efficacy aspects that change after the intervention and is consistent with self-efficacy theory which posits that confidence in self-care is not of a general nature but related to specific situations (Bandura & National Inst of Ment Health, 1986; van der Bijl & Shortridge-Baggett, 2001).

Our study has some limitations. This was a cross-sectional study measuring self-efficacy during a single study visit; therefore, we were unable to ascertain the persistence of self-efficacy in diabetes management over time or the effects of educational intervention.

The generalizability of these study findings above and beyond this patient population should be done with caution because our sample is not representative of patients with type 2 and type 1 diabetes in other settings, such as, for instance, primary care. Moreover, self-efficacy was assessed using a self-report measure. Patients' perceived ability in diabetes management may be overestimated due to a social desirability bias since patients completed questionnaires in the presence of the researcher. Moreover, this self-report

instrument may have limitations for routine use in clinical settings where supported administration may be needed for elderly people or for people with vision problems.

CHAPTER 6

6. Conclusion

6.1 Study I

IT-DMSES version has sound psychometric properties and measures two different dimensions of self-efficacy: disease and lifestyle management. Results support the validity and reliability of the instrument. IT-DMSES can be used in people living with type 2 diabetes to monitor diabetes self-management over time.

6.2 Study II

Network comparisons revealed differences between type 1 and type 2 diabetes concerning the centrality of specific self-efficacy aspects and the way in which these aspects are connected to each other. In particular, in type 1 diabetes, the ability to face non–regular self-management activities plays a central role because it is more interconnected with the other aspects of lifestyle and disease management than in type 2 diabetes. Knowledge of these aspects can give useful directions to clinicians to target psychoeducational interventions to support patient in the self-management of their condition. No significant gender differences emerged in the network structure. Future perspectives include the use of the network approach to analyze the efficacy of self-management educational programs in clinical trials and intervention studies.

REFERENCES

Ahmed N, Bestall JC, Payne SA, Noble B, Ahmedzai SH. *The use of cognitive interviewing methodology in the design and testing of a screening tool for supportive and palliative care needs*. Support Care Cancer. 2009; 17:665-673.

Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. *The diabetes empowerment scale: a measure of psychosocial self-efficacy*. Diabetes Care. 2000; 23:739–743.

Anderson RM. *Is the problem of noncompliance all in our heads*. Diabetes Educ. 1985;11:31–36.

Bandura A. *Health Promotion from the Perspective of Social Cognitive Theory*. Psychol Health. 1998; 13:623–649.

Bandura A. *The nature and structure of self-efficacy*. New York: W.H. Freeman and Company; 1997.

Bandura A. *Self-Efficacy*. In V.S. Ramachaudran (Ed.), Encyclopedia of Human Behavior. 1994; 4: 71–81.

Bandura A & National Inst of Ment Health. *Social foundations of thought and action: A social cognitive theory*. In Prentice-Hall series, Social learning theory. NJ, US: Englewoods Cliffs; 1986.

Ballotari P, Venturelli F, Greci M, et al. *Sex Differences in the Effect of Type 2 Diabetes on Major Cardiovascular Diseases: Results from a Population-Based Study in Italy*. International Journal of Endocrinology. 2017.

Bech P, Gudex C, Johansen KS. *The WHO (Ten) Well-Being Index: validation in diabetes*. Psychother Psychosom. 1996; 65:183–90.

Beck J, Greenwood DA, Blanton L, et al. 2017 *National Standards for Diabetes Self-Management Education and Support*. Diabetes Care. 2017; 40(10):1409–1419.

Beckerle CM & Lavin MA. *Association of Self-Efficacy and Self-Care With Glycemic Control in Diabetes*. Diabetes Spectrum. 2013; 26(3):172–178.

Carlson ED. *A Case Study in Translation Methodology Using the Health- Promotion Lifestyle Profile II*. Public Health Nurs. 2000; 17:61–70.

Cattell RB. *The scree test for the number of factors*. Multivar Behav Res. 1983; 1(2):245-276.

Chen Z & Chen J. *Extended Bayesian Information Criteria for Model Selection with Large Model Spaces*. Biometrika. 2008; 95(3):759–771.

Coyle ME, Francis K, Chapman Y. *Self-management activities in diabetes care: A systematic review*. Australian Health Review. 2013; 37(4):513–522.

Devarajooh C & Chinna K. *Depression, distress and self-efficacy: The impact on diabetes self-care practices*. PLoS One. 2017; 12(3):1-16.

De Vellis RF. *Scale development: theory and applications*. 2nd ed., vol.26. Sage Publications. 2003.

Erkut S, Alarcón O, Coll CG. *The dual-focus approach to creating bilingual measures*. J Cross Cult Psychol. 1999; 30(2):206-218.

Fappa E, Efthymiou V, Landis G, et al. *Validation of the Greek Version of the Diabetes Management Self-Efficacy Scale (GR-DMSES)*. Adv Ther. 2016; 33(1):82-95.

Fisher EB, Thorpe CT, Devellis BM, Devellis RF. *Healthy coping, negative emotions, and diabetes management*. The Diabetes Educator. 2007; 33(6):1080-1103.

Fruchterman TMJ & Reingold EM. *Graph drawing by force-directed placement*. Software: Practice and Experience. 1991; 21(11):1129–1164.

Hamzah M, Mohamad E, Suanda J. *Systematic Review: The Measurement of Health Self-Efficacy to Diabetes*. Aust J Basic Appl Sci. 2013; 7:295–302.

International Diabetes Federation. *The Global burden*. In: International Diabetes Federation, Diabetes Atlas 6th edition. 2013.

Iannotti R, Schneider S, Nansel T, et al. *Self-efficacy, outcome expectations, and diabetes self-management in adolescents with type 1 diabetes*. J Dev Behav Pediatr. 2006; 27(2):98–105.

Istituto Nazionale di Statistica (Istat). *Il diabete in Italia 2000-2016*. https://www.istat.it/it/archivio/202600 Accessed July 2017.

Kara M, van der Bijl J, Shortridge-Baggett LM, et al. *Cross-cultural adaptation of the diabetes management self-efficacy scale for patients with type 2 diabetes mellitus: Scale development*. Int J Nurs Stud. 2006; 43(5):611-621.

King DK, Glasgow RE, Toobert DJ, et al. *Self-efficacy, problem solving, and social-environmental support are associated with diabetes self-management behaviors*. Diabetes Care. 2010; 33(4):751–753.

Kroenke K, Spitzer RL, Williams JBW & Löwe B. *The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: A systematic review*. Gen Hosp Psychiatry. 2010; 32(4):345-59.

Lee EU, Van der Bijl J, Shortridge-Baggett LM, et al. *Psychometric Properties of the Diabetes Management Self-Efficacy Scale in Korean Patients with Type 2 Diabetes*. Int J Endocrinol. 2015; (3):1-9.

Lenz ER, Shortridge-Baggett LM. *Self-efficacy in nursing: research and measurement perspectives*. Springer Publishing Company. 2002.

Liu H, Lafferty J, & Wasserman L. *The Nonparanormal: Semiparametric Estimation of High Dimensional Undirected Graphs*. J Mach Learn Res. 2009; 10:2295-2328.

Maiorino MI, Bellastella G, Casciano O, et al. *Gender-differences in glycemic control and*

diabetes related factors in young adults with type 1 diabetes: results from the METRO study. Endocrine. 2018; 61(2):240–247.

Mazzotti E, Fassone G, Pasquini P. *The Patient Health Questionnaire (PHQ) for the screening of psychiatric disorders: a validation study versus the Structured Clinical Interview for DSM-IV axis I (SCID-I).* Ital J Psychopathol. 2003; 9:235–242.

McCollum M, Hansen LS, Lu L, & Sullivan PW. *Gender differences in diabetes mellitus and effects on self-care activity*. Gender Med. 2005; 2(4), 246–254.

McDowell J, Courtney M, Edwards H, Shortridge-Baggett LM. *Validation of the australian/english version of the diabetes management self-efficacy scale*. Int J Nurs Pract. 2005; 11(4):177-184.

McGuire BE, Morrison TG, Pibernik-Okanovic M. *Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1*. Diabetologia. 2010; 53:66-69.

Messina R, Rucci P, Sturt J, Mancini T, Fantini MP. *Assessing self-efficacy in type 2 diabetes management: Validation of the Italian version of the Diabetes Management Self-Efficacy Scale (IT-DMSES)*. Health and Quality of Life Outcomes. 2018; 16(1):71. doi: 10.1186/s12955-018-0901-3.

Nicolucci A, Rossi MC, Pellegrini F, et al. *Benchmarking network for clinical and humanistic outcomes in diabetes (BENCH-D) study: protocol, tools, and population*. Springerplus. 2014; 3:1–9.

Nicolucci A, Kovacs Burns K, Holt RIG, et al. J. *Diabetes Attitudes, Wishes and Needs second study (DAWN2^{TM}): cross-national benchmarking indicators for family members living with people with diabetes*. Diabet Med. 2013; 30(7):778-88.

Noroozi A, Tahmasebi R. *The diabetes management self-efficacy scale: Translation and psychometric evaluation of the Iranian version*. Nurs Pract. 2014; 1:9–16.

Nouwen A, Urquhart Law G, Hussain S et al. *Comparison of the role of self-efficacy and illness representations in relation to dietary self-care and diabetes distress in adolescents with type 1 diabetes*. Psychol Health. 2009; 24(9):1071–1084.

Nunnally J. *Psychometric theory*. 2nd ed. New York: McGraw-Hill; 1978.

Peyrot M, Rubin RR, Lauritzen T, et al. *Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study*. Diabet Med. 2005; 22:1379–1385.

Polonsky WH, Anderson BJ, Schwartz CE. *Assessment of diabetes-related distress*. Diabetes Care. 1995; 18:754–60.

Riddle MC, Bakris G, Blonde L, et al. *Standards of Medical Care in Diabetes—2018*. Diabetes Care. 2018; 41 (Supplement 1).

Rucci P, Messina R, Ubiali A, Rochira A, van der Bijl J, Mancini T, Fantini MP, Pagotto U.

Does self-efficacy in diabetes management differ by type of diabetes and gender? Results from network analysis. Journal of Health Psychology. 2018; Article in Press. doi: 10.1177/1359105318804866.

Sangruangake M, Jirapornkul C, Hurst C. *Psychometric properties of Diabetes Management Self-Efficacy in Thai type 2 diabetes mellitus patients: a multicenter study*. Int J Endocrinol. 2017; (Article ID 2503156).

Sarkar U, Fisher L, & Schillinger D. *Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy?* Diabetes Care. 2006; 29(4):823–829.

Snoek FJ, Kersch NYA, Skovlund SE. *Monitoring of Individual Needs in Diabetes (MIND): baseline data from the Cross-National Diabetes Attitudes, Wishes, and Needs (DAWN) MIND Study*. Diabetes Care. 2011; 34(3): 601-603.

Sturt J, Dennick K, Due-Christensen M, McCarthy K. *The detection and management of diabetes distress in people with type 1 diabetes*. Curr Diab Rep. 2015; 15(11):101.

Sturt J, Hearnshaw H, Wakelin M. *Validity and reliability of the DMSES UK: a measure of self-efficacy for type 2 diabetes self-management*. Prim Health Care Res. 2010.

Sturt J, Hearnshaw H, Farmer A, et al. *The Diabetes Manual trial protocol–a cluster randomized controlled trial of a self-management intervention for type 2 diabetes*. BMC Fam Pract. 2006; 7:45.

Thoolen GE, de Ridder BJ, Bensing DT, et al. *Psychological outcomes of patients with screen-detected type 2 diabetes*. Diabetes Care. 2006; 29(10):2257-2262.

Tibshirani R. *Regression Selection and Shrinkage via the Lasso*. J Roy Stat Soc B. 1996; 58(1):267-288.

van Borkulo C, Boschloo L, Kossakowski JJ. et al. *Comparing network structures on three aspects: A permutation test*. 2017. https://doi.org/10.13140/rg.2.2.29455.38569.

van Borkulo C, Boschloo L, Borsboom D, et al. *Association of symptom network structure with the course of longitudinal depression*. JAMA Psychiat. 2015; 72(12):1219–1226.

van der Bijl J, & Shortridge-Baggett L. *The theory and measurement of the self-efficacy construct*. Res Theor Nurs Pract. 2001; 15(3):189-207.

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; 30:352–359.

Vivienne Wu SF, Courtney M, Edwards H. et al. *Development and validation of the Chinese version of the Diabetes Management Self-efficacy Scale*. Int J Nurs Stud. 2008; 45(4):534-542.

World Health Organization. *Global report on diabetes 2016*.

doi:http://www.who.int/mediacentre/factsheets/fs312/en. Accessed October 2018.

Wroe J. *The 3rd International DAWN Summit: from research and practice to large-scale*

implementation. Pract Diab Int. 2006; doi:doi: 10.1002/pdi.993.

Young-Hyman D, De Groot M, Hill-Briggs F, Gonzalez JS. *Psychosocial care for people with diabetes: a position statement of the American Diabetes Association*. Diabetes Care. 2016; 39(12): 2126-2140.

.

TABLES AND FIGURES

Table 1. Comments to items during pilot administration

Items	**Comments**
2, 3	(1) people who do not have access to blood glucose monitors may just have the feeling of having high or low; (2) people guess whether their blood glucose is low or high based on expected or unknown symptoms; (3) people guess how to cope with these possible symptoms by changing food intake or insulin intake; (4) Never experienced a low glucose so they never had to correct it.
4	"even if I am able to choose correct foods for my health, doesn't mean that I do it because I am greedy"
7	Someone did not understand the term 'when I am ill', was clarified using examples like "when you have a high temperature".
11, 12	It was necessary to explain the difference between following a healthy diet when eating outside the home (in a place that the person chooses) or eating out in places that the person does not choose (eg parties, birthdays where the person cannot choose what to eat).

TABLES AND FIGURES

Table 2. Demographic and clinical characteristics of study participants (N=165) and scales measuring self-efficacy, depression, diabetes distress and well-being.

Characteristics	**N(%) or mean±SD**
Gender	
Males	110 (66.7%)
Female	55 (33.3%)
Age (years) (mean±SD)	65.2 ± 9 (range 35-80)
Living situation	
With a spouse/partner	114 (79.7%)
With parents	7 (4.9)
Alone	22 (15.4%)
Level of education	
Elementary school	54 (33.1%)
Middle school	63 (38.7%)
High school	34 (20.9%)
College and above	12 (7.4%)
No. of years since diagnosed with diabetes, no. (%)	
<1 year	11 (6.9%)
1-15 years	91 (56.9%)
>15 years	58 (36.3%)
Occupational status	
Employed	40 (24.2%)
Retired	118 (71.5%)
Unemployed	2 (1.2%)
Weight classification	
Normal weight	20 (12.1%)
Overweight	51 (30.9%)
Obese	94 (57.0%)
HbA1c* (mean±SD)	57.28±10.3
HbA1c ≤53mmol/mol	61 (37%)
HbA1c >53mmol/mol	104 (63%)
Treatment regimen	
Diet/exercise only	10 (6.1%)
Oral hypoglycemic agent	71 (43%)
Insulin	11 (6.7%)
Oral hypoglycemic agent + insulin	73 (44.2%)
Co-morbidities	
Hypertension	126 (76.4%)
Thyroid disease	45 (27.3%)
Dyslipidemia	141 (85.5%)
Ischemic heart disease	33 (20%)
Complications	
Kidney disease	23 (13.9%)
Eye damage	26 (15.8%)

Neurological disease	21 (12.7%)
Foot complications	2 (1.2%)
Peripheral circulatory complications	12 (7.3%)
DMSES scores *	
Mean DMSES 1 factor score	8.53±1.63
Mean DMSES 2 factor score	6.83±1.76
PHQ-9 score†	
No depression	99 (62.7%)
Mild depression	40 (25.2%)
Moderate depression	17 (10.8%)
Moderately severe depression	2 (1.3%)
Mean PAID-5 score ‡	39.32 ± 27.14
Cut-off ≥40 (elevated diabetes distress)	83 (51.2%)
Mean WHO-5 score §	63.43 ± 21.21
Good psychological well-being	118 (74.2%)
Poor psychological well-being	28 (17.6%)
Likely depression	13 (8.2%)

*HbA1c values: generic target, not modified on patient characteristics. Missing values: 22 living situation; 2 level of education; 5 n. of years since diagnosed with diabetes; 5 occupational status;

Abbreviations: DMSES, Diabetes Management Self-Efficacy Scale; PHQ-9, Patient Health Questionnaire; PAID-5, the Problem Areas in Diabetes-Short Form; WHO-5, Well-Being Index.
* 6 missing values; † 7 missing values; ‡ 3 missing values; § 6 missing values.

TABLES AND FIGURES

Table 3. Factor loadings of the two factors extracted using principal component analysis with promax rotation.

	Factor 1 ***Disease Management***	**Factor 2** ***Lifestyle Management***
DM1- Check my blood sugar where necessary	**.747**	
DM2 - Correct my blood sugar when the sugar level is too high	**.731**	
DM3 - Correct my blood sugar when the blood sugar level is too low	**.789**	
DM4 - Choose the correct foods		**.714**
DM5 - Keep my weight under control		**.732**
DM6 - Examine my feet for cuts	**.415**	.322
DM7 - Adjust my eating plan when ill	.359	**.444**
DM8 - Follow a healthy eating pattern most of the time		**.826**
DM9 - Take more exercise if the doctor advises me to		**.753**
DM10 - When taking more exercise I am able to adjust my eating plan		**.573**
DM11 - Follow a healthy eating pattern when I am away from home		**.865**
DM12 - Follow a healthy eating pattern when I am eating out or at a party		**.844**
DM13 - Adjust my eating plan when I am feeling stressed or anxious		**.638**
DM14 - Take my medication as prescribed	**.814**	
DM15 - Adjust my medication when I am ill	**.870**	

TABLES AND FIGURES

Table 4. Weights of the all items for the IT-DMSES scoring.

	Components	
	Lifestyle	***Disease***
DM1	-.006	.211
DM2	.024	.206
DM3	.006	.222
DM4	.146	.025
DM5	.151	-.021
DM6	.064	.116
DM7	.090	.099
DM8	.170	-.004
DM9	.155	-.019
DM10	.117	.046
DM11	.179	-.045
DM12	.174	-.047
DM13	.131	.035
DM14	-.031	.230
DM15	-.040	.246

TABLES AND FIGURES

Table 5. Socio-demographic and clinical characteristics of study participants (N=411).

	type 1 (n=105)	type 2 (n=306)	Comparison between type 1 and 2 diabetes Test, p
Female (%)	49.5	37.2	4.89 (0.027)^
Age (mean ± SD)	45.1±17.4	65.1±9.5	-14.80 (<0.001)†
Employed (%)	62.9	26.9	43.55 (<0.001)^
BMI (mean ± SD)	24.4±3.7	30.3±5.6	-9.78 (<0.001)†
HbA1c mmol/mol (mean ± SD)	59.1±10.6	58.6±13.7	0.36 (0.720)†
HbA1c % (mean ± SD)	7.6±1.0	7.5±1.2	0.35 (0.723)†
Education (%)			54.70 (<0.001)^
Elementary school	7.6	26.3	
Middle school	14.3	36.2	
High school	46.7	26.3	
College and above	31.4	11.2	
Duration of diabetes diagnosis (%)			25.08 (<0.001)^
<1 year	1.9	4.6	
1-15 years	28.6	54.1	
>15 years	69.5	41.2	
Living condition (%)			24.68 (<0.001)^
Alone	17.1	14.7	
With a spouse/partner	58.1	70.3	
With parents	20.9	5.6	
Other/unknown	3.8	9.5	
Treatment regimen (%)			
Diet/exercise only	0.0	3.6	3.88 (0.049)^
Oral hypoglycemic agent	0.0	42.2	64.51 (<0.001)^
Insulin	93.3	10.5	248.29 (<0.001)^
Oral hypoglycemic agent + insulin	6.7	43.8	47.81 (<0.001)^
Co-morbidities (%)			
Thyroid disease	14.3	17.5	0.58 (0.447)^
Hypertension	18.1	71.0	89.54 (<0.001)^
Dyslipidemia	11.4	58.5	69.62 (<0.001)^
Ischemic heart disease	9.5	25.7	12.03 (0.001)^
Complications (%)			
Kidney disease	4.8	14.5	6.98 (0.008)^
Eye damage	40.0	23.4	10.81 (0.001)^
Neurological disease	14.3	13.2	0.08 (0.770)^
Foot complications	7.6	3.9	5.26 (0.072)^
Peripheral circulatory complications	3.8	6.6	1.07 (0.301)^

† t-test; ^ chi-square

TABLES AND FIGURES

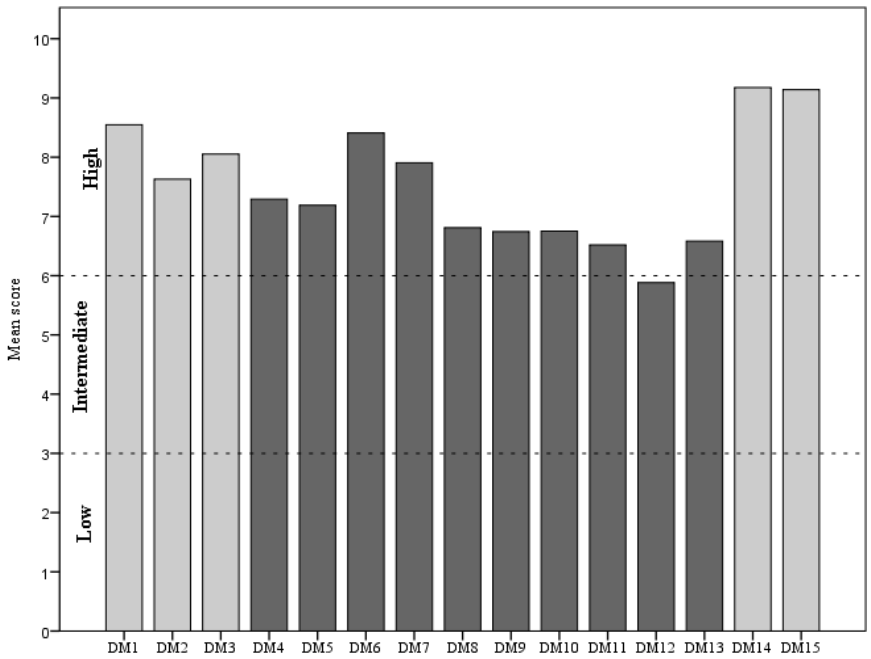
Table 6. Gender differences in type 1 and type 2 diabetes (n=411 patients).

	Males Type 2 Diabetes (n=192)	Females Type 2 Diabetes (n=114)	Comparison Test, p	Males Type 1 Diabetes (n=53)	Females Type 1 Diabetes (n=52)	Comparison Test, p
Age (mean ± SD)	65.6±9.2	64.4±9.9	1.13 (0.259)†	43.7±18.0	46.5±16.8	-0.82 (0.411)†
Employed (%)	25.9	28.6	0.25 (0.617)^	67.9	57.7	1.18 (0.278)^
BMI (mean ± SD)	30.3±5.2	30.4±6.7	-0.21(0.833)†	25.0±3.3	23.8±4.0	1.68 (0.096)†
HbA1c mmol/mol (mean ± SD)	58.0±12.5	59.6±15.6	-1.02 (0.309)†	55.5±10.2	62.7±9.7	-3.69(<0.001)†
HbA1c % (mean ± SD)	7.4±1.1	7.6±1.4	-1.01 (0.314)†	7.2±0.9	7.9±0.9	-3.66 (<0.001)†
Education (%)			3.59 (0.309)^			3.58 (0.311)^
Elementary school	24.1	30.1		5.7	9.6	
Middle school	35.1	38.0		17.0	11.5	
High school	29.8	20.3		52.8	40.4	
College and above	11.0	11.5		24.5	38.5	
Duration of diabetes (%)			0.90 (0.635)^			2.00 (0.367)^
<1 year	5.3	3.5		3.8	0.0	
1-15 years	55.2	52.6		28.3	28.8	
>15 years	39.6	43.9		67.9	71.1	
Living condition (%)			0.83 (0.842)^			1.90 (0.594)^
Alone	14.6	14.9		20.7	13.5	
With a spouse/partner	71.3	68.4		56.6	59.6	
With parents	5.7	5.3		20.7	21.1	
Other	8.3	11.4		1.9	5.8	
Treatment regimen (%)						
Diet/exercise	5.2	0.9	3.87 (0.050)^	0.0	0.0	
Oral hypo.	38.5	48.2	2.76 (0.100)^	0.0	0.0	
Oral hypo. + Insulin	42.2	46.5	0.54 (0.463)^	5.7	7.7	0.17 (0.676)^
Insulin	14.1	4.4	7.15 (0.007)^	94.3	92.3	0.17 (0.676)^
Co-morbidities (%)						
Thyroid disease	11.6	27.2	11.92(0.001)^	5.7	23.1	6.50 (0.011)^
Hypertension	72.1	69.3	0.27 (0.601)^	20.7	15.4	0.51 (0.475)^
Dyslipidemia	64.1	49.1	6.57 (0.010)^	9.4	13.5	0.42 (0.517)^
Ischemic heart disease	33.7	12.3	17.11(<0.001)^	7.5	11.5	0.48 (0.486)^
Complications (%)						
Kidney disease	18.9	7.0	8.19 (0.004)^	5.7	3.8	0.19 (0.663)^
Eye damage	22.6	24.6	0.15 (0.700)^	39.6	40.4	0.01 (0.936)^
Neurological dis.	16.8	7.0	6.01 (0.015)^	15.1	13.5	0.06 (0.811)^
Foot	4.7	2.6	0.82 (0.370)^	9.4	5.8	1.53 (0.465)^
Periph. circulatory	9.4	1.8	6.71 (0.010)^	1.9	5.8	1.08 (0.299)^

^ Chi-square test; † T-test

TABLES AND FIGURES

Figure 1. IT-DMSES items scores. All items indicate high level of diabetes management self-efficacy except for item 12 ‘follow a healthy eating pattern when I am eating out or at a party’.



TABLES AND FIGURES

Figure 2. Network of self-efficacy IT-DMSES items for type 1 (on the left) and type 2 diabetes (on the right) and centrality indices (panel C: red line= type 1 diabetes; blue line= type 2 diabetes).

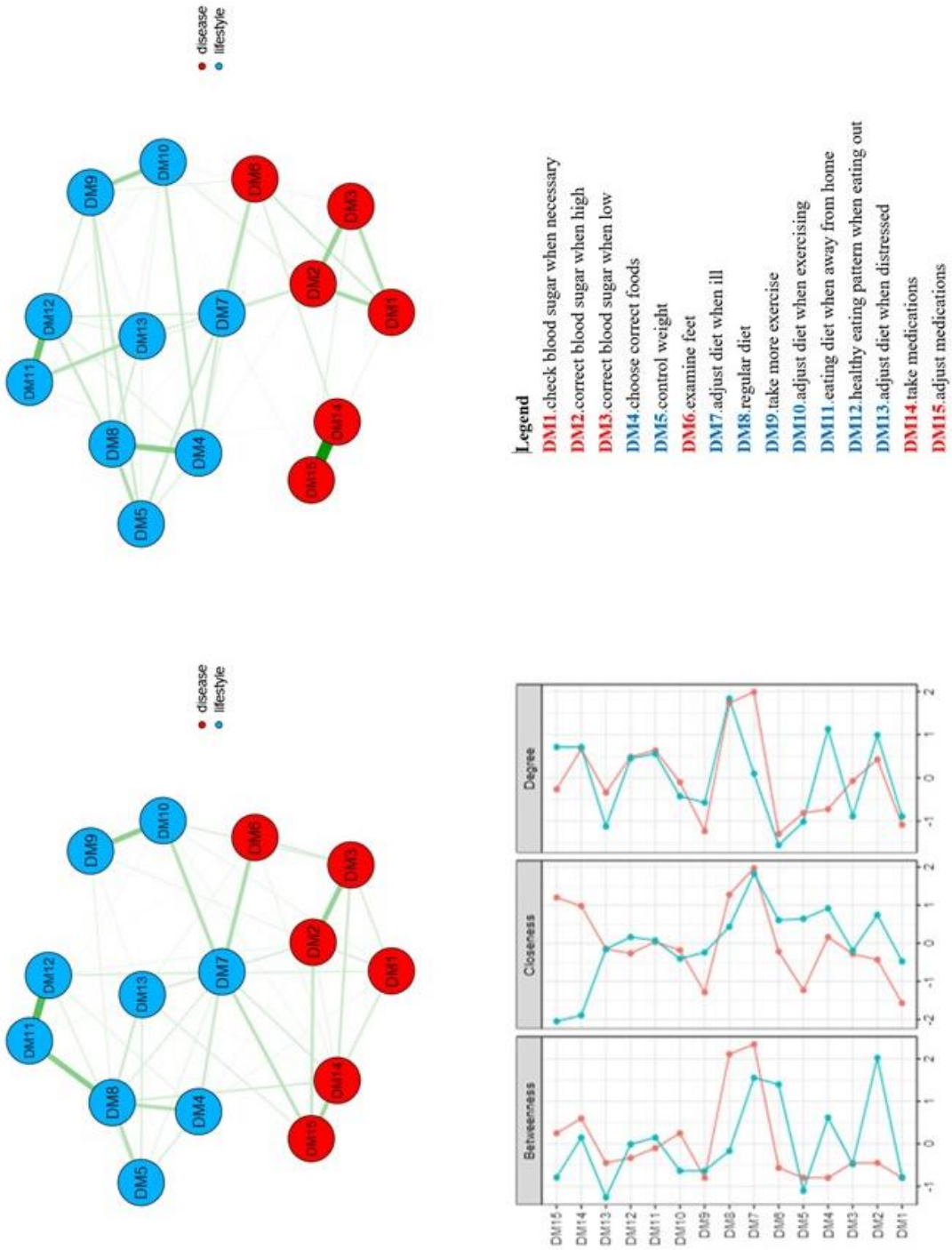
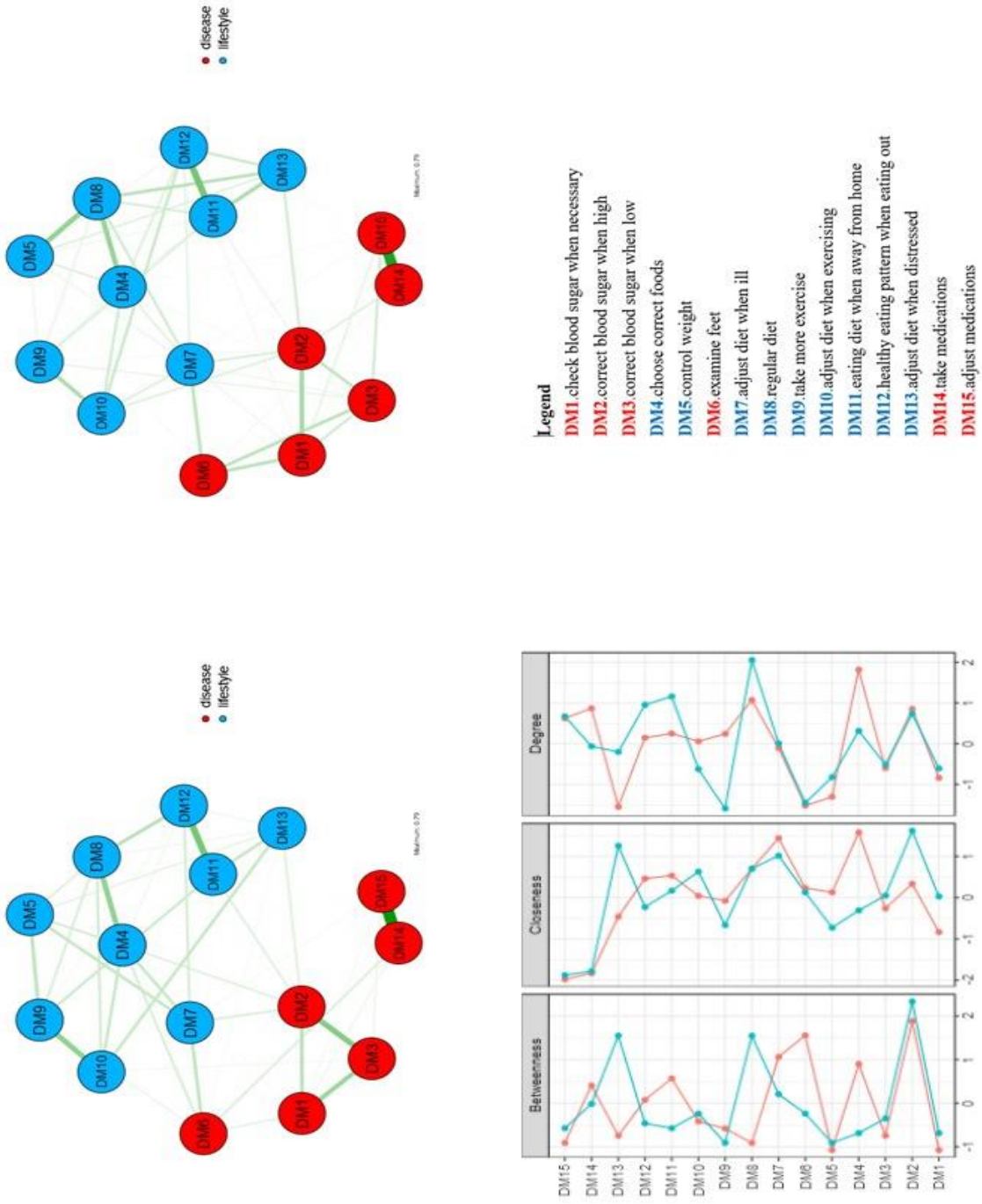
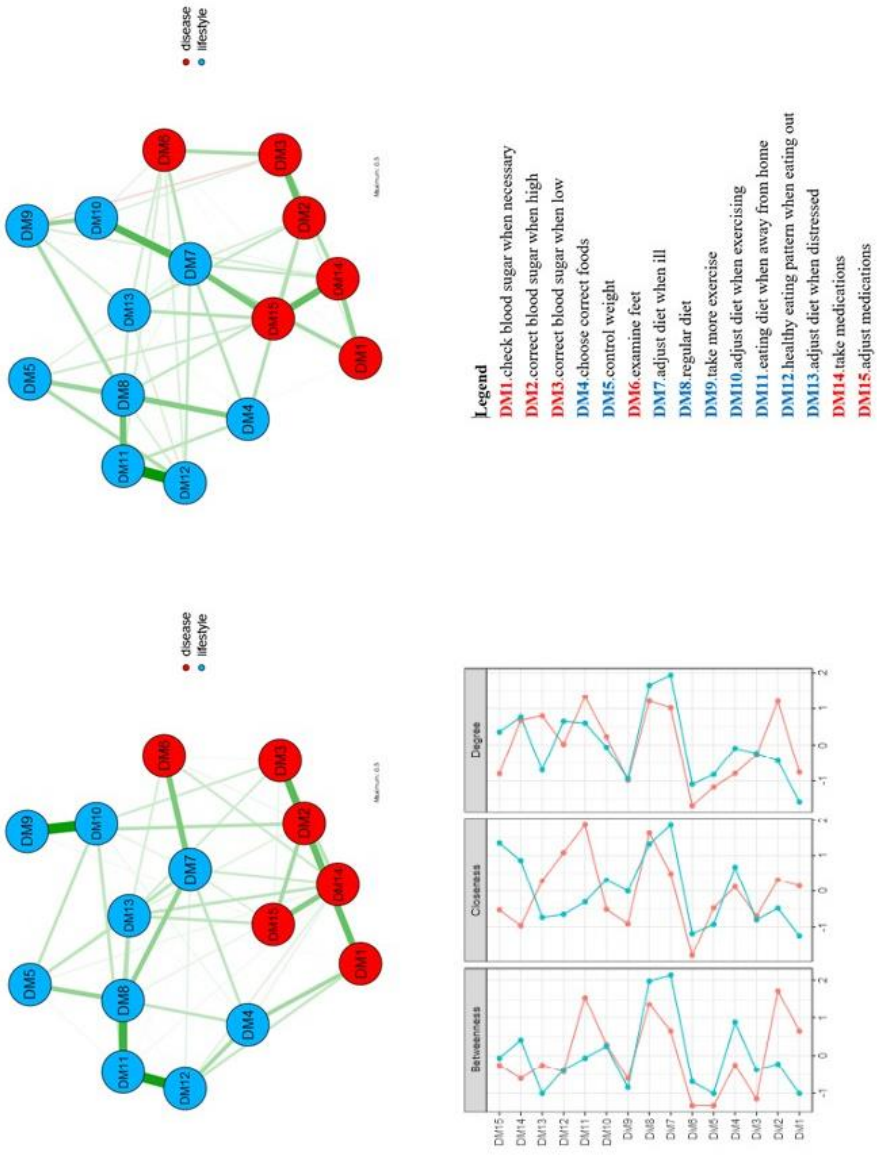


Figure 3. Network of self-efficacy IT-DMSES items for males (on the left) and females (on the right) in type 2 diabetes and centrality indices (blue line=females; red line=males).



TABLES AND FIGURES

Supplementary Figure 1. Network of self-efficacy IT-DMSES items for females (on the left) and males (on the right) in type 1 diabetes and centrality indices (blue line=females; red line=males).



SUPPLEMENTARY MATERIALS

Supplementary material 1. DMSES-UK

Self-Efficacy (or confidence) Questionnaire for people living with type 2 diabetes.

Directions
Below is a list of activities you have to perform to manage your diabetes. Please read each one and then put a line [/] through the number which best describes how **confident** you usually are that you could carry out that activity.
For example, if you are completely confident that you are able to check your blood sugar levels when nessessary, put a line through 10. If you feel that most of the time you could not do it, put a line through 1 or 2.

I am confident that …

	Cannot do At all				Maybe yes Maybe no						Certain can do
1	I am able to check my blood sugar if necessary										
	0	1	2	3	4	5	6	7	8	9	10
2	I am able to correct my blood sugar when the sugar level is too high										
	0	1	2	3	4	5	6	7	8	9	10
3	I am able to correct my blood sugar when the blood sugar level is too low										
	0	1	2	3	4	5	6	7	8	9	10
4	I am able to choose the correct foods										
	0	1	2	3	4	5	6	7	8	9	10
5	I am able to keep my weight under control										
	0	1	2	3	4	5	6	7	8	9	10
6	I am able to examine my feet for cuts										
	0	1	2	3	4	5	6	7	8	9	10
7	I am able to adjust my eating plan when ill										
	0	1	2	3	4	5	6	7	8	9	10

I am confident that …

8	I am able to follow a healthy eating pattern most of the time										
	0	1	2	3	4	5	6	7	8	9	10
9	I am able to take more exercise if the doctor advises me to										
	0	1	2	3	4	5	6	7	8	9	10
10	When taking more exercise I am able to adjust my eating plan										
	0	1	2	3	4	5	6	7	8	9	10
11	I am able to follow a healthy eating pattern when I am away from home										
	0	1	2	3	4	5	6	7	8	9	10
12	I am able to follow a healthy eating pattern when I am eating out or at a party										
	0	1	2	3	4	5	6	7	8	9	10
13	I am able to adjust my eating plan when I am feeling stressed or anxious										
	0	1	2	3	4	5	6	7	8	9	10
14	I am able to take my medication as prescribed										
	0	1	2	3	4	5	6	7	8	9	10
15	I am able to adjust my medication when I am ill										
	0	1	2	3	4	5	6	7	8	9	10

Sturt J, Hearnshaw H & Wakelin M. *Validity and reliability of the DMSES UK: a measure of self-efficacy for type 2 diabetes self-management.* Primary Health Care Research and Development. 2010;11:374–381.

SUPPLEMENTARY MATERIALS

Supplementary material 2. IT-DMSES

Scala di valutazione dell'autoefficacia nella gestione del diabete
IT-DMSES
(Messina R., et al. 2018)

Istruzioni:
Sotto sono indicate una serie di attività da mettere in atto per gestire il diabete. Segni con una **X** il numero che meglio descrive quanto lei ritiene di essere in grado di fare queste attività su una scala da 0 a 10. Per esempio, se crede di essere completamente capace di controllare la glicemia quando necessario, metta una X sul numero 10.

Quanto ritiene di essere in grado di …

Non sono in grado					Sono abbastanza in grado					Sono completamente in grado
1. Misurare la sua glicemia quando necessario										
0	1	2	3	4	5	6	7	8	9	10
2. Intervenire sulla sua glicemia quando è troppo alta (ad esempio mangiando cibi differenti)										
0	1	2	3	4	5	6	7	8	9	10
3. Intervenire sulla sua glicemia quando è troppo bassa (ad esempio mangiando cibi differenti)										
0	1	2	3	4	5	6	7	8	9	10
4. Scegliere gli alimenti corretti per la sua salute										
0	1	2	3	4	5	6	7	8	9	10
5. Tenere sotto controllo il suo peso										
0	1	2	3	4	5	6	7	8	9	10
6. Esaminare i suoi piedi (ad esempio verificare la presenza di lesioni o ulcere)										
0	1	2	3	4	5	6	7	8	9	10
7. Correggere la sua alimentazione quando è malato										
0	1	2	3	4	5	6	7	8	9	10

Quanto ritiene di essere in grado di …

Non sono in grado					Sono abbastanza in grado					Sono completamente in grado
8. Seguire solitamente una corretta alimentazione										
0	1	2	3	4	5	6	7	8	9	10
9. Fare più esercizio fisico se il medico glielo suggerisce										
0	1	2	3	4	5	6	7	8	9	10
10. Modificare la sua alimentazione se svolge più attività fisica del solito										
0	1	2	3	4	5	6	7	8	9	10
11. Seguire un'alimentazione sana anche quando è fuori casa										
0	1	2	3	4	5	6	7	8	9	10
12. Seguire un'alimentazione sana quando mangia fuori (ad esempio quando mangia al ristorante o ad una festa)										
0	1	2	3	4	5	6	7	8	9	10
13. Mantenere il piano alimentare quando si sente stressato o ansioso										
0	1	2	3	4	5	6	7	8	9	10
14. Assumere la terapia come da prescrizione medica										
0	1	2	3	4	5	6	7	8	9	10
15. Mantenere la sua terapia anche quando è malato										
0	1	2	3	4	5	6	7	8	9	10

Messina, R., Rucci, P., Sturt, J., Mancini, T., Fantini, M.P. *Assessing self-efficacy in type 2 diabetes management: Validation of the Italian version of the Diabetes Management Self-Efficacy Scale (IT-DMSES)*. Health and Quality of Life Outcomes. 2018; 16(1):71. doi: 10.1186/s12955-018-0901-3.

Rucci, P., Messina, R.*, Ubiali, A., Rochira, A., van der Bijl, J., Mancini, T., Fantini, M.P., Pagotto, U. *Does self-efficacy in diabetes management differ by type of diabetes and gender? Results from network analysis*. Journal of Health Psychology. 2018; Article in Press. doi: 10.1177/1359105318804866.

SUPPLEMENTARY MATERIALS

Supplementary material 3. PAID-5

Istruzioni: Quale dei seguenti problemi legati al diabete sono attualmente un problema per lei?

Cerchi il numero che corrisponde alla risposta migliore per lei. Si prega di fornire una risposta per ogni domanda.

Aree problematiche nel diabete (PAID-5)

	Non è un problema	**E' un problema minore**	**E' un problema moderato**	**E' un problema abbastanza serio**	**E' un problema serio**
Avere paura quando pensa di dover vivere con il diabete	0	1	2	3	4
Sentirsi depresso quando pensa di dover vivere con il diabete	0	1	2	3	4
Essere preoccupato per il futuro e per la presenza di complicanze serie	0	1	2	3	4
Sentire che il diabete assorbe ogni giorno troppe energie mentali e fisiche	0	1	2	3	4
Far fronte alle complicanze del diabete	0	1	2	3	4

Nicolucci A, Rossi MC, Pellegrini F, et al. *Benchmarking network for clinical and humanistic outcomes in diabetes (BENCHD) study: protocol, tools, and population.* SpringerPlus. 2014; 3:1-9.

SUPPLEMENTARY MATERIALS

Supplementary material 4. WHO-5

Istruzioni: Nelle ultime due settimane come si è sentito?

Cerchi il numero che corrisponde alla risposta migliore per lei. Si prega di fornire una risposta per ogni domanda.

Indice di benessere (WHO-5)

Nelle ultime due settimane	**Sempre**	**La maggior parte del tempo**	**Più della metà del tempo**	**Meno della metà del tempo**	**A volte**	**Mai**
Mi sono sentito allegro e di buon umore	5	4	3	2	1	0
Mi sono sentito calmo e rilassato	5	4	3	2	1	0
Mi sono sentito attivo ed energico	5	4	3	2	1	0
Mi sono svegliato sentendomi fresco e riposato	5	4	3	2	1	0
La mia vita di tutti i giorni è stata piena di cose che mi interessano	5	4	3	2	1	0

Bech P, Gudex C, Johansen KS. *The WHO (Ten) Well-Being Index: validation in diabetes*. Psychother Psychosom. 1996; 65:183–90.

SUPPLEMENTARY MATERIALS

Supplementary material 5. PHQ-9

QUESTIONARIO DELLA SALUTE - PHQ-9

Il presente questionario è importante perché ci consente di fornirLe la miglior assistenza possibile. Le Sue risposte ci aiuteranno a capire i problemi che Lei può avere. La preghiamo, perciò, di rispondere con la massima precisione possibile.

1. Durante le ultime due settimane, con quale frequenza è stato disturbato da qualcuno dei seguenti problemi?	Mai	Molti giorni	Più della metà dei giorni	Quasi tutti i giorni
a. Scarso interesse o piacere nel fare le cose	0	1	2	3
b. Sentirsi giù, depresso o disperato	0	1	2	3
c. Difficoltà ad addormentarsi o mantenere il sonno, o dormire troppo	0	1	2	3
d. Sentirsi stanco o avere poca energia	0	1	2	3
e. Scarso appetito o mangiare troppo	0	1	2	3
f. Sentirsi in colpa o di essere un fallito o di aver danneggiato se stesso o la sua famiglia	0	1	2	3
g. Difficoltà a concentrarsi sulle cose, come leggere il giornale o guardare la televisione	0	1	2	3
h. Muoversi o parlare così lentamente tanto che anche gli altri se ne accorgevano o, al contrario, essere così irrequieto o agitato da doversi muovere da ogni parte molto più del solito	0	1	2	3
i. Pensare che sarebbe meglio essere morto o di farsi del male in qualche modo	0	1	2	3

2. Se ha riscontrato la presenza di qualcuno dei problemi indicati nel presente questionario, in che misura quei problemi le hanno creato difficoltà nel suo lavoro, nel prendersi cura delle cose a casa o nello stare insieme agli altri?

Nessuna difficoltà	Qualche difficoltà	Notevole difficoltà	Estrema Difficoltà
☐	☐	☐	☐

Mazzotti E, Fassone G, Pasquini P. *The patient health questionnaire (PHQ) for the screening of psychiatric disorders: a validation study versus the structured clinical interview for DSM-IV axis I (SCID-I).* Ital J Psychopathol. 2003; 9:235–42.