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Patient self-care and caregiver contribution to self-care in type 2 diabetes mellitus: exploring the association with glycemic control and identifying dyadic patterns of care

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TABLE OF CONTENTS

Abstract

This thesis is focused on patient self-care and caregiver contribution to self-care as key elements in type 2 diabetes mellitus management.

The uncovered association between patient self-care and glycemic control suggested to deeper investigate the phenomenon of diabetes management, not only from the patient point of view but also considering the role of the main informal caregiver. Accounting for the interdependence between behaviors performed by patients and caregivers, a dyadic approach was used to jointly consider patient self-care and caregiver contribution to it. Furthermore, to comprehensively describe the dyadic engagement in type 2 diabetes care, three distinct and unobserved dyadic patterns were identified according to dyadic average (i.e., how patient and caregiver do together) and incongruence (i.e., the magnitude and direction of the gap between the two members of the dyad) of each dyad. To get these results, multilevel models and a latent class analysis were performed, respectively. Moreover, the characteristics of each pattern and their association with glycemic control were investigated. Lastly, a methodological exploration of an alternative way to deal with dyadic data to be used to identify patterns of dyadic engagement in illness care was conducted. Interestingly, using simpler observed measures (i.e., mean and difference between dyad members) instead of coefficients predicted by multilevel models as input variables for the latent class analysis yielded the same patterns as the other approach.

Overall, this thesis may provide useful suggestions to healthcare professionals and offer a starting point for further dyadic research in type 2 diabetes.

CHAPTHER 1

Ph.D. project overview

1.1 Background

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by high levels of blood glucose, insulin resistance, and impaired insulin secretion by pancreatic β-cells (American Diabetes Association, 2023d; Galicia-Garcia et al., 2020). T2DM has a complex and multifactorial etiology, with numerous risk factors, including age, ethnicity, family history, obesity, physical inactivity, and poor diet (Chatterjee et al., 2017).

The prevalence of T2DM has been increasing globally (Zhou et al., 2016), affecting over 90% of the 460 million adults worldwide who have been diagnosed with diabetes. This number is projected to rise to 700 million by 2045 (International Diabetes Federation, 2021). Moreover, T2DM typically has a prolonged pre-diagnostic period, meaning that between one-third and one-half of the individuals with T2DM in the population may be undiagnosed (International Diabetes Federation, 2021).

The impact of T2DM on patients' health, as the sixth leading cause of disability in 2015, is significant (Vos et al., 2016). Indeed, the incidence of T2DM complications such as cardiovascular disease, stroke, neuropathy, retinopathy, and kidney disease is very high, especially in the first five years after diagnosis (An et al., 2021; Sarwar et al., 2010). Consequentially, compared to individuals without diabetes, patients with T2DM have a 15% higher risk of all-cause mortality (Galicia-Garcia et al., 2020).

Addressing the problem of T2DM requires a comprehensive public health approach that includes primary prevention, early detection, and management of the disease (Chatterjee et al., 2017). Strategies for primary prevention of T2DM include lifestyle modifications such as a healthy diet, regular physical activity, and weight management (American Diabetes Association, 2023c; Green et al., 2012). Early detection of T2DM mostly consists of assessing risk factors and then laboratory testing on high-risk individuals (American Diabetes Association, 2023a). T2DM management requires

access to high-quality healthcare services (American Diabetes Association, 2023b) and ongoing support for self-care (American Diabetes Association, 2023e).

Indeed, self-care plays a crucial role in managing all chronic conditions (Luciani et al., 2022), where individuals are required to continuously implement complex behaviors and actions, as well as make difficult decisions lifelong (Riegel et al., 2012). Likewise, the support to self-care by healthcare providers gives patients with T2DM knowledge and skills, enabling them to adequately manage their disease (Powers et al., 2016). According to the Middle-Range Theory of Self-Care of Chronic Illness, self-care is defined as "a process of maintaining health through health promoting practices and managing illness" (Riegel et al., 2012). Self-care maintenance, self-care monitoring, and self-care management are the core concepts of the self-care process (Riegel et al., 2012, 2019). Self-care maintenance includes behaviors to maintain physical and emotional stability. Self-care monitoring concerns behaviors aimed at recognizing signs and symptoms in the body. Self-care management comprises behaviors employed in response to signs and symptoms. In diabetes, self-care means for example adherence to diet, medications, and physical activity recommendations (self-care maintenance), monitoring blood glucose, body weight, feet, and symptoms of hypo- or hyperglycemia (self-care monitoring), and managing episodes of hypo- and hyperglycemia (self-care management) (Ausili et al., 2017; Riegel et al., 2012, 2019).

Although the association between self-care behaviors and glycemic control has been widely demonstrated (American Diabetes Association, 2023e; Carpenter et al., 2019; Chatterjee et al., 2016; Lu et al., 2016; Modarresi et al., 2020; Powers et al., 2016; Tshiananga et al., 2012), previous studies mostly considered just one or some specific self-care behaviors (e.g. exercise, diet, adherence to medication). In this way, the dynamic and complexity of self-care as a process were never taken into account while studying its relationship with glycemic control. Furthermore, the association between self-care

maintenance, self-care monitoring, and self-care management and glycemic control as measured by glycated hemoglobin (HbA1c) was never assessed before.

However, performing recommended self-care behaviors can be struggling for patients (Bouldin et al., 2017; Riegel et al., 2012) for several reasons, such as a high number of medications, patient cognitive impairment, low income, and depression (De Maria et al., 2023a). Indeed, poor glycemic control is very common in people with T2DM (Afroz et al., 2019; Cedrick et al., 2021; Chetoui et al., 2020; Fiseha et al., 2018). The presence of an informal caregiver, namely a family member or a significant other providing unpaid help (Vellone et al., 2019), can support patients with chronic conditions in performing complex self-care behaviors (Chen et al., 2017; De Maria et al., 2021; Hooker et al., 2018). In fact, the caregiver contribution to patient self-care consists of the assistance provided to patients in managing their health condition (Bouldin et al., 2017; Vellone et al., 2019, 2020), even performing behaviors in their place when patients are not independent (Pressler et al., 2013). In chronic conditions, the caregiver contribution comprises for example emotional support, personal and clinical care, (Buck et al., 2015; Clark et al., 2008), health promotion, symptom monitoring, and decision-making (Chen et al., 2017). Significantly, previous studies in the field of chronic illnesses have shown that caregivers have a key role in improving patients' clinical outcomes (Bouldin et al., 2017; Trivedi et al., 2012).

The Theory of Dyadic Illness Management (K. Lyons & Lee, 2018) highlights that patient self-care and caregiver contribution to patient self-care in chronic illnesses should be considered as a dyadic phenomenon, in which both members of the patient-caregiver dyad mutually influence each other (De Maria et al., 2021; Iovino et al., 2021; Lee et al., 2015; Vellone et al., 2020). In T2DM, there is a lack of studies using a dyadic approach in assessing patient self-care and caregiver contribution to it. Furthermore, previous studies in heart failure (Lee et al., 2015) and multiple chronic conditions (De

Maria et al., 2023a) identified distinct patterns of dyadic engagement in illness care, with different levels of engagement performed both within and between each dyadic pattern. Identifying patterns of dyadic engagement in illness care permit to estimate the probability of poor dyadic illness management based on specific socio-demographic and clinical characteristics of both the patient and caregiver (Lee et al., 2015). Moreover, different dyadic patterns could be associated with different clinical outcomes, suggesting for example to lend more support to patients and caregivers belonging to a certain dyadic pattern (De Maria et al., 2023a). However, it seems that no previous studies have identified dyadic patterns of engagement in T2DM care based on patient self-care and caregiver contribution to it, using valid, reliable, and theoretically grounded tools, specifically developed for diabetes. Furthermore, no studies have investigated how glycemic control, as measured by HbA1c, is associated with the combination of patient self-care and caregiver contribution to it in T2DM.

In order to identify unobserved patterns of dyadic engagement in chronic illness care, the most common approach to dyadic data analysis is the implementation of mixed effects models (MM) (K. S. Lyons & Lee, 2020; Sayer & Klute, 2005), whose estimated coefficients are then used as input variables to perform a latent class analysis (LCA) (Bonds et al., 2021; De Maria et al., 2023b; Lee et al., 2015; Lee & Lyons, 2019). However, there is no evidence that the use of MM for this purpose is advantageous over simpler synthetic dyadic measures. The comparison of diverse approaches to obtain dyadic measures could encompass an evaluation of the respective limitations and strengths, providing useful insights for future research.

1.2 Aims

Considering the described background, the aims of this Ph.D. project are:

1. to investigate the association between self-care maintenance, self-care monitoring, and self-care management and HbA1c in patients with T2DM;
2. to identify distinct patterns of dyadic engagement in T2DM care and their characteristics;
3. to assess the association between patterns of dyadic engagement in T2DM care and HbA1c;
4. to compare different statistical methods of dyadic data analysis, to be used to identify unobserved dyadic patterns of engagement in T2DM care.

For aim 1, the candidate conducted a secondary analysis of a previous study in which she actively participated in data collection, performed statistical analysis, led the critical interpretation of the results, and the manuscript writing. For the other aims, the candidate consistently participated in the design and implementation of a multicenter observational study. She coordinated data collection, monitored data entry, performed statistical data analyses, led the critical interpretation of the results, and the manuscript writing.

1.3 Structure of the thesis

This Ph.D. thesis mainly consists of five chapters that follow a logical path, consistent with what has been illustrated above.

Chapter 2 addresses the relationship between self-care behaviors identifiable as self-care maintenance, self-care monitoring, and self-care management and HbA1c.

Chapter 3 faces the identification of distinct patterns of dyadic engagement in T2DM care and their characteristics, including the association with HbA1c.

Chapter 4 deals with comparing two different statistical approaches to measure dyadic T2DM management, to be used to classify dyads into patterns of dyadic engagement in T2DM care.

Chapter 5 highlights the overall conclusions of the project and suggests future perspectives.

Additionally, Chapter 6 reports a brief overview of the main projects in which the candidate participated concurrently. Lastly, the Appendix contains the core measurement tools used in the studies.

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CHAPTHER 2

How do self-care maintenance, self-care monitoring, and self-care management affect glycated hemoglobin in adults with type 2 diabetes? A multicenter observational study

Title

How do self-care maintenance, self-care monitoring, and self-care management affect glycated hemoglobin in adults with type 2 diabetes? A multicenter observational study

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2.1 Abstract

Purpose. To evaluate how self-care maintenance, self-care monitoring, and self-care management affect glycated hemoglobin in patients with type 2 diabetes mellitus and to set cut-off points of the Self-Care of Diabetes Inventory scales using glycated hemoglobin as outcome of interest.

Methods. A secondary analysis of a previous multicenter observational cross-sectional study was conducted. Overall, 540 adults with type 2 diabetes mellitus confirmed diagnosis were involved. Socio-demographic and clinical data were collected. Self-care maintenance, self-care monitoring, and self-care management were measured by the Self-Care of Diabetes Inventory. Linear regression models were performed to assess the relationship between self-care maintenance, self-care monitoring, and self-care management and glycated hemoglobin. Receiver operating characteristics curves were carried out to identify the best cut-off score for each self-care scale considering glycated hemoglobin >7% as outcome of interest.

Results. Self-care monitoring and self-care management were associated to glycated hemoglobin both in patients without (self-care monitoring p= 0.0008; self-care management p= 0.0178) and with insulin therapy (self-care monitoring p= 0.0007; self-care management p=- 0.0224). Self-care maintenance was associated to glycated hemoglobin in patients without insulin therapy (p= 0.0118). Cut-off scores providing the best performance were 70 points for self-care maintenance and self-care monitoring, and 60 points for self-care management.

Conclusion. Self-care maintenance, self-care monitoring and self-care management differently affect glycated hemoglobin in patients with type 2 diabetes mellitus. Clinicians could implement tailored interventions to improve glycemic control considering the lacking area of self-care.

2.2 Introduction

Diabetes is one of the most relevant public health challenges (Chen et al., 2011; Zhou et al., 2016), affecting 463 million people worldwide (International Diabetes Federation, 2019)[1]. Type 2 diabetes mellitus (T2DM) accounts for more than 90% of diabetes cases (Chatterjee et al., 2017). T2DM is associated with higher rate of cardiovascular disease (World Health Organization, 2016) and leads to serious microvascular and macrovascular complications (American Association of Diabetes Educators, 2009; Fowler, 2008; International Diabetes Federation, 2019). These cause blindness, lower limb amputation, kidney failure, and further disabling consequences, significantly compromising the quality of life, or leading to premature death (Jaacks et al., 2016; Tabesh et al., 2018; Visaria et al., 2019; World Health Organization, 2016). Many of these complications can be prevented by performing adequate self-care behaviors (Powers et al., 2016; Song, 2010).

Self-care was defined as "a process of maintaining health through health-promoting practices and managing illness" (Riegel et al., 2012, 2019). Self-care includes self-care maintenance, self-care monitoring, and self-care management. Self-care maintenance comprises those behaviors aimed at maintaining physical and emotional stability. In diabetes, it means for example adherence to medications, diet, and physical activity recommendations. Self-care monitoring includes behaviors to monitor changes in the body and recognise signs and symptoms. In diabetes, it comprises blood glucose and blood pressure monitoring, and symptoms of hypo- or hyperglycemia recognition. Self-care management is the process of responding to those changes when they occur. In diabetes, this is for example to manage episodes of hypo- or hyperglycemia (Ausili et al., 2017; Riegel et al., 2012, 2019). Self-care in diabetes is associated with improved glycemic control (American Association of Diabetes Educators, 2009; Powers et al.,

[1] The epidemiological data refer to the information available at the time of article submission.

2016; Tshiananga et al., 2012). Glycated hemoglobin (HbA1c) is the main indicator of long-term glycemic control because it is able to reflect the cumulative glycemic trend of the last two-to-three months (American Diabetes Association, 2019b; Sherwani et al., 2016). Higher HbA1c was associated with higher risk of diabetes complications, coronary heart disease, and stroke (Sherwani et al., 2016). Reduction in HbA1c levels was associated with a decrease in the risk of microvascular complications and diabetes mortality (Schnell et al., 2013).

Several studies assessed the association between one or more specific self-care behaviors (i.e. exercise, diet, foot care, adherence to medication) and HbA1c (American Association of Diabetes Educators, 2009; American Diabetes Association, 2019a; Caro-Bautista et al., 2014; Carpenter et al., 2019; Deakin et al., 2005; Lu et al., 2016; Powers et al., 2016; Tshiananga et al., 2012). However, the dynamic and complexity of self-care as a process were never taken into account while studying the relationship between self-care and glycemic control. Furthermore, the association between self-care maintenance, self-care monitoring, and self-care management and HbA1c was never assessed before. Having this knowledge could be relevant for several reasons. First, it could help clinicians in identifying patients at risk of poor glycemic control, according to their self-care levels. Second, it could allow to personalize interventions to improve self-care and glycemic control: self-care maintenance, for example, requires motivation while self-care monitoring and self-care management require skills and problem-solving abilities respectively (Riegel et al., 2012). Third, it could deepen the overall understanding of the phenomenon of self-care and its relationship with T2DM patients' clinical outcomes.

The primary objective of this study was to assess the associations between self-care maintenance, self-care monitoring, and self-care management and HbA1c in T2DM patients. To do so, the Self-Care of Diabetes Inventory (SCODI) has been used because it was specifically developed to measure these three concepts (Ausili et al., 2017). It was

also shown to be a psychometrically sound tool to measure self-care in the T2DM population (Ausili et al., 2018, 2019). However, cut-off scores defining adequate or inadequate self-care of the SCODI scales by objective external criteria have not been defined yet. Thus, the secondary aim of this study was to estimate cut-off scores of self-care maintenance, self-care monitoring and self-care management scales using HbA1c as the outcome of interest.

2.3 Methods

This study is a secondary analysis of a previous multicenter observational cross-sectional study (Ausili et al., 2018). No further data have been collected for this study. Ethical approval was obtained by the Institutional Review Boards of participating centres. Signed informed consent was obtained from all study participants. Study procedures were conducted according to the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Declaration of Helsinki (World Medical Association, 2013).

Sample

A consecutive sample of 540 T2DM patients was recruited in six outpatient diabetes clinics in the North of Italy during outpatient visits, as described in the parent study (Ausili et al., 2018). Briefly, inclusion criteria were: confirmed diagnosis of T2DM according to guidelines criteria (American Diabetes Association, 2016) and age ≥18 years. Exclusion criteria were: first visit to the diabetes centre; time since the diagnosis of diabetes less than 1 year; inability to read the study questionnaire; documented cognitive impairment; types of diabetes different from type 2 (as type 1 diabetes, gestational diabetes, or impaired glucose tolerance) (American Diabetes Association, 2016).

Measurement

Socio-demographic data including gender, age, occupational status, family income, school education, and family support were collected. Clinical data such as years from T2DM diagnosis, body mass index (BMI), presence of comorbidities, presence of diabetes microvascular complications (diabetic retinopathy, diabetic kidney disease, diabetic foot, diabetic neuropathy), and last available value of glycated hemoglobin (HbA1c) were collected by reviewing medical records. Standardized criteria from clinical guidelines were used to verify the T2DM diagnosis and to assess the presence of comorbidities (American Diabetes Association, 2016).

The SCODI is the self-report tool used to measure self-care maintenance, self-care monitoring, and self-care management as main variables of this study (Ausili et al., 2017).The SCODI was developed based on the Middle-Range Theory of Self-Care of Chronic Illness (Riegel et al., 2012) and it was demonstrated to be a valid and reliable measure of diabetes self-care (Ausili et al., 2017). Briefly, the self-care maintenance scale measures adherence to main diabetes treatments (i.e. medication, diet, exercise). The self-care monitoring scale includes body listening behaviors, such as blood glucose or blood pressure monitoring and symptom recognition behaviors. The self-care management scale includes those behaviors performed by patients to manage symptoms, high or low blood glucose levels, and health problems when they occur. Furthermore, the SCODI allows to measure self-care confidence that is known to be a strong determinant of self-care (Ausili et al., 2017, 2018; Riegel et al., 2012; Vellone et al., 2016).Self-care confidence was defined as the degree of confidence a patient has in her/his ability to perform adequate self-care (Riegel et al., 2012). In this study, self-care confidence was used to adjust the association between self-care behaviors and HbA1c, as better described below. A five-point Likert-type scale measures every item of the SCODI. All the SCODI scales provide a 0-100 standardized score where higher scores mean better self-care. Until now, a cut-

off of 70 points has been used to classify self-care maintenance, self-care monitoring, self-care management, and self-care confidence as adequate (≥70) or inadequate (<70), as per previous similar studies and tools (Ausili et al., 2016, 2017; Caruso et al., 2019; Riegel et al., 2009).

Statistical analysis

Socio-demographic and clinical data were described with frequencies and percentages when variables were categorical and with median and interquartile range (Q1-Q3) when continuous. Patients were stratified according to whether they had insulin treatment because of the differences in their clinical history and self-care behaviors (Erpeldinger et al., 2016). Moreover, we found a significant interaction between insulin treatment and self-care in the linear regression models on HbA1c. Comparisons of sociodemographic and clinical characteristics between patients with and without insulin treatment were performed using χ^2 test or Mann-Whitney U test, as appropriate.

To investigate the association between self-care maintenance, self-care monitoring, and self-care management and HbA1c, linear regression models were adopted, after checking on the linearity assumption. Quadratic and cubic terms were added among the regressors in case of departure from linearity and the likelihood ratio test (LRT) was used to test the overall significance. The associations were adjusted for the following covariates: gender, age, low income, school education, occupation, family support, years from diagnosis of diabetes, number of comorbidities, BMI, self-care confidence, and education in diabetes over the last year. The HbA1c value was considered as percentage in the models and also converted in mmol/mol for descriptive purposes.

Receiver operating characteristics (ROC) curve was applied out to identify the best cut-off score by Youden method for each self-care scale using HbA1c as gold standard and considering a value >7% as inadequate (American Diabetes Association, 2019b). The area under the ROC curve (AUC), as the measure of the ability of each self-

care scale to distinguish between adequate and inadequate HbA1c, was also calculated. Moreover, sensitivity and specificity of the best cut-off score were calculated for each scale and compared with the commonly used threshold score of 70 points.

2.4 Results

Socio-demographic and clinical data of the patients, overall and divided according to the presence or not of insulin treatment, are shown in **Table 2.1** together with self-care scales' scores. The overall sample of 540 T2DM patients was mostly composed by men (58%; n= 311) aged 60 years or more (77%; n= 415), retired (75%; n= 402) and with a low level of education (none, elementary or middle school: 83%; n= 448). Almost half of the sample (47%; n= 252) have had T2DM for at least 10 years, and the vast majority (87%; n= 469) had at least one comorbidity. Only a small proportion of patients (6%; n= 32) had received education about self-management in diabetes over the last year. Most of the patients (69%; n= 370) were taking oral glucose-lowering medications, the remaining part (31%; n= 170) were taking also insulin. HbA1c blood level was mostly (58%; n= 311) over the typically suggested glycemic goal of 7% (53 mmol/mol) (American Diabetes Association, 2019b) (median= 7.2% (55 mmol/mol)), and the BMI mostly (77%; n= 417) pointed out overweight (BMI ≥25) (median= 28.1). Almost 40% of the sample had at least one diabetes complication (39%; n= 209), whose the most frequent was retinopathy (22%; n= 119). Patients under insulin treatment were typically older ($p= 0.025$), had diabetes for longer ($p<0.001$), were more frequently retired ($p= 0.033$) and had more comorbidities ($p<0.001$) than those without insulin. Furthermore, they had higher levels of HbA1c ($p<0.001$) and more complications ($p<0.001$) than patients without insulin therapy (**Table 2.1**).

Accounting 70 points as the cut-off score, only self-care maintenance (median= 81.3; Q1-Q3= 72.9-89.6) and self-care confidence (median= 79.6; Q1-Q3= 66.9-93.2)

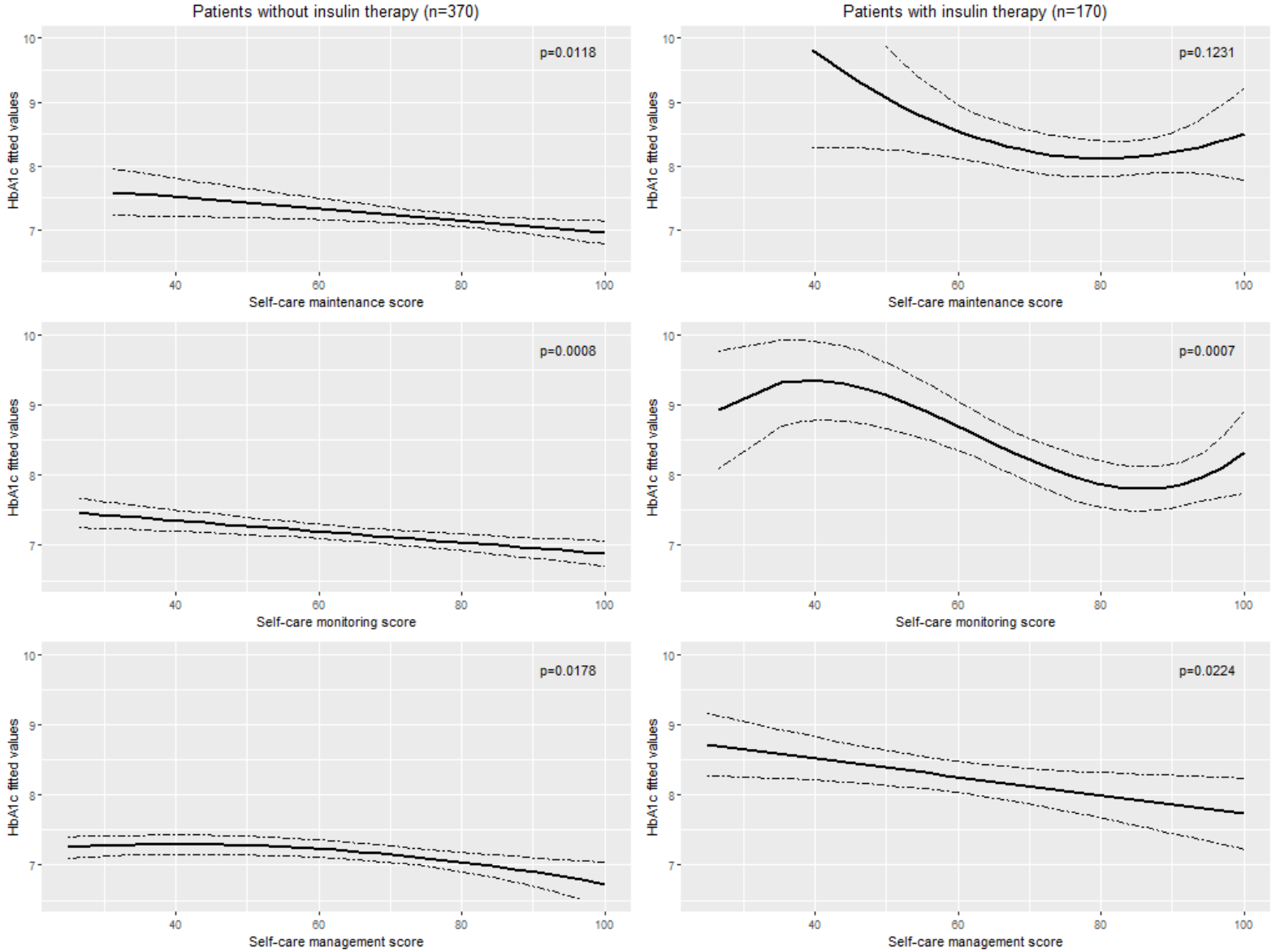
were adequate in most of the patients, respectively in 80% (n= 432) and 70% (n= 377). Self-care monitoring was adequate in half of the patients (median= 70.6) and self-care management scores were mostly low (median= 59.4). Self-care monitoring ($p<0.001$) and self-care confidence ($p= 0.023$) scores were better for patients under insulin treatment than for the others (**Table 2.1**).

Table 2.1 Socio-demographic and clinical characteristics of the sample overall and divided by the presence or absence of insulin therapy

Characteristics	**Total** n= 540	**Patients without insulin therapy** n= 370	**Patients with insulin therapy** n= 170	**p-value**
		Median [1st–3rd quartile]		
Age (years)	69 [61−77]	68 [59−76]	72 [63−78]	0.025
		n (%)		
Gender				
Female	229 (42%)	151 (41%)	78 (46%)	0.311
Occupation				
Unemployed	12 (2%)	7 (2%)	5 (3%)	
Working	126 (23%)	98 (26%)	28 (16%)	0.033
Retired	402 (75%)	265 (72%)	137 (81%)	
Low income				
Yes	209 (39%)	141 (38%)	68 (40%)	0.746
School education				
None	2 (1%)	1 (0%)	1 (1%)	
Elementary	277 (51%)	190 (51%)	87 (51%)	
Middle school	169 (31%)	109 (30%)	60 (35%)	0.401
High School	80 (15%)	61 (17%)	19 (11%)	
Degree	12 (2%)	9 (2%)	3 (2%)	
Family support				
Lives alone	93 (17%)	61 (16%)	32 (19%)	
Lives with at least one person	389 (72%)	272 (74%)	117 (69%)	0.515
Presence of caregiver	58 (11%)	37 (10%)	21 (12%)	
Education in diabetes				
Yes	32 (6%)	21 (6%)	11 (6%)	0.867
Retinopathy				
Yes	119 (22%)	56 (15%)	63 (37%)	<0.001
Kidney disease				
Yes	75 (14%)	28 (8%)	47 (28%)	<0.001
Diabetic foot				
Yes	24 (4%)	10 (3%)	14 (8%)	0.008
Neuropathy				
Yes	50 (9%)	29 (8%)	21 (12%)	0.128
Number of complications				
0	331 (61%)	266 (72%)	65 (38%)	
1	161 (30%)	88 (24%)	73 (43%)	<0.001
2	39 (7%)	14 (4%)	25 (15%)	
3	9 (2%)	2 (1%)	7 (4%)	
		Median [1st–3rd quartile]		
Time since T2DM diagnosis (years)	8 [4−15]	7 [4−11]	13 [8−20]	<0.001
BMI	28.1 [25.3−32.0]	28.1 [25.3−32.3]	28.1 [25.3−31.7]	0.653
Number of comorbidities	2 [1−3]	2 [1−3]	3 [2−4]	<0.001
Self-care confidence score (0-100)	79.6 [66.9−93.2]	77.3 [63.6−93.2]	84.1[70.5−95.5]	0.023
Self-care maintenance score (0-100)	81.3 [72.9−89.6]	81.3 [72.9−89.6]	81.3 [72.9−87.5]	0.551
Self-care monitoring score (0-100)	70.6 [55.9−85.3]	67.7 [52.9−82.4]	79.4 [61.8−88.2]	<0.001
Self-care management score (0-100)	59.4 [40.2−75.0]	59.4 [37.5−75.0]	62.5 [47.2−72.2]	0.212
HbA1c				
%	7.2 [6.7−8.0]	7.0 [6.6−7.5]	8.1 [7.2−9.0]	<0.001
mmol/mol	55 [50−64]	53 [49−58]	65 [55−75]	

The presence of insulin therapy was shown to be a modifier of the effect of self-care monitoring (LRT between model without and model with an interaction term of insulin therapy with self-care monitoring p= 0.041) and self-care management (LRT between model without and model with interaction p= 0.001) on HbA1c, showing that their effect was different in the two subgroups. Thus, we stratified the sample by insulin therapy, including also self-care maintenance for homogeneity (LRT between model without and model with interaction p= 0.144). We did not find any other variable as modifier of the effect of self-care on HbA1c. As showed in **Figure 2.1**, HbA1c was inversely correlated with self-care. In patients without insulin therapy, for each increment of 10 points of self-care maintenance, HbA1c percentage decreased by 0.09 (β= -0.009; 95% CI= -0.016; -0.002) and for each increment of 10 points of self-care monitoring, HbA1c decreased by 0.08 (β= -0.008; 95% CI= -0.012; -0.003). Self-care management had a quadratic relationship with HbA1c (LRT p= 0.0178): the curve showed very stable values of HbA1c up to about 55 points score, beyond which the concentration of HbA1c was slowly reduced by the increase in the self-care management scores. For patients under insulin treatment, there was no significant relationship between self-care maintenance and HbA1c (LRT p= 0.1231). We found a cubic relationship between self-care monitoring and HbA1c (LRT p= 0.0007): from 40 to 80 points in self-care monitoring score, HbA1c blood level was progressively reduced; from 80 to 100 points the relationship seemed to reverse its trend. Finally, self-care management had a linear relationship with HbA1c: for each increment of 10 points in self-care management, HbA1c measured as a percentage decreased by 0.13 (β= -0.013; 95% CI= -0.024; -0.002). The results of univariable models are showed in **Tables 2.5**, **2.6**, and **2.7** in Supplementary Material.

Figure 1 Regression lines and curves of self-care maintenance, self-care monitoring, and self-care management and HbA1c



When adjusting for relevant covariates, the association between self-care maintenance and HbA1c in patients without insulin therapy became not significant (p= 0.2000) (**Table 2.2**). Presence of family support (p= 0.0383), years from diagnosis (p<0.0001), BMI (p= 0.0080), and self-care confidence (p= 0.0024) resulted significantly associated with the outcome. For patients under insulin treatment, only age (p= 0.0303) and presence of family support (p= 0.0168) showed a statistically significant association with HbA1c (**Table 2.2**).

Table 2.2 Association between self-care maintenance and HbA1c by multivariable regression models in patients without and with insulin therapy

Variable	Patients without insulin therapy (n= 370)		Patients with insulin therapy (n= 170)	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	7.645 (6.525;8.765)	<0.0001	14.341 (7.057;21.626)	<0.0001
Self-care maintenance	-0.005 (-0.012;0.002)	0.2000	-0.091 (-0.275; 0.094)	0.3334
Self-care maintenance^2	-	-	0.001 (-0.001; 0.002)	0.3163
Gender *(male)*	0.024 (0.177; 0.224)	0.8158	0.099 (-0.353; 0.551)	0.6660
Age	-0.005 (-0.016; 0.005)	0.3155	-0.030 (-0.058; -0.003)	0.0303
Occupation *(non-working)*	-0.252 (-0.516; 0.011)	0.0606	0.207 (-0.576; 0.990)	0.6025
Low income *(yes)*	-0.113 (-0.325; 0.100)	0.2975	0.271 (-0.197; 0.740)	0.2547
School education *(low)*	0.233 (-0.029; 0.495)	0.0806	0.418 (-0.274; 1.111)	0.2344
Family support *(presence of cohabitant or caregiver)*	-0.276 (-0.537; -0.015)	0.0383	-0.712 (-1.293; -0.130)	0.0168
Years from T2DM diagnosis	0.030 (0.013; 0.047)	<0.0001	0.009 (-0.017; 0.036)	0.4899
Education in diabetes *(yes)*	0.198 (-0.216; 0.613)	0.3469	0.785 (-0.177; 1.747)	0.1088
BMI	0.025 (0.007; 0.044)	0.0080	-0.011 (-0.053; 0.031)	0.6018
Comorbidities	0.019 (-0.055; 0.092)	0.6181	-0.002 (-0.162; 0.157)	0.9768
Self-care confidence	-0.007 (-0.012; -0.003)	0.0024	-0.009 (-0.022; 0.004)	0.1579

Note: **Patients without insulin therapy**: R^2= 0.1128, model p-value (F-statistic)= $1.989*10^{-5}$.
Patients with insulin therapy: R^2= 0.1409, model p-value (F-statistic)= 0.0268, self-care maintenance p-value (LRT)= 0.5554.

Self-care monitoring in patients without insulin therapy was associated with HbA1c (p= 0.0432) together with lack of occupation (p= 0.0494), presence of family support (p= 0.0483), years from diagnosis (p= 0.0003), BMI (p= 0.0058), and self-care confidence (p= 0.0301). For patients with insulin therapy the cubic relationship between self-care monitoring and HbA1c was significant (LRT p= 0.0004), together with the association of age (p= 0.0095) and presence of family support (p= 0.0047) with HbA1c (**Table 2.3**).

Table 2.3 Association between self-care monitoring and HbA1c by multivariable regression models in patients without and with insulin therapy

Variable	**Patients without insulin therapy (n= 370)**		**Patients with insulin therapy (n= 170)**	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	7.446 (6.454; 8.437)	<0.0001	5.981 (0.983; 10.979)	0.0193
Self-care monitoring	-0.005 (-0.010; 0.000)	0.0432	0.345 (0.102; 0.587)	0.0057
Self-care monitoring^2	-	-	-0.006 (-0.011; -0.002)	0.0021
Self-care monitoring^3	-	-	$0.3519*10^{-4}$ $(0.1619; 0.5699)*10^{-4}$	0.0015
Gender *(M)*	0.0003 (-0.202; 0.201)	0.9977	0.007 (-0.431; 0.446)	0.9740
Age	-0.005 (-0.015; 0.006)	0.3626	-0.035 (-0.061; -0.009)	0.0095
Occupation *(non-working)*	-0.263 (-0.526; -0.001)	0.0494	0.299 (-0.450; 1.049)	0.4313
Low income *(yes)*	-0.117 (-0.329; 0.094)	0.2764	0.292 (-0.157; 0.741)	0.2003
School education *(low)*	0.233 (-0.028; 0.493)	0.0801	0.341 (-0.317; 0.998)	0.3079
Family support *(presence of cohabitant or caregiver)*	-0.262 (-0.522; -0.002)	0.0483	-0.799 (-1.350; -0.248)	0.0047
Years from diagnosis	0.032 (0.015; 0.049)	0.0003	0.017 (-0.009; 0.043)	0.1935
Education in diabetes *(yes)*	0.182 (-0.231; 0.595)	0.3864	0.859 (-0.045; 1.763)	0.0623
BMI	0.026 (0.008; 0.045)	0.0058	-0.007 (-0.047; 0.033)	0.7364
Comorbidities	0.014 (-0.060; 0.087)	0.7108	0.037 (-0.117; 0.191)	0.6380
Self-care confidence	-0.006 (-0.011; -0.001)	0.0301	0.0005 (-0.013; 0.014)	0.9465

Note: **Patients without insulin therapy**: R^2= 0.1188, model p-value (F-statistic)= $7.577*10^{-6}$.
Patients with insulin therapy: R^2= 0.2222, model p-value (F-statistic)= 0.0002, self-care monitoring p-value (LRT)= 0.0004.

Concerning self-care management in patients without insulin treatment, there was a significant quadratic relationship with HbA1c (LRT p= 0.0278). In the same model, lack of occupation (p= 0.0450), low level of education (p= 0.0463), presence of family support (p= 0.0309), years from diagnosis (p= 0.0007), BMI (p= 0.0034), and self-care confidence (p= 0.0005) were associated with HbA1c. For patients under insulin treatment, the HbA1c level was significantly influenced by self-care management (p= 0.0375), age (p= 0.0157), and presence of family support (p= 0.0098) (**Table 2.4**).

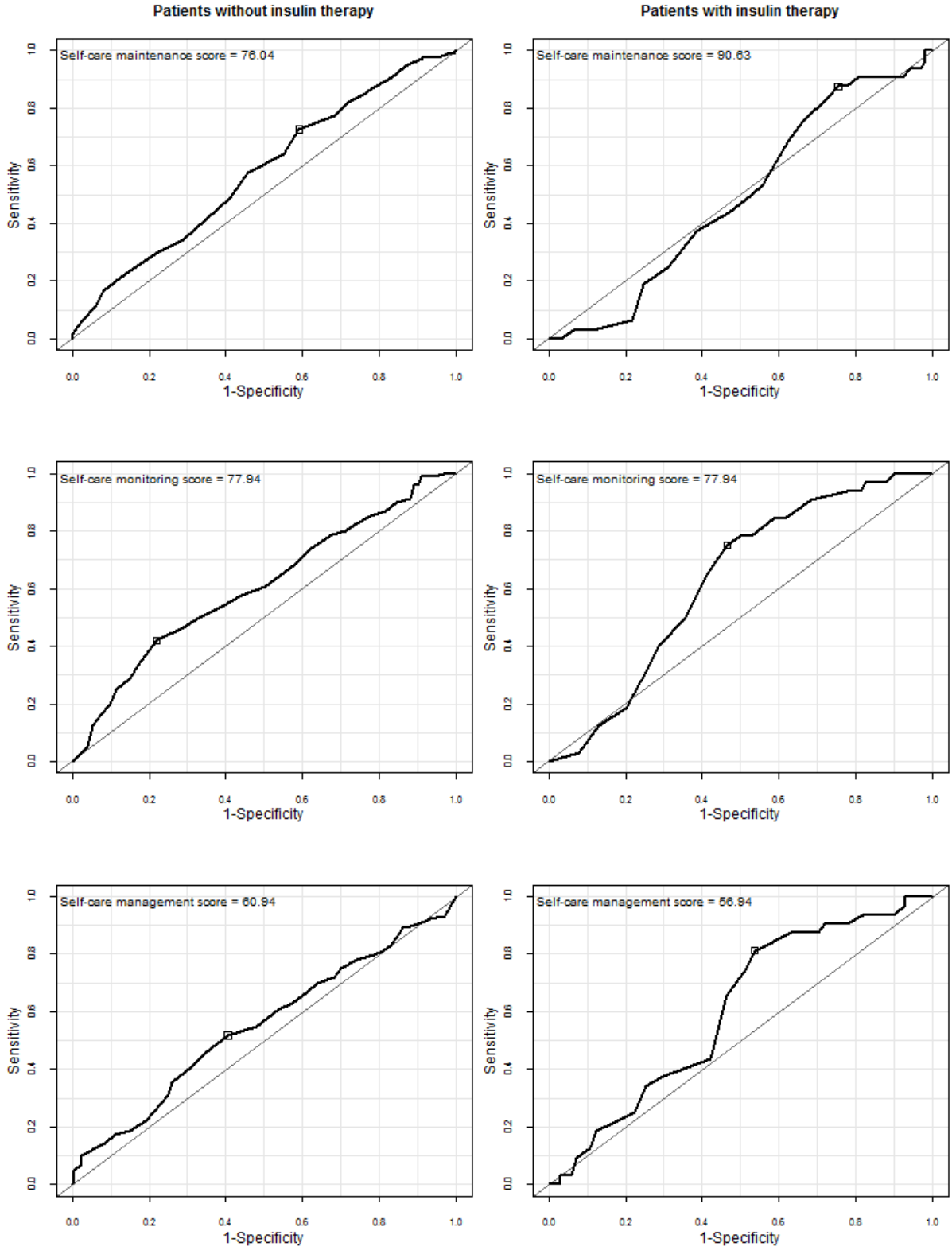
Table 2.4 Association between self-care management and HbA1c by multivariable regression models in patients without and with insulin therapy

Variable	Patients without insulin therapy (n= 370)		Patients with insulin therapy (n= 170)	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	6.886 (5.862; 7.911)	<0.0001	11.776 (9.267; 14.285)	<0.0001
Self-care management	0.018 (0.004; 0.031)	0.0089	-0.014 (-0.026; -0.001)	0.0375
Self-care management^2	-0.00016 (-0.00028; -0.00003)	0.0165	-	-
Gender *(M)*	0.058 (-0.143; 0.258)	0.5718	0.030 (-0.416; 0.476)	0.8954
Age	-0.005 (-0.015; 0.005)	0.3434	-0.034 (-0.061; -0.006)	0.0157
Occupation *(non-working)*	-0.269 (-0.533; -0.006)	0.0450	0.260 (-0.510; 1.030)	0.5052
Low income *(yes)*	-0.079 (-0.290; 0.133)	0.4638	0.181 (-0.286; 0.647)	0.4456
School education *(low)*	0.266 (0.004; 0.527)	0.0463	0.332 (-0.346; 1.010)	0.3353
Family support *(presence of cohabitant or caregiver)*	-0.287 (-0.547; -0.027)	0.0309	-0.751 (-1.319; -0.184)	0.0098
Years from diagnosis	0.030 (0.013; 0.047)	0.0007	0.012 (-0.015; 0.038)	0.3852
Education in diabetes *(yes)*	0.232 (-0.182; 0.646)	0.2717	0.921 (-0.002; 1.844)	0.0505
BMI	0.028 (0.009; 0.046)	0.0034	-0.013 (-0.054; 0.028)	0.5177
Comorbidities	0.026 (-0.048; 0.101)	0.4846	-0.003 (-0.160; 0.155)	0.9736
Self-care confidence	-0.009 (-0.015; -0.004)	0.0005	-0.002 (-0.016; 0.012)	0.7649

Note: **Patients without insulin therapy**: R^2= 0.1257, model p-value (F-statistic)= $5.245*10^{-6}$, self-care management p-value (LRT)= 0.0278. **Patients with insulin therapy**: R^2= 0.1585, model p-value (F-statistic)= 0.0057.

The ROC curves identifying best cut-offs of self-care scales with respect to suboptimal HbA1c (HbA1c >7%) (American Diabetes Association, 2019b) are shown both for patients without and with insulin therapy in **Figure 2.2**.

Figure 2.2 Best cut-off (by Youden method) for self-care scales in patients without and with insulin therapy



The best cut-off for self-care maintenance scale in patients without insulin therapy was 76.04 points, with AUC of 0.578. For patients with insulin therapy, it was not meaningful to identify a cut-off, because the association between self-care maintenance and HbA1c was not significant in the linear regression model. However, although it is not properly useful, we reported this cut-off in **Figure 2.2** for homogeneity. ROC curve of self-care monitoring scale, both in patients without and with insulin therapy showed best cut-off equal to 77.94 points, with AUC respectively of 0.608 and 0.627 (**Table 2.8** in Supplementary material). For self-care management scale in patients without insulin treatment, the best cut-off was 60.94, with AUC of 0.552. For patients with insulin therapy, the best cut-off was 56.94 and the AUC was 0.604. When compared with the 70 points cut-off – the one used by previous studies (Ausili et al., 2016, 2017; Caruso et al., 2019; Riegel et al., 2009) – best cut-off scores by Youden method had lower sensitivity than 70 for self-care maintenance in patients without insulin therapy (0.85 vs 0.73) and for self-care monitoring both in patient without (0.54 vs 0.42) and with insulin therapy (0.84 vs 0.75). For self-care management, sensitivity was higher using best cut-offs by Youden method both in patients without (0.52 vs 0.36) and with insulin therapy (0.81 vs 0.34). AUC, sensitivity, and specificity of the best cut-off scores compared to 70 points cut-off were shown in **Table 2.8** in Supplementary Material for each self-care scale.

2.5 Discussion

The aims of this study were to evaluate how self-care maintenance, self-care monitoring, and self-care management affect HbA1c in T2DM patients and to identify cut-off scores of self-care scales using HbA1c as gold standard. To the best of our knowledge, this is the first study addressing these issues. We found that self-care maintenance, self-care monitoring, and self-care management differently affect glycemic control in patients with T2DM. Self-care monitoring and self-care management are

associated with HbA1c in both patients without and with insulin therapy. Self-care maintenance is associated with HbA1c in patients without insulin therapy. Furthermore, we found that cut-off scores providing the best sensitivity and specificity to identify suboptimal HbA1c (>7%) for the three self-care scales are different among the scales, and also different from the ones used in previous studies (Ausili et al., 2016, 2017; Caruso et al., 2019; Riegel et al., 2009). These findings are relevant for several reasons. First, clinicians can identify patients at risk of poor glycemic control, according to their self-care levels. Second, interventions to improve glycemic control can be tailored, accounting for the area of self-care that is lacking. Finally, the cut-off scores we identified can be used in future research to identify inadequate self-care, according to the patients' likelihood to have suboptimal glycemic control.

We found that higher scores of self-care monitoring in patients not receiving insulin were associated with lower HbA1c.This is consistent with previous studies where interventions aimed to improve patients' self-monitoring of blood glucose significantly reduced HbA1c (Cypress & Tomky, 2013; International Diabetes Federation, 2009; Schnell et al., 2013). However, explaining this finding, we need to consider that the self-care monitoring scale includes also weight monitoring (Gummesson et al., 2017; Wilding, 2014), blood pressure monitoring (Grossman & Grossman, 2017), feet examination, and symptom recognition that were shown to be relevant for T2DM patients. Interestingly, although these behaviors do not directly affect HbA1c, they probably support patients' self-awareness (Jurgens, 2006), which contributes to guide self-care decision-making and, consequently, improves health outcomes (American Diabetes Association, 2019b; Schnell et al., 2013). Higher self-care monitoring was also associated with lower HbA1c in patients under insulin treatment. Surprisingly, looking at the regression curve, after the score of about 80 points, we found that higher scores of self-care monitoring were progressively associated with increasing values of HbA1c. This pattern might reflect the

cross-sectional nature of the study. In fact, it seems that these patients improved their self-care monitoring in response to their inadequate HbA1c, as also found in previous studies (Iqbal et al., 2008; Trivedi et al., 2017). Indeed, the HbA1c of patients under insulin treatment was significantly higher, and we argue that the perceived severity of their clinical situation was higher in these patients, leading to the improvement of self-care monitoring (Adejoh, 2014; Shabibi et al., 2017).

Self-care management was also significantly associated with HbA1c in patients both without and with insulin therapy. In the first group we found an almost flat curve up to a self-care management of about 55, representing a probably low influence of poor self-care management on HbA1c. This could be due to the rare incidence of the signs and symptoms, measured by the self-care management scale, in this group of patients (Gupta et al., 2013). However, higher scores of self-care management showed an association with lower HbA1c (Captieux et al., 2018): according to the model, a patient with a 60 points score will have an HbA1c of 7.2%, while a patients with a 90 or 100 points score will have respectively an HbA1c of 6.9 and 6.7%. In patients under insulin treatment, we found a relevant inverse association both in univariable and in multivariable linear models. These patients had significantly worst HbA1c when compared to the other group and probably they experienced more signs and symptoms (Erpeldinger et al., 2016). Therefore, the more patients were able to perform self-care management when signs and symptoms occurred, the more HbA1c level improved, as also reported in the literature (Rusdiana et al., 2018; Yuan et al., 2014).

As per self-care maintenance, in the simple linear model we found a significant association with HbA1c in patients without insulin therapy, but not in patients taking insulin. When adjusting for other sociodemographic and clinical variables, the association was not significant in both groups. This is surprising because we expected self-care maintenance to be strongly associated with HbA1c, as the scale assesses the adherence to

major diabetes treatments. However, the scale is multidimensional and investigates heterogeneous behaviors (Ausili et al., 2017). In fact, self-care maintenance concerns diet, physical activity, and medications, that directly influence HbA1c (American Diabetes Association, 2019c), but also oral hygiene, smoking, feet care, vaccinations, hand washing, and adherence to visits and check-ups, that have not a direct influence on HbA1c. Thus, as the self-care maintenance construct is so complex, future research should study it longitudinally to better understand if changes in self-care maintenance have an effect on HbA1c.

ROC curves showed that the best cut-off scores for the self-care maintenance, self-care monitoring, and self-care management scales to identify patients with suboptimal HbA1c should be different from the score of 70, used until now (Ausili et al., 2016, 2017; Caruso et al., 2019; Riegel et al., 2009). However, this finding should be discussed according to the aim of the instrument and the area of its application. First, the SCODI was not developed with a diagnostic purpose for HbA1c, but to measure patients' self-care behaviors. That is why we did not expect to find high AUCs, as our results showed. Second, for a clinical purpose, we believe that sensitivity is the most relevant parameter to consider because we would rather have more false-positive than false-negative cases, based on the HbA1c outcome. In fact, although false-positives might have good glycemic control, they could benefit anyway from a more in-depth assessment of their knowledge, attitudes, and self-care (Powers et al., 2016). Thus, based on our results, we recommend a cut-off score of 70 points for self-care maintenance and self-care monitoring, and a cut-off score of 60 points for self-care management. Again, these cut-off scores should be studied longitudinally in the future. However, our findings add relevant information because they are based on an external objective criterion never tested before for the SCODI scales.

Limitations and Strengths

The cross-sectional nature of this study represents its main limitation because it does not allow to determine if self-care behaviors put in place by patients are the

antecedents or the consequences of the HbA1c level. Another weakness of the study is not having considered patients' hemoglobin level: it could affect HbA1c independently of glycemic control, especially in patients with renal failure (Kuo et al., 2018). However, not having collected this information, we have performed a sensitivity analysis excluding the 75 patients with diabetic kidney disease and we have verified that our results did not undergo any significant change. Although the study was conducted in one country, the main socio-demographic and clinical characteristics of the sample were comparable to those in the international literature (Nicolucci et al., 2013). Moreover, sample size was quite large and the recruitment was consecutive. To the best of our knowledge, this was the first study investigating the relationship between self-care and HbA1c taking into account the complexity of the self-care process as defined by the Middle-Range Theory of Self-Care of Chronic Illness (Riegel et al., 2012) and using a theoretically grounded psychometrically sound measure(Ausili et al., 2017) for this purpose.

2.6 Conclusion

Measuring self-care and supporting patients to improve self-care is relevant for achieving good health outcomes in diabetes. Knowing how self-care maintenance, self-care monitoring, and self-care management affect HbA1c has implications both for clinical practice and research. Clinically, patients with inadequate self-care monitoring and self-care management should be considered at high risk of inadequate glycemic control. Therefore, interventions should be administered to them to improve their clinical condition. Even if self-care maintenance was not associated with patients' glycemic control, patients with inadequate self-care maintenance require further assessment according to the complexity of this part of the self-care process. Further research should: assess the association between self-care maintenance, self-care monitoring, and self-care management and HbA1c by longitudinal designs, also using other instruments than the

SCODI; estimate prospectively the best cut-off scores of the SCODI scales assessing changes in HbA1c over time; and develop and test interventions to improve HbA1c through tailored self-care maintenance, self-care monitoring, and self-care management support.

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Supplementary Material

Table 2.5 Association between self-care maintenance and HbA1c by univariable linear regression models in patients without and with insulin therapy

Variable	Patients without insulin therapy		Patients with insulin therapy	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	7.881 (7.305;8.457)	<0.0001	14.706 (7.921;21.491)	<0.0001
Self-care maintenance	-0.009 (-0.016;-0.002)	0.0118	-0.164 (-0.346;0.019)	0.0790
Self-care maintenance ^2	-	-	0.001 (-0.0001;0.002)	0.0996

Note: **Patients without insulin therapy**: R^2= 0.0171.
Patients with insulin therapy: R^2= 0.0243, self-care maintenance p-value (LRT)= 0.1231.

Table 2.6 Association between self-care monitoring and HbA1c by univarible linear regression models in patients with and without insulin therapy

Variable	Patients without insulin therapy		Patients with insulin therapy	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	7.671 (7.354;7.987)	<0.0001	4.184 (-0.304;8.671)	0.0674
Self-care monitoring	-0.008 (-0.012;-0.003)	0.0008	0.310 (0.065;0.555)	0.0134
Self-care monitoring ^2	-	-	-0.006 (-0.010;-0.002) $*10^{-3}$	0.0067
Self-care monitoring ^3	-	-	$3.067*10^{-5}$ (0.891;5.242) $*10^{-5}$	0.0060

Note: **Patients without insulin therapy**: R^2= 0.0303.
Patients with insulin therapy: R^2= 0.0956, Self-care Monitoring p-value (LRT)= 0.0007.

Table 2.7 Association between self-care management and HbA1c by univariable linear regression models in patients with and without insulin therapy

Variable	Patients without insulin therapy		Patients with insulin therapy	
	Est (95% CI)	**p-value**	**Est (95% CI)**	**p-value**
(Intercept)	7.023 (6.702;7.345)	<0.0001	9.045 (8.345;9.744)	<0.0001
Self-care management	0.013 (-0.0002;0.026)	0.0536	-0.013 (-0.024;-0.002)	0.0223
Self-care management ^2	$-1.606*10^{-4}$ ($-2.898*10^{-4}$;$-3.138*10^{-5}$)	0.0150	-	-

Note: **Patients without insulin therapy**: R2= 0.0215, Self-care Management p-value (LRT)= 0.0178.
Patients with insulin therapy: R^2= 0.0307.

Table 2.8 Parameters of best (by Youden method) and 70 points cuts-off of self-care scales

Self-care scale	Insulin therapy	Cut-off	ROC curve AUC	Sensitivity	Specificity
Self-care maintenance	No	**76.04** ***(best)***	0.578	0.73	0.41
		70		0.85	0.24
	Yes	**90.63** ***(best)***	0.507	0.94	0.22
		70		0.13	0.75
Self-care monitoring	No	**77.94 (*best)***	0.608	0.42	0.78
		70		0.54	0.61
	Yes	**77.94** ***(best)***	0.627	0.75	0.54
		70		0.84	0.41
Self-care management	No	**60.94** ***(best)***	0.552	0.52	0.60
		70		0.36	0.74
	Yes	**56.94** ***(best)***	0.604	0.81	0.46
		70		0.34	0.75

Note: **Sensitivity** is here considered as the probability to have a self-care scale score higher than cut-off, given that the HbA1c is ≤ 7%. **Specificity** is here considered as the probability to have a self-care score lower than cut-off, given that the HbA1c is >7%.

CHAPTHER 3

Dyadic patterns of patient and caregiver engagement in type 2 diabetes mellitus care: characteristics and glycemic control

Title

Dyadic patterns of patient and caregiver engagement in type 2 diabetes mellitus care: characteristics and glycemic control

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3.1 Abstract

Introduction and Aim. In chronic conditions, patient self-care and caregiver contribution to it should be considered as a dyadic phenomenon in which each dyad member influences and is influenced by the other. In type 2 diabetes mellitus (T2DM), a dyadic approach has never been used. Furthermore, distinct patterns of dyadic engagement in T2DM care have never been identified. The aim of this study was to identify distinct patterns of dyadic engagement in T2DM care, describe their characteristics and their association with glycated hemoglobin.

Methods. A multicenter cross-sectional study was conducted, enrolling patients with T2DM and their primary informal caregivers. Patient self-care and caregiver contribution were assessed using the Self-Care of Diabetes Inventory and the Caregiver Contribution to Self-Care in Diabetes Inventory, respectively. To identify patterns of dyadic T2DM management, a latent class analysis was performed, using as input variables the average and the incongruence in dyadic T2DM management estimated by multilevel models. The association between the obtained classes and glycated hemoglobin was estimated by a multivariable linear regression model.

Results. A total of 251 dyads were enrolled. Patients were mostly males (55%) with a median age of 72 years. Caregivers were mostly females (71%) with a median age of 64 years. Three distinct patterns of dyadic engagement in T2DM care were identified. The "equally engaged-low care" pattern (14%, n= 34) showed low engagement by both patients and caregivers in self-care behaviors. The "mostly patient engaged-middling care" pattern (25%, n= 63), displayed moderate patient engagement with notable discrepancies favoring patients. The "equally engaged-high care" pattern (61%, n= 154) demonstrated high dyadic involvement with minimal incongruences in T2DM care engagement. The membership in these patterns was associated with patient gender, education level, and self-efficacy and with caregiver burden and the presence of chronic

disease in the caregiver. Furthermore, dyadic patterns were associated to patient glycemic control (HbA1c): the membership in the "mostly patient engaged-middling care" and "equally engaged-high care" patterns was associated with decreased HbA1c compared to the "equally engaged-low care" pattern.

Conclusion. The three identified patterns of dyadic engagement in T2DM showed differences in patient and caregiver characteristics and were associated with glycemic control. These patterns should be considered by healthcare professionals. Further research is needed to deepen the understanding of dyadic management in T2DM.

3.2 Introduction

It is estimated that currently 537 million adults aged 20 to 79 years are affected by diabetes, and this prevalence is expected to consistently increase in the coming years (International Diabetes Federation, 2021; Khan et al., 2020). Over the 90% of diabetes diagnoses correspond to type 2 diabetes mellitus (T2DM) (International Diabetes Federation, 2021; Zheng et al., 2018). T2DM carries the weight of severe complications that contribute to elevated rates of morbidity, mortality, and healthcare expenditures (Harding et al., 2019). However, the involvement of the patient in T2DM management had shown to be effective in mitigating the impact of these complications (American Diabetes Association, 2023b; International Diabetes Federation, 2021).

The process wherein individuals actively maintain their health and well-being, recognize symptoms, and manage the challenges presented by illness is known as self-care (Riegel et al., 2012, 2019). According to the Middle-Range Theory of Self-Care of Chronic Illness, the core concepts of self-care are self-care maintenance, self-care monitoring, and self-care management (Riegel et al., 2012, 2019). Self-care maintenance comprises behaviors aimed at maintaining physical and emotional stability. Self-care monitoring involves the vigilant observation of bodily signs and symptoms. Self-care management entails the implementation of appropriate actions in response to such signs and symptoms. In the context of diabetes, self-care encompasses various activities, including adhering to dietary plans, following medication regimens, and adhering to physical activity recommendations (self-care maintenance). It also involves the regular monitoring of blood glucose levels, body weight, foot health, and signs and symptoms of hypo- or hyperglycemia (self-care monitoring), as well as the management of episodes characterized by hypo- or hyperglycemia (self-care management) (Ausili et al., 2017; Riegel et al., 2012, 2019).

Although the key role of self-care in improving glycemic control is widely recognized (American Diabetes Association, 2023c; Fabrizi et al., 2020; International Diabetes Federation, 2021; Modarresi et al., 2020), patients may struggle in following recommendations of such complex and various behaviors (Bouldin et al., 2017; Riegel et al., 2012). Consequently, suboptimal glycemic control prevails among individuals living with T2DM (Afroz et al., 2019; Cedrick et al., 2021; Chetoui et al., 2020; Fiseha et al., 2018). To address this challenge, the presence of informal caregivers, such as family members or significant others, can be decisive in supporting patients in managing chronic conditions by facilitating the implementation of complex self-care behaviors (Chen et al., 2017; Hooker et al., 2018). Caregiver contribution to patient self-care entails providing assistance in managing the individual's health condition (Bouldin et al., 2017; Trivedi et al., 2012; Vellone et al., 2019, 2020). This assistance includes assuming responsibility for tasks on behalf of the patient when independence is compromised (Pressler et al., 2013). In the context of chronic illnesses, caregiver contribution encompasses a range of crucial activities, such as emotional support, personal and clinical care (Buck et al., 2015; Clark et al., 2008), health promotion, symptom monitoring, and shared decision-making (Chen et al., 2017).

In investigating patient self-care and caregiver contribution to it, a dyadic phenomenon should be recognized, wherein interdependence occurs between dyad members, as each one influences and is influenced by the other (K. Lyons & Lee, 2018). Furthermore, the dyadic management of a chronic condition can be expressed according to a huge variability, contingent upon the stage of illness, the type of dyad, available support, and cultural factors (K. Lyons & Lee, 2018). This heterogeneity represents a very useful wealth for understanding the phenomenon of dyadic illness management, and it would therefore be essential to identify and describe it, albeit necessarily in a parsimonious way (Lee et al., 2020; K. Lyons & Lee, 2018). To address this issue, distinct

patterns of dyadic engagement in illness care have been identified in previous studies, involving patients with heart failure (Lee et al., 2015) or with multiple chronic conditions (De Maria et al., 2023) and their informal caregivers. To the best of our knowledge, a dyadic approach in assessing patient self-care and caregiver contribution to it in T2DM has never been adopted. Furthermore, no previous studies have identified distinct patterns of dyadic engagement in T2DM care based on the combination of patient and caregiver involvement in behaviors specifically recommended for T2DM. Bringing this shortcoming could be a starting point to understand the dyadic functioning of diabetes management. Indeed, patterns identification could be useful to assess patient and caregiver characteristics associated to the membership in dyadic patterns. Furthermore, by examining a potential association between dyadic pattern membership and critical health outcomes relevant to T2DM, it would be feasible to devise targeted interventions aimed at enhancing patient and caregiver engagement, which could subsequently lead to improved health outcomes.

Therefore, the aims of this study were: 1) to identify unobserved distinct patterns of dyadic engagement in T2DM care; 2) to identify predictors of patterns membership at patient, caregiver, and dyadic level; 3) to assess the association between patterns membership and patient glycemic control as measured by glycated hemoglobin (HbA1c).

3.3 Methods

A multicenter cross-sectional study was conducted involving patients with T2DM and their informal caregivers from four outpatient diabetes clinics in the North of Italy.

Ethical considerations

The study received approval from the Institutional Review Board of each center, and all enrolled participants provided signed informed consent. The study procedures adhered to the ethical standards set by the responsible committee on human

experimentation, both at the institutional and national levels, and followed the principles outlined in the Declaration of Helsinki.

Sample

During outpatient visits, a convenience sample of patient-caregiver dyads was recruited. Patients were deemed eligible for inclusion if they fulfilled the diagnostic criteria for T2DM as outlined by guidelines (American Diabetes Association, 2023a), were aged 18 years or older, and provided written informed consent. Patients were excluded from the study if they had a T2DM diagnosis of less than one year, were making their initial visit to the diabetes center, showed difficulty in understanding the study questionnaire, or had confirmed cognitive impairment. Caregivers were eligible for participation if they were the primary informal caregiver for the patient, were aged 18 years or older, and provided written informed consent. Caregivers were excluded if they showed difficulties in understanding the study questionnaire or had confirmed cognitive impairment.

Measurement

Patient self-care and caregiver contribution to self-care were measured respectively by the Self-Care of Diabetes Inventory (SCODI) (Ausili et al., 2017) and the Caregiver Contribution to Self-Care in Diabetes Inventory (CC-SCODI),[2] whose validity was already supported (Ausili et al., 2017; De Maria et al., 2022)[3]. These two tools consist of the same three scales (self-care/contribution to self-care maintenance, monitoring, and management) assessing the same behaviors, but differing for the considered viewpoint. Specifically, the content of each single item is maintained but introduction is changing: where for patients the item starts with: *"How often or routinely do you do these behaviors?"*, for caregivers it is: *"How often do you recommend the following behaviors to the person you care for? (Or how*

[2] See Paragraph 6.2
[3] See also Paragraph 6.2

often do you do these activities because the person you care for is not able to do them autonomously?)". The self-care/contribution to self-care maintenance scale assesses behaviors to maintain physical and emotional stability (e.g., adherence to diet, medications, and physical activity recommendations). The self-care/contribution to self-care monitoring scale evaluates behaviors aimed at recognizing signs and symptoms in the body (e.g., monitoring blood glucose, body weight, feet, and symptoms of hypo- or hyperglycemia). The self-care/contribution to self-care management scale appraises behaviors employed in response to signs and symptoms (e.g., managing episodes of hypo- and hyperglycemia) (Ausili et al., 2017; Riegel et al., 2012). The SCODI and the CC-SCODI also allowed to measure the patient self-care self-efficacy and the caregiver contribution to self-care self-efficacy, respectively. With these scales, the patient confidence and persistence in self-care behaviors or the caregiver confidence and persistence in supporting patient self-care behaviors were investigated (Ausili et al. 2017)[4]. Each item uses a five-point Likert-type scale from "never" to "always", and each scale provides a 0-100 standardized score, where higher scores denote higher self-care or higher contribution to self-care (Ausili et al. 2017)[5]. For the SCODI, the cut-point used to classify self-care as adequate or inadequate is ≥70 for self-care maintenance and monitoring, and ≥60 for self-care management (Fabrizi et al., 2020). Cut-points have not yet been defined for the CC-SCODI.

Diabetes-related knowledge was measured administering to both patient and caregiver the Revised Brief Diabetes Knowledge Test (DKT2), a valid and reliable self-report tool that can be administered to both patients and caregivers (Baroni et al., 2023; Fitzgerald et al., 2016). The DKT2 consists of two sections, each one scored separately. The first section consists of 14 items assessing general knowledge of diabetes regarding diet, glycemia, feet, physical activity, symptoms, and complications. The second section is an additional part of

[4] See also Paragraph 6.2
[5] See also Paragraph 6.2 and Appendix

nine items to be completed only in the presence of insulin therapy, as this part investigates the knowledge about insulin therapy management. The score is the percentage of correct answers for each section (Baroni et al., 2023; Fitzgerald et al., 2016).

Quality of life was measured administering to both patient and caregiver the EuroQol-five Dimensions Visual Analogue Scale (EQ-5D VAS), a 20-cm vertical graded VAS having a value of 100 (i.e., the best possible health state) at its top and 0 (i.e., the worst possible health status) at its bottom (Rabin & De Charro, 2001).

Mutuality was assessed administering to both patient and caregiver the Mutuality Scale (MS) (Archbold et al., 1990; Pucciarelli et al., 2016). The MS is a 15-item scale investigating four domains: love, shared pleasurable activities, shared values, and reciprocity. Each item is scored on a five-point Likert-type scale from 0 (not at all) to 4 (a great deal). The total scale score consists of the mean of all item scores, ranging from 0 to 4: higher scores mean greater mutuality (Archbold et al., 1990; Pucciarelli et al., 2016).

Caregiver burden was measured by the Caregiver Burden Inventory (CBI). The CBI is a self-reported multidimensional tool that assesses caregiver burden, explored in terms of time-dependence and developmental, physical, social, and emotional burden (Novak & Guest, 1989). The CBI comprises 24 items requiring a five-point Likert-type scale response from 0 (minimum burden) to 4 (maximum burden). The CBI provides a 0-100 total score or a 0-20 score for each subscale, where higher scores mean more burden (Greco et al., 2017; Novak & Guest, 1989).

Caregiver preparedness was measured using the Caregiver Preparedness Scale (CPS), a eight-items scale investigating the self-perceived caregiver preparedness to care for a patient physical and emotional needs, setting up services, coping with the stress of caregiving, making caregiving activities pleasant, responding and managing emergencies, getting help and information from the health care system, and overall preparedness. Each item is rated between 0 (not at all prepared) to 4 (very well prepared), and items are summed for a total

score that can range from 0 to 32, with higher scores indicative of feeling better prepared for the caregiving role (Archbold et al., 1990; Pucciarelli et al., 2014).

Statistical analysis

To describe patients and caregivers, frequencies and percentages were used for categorical variables, median and interquartile range (Q1-Q3) for continuous variables.

To identify distinct patterns of dyadic engagement in T2DM care, two steps were followed. First, multilevel models with random intercept and random slope were used to estimate the dyadic average and incongruence in dyadic T2DM management within each dyad and for each SCODI/CC-SCODI scale (i.e., self-care maintenance, self-care monitoring, and self-care management) (De Maria et al., 2023; Lee et al., 2015; K. S. Lyons & Lee, 2020). The dyadic average denoted the mean of the dyadic involvement in the investigated behaviors between the two members of the dyad, while the dyadic incongruence reflected the magnitude and the direction of the incongruence in the dyadic involvement (negative values indicated that the caregiver contributed more than the patient and vice versa). Second, a latent class analysis (LCA) was performed using the previous estimated six parameters for each dyad (i.e., two predicted random effects for three scales) (De Maria et al., 2023; Lee et al., 2015). To support the LCA model selection (i.e., number of classes), the Bayesian Information Criteria (BIC, the lower the better), posterior probabilities (average posterior probabilities for most likely class near 1.0), the size of the observed profiles (not less than 5% of the sample), the model convergence (entropy near 1.0), the Lo-Mendell-Rubin adjusted likelihood ratio test (LMR-LRT), and the parametric bootstrap likelihood ratio test (PBLRT) were used as fit indices (Lee et al., 2020; Ram & Grimm, 2009). Differences between identified patterns were tested using the Kruskal-Wallis test or the chi-square (χ^2) test, as appropriate.

To identify predictors of patterns' membership, multinomial regression was adopted. A backward stepwise procedure with significance criteria (Heinze et al., 2018) was used to

select covariates, with a p-value threshold of 0.05. Age and gender of both patient and caregiver were included a priori, regardless of the procedure. A complete case analysis was performed on the final selected model, due to the limited number of observations containing missing data (i.e., 17 missing in Caregiving hours per day) (Lachenbruch, 2011; Ross et al., 2020). Results were reported as odds ratios (OR)s and 95% confidence intervals (CI)s.

To investigate the association between patterns membership and patient glycemic control as measured by HbA1c, linear regression was performed, adjusting for the following pre-specified covariates: patient age, gender, body mass index, presence of diabetes complications, time since diagnosis of T2DM, and presence of insulin therapy. In this model, the HbA1c value was considered both as percentage and in mmol/mol.

3.4 Results

A total of 251 patient-caregiver dyads were enrolled. Patients were mostly males (55%, n= 138) aged 70 years or more (67%, n= 169), married or cohabiting with the partner or spouse (76%, n= 191), with low education (76%, n= 190), and retired (79%, n= 198). HbA1c value was over the goal of <7% (53 mmol/mol) (American Diabetes Association, 2023d) for 59% of patients (n= 147), BMI indicated overweight (≥25 kg/m^2) for 78% of cases (n= 195), and more than half of patients had needed hospitalization, emergency care access, or unscheduled visits in the last year (55%, n= 139). Caregivers were mostly women (71%, n= 178), aged 60 years or over (64%, n= 161), married or having a cohabitant partner (90%, n= 225), with low education (primary or secondary school; 59%, n= 148), and retired (55%, n= 138). Caregivers were mostly the patient spouses or partners (66%, n= 166) and were cohabitant with the patient (75%, n= 188). About a quarter of caregivers (25%, n= 63) spent at least eight hours per day in caregiving, and over 60% had been taking care of the patient for at least 10 years (63%, n= 157). Only 11% (n= 28) had received education in diabetes, and more than half of them stated that they had at least one chronic disease (55%, n= 139). Patients' and caregivers' characteristics were reported in **Table 3.1**.

Table 3.1 Patients' and caregivers' characteristics

Characteristics	Patient n= 251	Caregiver n= 251
	Median [1st–3rd quartile]	
Age (years)	72 [67-79]	64 [54-71]
	n (%)	
Gender		
Male	138 (55)	73 (29)
Marital status		
Married/Cohabitant	191 (76)	225 (90)
Divorced/Separated	7 (3)	13 (5)
Single/Never married	4 (2)	7 (3)
Widower/Widow	49 (19)	6 (2)
Education level		
Primary school	115 (46)	49 (20)
Secondary school	75 (30)	99 (39)
High school	51 (20)	93 (37)
University	10 (4)	10 (4)
Employment status		
Employed	26 (10)	78 (31)
Retired	198 (79)	138 (55)
Housewife	9 (4)	13 (5)
Unemployed	17 (7)	22 (9)
Exemption for low income		
Yes	129 (51)	-
Relationship with patient		
Spouse/Partner		166 (66)
Son/daughter		60 (24)
Brother/Sister	-	6 (2)
Son-/daughter-in-law		7 (3)
Other		12 (5)
Cohabitation with patient		
Yes	-	188 (75)
	Median [1st–3rd quartile]	
Years from diagnosis	12 [6-20]	-
Caregiving hours per day	-	3 [1-6]
Years of caregiving	-	10 [5-20]
	n (%)	
Presence of at least one chronic disease		
Yes	-	139 (55)
Education in diabetes		
Yes	89 (35)	28 (11)
Hospitalization*		
Yes	78 (31)	-
Access to Emergency Care*		
Yes	73 (29)	-
Unscheduled visit*		
Yes	41 (16)	-
Presence of diabetes complications		
Yes	102 (41)	-
	Median [1st–3rd quartile]	
Body Mass Index	28.1 [25.4-31.7]	-
HbA1c		-
(%)	7.1 [6.6-7.8]	
mmol/mol	54 [49-62]	
Number of comorbidities	3 [2-4]	-

Note: Missing data among patients: 1 in Employment status; 1 in Body Mass Index.
Missing data among caregivers: 17 in Caregiving hours per day; 13 in Years of caregiving.
*In the last year.

Patients mostly reported adequate levels of self-care maintenance (73%, n= 182 score ≥70), while self-care monitoring (54%, n= 135 score <70) and self-care management (57%, n= 142 score <60) were mostly inadequate. Furthermore, they mostly

showed good self-care self-efficacy, answered just over half of the diabetes knowledge questions correctly, and reported good levels of quality of life and mutuality. The majority of caregivers reported poor scores in CC-SCODI scales. Furthermore, they mostly showed good levels of self-efficacy, answered over half of the diabetes knowledge questions correctly, reported high quality of life and mutuality, low burden, and discrete preparedness (**Table 3.2**).

Table 3.2 Scores in administered tools

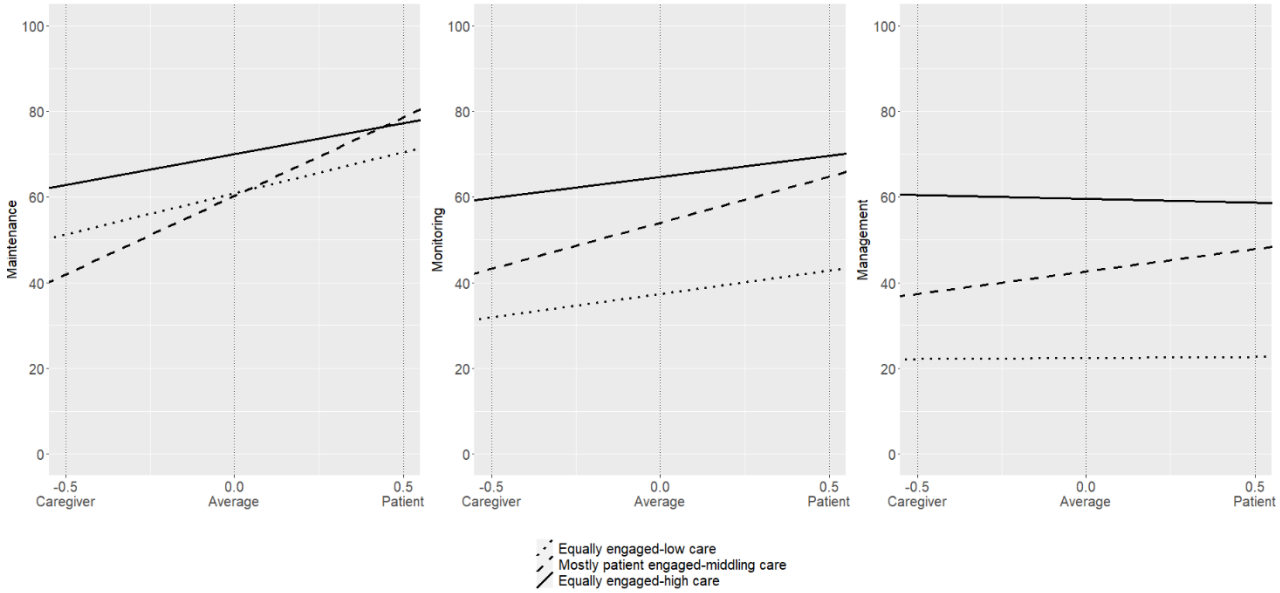
Tools	**Patient** n= 251	**Caregiver** n= 251
	Median [1st–3rd quartile]	
Self-care maintenance (SCODI)	79 [69-88]	-
Self-care monitoring (SCODI)	68 [50-85]	-
Self-care management (SCODI)	56 [26-75]	-
CC to self-care maintenance (CC-SCODI)	-	60 [38-75]
CC to self-care monitoring (CC-SCODI)	-	56 [29-76]
CC to self-care management (CC-SCODI)	-	53 [19-81]
Self-care self-efficacy (SCODI)	75 [59-91]	-
Caregiver self-efficacy in contributing to patient self-care (CC-SCODI)	-	75 [52-90]
Diabetes knowledge – General (DKT2)	57 [43-71]	64 [50-71]
Diabetes knowledge – Insulin* (DKT2)	56 [33-78]	56 [44-78]
Quality of life (EQ5D-VAS)	70 [50-80]	80 [70-90]
Mutuality (MS)	3.2 [2.8-3.6]	3.1 [2.5-3.6]
Caregiver burden (CBI)	-	7 [2-17]
Caregiver preparedness (CPS)	-	19 [15-24]

Note: SCODI= Self-Care of Diabetes Inventory; CC= caregiver contribution; CC-SCODI= Caregiver Contribution to Self-Care of Diabetes Inventory; DKT2= Revised Diabetes Knowledge Test; EQ5D-VAS= EuroQol Five-Dimension–Visual Analogue Scale; MS= Mutuality Scale; CBI= Caregiver Burden Inventory; CPS= Caregiver Preparedness Scale.
Missing data among patients: 1 in Mutuality.
Missing data among caregivers: 8 in Diabetes knowledge – Insulin; 3 in Mutuality.
*Responses required only for patients with insulin therapy (n= 105) and their caregivers.

Three patterns of dyadic engagement in T2DM care emerged from the LCA (entropy= 0.871; lowest classification probability= 0.910; LMR-LRT p= 0.0190; PBLRT p<0.001). The indices of fit of models performed with LCA are reported in **Table 3.7** (Supplementary Material). Indeed, the model with three classes was the one that, in addition to displaying the highest entropy and good performances in further fit indices, identified better clinically characterized classes. Labels were attributed to patterns consistently with the dyadic engagement in T2DM care of each pattern (**Figure 3.1** and

Table 3.3). The demographical and clinical characteristics of patients and caregivers in the identified patterns are presented in **Table 3.4.**

Figure 3.1 Patterns of dyadic engagement in T2DM care behaviors as estimated by the latent class analysis



Legend: x axis reports the dyad member (-0.5 refers to caregiver and 0.5 to the patient), while y axis the self-care maintenance, monitoring, or management behaviors score. Thus, the level of self-care (y axis) corresponding to: i) -0.5 on the x axis coincides with the estimated mean of caregiver contribution to self-care maintenance, monitoring, or management behaviors in each pattern; ii) 0.0 on the x axes coincides with the estimated mean dyadic engagement in self-care maintenance, monitoring, or management behaviors in each pattern; iii) 0.5 on the x axis coincides with the estimated mean of patient self-care maintenance, monitoring, or management behaviors in each pattern.

Table 3.3 Dyadic average and incongruence in self-care behaviors scales (SCODI/CC-SCODI) in each identified pattern

		Equally engaged-low care	**Mostly patient engaged-middling care**	**Equally engaged-high care**
	n (%)	34 (14)	63 (25)	154 (61)
		Est (95% C.I.)		
Maintenance	Dyadic average	60.9 (57.4; 64.4)	60.4 (58.8; 62.0)	70.1 69.3; 70.9)
	Dyadic incongruence	19.2 (14.1; 24.3)	36.7 (33.3; 40.1)	14.4 (12.7; 16.1)
Monitoring	Dyadic average	37.4 (32.1; 42.7)	54.0 (50.3; 57.6)	64.7 (62.7; 66.7)
	Dyadic incongruence	10.9 (7.9; 14.0)	21.5 (19.7; 23.4)	9.9 (8.3; 11.5)
Management	Dyadic average	22.4 (18.9; 25.9)	42.6 (38.0; 47.2)	59.6 (56.8; 62.4)
	Dyadic incongruence	0.5 (-1.3; 2.7)	10.5 (7.8; 13.1)	-1.8 (-3.5; -0.1)

Note: The mean dyadic average and incongruence for each identified pattern were estimated by the latent class analysis, using the maximum likelihood with robust standard errors estimator.

First, the dyadic class labelled as “equally engaged-low care” (14%, n= 34) showed a low dyadic average in self-care maintenance behaviors and the lowest dyadic averages in self-care monitoring and management behaviors with slight incongruence between patient self-care and caregiver contribution (**Figure 3.1** and **Table 3.3**). In this dyadic class, patients had a median age of 72 years, were mostly retired males, with low education and high income. Furthermore, their median time since diabetes diagnosis was nine years and more than 40% of them had at least one diabetes complication. Caregivers belonging to this dyadic pattern had a median age of 64 years, were mostly retired females or housewives with low education. They had been engaged in caregiving for a median of seven years and referred to spend a median of four hours per day in caregiving activities. The vast majority of the dyads of this pattern were cohabitant and the most frequent type of relationship existing between the two members of the dyad is the spousal one. As compared to the other classes, the patients of this class had the lowest level of education and had been the most hospitalized over the last year. Furthermore, caregivers had a chronic disease less often than the other classes (**Table 3.4**).

The second class labelled as “mostly patient engaged-middling care” (25%, n= 63) was characterized by intermediate dyadic averages with large dyadic incongruences in favor of the patient (**Figure 3.1** and **Table 3.3**). In this class, patients had a median age of 72 years, were almost equally distributed between males and females, had a high education in 40% of the cases, and low income in more than half of the cases. Furthermore, their median time since diabetes diagnosis was 12 years and almost half of them had at least one diabetes complication. Caregivers belonging to this class had a median age of 66 years, were mostly females, retired or housewives, with a high education level in almost half of the cases. They had been engaged in caregiving for a median of 11 years and referred to spend a median of three hours per day in caregiving activities. The vast majority of the dyads of this pattern were cohabitant and the most frequent type of

relationship existing between the two members of the dyad was spousal. Compared to the other classes, patients had the highest level of education and an intermediate frequency of hospitalizations in the last year, while caregivers had at least one chronic disease more often than in the previous class (**Table 3.4**).

The third class labelled as "equally engaged-high care" (61%, n= 154) was characterized by the highest dyadic averages with small dyadic incongruences in T2DM care engagement (**Figure 3.1** and **Table 3.3**). In this dyadic pattern, patients had a median age of 73 years, were slightly more often males than females, mostly had a low education and had a low income in more than half of the cases. Furthermore, their median time since diagnosis of diabetes was 12 years and less than 40% of them had at least one diabetes complication. Caregivers belonging to this dyadic pattern had a median age of 64 years, were mostly females, retired or housewives, with a high education level in 40% of the cases. They had been engaged in caregiving for a median of 10 years and referred to spend a median of three hours per day in caregiving activities. As in the other classes, the vast majority of the dyads of this pattern were cohabitant and the most frequent type of relationship existing between the two members of the dyad is the spousal one, even if in almost 30% of cases the caregiver is the adult child. Compared to the other classes, patients had the intermediate level of education and the lowest frequency of hospitalizations in the last year, while caregivers had at least one chronic disease with the same frequency as the previous class and higher than the first class. Further descriptive characteristics of the identified patterns are presented in **Table 3.4**.

Table 3.4 Patterns of dyadic engagement in type 2 diabetes mellitus care characteristics

Characteristics	Equally engaged-low care	Mostly patient engaged-middling care	Equally engaged-high care	p-value
Patient				
Age (years)	72 [65-80]	72 [65-79]	73 [67-78]	0.775
Gender: Male	23 (68)	32 (51)	83 (54)	0.256
Marital status: Married/Cohabitant	27 (79)	52 (82)	112 (73)	0.272
Education: High	5 (15)	26 (41)	30 (19)	0.001
Employment status: Employed	3 (9)	9 (14)	14 (9)	0.505
Low income: Yes	14 (41)	33 (52)	82 (54)	0.437
Education in diabetes: Yes	15 (44)	18 (29)	56 (36)	0.095
Hospitalization: Yes	17 (50)	19 (30)	42 (27)	0.034
Access to Emergency Care: Yes	11 (32)	19 (29)	44 (29)	0.903
Unscheduled visit: Yes	6 (18)	13 (21)	22 (14)	0.504
Diabetes complication(s): Yes	14 (41)	29 (46)	59 (38)	0.574
Body Mass Index (kg/m^2)	28.1 [26.0-32.1]	26.9 [24.9-30.6]	28.4 [25.5-32.5]	0.248
Time since diagnosis (years)	9 [3-22]	12 [6-20]	12 [7-20]	0.264
HbA1c (%)	7.3 [6.7-8.3]	7.0 [6.5-7.7]	7.2 [6.5-7.8]	0.212
HbA1c (mmol/mol)	56 [50-67]	53 [48-61]	55 [48-62]	
Number of comorbidities	3 [2-4]	3 [2-4]	3 [2-4]	0.830
Self-care self-efficacy (SCODI)	74 [50-86]	80[64-100]	77 [64-91]	0.118
Diabetes knowledge – General (DKT2)	53 [38-71]	57 [43-71]	57 [43-64]	0.381
Diabetes knowledge – Insulin (DKT2)	55 [44-75]	67 [33-89]	56 [33-78]	0.439
Quality of life (EQ5D – VAS)	70 [66-80]	70 [60-80]	70 [50-80]	0.512
Mutuality (MS)	3.3 [2.8-3.6]	3.3 [2.8-3.8]	3.2 [2.8-3.6]	0.573
Caregiver				
Age	64 [55-74]	66 [54-71]	64 [53-71]	0.672
Gender: Male	10 (29)	17 (27)	46 (30)	0.913
Marital status: Married/Cohabitant	29 (85)	58 (92)	138 (90)	0.580
Education: High	12 (35)	30 (47)	61 (40)	0.423
Employment status: Employed	8 (23)	21 (33)	49 (32)	0.579
Education in diabetes: Yes	5 (15)	11 (18)	12 (8)	0.095
Chronic disease(s): Yes	11 (32)	37 (59)	91 (59)	0.015
Years of caregiving	7 [2-10]	11 [5-18]	10 [6-20]	0.065
Caregiving hours per day	4 [2-8]	3 [2-7]	3 [1-4]	0.136
Self-efficacy in contributing to patient self-care (CC-SCODI)	69 [50-92]	75 [56-100]	75 [52-86]	0.238
Diabetes knowledge – General (DKT2)	64 [50-71]	64 [50-71]	64 [50-71]	0.710
Diabetes knowledge – Insulin (DKT2)	67 [47-78]	67 [44-89]	56 [33-78]	0.305
Quality of life (EQ5D – VAS)	80 [75-90]	80 [70-90]	80 [66-90]	0.512
Mutuality (MS)	3.2 [2.9-3.6]	3.2 [2.6-3.7]	3.0 [2.5-3.5]	0.096
Burden (CBI)	4 [1-11]	7 [2-17]	7 [3-18]	0.222
Preparedness (CPS)	19 [13-24]	22 [16-24]	18 [15-24]	0.574
Dyad				
Cohabitation: Yes	25 (74)	46 (73)	117 (76)	0.509
Relationship type				
Spousal	23 (68)	42 (67)	101 (66)	
Adult-child	6 (18)	12 (19)	42 (27)	0.276
Other family/friend	5 (15)	9 (14)	11 (7)	

Note: Differences between identified patterns were tested using the Kruskal-Wallis test or the chi-square (χ^2) test, as appropriate.
SCODI= Self-Care of Diabetes Inventory; CC= caregiver contribution; CC-SCODI= Caregiver Contribution to Self-Care of Diabetes Inventory; DKT2= Revised Diabetes Knowledge Test; EQ5D-VAS= EuroQol Five-Dimension-Visual Analogue Scale; MS= Mutuality Scale; CBI= Caregiver Burden Inventory; CPS= Caregiver Preparedness Scale.

According to the multinomial regression model, dyads belonging to the "mostly patient engaged-middling care" pattern, compared to dyads belonging to the "equally engaged-low care" pattern, were most often characterized by patients being females (OR

males= 0.12; 95% C.I.: 0.03; 0.51), having high education (OR= 5.64; 95% C.I.: 1.59; 20.00), and higher self-care self-efficacy (OR= 1.03; 95% C.I.: 1.01; 1.05), and caregivers having at least one chronic disease (OR= 4.95; 95% C.I.: 1.59; 15.44). On the other hand, dyads belonging to the "equally engaged-high care" pattern, compared to dyads belonging to the "equally engaged-low care" pattern were most often characterized by patients having higher self-care self-efficacy (OR= 1.02; 95% C.I.: 1.01; 1.04) and caregivers having at least one chronic disease (OR= 4.76; 95% C.I.: 1.73; 13.13) and higher burden (OR= 1.05; 95% C.I.: 1.01; 1.09) (**Table 3.5**).

Table 3.5 Patterns of dyadic engagement in type 2 diabetes mellitus care adjusted characteristics by multinomial regression model

	Mostly patient engaged-middling care *vs* Equally engaged-low care			**Equally engaged-high care** *vs* Equally engaged-low care		
Characteristics	**β**	**OR (95% C.I.)**	**p- value**	**β**	**OR (95% C.I.)**	**p- value**
Patient						
Age (years)	-0.02	0.98 (0.92; 1.04)	0.486	-0.01	0.99 (0.94; 1.04)	0.739
Gender: Male *vs* Female	-2.12	0.12 (0.03; 0.51)	0.004	-1.06	0.35 (0.10; 1.16)	0.085
Low income: Yes *vs* No	0.99	2.69 (0.94; 7.75)	0.066	0.81	2.25 (0.88; 5.78)	0.090
Marital status: Married/Cohabitant	0.80	2.23 (0.50; 9.89)	0.296	-0.16	0.85 (0.23; 3.14)	0.812
Education: High *vs* Low	1.73	5.64 (1.59; 20.00)	0.007	0.30	1.35 (0.41; 4.49)	0.625
Education in diabetes: Yes *vs* No	-1.49	0.23 (0.06; 0.81)	0.023	-0.36	0.70 (0.24; 1.99)	0.497
Self-care self-efficacy (SCODI)	0.03	1.03 (1.01; 1.05)	0.006	0.02	1.02 (1.01; 1.04)	0.011
Caregiver						
Age (years)	0.00	1.00 (0.94; 1.07)	0.892	-0.02	0.98 (0.93; 1.03)	0.423
Gender: Male *vs* Female	-1.46	0.23 (0.05; 1.09)	0.064	-0.48	0.62 (0.17; 2.22)	0.465
Employment status: Employed *vs* Unemployed	1.33	3.78 (0.77; 18.48)	0.100	0.38	1.46 (0.36; 6.08)	0.595
Caregiving hours per day	0.03	1.03 (0.96; 1.11)	0.388	-0.04	0.96 (0.90; 1.03)	0.270
Education in diabetes: Yes *vs* No	1.72	5.58 (0.99; 31.69)	0.051	-0.32	0.73 (0.15; 3.51)	0.693
Chronic disease(s): Yes *vs* No	1.60	4.95 (1.59; 15.44)	0.006	1.56	4.76 (1.73; 13.13)	0.003
Quality of life (EQ5D – VAS)	0.01	1.01 (0.97; 1.04)	0.718	-0.02	0.98 (0.95; 1.01)	0.149
Burden (CBI)	0.03	1.03 (0.99; 1.08)	0.170	0.05	1.05 (1.01; 1.09)	0.023
Preparedness (CPS)	-0.06	0.94 (0.87; 1.01)	0.114	-0.04	0.96 (0.90; 1.03)	0.255

Legend: Reference category: equally-engaged-low care. Independent variables included in the model emerged from the backward stepwise procedure, in which the significance criterion with a p-value threshold of 0.05 was adopted.

According to the multivariable linear regression model, there was an association between the class and the glycemic control as measured by HbA1c. Net of the patient age, gender, BMI, diabetes complications, time since diagnosis, and insulin therapy, the membership in the "mostly patient engaged-middling care" pattern compared to the "equally engaged-low care" pattern, was associated with a decrease in HbA1c of 0.57%

(95% C.I.: -1.07; -0.08%, Table 3.6). Instead, the class "equally engaged-high care", was associated with a decrease in HbA1c of 0.45% (95% C.I.: -0.89; -0.01%) as compared to the "equally engaged-low care" class. The male patient gender and the presence of insulin therapy were also associated with a decrease in HbA1c (β= -0.39: 95% C.I.: -0.69; -0.09 and β= 0.62; 95% C.I.: 0.29; 0.95, respectively) (**Table 3.6**).

Table 3.6 Association between patterns of dyadic engagement in type 2 diabetes mellitus care and glycated hemoglobin by multivariable linear regression models

	HbA1c (%)	**HbA1c (mmol/mol)**	
Variable	**β (95% C.I.)**	**β (95% C.I.)**	**p-value**
(Intercept)	7.93 (6.36; 9.49)	63.17 (46.06; 80.28)	<0.001
Mostly patient engaged-middling care *vs* Equally engaged-low care	**-0.57 (-1.07; -0.08)**	**-6.28 (-11.71; -0.85)**	**0.024**
Equally engaged-high care *vs* Equally engaged-low care	**-0.45 (-0.89; -0.01)**	**-4.88 (-9.69; -0.06)**	**0.047**
Age (years)	-0.01 (-0.02; 0.01)	-0.09 (-0.75; 0.08)	0.299
Gender: Male *vs* Females	-0.39 (-0.69; -0.09)	-4.25 (-7.53; -0.96)	0.011
Body Mass Index (kg/m^2)	0.01 (-0.02; 0.04)	0.08 (-0.22; 0.39)	0.596
Diabetes complications. Yes *vs* No	0.08 (-0.24; 0.39)	0.84 (-2.63; 4.31)	0.634
Time since diagnosis (years)	0.01 (-0.01; 0.03)	0.11 (-0.09; 0.31)	0.269
Insulin therapy: Yes *vs* No	0.62 (0.29;0.95)	6.77 (3.17; 10.38)	<0.001

3.5 Discussion

The aim of this study was to identify and characterize distinct patterns of dyadic engagement in T2DM care. Three well characterized patterns were found: "equally engaged-low care", "mostly patient engaged-middling care", and "equally engaged-high care". Several characteristics at both patient and caregiver level showed to be associated with the membership in each class. Furthermore, these dyadic classes were associated with patient glycemic control. In particular, the membership in the classes "mostly patient engaged-middling care" and "equally engaged-low care" was associated with lower levels of HbA1c compared to the class "equally engaged-low care". To the best of our knowledge, a dyadic approach accounting for the interdependence between patient self-care and caregiver contribution was never adopted before in T2DM. Furthermore, no previous studies identified patterns of patient-caregiver engagement in T2DM care behaviors. The availability of these patterns and their characteristics may offer a more

comprehensive understanding of the T2DM care process and may represent a relevant starting point for interventions tailored to the dyads rather than individuals.

The "equally engaged-low care" pattern clustered dyads reporting poor implementation of self-care behaviors both in patients and caregivers. In particular, self-care monitoring and management behaviors were lower than self-care maintenance behaviors. This result suggests that these dyads were quite aware of lifestyles to lead or recommend, but they seemed to pay less attention to the disease itself, both as symptoms occurrence and as consequent actions to be implemented. Indeed, symptoms of T2DM may be mild and difficult to recognize and, consequently, to manage (International Diabetes Federation, 2021). Nevertheless, self-care monitoring and self-care management behaviors are essential in the self-care process (Riegel et al., 2012) and they had yet shown to be associated with patient outcomes (Fabrizi et al., 2020). Interestingly, this result is confirmed at the dyadic level, as in this dyadic pattern, patients had the poorest glycemic control and had been the most hospitalized. These dyads could be the primary focus of interventions by healthcare providers, as the empowerment of their engagement in self-care behaviors could lead to improved patient outcomes.

The "mostly patient engaged-middling care" pattern clustered dyads with intermediate implementation of self-care behaviors and showed a predominant involvement of the patient over that of the caregiver. In these dyads, patients had the highest and caregiver the lowest score in self-care maintenance behaviors, while for the other scales, their score were included between those of the other two classes for both the dyad members. In this pattern, the T2DM management was predominantly by the patient, while the caregiver seemed to intervene only in support or integration of the patient for the strictly necessary. Interestingly, patients belonging to this pattern, with respect of the previous pattern, were more often women and had more often a high education. These characteristics could support the division of tasks highlighted by the pattern as a

consequence of the patients' capacity for autonomy (Ausili et al., 2018; Caruso et al., 2020). Furthermore, caregivers belonging to this pattern had at least one chronic disease more often than caregivers belonging to the previous pattern. Consequently, being the patient able to perform most of the self-care behaviors autonomously, caregivers could have afforded to make a limited contribution and to be dedicated to their own condition. About glycemic control, the membership in this pattern showed the greatest decrease in HbA1c with respect to the “equally engaged-low care” pattern. This result suggests that a predominant role of the patient accompanied by a vigilant compensatory role of the caregiver in the strictly necessary areas could bring optimal benefits on patient glycemic control in the management of T2DM. Thus, patient empowerment and caregiver education in terms of support and compensation could be the most appropriate interventions for this dyadic pattern.

The “equally engaged-high care” pattern, clustered most of the dyads. Both patients and caregivers belonging to this pattern showed higher scores than the others in almost all scales of self-care behaviors. With respect to the “equally engaged-low care” pattern, dyads belonging to this pattern did not have characteristics that significantly distinguished them, except for higher caregiver burden, reflecting greater caregiver involvement, and the presence of at least one chronic disease in the caregiver. This last characteristic could have led to a greater awareness of the chronic situation from the caregiver. Furthermore, the presence of the chronic disease could have created different functioning conditions for the dyad with respect to the "mostly patient engaged-middling care" pattern. Although also in this case patients reported high self-care scores, caregivers seemed to be involved in a virtuous circle of close collaboration with them, participating in all the activities in which the patient is already engaged (De Maria et al., 2023). This difference compared to the previous pattern could be traced back at least in part to the CC-SCODI wording (Lee et al., 2015). In fact, it is not possible to predict based on the

scores whether the caregiver contribution takes place in terms of recommendation, support, or replacement for the patient[6]. These different modes of contribution by the caregiver may have partially emerged in a latent form from the distinction between the "mostly patient engaged-middling care" class and the "equally engaged-high care" class resulting from the LCA. The patient glycemic control benefited from the dyadic engagement scores in T2DM of this pattern, compared to the "equally engaged-low care" pattern. This result suggested that, even in the absence of substantial differences between groups, a greater commitment to jointly perform self-care behaviors by patient and caregiver could be associated with lower levels of HbA1c. In these dyads could be useful to monitor the persistence of adequate scores over time for both members of the dyad, also paying attention that the burden associated with caregiving does not compromise caregivers' health and well-being (De Maria et al., 2023).

Limitations and Strengths

Acknowledging the study limitations, it is essential to highlight three main aspects. Firstly, the study utilized a convenience sample, which may introduce potential biases, and the sample size was quite limited. Secondly, the study was conducted in a single country, so differences in results may be found elsewhere due to cultural and socioeconomic factors (De Maria et al., 2021). Therefore, the findings of this study should be validated by conducting international studies. Thirdly, the cross-sectional nature of the study did not provide information about the trend and stability over time of the results of this study.

However, the study employed valid and reliable tools to collect measures. Furthermore, a dyadic approach was adopted, encompassing both patients and caregivers and providing a comprehensive understanding of the dynamics involved in T2DM care.

[6] See also A2 in Appendix

Lastly, the integrated use of multilevel modeling and LCA provided robustness in dyadic patterns identification.

3.6 Conclusion

Three distinct patterns of dyadic engagement in T2DM care were identified according to patient self-care and caregiver contribution to it: “equally engaged-low care”, “mostly patient engaged-middling care”, and “equally engaged-high care”. Furthermore, these patterns showed differences in characteristics both at the patient and caregiver level. Lastly, an association between patterns membership and glycemic control was found, integrating the pre-existing knowledge about the relationship between patient self-care and glycated hemoglobin. Accordingly, these dyadic patterns should be considered by healthcare professionals in order to provide tailored interventions focused on both members of the dyad. Future research is needed to further investigate T2DM management under a dyadic approach, also adopting international, longitudinal, and experimental designs.

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Supplementary material

Table 3.7 Performance assessment of latent class analysis models with increasing number of classes

Number of classes	Performances assessment criteria					
	BIC	**< Post. prob.**	**< Class size**	**Entropy**	**LMR-LRT (p)**	**PBLRT (p)**
2	13778.782	0.941	0.35	0.828	0.0000	0.0000
3	13726.389	0.910	0.14	0.871	0.0190	0.0000
4	13692.062	0.864	0.14	0.813	0.0161	0.0000
5	13658.800	0.871	0.10	0.838	0.0988	0.0000

Note: Fit indices were identical when performing latent class analysis using either the coefficients from multilevel models or the observed measures as input.
Legend: **BIC**= Bayesian Information Criteria (the lower the better); **< Post. Prob**= Minor posterior probability (the average of latent class probabilities for the most likely latent class membership by latent class. It must be close to 1); **<Class size**= Minor class size (it must be not less than 5% of the sample); **Entropy**= index of model convergence (it must be close to 1); **LMR-LRT (p)**= p-value of the Lo-Mendell-Rubin adjusted likelihood ratio test (if p>0.05, the identified model it is not better compared to the previous one (number of classes-1)); **PBLRT (p)**= p-value of the parametric bootstrapped likelihood ratio test (if p>0.05, the identified model it is not better compared to the previous one (number of classes-1)(Ram & Grimm, 2009).

CHAPTHER 4

Dyadic approaches for patient self-care and caregiver contribution to self-care assessment in type 2 diabetes mellitus

Title

Dyadic approaches for patient self-care and caregiver contribution to self-care assessment in type 2 diabetes mellitus

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4.1 Abstract

Introduction and Aim. Patient self-care and caregiver contribution to self-care in chronic illnesses should be considered together as a dyadic phenomenon called "dyadic illness management". The possibility of classifying dyadic engagement in type 2 diabetes mellitus (T2DM) care may uncover patterns of behavior useful for improving T2DM management. Mixed effects models (MM) have been used to obtain dyadic scores to be used as input of latent class analysis (LCA). However, the advantages of this approach over simpler synthetic dyadic measures are not clear. This study aimed at comparing two methods of dyadic data analysis to assess dyadic T2DM management to be used to identify distinct patterns of dyadic T2DM management.

Methods and Results. This cross-sectional study involved 251 patients with T2DM and their caregivers. Patient self-care and caregiver contribution to self-care were measured respectively by the Self-Care of Diabetes Inventory and the Caregiver Contribution to Self-Care in Diabetes Inventory, each one consisting in three scales scored 0-100. To assess the dyadic T2DM management, as first approach we adopted MM with random intercept and slope, respectively obtaining the estimated average and the incongruence in dyadic T2DM management within the dyad. Then, we used the MM coefficients to perform a LCA able to identify patterns of dyadic management. As alternative approach, we estimated dyadic average and incongruence by the raw mean and by the difference between patient and caregiver scores. Then, we used them as input to perform the LCA. Interestingly, the LCA clustered the same dyads in the same classes in both approaches, with identical fit indices. The model with three classes showed the best performances both in terms of fit and clinical characterization of the dyads.

Conclusion. MM accounts for the interdependence within the dyad and for the measurement error, returning predicted measures shrunk towards the overall mean.

However, it yielded the same clusters of the simpler approach which used observed measures.

4.2 Introduction

The need to consider both patient and caregiver in the field of chronic illnesses has been highlighted both by theoretical and empirical evidences, sparking a growing interest in understanding how they manage illness together (K. Lyons & Lee, 2018). Indeed, the informal caregiver who provides unpaid assistance has been shown to support the patient with chronic conditions in adhering to complex self-care behaviors (Vellone et al., 2019). Hence, patient self-care and caregiver contribution to self-care in chronic illnesses should be considered as a dyadic phenomenon, identifiable as "dyadic illness management", in which both members of the patient-caregiver dyad mutually influence each other (K. Lyons & Lee, 2018).

The identification of distinct and unobserved patterns of dyadic illness management could be very useful when studying chronic illness care and several studies performed it adopting the latent class analysis (LCA) (Bonds et al., 2021; De Maria et al., 2023a; Lee et al., 2015; Lee & Lyons, 2019). The general recommendation in dyadic research, and specifically in caregiving research, is to use the parameters estimated by the so called incongruence model (IM) on the dyadic engagement in T2DM care as input variables of the LCA (Kenny et al., 2006; Lee et al., 2020; K. S. Lyons & Lee, 2020a; Sayer & Klute, 2005). The incongruence model is a MM with a codification that allows to directly estimate the average level of the outcome (e.g., dyadic illness management) within the dyad (dyadic mean) and the incongruence or gap between the two members of the dyad (K. S. Lyons & Lee, 2020a). In the first level – within dyads –, IM estimates these two latent variables that characterize each dyad by the intercept, that represents the dyadic average level of the variable of interest, and the slope, that represents the incongruence in the variable of interest between members of the dyad (K. S. Lyons & Lee, 2020a, 2020b; Sayer & Klute, 2005). In the second level – between the dyads –, IM estimates the population mean of dyad average and dyad incongruence (Sayer & Klute, 2005).

The advantages over simpler synthetic dyadic measures are still unclear in the specific context of LCA. Sayer and Klute (2005), reviewing traditional methods for constructing new dyadic measures from individual data, argued that measurement approaches such as mean and difference scores have strong limitations. According to them, mean scores are useful only if there is concordance between scores of both dyad members, while difference scores, although they correct the problem of discrepancy, do not consider the location of the dyad on the outcome scale. However, these limitations seem to reflect what would happen if the two parameters were considered separately. Instead, if both mean and difference scores are jointly considered, the information obtained may not be deficient compared to that estimated by the MM.

As the complexity of MM might compromise the correct application of the methods and a deep interpretation of results, the comparison between the two methods for obtaining dyadic measures to be used to identify patterns of dyadic behavior could delve into the limits and strengths of each approach and guide future research. Therefore, the aim of this study was to compare the MM approach with a simpler one for measuring dyadic T2DM management, to be used to classify dyads into unobserved distinct patterns of dyadic engagement in T2DM care.

4.3 Methods

This study used data from a multicenter cross-sectional study[7] conducted involving patients with T2DM and their informal caregivers from four outpatient diabetes clinics in the North of Italy. The study received approval from the Institutional Review Board of each center. Further details have been described in Chapter 3.

Sample

[7] See Chapter 3

Briefly, a sample of adult T2DM patient-caregiver dyads was recruited during outpatient visits. Patients were excluded if they had difficulties reading the study questionnaire, had been diagnosed with T2DM for less than one year, were making their first visit to the diabetes center, or had confirmed cognitive impairment. Caregivers were excluded if they had difficulties reading the study questionnaire or had confirmed cognitive impairment.

Measurement

Patient self-care and caregiver contribution to self-care were measured respectively by the Self-Care of Diabetes Inventory (SCODI) (Ausili et al., 2017a) and the Caregiver Contribution to Self-Care in Diabetes Inventory (CC-SCODI)[8], whose validity was already supported (Ausili et al., 2017b; De Maria et al., 2022)[9]. These two tools consist of the same three scales (self-care/contribution to self-care maintenance, monitoring, and management) assessing the same behaviors and differing for the considered viewpoint. The self-care/contribution to self-care maintenance scale assesses behaviors to maintain physical and emotional stability (e.g., adherence to diet, medications, and physical activity recommendations). The self-care/contribution to self-care monitoring scale evaluates behaviors aimed at recognizing signs and symptoms in the body (e.g., monitoring blood glucose, body weight, feet, and symptoms of hypo- or hyperglycemia). The self-care/contribution to self-care management scale appraises behaviors employed in response to signs and symptoms (e.g., managing episodes of hypo- and hyperglycemia) (Ausili et al., 2017a; Riegel et al., 2012). Each item uses a five-point Likert-type scale from “never” to “always”, and each scale provides a 0-100 standardized score, where higher scores denote higher self-care or higher contribution to self-care (Ausili et al. 2017)[10].

[8] See Paragraph 6.2
[9] See also Paragraph 6.2
[10] See also Paragraph 6.2

Statistical analysis

As first approach, the dyadic T2DM management was estimated by adopting three incongruence models (one for each pair of SCODI/CC-SCODI scales) with random intercept and slope (K. S. Lyons & Lee, 2020a; Raudenbush & Bryk, 2002; Sayer & Klute, 2005):

$$\text{Dyadic T2DM management}_{ij} = \beta_{0j} + \beta_{1j} I_{ij} + r_{ij} \quad (1)$$

where Dyadic T2DM management$_{ij}$ represents the self-care/contribution to self-care score for the person i in the dyad j and I_{ij} is an indicator variable representing the dyad member who reports the score (codified as -0.5 for the caregiver and 0.5 for the patient) (K. S. Lyons & Lee, 2020a; Raudenbush & Bryk, 2002). Under this codification, the intercept (β_{0j}) represents the expected value of Dyadic T2DM management in the dyad j and the slope (β_{1j}) the expected incongruence in dyadic engagement, reflecting the magnitude and the direction of the incongruence in the outcome between the two members of the dyad (K. S. Lyons & Lee, 2020a). The coefficients β_{0j} and β_{1j} are conceived as varying randomly across dyads (random effects reflecting the variability around the average level of Dyadic T2DM management and incongruence) and are assumed to follow a Normal distribution with mean of zero and variance σ^2 (Raudenbush & Bryk, 2002; Sayer & Klute, 2005). The residuals (r_{ij}) captures measurement error and are assumed to follow a Normal distribution with a mean of zero and variance σ^2 (Raudenbush & Bryk, 2002; Sayer & Klute, 2005). The incongruence model can be described as a multilevel model, in which the first level – within the dyads – estimates the two latent variables that characterize each dyad by the intercept, that represents the dyadic average level of the variable of interest, and the slope, that represents the incongruence in the variable of interest between members of the dyad (K. S. Lyons & Lee, 2020a, 2020b; Sayer & Klute, 2005). In the second level – between the dyads –, IM

estimates the population mean of dyadic average and incongruence (Sayer & Klute, 2005).

To identify patterns of dyadic engagement in T2DM care, a LCA was performed (De Maria et al., 2023b; Lee et al., 2015, 2020). For each dyad, the previously predicted average and incongruence of each SCODI/CC-SCODI scale (two predicted random effects for three scales, for a total of six parameters) were included in the analysis. The mean dyadic average and incongruence for each identified pattern were also estimated by the LCA, using the maximum likelihood with robust standard errors estimator (Berlin et al., 2014).

As an alternative approach, for each SCODI/CC-SCODI scale dyadic average and incongruence were estimated by the raw mean and by the difference between SCODI/CC-SCODI scores obtained by patients and caregiver, respectively. These six measures were used as input to perform the LCA again.

To support the LCA model selection (i.e., number of classes), the Bayesian Information Criteria (BIC, the lower the better), posterior probabilities (average posterior probabilities for most likely class near 1.0), the size of the observed profiles (not less than 5% of the sample), the model convergence (entropy near 1.0), the Lo-Mendell-Rubin adjusted likelihood ratio test (LMR-LRT), and the parametric bootstrap likelihood ratio test (PBLRT) were used as fit indices (Lee et al., 2020; Ram & Grimm, 2009).

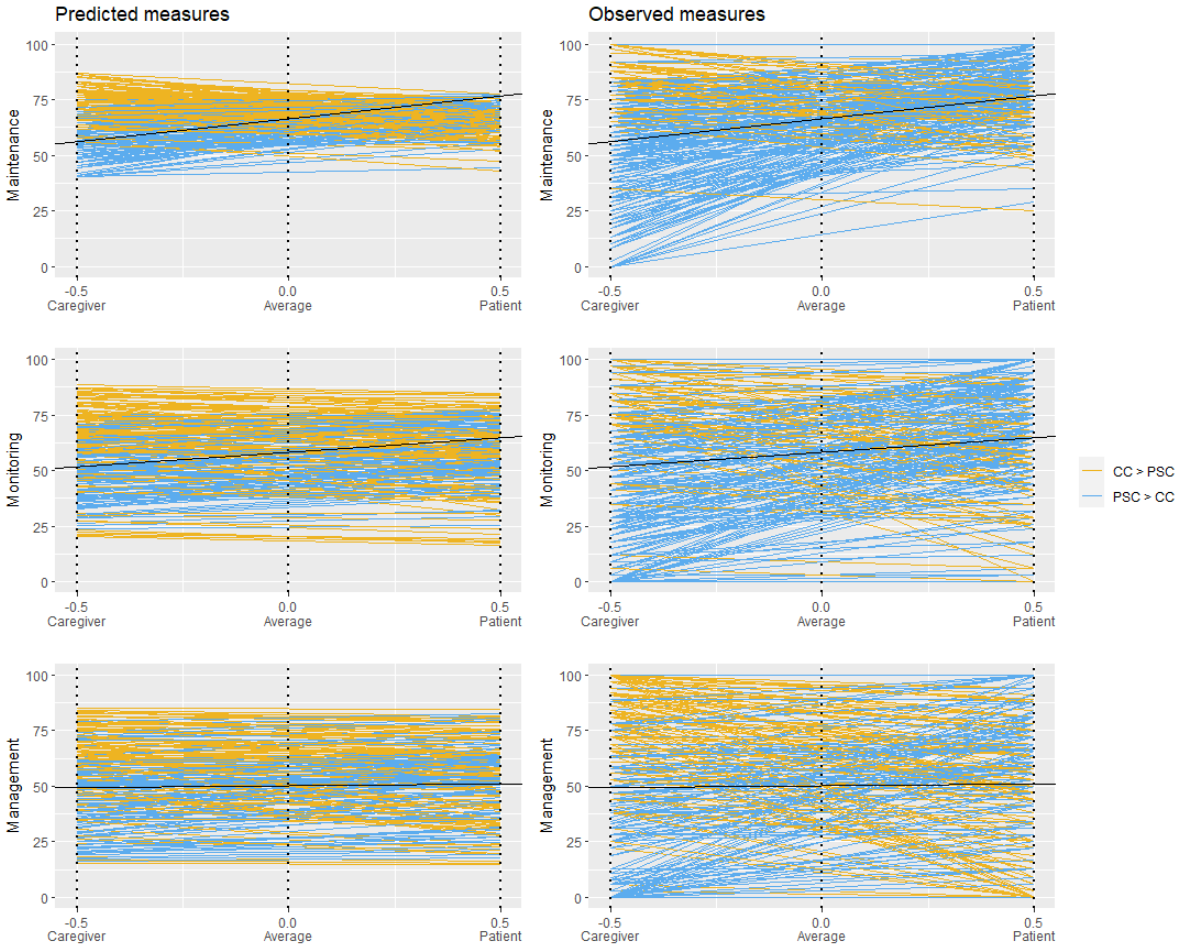
4.4 Results

A total of 251 patient-caregiver dyads were enrolled. Patients were mostly males (55%) with a mean age of 72 years (standard deviation (sd)= 10). Caregivers were mostly females (71%) with a mean age of 63 years (sd= 13). Patients' mean scores in SCODI scales were: 77 (sd= 14) in self-care maintenance, 65 (sd= 23) in self-care monitoring, and 51 (sd= 30) in self-care management. Caregivers' mean scores in CC-SCODI scales

were: 56 (sd= 26) in caregiver contribution to self-care maintenance, 52 (sd= 29) in caregiver contribution to self-care monitoring, and 49 (sd= 34) in caregiver contribution to self-care management. Dyadic mean scores were 66 (sd= 23) in self-care maintenance behaviors, 58 (sd= 27) in self-care monitoring behaviors, and 50 (sd= 32) in self-care management behaviors.

Figure 4.1 shows the patient (I_{ij}= 0.5) and caregiver (I_{ij}= -0.5) scores as predicted by the incongruence model (on the left side) and observed (right side). As expected, the average and incongruence of dyadic T2DM management predicted for each dyad by the incongruence models' coefficients were shrunk towards the overall mean (i.e., fixed effects), with respect to the observed measures.

Figure 4.1 Predicted and observed dyadic engagement in self-care maintenance, monitoring, and management behaviors for each dyad (n= 251)



Legend: CC= caregiver contribution to patient self-care; PSC= patient self-care.
Each line coincides with one dyad. For each dyad, -0.5 on the x axis coincides with the caregiver contribution to self-care maintenance, monitoring, or management score; 0.0 on the x axes coincides with the mean dyadic engagement in self-care maintenance, monitoring, or management score. 0.5 on the x axis coincides with the patient self-care maintenance, monitoring, or management score. Yellow lines denote that caregiver contribution to patient self-care score is higher than patient self-care score. Blue lines denote that patient self-care score is higher than caregiver contribution to self-care score. The black line coincides with the overall dyadic mean (fixed effects).

Using as input variables the parameters estimated by MM, the LCA model with three classes was the one that, in addition to displaying the highest entropy and good performances in further fit indices, it was capable of identifying better-clinically characterized classes (**Table 4.2**). Class 1 clustered 14% of dyads (n= 34), class 2 clustered 61% of dyads (n= 154), and class 3 clustered 25% of dyads (n= 63).

Table 4.2 Performance assessment of latent class analysis models with increasing number of classes

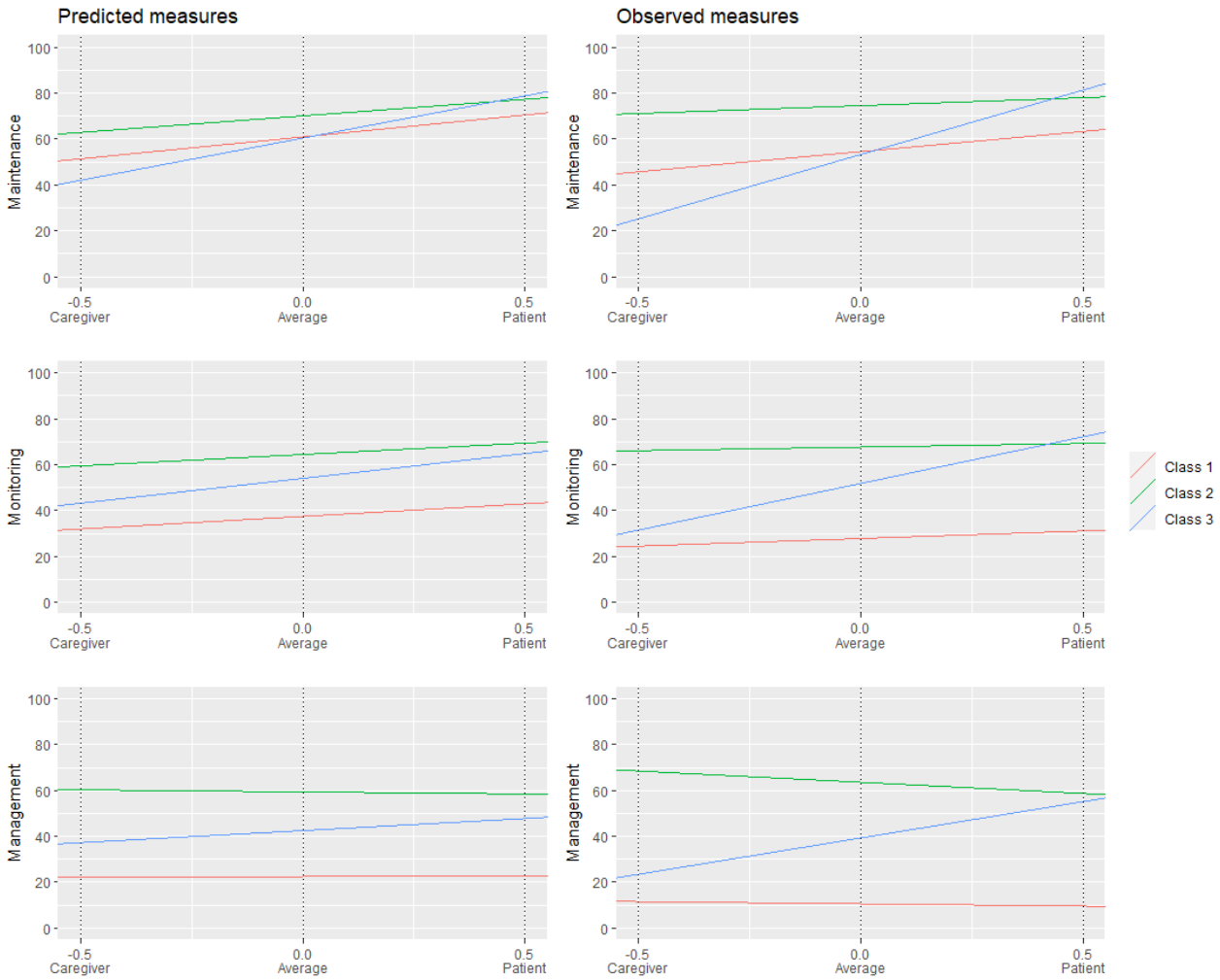
Number of classes	Performances assessment criteria					
	BIC	**< Post. prob.**	**< Class size**	**Entropy**	**LMR-LRT (p)**	**PBLRT (p)**
2	13778.782	0.941	0.35	0.828	0.0000	0.0000
3	13726.389	0.910	0.14	0.871	0.0190	0.0000
4	13692.062	0.864	0.14	0.813	0.0161	0.0000
5	13658.800	0.871	0.10	0.838	0.0988	0.0000

Note: Fit indices were identical when performing latent class analysis using either the coefficients from mixed effects models or the observed measures as input.
Legend: **BIC**= Bayesian Information Criteria (the lower the better); **< Post. Prob**= Minor posterior probability (the average of latent class probabilities for the most likely latent class membership by latent class. It must be close to 1); **< Class size**= Minor class size (it must be not less than 5% of the sample); **Entropy**= index of model convergence (it must be close to 1); **LMR-LRT (p)**= p-value of the Lo-Mendell-Rubin adjusted likelihood ratio test (if p>0.05, the identified model it is not better compared to the previous one (number of classes-1)); **PBLRT (p)**= p-value of the parametric bootstrapped likelihood ratio test (if p>0.05, the identified model it is not better compared to the previous one (number of classes-1)(Ram & Grimm, 2009).

The left side of **Figure 4.2** presents the results of LCA for the three scales of self-care. Class 1 dyads were mostly characterized by low dyadic averages with small dyadic incongruences in T2DM care engagement. Class 2 dyads were mostly characterized by high dyadic averages with small dyadic incongruences in T2DM care engagement. Class 3 dyads were mostly characterized by intermediate dyadic averages with large dyadic incongruences in favor of the patient.

When the alternative approach was performed by using the raw mean and difference between care engagement of the dyad as input for the LCA, the dyads were actually clustered in the same classes as first approach, with identical fit indices (**Table 4.2**). The LCA clustered exactly in the same way, as the ordinality of the scores between the observed and the predicted measures remained unchanged for each dyad (Raudenbush & Bryk, 2002). Thus, the use of the MM did not have any impact on classification. The only difference among the two approaches resulted in the self-care/contribution to self-care behaviors estimated by MM (see comparison in **Figure 4.2** and **Table 4.3**), due to the shrinkage produced by the MM approach. Class trends were anyway similar in the two approaches.

Figure 4.2 Dyadic engagement in self-care/contribution to self-care behaviors estimated by mixed effects models' coefficients (left side) and observed measures (right side) in dyads classes as identified by latent class analysis



Legend: -0.5 on the x axis coincides with the estimated mean of caregiver contribution to self-care maintenance, monitoring, or management behaviors in each class; 0.0 on the x axes coincides with the estimated mean dyadic engagement in self-care maintenance, monitoring, or management behaviors in each class. 0.5 on the x axis coincides with the estimated mean of patient self-care maintenance, monitoring, or management behaviors in each class.

Table 4.3 reported the dyadic average and incongruence and the dyadic mean and difference respectively by predicted and observed measures in self-care maintenance, monitoring, and management scores for each identified class, as estimated by the LCA.

Table 4.3 Dyadic average and incongruence by predicted measures and dyadic mean and difference by observed measures in self-care maintenance, monitoring, and management scores for each identified class (mean, 95% confidence interval), as estimated by the latent class analysis

			Class 1	Class 2	Class 3
		n (%)	34 (13.5)	154 (61.4)	63 (25.1)
Predicted measures	**Maintenance**	Dyadic average	60.9 (57.4, 64.4)	70.1 69.3, 70.9)	60.4 (58.8, 62.0)
		Dyadic incongruence	19.2 (14.1, 24.3)	14.4 (12.7, 16.1)	36.7 (33.3, 40.1)
	Monitoring	Dyadic average	37.4 (32.1, 42.7)	64.7 (62.7, 66.7)	54.0 (50.3, 57.6)
		Dyadic incongruence	10.9 (7.9, 14.0)	9.9 (8.3, 11.5)	21.5 (19.7, 23.4)
	Management	Dyadic average	22.4 (18.9, 25.9)	59.6 (56.8, 62.4)	42.6 (38.0, 47.2)
		Dyadic incongruence	0.5 (-1.3, 2.7)	-1.8 (-3.5, -0.1)	10.5 (7.8, 13.1)
Observed measures	**Maintenance**	Dyadic mean	54.5 (47.0; 62.0)	74.4 (72.6; 76.1)	53.4 (49.9; 56.9)
		Dyadic difference	17.6 (6.3; 28.9)	6.9 (3.2; 10.6)	56.3 (48.7; 63.8)
	Monitoring	Dyadic mean	27.8 (20.1; 35.5)	67.7 (64.7; 70.6)	52.0 (46.7; 57.2)
		Dyadic difference	6.5 (-3.4; 16.4)	3.2 (-1.9; 8.3)	40.7 (34.9; 46.5)
	Management	Dyadic mean	10.5 (5.5; 15.5)	63.6 (59.6; 67.6)	39.3 (32.7; 45.9)
		Dyadic difference	-1.9 (-9.3; 5.6)	-9.7 (-15.4; -4.0)	31.6 (22.6; 40.6)

Note: Positive values of dyadic incongruence/difference denote that the patient score is on average higher than the caregiver score. Negative values of dyadic incongruence/difference denote that the caregiver score is on average higher than the patient score.

4.5 Discussion

This study aimed at comparing two methods of dyadic data analysis for assessing dyadic illness management to be used to identify distinct patterns of dyadic engagement in T2DM care. When used to identify patterns of dyadic engagement, the dyadic averages and incongruences predicted by the incongruence (mixed effects) model showed no advantage over the observed means and differences. Indeed, dyads clustered in the same classes with both approaches. This finding is relevant because it suggests that this type of dyadic data can be simpler to approach when the aim is to identify classes.

Since the ordinality of the scores of each dyad remains unchanged (Raudenbush & Bryk, 2002), the clustering was identical in both approaches, as well as the fit indices of the models with different numbers of classes. Although the trends in dyadic engagement were also the same using both approaches, the shrinkage on fixed effects

produced by MM resulted in the loss of a significant portion of the heterogeneity that we aimed to explain through LCA (Copas, 1983; Lee et al., 2020). This result is important to consider, because the classes identified using predicted measures were more similar to each other compared to the clear characterization obtained using observed measures. It is then necessary to ask whether it is worth losing information to obtain the same result in terms of clustering. One might argue that using a MM with additional covariates (i.e., characteristics of the patient, caregiver, or dyad) might not lead to the same result. However, identifying patterns of dyadic engagement in care net of these characteristics (i.e., by including covariates in the MM) would determine the flattening in attributes that would instead be useful for patterns' characterization. Indeed, the result of LCA performed using coefficients from a MM with covariates would be the identification of classes not only based on dyadic engagement in care, but also in relation to other characteristics, making a subsequent evaluation of potential differences between classes meaningless. Instead, it would be more useful to evaluate these characteristics after pattern identification, such as examining if there are differences between classes (De Maria et al., 2023a; Iovino et al., 2021) or if there are characteristics whose presence is associated with a certain probability of belonging to a specific class (Lee et al., 2015)[11].

Notably, if the focus is on examining the association between independent variables (at the patient, caregiver, or dyad level) and dyadic illness management rather than identifying patterns, the use of MM is necessary and undoubtedly more appropriate (Kenny et al., 2006; Raudenbush & Bryk, 2002; Sayer & Klute, 2005).

Limitations and Strengths

The comparison of the two methods was done in a specific context (T2DM) and for specific data with limited sample size: however, the study intended to show some methodological considerations in a practical setting. The main result on the equal

[11] See also Chapter 3

classification with the two approaches would have arisen in the same way even with larger samples and in different contexts, as justified by the methodological theory (Berlin et al., 2014).

4.6 Conclusion

Two different approaches to dyadic data analysis, then used to identify patterns of dyadic engagement in T2DM were compared. The first approach (i.e., MM) accounted for the interdependence within the dyad and for the measurement error returning predicted measures shrunk towards the overall mean. However, it yielded the same clusters of the simpler approach which used dyadic mean and difference, as the ordinality of the scores between the observed and the predicted measures remained unchanged for each dyad.

The results of this study highlight the need for further investigation into the dyadic data analysis, also to facilitate a wider clinical use of the findings that emerge from them.

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CHAPTHER 5

Conclusions and future perspectives

In this Ph.D. thesis, a comprehensive evaluation of self-care maintenance, self-care monitoring, and self-care management behaviors in patients with type 2 diabetes mellitus (T2DM) and their caregivers has been performed. A dyadic approach to identify distinct patterns of dyadic engagement in T2DM care and their relationship with glycemic control was also used. Moreover, an in-depth study of statistical methods traditionally used for dyadic data and pattern identification was carried out.

In Chapter 2 the association between self-care and glycated hemoglobin (HbA1c) was assessed in patients with T2DM. Differences were found in glycemic control as influenced by self-care maintenance, self-care monitoring, and self-care management. Patients both with and without insulin therapy showed an association between self-care monitoring and self-care management and HbA1c levels. Otherwise, self-care maintenance was associated with HbA1c levels only in patients without insulin therapy. Showing the relationship between self-care and HbA1c in T2DM holds significance for both clinical practice and research. Healthcare professionals should provide special attention to individuals displaying inadequate self-care monitoring and self-care management, as they stand at an elevated risk of reporting suboptimal glycemic control. Consequently, targeted interventions should be employed to enhance their clinical status. Although the association between self-care maintenance and patients' glycemic control might not be as evident, patients reporting inadequate self-care maintenance necessitate further evaluation, given the complexity of this facet of the self-care process.

In Chapter 3, three distinct patterns of dyadic engagement in T2DM care were identified. These patterns encompassed patient self-care as well as caregiver contribution to it, delineating differences in both engagement and levels of care. Specifically, the "equally engaged-low care" pattern indicated low engagement from both patients and

caregivers in self-care behaviors. The “mostly patient engaged-middling care” pattern showed moderate dyadic engagement with the patient role significantly predominant over the caregiver. The “equally engaged-high care” pattern highlighted high dyadic participation with minimal discrepancies in T2DM care involvement between patient and caregiver. Several characteristics, such as patient gender, education level, and self-efficacy, as well as caregiver burden and the presence of at least one chronic illness in the caregiver were associated to the membership in these dyadic patterns. Moreover, the patterns of dyadic engagement in T2DM were associated with patient glycemic control, quantified through HbA1c levels. Specifically, membership in the “mostly patient engaged-middling care” and “equally engaged-high care” patterns linked to reduced HbA1c compared to the “equally engaged-low care” pattern. This finding is consistent with the results of Chapter 2 and, including the caregiver contribution in the T2DM care, provides a more comprehensive understanding of the T2DM care process. Furthermore, these patterns could present a useful foundation for tailoring interventions to the dyads rather than focusing solely on individual patients. As such, healthcare professionals should incorporate these dyadic patterns into their considerations.

In Chapter 4, two statistical methods for analyzing dyadic data were compared, specifically investigating strengths and limitations of their use to identify distinct patterns of dyadic engagement in T2DM care. To this purpose, the dyadic averages and incongruences predicted by multilevel models showed no advantage over the observed means and differences. Indeed, performing two distinct latent class analysis using predicted or observed measures as input variables, dyads clustered in the same classes with both approaches, as the ordinality of the scores between the observed and the predicted measures remained unchanged for each dyad. Furthermore, the first approach returned predicted measures shrunk towards the overall mean. This result suggests that the most widespread approach for dyadic studies in chronic diseases, also used in Chapter

3 of this thesis, might not be the most beneficial as used to provide the input for LCA. Indeed, this kind of dyadic data could be approached in a simpler way when the aim is to identify dyadic patterns.

Overall, this thesis could provide new insights into the relationship between self-care in patients with T2DM and glycemic control, while also considering the role of caregivers. To the best of our knowledge, no previous studies of this kind have comprehensively examined self-care in all its complexity, referring to a consolidated theory in the field of chronic illnesses and using tools consistent with it, whose validity and reliability have been demonstrated. Furthermore, the role of the caregiver as a member of the dyad responsible for self-care behaviors has not been previously explored in T2DM. By adopting a dyadic approach throughout all the research process, it has been possible to identify dyadic patterns of T2DM management for the first time. Additionally, methodological aspects of dealing with dyadic data have been addressed and have provided new evidence potentially useful in dyadic studies in chronic diseases. Hence, this thesis could offer a meaningful contribution to a crucial public health area, such as T2DM care. Furthermore, it could lay the basis for future research that ought to delve into several aspects. These include examining the association between HbA1c levels and self-care maintenance, self-care monitoring, and self-care management over time, by longitudinal designs. Moreover, the development and testing of interventions tailored to fostering HbA1c improvement through personalized support for self-care maintenance, self-care monitoring, and self-care management should be a focal point. Additionally, to advance the field of dyadic research in T2DM management, dyadic data analysis methodologies should be further investigated, and a dyadic framework should be employed in international, longitudinal, and experimental designs.

CHAPTER 6

Other projects

The path depicted in Chapters 2, 3, and 4 highlights the main areas in which the candidate's research has taken place. However, during the Ph.D. program, the candidate participated in further projects that have been published as research articles or are under submission in scientific journals. Each of these projects will be presented in the following paragraphs by reporting the abstract of the respective article.

6.1 Further evidence of psychometric performance of the Self-care of Diabetes Inventory in adults with type 1 and type 2 diabetes

Authors

Maddalena De Maria, Diletta Fabrizi, Michela Luciani, Rosario Caruso, Stefania Di Mauro, Barbara Riegel, Claudio Barbaranelli, Davide Ausili

Abstract

Background. The Self-care of Diabetes Inventory (SCODI) is a theory-based tool that measures self-care, a key strategy in the appropriate treatment of diabetes. However, despite the clinical differences between people with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM), the psychometric properties of the SCODI were only tested in mixed samples.

Purpose. This study aims to test the psychometric performances of the SCODI in two separate groups of adults with T1DM and T2DM.

Methods. This is a secondary analysis from two previous multicenter cross-sectional observational studies involving patients with T1DM (n= 181) and T2DM (n= 540). We tested dimensionality with confirmatory factor analysis and reliability with a multidimensional model-based coefficient for every scale of the SCODI: self-care maintenance, self-care monitoring, self-care management, and self-care self-efficacy.

Results. We found that the SCODI showed the same dimensionality, with minimal variation in factor loadings for each factor and each scale among T1DM and T2DM groups. High reliability for each scale in both groups was also found (self-care maintenance: T1DM= 0.86, T2DM= 0.83; self-care monitoring: T1DM= 0.84, T2DM= 1.00; self-care management: T1DM= 0.87, T2DM= 0.86; self-care self-efficacy: T1DM= 0.88; T2DM= 0.86).

Conclusion. The SCODI can be used for measuring selfcare in people with T1DM, T2DM, or mixed groups using identical scoring procedures. Considering the well-known

differences between T1DM and T2DM diseases and patients' characteristics, our results support the generalizability of the self-care theory on which the instrument is based.

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6.2 Development and psychometric testing of the Caregiver Contribution to Self-Care of Diabetes Inventory

Authors

Diletta Fabrizi, Maddalena De Maria, Claudio Barbaranelli, Marta Aber Rizzo, Stefania Di Mauro, Annalisa Giancaterini, Paola Rebora, Davide Ausili, Michela Luciani

Abstract

Background. The caregiver contribution to self-care can help patients with diabetes improve behaviors to control the chronic condition and manage its signs and symptoms. However, the literature seems to lack a tool for assessing caregiver contribution to self-care in diabetes. Having a valid, reliable, and theoretically grounded tool could be useful to study caregiver contribution to self-care more thoroughly and systematically in diabetes and to build specific interventions aimed at improving self-care.

Purpose. The aim of this study was to develop and psychometrically test the Caregiver Contribution to Self-Care of Diabetes Inventory (CC-SCODI), a new tool grounded on the Middle-Range Theory of Self-Care of Chronic Illness.

Methods. A multicenter cross-sectional observational study was performed. A total of 251 patients with type 2 diabetes mellitus and their informal caregivers were involved. The CC-SCODI measures the self-reported caregiver contribution to patients' self-care maintenance, self-care monitoring and self-care management. It also assesses caregiver self-efficacy in contributing to patient self-care. To evaluate the dimensionality, a confirmative factory analysis was conducted. To evaluate the reliability, the Cronbach alpha coefficient and the multidimensional model-based reliability index were estimated for unidimensional and multidimensional scales, respectively. To assess the construct validity, associations between caregiver contribution to self-care maintenance, monitoring, and management and caregiver self-efficacy, caregiver burden, and dyadic

care type were tested. For the same purpose, both univariable and multivariable linear regression models were also adopted.

Results. A multidimensional structure emerged for caregiver contribution to self-care maintenance and caregiver contribution to self-care monitoring, while a unidimensional structure emerged for caregiver contribution to self-care management and caregiver self-efficacy. The reliability indices were all higher than 0.70. Significant associations were found between caregiver contribution to self-care maintenance, monitoring, and management and caregiver self-efficacy ($p<0.001$), caregiver burden ($p<0.001$ for caregiver contribution to self-care maintenance and monitoring; $p= 0.015$ for caregiver contribution to self-care management), and dyadic care type ($p<0.001$).

Conclusion. The CC-SCODI is a theoretically grounded tool that suggested to be valid and reliable for assessing caregiver contribution to self-care in patients with type 2 diabetes mellitus.

(Submitted)

6.3 Self-care in people with type 2 diabetes mellitus – research protocol of a multicenter mixed methods study (SCUDO)

Authors

Michela Luciani, Diletta Fabrizi, Paola Rebora, Emanuela Rossi, Stefania Di Mauro, Susan Kohl Malone, Davide Ausili

Abstract

Background. About 11% of the adult global populations is estimated to be living with type 2 diabetes mellitus (T2DM) by 2040. T2DM requires people to make decisions regarding complex therapeutic regimes, to maintain their well-being and quality of life, to manage symptoms and to reduce disease complications. All these behaviors, requiring knowledge, motivation, experience, and skills, have been referred to the concept of self-care. The intricacy and multidimensionality of T2DM self-care requires a complex approach to its overall comprehension.

Purpose. This Embedded Mixed Method study aims to investigate the experience of self-care in T2DM adult patients. It comprises a prospective observational design, and an interpretive description. Quantitative data will be collected with validated questionnaires from 300 patients at baseline and once a year for two years on: diabetes self-care, quality of life, diabetes related distress, and sleep quality. Socio-demographic and clinical data will be collected from medical records. Qualitative data will be collected using semi-structured interviews on about 10-20 patients, at baseline and once a year for two years, analyzed according to interpretive description. Quantitative and qualitative data will be analyzed separately and then merged and interpreted. This study will expand our understanding of self-care in people with T2DM. The expected outcome will be a better understanding of the effect of self-care on glycemic control and therefore clinical outcomes and costs.

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6.4 Self-care and caregiver contribution to self-care in adolescents with type 1 diabetes mellitus: a pilot cross-sectional study

Authors

Diletta Fabrizi, Irene Natta, Michela Luciani, Stefania Di Mauro, Paola Rebora, Davide Ausili

Abstract

Background. Type 1 diabetes mellitus requires complex skills of self-care that, during adolescence, need to be adapted to continuous major changes. Therefore, adolescents could struggle in performing adequate self-care, with consequences on glycemic control. Caregiver contribution to self-care could be useful for reaching health outcomes. Existing studies lacked a theoretical framework, and tools administered for measuring adolescents' self-care and caregivers' contribution to self-care were not theory grounded.

Purpose. To describe adolescents' self-care and caregiver contribution to self-care within the theoretical framework of the Middle-Range Theory of Self-Care of Chronic Illness.

Methods. A cross-sectional observational study was conducted enrolling 153 adolescent-caregiver dyads. The Self-Care of Diabetes Inventory (SCODI), including self-care maintenance, monitoring and management, was administered to adolescents. The Caregiver Contribution to Self-Care of Diabetes Inventory (CC-SCODI), including caregiver contribution to self-care maintenance, monitoring and management, was administered to caregivers. We analyzed the differences in caregiver contribution according to adolescents' self-care level and the differences in caregiver characteristics according to their contribution to self-care level.

Results. Adolescents mostly obtained adequate scores for self-care maintenance (74%), monitoring (52%) and management (58%). Caregivers mostly obtained adequate

scores for contribution to self-care maintenance (72%) and monitoring (52%), and almost adequate scores for contribution to self-care management (41%). Scores were consistent within the dyads for self-care monitoring and management: high caregiver contribution when adequate adolescent self-care and vice-versa ($p<0.001$). Higher caregiver self-efficacy in contributing to patient self-care was associated with higher caregiver contribution to self-care maintenance ($p= 0.022$), monitoring ($p<0.001$) and management ($p<0.001$).

Conclusion. Caregivers can contribute significantly to the self-care of adolescents with type 1 diabetes. Health professionals could implement interventions aimed at improving caregivers' contribution through enhancing caregiver self-efficacy in contributing to patient self-care. Researchers could deepen the understanding of the relationship between adolescent self-care and caregiver contribution to self-care, as well as the determinants of caregiver contribution to self-care, and its effects on health outcomes.

(Published in: International Diabetes Nursing (2022) 15. DOI: 10.57177/idn.v15.12)

6.5 Cross-cultural adaptation and validation of the Revised Brief Diabetes Knowledge Test (DKT2) in individuals with type 2 diabetes mellitus and their caregivers

Authors

Irene Baroni, Rosario Caruso, Cristina Arrigoni, Diletta Fabrizi, Floriana Pinto, Michela Luciani, Davide Ausili

Abstract

Purpose. The purpose of the study was to develop an Italian version of the Revised Brief Diabetes Knowledge Test (DKT2), providing a cultural and linguistic validation supported by psychometrics and hypotheses testing.

Methods. This multimethod study was divided into 4 phases: (a) cultural-linguistic validation, with a translation and back-translation process; (b) confirmatory factor analysis (CFA) considering the original scale structure (knowledge and insulin-specific knowledge); (c) criterion validity via hypotheses testing; and (d) cross-group measurement invariance. The internal consistency reliability was assessed by the Kuder-Richardson Formula 20 (KR-20) of the overall scale.

Results. A total of 251 patients and 251 caregivers were enrolled. The CFA showed good goodness of fit for both patients and caregivers. The tested hypotheses supported criterion validity in both groups. Reliability was adequate: All KR-20 values in both groups and domains were higher than 0.60. The mean percentage of knowledge score on DKT2 was lower for patients than caregivers.

Conclusion. The DKT2 is a valid and reliable scale to assess overall knowledge of diabetes, considering its role in promoting appropriate self-care behaviors in patients with type 2 diabetes mellitus. The Italian version of DKT2 demonstrated reliability and validity, and it can be used by researchers and diabetes care and education specialists to assess a patient or population overall knowledge of diabetes.

(Published in The Science of Diabetes Self-Management and Care (2023). DOI: 10.1177/26350106231192354)

6.6 Diabesity in adults with type 2 diabetes mellitus: a cross-sectional study exploring self-care and its determinants

Authors

Irene Baroni, Rosario Caruso, Federica Dellafiore, Cristina Arrigoni, Diletta Fabrizi, Michela Luciani, Paola Rebora, Davide Ausili

Abstract

Background. Self-care is one of the main treatments for adults with type 2 diabetes mellitus (T2DM). However, self-care has been poorly described in people with diabesity, and differences in clinical and sociodemographic determinants of self-care between patients with diabesity and patients with T2DM and body mass index (BMI)<30 kg/m^2 have, to our knowledge, not been assessed.

Purpose. The purpose of this study was to describe self-care maintenance, self-care monitoring, selfcare management and self-care self-efficacy in adults with T2DM and BMI <30 kg/m^2 and adults with T2DM and BMI ≥30 kg/m^2 ("diabesity"), and to identify their clinical and sociodemographic determinants.

Methods. A secondary analysis was performed of sociodemographic and clinical data using a multicenter, observational, cross-sectional design, wherein 540 adults diagnosed with T2DM were included in a consecutive and convenience sampling procedure.

Results. Self-care maintenance and management were significantly lower among patients with diabesity (p<0.001 and p= 0.025, respectively). Among patients with diabesity, low income (relative risk [RR]= 3.27; p= 0.01) and presence of diabetic neuropathy (RR= 4.16; p= 0.03) were strongly associated with inadequate self-care maintenance; completion of high school (RR= 0.45; p= 0.01), availability of a family caregiver (RR= 0.52; p= 0.04) and the use of insulin as the main treatment (RR= 2.09; p= 0.01) decreased the likelihood of inadequate self-care monitoring.

Conclusion. The unfavorable behavioral profile of patients with diabesity could be further worsened by their lower level of confidence in performing adequate self-care. (Published in Canadian Journal of Diabetes (2022) 46: 662-670. DOI: 10.1016/j.jcjd.2022.03.009)

6.7 The association between self-reported sleep quality and self-care in adults with heart failure: a cross-sectional study

Authors

Valentina Spedale, Diletta Fabrizi, Paola Rebora, Michel Luciani, Rosaria Alvaro, Ercole Vellone, Barbara Riegel, Davide Ausili

Abstract

Background. Sleep disturbance is one of the most common symptoms among patients with heart failure (HF), and it may affect the ability of patients to perform self-care. There is a lack of evidence on the association between sleep quality and its components and self-care in adults with HF.

Purpose. The aim of this study was to evaluate the association between sleep quality and its components and self-care in adults with HF.

Methods. This study is a secondary analysis of baseline data from the MOTIVATE-HF study, a randomized controlled trial on patients with HF and their caregivers. Only patients' data were analyzed in this study (n= 498). Sleep quality and self-care were evaluated with the Pittsburgh Sleep Quality Index and the Self-Care of Heart Failure Index v6.2, respectively.

Results. A habitual sleep efficiency of 75% to 84% was associated with lower self-care maintenance compared with a habitual sleep efficiency of 85% or greater (p= 0.031), as was taking sleep medications once or twice a week compared with less than once a week (p= 0.001). A frequency of daytime dysfunction less than once a week was associated with lower self-care management compared with a frequency of daytime dysfunction of 3 or more times a week (p= 0.025). Taking sleep medications less than once a week was associated with lower self-care confidence compared with taking sleep medications 3 or more times a week (p= 0.018).

Conclusion. Poor sleep quality is frequently reported by patients with HF. Sleep efficiency, sleep medications, and daytime dysfunction may influence self-care more than the other sleep quality components.

(Published in Journal of Cardiovascular Nursing (2022) 38(3): 98-109 662-670. DOI: 10.1097/JCN.0000000000000929)

APPENDIX

A.1 Self-Care of Diabetes Inventory (SCODI)

Please, think about what you did and how you felt in the last month.

SECTION A – Self-care maintenance

Below are listed some behaviors that a person with diabetes could perform to maintain health and wellness.
How often or routinely do you do the following behaviors?

*(circle **one** number)*

		Never				Always
1	To maintain an active lifestyle (e.g., walking, going out, doing activities).	1	2	3	4	5
2	To perform physical exercise for 2 hours and 30 minutes each week (e.g., swimming, going to the gym, cycling, walking).	1	2	3	4	5
3	3. To eat a balanced diet of carbohydrates (e.g., pasta, rice, sugars, bread), proteins (e.g., meat, fish, legumes), fruits and vegetables.	1	2	3	4	5
4	To avoid eating salt and fats (e.g., cheese, cured meats, sweets, red meat).	1	2	3	4	5
5	To limit alcohol intake (no more than 1 glass of wine/day for women and 2 glasses/day for men).	1	2	3	4	5
6	To try to avoid getting sick (e.g., washing your hands, getting recommended vaccinations).	1	2	3	4	5
7	To avoid cigarettes and tobacco smoke.	1	2	3	4	5
8	To take care of your feet (e.g., washing and drying the skin, applying moisture, using correct socks).	1	2	3	4	5
9	To maintain good oral hygiene (e.g., brushing your teeth at least twice/day, using mouthwash, using dental floss).	1	2	3	4	5
10	To keep appointments with your healthcare provider.	1	2	3	4	5
11	To have your health check-ups on time (e.g., blood tests, urine tests, ultrasounds, eyes exams).	1	2	3	4	5
	Many people have problems taking all their prescribed medicines.					
12	To take all your medicines as prescribed by your healthcare provider (please also consider insulin if prescribed).	1	2	3	4	5

SECTION B – Self-care monitoring

Below are listed some behaviors that a person with diabetes could practice to monitor diabetes.
How often or routinely do you do the following behaviors?

*(circle **one** number)*

		Never				Always
13	To monitor your blood sugar regularly.	1	2	3	4	5
14	To monitor your weight.	1	2	3	4	5
15	To monitor your blood pressure.	1	2	3	4	5
16	To keep a record of your blood sugars in a diary or notebook.	1	2	3	4	5
17	To monitor the condition of your feet daily to see if there are wounds, redness, or blisters.	1	2	3	4	5
18	To pay attention to symptoms of high blood sugar (e.g., thirst, frequent urination) and low blood sugar (e.g., weakness, perspiration, anxiety).	1	2	3	4	5

The last time you had symptoms: *(circle **one** number)*

Not recog-nized	Not quickly			Very quickly

19	How quickly did you recognize that you were having symptoms?	0	1	2	3	4	5
20	How quickly did you know that your symptoms were due to diabetes?	0	1	2	3	4	5

SECTION C – Self-care management

Below are listed some behaviors that people with diabetes could do to improve blood sugar when it is too high or too low.
How often do you do (or would you do) the following behaviors when symptoms occur or when your blood sugar is out of range?

*(circle **one** number)*

		Never				Always
21	If you feel symptoms (e.g., thirst, frequent urination, weakness, perspiration, anxiety), to check your blood sugar.	1	2	3	4	5
22	If you have abnormal blood sugar levels, to take notes about the events that could have caused it and actions you took.	1	2	3	4	5
23	If you have abnormal blood sugar levels, to ask a family member or friend for advice.	1	2	3	4	5
24	If you have symptoms and discover that your blood sugar is low, to eat or drink something with sugar to solve the problem.	1	2	3	4	5
25	If you find out that your blood sugar is high, to adjustyour diet to fix it.	1	2	3	4	5
26	In you find out that your blood sugar is high, to adjust physical activity to fix it.	1	2	3	4	5
27	After taking actions to adjust an abnormal blood sugar level, to re-check your blood sugar to assess if the actions you took were effective.	1	2	3	4	5
28	If you find out that your blood sugar is very low or very high, to call your healthcare provider for advice.	1	2	3	4	5
	Do you take insulin? If yes, please answer the following question.					
29	If you find out that your blood sugar is too high or too low, to adjust your insulin dosage in the way your healthcare provider suggested.	1	2	3	4	5

SECTION D – Self-care self-efficacy

People with diabetes have to develop skills to take care of themselves and to maintain their health.
How confident do you feel doing the following behaviors?

*(circle **one** number)*

		Not confident at all				Extremely confident
30	To prevent high or low blood sugar levels and its symptoms.	1	2	3	4	5
31	To follow advice about nutrition and physical activity.	1	2	3	4	5
32	To take medicines in the appropriate way (including insulin if prescribed).	1	2	3	4	5
33	To persist in following the treatment plan even when it is difficult.	1	2	3	4	5
34	To monitor your blood sugar as often as your healthcare provider asked to do.	1	2	3	4	5
35	To understand if your blood sugar levels are good or not.	1	2	3	4	5
36	To recognize the symptoms of low blood sugar.	1	2	3	4	5
37	To persist in monitoring your diabetes even when it is difficult.	1	2	3	4	5

38	To take action to adjust your blood sugar and relieve your symptoms.	1	2	3	4	5
39	To evaluate if your actions were effective to change your blood sugar and relieve your symptoms.	1	2	3	4	5
40	To persist in carrying out actions to improve your blood sugar even when it is difficult.	1	2	3	4	5

A.2 Caregiver Contribution to Self-Care Inventory (CC-SCODI)

Please, think about what you did in the last month.

SECTION A – Caregiver contribution to self-care maintenance

Below are listed some behaviors that a person with diabetes could perform to maintain health and wellness.
*How often do you **recommend** the following behaviors to the person you care for? Or how often do you **do** these activities because the person you care for is not able to do them autonomously?*

*(circle **one** number)*

		Never				Always
1	To maintain an active lifestyle (e.g., walking, going out, doing activities).	1	2	3	4	5
2	To perform physical exercise for 2 hours and 30 minutes each week (e.g., swimming, going to the gym, cycling, walking).	1	2	3	4	5
3	To eat a balanced diet of carbohydrates (e.g., pasta, rice, sugars, bread), proteins (e.g., meat, fish, legumes), fruits and vegetables.	1	2	3	4	5
4	To avoid eating salt and fats (e.g., cheese, cured meats, sweets, red meat).	1	2	3	4	5
5	To limit alcohol intake (no more than 1 glass of wine/day for women and 2 glasses/day for men).	1	2	3	4	5
6	To try to avoid getting sick (e.g., washing hands, getting recommended vaccinations).	1	2	3	4	5
7	To avoid cigarettes and tobacco smoke.	1	2	3	4	5
8	To take care of feet (e.g., washing and drying the skin, applying moisture, using correct socks).	1	2	3	4	5
9	To maintain good oral hygiene (e.g., brushing teeth at least twice/day, using mouthwash, using dental floss).	1	2	3	4	5
10	To keep appointments with healthcare provider.	1	2	3	4	5
11	To have health check-ups on time (e.g., blood tests, urine tests, ultrasounds, eye exams).	1	2	3	4	5
	Many people have problems taking all their prescribed medicines.					
12	To take all medicines as prescribed by the healthcare provider (please also consider insulin if prescribed).	1	2	3	4	5

SECTION B – Caregiver contribution to self-care monitoring

Below are listed some behaviors that a person with diabetes could practice to monitor diabetes.
*How often do you **recommend** the following behaviors to the person you care for? Or how often do you **do** these activities because the person you care for is not able to do them autonomously?*

*(circle **one** number)*

		Never				Always
13	To monitor blood sugar regularly.	1	2	3	4	5
14	To monitor weight.	1	2	3	4	5
15	To monitor blood pressure.	1	2	3	4	5
16	To keep a record of blood sugars in a diary or notebook.	1	2	3	4	5
17	To monitor the condition of feet daily to see if there are wounds, redness, or blisters.	1	2	3	4	5

18	To pay attention to symptoms of high blood sugar (e.g., thirst, frequent urination) and low blood sugar (e.g., weakness, perspiration, anxiety).	1	2	3	4	5
	The last time the person you care for had symptom *(circle **one** number)*	Not recog-nized	Not quickly			Very quickly
19	How quickly did you recognize that he/she was having symptoms?	0	1	2	3	4	5
20	How quickly did you know that the symptoms were due to diabetes?	0	1	2	3	4	5

SECTION C – Caregiver contribution to self-care management

Below are listed some behaviors that people with diabetes could do to improve blood sugar when it is too high or too low.
*How often do you **recommend** the following behaviors to the person you care for? Or how often do you **do** these activities because the person you care for is not able to do them autonomously?*

	*(circle **one** number)*	Never				Always
21	If the person you care for feels symptoms (e.g., thirst, frequent urination, weakness, perspiration, anxiety), to check blood sugar.	1	2	3	4	5
22	If the person you care for has abnormal blood sugar levels, to take notes about the events that could have caused it and actions he/she took.	1	2	3	4	5
23	If the person you care for has abnormal blood sugar levels, to ask a family member or friend for advice.	1	2	3	4	5
24	If the person you care for has symptoms and discovers that blood sugar is low, to eat or drink something with sugar to solve the problem.	1	2	3	4	5
25	If the person you care for finds out that blood sugar is high, to adjust the diet to fix it.	1	2	3	4	5
26	If the person you care for finds out that blood sugar is high, to adjust physical activity to fix it.	1	2	3	4	5
27	After taking actions to adjust an abnormal blood sugar level, to re-check blood sugar to assess if the actions were effective.	1	2	3	4	5
28	If the person you care for finds out that blood sugar is very low or very high, to call the healthcare provider for advice.	1	2	3	4	5
	Does the person you care for take insulin? If yes, please answer the following question.					
29	If the person you care for finds out that blood sugar is too high or too low, to adjust the insulin dosage in the way the healthcare provider suggested.	1	2	3	4	5

SECTION D – Caregiver self-efficacy in contributing to patient self-care

People with diabetes have to develop skills to take care of themselves and to maintain their health.
In reference to the person you care for, how much do you feel confident that you can recommend or do these activities?

	*(circle **one** number)*	Not confident at all				Extremely confident
30	To prevent high or low blood sugar levels and its symptoms.	1	2	3	4	5
31	To follow advice about nutrition and physical activity.	1	2	3	4	5
32	To take medicines in the appropriate way (including insulin if prescribed).	1	2	3	4	5
33	To persist in following the treatment plan even when it is difficult.	1	2	3	4	5
34	To monitor his/her blood sugar as often as the health care provider asked that it be done.	1	2	3	4	5

35	To understand if his/her blood sugar levels are good or not.	1	2	3	4	5
36	To recognize the symptoms of low blood sugar.	1	2	3	4	5
37	To persist in monitoring his/her diabetes even when it is difficult.	1	2	3	4	5
38	To take action to adjust his/her blood sugar and relieve his/her symptoms.	1	2	3	4	5
39	To evaluate if the implemented actions were effective to change his/her blood sugar and relieve his/her symptoms.	1	2	3	4	5
40	To persist in carrying out actions to improve his/her blood sugar even when it is difficult.	1	2	3	4	5