Self-care in People with Type 2 Diabetes Mellitus – Research Protocol of a Multicenter Mixed Methods Study (SCUDO)

Self-care nelle persone con diabete mellito di tipo 2 - Protocollo di ricerca di uno studio multicentrico con metodo misto (SCUDO)

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ABSTRACT

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 behaviours, 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. This Embedded Mixed Method study aims to investigate the experience of self-care in Type 2 Diabetes Mellitus 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 circa 10-20 patients, at baseline and once a year for two years, analysed according to interpretive description. Quantitative and qualitative data will be analysed 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 glycaemic control and therefore clinical outcomes and costs.

KEY WORDS: Type 2 Diabetes Mellitus, Self-care, Mixed Method Research, Research Protocol, Self-management, Self-care of Diabetes Inventory

RIASSUNTO

Si stima che entro il 2040 circa l'11% della popolazione mondiale sarà affetta da diabete mellito di tipo 2 (T2DM). Il T2DM richiede che le persone che ne sono affette prendano decisioni rispetto a complessi regimi terapeutici, per mantenere il loro benessere e qualità di vita, per gestire sintomi e ridurre le complicanze legate alla malattia. Tutti questi comportamenti che richiedono conoscenze, motivazione, esperienza e abilità, vengono identificate col concetto di self-care. La complessità e la multidimensionalità del self-care richiedono un approccio adeguato alla loro comprensione. Questo studio mixed method ha lo scopo di esplorare l'esperienza del self-care nelle persone affette da diabete mellito di tipo 2. Comprende uno studio osservazionale longitudinale e una interpretive description. I dati quantitativi verranno raccolti attraverso la somministrazione a 300 persone, all'inizio dello studio e poi una volta all'anno per due anni, di questionari validati circa: il self-care nel diabete, la qualità di vita, il distress legato al diabete, la qualità del sonno. Dati socio-demografici e clinici verranno raccolti attraverso la consultazione delle cartelle cliniche. I dati qualitativi, raccolti attraverso interviste semi-strutturate con circa 10-20 pazienti, all'inizio dello studio e poi una volta all'anno per due anni, verranno analizzati secondo l'interpretive description. I dati quantitativi e qualitativi verranno analizzati separatamente, dopodiché uniti ed interpretati. Questo studio vuole aumentare la nostra comprensione del self-care nelle persone con T2DM. L'outcome atteso sarà una migliore comprensione del self-care e dell'effetto del self-care sul controllo glicemico e quindi sugli outcome clinici ed i costi.

PAROLE CHIAVE: Diabete mellito di tipo 2, Self-care, metodi misti, protocollo di ricerca, Self-management, Self-care of Diabetes Inventory

INTRODUCTION

Diabetes affects 629 million people worldwide and, in 2017, the number of deaths directly due to diabetes was 4 million. Diabetes mellitus is in about 90% of cases type 2 diabetes mellitus (T2DM) (International Diabetes Federation, 2017). T2DM complications, such as stroke, heart attack, kidney failure, amputation, and blindness, lead to a poor quality of life and rising health care costs (Handelsman et al., 2015; International Diabetes Federation, 2017; Schunk et al., 2012; Scollan-Koliopoulos et al., 2013; World Health Organization, 2016). Collectively, T2DM complications account for up to 90% of diabetes health care expenditures (International Diabetes Federation, 2017) and costs are projected to rise (International Diabetes Federation, 2017). Cost effective strategies are critically needed to reduce T2DM complications. Without such strategies, people with T2DM will remain at high risk for a poor quality of life and T2DM will exact an increasing toll on the health care system.

Self-care is "a process of maintaining health through health promoting practices and managing illness" (Riegel, Jaarsma, & Strömberg, 2012), able to reduce co-morbidities, to improve quality of life, and to reduce health care costs (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Powers et al., 2015; Riegel et al., 2012; Shrivastava, Shrivastava, & Ramasamy, 2013). . Self-care requires knowledge, motivation, experience, and skills (Ausili, Masotto, Dall'Ora, Salvini, & Di Mauro, 2014; Baumann & Dang, 2012; Godfrey et al., 2011; Ryan & Sawin, 2009). Self-care is affected by habits, support from others, and access to care, as well as cultural beliefs and values (Riegel et al., 2012). Several studies have examined self-care in persons with T2DM (Holt et al., 2013; Kovacs Burns et al., 2013; Nicolucci et al., 2014; Peyrot et al., 2013). Self-care effectively reduced glycated haemoglobin (HbA1c), hospitalisation and BMI in people with T2DM (Song, Ratcliffe, Tkacs, & Riegel, 2012; Ouyang et al., 2015; Ausili, Bulgheroni, et al., 2017). But these studies are limited by cross-sectional study designs, use of non-validated measurement tools , omission of potentially influential variables, lack of culturally diverse groups, and lack of a theoretical background guiding the study (Caro-Bautista, Martín-Santos, & Morales-Asencio, 2014; Lu, Xu, Zhao, & Han, 2016; Riegel & Weaver, 2009). Moreover, relationships between self-care, T2DM, and health care utilisation costs are understudied. Therefore,

the overall purpose of this mixed method study is to describe and measure self-care and its experience in adults with T2DM.

Conceptual framework

This study is guided by the "Middle Range Theory of Self-Care of Chronic Ilness", developed by Riegel and colleagues (Riegel et al., 2012) (Table 1). According to this theory, self-care comprises self-care maintenance, self-care monitoring, self-care management. Self-care maintenance includes "those behaviours used by patients with a chronic illness to maintain physical and emotional stability" (Riegel et al., 2012, p. 195). Self-care maintenance consists of the recommendations and advice both from providers and significant others, as well as a person's adherence to treatment regimes. Self-care maintenance is improved by the ability of persons to reflect on and adapt to situations. Self-care monitoring is "the process of observing oneself for changes in signs and symptoms" (Riegel et al., 2012, p. 196). The objective of self-care monitoring is to recognise physiological changes. Self-care monitoring is influenced by one's personal insight and interpersonal awareness. Self-care monitoring ignites the process of decision-making and, therefore, self-care management. Self-care management is a "response to signs and symptoms when they occur" (Riegel et al., 2012, p. 196). Once individuals recognise a change, they needs to evaluate it and act accordingly. This requires simulating options in one's mind, deciding the course of action, and evaluating its effectiveness. Consultation with health care providers may be required during self-care management (Riegel et al., 2012). Self-care maintenance, self-care monitoring, and self-care management interact and function synchronously. "Mastery of self-care maintenance precedes mastery of self-care management" (Riegel et al., 2012, p. 200) due to the complexity of the latter. "Self-care monitoring is necessary for effective self-care management because one cannot make a decision about a change unless it has been noticed and evaluated" (Riegel et al., 2012, p. 200).

Several factors influence self-care (Table 1), including socio-demographic characteristics, experience and skills, functional and cognitive abilities, support from others, confidence, distress, and sleep quality. Self-care confidence underlies these factors and mediates cognitive abilities and self-care behaviours (Riegel & Dickson, 2008; Vellone et al., 2015; Vellone, Pancani, Greco, Steca, & Riegel, 2016; Jaarsma, Cameron, Riegel, & Stromberg, 2017; Ausili,

Table 1. Antecedents and consequences of self-care in T2DM.

Antecedents	Self-care	Consequences
Socio-demographic characteristics Experience and skill Functional and cognitive abilities Support from others Self-care Confidence Distress Sleep quality Distress Sleep quality	Self-care Maintenance Self-care Monitoring Self-care Management	Hb1Ac Complications Quality of life Hospitalization Costs Mortality

Barbaranelli, et al., 2017). Self-care influences illness stability, quality of life, mortality, and health care utilization. Factors not included in the "Middle Range Theory of Self-Care" (Riegel et al., 2012), but relevant for this study include socio-demographic characteristics and sleep quality

Antecedents

Socio-demographic characteristics. Several socio-demographic characteristics influence T2DM such as: social support, gender, education and income (Clark & Utz, 2014; Glasgow & Toobert, 1988; Hill et al., 2013; Lidfeldt et al., 2003; Schub & Smith, 2016).

Experience and skill. Experience is needed to develop skills that are essential for self-care. These skills include recognizing patterns, setting goals, making decisions, and predicting outcomes (Paterson, Thorne, & Dewis, 1998; Riegel et al., 2012).

Functional and Cognitive Abilities. Functional abilities that impact self-care behaviours include difficulties with hearing, vision, manual dexterity, and energy (Riegel et al., 2012). Impairments in these functional abilities may particularly impact elderly adults with diabetes (Hiltunen, Keinänen-Kiukaanniemi, Läärä, & Kivelä, 1996). Cognitive abilities that impair self-care (Riegel et al., 2012) include attention, awareness, memory, decision making, perception, planning, reasoning, judgement, language, general knowledge, visuospatial, intuition (Cognitive Deficits, 2017). Cross-sectional studies have demonstrated that poorer cognitive abilities reduce self-care (Sinclair, Girling, & Bayer, 2000; Feil, Zhu, & Sultzer, 2012; Primožič, Tavčar, Avbelj, Dernovšek, & Oblak, 2012; Wykes, Lee, McKibbin, & Laurent, 2016). Prospective studies are needed to elucidate the direction of this relationship (Tomlin & Sinclair, 2016).

Support from Others. Support from others can impede or facilitate self-care. More support is associated with improved self-care behaviours in some, but not all studies (Badedi et al., 2016; Bohanny et al., 2013; van Dam et al., 2005). Relationships between support and self-care may vary by gender or support type, such as formal versus informal. Consensus for social support measures and prospective study designs are needed to improve our understanding of these relationships (Stopford, Winkley, & Ismail, 2013).

Confidence. It is the "confidence one has in the ability to perform a specific action and to persist in performing that action despite barriers" (Riegel et al., 2012, p. 201). Confidence is called self-care confidence when actions performed are related to self-care (Riegel & Dickson, 2008; Vellone et al., 2015, 2016; Jaarsma et al., 2017). It has been strongly correlated with self-care behaviours in T2DM (Aljasem, Peyrot, Wissow, & Rubin, 2001; Gherman et al., 2011; Bohanny et al., 2013; Adam & Folds, 2014; Badedi et al., 2016; Devarajooh & Chinna, 2017).

Distress. Distress is defined as "an emotional response towards adverse or unpleasant stressors" (Snoek, Bremmer, & Hermanns, 2015, p. 452). Chronic illnesses impact distress and challenge coping strategies (Riegel et al., 2012; Snoek et al., 2015). T2DM distress is rooted in the demands of diabetes management and it is a product of emotional adjustment (Berry, Lockhart, Davies, Lindsay, & Dempster, 2015). T2DM distress is linked to self-care but it is uncertain how distress interacts with T2DM self-care (Berry et al., 2015; Devarajooh & Chinna, 2017; Snoek et al., 2015).

Sleep quality. Sleep quality refers to individuals' assessment of their sleep as 'good' or 'poor' (Daniel J. Buysse, 2014). Sleep quality indicators include the ease of falling asleep, number of nocturnal awakenings, time spent awake after sleep onset, and the ratio of time in bed to time asleep. T2DM increases the risk for poor sleep quality (Foster et al., 2009; Lopes et al., 2005). Sleep quality is associated with quality of life (Chasens, Korytkowski, Sereika, & Burke, 2013; Lou et al., 2015; Marcum et al., 2013) and antecedents of self-care, such as self-care confidence, functional and cognitive abilities, and distress (Byun, Kim, & Riegel, 2017; Chasens et al., 2013; Seligowski et al., 2013). Prospective studies are needed to elucidate the direction of these associations.

Consequences

Hb1Ac. HbA1c has a key role in clinical assessment of patient's metabolic control. HbA1c has been validated as a surrogate endpoint of microvascular complications associated with diabetes (FDA-NIH Biomarker Working Group, 2017) and is associated with T2DM control (Badedi et al., 2016).

Complications, hospitalisation, mortality, and costs. Self-care behaviours have been linked to illness stability and reduced T2DM complications (Al-Khawaldeh, Al-Hassan, & Froelicher, 2012; Austin Boren, Gunlock, Schaefer, & Albright, 2007; Badedi et al., 2016; Powers et al., 2015; Riegel et al., 2012). Fewer T2DM complications leads to reduced hospitalisation and mortality, and therefore costs (Haw, Tantry, Vellanki, & Pasquel, 2015; Powers et al., 2015).

Quality of Life. Quality of Life is a complex multidimensional construct which includes the subjective perception of physical, emotional and social well-being (Rubin & Peyrot, 1999). A better quality of life is associated with improved self-care activities (D'Souza, Ruppert, Karkada, & Jacob, 2015; Timar et al., 2016), and adherence to self-care practices and medications (Saleh, Mumu, Ara, Hafez, & Ali, 2014). Comorbidities (O'Shea, Teeling, & Bennett, 2014) and diabetes complications (Rubin & Peyrot, 1999; Laiteerapong et al., 2011; Timar et al., 2016) reduce the quality of life. However, the relationship between quality of life Hb1Ac is undetermined (Timar et al., 2016; Trikkalinou, Papazafiropoulou, & Melidonis, 2017).

THE STUDY

Aims

The overall purpose of this study is to investigate the experience of self-care in adults with T2DM. To accom-

plish this, we will recruit 300 participants with T2DM and we will perform a mixed method longitudinal study over a 2 years follow-up.

The primary quantitative objective of this study is to estimate associations between self-care maintenance, self-care monitoring, and self-care management at baseline and HbA1c in adults with T2DM, after a follow up of 12 months. Secondary objectives will be: 1) to estimate associations between self-care maintenance, self-care monitoring, and self-care management at baseline and HbA1c level in adults with T2DM after a follow up of 24 months; 2) to identify longitudinal associations between self-care and HbA1c, and self-care and clinical outcomes of T2DM patients (e.g. unplanned medical referral, access to emergency department, hospitalisation, indicators of metabolic control, incidence of diabetes complications, quality of life, and death over a 24 months follow-up); 3) to describe self-care maintenance, self-care monitoring, and self-care management of people with T2DM and their directions over a 24 months follow-up; 4) to identify clinical and socio-demographic determinants of self-care maintenance, self-care monitoring, and self-care management in T2DM patients; 5) to estimate the association between the trends of self-care and HbA1c level over a 24 months follow-up. The qualitative objective of the study is to gain a better understanding of the self-care experience in people with T2DM and its evolution over time.

Study Design

The study is a mixed method embedded design (Figure 1) that uses a prospective observational design and an interpretive description. The mixed method design was chosen because it is an approach to knowledge that considers multiple perspectives (Holloway & Wheeler, 2010) while maintaining the focus on people and their perceptions and experiences (Johnson & Onwuegbuzie, 2004; Östlund, Kidd, Wengström, & Rowa-Dewar, 2011). Data will be integrated for corroboration (Halcomb & Hickman, 2015). Specifically, data will be collected concurrently and analysed separately. Integration will

occur during the interpretation phase. The results of one method will be used to support and verify the findings of the other on the same topic (Greene, Caracelli, & Graham, 1989; Halcomb & Hickman, 2015). The prospective observational design was chosen to collect clinical and self-care behaviour data over time so that strong inferences about self-care and its relationship with health outcomes could be made. Annual follow up periods for 2 years will be able to detect significant changes in a slowly evolving disease. Interpretive description stems from nursing science and it was chosen because of the shared disciplinary lens and the fit to the research question (Thorne, 2016, p. 57).

Recruitment

Subjects will be contacted during their outpatient visit to the diabetes centre. Inclusion criteria will be: T2DM diagnosis, adequate comprehension of Italian language. Exclusion criteria will be: age < 18; Type 1 Diabetes or another type of diabetes (other than T2DM) as described in the available guidelines (Associazione Medici Diabetologi (AMD) & Società Italiana di Diabetologia (SID), 2018); documented psychiatric or neurodegenerative disease; pregnancy; inability to provide informed consent. Eligible participants will provide an informed consent prior to participating.

Sample size/Power evaluation

We will enrol an overall sample size of 300 subjects, of which 150 are expected to be at a low level of self-care maintenance. This sample size achieves 80% power at a 0.05 significance level to detect a difference of about 0.4% (with a standard deviation of 1.1%) in HbA1c level between patient with lower and higher self-care maintenance after a follow-up of 12 months. This sample size accounts for a 20% of lost to follow-up and has been sized on self-care maintenance, but similar results could be expected also in the other scales of self-care

From this sample of 300, a subsample will be recruited for the qualitative study using purposive sampling
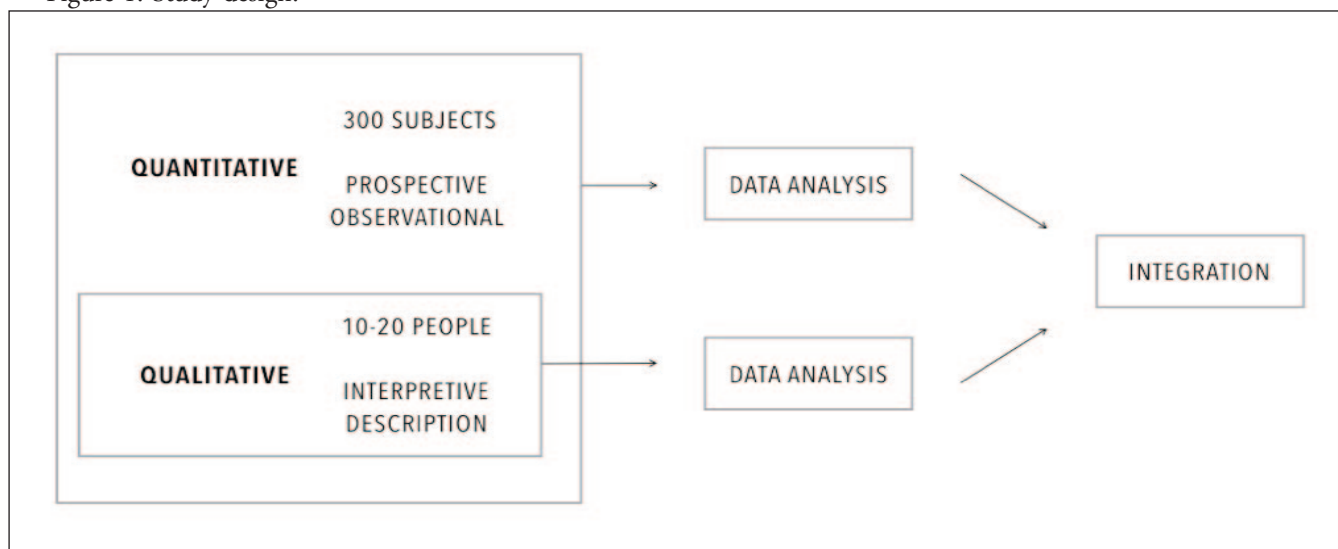
Figure 1. Study design.

Table 2. Study Indicators

STUDY INDICATORS	
Resource utilization/health outcomes indicators*	- Number of unplanned diabetes medical referral per year - Number of all-cause accesses to emergency departments per year, - Number of all-cause hospitalizations per year; - Death.
Clinical Indicators*	- Time from the diagnosis of T2DM - Presence or absence and number of diabetes-related complications - Presence or absence and number of co-morbidities; - Ongoing medications and number of medications (or injections if patients are treated by insulin); - Smoking habits; - Glycated haemoglobin (HbA1c); - Lipid Profile (Total Cholesterol, HDL Cholesterol, LDL Cholesterol, Triglycerides); - Liver Profile (ALT, AST, GGT) - Renal Profile (Creatinine, estimated Glomerular Filtration Rate); - Height, weight, abdominal circumference and Body Mass Index (BMI); - Presence of insulin lipodystrophy; - Arterial Blood Pressure and Hearth Rate.
Person-centered indicators	- Self-care confidence (measured by the Self-Care of Diabetes Index, SCODI); - Self-care maintenance of diabetes (measured by the Self-Care of Diabetes Index, SCODI); - Self-care monitoring of diabetes (measured by the Self-Care of Diabetes Index, SCODI); - Self-care management of diabetes (measured by the Self-Care of Diabetes Index, SCODI); - Functional status (measured by the SF12 questionnaire); - Cognitive status (measured by the SF12 questionnaire); - Quality of life (measured by the EQ-5D-3L Quality of life Questionnaire); - Diabetes-related distress (measured by the Problem Areas in Diabetes Questionnaire Short Form, PAID-5); - Sleep quality (measured by the Pittsburgh Sleep Quality Index, PSQI).
Socio-demographic indicators*	- Age; - Gender; - Educational level; - Employment status; - Income level; - Presence of formal or informal caregiver.

(Palinkas et al., 2015; Thorne, 2016, p. 99). We will recruit people who are either suggested by the center Principal Investigator for having a meaningful experience or which will have "critical" score on the Self-care of Diabetes Inventory (very high or very low). An additional informed consent will be required prior to participation in this section of the study. We expect to enroll between 10 and 20 people in this subsample, according to the quality of data collected (Thorne, 2016).

Study Procedure

After signing the informed consent, socio-demographic and clinical data will be collected by medical records (Table 2). Clinical data will be updated every year (for a total of 2 years) at the beginning or at the end of the clinical standard outpatient visit. At the screening visit and at the follow-up visits, patients will be asked to complete five study questionnaires described in paragraph "Measurements". Quantitative data will be collected at baseline, 12 months, and 24 months. For the study procedures details, please refer to the Schedule of Events (Table 3).

Qualitative data will be collected, within the framework of Interpretive Description, with in depth semi-structured interviews. For each person enrolled, it will be done one interview per time point. Eventually, participants can be contacted for additional interviews, in presence or by phone. Interviews will be audiotaped and transcribed. Interviews will be directed by a topic guide (or interview schedule), that allows the exploration of main themes, still leaving the possibility to probe emerging subjects.

Table 3. Schedule of Events (quantitative)

Protocol Activities	VISIT 1 Screening – Day 1	VISIT 2 Month 12 ± 28 days	VISIT 3 Month 24± 28 days
BASELINE DOCUMENTATION			
Informed consent *No activity should be performed before obtaining signed and dated informed consent*	x		
Review of inclusion and exclusion criteria	x		
Disease history *Assess diabetes history, diabetes-related medications and complications, co-morbidities, ongoing drugs, smoking habits.*	x	x	x
Physical assessment *Height (at screening only), weight, abdominal circumference, presence of insulin lipodystrophy, BMI, blood pressure and pulse rate*	x	x	x
LABORATORY STUDIES			
HbA1c (mmol and %)	x	x	x
Lipid profile*Total Cholesterol, HDL Cholesterol, LDL Cholesterol, Triglycerides*	x	x	x
Renal and Liver profile *Creatinine, estimated GFR, ALT, AST, GGT*	x	x	x
QUESTIONNAIRES			
Short Form 12 (SF-12)	x	x	x
Self-Care of Diabetes Inventory (SCODI)	x	x	x
Quality of Life (EQ-5D-5L)	x	x	x
Problem Areas in Diabetes Questionnaire Short Form (PAID-5)	x	x	x
Pittsburgh Sleep Quality Index (PSQI)	x	x	x
OTHER ASSESSMENT			
Events *Any referral or unplanned diabetes visit, request for home care assistance, hospitalization, access to emergency care, death, received diabetes education in the last year.*	x	x	x

Measurements

Quantitative data will be gathered from clinical charts and questionnaires. Short forms of the questionnaires have been chosen to reduce subject burden, improve response rates, and protocol adherence.

Outcome Variables

The primary outcome is HbA1c (measured in mmol and %). Secondary outcomes are unplanned medical referrals, hospitalisations, mortality, T2DM complications, and quality of life. Further information will be collected about the opportunity that patients had to participate to diabetes education programs during the previous year.

Unplanned medical referral is the number of unplanned medical visits.

ED visits is the number of visits to the Emergency Department.

Hospitalisations are defined as being admitted to a hospital overnight.

Mortality will be considered as all-causes mortality.

T2DM complications regards the presence of one or more T2DM complications such as retinopathy, nephropathy, neuropathy, etc. These data will be collected from medical charts.

Quality of life will be measured by the EQ-5D-3L. The 5-item EQ-5D-3L queries participants about movement, hygiene, daily living activities tolerance, pain/discomfort, and anxiety/depression. General health status is also assessed. The EQ-5D-3L is a valid and reliable tool to measure quality of life in diabetes population (Konerding et al., 2014).

Independent Variables

Independent variables include self-care (maintenance, monitoring and management), functional and cognitive function, sleep quality, socio-demographic characteristics, and distress.

Self-care will be measured using the Self-care of Diabetes Inventory - SCODI (Italian). SCODI has been demonstrated to be a valid, reliable, and theoretically grounded tool for measuring self-care in patients with T2DM (Ausili, Barbaranelli, et al., 2017). SCODI comprises 40 items (5 points Likert type), developed according to the most recent evidence-based clinical recommendations. These items are grouped into 4 dimensions: self-care maintenance (12 items), self-care monitoring (8 items), self-care management (9 items), and self-care confidence (11 items). Factor analysis and model based reliability coefficients showed high internal consistency and construct validity was demonstrated through the association of SCODI scores with relevant clinical criteria such as glycated haemoglobin, body mass index

and diabetes-related complications (Ausili, Barbaranelli, et al., 2017).

Functional and cognitive status will be measured using the Short Form 12 - SF-12. The 12-item, self-administered SF-12 queries participants about social discomfort, disabilities, and level of health perceived over the previous 4 weeks, physical functioning, role limitation due to physical health, pain, general health, and fatigue (Kodraliu et al., 2001; Ware, A. Kosinski, & D. Keller, 1998).

Sleep quality will be measured using the Pittsburgh Sleep Quality Index – PSQI (Italian). This 19-item self-rated questionnaire assesses sleep quality over the previous month across seven domains; sleep quality, sleep latency, sleep duration, sleep disturbances, sleep medication use, and daytime functioning (D. J. Buysse, Reynolds, Monk, Berman, & Kupfer, 1989; Curcio et al., 2013). Scores range from 0 to 21. PSQI scores higher than five indicate poor sleep quality. Reliability and validity of the PSQI (Italian version) have been established (Curcio et al., 2013).

Socio-demographic characteristics collected from medical records include age, gender, educational level, employment status, income level, and presence of formal or informal caregiver.

Distress. The 5-item PAID-5 (Problem Areas in Diabetes Questionnaire) measures diabetes related emotional distress concerning treatment-related, food-related, and social support-related problems. Scores range from 0 to 100 with > 40 points score indicating depression and other negative psychological outcomes. Good sensitivity (94%) and specificity (89%) for recognition of diabetes-related emotional distress have been established (McGuire et al., 2010).

Analysis

Study indicators are outlined in Table 2. HbA1c is the primary endpoint of this study. Clinical, person-centered indicators, and resources utilization indicators are the secondary endpoints. As visually explained in Figure 1, qualitative and quantitative data will be analyzed separately and integrated subsequently according to the embedded mixed-methods design (Creswell, 2014; Halcomb & Hickman, 2015; Yardley, 2017).

Continuous data will be summarized with number of observations, mean value, standard deviation, median, quartiles, minimum, maximum and 95% confidence intervals for the mean. Categorical data will be summarized by means of absolute and relative frequencies (counts and percentages). Scores of SCODI's self-care scales will be standardized to 100 (Ausili et al., 2017).

Disposition of subjects enrolled will be presented and the number of subjects at each visit will be tabulated. The reason for inclusion/exclusion will be tabulated and listed. To estimate associations between self-care maintenance, monitoring, management and confidence at baseline and HbA1c level at 12 months a t-test will be used. The incidences of health and clinical outcomes over the follow-up will be computed by the Kaplan-Meier estimator in patients with low and high self-care at baseline and they

will be compared by the log-rank test. The Cox model will be used to account for confounders (age, gender, time from diagnosis, comorbidity, cognitive and functional status). A Cox model will be also used to evaluate the impact of the SCODI (as continuous score) on health and clinical outcomes. Self-care care behaviors of people with type 2 diabetes will be described by a box-plot and their relation with health/clinical outcomes over the whole follow-up will be modelled by longitudinal models. In order to identify clinical and socio-demographic determinants of self-care behaviours multiple linear regression analyses will be performed. Explorative and confirmative factor analyses will be used to further evaluate the construct validity of the SCODI. Chronbach Alpha and other inter-item coefficients will be used to measure on a large sample the internal consistency of the tool.

The focus of interpretive description is to generate new knowledge that can be relevant and meaningful for the applied practice context (Thorne, 2016), here nursing. Despite its ontological flexibility, the qualitative data analysis is composed by three main moments: sorting and organising data, making sense of pattern, and transforming pattern into findings (Thorne, 2016).

Ethical Considerations

Approval from Institutional Review Board (IRB)/Independent Ethics Committee (IEC) was obtained for the protocol and the informed consents. Participants will receive an informative sheet to read and discuss with the Principal Investigator (PI) or his delegate. The PI or his delegate will ensure that each study participant is fully informed about the nature and objectives of the study and possible risks associated with participation. Written informed consent will be obtained from each participant before any study-specific activity is performed. Personal data will be protected. Participants' names will not be included on any forms, reports, publications, or in any other disclosures. A sequential identification number will be attributed to each patient enrolled in the study in order to maximise anonymity. Concerning the qualitative phase, names will be changed and details, which will make persons identifiable, will be removed. Participant will be made aware that in report and publication will be used quotes of their sentences. They will be informed that, despite every effort made to protect people's privacy, their words might make them recognizable by their peers or acquaintances.

Validity and Reliability / Rigour

The first step undertaken to ensure the validity of this study is the design itself. Mixed methods allows the integration the quantitative and qualitative data to increase the integrity of the research (Greene et al., 1989) and its internal validity (Barbour, 2001). For the quantitative phase we consulted a panel of experts to design the study, which is grounded in practice. Only validated and reliable instruments will be used to collect quantitative data. Sensitivity to context, commitment and rigour, transparency and coherence, impact and importance will be used to

guide the qualitative data collection and analysis (Yardley, 2000). This study is grounded both in practice and in theory, and it is supported by a skilled multi-disciplinary team. Results from this study will have an impact on clinical practice, health expenditures, and the quality of life of people living with diabetes

Strengths and limitations

One limitation of this study is the mono-country nature of the study. To address this limitation, multiple centres will be represented. Another limitation of this study is that some variables influencing self-care, such as coping and resilience, will not be measured quantitatively. However, we expect some of these variables will be illuminated by the qualitative part of the study and therefore integrated by the merging process during interpretation (Yardley, 2017). A major strength of this study is the longitudinal study design. Few longitudinal studies have investigated self-care in T2DM. Self-care maintenance, self-care monitoring, and self-care management have never been studied prospectively and longitudinally in T2DM patients.

CONCLUSION

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 glycaemic control and therefore clinical outcomes and costs. This will lead to more informed clinical interventions, educational programs, healthcare services, and future research developments in the field.

T2DM is widespread and increases both in direct and indirect healthcare costs. Self-care in T2DM is a complex phenomenon that has not been thoroughly investigated and described. Therefore, we designed a mixed methods multi-centred study in order to shed insights on experience of self-care in people with T2DM.

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