

## **TITLE**

Socio-demographic and clinical determinants of self-care in adults with type 2 diabetes: a multicentre observational study.

## **RUNNING TITLE**

Determinants of self-care in adults with type 2 diabetes

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### **ABSTRACT**

**Aims.** To describe self-care as defined by the Middle-Range Theory of Self-Care of Chronic Illness and to identify clinical and socio-demographic determinants in a T2DM population. **Methods.** A multicentre observational cross-sectional study was conducted involving 540 adults with a confirmed diagnosis of T2DM from 6 outpatient diabetes services in Italy. Socio-demographic and clinical data were collected from medical records. The Self-Care of Diabetes Inventory (SCODI) was used to measure self-care maintenance, monitoring, management and confidence dimensions. For each separate scale, scores were standardized 0-100 with higher SCODI scores indicating better self-care; a score  $\geq 70$  is adequate. Multiple quantile regression models were performed to identify determinants of each self-care dimension. **Results.** Self-care maintenance (median = 81.3) and self-care confidence (median = 79.5) were adequate in most of the subjects. Self-care monitoring was adequate in only half of the sample (median = 70.6). Self-care management was poor (median = 59.4). Lower self-care maintenance was associated with lower self-care confidence ( $p < 0.001$ ). Lower self-care monitoring was associated with being male ( $p < 0.001$ ), having lower self-care confidence ( $p < 0.001$ ), and having diabetes for  $< 10$  years ( $p < 0.001$ ). Lower self-care management was associated with being male ( $p = 0.002$ ), being older ( $p = 0.005$ ), having a low income ( $p = 0.030$ ),

being employed ( $p=0.008$ ), having missed diabetes education in the last year ( $p=0.002$ ), and lower self-care confidence ( $p<0.0001$ ). Lower self-care confidence was associated with having diabetes for  $< 10$  years ( $p=0.008$ ), and having at least one comorbid condition ( $p=0.006$ ). **Conclusions.** Determinants of self-care maintenance, monitoring, management and confidence include both clinical and socio-demographic variables. Modifiable determinants such as self-care confidence and diabetes self-care management education could be used to tailor interventions to improve diabetes self-care.

### **KEY WORDS**

Diabetes Mellitus, Type 2 Diabetes Mellitus, Self-Management, Chronic Disease, Self-efficacy, Risk factors, Health Education

## INTRODUCTION

Diabetes is one of the health emergencies of the 21<sup>st</sup> century affecting 415 million people worldwide and accounting for 5.0 million deaths globally in 2015 [1]. Having diabetes is associated with cardiovascular disease, stroke, diabetic nephropathy, neuropathy, retinopathy, pregnancy complications [1, 2], poor quality of life [3, 4], high economic burden [1, 5], and the risk of premature death [1, 6]. Type 2 diabetes mellitus (T2DM) accounts for 90% of cases of diabetes [7]. Its rise is connected with rising rates of overweight and obesity in adults and youth and a complex interaction of genetic and epigenetic factors [7].

Self-care of T2DM has proven to be cost effective for decreasing complications [8], reducing Hb1Ac [9, 10], reducing hospital admissions [9, 10] and therefore costs; it also positively affects quality of life [9, 10], promotes empowerment [10] and improves other psychosocial and behavioural factors associated with diabetes [9, 10]. Unfortunately, little is known about the characteristics of individuals least likely to engage in self-care. **Previous studies have shown that T2DM patients with low diabetes-treatment-related quality of life are less likely to perform adequate self-management of insulin injections [11], and that functional status plays a role in patients' health-related quality of life [12]. Knowledge of diabetes following therapeutic education [13] predicts diabetes self-management [14] and quality of life is associated with the quality of diabetes care. However, little information is available on socio-demographic and clinical determinants of self-care in T2DM. Without this knowledge, interventions aimed at promoting self-care are unable to be targeted to those most likely to benefit.**

We examined the socio-demographic and clinical determinants of self-care in adults with T2DM, defining self-care based on the Middle Range Theory of Self-Care of Chronic Illness [15]. This theory has been used widely in the study of cardiovascular diseases [16–18] and other chronic conditions [9, 17, 19, 20]. In the theory, self-care is defined as “process of maintaining health through health promoting practices and managing illness” [15]. Self-care comprises three dimensions that interplay: self-care maintenance, monitoring, and management [15]. Self-care

confidence is not self-care per se, but a factor strongly influencing self-care. Confidence is thought to underlie all self-care behaviours and mediate the relationship between factors such as cognition and self-care behaviours [16, 17, 21]. This theoretical approach acknowledges the dynamic nature and complexity of the self-care process.

According to the theory, self-care maintenance describes those behaviours that improve well-being, preserve health, or maintain physical and emotional stability [15]. In T2DM, these behaviours, either prescribed or self-determined, comprise healthy lifestyle (e.g., appropriate diet, physical exercise, avoiding alcohol and tobacco, foot care), taking medicine as prescribed, and attending medical appointments. Self-care monitoring refers to the monitoring of changes in signs and symptoms such as blood glucose and indicators of hypo/hyper-glycaemia. Self-care management reflects those behaviours used to actively address signs and symptoms when they occur such as adjusting medication or physical activity levels or checking with a health care provider or caregiver. Self-care confidence or self-efficacy is the belief that one has the ability to perform a specific self-care action and to persist in performing that action despite barriers [15].

Self-care by individuals with T2DM has been explored in many studies, [22–25] but the existing literature has a number of important limitations. Determinants of self-care have been described previously but only in relation to single self-care behaviours (i.e. blood glucose monitoring, diet, exercise) [26, 27]. Prior studies have lacked a theoretical framework [28, 29] and therefore self-care of T2DM has not been explored as a dynamic and complex phenomenon with multiple dimensions. Instruments used to measure self-care have not been theoretically based [30, 31]. Comorbid conditions have not been addressed as potentially influencing the self-care process. To address these gaps in the literature, the objectives of this study were: 1) to describe self-care maintenance, self-care monitoring, self-care management and self-care confidence in T2DM patients; and 2) to identify clinical and socio-demographic determinants of self-care maintenance, self-care monitoring, self-care management and self-care confidence in T2DM patients. Having this information can help scientists and professionals to better understand the complexity of self-care in

T2DM, to identify patients at risk of poor self-care, and to design targeted interventions to improve the health and quality of life of people with T2DM.

## METHODS

A multicentre cross-sectional study was conducted involving T2DM patients from six outpatient diabetes clinics in the North of Italy. 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 and with the Helsinki Declaration of 1975, as revised in 2008.

### Sample

We recruited a consecutive sample of 540 adult T2DM patients during outpatient visits. Inclusion criteria were: confirmed diagnosis of T2DM diabetes diagnosed according to guidelines criteria [32] and age  $\geq 18$  years. Exclusion criteria were: screening or first visit to the diabetes centre; time since the diagnosis of diabetes of  $< 1$  year; inability to read the study questionnaire; documented cognitive impairment; other types of diabetes (e.g. impaired glucose tolerance or gestational diabetes) [32].

### Measurement

Socio-demographic and clinical data were collected by reviewing medical records. Based on prior studies [20, 24, 29, 33–35], we measured the following potential determinants of self-care: age, gender, education (low = primary or secondary vs. high = higher or academic), income, time since the diagnosis of T2DM as an indicator of experience, presence of comorbidities (at least one vs. none), type of medications (insulin therapy vs. oral blood glucose lowering medications only), self-management education (received vs. not received in the last year). Furthermore, to assess the presence of family support, patients were asked to report if at least one person in their family was giving constant support to them for the management of diabetes (yes vs. not, as self-reported by patients). Standardized criteria from updated clinical guidelines were used to verify the T2DM diagnosis and to assess the presence of comorbidities [32]. Diabetes microvascular complications

were not included in the count of comorbidities because, according to the theory underlying the study [15], we conceptualized comorbidities as consequences of poor self-care rather than antecedents.

The *Self-care of Diabetes Inventory* (SCODI), a self-report instrument, was used to measure self-care maintenance, self-care monitoring, self-care management and self-care confidence [36]. The SCODI was developed based on the Middle Range Theory of Self-care of Chronic Illness [15] and demonstrated to be a valid and reliable measure of self-care in the Italian diabetes population [36]. The SCODI had good fit indices and high multiple model based reliability for all four scales (self-care maintenance = 0.81; self-care monitoring = 0.84; self-care management = 0.86; and self-care confidence = 0.89). Construct validity of the SCODI was demonstrated with an association between SCODI scores and objective clinical criteria such as glycated haemoglobin, body mass index, and the presence of diabetes microvascular complications.

Each of the SCODI scales has dimensions that illustrate different elements of self-care. The self-care maintenance scale has 4 dimensions that measure health promoting behaviours (adherence to diabetes treatments such as diet and medications, reliability = 0.77), health promoting exercise behaviours (adherence to physical activity and active lifestyle, reliability = 0.85), disease prevention behaviours (behaviours aimed at avoiding risk and complications such as vaccination, avoiding alcohol and tobacco, reliability = 0.79), and illness related behaviours (screening examinations, diagnostic tests, and follow-up visits, reliability = 0.95)).

The self-care monitoring scale includes 2 dimensions. The body listening element addresses behaviours like blood glucose or blood pressure monitoring. The symptom recognition element addresses the ability to recognize diabetes symptoms.

The self-care management scale includes autonomous and consultative self-care management behaviour dimensions. Autonomous self-care management involves those behaviours directly performed by patients to manage symptoms or problematic blood glucose levels (reliability

= 0.89). Consultative self-care management involves those behaviours performed in consultation with health professionals or caregivers to solve problematic signs or symptoms (reliability = 0.77).

The self-care confidence scale has 2 dimensions that address task-specific self-care confidence (reliability = 0.90), and persistence (reliability = 0.88). All the SCODI scales and subscales or dimensions provide a 0-100 standardized score where higher score means better self-care. 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 ( $\geq 70$ ) or inadequate ( $< 70$ ) [36].

### **Statistical Analysis**

Socio-demographic and clinical characteristics were described with frequencies and percentages. Box and whiskers plots were used to examine the distributions of the self-care scales. To identify which factor was associated with the self-care scales, median and interquartile range (IQR) were reported for each category and differences tested by means of median test, due to the non-normal distribution of the scales scores. For the same reason, instead of performing linear regression, quantile regression models were adopted to regress the median of scales, and dimension scores, on each variable collected. Thus, the parameter estimated by the model is interpreted as the increment in the median (instead of the mean), for each unit increment in the independent factors. The regression parameters were estimated by the algorithm Simplex due to the number of independent variables included in the models. Confidence intervals and p-values were estimated by using the sparsity function and assuming that errors in the linear model are independent and identically distributed. P-values were considered statistically significant if lower than 0.05.

## **RESULTS**

The sample of 540 T2DM patients was typically male and most (77%, n=415) were aged 60 years or more. Most were retired (75%; n=402) with a low level (primary or secondary) of education (83%; n= 448). A large proportion (47%, n=252) had T2DM for 10 years or more. Most (67%, n=363) were taking oral glucose lowering medications, but a third (33%, n=177) were taking insulin. The vast majority (87%, n=469) had at least one comorbid condition. Only 6% of the



sample had received diabetes self-management education in the last year. Socio-demographic and clinical characteristics of the study sample - as well as self-care maintenance, self-care monitoring, self-care management and self-care confidence scores by the same characteristics - are shown in

**Table 1.**

Self-care maintenance (median = 81.3, Q1-Q3: 72.9-89.6) and self-care confidence (median = 79.5, Q1-Q3: 65.9-93.2) were adequate in most of the subjects. Self-care monitoring was adequate in only half of the sample (median = 70.6, Q1-Q3: 55.9-85.3). Self-care management was poor (median = 59.4, Q1-Q3: 39.8-75.0). Within self-care maintenance, the health promotion exercise behaviours were the poorest (median = 50.0, Q1-Q3: 25.0-87.5) while illness related behaviours were practiced the most (median = 91.7, Q1-Q3: 75.0-100.0). Body listening was the dimension of self-care monitoring with the highest score (median = 80.0, Q1-Q3: 60.0-90.0) while symptom recognition was borderline (median = 71.4, Q1-Q3: 28.6-92.9). Both autonomous (median = 66.7, Q1-Q3: 41.7-91.7) and consultative (median = 55.0, Q1-Q3: 35.0-70.0) self-care management behaviours were inadequate. In self-care confidence, both task specific (median = 79.2, Q1-Q3: 62.5-95.8) and persistence (median = 80.0, Q1-Q3: 65.0-95.0) self-care confidence were adequate. Self-care maintenance, self-care monitoring, self-care management, self-care confidence and their dimension distributions are reported in **Figure 1**.

Lower self-care maintenance was associated with lower self-care confidence ( $p<0.001$ ). Lower health promoting exercise behaviours were associated with being female ( $p=0.011$ ), low income ( $p=0.002$ ) and the presence of comorbidities ( $p=0.008$ ). Lower disease prevention behaviours were associated with being male ( $p<0.001$ ) and being younger than 60 years ( $p=0.001$ ). Lower health promoting behaviours were associated with being employed ( $p=0.039$ ), having low education ( $p=0.023$ ) and low persistence self-care confidence ( $p<0.001$ ). Determinants of self-care maintenance and its dimensions are shown in **Table 2**.

Lower self-care monitoring was associated with being male ( $p<0.001$ ), having lower self-care confidence ( $p<0.001$ ), and having diabetes for  $< 10$  years ( $p<0.001$ ). Lower body listening was

associated with being male ( $p=0.002$ ), and lower task specific self-care confidence ( $p<0.001$ ).

Lower symptom recognition was associated with being male ( $p=0.006$ ), having diabetes for  $< 10$  years ( $p<0.001$ ), and lower task specific self-care confidence ( $p<0.001$ ). Determinants of self-care monitoring and its dimensions are reported in **Table 3**.

Lower self-care management was associated with being male ( $p=0.002$ ), being older ( $p=0.005$ ), having a low income ( $p=0.030$ ), being employed ( $p=0.008$ ), having missed diabetes education in the last year ( $p=0.002$ ), and lower self-care confidence ( $p<0.001$ ). Lower autonomous self-care management behaviours were associated with being male ( $p=0.043$ ), lower task specific self-care confidence ( $p<0.001$ ) and higher persistence self-care confidence ( $p=0.0001$ ). Lower consultative self-care management behaviours were associated with low income ( $p=0.035$ ), having diabetes for  $\geq 10$  years ( $p=0.041$ ), being employed ( $p=0.019$ ), having missed diabetes self-management education in the last year ( $p=0.023$ ) and lower task specific self-care confidence ( $p<0.001$ ). Determinants of self-care management and its dimensions are reported in **Table 4**.

Lower self-care confidence was associated with having diabetes  $< 10$  years ( $p=0.008$ ) and having at least one comorbid condition ( $p=0.006$ ). No statistically significant associations were found between the clinical and socio-demographic variables and the task-specific self-care confidence dimension. Lower persistence self-care confidence was associated with high income ( $p=0.010$ ), low education ( $p=0.047$ ), and presence of comorbidities ( $p=0.001$ ). Determinants of self-care confidence and its dimensions are reported in **Table 5**.

## DISCUSSION

The aims of this study were to describe self-care of T2DM patients and to identify the clinical and socio-demographic determinants. We found that self-care maintenance and self-care confidence were adequate in most, self-care monitoring was adequate in half, but self-care management had the poorest score in this T2DM population. Characteristics significantly associated with self-care were confidence, gender, age, income, employment, family support, and length of experience with T2DM, diabetes self-management education, and comorbidity.

We found that both autonomous and consultative diabetes self-management behaviours were extremely poor in this T2DM population, consistent with our previous results in a sample with concomitant diabetes mellitus and heart failure [20]. It is not surprising that this self-care behaviour is poorest because management requires complex problem-solving and decision making skills as well as the knowledge and skill in managing signs and symptoms [15]. Further, few of these participants received diabetes self-management education in the last year. Persons with T2DM have been shown to benefit from periodic diabetes self-management education [10].

Specific self-care behaviours found to be inadequate or border line were exercise and symptom recognition. Previous investigators have found that physical exercise is suboptimal in people with T2DM [8, 37]. Exercise behaviours in T2DM are determined by complex physical and psycho-social factors [27] and these factors could represent barriers to exercise behaviours [38]. Symptom recognition was also poor, which is concerning because symptom recognition begins the self-care management process. Others have noted that symptom recognition is affected by the disease (i.e. comorbid conditions or diabetes microvascular complications), and often difficult for people with diabetes [39, 40].

Our second aim was to identify clinical and socio-demographic determinants of self-care. We found that lower self-care confidence was associated with all the self-care processes (maintenance, monitoring, and management), as others have found [15, 20, 21, 41]. This is important because self-care confidence can be increased by improving patients' knowledge and skills through therapeutic education [42, 43]. Factors associated with lower self-care confidence included insufficient income, relatively more recent T2DM diagnosis, and having at least one comorbid condition. Others have noted the influence of income on self-care [35, 44]. Time since diagnosis is a surrogate for experience acquired living with diabetes. Consistent with previous studies, experienced patients may be more confident in their ability to manage a chronic illness [20, 45]. Having a comorbid condition decreases confidence by requiring that the patient consider two or more conditions simultaneously when making self-care decisions [20].

Lower self-care monitoring was associated with shorter time since diagnosis. Patients with a more recent diagnosis of T2DM are more likely to perceive themselves as “moderately ill” because they have not experienced severe and long-term disease complications. Thus, consistent with previous studies [8, 20, 36, 45], they seem to postpone persistent self-care monitoring activities.

Poorer self-care management was associated with being male, being older, having a low income, being employed, and having missed diabetes education in the last year. Gender differences in self-care of T2DM patients were found in previous studies [46, 47] in which men were shown to be less likely to perform adequate self-care than women. Similar results have been found in other chronic conditions [20, 45]. However, gender itself - as a determinant of self-care - should be considered with caution because the results differed depending on the specific dimension of self-care. More evidence exists supporting our finding that older age may be associated with poor self-care management [48].

Several prior studies have shown that low income is a barrier to T2DM self-care [44, 49]. However, we found that being employed was associated with worse self-care management, consistent with research in other patient populations [50]. It may be that those who are actively working face more competing demands on their time. This conclusion is supported both by previous research [22] and our clinical experience, suggesting that self-care may be less of a priority when work activities are pressing. Finally, lack of recent diabetes education was associated with poor self-care management, confirming the importance of diabetes self-management education (DSME) in improving self-care in T2DM patients [37, 51].

Finally, when we examined the dimensions of each self-care behaviour (i.e. body listening and symptom recognition as dimensions of self-care monitoring) we found evidence that certain variables were protective for one dimension and a risk factor for another one. For example, men were more likely to exercise but less likely to practice illness prevention behaviours. This discrepancy is reflected in other studies that found males to be more physically active but also more likely to smoke and drink alcohol [52, 53].

## **Strengths and limitations**

To the best of our knowledge, this is the first study investigating the whole self-care process in a T2DM population. This is relevant because the main limitation of previous research was that the complexity of self-care was not acknowledged. Furthermore, this study was the first to use a psychometrically sound, theoretically grounded measure of diabetes self-care, addressing another limitation of previous research. Finally, the use of a theoretical framework that is widely used to study other chronic diseases contributes to further theoretical development [15, 17, 19].

This study has several limitations. The sample comes from one country and generalization to another requires caution. The cross-sectional nature of the study is another limitation. Psychological variables that can potentially affect self-care – anxiety or depression – were not measured. However, the study was conducted at multiple centres; the sample was large and was enrolled consecutively to avoid selection bias; self-care was measured by a valid and reliable theory-based tool [36], and main clinical and socio-demographic characteristic of the sample are similar to those in the literature [37], suggesting that these results may be useful internationally.

## **CONCLUSION**

Based on the results of this study, we encourage T2DM health care providers to focus education on the autonomous and the consultative dimensions of self-care management. For self-care monitoring, symptom recognition should be emphasized. Another area to be emphasized is building self-care confidence. We demonstrated that task-specific and persistence self-care confidence play different roles in the self-care process. As confidence is an indicator of self-efficacy [15, 41], persistence despite barriers is key to promoting self-care maintenance behaviours such as diet and medication adherence [16, 27]. Task-specific self-care confidence is important in body listening and symptom recognition because these behaviours require specific knowledge and skill [15, 36]. These findings could help healthcare providers to stratify and classify patients at risk of poor self-care, tailoring appropriate and effective interventions. For this reason, we provide a synthesis for clinicians showing the significant influences of each socio-demographic and clinical

variable on the specific dimensions of self-care maintenance, monitoring, management, and confidence (**Supplementary**).

The determinants of self-care should be systematically assessed to identify patients at risk of poor self-care. As some of these determinants are modifiable factors (i.e., self-care confidence and recent diabetes self-management education), these factors are reasonable to target in order to improve self-care behaviours. Further research is needed to describe how the self-care process and its determinants change over time and the effectiveness of interventions designed to improve self-care.

### **Compliance with ethical standards**

### **Conflict of interest**

The authors declare that they have no conflicts of interest.

### **Human and animal rights**

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

### **Informed consent**

Informed consent was obtained from all patients for being included in the study.

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